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FOREWORD

Nicole Boucher[†] and John Moore[‡]

The Berkeley Technology Law Journal's Annual Review provides a summary of many of the year's most important developments at the intersection of law and technology. Our goal is to provide a valuable resource for students, professors, practitioners, judges, and policymakers. This year, we are excited to publish twelve student Notes and, for the first time since 2020, short summaries of additional recent developments in technology law not covered by our longer format Notes.

The Notes and summaries continue the Annual Review's tradition of covering a wide range of topics. This year, our Notes and summaries cover developments in patent, copyright, trademark, trade secret, antitrust, technology regulation, and healthcare law.

I. PATENT LAW

The first Note provides recommendations to the Federal Trade Commission (FTC), United States Patent and Trademark Office, and the Food and Drug Administration (FDA) for strategically policing patent listings in the FDA's Orange Book, a publication listing all approved drugs in the United States with relevant information, including any patents covering the drugs.¹ The Note covers the overlapping administrative regimes covering patents, medical devices and drugs, and antitrust enforcement. Then, the Note explores current problems with antitrust enforcement of improper Orange Book listings and provides recommendations to relevant agencies.

The second Note discusses the topic of parallel proceedings in front of federal district courts and the Patent Trial and Appeal Board (PTAB), and it explores the quandary of a district court and the PTAB reaching different conclusions about a patent's validity.² In *United Therapeutics Corporation v. Liquidia Technologies, Inc.*, the Federal Circuit held that PTAB decisions lack

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1. Monica Jeung, Note, *Antitrust and the Orange Book: An Analysis of Efforts to Reduce Improper Listings*, 40 BERKELEY TECH. L.J. 525 (2025).

2. Jesse Wang, Note, *Collateral Estoppel of PTAB Decisions in the Wake of United Therapeutics Corp. v. Liquidia Tech., Inc.*, 40 BERKELEY TECH. L.J. 573 (2025).

collateral estoppel effect until affirmed on appeal, which led to a scenario in which a company was liable for infringing an invalid patent.³ The Note proposes several reforms to improve the efficiency of the patent system and prevent further confusing results.

The third Note analyzes the complex interactions between the different mechanisms by which the patent office may lengthen or shorten the standard twenty-year patent term.⁴ Specifically, the Note analyzes the interaction between obviousness-type double patenting (ODP), in which a second patent's term in a patent family is shortened to the same term as that of the first patent, and patent term adjustment, in which a patent's term is extended due to delays at the patent office. The Note concludes by suggesting a new framework for ODP analysis.

The fourth patent Note covers recent developments in using extraterritorial conduct to inform patent damages.⁵ In *Brumfield v. IBG LLC*, the Federal Circuit found that foreign conduct can be used to increase a reasonable-royalty award, so long as it has the “the needed causal relationship” to making the accused products in the United States.⁶ The Note examines various examples of how foreign conduct might be used in damages calculations, but suggests that foreign conduct should only be used as a measure of damages, not a cause of legal injury.⁷

The final patent Note examines new developments in obviousness analysis for design patents.⁸ In *LKQ Corporation v. GM Global Technology Operations LLC*, the Federal Circuit determined that design patents should be evaluated for obviousness under the same flexible framework the Supreme Court laid out for utility patents.⁹ This Note explores the implications of the Federal Circuit's ruling, examines recent proceedings in front of the PTAB, and proposes additional considerations to prevent functional elements of designs from receiving design patent protection.

3. *United Therapeutics Corp. v. Liquidia Techs., Inc.*, 74 F.4th 1360, 1363 (Fed. Cir. 2023).

4. Han K. D. Le, Note, *The Interaction of Obviousness-Type Double Patenting and Patent Term Adjustment*, 40 BERKELEY TECH. L.J. 607 (2025).

5. William R. Clark, Note, *Foreign Conduct as a Measure of Patent Damages After Brumfield v. IBG*, 40 BERKELEY TECH. L.J. 657 (2025).

6. *Brumfield v. IBG LLC*, 97 F.4th 854 (Fed. Cir. 2024).

7. *Id.* at 877.

8. Tyler Kotchman, Note, *Designing Around Obviousness: The Implications of LKQ v. GM Global*, 40 BERKELEY TECH. L.J. 689 (2025).

9. *See LKQ Corp. v. GM Glob. Tech. Operations LLC*, 102 F.4th 1280, 1295 (Fed. Cir. 2024).

II. TECHNOLOGY REGULATION AND INTERNET PLATFORMS

The first Note¹⁰ discusses the timely topic of whether apps offering a blend of technology, content, and services can be considered a product for the purposes of product liability law. In the recent decision *In re Social Media Adolescent Addiction/Personal Injury Products Liability Litigation*, the court tried to condense the varying approaches to handling this timely issue by looking at functionality within an app separately rather than analyzing an app as a single entity.¹¹ This Note argues for extending the *In re Social Media* approach to classify an app as a product based on when the app has a user experience or user interface intended for consumer use.

The second Note¹² examines how courts have typically handled §230 of the Communications Decency Act.¹³ Section 230 has long served as a protective law to internet platforms, providing a broad shield from liability for the content posted on these platforms. Courts have trended towards treating platforms, algorithms, and other technologies under § 230 as a monolith. Thus, this Note proposes a new approach that considers the differences within and among platforms and algorithms through a fact-specific, sliding scale approach of these technologies within the § 230 context.

The final Note¹⁴ analyzes the Export Control Reform Act (ECRA)¹⁵ as it applies to artificial intelligence (AI). The Note explains how AI's dual-use nature, benefiting both civilian and military sections, makes export control regulation particularly complex. The Note applies ECRA's three-prong test to argue that some current controls may harm U.S. innovation and market strength, which is even more important with increasing U.S.-China competition. The Note concludes with recommending narrowly tailored, sector-specific controls and urges a balance between national security and global competitiveness.

10. Karina A. Sanchez, Note, *Are Apps Products?: Consumer Software and Products Liability*, 40 BERKELEY TECH. L.J. 723 (2025).

11. *In re Soc. Media Adolescent Addiction/Pers. Inj. Prod. Liab. Litig.*, 702 F. Supp. 3d 809, 849 (N.D. Cal. 2023).

12. Andra Cernavskis, Note, *Immunitizing the Algorithm Only as Much as It Needs: Rethinking How Courts Analyze Algorithms Under Section 230*, 40 BERKELEY TECH. L.J. 765 (2025).

13. 47 U.S.C. § 230.

14. Siwen D. Cremean, Note, *Are Export Controls for Artificial Intelligence a Safeguard or a Straitjacket?*, 40 BERKELEY TECH. L.J. 809 (2025).

15. 50 U.S.C. §§ 4801–4852.

III. TRADE SECRET LAW

The first Trade Secret Note examines the extraterritoriality limits of the Defend Trade Secrets Act (DTSA).¹⁶ In *Motorola Solutions, Inc. v. Hytera Communications Corporation Ltd.*, the Seventh Circuit held that the DTSA “does not require a completed act of misappropriation, nor does it impose a specific causation requirement” for extraterritorial liability.¹⁷ The Note argues that courts should interpret the DTSA with a significantly more limited extraterritorial application than the Seventh Circuit’s holding in *Hytera*.

The second Note explores the unjust enrichment remedy in trade secret cases.¹⁸ In *Syntel Sterling Best Shores Mauritius Ltd. v. The TriZetto Group, Inc.*, the Second Circuit vacated an approximately \$285 million unjust enrichment award, finding that TriZetto was not entitled to unjust enrichment damages because an injunction had already prevented potential future harms to TriZetto.¹⁹ This Note explores the implications of the *Syntel* decision and suggests different damages schemes that will fairly compensate trade secret owners while discouraging would-be trade secret misappropriators.

IV. ANTITRUST AND GOVERNMENT REGULATION

The first Note²⁰ in this Section explores the regulatory challenges of sponsored genetic testing programs, particularly at the intersection of the FDA’s oversight of test safety and the Office of Inspector General (OIG)’s enforcement of the Anti-Kickback Statute.²¹ Through case studies like favorable OIG advisory opinions and the *Ultragenyx* settlement,²² the Note highlights inconsistencies in current enforcement and issues of compliance uncertainty facing pharmaceutical sponsors. The Note ultimately calls for a unified FDA-OIG framework with risk-based guidance to ensure both innovation and regulatory integrity in federal healthcare programs.

16. Ben Clifner, Note, *Hyter-ritoriality: The Proper Extraterritorial Scope of the Defend Trade Secrets Act*, 40 BERKELEY TECH. L.J. 865 (2025).

17. *Motorola Sols., Inc. v. Hytera Commc’n Corp. Ltd.*, 108 F.4th 458 (7th Cir. 2024), *reh’g dismissed*, No. 22-2370, 2024 WL 4416886 (7th Cir. 2024).

18. Duane H. Yoo, Note, *Syntel v. TriZetto: Balancing Compensation and Deterrence in Trade Secret Remedies*, 40 BERKELEY TECH. L.J. 907 (2025).

19. *Syntel Sterling Best Shores Mauritius Ltd. v. The TriZetto Grp., Inc.*, 68 F.4th 792, 797 (2d Cir. 2023), *cert. denied*, 144 S. Ct. 352 (2023).

20. Yasameen Joulaee, Note, *Developing Anti-Kickback Compliance Guidance at the Intersection of “Sponsored” and “Genetic Testing” Programs*, 40 BERKELEY TECH. L.J. 957 (2025).

21. 42 U.S.C. § 1320a-7b(b).

22. *See generally* *United States ex rel. Ruggiero v. Ultragenyx Pharm. Inc.*, No. 1:21-cv-11176 (D. Mass. Dec. 19, 2023).

The second Note²³ considers how the FTC's updated Health Breach Notification Rule²⁴ relates to privacy violations in health information technologies not currently regulated under the Health Insurance Portability and Accountability Act.²⁵ The FTC's update to outdated definitions is beneficial, but significant issues remain related to inconsistent enforcement and increased procedural scrutiny. Thus, this Note advocates for further clarity and increased administrative efficiency in enforcing the updated definitions.

23. Alexis Tatum, Note, *Ring the Alarm: An Analysis of the FTC's Health Breach Notification Breach Rule*, 40 BERKELEY TECH. L.J. 1009 (2025).

24. Health Breach Notification Rule, 16 C.F.R. § 318 (2024).

25. Health Insurance Portability and Accountability Act of 1996 (HIPAA), 42 U.S.C. §§ 1320d–d-9.

ANTITRUST AND THE ORANGE BOOK: AN ANALYSIS OF EFFORTS TO REDUCE IMPROPER LISTINGS

Monica Jeung[†]

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† J.D. Candidate, 2026, University of California, Berkeley, School of Law. With thanks to my advisors Allison Schmitt and Wayne Stacy, and my peers John Moore, Gunn Jiravuttipong, and Duane Yoo for their review and advice.

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I. INTRODUCTION

The system of intellectual property in the United States is built upon the idea that Congress has the power to grant innovators limited monopolies or order to encourage further development of the sciences and arts.¹ In line with this idea, U.S. patent law gives creators of new drugs and other medical treatments limited monopolies to further encourage new drug development. At the same time, it is also important to ensure that drug products and medical treatments are affordable for all. As a result, the U.S. government also established a regulatory system designed to balance incentivizing the creation of inexpensive generic drugs and the creation of novel drugs.²

Antitrust enforcement has been used on and off by both the government and private parties to increase generic entry in the pharmaceutical industry for years.³ This approach had some success in 2003, when recommendations from a Federal Trade Commission report on generic entry were reflected in amendments to the patent-regulatory scheme that controls the pharmaceutical industry.⁴ In 2023, the Federal Trade Commission (FTC) returned to its consumer protection and antitrust approach in the patent-regulatory scheme, issuing a policy statement which “warned that the agency would be scrutinizing the improper submission of patents for listing in the Orange Book.”⁵ But antitrust, and therefore FTC involvement, may not be the most productive way for the government to increase generic drug entry in the future. This Note will discuss the weaknesses of an FTC antitrust approach to increase generic

1. U.S. CONST. art. I, § 8, cl. 8 (“The Congress shall have Power . . . To promote the Progress of Science and useful Arts, by securing for limited Times to Authors and Inventors the exclusive Right to their respective Writings and Discoveries.”).

2. Drug Price Competition and Patent Term Restoration Act, Pub. L. No. 98-417 (1984) (commonly referred to as the “Hatch-Waxman Act”).

3. *See, e.g.*, FED. TRADE COMM’N, GENERIC DRUG ENTRY PRIOR TO PATENT EXPIRATION: AN FTC STUDY, (2002), https://www.ftc.gov/sites/default/files/documents/reports/generic-drug-entry-prior-patent-expiration-ftc-study/genericdrugstudy_0.pdf (a 2002 effort from the FTC to call out antitrust issues created by the original version of the Hatch-Waxman Act); *In re Warfarin Sodium Antitrust Litig.*, 214 F.3d 395 (3d. Cir. 2000) (providing an example of one of many monopolization cases between private parties in the pharmaceutical industry).

4. FED. TRADE COMM’N, GENERIC DRUG ENTRY PRIOR TO PATENT EXPIRATION: AN FTC STUDY, *supra* note 3, at iv–v (2002) (recommending removing multiple thirty-month stays); Medicare Prescription Drug, Improvement, and Modernization Act of 2003, Pub. L. 108-173, 117 Stat. 2066, § 1101 (removing multiple thirty-month stays).

5. FED. TRADE COMM’N, FTC CHALLENGES MORE THAN 100 PATENTS IMPROPERLY LISTED IN THE FDA’S ORANGE BOOK (Nov. 7, 2023), <https://www.ftc.gov/news-events/news/press-releases/2023/11/ftc-challenges-more-100-patents-improperly-listed-fdas-orange-book> [<https://perma.cc/Q2EL-DQXX>].

entry and recommend alternate approaches the government may take to increase generic drug entry.

The Orange Book, published by the FDA, contains a list of patents provided by drug manufacturers covering FDA-approved drugs. The existence of patents on drug products deters potential generic competitors from attempting to make equivalent products, and Orange Book patent listing allows the owners of new drug products to gain certain regulatory protections which can stall generic competitor entry.⁶ These listed patents also inform potential generic entrants of which drugs are patent-protected, influencing generic drug-makers' choices of which drug products to replicate. Thus, the Orange Book listings have the potential to significantly impact drug competition and prices.

Between October 2023, when FTC released its policy statement, and April 2024, the FTC challenged over three hundred patent listings in the Orange Book.⁷ The agency notified ten major pharmaceutical companies.⁸ Of these,

6. 21 U.S.C. § 355(c)(3)(E)(ii), (j)(5)(B)(iii).

7. FED. TRADE COMM'N, FTC EXPANDS PATENT LISTING CHALLENGES, TARGETING MORE THAN 300 JUNK LISTINGS FOR DIABETES, WEIGHT LOSS, ASTHMA AND COPD DRUGS (Apr. 30, 2024), <https://www.ftc.gov/news-events/news/press-releases/2024/04/ftc-expands-patent-listing-challenges-targeting-more-300-junk-listings-diabetes-weight-loss-asthma> [<https://perma.cc/HF7A-DSYS>].

8. FED. TRADE COMM'N, IMPROPER ORANGE BOOK-LISTED PATENTS FOR QVAR REDIHALER (Nov. 7, 2023), https://www.ftc.gov/system/files/ftc_gov/pdf/norton-orange-book.pdf [<https://perma.cc/ULF5-HSCC>]; FED. TRADE COMM'N, IMPROPER ORANGE BOOK-LISTED PATENTS FOR EPIPEN AND EPIPEN JR. (Nov. 7, 2023), https://www.ftc.gov/system/files/ftc_gov/pdf/mylan-specialty-orange-book.pdf [<https://perma.cc/FWN9-VCHM>]; FED. TRADE COMM'N, IMPROPER ORANGE BOOK-LISTED PATENTS FOR AUVI-Q (Nov. 7, 2023), https://www.ftc.gov/system/files/ftc_gov/pdf/kaleo-orange-book.pdf [<https://perma.cc/C3RP-37N6>]; FED. TRADE COMM'N, IMPROPER ORANGE BOOK-LISTED PATENTS FOR ADRENACLICK (Nov. 7, 2023), https://www.ftc.gov/system/files/ftc_gov/pdf/impax-labs-orange-book.pdf [<https://perma.cc/3WF3-4VUA>]; FED. TRADE COMM'N, IMPROPER ORANGE BOOK-LISTED PATENTS FOR ARNUITY ELLIPTA AND VENTOLIN HFA (Nov. 7, 2023), https://www.ftc.gov/system/files/ftc_gov/pdf/glaxosmithkline-orange-book.pdf [<https://perma.cc/R84W-JZNR>]; FED. TRADE COMM'N, IMPROPER ORANGE BOOK-LISTED PATENTS FOR ADVAIR HFA AND FLOVENT HFA (Nov. 7, 2023), https://www.ftc.gov/system/files/ftc_gov/pdf/glaxo-group-orange-book.pdf [<https://perma.cc/5DVR-25YJ>]; FED. TRADE COMM'N, IMPROPER ORANGE BOOK-LISTED PATENTS FOR ATROVENT HFA, COMBIVENT RESPIMAT, SPIRIVA, AND SPIRIVA RESPIMAT (Nov. 7, 2023), https://www.ftc.gov/system/files/ftc_gov/pdf/boehringer-ingelheim-orange-book.pdf [<https://perma.cc/6ZR7-43LG>]; FED. TRADE COMM'N, IMPROPER ORANGE BOOK-LISTED PATENTS FOR SYMBICORT (Nov. 7, 2023), https://www.ftc.gov/system/files/ftc_gov/pdf/astrazeneca-orange-book.pdf [<https://perma.cc/538P-NH9K>]; FED. TRADE COMM'N, IMPROPER ORANGE BOOK-LISTED PATENTS FOR RESTASIS MULTIDOSE (Nov. 7, 2023), https://www.ftc.gov/system/files/ftc_gov/pdf/abbvie-orange-book.pdf [<https://perma.cc/W3UK-YAEP>]; FED. TRADE COMM'N, IMPROPER ORANGE BOOK-LISTED

one delisted all challenged patents from the Orange Book, plus three additional patents.⁹ Others delisted only some of the challenged patents, or stated they would not be delisting any challenged patents.¹⁰

Based on the FTC's Orange Book policy and subsequent actions, it was clear that the agency was concerned that pharmaceutical companies were using improper Orange Book listings to “distort[] pharmaceutical markets” by using the benefits of listing patents to block or disincentivize generic drug makers from entering the market.¹¹ It is also clear that the agency believed it could alleviate this issue through antitrust enforcement.¹² In Part II, this Note will examine the context of the pharmaceutical industry's relationship with the Orange Book, the authority of the FTC in this action, and the case law surrounding regulatory abuse in the monopoly and antitrust framework. Part III will address both studies and case law discussing whether improper listing causes harm to consumers. Part IV will address the capacity of the FDA, U.S. Patent and Trademark Office (USPTO), and FTC to affect Orange Book listings as separate agencies, how the FTC's authority in this area may have been affected by the Supreme Court's recent decision in *Loper Bright Enterprises v. Raimondo*, and why antitrust enforcement in general may be a poor choice for regulating Orange Book listings. Finally, this Note will suggest how the FDA and USPTO, rather than the FTC and its antitrust mechanisms, can and should be the agencies to encourage proper initial listings via voluntary listing procedures with the support of the courts.

PATENTS FOR QVAR 40, PROAIR HFA, PROAIR DIGIHALER (Nov. 7, 2023), https://www.ftc.gov/system/files/ftc_gov/pdf/teva-branded-pharma-orange-book.pdf [https://perma.cc/NR3F-BEWP] [hereinafter FTC PHARMACEUTICAL NOTICES]; see also FED. TRADE COMM'N, FTC CHALLENGES MORE THAN 100 PATENTS IMPROPERLY LISTED IN THE FDA'S ORANGE BOOK (Nov. 7, 2023), <https://www.ftc.gov/news-events/news/press-releases/2023/11/ftc-challenges-more-100-patents-improperly-listed-fdas-orange-book> [https://perma.cc/Q2EL-DQXX].

9. Letter from Elizabeth Warren & Pramila Jayapal to FDA Comm'r Robert M. Califf on Orange Book Guidance, at 2 (Feb. 15, 2024), <https://www.warren.senate.gov/imo/media/doc/2024.02.15%20Letter%20to%20FDA%20re%20Orange%20Book%20Guidance.pdf> [https://perma.cc/36V2-EQF8].

10. *Id.*

11. FED. TRADE COMM'N, FEDERAL TRADE COMMISSION STATEMENT CONCERNING BRAND DRUG MANUFACTURERS' IMPROPER LISTING OF PATENTS IN THE ORANGE BOOK 3–4, https://www.ftc.gov/system/files/ftc_gov/pdf/p239900orangebookpolicystatement092023.pdf [https://perma.cc/F2TG-8NB3] (last visited Aug. 28, 2024).

12. *Id.*

II. BACKGROUND

This Part will discuss the creation of the Orange Book as well as the Hatch-Waxman Act, the legal framework meant to balance the interests of generic and brand drug manufacturers which shaped the modern Orange Book. It will briefly discuss how Congress has amended the Hatch-Waxman Act over time. It will then address the legal context in which the FTC has found authority for its Orange Book policy, and the case history surrounding previous actions against improper listing.

A. THE HATCH-WAXMAN ACT

In 1984, Congress passed the Hatch-Waxman Act in an attempt to balance two major policy interests: encouraging the creation of new drugs via protection of patent rights for new drug developers, and increasing market competition, therefore the accessibility of medication, by encouraging generics companies to enter the market with a shorter and less expensive regulatory process.¹³ According to the FDA, at the time of the enactment of the Hatch-Waxman Act in 1984, generics constituted only 19 percent of prescription drug purchases.¹⁴ After Hatch-Waxman, this number soared to 53 percent in 2004, and may be as much as 90 percent today.¹⁵ The Hatch-Waxman Act was an attempt to fit generic competition into this patent-based exclusivity scheme by allowing generic manufacturers to use a shortened version of the regulatory process and therefore avoid some development costs while still giving drug developers their full patent term.¹⁶

1. *New Drug Applications*

The Hatch-Waxman Act established procedures for makers of novel drugs to apply for FDA approval. New drug makers are required to submit a New Drug Application (NDA) to the FDA to have the drug approved for use.¹⁷ When new drug makers file an NDA, they are required to submit full reports of their investigations into the safety and efficacy of the drug; the methods, facilities and controls for manufacture, packaging, and processing; and the patent number and expiration date of certain types of patents which could be reasonably asserted in a patent infringement case.¹⁸ Patents listed in the Orange

13. *Andrx Pharms., Inc. v. Biovail Corp.*, 276 F.3d 1368, 1371 (Fed. Cir. 2002).

14. U.S. FOOD & DRUG ADMIN., 40TH ANNIVERSARY OF THE GENERIC DRUG APPROVAL PATHWAY (Sep. 23, 2024), <https://www.fda.gov/drugs/cder-conversations/40th-anniversary-generic-drug-approval-pathway>.

15. *Id.*

16. 21 U.S.C. § 355(j).

17. 21 U.S.C. § 355(a).

18. 21 U.S.C. § 355(b)(1)(A).

Book must claim the drug itself, a product in which it is an active ingredient, or claim a method of using the drug which the NDA also asserts.¹⁹ Once approved, the FDA lists the patents provided with the NDA in the Orange Book.²⁰

2. *The Abbreviated New Drug Application Process and Thirty-Month Stays*

With the Hatch-Waxman Act, Congress created a shortened drug approval process for generic manufacturers and balanced that advantage by granting brand manufacturers regulatory stays on generic entry under certain conditions to be discussed later in this Section. Generic drug manufacturers can use the Abbreviated New Drug Application (ANDA) process to obtain marketing approval for their products.²¹ The ANDA process provides two primary incentives for generic manufacturers. First, ANDA applicants can avoid many of the time and financial costs associated with human clinical testing by submitting information that shows that the active ingredient(s) are the same or bioequivalent to that of an approved drug.²² Second, if approved, the first-filing ANDA applicant gains a 180-day exclusivity period to market their generic version of the drug.²³ This allows the first-filing generic brand to profit without competition from other generics.

In addition to proving bioequivalence, an ANDA filer must also certify that its generic version of the drug will not infringe on any valid patents held by the brand manufacturer for each listed patent. More specifically, an ANDA filer may certify that to the best of their knowledge, (1) there are no relevant patents; (2) that there is such a patent, but it is expired; (3) that there is such a patent, and said patent will expire at a provided date; or (4) that such patents exist but are either invalid or will not be infringed.²⁴ The fourth type of certification is known as a Paragraph IV certification, and, as shown in Figure 1, is the only pathway that would allow a generic manufacturer to enter the market while a relevant patent is still unexpired.²⁵ Thus, only ANDA filers using a Paragraph IV certification are required to give notice of the certification to patent owners and the holder of the NDA related to the

19. *Id.*

20. U.S. FOOD & DRUG ADMIN., APPROVED DRUG PRODUCTS WITH THERAPEUTIC EQUIVALENCE EVALUATIONS AD2 (44th ed. 2024) [hereinafter ORANGE BOOK].

21. 21 U.S.C. § 355(j).

22. 21 U.S.C. § 355(j)(2)(A).

23. 21 U.S.C. § 355(j)(5)(B)(iv).

24. 21 U.S.C. § 355(j)(2)(A)(vii).

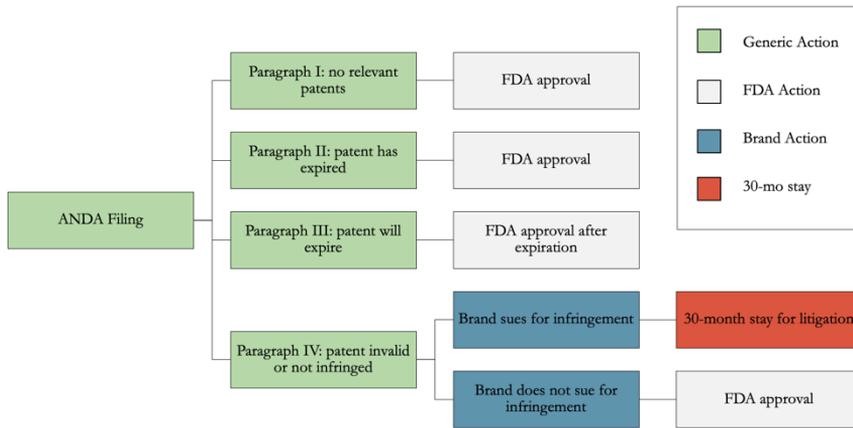
25. 21 U.S.C. § 355(j)(2)(A)(vii). Paragraph IV certifications are named after the subsection of the ANDA filing requirements it falls under.

relevant patent.²⁶ This notice must state that an ANDA with bioequivalence or bioavailability data has been filed in order to gain approval for commercial use before the expiration of the challenged patent, and it must include a detailed statement of the factual and legal basis under which the ANDA applicant claims the patent is invalid or not infringed.²⁷

26. 21 U.S.C. § 355(j)(2)(B), (c)(3)(A)–(C).

27. 21 U.S.C. § 355(j)(2)(B)(iv).

Figure 1: Possible Outcomes of an ANDA Filing Assuming No Issues with the Generic Product's Safety



The Hatch-Waxman Act balances the shortened approval time frame for generics with significant patent protection for brand name manufacturers. As Figure 2 shows, there is a minimum four-year block on an ANDA filing on a brand manufacturer's drug beginning from the approval of the NDA for a novel drug.²⁸ Once an ANDA is filed with a Paragraph IV certification and notice is sent to the brand manufacturer, the brand manufacturer has forty-five days to bring an action for infringement.²⁹ When the action is filed, a thirty-month stay is automatically placed on the approval of the ANDA.³⁰ Since the action is brought in response to the ANDA, and not to actual market entry, the generic manufacturer's ANDA is only a technical act of infringement.³¹ Although the thirty-month stay is triggered automatically, the NDA holder

28. 21 U.S.C. § 355(c)(3)(E)(ii). Four years is the minimum if the generic filer makes a Paragraph IV certification. Five years is the minimum for all other forms of generic entry and for NDAs containing new chemical entities. In addition, if the brand manufacturer challenges the Paragraph IV certification for patent infringement within a year of an ANDA filed at exactly the 4-year mark, the normal thirty-month stay will be extended to block generic entry until a total of 7.5 years have passed from NDA approval.

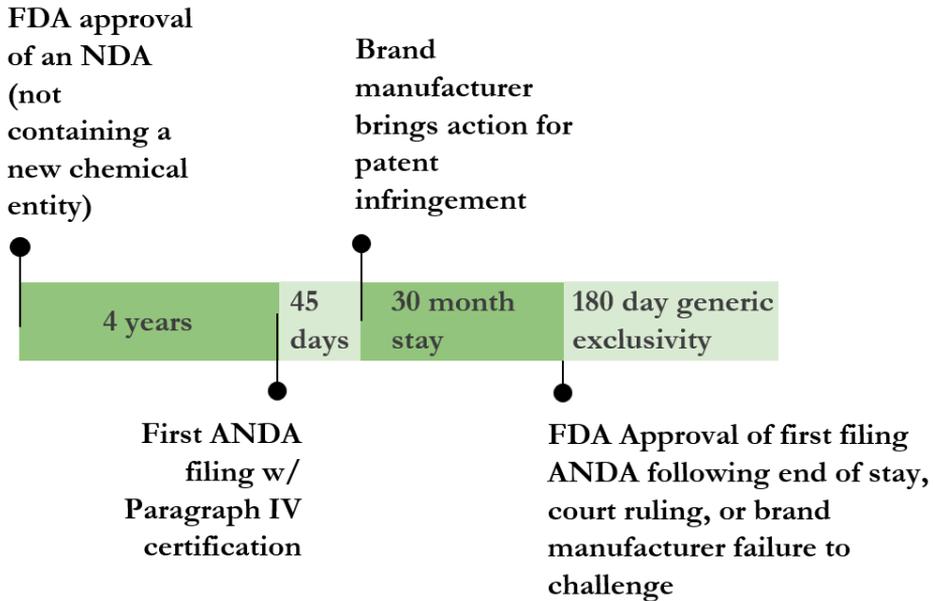
29. 21 U.S.C. § 355(j)(5)(B)(iii). *See supra* Figure 1 for further reference.

30. 21 U.S.C. § 355(j)(5)(B)(iii).

31. 35 U.S.C. § 271(e)(2).

must still prove that the generic will infringe on valid patents.³² If a court decides that the patent is invalid or not infringed before the thirty-month stay ends, the FDA will approve the generic's application, effective when the court order is entered.³³ If a court finds that the patent has been infringed, the approval of the generic's application will be approved on the date specified by the court order, which will be after the expiration of the infringed patent.³⁴

Figure 2: The Timeline for an ANDA Filed with a Paragraph IV Certification



32. See 21 U.S.C. § 355(j)(5)(B)(iii)(II)–(IV) (requiring that the NDA holder obtain a court ruling that the patent was infringed to block FDA approval until a date specified by a court order).

33. 21 U.S.C. § 355(j)(5)(B)(iii)(I).

34. 21 U.S.C. § 355(j)(5)(B)(iii)(II); 35 U.S.C. § 271(e)(4)(A).

3. *Amendments to Hatch-Waxman: The Medicare Modernization Act of 2003*

In 2003, Congress amended the Hatch-Waxman Act as part of an overhaul of Medicare aimed at making pharmaceuticals more affordable.³⁵ Among other issues, the amendments fixed concerns with the thirty-month stay rules which the FTC identified in a study in 2002.³⁶ Under the original version of the Hatch-Waxman Act, drug innovators could obtain multiple thirty-month stays on the generic entry of a single ANDA by “late listing” a patent.³⁷ By submitting a patent for listing after the ANDA was filed, a brand manufacturer could force the ANDA applicant to file a new ANDA for that later-listed patent, triggering a new opportunity for a new thirty-month stay.³⁸

In 2002, the FTC performed a study on generic entry, which identified seven instances of brand name manufacturers earning more than one stay on the basis of a patent listed in the Orange Book after the filing of an ANDA.³⁹ As a result, the FTC recommended that only one thirty-month stay should be permitted per drug product per ANDA.⁴⁰ Congress responded with the Medicare Modernization Act (MMA), which limited the brand drug manufacturer from obtaining more than one thirty-month stay per ANDA.⁴¹ Under the current FDA rules, newly issued drug substance, drug product, method of use patents, or patents associated with changes to usage granted after the approval of an NDA must be submitted for listing in the Orange Book within thirty days of the patent issuance.⁴² However, any generic manufacturer with a pending ANDA who submitted their application prior to the listing of the late patent is not required to submit a patent certification to address that late-listed patent.⁴³ This means that the NDA holder loses the opportunity to get automatic regulatory exclusivity in the form of a thirty-

35. Medicare Prescription Drug, Improvement, and Modernization Act of 2003, Pub. L. 108-173, 117 Stat. 2066, § 1101.

36. FED. TRADE COMM’N, GENERIC DRUG ENTRY PRIOR TO PATENT EXPIRATION: AN FTC STUDY, *supra* note 3, at iv-v (recommending removing multiple thirty-month stays); Medicare Prescription Drug, Improvement, and Modernization Act of 2003, Pub. L. 108-173, 117 Stat. 2066, § 1101 (removing multiple thirty-month stays).

37. FED. TRADE COMM’N, GENERIC DRUG ENTRY PRIOR TO PATENT EXPIRATION: AN FTC STUDY, *supra* note 3, at iv-v, 48–49.

38. *Id.*

39. *Id.* at 48–49.

40. *Id.* at ivv.

41. Medicare Prescription Drug, Improvement, and Modernization Act of 2003, Pub. L. 108-173, 117 Stat. 2066, § 1101.

42. 21 C.F.R. § 314.53(d)(2)–(3).

43. 21 C.F.R. § 314.94(a)(12)(vi).

month stay on the late listed patent with regards to that ANDA.⁴⁴ However, the generic may still risk infringement if it goes to market, as the patent may still be enforceable, despite falling outside the time frame required by the regulatory scheme. Given that these amendments came in response to the FTC study, these modifications to the Hatch-Waxman Act appear to work to disincentivize brand manufacturers from strategically delaying their patent listings and instead encourage prompt listing to take full advantage of the available regulatory protections.

B. THE ORANGE BOOK PROVIDES PATENT EXCLUSIVITY INFORMATION TO GENERIC MANUFACTURERS

The FDA originally created the Orange Book to help pharmacists decide when it was safe to substitute generic versions of a drug for a prescribed brand name version of the same drug.⁴⁵ In 1984, as part of a larger effort to encourage drug development, Congress expanded the Orange Book from a simple drug-equivalence resource to an exclusivity information resource by requiring the FDA to publish a list containing the official and proprietary name of a given drug, its date of approval, and what kinds of studies are required for applications filed regarding the drug.⁴⁶ The modern Orange Book is comprised of four main sections: the prescription drug product list, the over-the-counter drug product list, and the drug products with approval under § 505 of the Food, Drug, and Cosmetic Act (“FD&C Act”) list, and the discontinued drug products list.⁴⁷ The Addendum to the Orange Book contains a list of drugs that qualify under the FD&C Act for periods of exclusivity and, importantly, contains patent information for newly innovated drugs.⁴⁸ Therefore, in addition to providing pharmacists with substitution guidance, the Orange Book also provides generic manufacturers notice of any patents covering drug products they wish to market. The FDA is obligated to revise the list once a month, include any newly submitted patent information for listed drugs, and specify any applicable exclusivity period.⁴⁹

44. *Id.*; 21 U.S.C. § 355(j)(5)(B)(iii) (predicating the thirty-month stay on an ANDA applicant filing a Paragraph IV certification).

45. 44 Fed. Reg. 2932-2933.

46. 21 U.S.C. § 355(j)(7)(A)(i)–(iii) (adding to Title 21 by the Hatch-Waxman Act).

47. *See generally* ORANGE BOOK.

48. *Id.*

49. 21 U.S.C. § 355(j)(7)(A)(i)–(iii).

C. THE FDA LIMITS LISTING AND ALLOWS FOR THIRD-PARTY DELISTING

The FDA requires that patents relating to the core formulation of a drug be listed in the Orange Book, and prohibits the listing of certain categories of peripheral patents.⁵⁰ Beyond the explicitly stated listing rules held by the FDA, courts have made efforts to clarify whether certain frequently contested types of patents are appropriate for listing, such as risk-management system patents and device component patents.⁵¹ In addition to its own stated listing rules, the FDA allows parties to challenge any Orange Book listings they think are improper through a neutral dispute process.⁵² This Section will cover the FDA's patent listing rules, the gray areas addressed by case law, and the process for challenging and delisting improperly listed patents.

1. *Listing Rules for Orange Book Patents*

The FDA requires an NDA applicant to submit all patents that claim the drug, or any method of using the drug from which a claim of patent infringement could “reasonably be asserted” if a non-licensed party manufactured, used, or sold the drug.⁵³ Drug substance patents which claim the active ingredient of the drug, drug product patents which claim the formulation or composition of the drug, and method-of-use patents which claim specific indications or conditions of use must be submitted with the NDA.⁵⁴ Furthermore, if a patent only claims the polymorph of a drug substance, the NDA applicant must submit additional clinical test data showing that the drug product will perform the same as the drug product described in the original NDA.⁵⁵

Conversely, the FDA also forbids the submission of certain types of patents to the Orange Book. The agency will not accept process patents, or

50. 21 C.F.R. § 314.53(b)(1).

51. *See, e.g.*, *Cesar Castillo, Inc. v. Sanofi-Aventis U.S., LLC* (*In re Lantus Direct Purchaser Antitrust Litigation*), 950 F.3d 1 (1st Cir. 2020) [hereinafter *Lantus*] (restricting device component patent listings); *Jazz Pharms. v. Avadel CNS Pharms.*, 60 F.4th 1373 (Fed. Cir. 2023) (restricting risk management systems listings).

52. 21 C.F.R. § 314.53(f).

53. 21 C.F.R. § 314.53(b)(1).

54. 21 U.S.C. § 355(b)(1)(A)(viii); 21 C.F.R. § 314.53(b)(1). In this context, indications are the medical conditions which a drug is approved to treat.

55. 21 C.F.R. § 314.53(b)(1). Polymorphs refer to the different molecular structures which a drug compound may exist in. They often have slightly different physical, and therefore medical properties. U.S. FOOD & DRUG ADMIN., ANDAS: PHARMACEUTICAL SOLID POLYMORPHISM CHEMISTRY, MANUFACTURING, AND CONTROLS INFORMATION at 2 (July 2007).

patents claiming packaging, metabolites, or intermediates.⁵⁶ In between these clearly permitted and clearly forbidden patent types is an indefinite gray area containing device component and risk management systems patents. These patents have been listed in the Orange Book and subsequently disputed in court, providing some limited clarification. In *In re Lantus Direct Purchaser Antitrust Litigation*, the First Circuit held that device components that did not claim a reference listed drug (RLD) should not be listed, even if the components were integral to the drug product.⁵⁷ In this case, Sanofi-Aventis listed a patent claiming one component of the injector pen as a dosage form and, therefore, a drug product under the FDA listing rules.⁵⁸ However, the patent itself did not mention insulin, except as an example of use in the specification, or claim the pen as a whole.⁵⁹ Instead, it only claimed the drive mechanism.⁶⁰ The First Circuit stated that an integral component could not be stretched to be considered the finished product and, therefore, could not claim the drug.⁶¹ It further noted that the FDA had already passed on the opportunity to adopt rules that would allow this interpretation.⁶² As a result, the First Circuit eliminated device component patents from an Orange Book listing.

In *Jazz Pharmaceuticals v. Avadel CNS Pharmaceuticals*, the Federal Circuit held that patents on risk management systems for managing drug abuse risks could not be listed in the Orange Book.⁶³ Jazz Pharmaceuticals held the NDA for a commonly abused narcolepsy drug.⁶⁴ Jazz produced and patented a computerized pharmacy distribution system that controlled access to the drug, and submitted this patent for Orange Book listing as a method-of-use patent.⁶⁵ The Federal Circuit held that the patent claimed the physical components of a system, rather than a performance of steps, and that the patent would have needed to claim a performance of steps to qualify as a method-of-use patent.⁶⁶ As a result, the Federal Circuit instructed Jazz to request the delisting of the

56. *Id.*

57. *Lantus*, 950 F.3d at 8–10.

58. *Id.* at 7.

59. *Id.* at 5.

60. *Id.*

61. *Lantus*, 950 F.3d at 8–10.

62. *Id.*; see also 68 Fed. Reg. 36680 (a notice-and-comment rulemaking cited by the *Lantus* court, where the FDA declined to include patents claiming containers that did not also claim the drug product).

63. *Jazz Pharms.*, 60 F.4th at 1382.

64. *Id.* at 1367.

65. *Id.* at 1376–77.

66. *Id.* at 1379–80.

patent from the Orange Book, demonstrating that risk management systems patents do not qualify for listing.⁶⁷

2. *The Orange Book Dispute and Delisting Process*

The FDA does not require parties to become involved in an infringement suit to challenge the inclusion of a patent in the Orange Book.⁶⁸ Any person other than the NDA holder may dispute the accuracy or relevance of patent information submitted to the FDA as part of an NDA.⁶⁹ Parties may also use the process to challenge NDA holders for failing to submit required patent information.⁷⁰ The patent listing dispute must include a statement providing the specific grounds for disagreement.⁷¹ Once the statement is submitted, the FDA sends it to the NDA holder, who must confirm the correctness of the patent information, or alternatively, amend or delist the patent.⁷² If the NDA holder provides the necessary confirmation of correctness within thirty days of the FDA sending the notice, the agency will not change the patent information in the Orange Book.⁷³

D. THE FEDERAL TRADE COMMISSION ASSERTED POTENTIAL ANTITRUST LIABILITY UNDER THE FTC ACT AND THE SHERMAN ACT

While the contents of the Orange Book have historically been a concern for the FDA, the FTC asserted authority to limit improper Orange Book patent listings through antitrust using the Federal Trade Commission Act in its 2023 Orange Book policy. In that policy, the FTC stated that the improper listing of patents may constitute an unfair method of competition under § 5 of the FTC Act.⁷⁴ The agency further noted that improper listing may potentially constitute illegal monopolization under § 2 of the Sherman Act.⁷⁵ This Section will address the legal background of § 5 of the FTC Act and § 2 of the Sherman Act. Section IV.C will discuss limitations on the FTC's authority under these

67. *Id.* at 1382.

68. 21 C.F.R. § 314.53(f).

69. 21 C.F.R. § 314.53(f)(1).

70. *Id.*

71. *Id.*

72. 21 C.F.R. § 314.53(f)(1)(i).

73. *Id.*

74. FED. TRADE COMM'N, FEDERAL TRADE COMMISSION STATEMENT CONCERNING BRAND DRUG MANUFACTURERS' IMPROPER LISTING OF PATENTS IN THE ORANGE BOOK 3–4, https://www.ftc.gov/system/files/ftc_gov/pdf/p239900orangebookpolicystatement092023.pdf [<https://perma.cc/F2TG-8NB3>] (last visited Aug. 28, 2024).

75. *Id.* at 5–6.

acts, including those introduced by the Supreme Court's *Loper Bright Enterprises v. Raimondo* decision.

1. *Section 5 of the FTC Act: Unfair Methods of Competition*

Under § 5 of the FTC Act, the Commission has the authority to prevent persons, partnerships, and corporations from using unfair methods of competition or deceptive acts and practices in commerce.⁷⁶ Before any discussions of the FTC's actual authority, it is necessary to understand how the FTC currently defines "unfair methods of competition." In 2022, the FTC published a policy statement regarding the scope of unfair methods of competition under § 5 of the FTC Act, overriding a previous 2015 policy statement.⁷⁷ The FTC has the flexibility to define and redefine the term "unfair methods of competition" because § 5 does not define the scope of the conduct it covers.⁷⁸ Instead, both Congress and the Supreme Court have allowed the FTC very broad reach under this Section.⁷⁹ Congress also indicated that the courts should give some deference to the FTC as an independent, expert agency.⁸⁰

According to the more recent policy, the alleged unfair conduct must be a method of competition.⁸¹ The FTC defines unfair methods of competition as conduct undertaken by an actor in the marketplace with anticompetitive intent or without other legitimate business reason for that conduct, rather than a

76. 15 U.S.C. § 45(a)(2).

77. FED. TRADE COMM'N, POLICY STATEMENT REGARDING THE SCOPE OF UNFAIR METHODS OF COMPETITION UNDER SECTION 5 OF THE FEDERAL TRADE COMMISSION ACT COMMISSION FILE NO. P221202, 1 (Nov. 10, 2022) https://www.ftc.gov/system/files/ftc_gov/pdf/P221202Section5PolicyStatement.pdf [https://perma.cc/7YJJ-LR5R]. [hereinafter FTCA SECTION 5 POLICY].

78. See S. REP. NO. 63-597, at 13 (A Senate report made during the creation of the FTC Act, stating that "The committee gave careful consideration to the question as to whether it would attempt to define the many and variable unfair practices . . . it concluded that [a general declaration] would be better, for the reason . . . that there were too many unfair practices to define, and after writing 20 of them into the law it would be quite possible to invent others.").

79. See, e.g., *id.*; H.R. CONF. NO. 63-1142, at 19 (1914) (Conf. Rep.) (accompanying the FTC Act and stating "It is impossible to frame definitions which embrace all unfair practices. . . . Whether competition is unfair or not generally depends upon the surrounding circumstances of the particular case."); *FTC v. Sperry & Hutchinson Co.*, 405 U.S. 233, 244 (1972) (holding that the Commission is not exceeding its authority if it "considers public values beyond simply those enshrined in the letter or encompassed in the spirit of the antitrust laws.").

80. S. REP. NO. 63-597, at 11 ("One of the chief advantages of the proposed commission over the Bureau of Corporations lies in the fact that it will have greater prestige and independence, and its decisions, coming from a board of several persons, will be more readily accepted as impartial and well considered.").

81. FTCA SECTION 5 POLICY, *supra* note 77, at 8.

condition of the market that the actor did not create.⁸² For example, the FTC suggested that high entry barriers to an industry, or small numbers of existing competitors due to declining demand, could be conditions a competitor did not create, and would not be unfair methods of competition.⁸³

In addition, an actor's unfair method of competition must go beyond competition on the merits of the business itself.⁸⁴ Competition on the merits can include superior products or services, work environment for employees, truthful advertising, or high investment in useful research and development.⁸⁵ In contrast, unfair conduct may be coercive, exploitative, deceptive, or collusive, and must tend to negatively affect competitive conditions.⁸⁶ The FTC may identify negative effects by looking at the collective conduct of an industry,⁸⁷ or the cumulative practices of an individual actor.⁸⁸

Although the FTC has historically had a large amount of freedom to define and enforce the terms of § 5, there are some restrictions to this authority. For example, the accused conduct must be “in or affecting commerce”⁸⁹ either within the United States or between the United States and foreign countries.⁹⁰ In addition, any proceedings the FTC undertakes under § 5 must be in the public interest.⁹¹ Most importantly, it is possible that the FTC's authority under § 5 may be abrogated by the Supreme Court's recent ruling in *Loper-Bright Enterprises v. Raimondo*, which will be discussed in Section IV.C.1.

2. Section 2 of the Sherman Act: Illegal Monopolization

The FTC also states in its Orange Book policy that improper listing of patents may constitute illegal monopolization.⁹² Monopolization of trade or

82. *Id.*

83. *Id.*; *E.I. Du Pont de Nemours & Co. v. FTC*, 729 F.2d 128, 139–141 (2d Cir. 1984) (holding that similar business practices by all four players in a declining industry was not inherently anticompetitive, since there were legitimate reason for the conduct—regardless of the fact that it was occurring in an oligopolistic market).

84. FTCA SECTION 5 POLICY, *supra* note 77, at 8.

85. *See, e.g.*, *United States v. Grinnell Corp.*, 384 U.S. 563, 570–71 (1966).

86. FTCA SECTION 5 POLICY, *supra* note 77, at 8–9.

87. *FTC v. Motion Picture Advert.*, 344 U.S. 392, 395 (1953) (holding that the collective practice by four major players in the market of making exclusive contracts limited competition to the point of being an unfair method of competition).

88. FTCA SECTION 5 POLICY, *supra* note 77, at 10.

89. 15 U.S.C. § 45(a)(2).

90. 15 U.S.C. § 44.

91. 15 U.S.C. § 45(b).

92. FED. TRADE COMM'N, FEDERAL TRADE COMMISSION STATEMENT CONCERNING BRAND DRUG MANUFACTURERS' IMPROPER LISTING OF PATENTS IN THE ORANGE BOOK 5–6, https://www.ftc.gov/system/files/ftc_gov/pdf/p239900orangebookpolicystatement092023.pdf [<https://perma.cc/F2TG-8NB3>] (last visited Aug. 28, 2024).

commerce, or an attempt to monopolize trade or commerce, is illegal under § 2 of the Sherman Act.⁹³ Illegal monopolization contains two elements: (1) the possession of monopoly power in the relevant market, and (2) the willful acquisition or maintenance of that power in ways that are not simply consequences of having a better product or business.⁹⁴ To prove that a company possesses monopoly power, a plaintiff must demonstrate that the company has the ability to control prices or exclude competition.⁹⁵ Therefore, it is important to show that an actor both engaged in illegitimate conduct, and that this conduct resulted in actual acquisition or maintenance of monopoly power.⁹⁶ In the pharmaceutical monopolization cases discussed in Section II.E, many of the plaintiffs allege an overall scheme comprised of multiple acts, including improper listing and subsequent sham litigation, that prevented or delayed generic entry.⁹⁷

Despite the use of the term “willful” in the definition of monopolization, courts in § 2 cases generally do not look for specific intent to monopolize, but rather to the “deliberateness,” or general intent to engage in conduct that had the consequence of establishing or maintaining a monopoly.⁹⁸ In *United States v. Griffith*, the Supreme Court held that it was not necessary to prove specific intent to build a monopoly when a group of cinemas negotiated agreements to pool their buying power in film screenings.⁹⁹ The court held that it was “sufficient that a restraint of trade or monopoly results as the consequence of a defendant’s conduct or business arrangements.”¹⁰⁰ Specific intent is required only if the defendant’s actions did not quite reach the point of creating a monopoly.¹⁰¹ Showing an intent to create the monopoly is only necessary when actions beyond natural business forces would have been required to create a monopoly.¹⁰² In *Barry Wright Corp. v. ITT Grinnell Corp.*, the First Circuit stated

93. 15 U.S.C. § 2.

94. *Grinnell Corp.*, 384 U.S. at 570–71.

95. *Pepsico, Inc. v. Coca-Cola Co.*, 315 F.3d 101, 107–08 (2d Cir. 2002). Note that the FTC itself does not have the power to bring actions under the Sherman Act, and thus cases involving a Sherman Act § 2 claims are not brought under the FTC’s name. The agency may intervene, but it cannot initiate the suit. *See* 15 U.S.C. § 21(b) (permitting the FTC to initiate actions under 15 U.S.C. §§ 13, 14, 18, and 19—notably not including § 2, the illegal monopolization provision of the Sherman Act); 15 U.S.C. § 45(b) (permitting the FTC to initiate actions under the FTC Act).

96. *Pepsico, Inc.*, 315 F.3d at 108.

97. *See, e.g., In re Remeron Antitrust Litig.*, 335 F. Supp. 2d 522, 526–27 (D.N.J. 2004).

98. 2 ANTI-TRUST LAWS AND TRADE REGULATION § 25.04 (2d ed. 2024).

99. *United States v. Griffith*, 334 U.S. 100, 105 (1948).

100. *Id.*

101. *Id.* (requiring specific intent “only where the acts fall short of the results condemned by the Act”).

102. *Id.* (quoting *Swift & Co. v. United States*, 196 U.S. 375, 396 (1905)).

that “intent to harm without more offers too vague a standard in a world where executives may think no further than [l]et’s get more business.”¹⁰³ Furthermore, if the search for intent to harm required a search for tangible documentation, strategic firms would simply not make such records.¹⁰⁴ Therefore, courts often judge willfulness in monopoly cases by the relation of the suspect price to the firm’s costs, rather than using intent.¹⁰⁵

However, in the area of complex regulatory policy, the general intent standard may not apply. For example, the Seventh Circuit has allowed antitrust defendants to raise their good-faith attempt to adhere to regulatory obligations as a legitimate antitrust defense, particularly for heavily regulated utilities such as the telecommunications industry.¹⁰⁶ In *MCI Communications Corporation v. American Telephone and Telegraph Company*, the Seventh Circuit held that while the existence of a complex regulatory scheme did not grant antitrust immunity, a sufficiently complex body of regulation permits parties accused of monopolization to raise a good-faith compliance defense.¹⁰⁷ MCI Communications alleged that the American Telephone and Telegraph Company (AT&T) had illegally created and maintained a monopoly.¹⁰⁸ The telecommunications industry was controlled by a complex regulatory policy based on the Federal Communications Commission’s (FCC) *Specialized Common Carriers* decision, which the court described as “hardly a model of clarity.”¹⁰⁹ AT&T argued that the FCC had approved each of the individual alleged anticompetitive activities, and should therefore at least have ad hoc immunity.¹¹⁰ The Seventh Circuit explained that the Communications Act of 1934 did not expressly grant antitrust immunity, and that it was well established that regulated industries are not immunized from antitrust liability for voluntarily initiated conduct.¹¹¹ Antitrust immunization should only be granted to the minimum extent necessary to make the regulatory scheme work.¹¹² Furthermore, the court observed that the FCC’s interconnection policies appeared to be designed to promote competition, meaning antitrust liability was likely to complement, rather than undermine, the regulatory framework.¹¹³

103. *Barry Wright Corp. v. ITT Grinnell Corp.*, 724 F.2d 227, 232 (1st Cir. 1983) (internal quotation marks omitted).

104. *Id.* at 232.

105. *Id.*

106. *MCI Commc’ns Corp. v. Am. Tel. & Tel. Co.*, 708 F.2d 1081, 1109 (7th Cir. 1983).

107. *Id.* at 1106–10.

108. *Id.* at 1092.

109. *Id.* at 1095.

110. *Id.* at 1102.

111. *Id.* at 1103.

112. *Id.* at 1102.

113. *Id.* at 1104.

Despite finding that AT&T did not have antitrust immunity, the Seventh Circuit noted that substantial regulation in an industry might alter the scope of behaviors that fall under willful acquisition or maintenance of monopoly power.¹¹⁴ The Seventh Circuit thus agreed with the district court that an antitrust defendant is entitled to raise and have the jury consider a good-faith attempt to adhere to a regulatory scheme as a legitimate antitrust defense.¹¹⁵ These cases demonstrate that the standards for antitrust violations may be different for highly regulated industries, and they may include an allowance for a good-faith defense.

E. COURTS HAVE FOUND THAT IMPROPER LISTING MAY SUPPORT CLAIMS OF MONOPOLIZATION, BUT HAVE NOT PROVIDED A FINAL DETERMINATION ON THE ISSUE

Courts have recognized that improper submissions to the Orange Book could create antitrust liability for drug companies under a monopolization theory, but none so far have issued a ruling of antitrust liability.¹¹⁶ This has left antitrust claims based on Orange Book listings an area of unsettled case law. Cases where courts recognize a potential for antitrust liability tend to follow a pattern: a group of direct purchasers or a prospective generic competitor will sue a brand manufacturer for an ongoing pattern of behavior, which may include fraudulent patents, improper listings, and sham litigations based on those improper listings or fraudulent patents.¹¹⁷ The brand manufacturer will claim some form of antitrust immunity, and the court will either find that improper listing may qualify as part of a pattern of anticompetitive behavior or disqualify improper listing but uphold the plaintiff's overall complaint. In the cases below which follow this pattern, the courts have not yet provided final rulings on the issue of antitrust liability. This suggests that private antitrust enforcement is poorly suited to regulating patents in the Orange Book.

1. *District Courts Find That Improper Listings Have Potential to Be Antitrust Violations: In re Buspirone Antitrust Litigation and In re Remeron Antitrust Litigation*

In re Buspirone was one of the earliest cases to test the idea that improper listing could qualify as a Sherman Act § 2 violation, and thus the *Buspirone* court was one of the first to suggest that misrepresentations in making Orange Book listings might constitute fraud on the government resulting in antitrust

114. *Id.* at 1106.

115. *Id.* at 1109–10.

116. *See, e.g., Lantus*, 950 F.3d 1, 13–15 (1st Cir. 2020).

117. *See, e.g., id.; In re Buspirone Pat. & Antitrust Litig.*, 185 F. Supp. 2d 363, 365–67 (S.D.N.Y. 2002).

liability.¹¹⁸ In *Buspirone*, a group of generic drug manufacturers, direct purchasers, end-payers, and consumer protection organizations brought a suit against pharmaceutical giant Bristol-Myers Squibb (BMS).¹¹⁹ The plaintiffs alleged that BMS violated § 2 of the Sherman Act through (1) a reverse payment settlement¹²⁰ on an infringement suit and (2) an improper Orange Book listing for a patent for its drug buspirone, submitted less than one day before the existing patent expired.¹²¹ Plaintiffs believed that the patent was fraudulently represented to the FDA to cover uses of buspirone that should have gone into the public domain with the expiration of the prior patent.¹²² They then alleged that BMS asserted this fraudulent patent against generic competitors, triggering a thirty-month stay under Hatch-Waxman and unfairly delaying generic entry.¹²³

BMS raised a *Noerr-Pennington* immunity defense.¹²⁴ *Noerr-Pennington* immunity refers to a pair of cases in which the Supreme Court held that the Sherman Act did not prevent concerted efforts to persuade or influence legislation.¹²⁵ However, the district court observed two exceptions to this defense.¹²⁶ The first is the *Walker-Process* exception, which removed *Noerr-Pennington* immunity if a party knowingly and willfully made false representations to the government.¹²⁷ The second applies if the monopoly is sustained by “sham” litigation, or in other words, a baseless lawsuit used to interfere with the business relationships of a competitor through the use of government processes, rather than waiting for the outcome of those processes.¹²⁸

118. *Buspirone*, 185 F. Supp. 2d at 374–75. There was one other suit before *Buspirone* in 2000, which will be discussed *infra* Part II.E.2. See *Warfarin Sodium*, 214 F.3d at 401.

119. *Buspirone*, 185 F. Supp. 2d at 365–66.

120. A reverse payment settlement in the pharmaceutical patent context is when a patent-holding brand manufacturer pays a potential generic competitor to stay out of the market and to not create the risk of patent invalidation by challenging the patent in court. See *FTC v. Actavis, Inc.*, 570 U.S. 136, 140 (2013). While reverse payment settlements in patent cases are not presumptively unlawful because patents allow the patent-holder to legally exclude others from a market, they may be antitrust violations depending on their size and scale. *Id.* at 158–59.

121. *Buspirone*, 185 F. Supp. 2d at 366–67.

122. *Id.* at 366.

123. *Id.*

124. *Id.* at 368.

125. *E. R.R. Presidents Conf. v. Noerr Motor Freight, Inc.*, 365 U.S. 127 (1961); *United Mine Workers v. Pennington*, 381 U.S. 657 (1965) (collectively establishing the *Noerr-Pennington* doctrine).

126. *Buspirone*, 185 F. Supp. 2d at 368–69.

127. *Id.*

128. *Id.* at 368.

The district court ruled that the *Noerr-Pennington* doctrine did not apply to BMS's conduct.¹²⁹ The court found that since the FDA must include patents in the Orange Book under the law, and does not make decisions about the representations made in the Orange Book, BMS's patent filings were not acts of petitioning or persuading the government.¹³⁰ The court further ruled that even if *Noerr-Pennington* had applied to BMS's conduct, "the [FDA] listing process is nevertheless such that misrepresentations as to the scope of a patent can be fraudulent for *Walker Process* purposes."¹³¹ In addition, BMS could not have reasonably asserted infringement claims based on a patent that did not claim the drug against generic competitors seeking to market that drug.¹³² After the majority of BMS's motions to dismiss were denied, the parties agreed to dismiss the proceedings.¹³³ The lack of a final ruling makes it difficult to determine what role, if any, improper listing could play in the finding of antitrust liability under the Sherman Act.

The District Court for the District of New Jersey in *In re Remeron Antitrust Litigation* looked at similar facts and followed similar reasoning to the New York district court.¹³⁴ The New Jersey court held that manipulation of the ANDA process might mean that relief could be granted under § 2 of the Sherman Act, but, like the New York court, declined to rule definitively on the question of actual antitrust liability.¹³⁵ The Remeron direct purchasers filed antitrust complaints against Organon, alleging an "overall scheme" to monopolize the relevant market on the basis of a fraudulently obtained patent, submitting patents to the Orange Book that do not qualify for listing, baseless patent infringement actions, and improperly delayed Orange Book listing.¹³⁶ The district court denied Organon's motion to dismiss in part, dismissing the improper listing and sham litigation claims, but allowing the "overall scheme" claims because "[w]ithin the maze of Hatch-Waxman, if a patent-holder's actions unlawfully maintain otherwise lawful monopoly power or use a lawful patent to manipulate the ANDA process, such actions could lead to anticompetitive effects . . . it cannot be said to a legal certainty that no relief

129. *Id.* at 371–73.

130. *Id.*

131. *Id.* at 374.

132. *Id.* at 375.

133. Bristol-Myers Squibb Co. v. Mylan Pharms., Inc. (*In re Bupirone Patent Litigation*), 60 Fed. Appx. 806 (Fed. Cir. 2003).

134. Walgreen Co. v. Organon, Inc. (*In re Remeron Antitrust Litig.*), 335 F. Supp. 2d 522 (D.N.J. 2004).

135. *Id.* at 525.

136. *Id.* at 526–27.

could be granted under § 2.”¹³⁷ The case later settled, meaning that *Remeron* also does not provide concrete answers on potential antitrust liability associated with improper listings.¹³⁸ Notably, a settlement may have been reached in this case, and in many of the other cases discussed in this Part, specifically to avoid setting a precedent of antitrust liability for creating improper Orange Book listings.¹³⁹ If a party to a litigation is concerned about the effect of a precedent that could result from a trial, it is reasonable for that party to settle for some price that they believe to be worth avoiding that precedent.¹⁴⁰

2. *Circuit Courts Find That Improper Listings Have Potential to be Antitrust Violations: In re Warfarin Sodium Antitrust Litigation and In re Lantus Direct Purchaser Antitrust Litigation*

In 2000, the Third Circuit Court of Appeals took on a case addressing the potential for antitrust liability for improper listing.¹⁴¹ The Third Circuit found that the dissemination of misleading information regarding a generic, and an attempt to delay FDA approval of generic drugs that resulted in inflated prices for consumers, was sufficient to grant antitrust standing.¹⁴² In *In re Warfarin Sodium Antitrust Litigation*, a class of the drug’s users alleged that they had paid inflated prices due to the brand manufacturer DuPont delaying FDA approval of a generic drug, and disseminating false information about the generic.¹⁴³ The district court had dismissed the complaints for lack of standing based on factors outside of those alleged in the complaint, namely the existence of third-party payors, which likely absorbed the impact of the high prices.¹⁴⁴ The Third Circuit overturned the dismissal, stating that the district court applied the rules of standing incorrectly by considering external factors, and that the drug’s purchasers could be the target of an antitrust violation.¹⁴⁵ Regardless of the actions of middlemen, the court stated that “the overcharge was the aim of DuPont’s preclusive conduct. It is difficult to imagine a more formidable demonstration of antitrust injury.”¹⁴⁶ While this ruling does not state that

137. *Id.* at 532.

138. *In re Remeron Direct Purchaser Antitrust Litig.*, No. 03-CV-0085, 2005 U.S. Dist. LEXIS 47058 (D.N.J. 2005) (the order settling the case).

139. Leandra Lederman, *Precedent Lost: Why Encourage Settlement, and Why Permit Non-Party Involvement in Settlements*, 72 NOTRE DAME L. REV. 221, 231 (Oct. 1999).

140. *Id.*

141. *Warfarin Sodium*, 214 F.3d at 396–97.

142. *Id.*

143. *Id.* at 397.

144. *Id.* at 397–98.

145. *Id.* at 401.

146. *Id.*

delaying FDA approval of a generic was in fact an antitrust injury, it suggested that it could be if a court later found that end users actually suffered higher prices.¹⁴⁷ The case subsequently settled.¹⁴⁸

The First Circuit has also found that improper listings could be indicative of an extension of monopoly power. In *In re Lantus Direct Purchaser Antitrust Litigation*, the First Circuit considered the applicability of Sherman Act § 2 claims against Sanofi's listing of a "drive mechanism" patent for an insulin glargine injector pen.¹⁴⁹ The court found that Sanofi improperly listed the patent, because the patent did not claim the drug under which it was submitted.¹⁵⁰ The court also held that antitrust causation only required that the accused activity be a "substantial" cause of injury, and that it was possible that the automatic thirty-month stay on FDA approval of the generics had affected the course of the subsequent litigation.¹⁵¹ However, this was not in itself sufficient to demonstrate willful maintenance of Sanofi's monopoly power, and the court remanded for further proceedings, placing the burden on Sanofi to demonstrate that its conduct was both reasonable and in good faith.¹⁵² The district court has not reached a decision on this point, as the case appears to still be ongoing.¹⁵³ *Lantus* came very close to providing a concrete decision on whether improper listing, on its own, constitutes willful maintenance of monopoly power. However, the First Circuit did not definitively state that it would constitute antitrust liability or suggest how Sanofi might prove that it had acted in good faith.¹⁵⁴ Thus, *Lantus* is instructive of what courts may decide, but is not definitive, and does not provide a good basis for antitrust regulation of Orange Book listings.

III. IMPROPER LISTING CAN LEAD TO UNWARRANTED DELAYS IN NARROW CIRCUMSTANCES

This Part will discuss viewpoints on whether improper Orange Book listings harm consumers, as consumer welfare has long been a motivating force

147. *See id.*

148. *In re Warfarin Sodium Antitrust Litig.*, 212 F.R.D. 231 (D. Del. 2002).

149. *Lantus*, 950 F.3d at 7–10.

150. *Id.*

151. *Id.* at 14–15.

152. *Id.* at 13.

153. *In re Lantus Direct Purchaser Antitrust Litig.*, No. 16-12652-LTS, 2024 U.S. Dist. LEXIS 205081 (D. Mass. Nov. 12, 2024) (denying a request to strike three rebuttal expert reports).

154. *See Lantus*, 950 F.3d at 13–15.

behind antitrust enforcement.¹⁵⁵ Some studies on the Orange Book have indicated that improper listing as a general matter does not appear to cause harm to consumers. On the other hand, there are nevertheless acute cases, such as *Teva Pharmaceuticals v. Amneal Pharmaceuticals*, where intervenors, including the FTC, have observed that improper listings can have a negative impact on both consumers and industry competition.¹⁵⁶ This difference in views on consumer harm indicates that antitrust mechanisms are not well suited to Orange Book listing regulation. Different courts could arrive at different conclusions about whether improper listing can be a component of an antitrust violation or even an antitrust violation in and of itself. If the differences resulted in a circuit split, industry would be forced to contend with inconsistent standards for listing behavior. In addition, not all improperly listed patents could be found and corrected through antitrust mechanisms. However, the existence of these acute cases also suggests that improper Orange Book listing should, in general, be addressed.

A. STUDIES INDICATE THAT IMPROPER LISTING DOES NOT APPEAR TO HAVE NEGATIVE EFFECTS

To date, studies analyzing the effect of Orange Book patent listing on consumers have not found indications that improper listing results in consumer harm. One Orange Book landscape study found that most drug products had no Orange Book patent listing at all, which suggests that improper listing rates are low because listing rates of patents are low, regardless of whether the drug products are patented.¹⁵⁷ Another study examining the effect of patents on generic entry found that generic entry timing did not appear to be affected by the number or type of patents listed in the Orange Book under a given drug.¹⁵⁸ Both landscape studies indicated that Orange

155. See Murat C. Mungan & John M. Yun, *A Reputational View of Antitrust's Consumer Welfare Standard*, 61 HOUS. L. REV. 569 (2024) (noting that consumer welfare has guided antitrust agencies for the last 50 years and arguing against the push away from consumer welfare as a driving force).

156. Fed. Trade Comm'n's Brief as Amicus Curiae at 28–29, *Teva Branded Pharm. Prods. R&D v. Amneal Pharms. of N.Y., LLC*, 736 F. Supp. 3d (D.N.J. 2024) (No. 23-20964).

157. Jonathan J. Darrow & Daniel C. Mai, *An Orange Book Landscape: Drugs, Patents, and Generic Competition*, 77 FOOD & DRUG L.J. 51, 56 (2022).

158. C. Scott Hemphill & Bhaven N. Sampat, *Weak Patents Are a Weak Deterrent: Patent Portfolios, the Orange Book Listing Standard, and Generic Entry in Pharmaceuticals*, NBER 14 (2011).

Book patent listing does not affect the prices customers pay.¹⁵⁹ However, both studies also stated caveats to their findings.¹⁶⁰

1. *The Number and Type of Patents Do Not Affect the Timing of Generic Entry*

A 2011 study found that despite an increase in the number of patents listed per drug product, the number and type of patents listed for a given drug had little effect on the timing of generic entry.¹⁶¹ This study suggested that improper listings may not be a significant problem for consumers.¹⁶² Working with a Patent and Trademark Office examiner of drug patent applications, Professors C. Scott Hemphill and Bhaven N. Sampat counted and classified Orange Book-listed patents on new molecular entities, which they defined as drugs with both a novel and previously approved active ingredient.¹⁶³ They classified the patents as claiming or not claiming an active ingredient.¹⁶⁴ The authors observed that the number of new molecular entities with a listed non-active ingredient patent increased sharply, from less than 60 percent of newly approved drugs in 1985 to 85 percent of newly approved drugs in 2002, and suggested that this data shows strong evidence of aggressive patenting.¹⁶⁵

Hemphill and Sampat also examined generic entry at the end of 2011 for new molecular entities patented between 1992 and 1996.¹⁶⁶ They observed that the total number and type of listed patents had no statistically significant effect on whether or not a drug was subject to generic entry, or the time to generic launch.¹⁶⁷ The authors posited that this was because non-active ingredient patents, particularly term-extending weak patents, were likely to draw Paragraph IV challenges, resulting in a stable effective market life despite a rise in the frequency of challenges.¹⁶⁸ They noted that while this system may not create significant generic entry delays, it does create significant transaction costs as brands and generics engage in litigation without creating change in the

159. Darrow & Mai, *supra* note 157, at 60; *see also* Hemphill & Sampat, *supra* note 158, at 12.

160. Darrow & Mai, *supra* note 157, at 64–65; Hemphill & Sampat, *supra* note 158, at 23–24.

161. Hemphill & Sampat *supra* note 158, at 14.

162. *Cf. id.* at 19 (stating that effective market life of a brand name drug is stable at 12 years). This implies that the larger number of patents has not increased generic entry times, and therefore has not resulted in harm to consumers.

163. *Id.* at 8–9.

164. *Id.* at 9.

165. *Id.* at 10, 16.

166. *Id.* at 12.

167. *Id.* at 14.

168. *Id.* at 18–19.

system.¹⁶⁹ The Hatch-Waxman patent listing and challenge system has resulted in a stalemate where brands acquire patents and generics successfully challenge them, resulting in legal costs for activities that effectively cancel each other out.¹⁷⁰

They also acknowledged that there may be unobserved effects in the study. For example, the number of patents on a drug could affect the number of generic entrants, influence the bargaining power of brand name firms when seeking settlements, or only make a difference for certain blockbuster drugs.¹⁷¹ In addition, the date range of their data collection only analyzes brand name drug manufacturer behavior prior to the Medicare Modernization Act, covering brand manufacturer activity from 1985 to 2002.¹⁷² As such, it may not be fully representative of modern, post-MMA brand manufacturer behavior, where new strategies may increase or decrease generic entry times in new ways. A more modern Orange Book landscape study, discussed below, does not appear to differentiate between pre- and post-MMA behavior, which could be an avenue of interest for future study.

2. *Most NDAs Lack Associated Orange Book Patent Listings*

Despite the increase in patents Hemphill and Sampat observed, it also seems that the majority of NDAs do not have Orange Book patent listings. In a 2022 study, professors Jonathan J. Darrow and Daniel T.C. Mai observed that over half (61.7 percent) of NDAs were not associated with patents in the Orange Book, and a very small fraction of NDAs (5.3 percent) had more than ten listed patents.¹⁷³ They also found that over a quarter (28 percent) of NDAs had approved ANDAs despite retaining a patent exclusivity period.¹⁷⁴ Including regulatory exclusivity along with patents, still over half (57.6 percent) of the drugs in the study had no exclusivity protection whatsoever.¹⁷⁵ This finding implies that improper listing is infrequent because patent listing on drug products is infrequent.¹⁷⁶ Darrow and Mai noted that despite the common assumption that prices decline dramatically after patent expiration, this was

169. *Id.* at 22–23.

170. *Id.* at 23–24.

171. *Id.*

172. *Id.* at 10, 12 (listing the date ranges for the patents they studied). Note that they looked at generic entry in 2011, but these generic entries were based on brand manufacturer actions taken before the MMA. *See* Medicare Prescription Drug, Improvement, and Modernization Act of 2003, Pub. L. 108-173, 117 Stat. 2066, § 1101 (altering the stay provisions of the Hatch-Waxman Act in 2003).

173. Darrow & Mai, *supra* note 157, at 56.

174. *Id.* at 59.

175. *Id.* at 62.

176. *See id.*

only the case when ten or more generic competitors entered the market after expiration, and only 10.7 percent of NDAs had ten or more approved ANDAs.¹⁷⁷ Thus, they concluded that the impact of patent expiration on financial savings may be overstated.¹⁷⁸

This finding indicates that improper listings may not have as severe an effect on prices as many assume. However, Darrow and Mai acknowledged that regulatory exclusivities may be more important than they appear to be in this study, because regulatory exclusivities are frequently immune from judicial invalidation.¹⁷⁹ The authors also did not independently review or categorize the patents listed in the Orange Book, taking the categorizations as presented.¹⁸⁰ Since the authors did not review the patents' categorizations, the actual frequency of improper listing is unclear from this study. The study also did not examine whether improperly listed patents were concentrated around a few select drug products. This appears to have been the FTC's view, as prior to this Note, the agency focused much of its public effort on inhaler or injector patents.¹⁸¹ Additionally the study did not differentiate between Orange Book listings generated before and after the Medicare Modernization Act. Changes to the regulatory system due to the Medicare Modernization Act may have altered drug manufacturers' behavior, resulting in different amounts or different types of improper listings.

Collectively, the Darrow-Mai study and the Hemphill-Sampat study suggest that Orange Book listing may not significantly influence generic entry. If generic entry is not affected by listings generally, then it may be difficult to prove that improper listing is anticompetitive, and it may therefore be difficult to use antitrust enforcement to remove improper listings. On the other hand, some frequently prescribed drugs do lack generics and thus come with high prices, which other researchers argue may cost consumers millions of dollars per year above projected generic prices.¹⁸²

B. CASE STUDY ON THE HARMS OF IMPROPER LISTINGS: THE FTC'S AMICUS CURIAE BRIEFS IN *TEVA V. AMNEAL*

In contrast to the studies, recent case law presents acute examples of improper listings that may harm consumers. Soon after the release of the

177. *Id.* at 60.

178. *Id.*

179. *Id.* at 64–65.

180. *Id.*

181. See FTC PHARMACEUTICAL NOTICES, *supra* note 8 (flagging a collection of inhaler and injector patents as improper listings).

182. THE COSTS OF PHARMA CHEATING 13–18 (Am. Econ. Liberties Project & Initiative for Meds., Access, & Knowledge (I-MAK)) (May 2023).

FTC's Orange Book policy, Teva Pharmaceuticals ("Teva") brought an action against Amneal Pharmaceuticals ("Amneal") for infringement of a series of patents owned by Teva.¹⁸³ Teva listed a set of patents in the Orange Book under its NDA for the inhalable asthma medication albuterol sulfate aerosol.¹⁸⁴ Amneal filed an ANDA with a Paragraph IV certification to make a generic version of the drug with a certification that the generic product would not infringe any valid claims of the patents.¹⁸⁵ Teva filed suit in response to the Paragraph IV certification.¹⁸⁶ The FTC filed amicus curiae briefs in the district court and the appellate court.¹⁸⁷

In the amicus briefs, the FTC argued that improper listing creates delays to generic entry which harm consumers. In this particular case, the FTC asserted that Teva triggered a thirty-month stay based on inhaler and dose counter device patents that did not appear to be specific to any FDA drug, and were thus blocking generic entry on the basis of patents that did not claim the drug product.¹⁸⁸ The FTC expressed concerns that improper listings disrupt the balance Congress created in the Hatch-Waxman Act, allowing a brand manufacturer to keep a would-be generic competitor out of the market for thirty months without needing to show that it is likely to succeed on the merits of an infringement action.¹⁸⁹ More importantly, the FTC argued, when generics enter a market, prices can fall significantly.¹⁹⁰ However, the FTC was concerned that faced with the prospect of a thirty-month delay, a generic competitor may give up on marketing a generic version of that drug, keeping the prices of the drug high and ultimately harming both patient health and competition.¹⁹¹

Several legal, economic, and medical scholars also involved themselves in this case via an amicus brief. Like the FTC, they highlighted that the inhaler patents in question did not mention any drug, including the specific drug Teva

183. *Teva Branded Pharm. Prods. R&D v. Amneal Pharms. of N.Y., LLC*, 736 F. Supp. 3d 227 (D.N.J. 2024).

184. *Id.* at 229.

185. *Id.*

186. *Id.*

187. Fed. Trade Comm'n's Brief as Amicus Curiae, *Teva v. Amneal*, 736 F. Supp. 3d 227 (D.N.J. 2024) (No. 23-20964); Brief for the Fed. Trade Comm'n as Amicus Curiae in Support of Appellees Supporting Affirmance, *Teva Branded Pharm. Prods. R&D, Inc. v. Amneal Pharms. of N.Y., LLC*, 124 F.4th 898 (Fed. Cir. 2024) (No. 24-1936).

188. Fed. Trade Comm'n's Brief as Amicus Curiae, *supra* note 187, at 2.

189. Brief for the Fed. Trade Comm'n as Amicus Curiae in Support of Appellees Supporting Affirmance, *supra* note 187, at 16.

190. Fed. Trade Comm'n's Brief as Amicus Curiae, *supra* note 187, at 26.

191. *Id.* at 28–29.

submitted to the FDA.¹⁹² The patents did not claim any chemical, and they only referenced medical use as an example of the purpose of the device in the patent's preamble.¹⁹³ In its defense, Teva argued that its patent "claim[ed] the drug" as required by the FDA Orange Book listing standards, because some of the claim limitations are found in the drug product at issue.¹⁹⁴ However, as the scholars' brief points out, patents do not claim a product unless "each and every element" of the patent claims appears in the product.¹⁹⁵ The presence of just one patented element in a product does not mean the patent claimed the entire product, much like a patent on a single piece of software cannot claim the computer on which it operates.¹⁹⁶

The scholars also argued that the extension of Teva's period of exclusivity on albuterol sulfate HFA granted by the thirty-month stay caused actual harm to consumers.¹⁹⁷ Commentators have estimated that assuming a 60 percent drop in prices following a generic entry, Medicare and Medicaid paid an additional \$214 million in one year for Teva's specific product due to improper Orange Book listings.¹⁹⁸ While the Darrow and Mai study observed that drops in price of this size were uncommon unless there were ten or more generic entrants, inhaler products are common enough, and therefore lucrative enough, that a large drop in price is not impossible, and even a smaller drop in price may still save consumers a significant amount.¹⁹⁹ The amicus scholars also pointed to scholarship indicating that patients with common chronic lung diseases in particular suffer from a significant financial burden due to a lack of generic alternatives for inhalers.²⁰⁰

In *Teva v. Amneal*, the Federal Circuit ultimately concluded that a patent claims a drug when it distinctly points out the drug, and "not simply when the claim could somehow be interpreted to read on the drug."²⁰¹ It further held that the statutory context of the FDCA meant that for a patent to claim a drug for the purposes of listing within a drug application, the patent "must claim at

192. [Corrected] Brief of 52 Professors of Law, Economics, and Medicine as Amici Curiae in Support of Defendants-Appellees and Affirmance at 5–8, *Teva v. Amneal*, 124 F.4th 898 (Fed. Cir. 2024) (No. 24-1936) [hereinafter "Professor Amicus"].

193. *Id.* at 9.

194. *Id.* at 3–4.

195. *Id.* at 4–5.

196. *Id.*

197. *Id.* at 15.

198. *Id.*

199. Darrow & Mai, *supra* note 157, at 60.

200. Professor Amicus, *supra* note 192, at 16.

201. *Teva Branded Pharm. Prods. R&D, Inc. v. Amneal Pharms. of N.Y., LLC*, 124 F.4th 898, 916 (Fed. Cir. 2024).

least the active ingredient identified in the application.”²⁰² Finally, it concluded that a drug-device combination product being approved through an NDA does not make the device component a drug, affirming the lower court’s order to delist Teva’s contested inhaler patents.²⁰³

Teva has brought antitrust actions against other pharmaceutical companies for improper listings, indicating that they also believe improper listings can damage competition in certain circumstances. In *Teva Pharmaceuticals, Inc. v. Corcept Therapeutics, Inc.*, Teva brought an action against Corcept Therapeutics for “pervasive and highly damaging” antitrust violations in the mifepristone market.²⁰⁴ Teva alleged that Corcept subjectively understood that it had listed patents that did not directly read on Corcept’s brand-name drug, but still sued Teva for infringing the Corcept patents with Teva’s ANDA filing.²⁰⁵ Teva emphasized the subjective and knowing nature of Corcept’s improper listing.²⁰⁶ At the time of this Note, the Northern District of California stated that the delay Teva suffered in launching its product due to Corcept’s fraudulent Orange Book listings was sufficient injury to survive a motion to dismiss.²⁰⁷

Despite the results of the Darrow-Mai and Hemphill-Sampat studies, the two Teva cases imply that improper listings, while potentially rare, can have significant impact on consumers, and therefore should still be addressed. However, the uncertainty of the level of harm to consumers and competition suggests that antitrust may not be the optimal way to address the issue.

IV. AGENCIES CANNOT INDIVIDUALLY MAINTAIN QUALITY LISTINGS, BUT COLLABORATION MAY IMPROVE INFORMATIONAL ACCESS

The FDA, FTC, and USPTO are each unable to effectively limit improper Orange Book listings individually. The FTC has based its antitrust approach on unpredictable and inefficient mechanisms. In addition, private action under antitrust has not provided answers to the question of liability, as discussed above in Section II.E. This suggests that antitrust enforcement in general may not be the best way to address improper listings, as it is confined to questionably effective FTC action or private action in an area of unsettled case

202. *Id.* at 917.

203. *Id.* at 921–22.

204. Complaint at 1, *Teva Pharms. Inc. v. Corcept Therapeutics, Inc.*, No. 3:24-cv-03567 (June 13, 2024).

205. *Id.* at 2.

206. *Id.*

207. *Teva Pharms. Inc. v. Corcept Therapeutics, Inc.*, No. 3:24-cv-03567, 2025 U.S. Dist. LEXIS 179609, at *37–38 (N.D. Cal. Sep. 12, 2025).

law. But outside of antitrust, other agencies have a limited ability to regulate the quality of patent listings in the Orange Book on their own. The FDA has demonstrated a reluctance to either clarify its listing requirements or regulate the listing themselves, and the USPTO can only decide the validity of the patents themselves, not their FDA listing rules compliance. Instead of working on its own, the FDA should collaborate with the USPTO by using the USPTO's existing categorizations of patents in the Orange Book, which could help change the listing behaviors of brand manufacturers and decrease the Orange Book investigation costs for generic manufacturers.

A. THE FTC'S METHODS TO CONTROL IMPROPER LISTING MAY BE INEFFICIENT OR LIMITED IN THEIR EFFECTIVENESS

The FTC's uses § 5 of the FTC Act as one of its primary sources of authority to bring antitrust claims. However, this reliance could potentially lead to inconsistent results in the wake of the Supreme Court's *Loper Bright Enterprises v. Raimondo* decision, which overturned the previous precedent of deference to agency interpretations of ambiguous statutes.²⁰⁸ In the absence of deference to agency interpretation, the results of § 5 reliance become less predictable. The FTC has also been using the FDA's listing dispute process, which requires individual patent challenges and relies on the patent holders to re-evaluate the categorization of their patents, which may also generate inconsistent responses from companies.²⁰⁹ Lastly, the FTC has been relying on private parties to sue for illegal maintenance of monopoly, but these cases ended when the private parties settled, leaving other pharmaceutical companies with no further guidance on Orange Book listing.²¹⁰ Beyond these issues, both court cases and listing disputes rely to some extent on deterrence to encourage correct listings, but deterrence in isolation may not be the most effective strategy to ensure proper Orange Book listing.

1. *Potential New Limitations on FTC Authority: Loper Bright Enterprises v. Raimondo*

One of the two theories of antitrust liability that the FTC relied on in its Orange Book Policy is "unfair methods of competition" under § 5 of the FTC Act—but this theory may not be able to consistently support an antitrust suit in a regulated industry in the wake of *Loper Bright Enterprises v. Raimondo*. Congress intentionally did not define "unfair methods of competition" in § 5

208. *Loper Bright Enters. v. Raimondo*, 603 U.S. 369, 412–13 (2024).

209. See FTC PHARMACEUTICAL NOTICES, *supra* note 8 (disclosing examples of the FTC using the FDA's dispute process); 21 C.F.R. § 314.53(f) (describing the FDA procedure for listing disputes).

210. See *supra* Section II.E for a discussion of existing case law.

of the FTC Act, instead leaving the FTC to interpret the term.²¹¹ But Congress did not explicitly state in the statute that the FTC was responsible for defining the term.²¹² Administrative agencies are typically empowered through implied authorization and were offered deference based on this implied authorization.²¹³ However, the new *Loper Bright* decision noted that courts used to only offer agencies deference when they are “specifically” granted power by Congress, and perhaps not even then.²¹⁴ In the wake of *Loper Bright*, Congress’s choice not to explicitly grant the FTC definitional power under the FTC Act may make it more difficult for the FTC to persuade courts to accept its definitions.

Prior to 2024, interpretation of an ambiguous statute would likely have fallen under the *Chevron* deference doctrine. *Chevron* deference originated in the Supreme Court case *Chevron, U.S.A., Inc. v. Natural Resources Defense Council, Inc.*²¹⁵ The parties in the case disputed the Environmental Protection Agency’s interpretation of terms in the Clean Air Amendments of 1970.²¹⁶ In *Chevron*, the Court set out a two-part test for courts reviewing agency constructions.²¹⁷ First, a court should determine if Congress has spoken directly on the issue, rendering the statute unambiguous.²¹⁸ If Congress has not addressed the issue, and the statute is silent or ambiguous with regards to that issue, the court should merely evaluate whether the agency’s interpretation is a permissible construction of the statute.²¹⁹ Under the *Chevron* doctrine, judges deferred to legitimate and reasonable policy choices made by those to whom Congress had delegated policymaking responsibilities.²²⁰ Under this standard, a court evaluating the FTC’s interpretation of § 5 of the FTC Act would only be allowed to decide if the FTC’s interpretation of the ambiguous phrase ‘unfair methods of competition’ was a permissible construction.²²¹

However, *Loper Bright Enterprises v. Raimondo* overturned the *Chevron* deference doctrine.²²² In *Loper Bright*, the Supreme Court stated that agencies

211. 15 U.S.C. § 45(a)(2); see, e.g., S. REP. NO. 63-597, at 11, 13.

212. 15 U.S.C. § 45(a)(2).

213. See, e.g., *id.* (citing § 5 of the FTC Act as an example of implied authorization); *Chevron, U.S.A., Inc. v. Nat. Res. Def. Council, Inc.*, 467 U.S. 837 (1984) (deferring to agency interpretations on the basis of implied or explicit authorization).

214. *Loper Bright*, 603 U.S. at 388 (quoting *Gray v. Powell*, 314 U.S. 402, 411 (1941)).

215. *Chevron*, 467 U.S. at 842, 865.

216. *Id.* at 845.

217. *Id.* at 842–43.

218. *Id.*

219. *Id.*

220. *Id.* at 865.

221. See *id.* at 842–43.

222. *Loper Bright*, 603 U.S. at 371, 376.

“have no special competence in resolving statutory ambiguities” unlike courts, which are experienced in resolving interpretive issues in connection with a regulatory scheme.²²³ Furthermore, the Court held that “when the best reading of a statute is that it delegates discretionary authority to an agency, the role of the reviewing court . . . [is] to independently interpret the statute and effectuate the will of Congress”²²⁴ The Court explained that courts generally had been bypassing *Chevron*, and that the doctrine was “fundamentally misguided” and “unworkable.”²²⁵ Thus, it formally overruled *Chevron*, instead requiring fully independent review of agency interpretations of law by the courts when there is statutory ambiguity, even when there is reason to believe Congress delegated discretionary authority to an agency.²²⁶

With this ruling, the FTC’s ability to apply § 5 of the FTC Act to new issues becomes less predictable. Congress explicitly chose not to define “unfair methods of competition,” so it is unclear whether improper listing would fall under a court’s definition of the term.²²⁷ Furthermore, courts may choose not to consider the legislative history of § 5 of the FTC Act, and Congress only stated its intent to have the FTC define the term in that legislative history, rather than in the statute itself.²²⁸ This means that Congress’s intent to give the FTC expertise-based discretionary authority may not influence the level of review actually applied to the agency’s statutory interpretations.

On the other hand, by stating that the best reading of a statute may give an agency discretionary authority, the Court explicitly acknowledged that agencies can be granted a degree of authority by Congress.²²⁹ Additionally, the Court restated the *Skidmore* doctrine, which allows courts to give weight to an agency’s interpretation based on “the thoroughness evident in its consideration, the validity of its reasoning, its consistency with earlier and later pronouncements, and all those factors which give it power to persuade, if lacking power to control.”²³⁰ Because the Court overruled *Chevron* but retained *Skidmore*, it seems likely that the outcomes of challenges to agency interpretations will be unpredictable at best.

223. *Id.* at 400–01.

224. *Id.* at 371.

225. *Id.* at 374–75.

226. *Id.* at 371–75.

227. S. REP. NO. 63-597, at 13.

228. *See id.*; 15 U.S.C. § 45.

229. *Loper Bright*, 603 U.S. at 371.

230. *Id.* at 388 (quoting *Skidmore v. Swift & Co.*, 323 U.S. 134, 140 (1944)).

Even under *Chevron*, courts did not always follow agency interpretations.²³¹ In its absence, and with the effects of *Loper Bright* not yet clear, courts in different circuits may come to completely different conclusions. In a 2017 study, Professors Kent Barnett and Christopher J. Walker observed that in circuit courts, agency interpretations were significantly more likely to prevail under *Chevron* compared to *Skidmore* or de novo review.²³² However, even under *Chevron*, agency win rates varied considerably between circuit courts.²³³ Without *Chevron*, such variability seems even more likely. Some judges may emphasize the respect and weight owed to a thorough and reasonable agency interpretation under *Skidmore*, while others may focus on the fact that *Skidmore*, and now *Loper Bright*, do not require deference.²³⁴ Furthermore, research on the application of the *Chevron* doctrine suggests that the political inclinations of the presiding court matters to the outcome of a challenge to an agency's interpretation, perhaps more than the *Chevron* doctrine itself.²³⁵ This may still be true under *Loper Bright*. Differences in results between the two doctrines may also come from the incentives they create.²³⁶ Under *Chevron*, agencies might bring more novel interpretations of law, and litigants would be discouraged from challenging them.²³⁷ Under *Loper Bright*, the reverse could occur—agencies may be less adventurous and litigants more likely to challenge agency interpretations.²³⁸

In addition, as many courts have found, it is reasonable to allow parties to argue that they attempted to comply with a complex regulatory scheme in good faith.²³⁹ It is therefore more difficult for the FTC to simply argue that it had valid reasoning to conclude that improper listing is an antitrust violation. The outcome of such a case is unclear, given the uncertainty in both industry and scholarship regarding improper listing's capacity to harm consumers. Any

231. See, e.g., *Massachusetts v. EPA*, 549 U.S. 497, 532–35 (2007) (holding that even with *Chevron* deference, the EPA was incorrect to interpret carbon dioxide as outside the scope of air pollutants).

232. Kent Barnett & Christopher J. Walker, *Chevron in the Circuit Courts*, 116 MICH. L. REV. 1, 6–7 (2017).

233. *Id.* at 7.

234. Cass R. Sunstein, *The Consequences of Loper Bright* 14–15 (Harvard Pub. L. Working Paper, Paper No. 24-29, 2024), https://papers.ssrn.com/sol3/papers.cfm?abstract_id=4881501.

235. See generally Thomas J. Miles & Cass R. Sunstein, *Do Judges Make Regulatory Policy? An Empirical Investigation of Chevron*, 73 U. CHI. L. REV. 823 (2006) (analyzing the outcomes of challenges to agency interpretations based on the Supreme Court and appellate judges' political inclinations).

236. Sunstein, *supra* note 234, at 9.

237. *Id.*

238. *Id.*

239. See, e.g., *Lantus*, 950 F.3d at 13.

reliance on § 5 of the FTC Act by the FTC in an improper Orange Book listing case could lead to inconsistent results in different circuits or even a full circuit split, as different courts may choose to accept or overturn the FTC's definition. If the FTC intends for any form of its antitrust enforcement to discourage improper listings, inconsistent rulings between circuits are unlikely to aid in reaching that result.

2. *The Neutral-Party Orange Book Listing Dispute Method May Be Inefficient*

Beyond the difficulty of predicting results under § 5 of the FTC Act, the FDA's Orange Book listing dispute process, which the FTC was using to challenge improper listings, requires the disputing party to repeat the dispute process for each potentially improper listing with no guarantee of removing any one improper listing. The FTC has challenged over three hundred listed patents via the FDA's listing dispute process.²⁴⁰ The dispute process requires the disputing party to challenge each patent individually with a statement containing the specific grounds for dispute, which means combing through the Orange Book and evaluating each patent.²⁴¹ Furthermore, the NDA holder has the ultimate decision to either confirm the correctness of the listing or delist the patent, and no third party makes a separate evaluation.²⁴² From the named brand manufacturers in the FTC's blog post about challenging patent listings, many chose not to delist any patents.²⁴³ This suggests that the individual dispute method may not be the optimal way to remove improper listings. In addition, to maintain proper listings using this method, the FTC would need to comb through new patents on a regular basis, or else rely on the deterrence factor of its increased scrutiny to ensure good behavior. Additionally, with each new administration, the FTC's priorities may shift, and new FTC chairs may choose to allocate resources away from this issue. Thus, the deterrent factor of increased FTC scrutiny is likely to be low for this

240. FED. TRADE COMM'N, FTC EXPANDS PATENT LISTING CHALLENGES, TARGETING MORE THAN 300 JUNK LISTINGS FOR DIABETES, WEIGHT LOSS, ASTHMA AND COPD DRUGS (Apr. 30, 2024), <https://www.ftc.gov/news-events/news/press-releases/2024/04/ftc-expands-patent-listing-challenges-targeting-more-300-junk-listings-diabetes-weight-loss-asthma> [https://perma.cc/HF7A-DSYS]; *see, e.g.*, Letter from Rahul Rao, Deputy Dir., Fed. Trade Comm'n, to Teva Branded Pharms. on Improper Orange Book-Listed Patents for, ProAir HFA, ProAir DigiHaler (Nov. 7, 2023), https://www.ftc.gov/system/files/ftc_gov/pdf/teva-branded-pharma-orange-book.pdf [https://perma.cc/NR3F-BEWP]. The dispute process itself was discussed in more detail in this Note, *supra* Section II.C.2.

241. 21 C.F.R. § 314.53(f)(1)(i).

242. *Id.*

243. Warren & Jayapal, *supra* note 9, at 2.

particular strategy, because the FTC's ability to remove improperly listed patents is limited by its capacity to challenge those listings under antitrust law.

3. *Joining Private Parties in Sherman Act Section 2 Actions Does Not Lead to Court Rulings on Improper Listing Antitrust Liability Due to Parties Choosing to Settle*

As observed in *Lantus*, *Buspirone*, *Remeron*, and *Warfarin Sodium* discussed above in Section II.E, brands and direct purchasers often settle by the time a court concludes that there is a possibility for antitrust liability under § 2 of the Sherman Act.²⁴⁴ This is not unexpected; private parties have limited financial capacity to engage in prolonged litigation and may reach a point where it is no longer beneficial to litigate instead of settling. While settlements themselves may be efficient, they are not instructive for parties not privy to the settlement agreement and, therefore, cannot help to guide drug innovators' listing decisions. There is also no way to ensure a publicly visible, instructive court ruling on the antitrust liability of improper listings without private parties willing to continue to push the suit.

If the FTC seeks to initiate an antitrust suit in a federal court to get a judicial ruling its own name, it has limited options. Its first option is to initiate an administrative proceeding under either § 5 of the FTC Act or § 21 of the Clayton Act.²⁴⁵ If the respondent disagrees with the FTC's final decision, it can appeal the decision with any United States court of appeals where the act occurred or the respondent resides.²⁴⁶ Alternatively, the FTC may initiate a suit directly in the federal courts under § 13 of the FTC Act.²⁴⁷ Section 13(b) authorizes the FTC to seek preliminary and permanent injunctions when it believes a party is violating "any provision of law enforced by the Federal Trade Commission."²⁴⁸ However, the FTC does not have statutory authority to enforce the Sherman Act, thus excluding the anti-monopoly laws of the Sherman Act from the scope of 13(b).²⁴⁹ While all violations of the Sherman Act also violate § 5 of the FTC Act, this does not allow the FTC to bring a suit

244. *Lantus*, 950 F.3d at 13–15; *Buspirone*, 185 F. Supp. 2d at 365–67; *Remeron*, 335 F. Supp. 2d at 525–27, 532; *Warfarin Sodium*, 214 F.3d at 397–401.

245. 15 U.S.C. § 45(b); 15 U.S.C. § 21(b).

246. 15 U.S.C. § 45(c); 15 U.S.C. § 21(c).

247. 15 U.S.C. § 53(b).

248. *Id.*

249. *See* 15 U.S.C. § 21(b) (permitting the FTC to initiate actions under 15 U.S.C. §§ 13, 14, 18, and 19—notably not including § 2, the illegal monopolization provision of the Sherman Act); 15 U.S.C. § 45(b) (permitting the FTC to initiate actions under the FTC Act).

under the Sherman Act.²⁵⁰ It must bring the action under § 5 of the FTC Act, which may now lead to unpredictable results. This means that it cannot bring an illegal monopolization claim on its own using § 13(b). If the agency must rely on private parties to engage in suits, it cannot prevent a case from settling just to obtain a judicial decision.

4. *Deterrence Strategies Alone May Not Be the Best Way to Approach Improper Listings*

Getting a final ruling from a court may not deter against improper listings. In theory, when the FTC wins a case, the win is supposed to deter further bad action in an industry, and when the agency loses a case, the loss should signal to Congress that antitrust law requires updates for the modern economy.²⁵¹ However, court cases may result in unexpected outcomes, and it is unclear whether the FTC's attempts to deter behavior succeed. Losses may undermine the credibility of the FTC's deterrence efforts in the eyes of those in industry; for example, the chief executive of the tech trade group Chamber of Progress stated that the court losses made the FTC's threats "look more like a paper tiger."²⁵² Additionally, a ruling from a court case may set precedents that make it more difficult to pursue similar cases. In *Ohio v. American Express Co.*, the U.S. government and several states sued American Express for anticompetitive behavior, and the Supreme Court established a precedent for evaluating "two sided" platforms during the market definition stage of antitrust cases.²⁵³ This standard was later applied in an airline merger case, resulting in a ruling against the government for failing to identify a proper relevant market.²⁵⁴

Even when the FTC wins a case, the strength of the resulting deterrence effect is dependent in part on the probability of the FTC or other parties detecting violations and assumes that companies are cohesive rational actors,

250. *See, e.g.*, Fed. Trade Comm'n v. Cement Inst., 333 U.S. 683, 689–93 (1948) (finding that the Commission has the power to conclude that conduct that may violate the Sherman Act also violates § 5 of the FTC Act).

251. David McCabe, *Why Losing to Meta in Court May Still Be a Win for Regulators*, N.Y. TIMES (Dec. 7, 2022), <https://www.nytimes.com/2022/12/07/technology/meta-vr-antitrust-ftc.html>.

252. Cecilia Kang, *F.T.C.'s Court Loss Raises Fresh Questions About Its Chair's Strategy*, N.Y. TIMES (July 11, 2023), <https://www.nytimes.com/2023/07/11/technology/lina-khan-ftc-strategy.html>.

253. *Ohio v. Am. Express Co.*, 585 U.S. 529, 545–47 (2018).

254. *United States v. Sabre Corp.*, 452 F. Supp. 3d 97, 136–38 (D. Del. 2020) (*vacated as moot*); *United States v. Sabre Corp.*, No. 20-167, 2020 WL 4915824 (3d Cir. 2020) (*vacating because the parties terminated the acquisition, but expressing no opinion on the merits of the dispute or the district court's decision*).

rather than a group of corporate agents with potentially divergent interests.²⁵⁵ The action of listing is entirely lawful in isolation. This means that detection rates for improper listings, whether knowingly or unknowingly made, are likely low. Additionally, given the complexity of this area of overlapping regulatory and patent law, even idealized, rational corporate agents may genuinely disagree on the best courses of action with regards to listing, reducing the overall potential for effective deterrence.²⁵⁶

Although the FTC's Orange Book listing policy is the basis for this Note, it may not be the most effective actor to address this issue. The Commission's ability to pursue action under § 5 of the FTC Act may have been destabilized by *Loper Bright*, and as improper listing is not inherently unlawful, it could be difficult to convince a skeptical court that the practice constitutes an unfair method of competition. Individual challenges to patents are time-consuming and risk not addressing the problem in the long term, as they seem to be a weak deterrent to improper listing. The FTC also cannot pursue action under the Sherman Act alone, and private parties seem likely to settle rather than push for a final judicial decision on whether improper listing alone is an antitrust violation. In addition, while the political dynamics of the FTC are not a point of this Note, FTC policy and priorities often change with each administration, which makes it difficult to rely on for consistency in any one industry in the long term. Ultimately, antitrust enforcement through the FTC, or even in general, is likely a poor choice for controlling Orange Book listings.

B. THE FDA HAS DISCLAIMED RESPONSIBILITY FOR ENSURING THE CORRECTNESS OF ORANGE BOOK LISTINGS

Outside of antitrust, options for regulation by other individual agencies also appears limited. The FDA has disclaimed responsibility for patent listings in the Orange Book, and seems unwilling to provide clarification on its listing rules.²⁵⁷ When Hatch-Waxman was enacted, the FDA released a final rule on the patent issues raised by the Act, stating that the agency was “neither prepared nor required” to become involved in issues of sufficiency of notice

255. See Jack Bilmes & John Woodbury, *Deterrence and Justice: Setting Civil Penalties in the Federal Trade Commission*, 14 RSCH. L. & ECON. 191, 202–03 (1991) (discussing probability of detection as a factor in deterrence and the degree to which companies can be treated as rational actors); Jesse W. Markham Jr., *The Failure of Corporate Governance Standards and Antitrust Compliance*, 58 S.D. L. REV. 499, 508 (2013) (“[T]he first problem with the orthodoxy of antitrust deterrence is that it confuses the actor with the sanction bearer.”).

256. See *supra* Section II.D.2 for a discussion of the good-faith defense in highly regulated industries.

257. 59 Fed. Reg. 50342–43.

for patent enforcement,²⁵⁸ and the agency “does not have the expertise to review patent information.”²⁵⁹ The FDA has reiterated this position more recently, again disclaiming both expertise and authority, and when asked, declined to create further administrative processes for challenging a listed patent beyond the procedure already set out in the Hatch-Waxman Act.²⁶⁰

The agency’s own statements demonstrate that it does not believe it is in a position to ensure compliance with the listing rules for the patents in the Orange Book. Not only has the FDA disclaimed the expertise and authority to review patent information, it is also already a fairly busy organization and has been criticized for inefficiency in other studies.²⁶¹ Adding significant additional responsibilities onto what appears to be an already overburdened agency would not be productive.

Despite this, both Congress and private organizations have made efforts to get the FDA to clarify its rules on patent listings. The FDA and the pharmaceutical industry have engaged in repeated discussion via Federal Register public dockets over multiple years.²⁶² Additionally, Congress created the Orange Book Transparency Act (OBTA), which required the FDA to collect and present public comments on what kinds of patents should be listed in the Orange Book.²⁶³ In the agency’s responding report to Congress, it stated that it had received a variety of “different and sometimes competing views” on the types of patent information that should be included in the Orange

258. 59 Fed. Reg. 50342.

259. 59 Fed. Reg. 50343.

260. 68 Fed. Reg. 36683.

261. U.S. GOV’T ACCOUNTABILITY OFF., PRESCRIPTION DRUGS FDA’S OVERSIGHT OF THE PROMOTION OF DRUGS FOR OFF-LABEL USES 19 (2008), <https://www.gao.gov/assets/gao-08-835.pdf> [<https://perma.cc/Z4VL-WU9S>] (taking the FDA 7 months between finding a violation and sending a notice); Daniel R. Levinson, Memorandum, *Early Alert: The Food and Drug Administration Does Not Have an Efficient and Effective Food Recall Initiation Process*, OFF. OF INSPECTOR GENERAL 2–3 (June 8, 2016), <https://oig.hhs.gov/oas/reports/region1/11501500.pdf> [<https://perma.cc/38TZ-2G5X>] (explaining that FDA is slow to respond to unsafe foods because it has no policies for making sure voluntary food recalls happened promptly, and no timelines are given to companies on notice); Bradley Merrill Thompson, *Unpacking Averages: FDA’s Extraordinary Delay in Resolving Citizen Petitions*, EPSTEIN BECKER GREEN (Oct. 3, 2023), <https://www.healthlawadvisor.com/unpacking-averages-fdas-extraordinary-delay-in-resolving-citizen-petitions> [<https://perma.cc/KM7H-GXDL>] (noting that citizen petitions remain unanswered far past the 180-day statutory requirement). *But see* Nicholas S. Downing, Jenerius Aminawung, Nilay D. Shah, Joel B. Braunstein, Harlan M. Krumholz & Joseph S. Ross, *Regulatory Review of Novel Therapeutics—Comparison of Three Regulatory Agencies*, 366 N. ENG. J. MED. 2284 (2012) (noting that the FDA is actually faster in drug approvals than its European and Canadian counterparts).

262. *See, e.g.*, 68 Fed. Reg. 36680 (released in 2003); 85 Fed. Reg. 33169 (opened for discussion in 2020).

263. Orange Book Transparency Act (OBTA), Pub. L. 116-290 § 2(e)–(f).

Book.²⁶⁴ The FDA committed to making a multidisciplinary working group inside the agency to decide whether further clarification is needed, and chose to wait for the Government Accountability Office (GAO)'s OBTA report surveying the law scholars and the pharmaceutical industry before taking any further action.²⁶⁵

According to said GAO report, the FDA informed the GAO that it did not have enough information to evaluate how device-related patent listings affect generic entry, and that it does not track device-related patents separately for drug-device combination products.²⁶⁶ The FDA also repeated that it was not responsible for analyzing device-related patent listings.²⁶⁷ The stakeholders interviewed by the GAO were split on whether the FDA's current ministerial role in publishing patent listings was appropriate.²⁶⁸ Six stakeholders found the FDA's role appropriate as it is, noting that the FDA lacks either the resources, expertise, or authority to review patents.²⁶⁹ Seven others believed the FDA should take a more active role in enforcing the accuracy of patent listings by requesting clarification from the brand name sponsors or working with the USPTO.²⁷⁰ When the GAO asked the FDA about the status of its workgroup in December 2022, the FDA had not determined which specific issues the workgroup would be examining, and had not even selected the workgroup's members.²⁷¹ It is unclear if there has been any progress since then. Any ruling the FDA could make to expand or narrow listing rules would be unsatisfactory to at least some parties within the industry and would likely be challenged by various pharmaceutical companies. Furthermore, the FDA is likely correct to say that it lacks the authority to scrutinize patents, as issues of patent validity and claim interpretation are the purview of the USPTO.²⁷² When regulating a divided industry without clear answers on this issue, it may be logical for the FDA to avoid pushing the limits of its jurisdiction.

264. U.S. FOOD & DRUG ADMIN., THE LISTING OF PATENT INFORMATION IN THE ORANGE BOOK 24 (2020).

265. *Id.*

266. U.S. GOV'T ACCOUNTABILITY OFF., GAO-23-105477, GENERIC DRUGS: STAKEHOLDER VIEWS ON IMPROVING FDA'S INFORMATION ON PATENTS 19 (2023).

267. *Id.*

268. *Id.* at 23–24.

269. *Id.*

270. *Id.* at 24.

271. *Id.* at 27.

272. 35 U.S.C. § 2(a) (granting the USPTO the power to grant and issue patents); 35 U.S.C. §§ 100–105 (outlining the conditions for patentability followed by the USPTO).

C. LIMITING IMPROPER LISTINGS IN THE ORANGE BOOK IS OUT OF THE USPTO'S SCOPE OF AUTHORITY

The USPTO is responsible for issuing patents and determining their validity, including those that are eventually listed in the Orange Book.²⁷³ However, it may not have the authority to handle issues of FDA Orange Book listing rules alone. The USPTO has the authority to issue patents and trademarks.²⁷⁴ As part of that process, it must determine if a valid patent can be granted for an invention. In contrast to the USPTO's scope of authority, the task of screening and removing improper Orange Book listings is not a matter of patent validity, but of categorization. For example, device patents listed in connection with a drug product may be valid patents and still be improperly listed.²⁷⁵

Furthermore, it does not seem that there is a problem with the actual validity of Orange Book-listed patents. A 2021 study of all ANDA-filing patent litigations between 2000 and 2018 found an invalidation rate of 26 percent, which the authors, professors Mark Lemley and S. Sean Tu described as “well below” the general patent invalidation rate of 43 percent.²⁷⁶ However, they also pointed out that most litigated Orange Book patents were “follow-on” patents that claimed minor changes or new uses, and such secondary patents were somewhat more likely to be invalidated.²⁷⁷ While the authors made a good case that the USPTO should subject patents to be listed in the Orange Book to a higher level of scrutiny,²⁷⁸ discussing patenting procedures in detail is out of scope for this Note, and the validity of pharmaceutical patents does not appear to be lower than any other category of patent based on their data.²⁷⁹

Determining the validity of a patent is one of the USPTO's jobs.²⁸⁰ However, it cannot require patent holders to disclose their intent to list a patent in the Orange Book and ask for explicit FDA-listing categorization, as

273. 35 U.S.C. § 2(a).

274. *Id.*

275. *See Lantus*, 950 F.3d at 8 (holding that device patents which do not claim a reference listed drug should not be listed in the Orange Book); *Amneal*, 124 F.4th at 917 (holding that a listed patent must claim the active ingredient for the drug under which it is listed). In both cases, a device patent which does not claim the active ingredient or the reference listed drug would be improperly listed could still be a valid patent.

276. S. Sean Tu & Mark A. Lemley, *What Litigators Can Teach the Patent Office About Pharmaceutical Patents*, 99 WASH. U. L. REV. 1673, 1689–90 (2022).

277. *Id.* at 1691–92.

278. *Id.* at 1708–12 (suggesting (1) Orange Book-listed patents should be subject to higher scrutiny at examination than the average patent because they are litigated at higher rates; and (2) changes to the examination process to encourage that additional scrutiny).

279. *Id.* at 1689–90.

280. *See* 35 U.S.C. § 2.

that is not within the listed powers of the USPTO.²⁸¹ Even if it did have the power to compel patent applicants to disclose their intent to list a patent in the Orange Book, a rule requiring disclosure would likely be unenforceable. It would be nearly impossible to distinguish between patent holders who chose not to disclose despite knowing the rule, and patent holders who did not initially plan to list their patent in the Orange Book but had reason to do so later. Examining the USPTO in isolation, it seems that ensuring Orange Book listing rule compliance is unlikely to be within its scope of duties.

D. THE FDA AND USPTO SHOULD COLLABORATE TO INCREASE THE AVAILABILITY OF PATENT CATEGORIZATION INFORMATION

Rather than employing antitrust enforcement, or having a single agency attempt to fix the issue of improper Orange Book listings, it is more helpful to increase the amount of patent information available to generic manufacturers when deciding whether to create a generic drug. When a patent is listed in the Orange Book in association with a drug product, but does not claim that drug's active ingredient, it is a clear violation of the FDA's listing rules under the *Teva v. Amneal* decision.²⁸² However, it is not always clear from an Orange Book listing when a listed patent is unlikely to claim a drug's active ingredient, and therefore be an improper listing. In such cases, increasing informational access about Orange Book listed patents could increase generic and brand manufacturers' decision-making efficiency. Helping brand manufacturers decide which listed patents to concede or litigate and helping generic manufacturers decide which patents to challenge can reduce overall transactional costs.

The FDA and USPTO have already indicated an interest in working together to reduce patenting of incremental or obvious changes to drugs, but they have not yet committed to any action.²⁸³ The most efficient way to reduce improper listings would be to require brand manufacturers to inform the USPTO when they intend to submit a patent for Orange Book listing after approval, and have the USPTO classify the patent at approval. The USPTO could classify the patents within the FDA's listing categories or alert the brand

281. *Id.*

282. *See Amneal*, 124 F.4th at 917–19 (holding that a patent listed in the Orange Book must claim the active ingredient of the application it is listed under).

283. Letter from Janet Woodcock, Comm'r of Food & Drugs, to Andrew Hirschfeld, Performing the Functions and Duties of the Under Sec'y Com. for Intell. Prop. & Dir. of USPTO, at 3–4 (Sep. 10, 2021) (discussing collaboration on drug patent issues with the USPTO); Letter from Katherine K. Vidal, Under Sec'y Com. for Intell. Prop. & Dir. of USPTO, to Robert M. Califf, Comm'r of Food & Drugs, at 3–4 (July 6, 2022) (USPTO responding to the FDA).

manufacturer that the patent does not fall within the FDA's listing rules. The USPTO already classifies patents when they are approved to make it easier to determine the novelty of inventions for which patent applications are filed.²⁸⁴ Categorization according to the FDA's rules would in theory be a very similar process, but as discussed, *supra*, in Section IV.B, the USPTO's scope of authority is limited to determining the validity of a patent.²⁸⁵ The agency's ability to interfere in categorizations occurring at the FDA, even with the FDA's approval, would be limited unless Congress intervenes to expand the USPTO's authority.

Operating within the scope of the current legal framework and agency roles, the FDA could collect the patent classifications that the USPTO already creates during the patent approval process. The USPTO currently classifies patent documents into specific technology groupings.²⁸⁶ An increase in the available information about the classification of patents listed in the Orange Book under an NDA could give generic manufacturers more information about which patents are worth challenging and how likely they are to succeed in a Hatch-Waxman litigation. The USPTO's existing classifications provide information that could be useful if explicitly presented alongside Orange Book patent listings.

Lantus, discussed, *supra*, in Section II.E.2 and *Teva v. Amneal*, discussed, *supra*, in Section III.B are both good examples of the type of non-fraudulent but improper listing that this Note seeks to address. Thus, they are good examples of the kinds of patents where it might be useful to have the USPTO classifications at hand for a generic manufacturer conducting research in the Orange Book. The patent at issue in *Lantus* was Patent No. 8,556,864.²⁸⁷ The USPTO classified the patent as a USPC 604/207.000.²⁸⁸ 604 is the category for surgery, and 207 is the subcategory for "having means for metering material flow to or from body."²⁸⁹ One of the patents at issue in *Teva v. Amneal* was Patent No. 8,132,712.²⁹⁰ The USPTO classified that patent under 235/

284. 35 U.S.C. § 8.

285. *See* 35 U.S.C. § 2.

286. U.S. PAT. & TRADEMARK OFF. (USPTO), *Patent Classification*, <https://www.uspto.gov/patents/search/classification-standards-and-development> [https://perma.cc/5K6D-B7AH] (last visited Dec. 18, 2024).

287. *Lantus*, 950 F.3d at 5.

288. U.S. Patent No. 8,556,864 (filed Mar. 20, 2011). The USPC system is used in this Note because many of the patents discussed herein were issued prior to the adoption of the CPC in 2013.

289. U.S. PAT. & TRADEMARK OFF., CLASSIFICATION RESOURCES: CLASS 604, SURGERY, <https://www.uspto.gov/web/patents/classification/uspc604/defs604.htm#C604S207000> (last visited Feb. 2, 2025).

290. *Teva v. Amneal*, 736 F. Supp. 3d 227, at *2 (D.N.J. 2024) (No. 23-20964).

091.00R, which is the category for registers, in the subclass of operating devices.²⁹¹ In contrast, the drug Descovy has an NDA which is associated with a current, unexpired patent listed in the Orange Book that claims the drug substance and a method of use.²⁹² This patent, Patent No. 8,754,065 is classified as a 514/081.000, or a drug, bio-affecting and body treating composition.²⁹³ Table 1 contains the full list of patents which were still being contested on appeal in the *Lantus* and *Teva v. Amneal* cases, along with their USPTO categorizations. This data set is limited to *Lantus* and *Teva v. Amneal*, as these are the only cases discussed in this Note where there was no allegation that the patent at issue may have been fraudulently obtained. The data illustrates that the improperly listed types of patents this Note aims to address are classified in ways that do not link them clearly to a drug substance.

Table 1: Non-Fraudulent Patents for Which the Listing Was Contested at the Appellate Level.

Case	Patent No.	USPC Classification No.	Classification Name
<i>Lantus</i>	8,556,864	604/207.000	Surgery/ means for introducing or removing material from body for therapeutic purposes
<i>Amneal</i>	8,132,712	235/091.00R	Registers/operating devices
<i>Amneal</i>	9,463,289	235/008.000	Registers/key set
<i>Amneal</i>	9,808,587	235/008.000	Registers/key set
<i>Amneal</i>	10,561,808	235/008.000*	Registers/key set
<i>Amneal</i>	11,395,889	128/203.120*	Surgery/means for mixing treating agent with respiratory gas

*Note that the USPC numbers on these patents are only provided in the Related U.S. Application Section under field of classification search.

While the Orange Book lists the patents it receives as drug substance or drug product patents, it does not currently list the patent categorizations that the USPTO creates for approved patents.²⁹⁴ However, it could aid both brand

291. U.S. Patent No. 8,132,712 (filed Sep. 23, 2009); U.S. PAT. & TRADEMARK OFF., CLASSIFICATION RESOURCES: CLASS 235, REGISTERS, <https://www.uspto.gov/web/patents/classification/uspc235/defs235.htm#C235S091000> (last visited Dec. 18, 2024).

292. FOOD & DRUG ADMIN., *Orange Book: Approved Drug Products with Therapeutic Equivalence Evaluations*, https://www.accessdata.fda.gov/scripts/cder/ob/patent_info.cfm?Product_No=001&Appl_No=208215&Appl_type=N (last visited Dec. 18, 2024).

293. U.S. Patent No. 8,754,065 (filed Aug. 15, 2012); U.S. PAT. & TRADEMARK OFF., CLASSIFICATION RESOURCES: CLASS 514, DRUG, BIO-AFFECTING AND BODY TREATING COMPOSITIONS, <https://www.uspto.gov/web/patents/classification/uspc514/sched514.htm> (last visited Dec. 18, 2024).

294. *See generally* ORANGE BOOK, at Addendum.

and generic manufacturers to have those categorizations readily available in Orange Book listings. With additional categorization information, a generic manufacturer would be able to easily see that some drug products are only covered by nondrug composition patents in classifications that are frequently delisted by courts. Generic manufacturers could decide how likely they are to succeed in a Paragraph IV certification or eventual Hatch-Waxman litigation challenge more efficiently. Conversely, over time, brand manufacturers could observe which categories of Orange Book listed patents are likely to hold up in cases where courts might consider giving delisting orders. They would then be better equipped to decide which Orange Book listed patents would be worth litigating and which listings a court would be likely to remove based on which classes of patents survive challenges for improper listing. While this increase in informational access would not prevent improper Orange Book listing, it could make the system slightly more efficient.

To collect this information, the FDA would simply need to add the patent categorization code and categorization title to the information it collects with NDA and ANDA filings.²⁹⁵ This would be a purely ministerial change to the FDA's Orange Book patent information collection form 3542a, which the FDA has the authority to make. Ultimately, any increase in informational access has the potential to make the Hatch-Waxman system more efficient. More information could decrease the transactional costs associated with the research generics need to do to decide which generic drugs to make, and potentially increase the number of generic drugs on the market.

V. CONCLUSION

Patent listings in the Orange Book have the potential to be either useful or detrimental to generic manufacturers. It provides notice of protected intellectual property, but also can result in improper stays on the approval of generic drugs, and generic entry delay may result in reduced industry competition and harm to consumers. Despite initiating additional scrutiny of Orange Book listed patents, the FTC may not be the ideal agency to handle the issue of improper listings, and antitrust in general may not be a practical enforcement method in this area. The FTC's ability to define unfair methods of competition may now be less consistent across circuits, and thus it cannot leverage its authority to discourage potential improper listing as easily. In addition, the processes the FTC is using to clean up the Orange Book are time-

295. See 21 U.S.C. § 355(b)(1)(A) (requiring NDA applicants to submit patent information); FOOD & DRUG ADMIN., FORM 3542A (which does not require classification information).

consuming, and the effort of its staff may be better spent on other issues. On the other side, private monopoly suits are forced to rely on an unsettled area of case law.

Instead, the problem of improper listing would be better addressed by an increase in informational access within the Orange Book's listings. The FDA should include the USPTO's pre-existing categorizations in the patent information listed in the Orange Book to increase the decision-making ability of generic manufacturers seeking to make new generic versions of drug products. Although the Federal Circuit has clarified that patents must claim the drug substance in the associated NDA to qualify for Orange Book listing, courts should continue to support efforts to remove improper listings. Courts could reinforce this cleanup effort by holding that improper listings serve as evidence of antitrust violations absent a showing of good faith.

COLLATERAL ESTOPPEL OF PTAB DECISIONS IN THE WAKE OF *UNITED THERAPEUTICS CORP. V. LIQUIDIA TECH., INC.*

Jesse Wang[†]

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I. INTRODUCTION

America continues to be at the forefront of innovation, pioneering new technological and scientific inventions throughout its history. Indeed, America’s innovative drive is heavily bolstered by its robust patent system, which was established by Congress to “promote the Progress of Science and useful Arts,” as mandated by the Constitution.¹ But critical to maintaining this patent system is an equally robust litigation system to balance promoting innovation and defending already established intellectual property.

Congress has long recognized the patent system’s role in encouraging innovation, and, in 2011, passed the America Invents Act (AIA)² to further improve patent issuance and litigation.³ In particular, the AIA established the Patent Trials and Appeals Board (PTAB) within the United States Patent and Trademark Office (USPTO).⁴ Congress intended for the PTAB to serve as a cost-efficient alternative to the “excessively expensive” district court litigation process by providing an adjudicative process to reexamine the validity of granted patents.⁵ But when the resulting post-AIA patent litigation system

1. U.S. CONST. art. I, § 8, cl. 8.

2. Leahy-Smith America Invents Act, Pub. L. No. 112-29, 125 Stat. 284 (2011).

3. *Id.*

4. *Id.*

5. *Patent Quality Improvement: Post-Grant Opposition: Hearing Before the Subcomm. on Courts, the Internet, and Intellectual Prop. of the H. Comm. on the Judiciary*, 108th Cong. 29 (2004) (statement of Michael Kirk, Executive Director, AIPLA).

allows for a court to hold that a party has infringed a patent that the PTAB has already invalidated, that does not follow with Congress's intent or the Constitution's mandate to promote the Progress of the useful Arts.

The current post-AIA patent litigation system often involves two parallel proceedings in which parties to a case may opt to simultaneously litigate certain causes of action before the PTAB and others in district court. This parallel system arises primarily because the PTAB's primary reexamination proceeding, the *inter partes* review (IPR), is a litigative process limited only to the technical aspects of a patent's validity.⁶ However, collateral estoppel doctrine, which prevents parties from relitigating issues that courts have already ruled on, is insufficient in reconciling cases where a district court and an adjudicative administrative agency issue differing rulings in parallel. In the Federal Circuit's recent decision in *United Therapeutics Corp. v. Liquidia Technologies, Inc.*, the court held that PTAB decisions lack collateral estoppel effect until affirmed on appeal.⁷ As a result of this decision, the district court held Liquidia liable for infringing a patent that the PTAB had found to be invalid.⁸ This decision leaves future litigating parties uncertain as to whether they may fully rely on PTAB litigation as an alternative to district court litigation, which contradicts Congress's intent in passing the AIA.

This Note explores a combination of reforms to resolve this uncertainty surrounding the efficacy of PTAB litigation. In particular, this Note proposes amending the Federal Circuit's Rules of Practice to safeguard future parties from potentially confusing outcomes like the one Liquidia faced, and advocates for legislative reform in Congress to stress that rulings from administrative agencies such as the PTAB should have a collateral estoppel effect similar to that of district court decisions.

Part II of this Note provides background on the history of the administrative reexamination process for patents and the legal framework of collateral estoppel in the context of administrative agencies. Part III discusses *United Therapeutics* in detail, including its ramifications on the current patent litigation system. Part IV proposes a solution to the collateral estoppel issue raised in the wake of *United Therapeutics*. Part V briefly concludes.

6. See 35 U.S.C. § 311.

7. *United Therapeutics Corp. v. Liquidia Techs., Inc.*, 74 F.4th 1360, 1363 (Fed. Cir. 2023) [hereinafter *United Therapeutics*].

8. *United Therapeutics Corp. v. Liquidia Techs., Inc.*, 2023 WL 8794633, at *1 (Fed. Cir. Dec. 20, 2023).

II. THE EVOLUTION OF PARALLEL PATENT LITIGATION DOCTRINE

Accused patent infringers commonly assert both a defense of non-infringement and a separate defense of invalidity. Defendants claiming an invalidity defense, which is at issue in *United Therapeutics*, argue that the asserted patent is not valid and, therefore, could not have been enforceable in the first place.⁹ While non-infringement causes of action remain in district court, invalidity causes of action may be split between different forums, even within the same pending case.¹⁰ In particular, the PTAB can only hear arguments regarding a patent's validity based on its technical aspects in comparison to the prior art (i.e., anticipation and obviousness), whereas district courts can hear any invalidity cause of action, including anticipation and obviousness.¹¹ Consequently, multiple venues may simultaneously hear arguments about certain aspects of a single patent's validity—this is known as parallel litigation.¹²

Because Congress established the PTAB to relieve the burden on district courts and provide parties with a more cost-efficient alternative for challenging a patent's validity, incentives are in place to encourage PTAB litigation, such as a lower standard of review or a defined timeline of twelve to eighteen months to issue a final written decision.¹³ As a result, parallel patent litigation has increased post-AIA, raising a key issue: What happens when both venues rule in the same timeframe with opposing outcomes? This Part describes the history of reexamination proceedings in the USPTO and explores the legal background of how courts have previously applied collateral estoppel to administrative proceedings, including PTAB proceedings.

Section II.A includes the evolution of reexamination proceedings in the USPTO, including the significant overhaul introduced in the America Invents Act (AIA). Section II.B discusses how courts define the relationship between

9. See generally *MaxLinear, Inc. v. CF CRESPE LLC*, 880 F.3d 1373, 1376 (Fed. Cir. 2018) (“[A] judgment of invalidity in one patent action renders the patent invalid in any later actions based on the same patent.” (internal quotations omitted)).

10. See generally *Drink Tanks Corp. v. Growlerworks, Inc.*, No. 3:16-cv-410-SI, 2016 WL 3844209, at *2 (D. Or. July 15, 2016) (considering whether to stay district court proceedings while a parallel IPR for the same patent was being decided in the PTAB); *Surfcast, Inc. v. Microsoft Corp.*, No. 2:12-cv-333-JDL, 2014 WL 6388489, at *2 (D. Me. Nov. 14, 2014) (same).

11. See 35 U.S.C. § 311.

12. Jason E. Stach & Benjamin A. Saidman, *Maximizing the Likelihood of a Litigation Stay Pending Inter Partes Review*, FINNEGAN (Sep./Oct. 2016), <https://www.finnegan.com/en/insights/articles/maximizing-the-likelihood-of-a-litigation-stay-pending-inter.html> (“IPRs often occur in parallel with district court patent litigation on the same patent . . .”).

13. Joe Matal, *A Guide to the Legislative History of the America Invents Act: Part II of II*, 21 FED. CIR. B.J. 539, 627; see 35 U.S.C. § 316(a)(11), (e).

invalidity and infringement causes of action in patent litigation. Section II.C introduces the principle of collateral estoppel and its subsequent application by the courts. This Section then analyzes how the Federal Circuit has applied collateral estoppel effect to PTAB-issued decisions.

A. *INTER PARTES* REVIEW

The IPR system, one of the keynote features in the AIA, was established by Congress to serve as a cost-efficient alternative to district court litigation.¹⁴ IPRs are administrative adjudications conducted by the PTAB in the USPTO.¹⁵ This Section first explores both the history and the shortcomings of prior reexamination proceedings in the USPTO. It then examines the incentives and advantages in place to encourage parties to pursue IPRs. Finally, this Section discusses the estoppel provisions currently in place for IPR proceedings.

1. *Reexamination Proceedings in the USPTO*

In the preceding decades before the AIA, Congress had granted the USPTO the power to reexamine the validity of issued patents.¹⁶ The USPTO may need to reexamine issued patents because, for example, new prior art could emerge and undermine a patent's validity, or an examiner could have mistakenly allowed a patent. In 1980, Congress established the first reexamination proceeding in the USPTO—*ex parte* reexamination.¹⁷ Congress then reinforced the USPTO's standing to reexamine and potentially invalidate patents in 1999, by establishing an *inter partes* reexamination procedure.¹⁸ Generally, however, both procedures were costly and slow, leading parties to opt for litigation in district court instead.¹⁹

In 2011, the AIA introduced a series of reforms to modernize the U.S. patent system.²⁰ Among other legislative reforms, Congress aimed to reform the then highly expensive, inefficient, and rarely used USPTO reexamination procedures.²¹ Moreover, Congress intended for the AIA to establish a “more

14. Matal, *supra* note 13, at 627; see 35 U.S.C. §§ 311–318.

15. U.S. PAT. & TRADEMARK OFF., INTER PARTES DISPUTES (2012).

16. See 35 U.S.C. §§ 301–307.

17. See *id.*

18. Peter S. Menell, *Patent Case Management Judicial Guide*, FED. JUD. CTR. 2-54 (3d ed. 2016).

19. *Id.*

20. See 35 U.S.C. §§ 311–318.

21. H.R. REP. NO. 112-98, at 39–40 (2011) (stating that among the goals of the AIA were to “improv[e] patent quality and provid[e] a more efficient system for challenging patents that should not have issued” and to “limit unnecessary and counterproductive litigation costs.”).

efficient and streamlined patent system” that would increase patent quality while limiting “unnecessary and counterproductive litigation costs.”²² As such, the AIA codified *inter partes* review (IPR) and established the PTAB within the USPTO to oversee this process.²³

In particular, an IPR petitioner may only seek to cancel a patent’s claims on the grounds that a patent should have been anticipated by the prior art or should have been obvious to a person of ordinary skill in the art in light of the prior art.²⁴ But this is only a portion of all invalidity proceedings a party may bring in a patent litigation suit in district court.

As described in 35 U.S.C. § 101, a valid patent must satisfy all of the “conditions and requirements” of Title 35 (i.e., novelty, nonobviousness, adequate disclosure, and written description, etc.).²⁵ A patent claim that fails the validity analysis under just one of these sections is rendered wholly invalid. Therefore, to fully assess a patent’s validity, all invalidity arguments must be considered. Since IPR proceedings are limited to evaluating invalidity claims under § 102 (anticipation) and § 103 (obviousness), they cannot wholly address a patent’s validity.²⁶

Under 35 U.S.C. § 318(a), the PTAB is required to issue a “Final Written Decision” (FWD) with respect to the “patentability of any patent claim challenged” in an IPR (or *ex parte*) proceeding.²⁷ PTAB FWDs can be directly appealed to the Court of Appeals for the Federal Circuit.²⁸ For any patent claims held to be unpatentable in a PTAB FWD, 35 U.S.C. § 318(b) requires that the Director of the USPTO “issue and publish a certificate canceling any [such] claim[s].”²⁹

A question arises from § 318(a) and § 318(b): When exactly is a PTAB decision final? Is the decision final when the FWD is issued by the PTAB, or when the USPTO Director cancels the claims? In 2020, the Federal Circuit definitively answered this question in *Sec. People, Inc. v. Iancu*, holding that the agency’s decision-making process in an IPR “is complete after issuance of the final written decision.”³⁰ The Federal Circuit ultimately reasoned that the certificate of cancellation mandated by 35 U.S.C. § 318(b) is “irrelevant to the

22. *Id.* at 40.

23. 35 U.S.C. §§ 311–318.

24. 35 U.S.C. § 311(b) (noting that “section[s] 102 or 103” refer to the anticipation and obviousness statutes, respectively).

25. 35 U.S.C. § 101.

26. 35 U.S.C. § 311(b).

27. 35 U.S.C. § 318(a).

28. 35 U.S.C. § 141.

29. 35 U.S.C. § 318(b).

30. *Sec. People, Inc. v. Iancu*, 971 F.3d 1355, 1361 (Fed. Cir. 2020).

finality of the agency's action.”³¹ The court clarified that the Director's cancellation was a mere “nondiscretionary formality” because there is “no agency *decision-making*” involved in issuing the certificate.³²

Today, the PTAB continues to reexamine patent validity as parties continue to petition for IPR proceedings. The next Section discusses why parties are incentivized to bring parallel litigation proceedings to the PTAB and explores why the IPR system has been growing in popularity for parties in patent litigation.

2. *Why Parallel Litigation in the PTAB is Increasing in Popularity*

Because the PTAB only hears a subset of the possible invalidity causes of action—limited to whether the challenged patent was anticipated or rendered obvious by prior art (including patents and printed publications)—the current patent litigation scheme often involves parallel proceedings.³³ In this scheme, the defendant may split its invalidity causes of action between two tribunals.³⁴ For example, a common scenario may involve an accused infringer filing an IPR in the PTAB to invalidate the patent under § 102 or § 103, while simultaneously raising a non-infringement defense and other invalidity causes of action in district court.³⁵

While litigating in multiple venues may seem burdensome, there are several advantages to bringing an IPR before the PTAB while defending an infringement suit in district court. First, under 35 U.S.C. § 316(e), IPR petitioners need only establish invalidity by a preponderance of the evidence.³⁶ This evidentiary standard is lower than the standard in district court, which requires clear and convincing evidence to establish invalidity.³⁷ Moreover, the patent statute defines the PTAB's decision timeline: 35 U.S.C. § 316(a)(11) requires that the final determination in an IPR be issued within one year of

31. *Id.* at 1361.

32. *Id.* (emphasis added).

33. *See* Stach & Saidman, *supra* note 12.

34. Katherine K. Vidal, Memorandum on the Interim Procedure for Discretionary Denials in AIA Post-Grant Proceedings with Parallel District Court Litigation (June 21, 2022), <https://perma.cc/Z7GM-RC3F>.

35. *Id.* (stating that the PTAB will not deny institution of an IPR if the petitioner stipulates that they will not assert the same invalidity grounds in the district court case (i.e., that each parallel forum will hear different invalidity arguments)).

36. 35 U.S.C. § 316(e).

37. Jeffrey A. Freeman & Jason E. Stach, *District Court or the PTO: Choosing Where to Litigate Patent Invalidity*, FINNEGAN (Mar./Apr. 2014), <https://www.finnegan.com/en/insights/articles/district-court-or-the-pto-choosing-where-to-litigate-patent.html>.

institution.³⁸ This timeline is much more predictable and well-defined than the timeline in district courts, which have discretion to move at their own pace.³⁹

Since 2019, an average of roughly 1,200 IPR petitions have been filed yearly.⁴⁰ Of these petitioners, “about 80% or higher” have been sued in parallel by patent owners in another venue.⁴¹ Thus, PTAB litigation (and subsequently, parallel litigation) is a popular choice for defendants in district court proceedings.

B. HOW INVALIDITY AFFECTS INFRINGEMENT IN PATENT LITIGATION

Although the PTAB only reexamines a subset of patent validity actions and does not consider infringement actions at all, it still has a critical influence in patent litigation outcomes. A party sued for infringing a patent can completely avoid liability (whether they actually infringed or not) by proving that the asserted patent is invalid.

The Supreme Court emphasized this point in its 2015 decision in *Commil USA, LLC v. Cisco Systems, Inc.*, holding that when an act “would have been an infringement or an inducement to infringe pertains to a patent *that is shown to be invalid*, there is *no patent to be infringed*.”⁴² The Court repeatedly underscored that holding a patent invalid ultimately overrides whatever decision is reached in infringement proceedings and implied that a patent’s validity should be decided before an infringement judgment is made.⁴³

The Supreme Court then detailed the “various proper ways” to obtain a ruling of invalidity, with one of them being that the accused party “can seek *inter partes* review at the Patent Trial and Appeal Board and receive a decision as to validity.”⁴⁴ If the accused infringer “is successful, he will be immune from liability.”⁴⁵ However, *Commil* does not address parallel proceedings or what happens if an administrative agency (*e.g.*, the PTAB) and a district court issue differing decisions on patent invalidity.

38. 35 U.S.C. § 316(a)(11).

39. FED. R. CIV. P. 40 advisory committee’s notes to 2007 amendment (“The best methods for scheduling trials depend on local conditions. . . . It is not useful to limit or dictate the provisions of local rules.”).

40. U.S. PAT. & TRADEMARK OFF., PTAB TRIAL STATISTICS FY23 END OF YEAR OUTCOME ROUNDUP (2023).

41. U.S. PAT. & TRADEMARK OFF., PATENT TRIAL AND APPEAL BOARD PARALLEL LITIGATION STUDY (2022).

42. *Commil USA, LLC v. Cisco Sys.*, 575 U.S. 632, 644 (2015) (emphases added).

43. *Id.* at 645.

44. *Id.*

45. *Id.*

C. COLLATERAL ESTOPPEL AND ITS APPLICATION TO ADMINISTRATIVE AGENCY DECISIONS

Collateral estoppel (i.e., issue preclusion) is a judicial doctrine that prevents multiple claims from being brought on a singular issue once the issue has been litigated. The Restatement (Second) of Judgments, Section 27 provides the definition of collateral estoppel as follows:

When an issue of fact or law is actually litigated and determined by a valid and final judgment, and the determination is essential to the judgment, the determination is conclusive in a subsequent action between the parties, whether on the same or a different claim.⁴⁶

The Supreme Court has similarly long recognized that “the determination of a question directly involved in one action is conclusive as to that question in a second suit.”⁴⁷ The Court iterated that the purpose of collateral estoppel was to protect against “the expense and vexation attending multiple lawsuits, conserv[ing] judicial resources, and foster[ing] reliance on judicial action by minimizing the possibility of inconsistent decisions.”⁴⁸

This Section begins by analyzing the Supreme Court’s 2015 decision in *B & B Hardware, Inc. v. Hargis Industries, Inc.*, where the Court held that administrative agency decisions can have collateral estoppel effect.⁴⁹ This Section then explores how the Federal Circuit has applied collateral estoppel with respect to the PTAB and discusses how current collateral estoppel doctrine is inadequate in addressing the challenges posed by the parallel patent litigation system.

1. *B & B Hardware*

In 2015, the Supreme Court held in *B & B Hardware, Inc.* that collateral estoppel is “not limited to those situations in which the same issue is before two courts.”⁵⁰ Here, Hargis attempted to register its trademark SEALTITE in the USPTO, but B & B Hardware opposed the registration before the Trademark Trial and Appeal Board (TTAB), arguing that it was too similar to its SEALTIGHT mark.⁵¹ B & B Hardware then sued Hargis in district court, alleging, in parallel to the TTAB proceedings, that Hargis’s use of SEALTITE amounted to trademark infringement of the SEALTIGHT mark.⁵² In both

46. RESTATEMENT (SECOND) OF JUDGMENTS § 27 (A.L.I. 1980).

47. *Cromwell v. Cnty. of Sac*, 94 U.S. 351, 354 (1877).

48. *Montana v. United States*, 440 U.S. 147, 153–54 (1979).

49. *B & B Hardware Inc.*, 575 U.S. 138, 148 (2015).

50. *Id.*

51. *Id.* at 141.

52. *Id.*

proceedings, the tribunals considered whether a “likelihood of confusion” existed between the two marks as the legal standard.⁵³ So when the TTAB held that there was a likelihood of confusion and denied Hargis’s registration, B & B Hardware argued to the district court that the TTAB’s decision precluded Hargis from contesting likelihood of confusion in the then-pending district court litigation.⁵⁴

The Supreme Court held that the TTAB’s decision did have collateral estoppel effect, despite the two tribunals considering different factors when evaluating likelihood of confusion.⁵⁵ The Supreme Court referred to the Restatement (Second) of Judgments, Section 27, to define the ordinary elements of issue preclusion.⁵⁶

In its reasoning, the Court addressed administrative agencies generally, even though the case pertained only to the TTAB. The Court reiterated its “longstanding view” that when an “administrative agency . . . act[s] in a judicial capacity and resolves disputed issues of fact properly before it,” courts have “not hesitated to apply *res judicata* to enforce repose.”⁵⁷ The Court stressed that “our precedent holds that the Seventh Amendment [providing the right to a jury trial] does not strip competent tribunals of the power to issue judgments with preclusive effect.”⁵⁸ So long as the “ordinary elements of issue preclusion are met,” courts should give preclusive effect to administrative agency decisions.⁵⁹ If the facts presented to the agency and the federal court are materially the same, and the other requirements of collateral estoppel are satisfied, “[i]ssue preclusion is available unless it is ‘evident’ [] that Congress does not want it.”⁶⁰

What remains unclear is whether the Court in *B & B Hardware* intended for its decision to apply to an administratively decided issue that arises while parallel district court litigation over the same issue is occurring under a *different* legal standard. In applying its reasoning, the Supreme Court critically consolidated the likelihood of confusion issue into a single legal standard across both tribunals.⁶¹ However, modern patent litigation frequently involves a parallel scheme in which IPR proceedings occur before the PTAB while the

53. *Id.*

54. *See id.* at 154.

55. *Id.* at 141–42.

56. *Id.* at 148 (citing RESTATEMENT (SECOND) OF JUDGMENTS § 27).

57. *Id.* (quoting *Univ. of Tenn. v. Elliott*, 478 U.S. 788, 797–98 (1986)).

58. *Id.* at 150.

59. *Id.* at 141–42.

60. *Id.* at 153 (quoting *Astoria Fed. Sav. & Loan Assn. v. Solimino*, 501 U.S. 104, 108 (1991)).

61. *Id.* at 154.

same patents are simultaneously litigated in district court. As discussed in Section II.A.2, the PTAB applies a lower evidentiary standard than district courts.⁶² Because this specific question was not at issue in *B & B Hardware*, the application of its rule to PTAB proceeding poses a unique question: What happens if a district court and the PTAB issue conflicting rulings on patent validity?

2. *Federal Circuit Holdings on the Collateral Estoppel Effect of PTAB Decisions*

Through a series of cases, the Federal Circuit has moved toward answering this question but has not definitely determined whether a PTAB ruling has collateral estoppel effect while pending appeal. In 2013, the Federal Circuit held in *Fresenius USA, Inc. v. Baxter International, Inc.* that “when a claim is cancelled, the patentee loses any cause of action based on that claim, and any pending litigation in which the claims are asserted becomes moot.”⁶³ However, in the same decision, the Federal Circuit also underscored that this collateral estoppel effect cannot be used to “reopen a final damages judgment ending a suit based on those [patent] claims.”⁶⁴

As a result of *Fresenius*, parties litigating in parallel in district court and the PTAB have engaged in a race to final judgment.⁶⁵ It intuitively follows that a petitioner in an IPR proceeding would want to secure a final PTAB decision as quickly as possible. According to *Fresenius*, a final judgment of invalidity by the PTAB would immediately render the district court litigation moot.⁶⁶ By contrast, if the PTAB upholds a patent’s validity, the district court proceeding would continue.⁶⁷ Meanwhile, the patent owner (i.e., generally the plaintiff in district court) often has the opposite incentive—hoping that the district court will reach its final judgment before the PTAB has a chance to render the patent invalid.⁶⁸

In the race to final judgment, parties may attempt to manipulate the separate timelines of the two venues to advance their interests. For instance,

62. See 35 U.S.C. § 316(e).

63. *Fresenius USA, Inc. v. Baxter Int’l, Inc.*, 721 F.3d 1330, 1340 (Fed. Cir. 2013).

64. *Id.*

65. Lauren A. Degnan, Joshua A. Griswold, Ryan Patrick O’Connor & Kristi L. R. Sawert, *How the Timing of Director Review May Affect Co-Pending Litigation*, FISH & RICHARDSON P.C. (July 30, 2024), <https://perma.cc/7G95-AVTM>.

66. See *Fresenius*, 721 F.3d at 1340.

67. Jeffery C. Totten, *An Accused Infringer’s Guide to Parallel Proceedings*, FINNEGAN (Apr. 21, 2014), <https://www.finnegan.com/en/insights/articles/an-accused-infringer-s-guide-to-parallel-proceedings.html>.

68. See Degnan et al., *supra* note 65.

before appealing a PTAB decision to the Federal Circuit, a party (usually the patent owner) may seek Director Review, which allows for the USPTO Director to discretionarily review FWDs issued in IPR proceedings.⁶⁹ Because it takes time for the Director to institute or deny review, seeking Director Review may be “part of a strategy to delay the finality of a final written decision [by the PTAB], which is useful if a co-pending litigation is not stayed and especially if the litigation has already proceeded to judgment.”⁷⁰ This strategy can delay the start of a PTAB appeal by about three months.⁷¹

While parties race towards final judgment, the Federal Circuit faces its own challenges because it hears patent appeals from both district courts and the PTAB. As a result, the court may hear multiple appeals from different venues for the same case (i.e., between the same parties and/or for the same patent numbers).⁷² The Federal Circuit has dealt with an appeal from both a district court ruling and a PTAB ruling over the same patent number in *XY, LLC v. Trans Ova Genetics*, where it held that “affirmance [of a PTAB’s invalidity ruling] renders final a judgment . . . and has an immediate issue-preclusive effect on any pending or co-pending actions involving the patent.”⁷³ The court maintained that it had “previously applied collateral estoppel to such co-pending cases,” emphasizing that a patentee has already had his day in court, and a defendant should not be forced to continue defending a suit for infringement of a patent already found to be invalid.⁷⁴ As such, the court declined to address *Trans Ova*’s invalidity arguments in the district court appeal, and subsequently dismissed *Trans Ova*’s appeal “as moot.”⁷⁵

On its face, the Federal Circuit’s reasonings and holdings in both *Fresenius* and *XY* appear logical. However, in today’s parallel litigation system, where parties race to a final judgment, these cases do not establish a complete doctrine. For example, *Fresenius* pertained to the older *ex parte* reexamination proceeding and does not address the IPR system or any of the new statutes introduced in the AIA.⁷⁶ Under the statutes governing these older reexamination procedures, Congress did not distinguish between cancellation and a final decision⁷⁷ as it does for IPRs under the AIA.⁷⁸ Moreover, in

69. U.S. PAT. & TRADEMARK OFF., DIRECTOR REVIEW PROCESSES (2025).

70. See Degnan et al., *supra* note 65.

71. See *id.*

72. See, e.g., *XY, LLC v. Trans Ova Genetics, L.C.*, 890 F.3d 1282, 1294 (Fed. Cir. 2018).

73. *Id.*

74. *Id.* (internal quotations omitted).

75. *Id.* at 1295.

76. See *Fresenius*, 721 F.3d at 1334.

77. See 35 U.S.C. §§ 302–307.

78. See 35 U.S.C. § 318(a)–(b).

Fresenius, the Federal Circuit had remanded a prior appeal back to the district court and later ruled on the reexamination appeal before the second district court decision was appealed back to the Federal Circuit.⁷⁹ Similarly, though *XY* pertained to an IPR appeal specifically in parallel with a district court appeal, the court issued rulings for both appeals on the same day.⁸⁰ But Federal Circuit procedure does not mandate that appeals from the PTAB and district courts regarding the same patent number or issues be combined.⁸¹ In fact, only in the Practice Notes for Rule 15 in the Federal Circuit Rules of Practice is it mentioned that the clerk of court “will usually” consolidate appeals or petitions for review involving the “same or related patents,” but only if they originate “from the same tribunal.”⁸²

As such, it has not been definitively determined whether a PTAB ruling has a collateral estoppel effect while pending appeal. This differs from the collateral estoppel effect of district court decisions, for which the Federal Circuit has plainly ruled that “collateral estoppel can be applied based on a district court decision” even if it “is still pending on appeal.”⁸³

Currently, this lack of clarity poses potential problems. For example, it almost seems as if a PTAB ruling’s estoppel effect on a district court decision is based on considerations outside litigants’ control, such as whether the district court decides to consider the PTAB’s FWD, whether the Federal Circuit’s clerk of court opts to consolidate the district court and PTAB appeals, or whether the Federal Circuit opts to decide both appeals simultaneously. As the IPR system introduced by the AIA continues to grow in popularity as a faster and more cost-efficient alternative to district court litigation, the unresolved issues with parallel litigation system remain unaddressed by the courts. The facts in *United Therapeutics* fall into the gray area leading to an ultimately confusing outcome.

3. 3. *Federal Rules of Civil Procedure Rule 60*

The FRCP 60(b) motion is a last resort for parties seeking relief from an unjust judgment or order. FRCP 60(b) states that a court “*may* relieve a party” from a final judgment for reasons such as newly discovered evidence, mistake or neglect, fraud, a void judgment, or “any other reason that justifies relief.”⁸⁴

79. See *Fresenius*, 721 F.3d at 1341.

80. *XY, LLC*, 890 F.3d at 1294.

81. See generally FED. CIR. RULES OF PRAC. (2023).

82. *Id.* at 47.

83. *Uniloc USA Inc. v. Motorola Mobility LLC*, 52 F.4th 1340, 1347 (Fed. Cir. 2022).

84. FED. R. CIV. P. 60(b) (emphasis added).

However, there are several issues that would make FRCP 60(b) extremely difficult to rely on for resolving discrepancies in parallel patent litigation outcomes. FRCP 60(b) motions are rarely granted and are often narrowly limited to specific provisions in the rule and to “extraordinary circumstances” that “must justify reopening.”⁸⁵ Moreover, the rule’s language (i.e., that a court “*may*” relieve a party) grants courts full discretion to grant or deny relief.⁸⁶ Finally, FRCP 60(b) is necessarily retroactive—meaning that future or currently litigating parties do not have certainty as to the outcome of a future FRCP 60(b) motion.⁸⁷ Taken together, these factors strongly discourage parties from relying on FRCP 60(b) as a reliable and effective means of addressing conflicting outcomes in parallel litigation.

III. *UNITED THERAPEUTICS CORP. V. LIQUIDIA TECH., INC.*

United Therapeutics exemplifies the lack of clarity surrounding the collateral estoppel effect of the PTAB within the current parallel litigation system. In the district court decision, the court held Liquidia liable for infringing the patent-at-issue,⁸⁸ despite the PTAB having issued a Final Written Decision a month before invalidating the patent.⁸⁹ Instead, the district court declined to be bound by the PTAB’s decision when issuing its own decision.⁹⁰ While both decisions were appealed to the Federal Circuit, the court first heard only the district court appeal and affirmed the district court’s decision.⁹¹ In particular, the Federal Circuit ultimately held that Liquidia was liable for infringing the ’793 patent because the PTAB’s FWD did not have collateral estoppel effect while pending appeal.⁹² Later, however, the Federal Circuit affirmed the PTAB’s invalidity decision as well.⁹³ As a result, Liquidia was left with a strange and intuitively confusing outcome—being held liable for infringing a patent that had been declared invalid. Such a result seems to conflict with both Congress’s intent behind the AIA and the Supreme Court’s previous precedents.

85. *Kemp v. United States*, 596 U.S. 528, 533 (2022).

86. FED. R. CIV. P. 60(b).

87. *See id.*

88. *United Therapeutics Corp. v. Liquidia Techs., Inc.*, 624 F. Supp. 3d 436, 473 (D.D.E. Aug. 31, 2022) [hereinafter *District Court Decision*].

89. *Liquidia Techs., Inc. v. United Therapeutics Corp.*, 2022 Pat. App. LEXIS 3685, *52 (P.T.A.B. July 19, 2022) [hereinafter *PTAB FWD*].

90. *District Court Decision*, 624 F. Supp. 3d at 473 (“[T]he PTAB’s decision . . . has no impact on my finding of induced infringement.”)

91. *United Therapeutics*, 74 F.4th at 1374.

92. *Id.* at 1371.

93. *United Therapeutics Corp. v. Liquidia Techs., Inc.*, 2023 WL 8794633, at *1 (Fed. Cir. Dec. 20, 2023) [hereinafter *United Therapeutics II*].

Section III.A details the factual background of the case. Section III.B delineates the timeline of proceedings: Section III.B.1 details the timeline of district court proceedings, Section III.B.2 details the timeline of PTAB proceedings, and Section III.B.3 delineates the timeline of the two Federal Circuit appeals. Section III.C analyzes the ramifications of the case's final outcome and the issues posed as a result of the Federal Circuit's decisions.

A. FACTUAL BACKGROUND

United Therapeutics Corporation (“United Therapeutics”) is a biotechnology company that primarily develops drugs to treat rare diseases and end-stage lung diseases.⁹⁴ United Therapeutics owns the ’793 patent, which is “generally directed to methods of . . . pharmaceutical compositions comprising treprostinil.”⁹⁵ Treprostinil is a drug used to treat pulmonary arterial hypertension, a highly dangerous form of high blood pressure that affects the arteries in the lungs and heart.⁹⁶

Liquidia, Inc. (“Liquidia”) is a biopharmaceutical company that develops therapies for patients with cardiopulmonary diseases.⁹⁷ Liquidia created a dry powder inhalation formulation of treprostinil, which it called Yutrepia, and filed a New Drug Application with the Food and Drug Administration (FDA) in an effort to market the product.⁹⁸ United Therapeutics ultimately sued Liquidia in the United States District Court for the District of Delaware alleging that Liquidia induced infringement of the ’793 patent, among other asserted patents.⁹⁹ In response, Liquidia filed a petition for IPR of the ’793 patent, arguing that all claims of the ’793 patent were unpatentable (i.e., invalid) as obvious over the prior art at the time of the invention.¹⁰⁰

While the specific infringement and validity causes of action are not particularly significant to this Note, understanding the timeline of the parallel proceedings is critical.

94. *Therapeutic Areas*, UNITED THERAPEUTICS CORP., <https://perma.cc/Q3PL-35CK> (last accessed May 4, 2025).

95. *United Therapeutics*, 74 F.4th at 1363.

96. Pegah Zare & Daniel Heller, *Treprostinil*, NAT'L LIBR. MED. (May 8, 2023), <https://perma.cc/V8YU-47ZZ>.

97. *About Us*, LIQUIDIA, <https://www.liquidia.com/about-us> (last accessed May 4, 2025).

98. *United Therapeutics*, 74 F.4th at 1364.

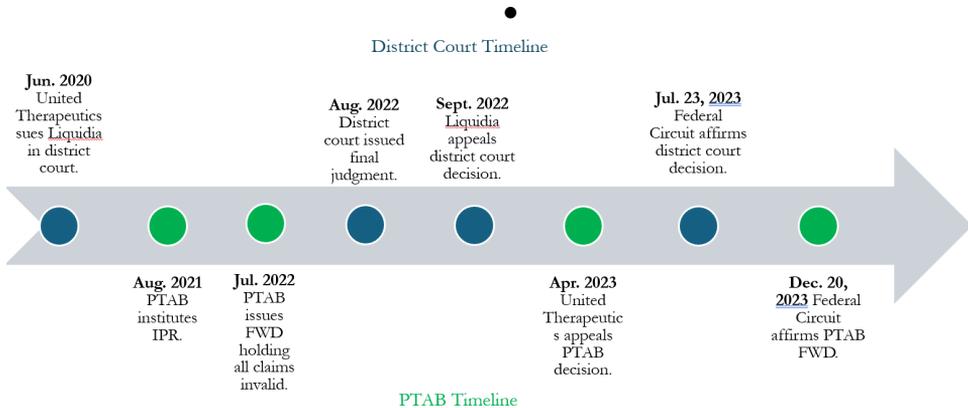
99. *Id.* at 1363.

100. *See PTAB FWD*, at *2.

B. PROCEDURAL HISTORY

The timeline of both parallel proceedings is summarized in the following chart and further discussed below:

Figure 1. Timeline of proceedings in the litigation between United Therapeutics and Liquidia. In particular, the blue and green dots on the timeline represent the separate proceedings in district court and in the PTAB, respectively.



This Section outlines the timeline of proceedings in both venues. This Section also analyzes how the district court and the Federal Circuit reached this counterintuitive decision regarding collateral estoppel.

1. PTAB

As shown in Figure 1, United Therapeutics first filed suit against Liquidia in the United States District Court of Delaware in June 2020.¹⁰¹ In response, Liquidia petitioned the PTAB for an IPR proceeding for the '793 patent, and the PTAB ultimately issued a ruling of invalidity before the district court issued its opinion.¹⁰²

The PTAB instituted review on August 11, 2021.¹⁰³ The parties litigated the IPR in parallel with the district court proceedings, and the PTAB issued a Final Written Decision on July 19, 2022.¹⁰⁴ In that decision, the PTAB held that all claims in the '793 patent were unpatentable as obvious over the prior art at the time of the invention.¹⁰⁵ United Therapeutics sought a Board

101. *United Therapeutics Corp. v. Liquidia Techs., Inc.*, 2020 U.S. Dist. LEXIS 205150, at *2 (D.D.E. Nov. 3, 2020) (“Plaintiff United Therapeutics filed a complaint for patent infringement against Defendant Liquidia on June 4, 2020.”).

102. *PTAB FWD*, at *52.

103. *PTAB FWD*, at *2.

104. *United Therapeutics*, 74 F.4th at 1364.

105. *Id.*; *PTAB FWD*, at *52.

rehearing, delaying the timeline to appeal the PTAB decision to the Federal Circuit until April 5, 2023.¹⁰⁶

2. District Court

Although United Therapeutics sued Liquidia in June 2020, the district court did not hold a bench trial until March 28, 2022.¹⁰⁷ During the trial, Liquidia did not maintain any grounds raised in its IPR (i.e., under 35 U.S.C. § 102 and 35 U.S.C. § 103) in district court.¹⁰⁸ Liquidia instead attempted to introduce the PTAB's FWD to the district court before the court rendered its decision.¹⁰⁹

However, the court issued its final opinion on August 31, 2022, ruling that all asserted claims of the '793 patent were not invalid and that Liquidia had induced infringement of the '793 patent.¹¹⁰ In its holding, the court noted that the PTAB had issued a FWD which invalidated all claims, but cited to the Federal Circuit's decision in *XY* and interpreted the Federal Circuit's holding that an "affirmance of an invalidity finding . . . has a collateral estoppel effect" to mean that "an IPR decision does not have collateral estoppel effect until that decision is affirmed or the parties waive their appeal rights."¹¹¹ Ultimately, the court held that "the PTAB's decision—which is not yet final—has no impact on [its] finding of induced infringement."¹¹² In other words, by interpreting the Federal Circuit's decision in *XY* to determine that the PTAB's decision lacked collateral estoppel effect, the district court obviated the PTAB's invalidity ruling.¹¹³

3. Federal Circuit Court of Appeals

Liquidia appealed the district court decision to the Federal Circuit on September 16, 2022.¹¹⁴ United Therapeutics appealed the PTAB's decision to

106. Notice of Appeal, United Therapeutics Corp. v. Liquidia Techs., Inc., IPR2021-00406 (P.T.A.B. Apr. 5, 2023), ECF No. 83.

107. See Official Transcript of Bench Trial held on 3/28/22 before Judge Richard G. Andrews, United Therapeutics Corp. v. Liquidia Techs., Inc., No. 20-00755 (D.D.E. 2022), ECF No. 402.

108. See generally *District Court Decision*.

109. *Id.* at 463.

110. *Id.* at 473.

111. *Id.* (citing *XY, LLC*, 890 F.3d at 1294).

112. *Id.* at 464.

113. *Id.*

114. Notice of Appeal, United Therapeutics Corp. v. Liquidia Techs., Inc., No. 20-00755 (D.D.E. 2022), ECF No. 440.

the Federal Circuit on April 26, 2023.¹¹⁵ Both appeals were on the Federal Circuit’s docket, and the court was aware that they were related to the same case, but it nonetheless considered both appeals separately.¹¹⁶

On July 24, 2023, the Federal Circuit issued its *United Therapeutics* decision, ruling only on the district court appeal and affirming the district court’s decision.¹¹⁷ In particular, the Federal Circuit rejected Liquidia’s argument that the PTAB’s FWD in the IPR proceeding for the ’793 patent estopped Liquidia from liability for induced infringement in the district court case.¹¹⁸ Liquidia cited the Supreme Court’s decision in *Commil*, in which the Court held that if “an act that would have been . . . an inducement to infringe pertains to a patent that is shown to be invalid, there is no patent to be infringed.”¹¹⁹ However, the Federal Circuit agreed with *United Therapeutics*’ argument that unpatentability is “relevant to infringement liability only once a final adjudication [made on appeal] of . . . invalidity rules that there is no such patent to infringe.”¹²⁰

Additionally, the Federal Circuit repeated the district court’s reasoning, including the district court’s interpretation of *XY*—that an IPR decision “does not have collateral estoppel effect until that decision is affirmed or the parties waive their appeal rights.”¹²¹ Ultimately, the Federal Circuit reached the same result, holding that the “’793 IPR decision . . . has no impact . . . on a finding of induced infringement.”¹²²

On December 20, 2023, the Federal Circuit then issued *United Therapeutics II*, affirming the PTAB’s decision and invalidating the ’793 patent as obvious over the prior art at the time of the invention.¹²³ At this point, Liquidia was liable for infringing the ’793 patent, while also having successfully invalidated the same patent.

Six days after the *United Therapeutics II* decision, Liquidia filed a FRCP 60(b) motion with the District of Delaware, seeking to vacate the original judgment

115. Notice of Appeal, *United Therapeutics Corp. v. Liquidia Techs., Inc.*, IPR2021-00406 (P.T.A.B. Apr. 5, 2023), ECF No. 83.

116. See *United Therapeutics*, 74 F.4th at 1364.

117. *Id.* at 1363.

118. *Id.* at 1371.

119. *Commil*, 575 U.S. at 644.

120. *United Therapeutics*, 74 F.4th at 1371.

121. *Id.* at 1372.

122. *Id.*

123. *United Therapeutics II*, at *1.

of infringement because the '793 was invalid and unenforceable.¹²⁴ On March 28, 2024, the Delaware district court granted Liquidia's motion and vacated the holding that Liquidia infringed the '793 patent.¹²⁵

The March 28 decision was the final decision in this series of cases. Liquidia filed a petition for a writ of certiorari to the Supreme Court regarding the collateral estoppel portion of the *United Therapeutics* decision, but was denied on February 20, 2024.¹²⁶ United Therapeutics also filed a petition for a writ of certiorari to the Supreme Court regarding the *United Therapeutics II* decision, but was denied on October 7, 2024.¹²⁷ As such, litigation between United Therapeutics and Liquidia regarding the '793 patent is now concluded.

C. ANALYZING THE UNITED THERAPEUTICS DECISIONS AND ITS RAMIFICATIONS

The Federal Circuit's decision in *United Therapeutics* is intuitively confusing but, more importantly, at odds with prior precedent from both the Supreme Court and its own prior holdings. On its face, the outcome of the *United Therapeutics* and *United Therapeutics II* decisions resulted in Liquidia being held liable for infringing an ultimately invalid patent—a result that seems to directly contradict the Supreme Court's assertion in *Commil* that “if . . . an act [of infringement or induced infringement] pertains to a patent that is shown to be invalid, there is no patent to be infringed.”¹²⁸ However, what makes *United Therapeutics* and *United Therapeutics II* noteworthy is that these decisions do not directly contradict or seek to overturn any particular previous decision. Rather, these decisions fall into a gap left unaddressed in prior decisions.

Indeed, the Federal Circuit in *United Therapeutics* (as well as the district court) held, in response to *Commil*, that the '793 patent is not invalid because the IPR proceeding holding the patent invalid was pending appeal in the very same court.¹²⁹ But this raises its own immediate question: Why wasn't the IPR appeal designated as a companion to the district court appeal, given that the Federal Circuit knew it was pending? *Commil* states plainly: “if the patent is indeed invalid, and shown to be so under proper procedures, there is no

124. Motion for Post Judgment Relief Pursuant to Federal Rule of Civil Procedure 60(b), *United Therapeutics Corp. v. Liquidia Techs., Inc.*, No. 20-00755 (D.D.E. 2023), ECF No. 461.

125. *United Therapeutics Corp. v. Liquidia Techs., Inc.*, 2024 U.S. Dist. LEXIS 56072, at *7 (D. Del. Mar. 28, 2024).

126. *United Therapeutics Corp. v. Liquidia Techs., Inc.*, 144 S. Ct. 873, 873 (2024).

127. *United Therapeutics Corp. v. Liquidia Techs., Inc.*, 145 S. Ct. 352, 352 (2024).

128. *Commil*, 575 U.S. at 644.

129. *United Therapeutics*, 74 F.4th at 1372.

liability.”¹³⁰ Under such a framework, it would be inefficient to consider infringement before invalidity, and in particular, to finalize an infringement judgment before finalizing the validity of the patent-at-issue.

Moreover, *Commil* even identifies IPRs as an example of a “proper way[]” to “obtain a ruling [of invalidity].”¹³¹ From a legislative standpoint, an IPR proceeding brought by Liquidia in response to an accusation of infringement should certainly qualify as a proper procedure if Congress intended for the IPR system to be a “cost-efficient alternative to litigation.”¹³² Therefore, the issue is how to incentivize parties to use the IPR system without also encouraging them to duplicate causes of action in district court. Duplication would, in fact, result in less efficiency, as both parties would be forced to litigate the same invalidity arguments in multiple venues, doubling the work for both parties and for the Federal Circuit if the parties appeal.

Moreover, a petitioner can stipulate that they will not bring any grounds that could be reasonably raised in an IPR to a parallel forum. In exchange, the PTAB would be less likely to exercise its discretion to deny institution of that party’s IPR petition. But in this scenario where a party moves one or more of its causes of actions to the PTAB and out of district court entirely, the lack of collateral estoppel effect for PTAB decisions is even more relevant.

Even though Liquidia did not make such a stipulation in this case, the result was functionally the same—only the PTAB heard its § 102 and § 103 arguments (anticipation and obviousness, respectively).¹³³ However, if a PTAB’s finding of invalidity reaches a final decision after infringement proceedings conclude, then the IPR system fails to serve as a “proper procedure” or a cost-efficient alternative to district court litigation.¹³⁴ If litigating parties cannot be certain that an IPR invalidity finding will take effect before infringement causes are decided, then there is a strong incentive not to pursue PTAB litigation unless the same invalidity grounds are also duplicated in district court.

Instead, *United Therapeutics* may actually encourage parties to bring duplicative parallel proceedings in district court and the PTAB, which is a practice that directly contradicts Congress’s intent in making the IPR process a cost-efficient alternative to district court litigation.¹³⁵ By removing 35 U.S.C. § 102 and 35 U.S.C. § 103 invalidity causes from district court proceedings and

130. *Commil*, 575 U.S. at 644.

131. *Id.* at 645.

132. Matal, *supra* note 13, at 640.

133. *See generally* *District Court Decision*.

134. *Id.*

135. 77 F. Reg. 48680-01 (Aug. 14, 2012).

instead raising them only before the PTAB (as Congress intended with the IPR system), Liquidia ultimately weakened its case.

It would have been safer for Liquidia to raise 35 U.S.C. § 102 and 35 U.S.C. § 103 arguments in both venues or even to forgo an IPR altogether. As it stands, the Federal Circuit may opt to rule on both the PTAB and district court appeals in tandem, as it did in *XY*.¹³⁶ However, where the court does not consolidate appeals, such as in *United Therapeutics*, litigants may find that they have a second bite at the apple, like *United Therapeutics* did when it successfully enforced an ultimately invalid patent.¹³⁷

The reasoning behind *United Therapeutics* is also difficult to reconcile with the Supreme Court's holding in *B & B Hardware*. Indeed, the Federal Circuit did not address *B & B Hardware* or any relevant Supreme Court precedent in its determination that IPR decisions have no collateral estoppel effect until affirmed on appeal.¹³⁸ While it is true that *B & B Hardware* pertains to a final TTAB decision on the issue of likelihood of confusion, the Supreme Court's analysis was broader.¹³⁹ The Court considered generally “whether an agency decision can ever ground issue preclusion,” not just the TTAB.¹⁴⁰ As discussed above, the Court observed that collateral estoppel “often applies” when an issue is litigated both “before a court and an administrative agency.”¹⁴¹ The Court detailed in length in its holding that collateral estoppel is so “‘well established’ at common law” that, as long as the “ordinary elements” of collateral estoppel are met, courts should “take it as given that Congress has legislated with the expectation that [collateral estoppel] will apply except when a statutory purpose to the contrary is evident.”¹⁴²

Yet, the Federal Circuit's holding in *United Therapeutics* does not even acknowledge *B & B Hardware* and its considerations.¹⁴³ Instead, the court relies on its previous decision in *XY*, holding that “an affirmance of an invalidity finding . . . has a collateral estoppel effect on all pending or co-pending actions.”¹⁴⁴ However, the Federal Circuit's subsequent interpretation of this statement, that an IPR decision not yet affirmed must not have collateral estoppel effect, is logically flawed.¹⁴⁵

136. *See XY, LLC*, 890 F.3d at 1294.

137. *See generally United Therapeutics*.

138. *Id.* at 1372.

139. *B & B Hardware*, 575 U.S. at 141.

140. *Id.* at 147.

141. *Id.* at 148.

142. *Id.* (internal citations omitted).

143. *See generally United Therapeutics*.

144. *Id.* at 1372 (quoting *XY, LLC*, 890 F.3d at 1294).

145. *See id.*

The Federal Circuit's reasoning regarding claim termination conflicts with its own prior decisions. For example, the court reasoned that claims are not canceled under 35 U.S.C. § 318(b) until the Director issues a certificate after the time for appeal has expired or any appeal has terminated.¹⁴⁶ However, in *Sec. People, Inc.*, the Federal Circuit previously held that “[t]he PTO’s decision-making process in an IPR is complete after issuance of the final written decision.”¹⁴⁷ In that opinion, the Federal Circuit stated that the certificate of cancellation mandated by 35 U.S.C. § 318(b) is wholly “irrelevant to the finality of the agency’s action,” calling it a mere “nondiscretionary formality.”¹⁴⁸ If the Federal Circuit had applied this reasoning to *United Therapeutics*, then the PTAB’s FWD of invalidity, issued before the district court case, should have immediately rendered the infringement action moot for the ’793 patent.

Finally, although Liquidia was able to successfully petition the district court for an FRCP 60(b) motion to vacate the infringement judgment, the issues posed by *United Therapeutics* are unresolved for future litigants. As discussed in Section II.C.3, FRCP 60(b) is a retroactive remedy and is rarely invoked.¹⁴⁹ FRCP 60(b) motions must also be made within a short and reasonable timeframe.¹⁵⁰ Moreover, Liquidia vacated an injunction on its drug, which it sought to introduce to the market.¹⁵¹ But the Supreme Court and the Federal Circuit are silent on how a party would be compensated for monetary damages or lost profits due to injunctions on products already in the market under a successful FRCP 60(b) motion. As such, future litigants have little certainty that FRCP 60(b) would be a reliable fallback option capable of providing adequate relief.

Without certainty of what the district courts and Federal Circuit will do, future litigants may find it most worthwhile to bring all invalidity arguments to district court while duplicating their § 102 and § 103 invalidity arguments in a parallel IPR proceeding. This would double the workload for both parties, maintain the same amount of work in district court, and double the burden on the Federal Circuit. The IPR system, in such a scheme, would ultimately become redundant rather than an effective alternative to district court litigation.

146. *Id.*

147. 971 F.3d at 1361.

148. *Id.*

149. *See Kemp*, 596 U.S. at 533.

150. FED. R. CIV. P. 60(c)(1).

151. Memorandum Order, *United Therapeutics Corp. v. Liquidia Techs., Inc.*, No. 20-00755 (D.D.E. 2024), ECF No. 479.

IV. COURT-SIDE AND LEGISLATIVE PROPOSALS TO RESOLVE THE COLLATERAL ESTOPPEL ISSUE

This Section proposes a multifaceted approach to reforming both the Federal Circuit Rules of Practice (court-side reform) and current AIA statutes. The court-side rule reforms are narrower in scope, specifically aimed at preventing scenarios like *United Therapeutics* from recurring. By targeting amendments to the Federal Circuit Rules of Practice, the proposed court-side solutions can be enacted immediately without waiting for another case with similar merits.

In particular, the proposed solution would require the clerk of court to designate parallel appeals from a district court and the PTAB (e.g., involving the same parties and the same patent number(s)) as companion cases. These companion cases would remain separate appeals (so as to not consolidate different standards of review), but the Federal Circuit would hear and decide them at the same time. This reform balances practicality with the urgent need for change, but it does not overturn the *United Therapeutics* decision and therefore does not affirmatively grant collateral estoppel effect to PTAB decisions. Instead, the court-side proposals aim to prevent situations like *Liquidia*'s, where it was held liable for infringing an ultimately invalid patent because the PTAB appeal was delayed until after the district court appeal was decided.¹⁵²

The legislative reform seeks to address the collateral estoppel issue at its root. In particular, the proposal would amend 35 U.S.C. § 318(a) to explicitly grant PTAB final written decisions the same collateral estoppel effect as district court decisions.

On July 10, 2023, Congress proposed Senate Bill 2220, otherwise known as the “Promoting and Respecting Economically Vital American Innovation Leadership Act” (“PREVAIL Act”), which seeks to address other issues in the patent litigation system that have arisen post-AIA.¹⁵³ Indeed, the PREVAIL Act may be amended to include the legislative proposals suggested in this Note—it is a strong vehicle to address the collateral estoppel issue because it already focuses on improving issues in the post-AIA patent system. Thus, by incorporating these changes, Congress could directly address the collateral estoppel issue raised by *United Therapeutics*.

The proposed solution requires reforms across multiple forums given the urgent need to correct the confusing doctrine left in the wake of *United*

152. See generally *United Therapeutics*.

153. See PREVAIL Act of 2023, S. 2220, 118th Cong. § 2 (2024) [hereinafter PREVAIL Act].

Therapeutics. A legislative solution alone may be impractical due to the difficulty of passing legislation through Congress.¹⁵⁴ On the other hand, a court-side rule reform alone would be insufficient, as it is unknown when the Federal Circuit will next address this issue again. Moreover, a lone court-side reform to address the entire collateral estoppel issue would necessitate a stronger measure, potentially requiring the Federal Circuit to overturn its *United Therapeutics* decision.

Section IV.A introduces the proposed court-side rule reform, analyzing its benefits and limitations. Section IV.B describes the proposed legislative reforms, namely amending 35 U.S.C. § 315(e) to grant final written decisions issued by the PTAB in IPR proceedings the same collateral estoppel effect as district court decisions.

A. THE FEDERAL CIRCUIT SHOULD REFORM ITS RULES OF PRACTICE TO DESIGNATE PARALLEL APPEALS FROM DISTRICT COURTS AND THE PTAB AS COMPANION CASES.

As a baseline change, the Federal Circuit should adopt a mandate in its Rules of Practice requiring the clerk of court to designate parallel appeals involving the same patent(s) as companion cases. For example, appeals from district courts and the PTAB involving the same parties and the same patent number(s) should be classified as companion cases, allowing the Federal Circuit to hear oral arguments and issue decisions for both appeals simultaneously. By doing so, the court could issue opinions for both appeals with the other in mind, as it did in *XY*.¹⁵⁵ This Section explores the practicality of implementing this reform, analyzing its pros and cons, particularly in comparison to other potential court-side solutions. Additionally, it also examines the impact of this potential reform on the broader collateral estoppel issue raised by *United Therapeutics*.

1. *Advantages of Court-Side Reform*

The immediate issue at hand is why court-side reform is necessary at all, particularly when the proposed reforms are so moderate and limited to court rules. However, in light of the *United Therapeutics* decisions, litigating parties now face uncertainty as to (1) whether the district court will rule before the PTAB does; and (2) whether the district court will consider or adopt the PTAB's decision. For example, in *United Therapeutics*, the Delaware district

154. See *Statistics and Historical Comparison*, GOVTRACK, <https://perma.cc/9GNE-ZKT8> (last visited Feb. 9, 2025) (tracking that every Congress since 1973 has had less than 10% of proposed legislation passed into law).

155. See *XY, LLC*, 890 F.3d at 1294.

court acknowledged the PTAB's decision but did not change its final ruling, even after Liquidia submitted the PTAB's invalidity finding to the court.¹⁵⁶

On its face, the most pressing collateral estoppel issue in this series of cases is that United Therapeutics was able to enforce a patent that Liquidia had already invalidated through an IPR, despite the PTAB's issuance of its decision before the district court ruling.¹⁵⁷ Through a combination of the district court disregarding the PTAB's decision in its final opinion, and the PTAB appeal being decided after the district court appeal (despite the PTAB decision being first), the *United Therapeutics* decisions essentially gave United Therapeutics two chances to argue the validity of its '793 patent.¹⁵⁸

Designating the two appeals concerning the validity of the '793 patent as companion cases would have prevented the Federal Circuit from issuing two conflicting validity holdings on the same patent in the same litigation. It is sensible to classify PTAB and district court appeals as companion cases, so the Federal Circuit can hear the full scope of invalidity arguments raised by a defending party before issuing a decision. Recall from Section II.A.1 that a patent claim that fails the validity analysis under just one statutory requirement is rendered wholly invalid.¹⁵⁹ Therefore, to fully consider a patent's validity, all invalidity arguments must be considered together. However, IPR proceedings are limited to invalidity causes of action under § 102 (anticipation) and § 103 (obviousness).¹⁶⁰ This means that a lone PTAB appeal before the Federal Circuit may not contain the full scope of invalidity proceedings raised by the defending party. Similarly, in a case like *United Therapeutics*, where Liquidia has moved its § 102 and § 103 causes of action out of district court and into the PTAB, the same problem arises if the Federal Circuit hears only the district court appeal without the PTAB appeal.¹⁶¹

While the proposed Federal Circuit reform does not directly address this collateral estoppel issue, it prevents the unfair outcome of allowing a party two bites at the apple in similar cases. By adopting this reform, future litigating parties would have reassurance that the full scope of their invalidity arguments would be considered together on appeal if they opt to pursue PTAB litigation. For example, had these reforms been in place, Liquidia could have been assured that even if the district court disregarded the PTAB's FWD, the

156. See generally *District Court Decision*.

157. See generally *United Therapeutics*.

158. See generally *United Therapeutics*; *United Therapeutics II*.

159. See 35 U.S.C. § 101.

160. 35 U.S.C. § 311(b).

161. See generally *United Therapeutics*.

Federal Circuit would have reviewed its arguments in light of all previous proceedings regarding the '793 patent.

The reform is also consistent with the spirit of the Supreme Court's doctrine outlined in *Commil* and would further establish IPR proceedings as a "proper procedure" for invalidating a patent, as intended by both the Supreme Court and Congress.¹⁶² As the *Commil* court stated, "there is no liability" if the patent at issue is "shown to be invalid," which strongly implies that invalidity should be considered before liability is assessed.¹⁶³

2. *Difficulties in Expanding Court-side Reforms*

Requiring companion case designation is a fairly modest reform and raises an inevitable question: Why not implement stronger court-side reform? For example, why not mandate district courts to stay their final decision until the PTAB issues its Final Written Decision? Or why not mandate that the Federal Circuit consolidate both appeals from different forums into a single case?

A proposed amendment to the Federal Circuit Rules of Practice requires a cautious approach that weighs the benefits of addressing the collateral estoppel issue against the potential drawbacks of disproportionality benefiting one party. Even the designation of companion cases—where the Federal Circuit groups PTAB and district court appeals between the same parties for the same patent(s)—poses some practical issues.

As described in Section II.C.2, parties in parallel patent litigation are often in a race to final judgment, and even the most moderate reform would likely alter one forum's litigation timeline to the detriment of one party. Currently, the parallel litigation scheme incentivizes patent owners (i.e., plaintiffs in district court and defendants in an IPR) to delay PTAB final judgment because the PTAB can only invalidate a patent in an IPR proceeding.¹⁶⁴ If the Board cannot find that a patent is invalid by a preponderance of the evidence, the patent remains valid.¹⁶⁵ In contrast, for defendants, a PTAB finding of invalidity would immediately render the district court infringement action against them moot once finalized.¹⁶⁶ However, the PTAB's litigation timeline from petition until final judgment varies markedly from that of district court proceedings. Even designating appeals as companion cases, such that they are ruled on together (as in *XY*) necessarily alters one forum's litigation timeline, often to the detriment of one party.

162. *Commil*, 575 U.S. at 644.

163. *Id.*

164. *See* 35 U.S.C. § 311(b).

165. *Id.*

166. *See* Totten, *supra* note 67.

The complex nature of parallel litigation across different forums with different standards of review also makes it difficult to expand the scope of Federal Circuit reform. For example, it may seem logical to consolidate a PTAB appeal and district court appeal involving the same parties and the same patent(s) into a single appeal before the Federal Circuit. Indeed, the Federal Circuit Rules of Practice, Rule 15, states that the clerk of court “will usually” consolidate appeals or petitions for review involving the “same or related patents” if they are “from the same tribunal.”¹⁶⁷ However, in reality, the different standards of review between the two forums make full consolidation into a single appeal impractical.

Similarly, mandating a stay (i.e., pausing proceedings) for a district court appeal in the Federal Circuit while the PTAB appeal is pending would also be difficult as it may have practical implications that outweigh its benefits. A mandatory stay would necessarily require delaying the district court decision in every scenario. While this may seem administratively efficient, in the race to final judgment, it would disproportionately benefit the defending party in district court, who often seeks to delay a final verdict on district court litigation. By contrast, designating appeals as companion cases would give litigants more control to petition the court on which decision’s timeline should be changed. This would also give the Federal Circuit more flexibility to decide whether to stay the district court appeal or expedite the PTAB appeal on a case-by-case basis.

Mandating that a district court stay its original final verdict while a PTAB parallel proceeding is ongoing is also problematic because of procedural differences across different district courts. The PTAB operates under a statutorily defined timeline to resolve an IPR, and some courts may already prefer to stay proceedings until the PTAB issues its FWD for the related IPR. In particular, if the PTAB issues a decision invalidating the patent, a district court may adopt the PTAB’s invalidity finding, effectively ending all remaining causes of action in the case. However, district courts have discretion to stay proceedings or defer to PTAB decisions. Some district courts may choose not to stay because they do not wish to grant too much deference to the PTAB.

Compared to other potential reforms to Federal Circuit proceedings, requiring companion case designation for already related cases is a fairer approach than forcing stays at the appeal or the district court level. Companion case designation would keep timing disruption to a minimum while also preserving feasibility.

167. *See* FED. CIR. RULES OF PRAC. at 47.

3. *A Band-Aid Fix to the Bigger Collateral Estoppel Problem*

The proposed Federal Circuit Rules of Practice reform, which would designate PTAB and district court appeals between the same parties for the same patent(s) as companion cases, does not resolve the root collateral estoppel issue. For example, it does not grant PTAB decisions the same collateral estoppel effect as that of district court decisions. It also does not overturn the *United Therapeutics* holding, which found that a PTAB decision pending appeal is “non-final litigation” and “does not have collateral estoppel effect.”¹⁶⁸ As such, district courts would still have the discretion to disregard PTAB decisions, as the Delaware district court did in this case. Additionally, under this reform, district courts would continue to enjoy the discretion to decide whether to stay a case while PTAB proceedings are pending. It is critical that court-side reforms do not present overly rigid mandates or directly strip district courts of their authority in favor of the PTAB.

It would be difficult to address the collateral estoppel issue solely through court-side reforms. For instance, courts have long called on the Federal Circuit to clarify its ambiguous language in *XY*, even before *United Therapeutics*.¹⁶⁹ And in *United Therapeutics*, the Federal Circuit did attempt to clarify its holding in *XY*. But before this case was decided, district courts have already interpreted *XY* differently than the Federal Circuit did, with some courts holding that collateral estoppel does extend to PTAB decisions pending appeal.¹⁷⁰ Cases where PTAB and district court appeals involving the same parties and the same patent(s) are pending in the Federal Circuit at the same time are rare. It may be a while before the Federal Circuit has another opportunity to clarify or overrule its holding in *United Therapeutics*. Because the Supreme Court has denied Liquidia’s petition for certiorari, the Federal Circuit’s decisions in both appeals are now final.

168. *United Therapeutics*, 74 F.4th at 1372.

169. *See, e.g.*, *TrustID, Inc. v. Next Caller Inc.*, 2021 WL 3015280, at *3–4 (D. Del. July 6, 2021) (stating that the Federal Circuit’s holding in *XY* “suggests” a result that “seems counterintuitive”—that “an IPR decision does not have preclusive effect until that decision is either affirmed or the parties waive their appeal rights”); *Indivior Inc. v. Alvogen Pine Brook LLC*, 681 F. Supp. 3d 275, 293 (D.N.J. July 10, 2023) (highlighting “difficulties in harmonizing” the *XY* decision with “traditional” collateral estoppel).

170. *See, e.g.*, *Inland Diamond Prods. Co. v. Cherry Optical Inc.*, 695 F. Supp. 3d 1031, 1039 (E.D. Wis. Sep. 28, 2023) (“The Federal Circuit confirmed that this general principle of issue preclusion extends to final written decisions rendered by the PTAB in IPR proceedings.”) (citing *Google LLC v. Hammond Dev. Int’l, Inc.*, 54 F.4th 1377, 1381 (Fed. Cir. 2022) and *Papst Licensing GMBH & Co. KG v. Samsung Elecs. Am., Inc.*, 924 F.3d 1243, 1250–51 (Fed. Cir. 2019)).

Even as a band-aid solution, it is important to adopt this proposal to prevent another case like *United Therapeutics*. It would also be an important step in ensuring parties continue to utilize the PTAB's IPR procedure as Congress intended under the AIA.

For other parties observing the *United Therapeutics* case, the safer approach may now be to bring an invalidity challenge in the PTAB while maintaining the same grounds in district court—a strategy that results in duplicative parallel litigation. Duplicative parallel litigation directly contradicts Congress's intent in establishing the IPR system under the AIA.¹⁷¹ Bringing the same causes of action in two different venues not only increases costs for the parties, but also demands more litigation resources than before the AIA. As such, while reforming Rule 15 of the Federal Circuit Rules of Practice to require the clerk of court to designate PTAB and district court appeals involving the same parties and patent(s) as companion cases is a temporary fix for the collateral estoppel issue, its implementation remains important.

Although a scenario like *United Therapeutics* is rare, it cannot simply be brushed aside. The uncertainty posed by the *United Therapeutics* decisions will affect future litigants, potentially forcing them to pursue duplicative parallel proceedings to avoid an outcome where they are found to infringe an invalid patent. While the proposed court-side reforms can help safeguard defending parties (such as Liquidia) from facing the confusing result of being held liable for infringing an invalid patent, Congress is in a stronger position to implement a more practical and comprehensive resolution.

B. CONGRESS SHOULD AMEND AND EXPAND 35 U.S.C. § 315(E) TO GRANT COLLATERAL ESTOPPEL EFFECT TO PTAB FINAL WRITTEN DECISIONS WHILE PENDING APPEAL.

The legislative approach proposes a more direct and sweeping solution by amending 35 U.S.C. § 315(e) to directly grant collateral estoppel effect to PTAB final written decisions, like district court decisions. This amendment would ensure that a PTAB decision has a preclusive effect even while pending appeal, unless the Federal Circuit reverses it.

Congress can practically implement this amendment by attaching it into existing legislative proposals aimed at amending post-grant proceedings, specifically the PREVAIL Act.¹⁷² This Note does not comment on the PREVAIL Act's existing provisions. However, the PREVAIL Act is an ideal vehicle for addressing the PTAB collateral estoppel issue, as it explicitly seeks

171. See Matal, *supra* note 13, at 653.

172. See PREVAIL Act § 2.

to address other PTAB shortcomings.¹⁷³ Section IV.B.1 introduces, in more detail, the key provisions of the PREVAIL Act. Section IV.B.2 analyzes the benefits of adding an amendment to 35 U.S.C. § 315(e) that incorporates collateral estoppel effect to PTAB FWDs. Section IV.B.3 addresses counterarguments and reconciles them with Supreme Court precedent.

1. *The Proposed PREVAIL Act and its Shortcomings in Dealing with United Therapeutics*

Congress has already recognized the “[u]nintended consequences” of post-grant proceedings under the AIA in its introduction of the PREVAIL Act.¹⁷⁴ As such, the PREVAIL Act seeks to amend Title 35 of the United State Code to address “the strategic filing of post-grant [and *inter partes*] review proceedings,” which result in “unnecessary duplication of work by the district courts . . . and the [PTAB].”¹⁷⁵

The proposed PREVAIL Act begins with an amendment to 35 U.S.C. § 311, which limits IPR petitions to only those parties that have been sued or charged with infringement of the patent in question.¹⁷⁶ This provision clarifies Congress’s intentions behind the IPR system—to shift § 102 and § 103 invalidity causes of action (as specified in 35 U.S.C. § 311(b)) out of district court and into the PTAB.¹⁷⁷ In doing so, the PREVAIL Act recognizes and preserves the current parallel litigation framework.

However, the proposed amendment to 35 U.S.C. § 315(c) introduces a significant limitation: Claims, counterclaims, and affirmative defenses brought to the PTAB would be restricted to that forum alone.¹⁷⁸ In other words, while the PREVAIL Act continues to allow for parallel litigation, it eliminates loopholes that would allow parties to duplicate claims in both forums.¹⁷⁹

While the PREVAIL Act identifies and addresses several key issues in the post-AIA patent system, it only prevents parties from duplicating issues in both the PTAB and a different forum.¹⁸⁰ But it does not address the collateral estoppel effect of a Final Written Decision issued by the PTAB. Additionally, it does not require that PTAB decisions be issued before district court decisions.

173. *Id.*

174. *Id.*

175. *Id.*

176. *See id.* § 4.

177. *See id.*

178. *Id.*

179. *See id.*

180. *See id.*

If Congress intends to preserve parallel litigation, it must determine if PTAB decisions should have collateral estoppel effect, especially in light of the *United Therapeutics* decisions. Notably, the PREVAIL Act was proposed before the *United Therapeutics* decisions were issued by the Federal Circuit, meaning Congress may not have anticipated such an unusual outcome.¹⁸¹ As it currently stands, the PREVAIL Act is insufficient to fully address the ongoing estoppel issues in the parallel litigation system.

Therefore, Congress should amend 35 U.S.C. § 315(e) to grant collateral estoppel effect to final written decisions by the PTAB in IPR proceedings.¹⁸² For example, Congress could define a PTAB final written decision as carrying the same finality as a district court decision, including its collateral estoppel effect. It is critical to expand the PREVAIL Act to prevent situations like *United Therapeutics*, where a party petitions for an IPR after being accused of patent infringement, only to find out that the IPR decision is ultimately meaningless. Without this expansion, parties trying to utilize the IPR system would face too much uncertainty at the whims of judicial discretion or potential litigation gamesmanship. Currently, the estoppel provision in 35 U.S.C. § 315(e) only bars the IPR petitioner from petitioning the PTAB again after a final decision is issued.¹⁸³ However, Congress should expand this section to ensure PTAB final written decisions carry collateral estoppel effect while pending appeal, just as final judgments from district courts do.

2. *Benefits of Adopting the Proposed Legislative Reform*

Like the court-side reform proposals described in Section IV.A, legislative reforms should also cautiously weigh the feasibility and practicality of implementation against the potential advantages and drawbacks. In this case, reforming 35 U.S.C. § 315(e) to grant collateral estoppel effect to PTAB decisions is both practical and aligned with existing legislative efforts, such as the PREVAIL Act. It would also better adhere to Supreme Court precedent set in *B & B Hardware* than the current Federal Circuit doctrine.

Granting collateral estoppel effect to PTAB final written decisions is a practical approach bolstered by Supreme Court precedent. In *B & B Hardware*, the Supreme Court held that administrative proceedings can have collateral estoppel effect if the “ordinary elements of issue preclusion” are met, unless a statutory purpose to the contrary is “evident.”¹⁸⁴ The Supreme Court further

181. *See generally id.* The bill was proposed on July 10, 2023, before *United Therapeutics* was decided.

182. *See* 35 U.S.C. § 318(a).

183. *See* 35 U.S.C. § 315(e).

184. *B & B Hardware*, 575 U.S. at 148.

clarified that the ordinary elements of issue preclusion are defined by the Restatement (Second) of Judgments, which states that a final judgment on an issue that was “actually litigated” carries collateral estoppel effect, even if issued by an administrative agency.¹⁸⁵ Moreover, the Court made clear that collateral estoppel can “often appl[y]” even in cases “where a single issue is before a court and an administrative agency.”¹⁸⁶

Indeed, Congress’s implementation of the IPR system is necessarily litigative, and 35 U.S.C. § 318(a) explicitly states that the PTAB issues a “final written decision.”¹⁸⁷ Therefore, granting collateral estoppel effect to PTAB decisions would be consistent with existing legislation, such as in 35 U.S.C. § 318, and with prior Supreme Court precedent.

3. *Potential Drawbacks—and How Commil Reconciles Them*

Congress has mandated in 35 U.S.C. § 101 that a patent claim found invalid in any proceeding is rendered wholly invalid.¹⁸⁸ Under the single forum clause in the newly proposed 35 U.S.C. § 315(c) of the PREVAIL Act, the grounds for invalidity argued before the PTAB would necessarily differ from those raised in district court.¹⁸⁹ Indeed, Congress appears to view patent validity to be a combination of separate standards, because parties petitioning for an IPR may only bring invalidity arguments under § 102 and § 103 before the PTAB.¹⁹⁰ Other invalidity grounds (if raised by the defendant/petitioner) must continue to be litigated in district court. Under such an interpretation for parallel litigation to remain viable, a final holding of invalidity should immediately render infringement proceedings moot. Likewise, an infringement finding should not be finalized until all validity proceedings are final. As the majority in *Commil* noted, if a patent is shown to be invalid, then it cannot be infringed.¹⁹¹

Granting PTAB decisions the same collateral estoppel effect as district court rulings presents potential drawbacks that must be considered. For example, if PTAB decisions are granted collateral estoppel effect while on appeal, a district court would face uncertainty as to (1) whether the PTAB will ultimately invalidate the patent initially, and (2) whether the Federal Circuit will affirm or reverse the PTAB’s decision. As such, granting PTAB final written decisions collateral estoppel effect while pending appeal could lead district

185. *Id.* (quoting RESTATEMENT (SECOND) OF JUDGMENTS § 27).

186. *Id.*

187. 35 U.S.C. § 318(a).

188. 35 U.S.C. § 101.

189. *See* PREVAIL Act § 4.

190. *See* 35 U.S.C. § 311(b).

191. *Commil*, 575 U.S. at 644.

courts to delay proceedings until the PTAB issues its decision and the entire appeal process is completed. Implementing a system in which a court must stay proceedings while concurrent PTAB litigation is pending would further delay litigation timelines and reduce court efficiency. Such a system would contradict Congress's intent in the PREVAIL Act, which allows for parallel litigation proceedings.

A potential compromise could help alleviate the uncertainty district courts face in such a scenario. PTAB decisions could carry a collateral estoppel effect without requiring a court to stay all proceedings while parallel PTAB litigation is pending. For example, even if the PTAB decides that a patent should be invalid on §§ 102 or 103 grounds, the district court could still issue its decision regarding the separate invalidity grounds, and vice versa. However, the patent would remain invalid unless the PTAB decision is reversed on appeal. In other words, a district would not need to fully stay all proceedings upon a PTAB invalidity finding—merely holding that its infringement ruling should not be finalized.

The Supreme Court's decision in *Commil* aligns with granting PTAB decisions collateral estoppel effect, without contradicting Congress's intent in the PREVAIL Act. As the majority in *Commil* states, infringement and validity are separate issues under patent law because they fall under separate sections of the Patent Act.¹⁹² Under this interpretation, a district court is free to consider infringement separately from (and in parallel to) invalidity arguments. However, under such an interpretation, if a district court finds that infringement occurred, then by granting collateral estoppel effect to PTAB decisions, the infringement finding cannot be finalized until the PTAB appeal is resolved in the Federal Circuit. A case such as *United Therapeutics*, where Liquidia was found to have infringed a patent that it later invalidated through the IPR system, would not be possible under this approach.

PTAB decisions on invalidity should carry the same collateral estoppel effect as district court decisions if they are to function as an effective alternative to district court litigation. At the same time, recognizing the differences between parallel proceedings in different forums, courts could retain discretion to issue decisions that take effect only if a PTAB's finding of invalidity is overturned.

192. *Id.* at 643.

V. CONCLUSION

The Federal Circuit's decisions in *United Therapeutics* and *United Therapeutics II* reflect a confusing cumulation of the unclear doctrines governing the parallel patent litigation system introduced post-AIA. However, the PTAB has only existed for just over a decade. Therefore, it is not surprising that time is needed to identify and clarify ambiguities in the parallel litigation framework.

To maintain Congress's intent in the AIA, reform is necessary to prevent the recurrence of the bizarre outcome in *United Therapeutics*, where a party was held liable for infringing an invalid patent. Adopting the proposed combination of court-side and legislative reforms can effectively resolve the issues raised in *United Therapeutics*, while upholding both Supreme Court precedent and Congress's original vision in the AIA.

THE INTERACTION OF OBVIOUSNESS-TYPE DOUBLE PATENTING AND PATENT TERM ADJUSTMENT

Han K. D. Le[†]

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I. INTRODUCTION

One of the highest-grossing drugs in the world, Humira reached a peak of \$21.2 billion in sales in 2022.¹ This equates to over \$58 million per day. In January 2023, nearly two decades after Humira first entered the market, its key patents expired, opening the floodgates to biosimilar competition.² The effects

1. Press Release, AbbVie, AbbVie Reports Full Year and Fourth Quarter 2022 Financial (Feb. 9, 2023), <https://investors.abbvie.com/news-releases/news-release-details/abbvie-reports-full-year-and-fourth-quarter-2022-financial>.

2. Noah Higgins-Dunn, *The Top 15 Blockbuster Patent Expirations Coming This Decade*, FIERCEPHARMA (July 12, 2021), <https://www.fiercepharma.com/special-report/top-15-blockbuster-patent-expirations-coming-decade>.

were immediate: Humira's sales plunged by nearly \$7 billion in 2023, translating to a daily loss of nearly \$20 million.³ Humira's story highlights just how critical each day of a patent term can be in the life sciences industry.

Currently, a United States utility patent expires twenty years from its effective filing date.⁴ This length of patent term may appear to be set in stone, but the reality strays far from this. In certain situations, a patent owner may seek to either shorten or extend this period. A patentee may voluntarily shorten the term of her patent by filing a terminal disclaimer to address a double patenting rejection.⁵ Under the doctrine of double patenting, inventors cannot improperly extend their patent monopoly by obtaining multiple patents on the same invention (statutory double patenting) or obvious variants of it (nonstatutory, or obviousness-type double patenting).⁶ By filing a terminal disclaimer to cure an obviousness-type double patenting (ODP) rejection, the second patent's term is shortened to the same term as that of the first patent.⁷ On the other hand, patent owners may also lengthen the term of their patent through mechanisms such as patent term adjustment (PTA). PTA is automatically granted when the United States Patent and Trademark Office (USPTO) causes delays in the patent prosecution process.⁸ A patent may be subjected to all of these term modification mechanisms simultaneously. In such cases, the doctrine of double patenting becomes complex and sometimes inconsistent when interacting with PTA.

The Federal Circuit's recent decision in *In re Collect* brought this complicated interaction to the forefront, threatening thousands of patents previously understood to be safe from double patenting challenges and leaving patentees scrambling to evaluate such risks in their portfolios.⁹ *Collect* held that if a patent's extended term is due to granted PTA, an ODP analysis must use the patent's expiration date *after* PTA has been added.¹⁰ This means that patents with awarded PTA can be invalidated for ODP based on earlier-expiring patents in the same family. Since *Collect*, courts have wrestled with ODP challenges involving PTA. In *Allergan USA, Inc. v. MSN Laboratories Private Ltd.*, a district court, relying on *Collect*, exposed the first patent in a family

3. Press Release, AbbVie, AbbVie Reports Full Year and Fourth Quarter 2023 Financial (Feb. 2, 2024), <https://investors.abbvie.com/news-releases/news-release-details/abbvie-reports-full-year-and-fourth-quarter-2023-financial>.

4. 35 U.S.C. § 154(a)(2).

5. 35 U.S.C. § 253; U.S. PAT. & TRADEMARK OFF., MPEP § 1490 (9th ed. Rev. 1, 2024).

6. 35 U.S.C. § 253; MPEP § 1490 (9th ed. Rev. 1, 2024).

7. *Id.*

8. 35 U.S.C. § 154(b).

9. *See generally In re Collect, LLC*, 81 F.4th 1216 (Fed. Cir. 2023).

10. *Id.* at 1229.

to ODP invalidation by a child patent simply because that first patent received PTA, but the child did not.¹¹ The Federal Circuit later dispelled this extreme interpretation on appeal, bringing a sigh of relief to patent owners.¹²

More than half of all U.S. patents receive PTA, making the interaction of ODP and PTA a critical matter for the patent community in all industries.¹³ On average, these patents get more than a year of PTA.¹⁴ For sectors like pharmaceuticals and biotechnology, where development timelines are long and investments are substantial, each additional day of patent term could amount to millions of dollars in revenue and is worth fighting for.¹⁵ Like PTA, ODP challenges are also prevalent, with nearly half of small-molecule and biologic drug patents facing ODP threats in the last two decades.¹⁶ Yet, the murky interaction between ODP and PTA continues to linger in the background. A lack of statutory and common law guidance directly linking statutory PTA

11. *See* Allergan USA, Inc. v. MSN Labs. Priv. Ltd., 694 F. Supp. 3d 511 (D. Del. 2023). A “patent family” refers to a group of patent applications related to each other by common priorities. A “child” patent application is a follow-up of a previously filed patent application, or a “parent” patent application. The various types of child applications include continuation applications, continuation-in-part applications, and divisional applications. When a child patent application is linked to a parent application through a priority claim, the child application benefits from the parent application’s earlier priority date.

12. Allergan USA, Inc. v. MSN Labs. Priv. Ltd., 111 F.4th 1358, 1361–78 (Fed. Cir. 2024).

13. Mark A. Lemley & Jason Reinecke, *Our More-Than-Twenty-Year Patent Term*, 39 BERKELEY TECH. L.J. 681, 683–84 (2024) (finding that, of the 4.5 million studied patents filed on or after May 29, 2000 and issued by the USPTO since 2005, 63.6% of these patents receive at least some PTA.); *see also* U.S. PAT. & TRADEMARK OFF., PATENT EXAMINATION RESEARCH DATASET (PatEx) (2002), <https://www.uspto.gov/ip-policy/economic-research/research-datasets/patent-examination-research-dataset-public-pair> (finding the total number of patents issued in 2023 is 144,054 patents, and 54 percent of those patents have PTA).

14. Lemley & Reinecke, *supra* note 13, at 683. The authors stated that “[t]he patents that do get PTA get more than a year on average (411 days, a median of 290 days), and more than 25% of all patents have more than a year of extra term. A small number of patents have much more PTA. Five percent of all patents get more than 1000 days of additional term; one percent get more than four years of additional term.”

15. *See* Henry G. Grabowski, Joseph A. DiMasi & Genia Long, *The Roles of Patents and Research and Development Incentives in Biopharmaceutical Innovation*, 34 HEALTH AFFS. 2, 302–03 (2015); *see also* Jaime F. Cárdenas-Navia, *Thirty Years of Flawed Incentives: An Empirical and Economic Analysis of Hatch-Waxman Patent-Term Restoration*, 29 BERKELEY TECH. L.J. 1301, 1317, 1347 (2014) (giving an example of U.S. Patent No. 7,037,917, covering the drug PREZISTA (darunavir) and INTELENCE (etravirine), and stating that two days of lost patent term for this patent could mean millions of dollars in lost revenue. The author also posits that a blockbuster drug with yearly revenues of \$1 billion could lose \$1.4 million per day once patent protection ends.).

16. S. Sean Tu, Aaron S. Kesselheim & Bernard Chao, *Extent of Drug Patents with Terminal Disclaimers and Obviousness-Type Double Patenting Rejections*, 332 JAMA 10, 837 (2024).

mechanisms to the judge-made ODP doctrine has done nothing but create uncertainty for courts, inventors, and other stakeholders alike.

This Note uses *Allergan* to outline the complex interactions of ODP and PTA. This Note argues that the Federal Circuit rightly decided *Allergan*, and that the first patent in a family with PTA-lengthened terms cannot, and should not, be invalidated for ODP based on other earlier-expiring patents without PTA. Part II of this Note traces the history of ODP jurisprudence and its interaction with patent term modification mechanisms to contextualize the decisions in *Allergan*. Part III delineates *Allergan*'s background, procedural history, and the Federal Circuit's reasoning for its decision. Part IV draws on legislative history and the context surrounding the establishment of ODP and PTA to explain why the Federal Circuit's decision in *Allergan* is a much-needed, necessary exception to *Collect*. Part IV then proposes a two-prong approach to an ODP analysis—one that considers both traditional equitable concerns and the propriety of reference patents used for invalidation. Additionally, Part IV poses ODP scenarios with PTA not covered by *Allergan* and, using the proposed approach, emphasizes that patent invalidation is possible in these scenarios based on the equitable circumstances underlying the ODP doctrine. Lastly, Part IV lays out practical strategies that practitioners and patentees can adopt to ameliorate ODP risks and uncertainties.

II. HISTORY OF OBVIOUSNESS-TYPE DOUBLE PATENTING JURISPRUDENCE WITH PATENT TERM ADJUSTMENT

The doctrine of double patenting is a simple rule: one invention, one patent.¹⁷ In practice, however, the doctrine has become troublesome, especially when interacting with other patent term modification mechanisms. Section II.A begins by providing a basic overview of obviousness-type double patenting (ODP). Section II.B explains patent term and patent term modification mechanisms, which are necessary to understand the complex interaction between ODP and patent term adjustment (PTA) in *Allergan*. Section II.C traces the formative ODP jurisprudence related to its interaction with term modification mechanisms before *Allergan*.

A. OVERVIEW OF OBVIOUSNESS-TYPE DOUBLE PATENTING

The statutory basis for double patenting is nothing more than a single letter in 35 U.S.C. § 101: “[w]hoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and

17. See discussion *infra* Section II.A for the doctrine of double patenting in 35 U.S.C. § 101.

useful improvement thereof, may obtain *a* patent therefor.”¹⁸ Thus, an inventor may obtain “*a* patent,” not multiple patents, for an invention. This provision forms the foundation of statutory, or same-invention, double patenting, which prohibits obtaining multiple patents for the “same invention.”¹⁹ Put another way, identical subject matter cannot be claimed twice.²⁰ Although identical wording in the claims is not required, two claims must be effectively identical in scope for statutory double patenting to apply.²¹

Statutory double patenting is seldom found in practice because patentees rarely file separate patent applications with identical claims. The doctrine of double patenting also covers, however, far more common situations where a later application claims not the exact same invention, but obvious variations of it—referred to as “obviousness-type double patenting” (ODP).²² The primary justification for ODP is to “prevent unjustified timewise extension of the right to exclude granted by a patent.”²³ This can happen when a patentee attempts to extend her patent monopoly by obtaining multiple patents that claim obvious variants of the same invention with different expiration dates. Thus, ODP ensures that the public is entitled to free use of “not only the invention claimed in the patent but also any modifications or variants thereof” after the original period of patent monopoly expires.²⁴ The public would be deprived of this right if a subsequent patent were granted on an invention that is not patentably distinct from the initial patent.²⁵

Because the primary purpose of ODP is to prevent a patentee from unduly extending their patent monopoly, for ODP to apply, the two patents or applications in consideration must have some commonality of inventorship or ownership.²⁶ In other words, the patents or applications must have at least one common inventor, be commonly assigned or owned, or be subject to a joint research agreement.²⁷ This means that the types of patents most likely to be at

18. 35 U.S.C. § 101 (emphasis added).

19. MPEP § 804 (9th ed. Rev. 1, 2024).

20. *Id.*

21. *Id.*

22. *Id.*

23. *In re Van Ornum*, 686 F.2d 937, 943–44 (C.C.P.A. 1982) (quoting *In re Schneller*, 397 F.2d 350, 354 (C.C.P.A. 1968)); see also *In re Hubbell*, 709 F.3d 1140, 1145 (Fed. Cir. 2013) (stating that “[t]here are two justifications for obviousness-type double patenting.” The first is to “prevent unjustified timewise extension of the right to exclude granted by a patent,” as stated. The second purpose of ODP is to avoid multiple lawsuits from owners of different patents with no collateral estoppel, if patent ownership is divided.).

24. *In re Longi*, 759 F.2d 887, 892–93 (Fed. Cir. 1985); *Eli Lilly & Co. v. Barr Labs., Inc.*, 251 F.3d 955, 967–68 (Fed. Cir. 2001).

25. *See id.*

26. MPEP § 804 (9th ed. Rev. 1, 2024).

27. *Id.*

risk for ODP are often continuations within the same patent family that claim additional aspects of an invention, or commonly owned patents from separate families where one patent is obvious over the other.

In an ODP analysis, an alleged reference patent is used to evaluate the challenged patent. The obviousness-type double patenting analysis involves two steps:

First, the court “construes the claim[s] in the *earlier* patent and the claim[s] in the *later* patent and determines the differences.” Second, the court “determines whether those differences render the claims patentably distinct.” “A later claim that is not patentably distinct from,” i.e., “is obvious over[] or anticipated by,” an earlier claim is invalid for obviousness-type double patenting.²⁸

Given that the terms “earlier” and “later” can be used to describe any of a patent’s filing, issuance, or expiration dates, courts have issued unclear guidance about what constitutes a proper ODP reference. This ambiguity becomes even more complicated when the various dates associated with a patent are shifted with patent term modification mechanisms, such as PTA.

A patentee can overcome ODP rejections by filing a terminal disclaimer under 35 U.S.C. § 253, which disclaims any portion of the patent term that extends beyond the expiration of the reference patent.²⁹ Filing of a terminal disclaimer permits the issuance of the patent on the obvious variation, provided that the term of this patent does not extend beyond that of the reference patent.³⁰ The terminal disclaimer must be filed before the reference patent expires.³¹

B. PATENT TERM AND PATENT TERM ADJUSTMENT (PTA)

The length of a U.S. patent term has changed under different patent law regimes, with mechanisms like PTA further adjusting the base term. As *Allergan* addresses the complex interaction between ODP and PTA, with rationales grounded in intricate patent term and ODP jurisprudence, this

28. *Sun Pharm. Indus., Ltd. v. Eli Lilly & Co.*, 611 F.3d 1381, 1385 (Fed. Cir. 2010) (emphasis added) (alteration in original) (quoting *Pfizer, Inc. v. Teva Pharm. USA, Inc.*, 518 F.3d 1353, 1363 (Fed. Cir. 2008) and *Eli Lilly v. Barr*, 251 F.3d at 968) (stating that “[t]he second step generally follows an obviousness analysis under 35 U.S.C. § 103.”); see also *AbbVie v. Mathilda & Terence Kennedy Inst. of Rheumatology Tr.*, 764 F.3d 1366, 1378 (Fed. Cir. 2014) (stating that “the law of obviousness-type double patenting looks to the law of obviousness generally.”).

29. 35 U.S.C. § 253; MPEP § 1490 (9th ed. Rev. 1, 2024).

30. *Id.*

31. *Id.*

Section provides an overview of patent term calculations under various U.S. patent law regimes and PTA mechanisms.

1. *Patent Term Before and After the Uruguay Round Agreements Act (URAA)*

35 U.S.C. § 154 governs the term length for a U.S. patent.³² Before 1994, the term of a U.S. patent was seventeen years from the issue date.³³ However, in 1994, Congress enacted the Uruguay Round Agreements Act (URAA) and amended 35 U.S.C. § 154 to align U.S. patent term provisions with international standards.³⁴ Under the URAA, patents filed on or after June 8, 1995 expire twenty years from their earliest effective U.S. filing date.³⁵ Thus, if the USPTO took three years to issue a patent, the applicant would still receive seventeen years of patent term, similar to the pre-URAA system. However, under the URAA, each day patent issuance was delayed from prosecution at the USPTO is a day lost from the overall patent term. As an extreme example, if the USPTO delays prosecution of a patent application for twenty years, the patentee will lose her entire patent term. This loss of term—arising entirely from administrative delay and beyond the applicant’s control—posed a significant challenge for patentees, until Congress passed the Patent Term Guarantee Act.

2. *Patent Term Adjustment (PTA) as a Term Modification Mechanism*

To remedy and compensate inventors for the shortened term caused by any prosecution delays at the USPTO after the URAA, Congress introduced the Patent Term Guarantee Act of 1999, outlining the provisions for patent term adjustment (PTA).³⁶ Governed by 35 U.S.C. § 154(b), PTA adds one day to the patent term for each day the USPTO delays prosecution.³⁷

32. 35 U.S.C. § 154(a)(2).

33. Patent Act, 950 Pub. L. No. 593, 66 Stat. 792, 804 § 154 (1952); 35 U.S.C. § 154 (1952); *see also, e.g.*, Mark A. Lemley, *An Empirical Study of the Twenty-Year Patent Term*, 22 AIPLA Q.J. 369, 374 (1994) (“[T]he fundamental baseline of the 1952 Act was a seventeen-year term across industries.”).

34. Uruguay Round Agreements Act, 103 Pub. L. No. 465, 108 Stat. 4809 (1994); *see* discussion *infra* Section IV.B for a legislative history behind the change in US patent term and introduction of PTA after the passage of the URAA.

35. *Id.* at 4983–85; 35 U.S.C. § 154(a)(2). The “effective filing date” is the earlier of: (1) the actual filing date of the application, or (2) the filing date of the earliest priority application (i.e., the earliest filed provisional, nonprovisional, international, or foreign application) to which a patent application is entitled to a right of priority.

36. *See* American Inventors Protection Act, Pub. L. No. 106-13, tit. IV, § 401–402 (1999).

37. 35 U.S.C. § 154(b), (b)(1)(A).

Three main categories of USPTO delays qualify for PTA. First, a patent is entitled to PTA if the USPTO fails to take specific administrative actions within certain timeframes (A-delays).³⁸ These actions include a failure to issue a first Office Action or Notice of Allowance within fourteen months of the application filing date, an Office Action within four months of an applicant's reply, or the patent within four months of issue fee payment.³⁹ Second, PTA is added if the USPTO takes more than three years to issue a patent (B-delays).⁴⁰ Third, Congress guarantees PTA for delays due to derivation proceedings, secrecy orders, and appeals (C-delays).⁴¹ However, any patentee-caused delays also reduce PTA. The patentee can lose PTA if they "fail to engage in reasonable efforts to conclude prosecution of the application."⁴² For instance, failing to respond to an Office Action within three months of receiving notice can result in the loss of PTA.⁴³ Thus, this statutory framework ensures compensation for USPTO delays, upholding Congress's longstanding policy of protecting diligent applicants from being penalized by such delays.

In the context of ODP, PTA can cause patents within the same family to have different expiration dates. For instance, patents in the same family usually share the same priority date and thus would expire at the same time (i.e., twenty years from the earliest effective filing date). However, if the USPTO causes a prosecution delay for a patent application, PTA can extend the patent's term and cause it to expire later than other patents in the family with the same priority date. This raises the question of whether a patent can be invalidated for ODP on the grounds of a PTA-lengthened term, and whether PTA, which is statutorily guaranteed by Congress, can trigger a judge-made doctrine such as ODP.

It is important to point out that while this Note focuses on PTA, there is another patent term modifier, known as "patent term extension," or "PTE."⁴⁴ PTE allows patentees to extend the patent term to compensate for delays in obtaining regulatory approval for a product covered by the patent.⁴⁵ Available under the Hatch-Waxman Act, PTE is codified in 35 U.S.C. § 156.⁴⁶ PTE is only available for specific types of patents, most commonly those related to

38. 35 U.S.C. § 154(b)(1)(A).

39. *Id.*

40. 35 U.S.C. § 154(b)(1)(B).

41. 35 U.S.C. § 154(b)(1)(C).

42. 35 U.S.C. § 154(b)(2)(C)(i).

43. 35 U.S.C. § 154(b)(2)(C)(ii).

44. 35 U.S.C. § 156.

45. 35 U.S.C. § 156(a).

46. 35 U.S.C. § 156; Drug Price Competition and Patent Term Restoration (Hatch-Waxman) Act of 1984, Pub. L. No. 98-417, 98 Stat. 1585.

pharmaceuticals and medical devices that undergo lengthy review by the Food and Drug Administration (FDA) before they can be marketed.⁴⁷ PTE is essential because, although the USPTO may grant a patent, FDA approval can take several years, delaying the company's ability to market the product.⁴⁸ As a result, the patent term would continue running during such regulatory delays, depriving the company of any patent-based market exclusivity benefits.⁴⁹ PTE thus compensates the patentees for any patent term lost due to regulatory processes.⁵⁰ There have been debates over the statutory differences and purposes of PTA and PTE, as well as how each interacts with ODP.⁵¹

C. EVOLUTION OF ODP JURISPRUDENCE INVOLVING PATENT TERM MODIFICATION

Several seminal cases trace the evolution of ODP jurisprudence, providing nuances into what qualifies as a proper ODP reference while underscoring the equitable roots that form the foundation of the doctrine. Despite a few district court cases, prior to *In re Collect* (“*Collect*”) and *Allergan*, the Federal Circuit had scarcely addressed the interaction between ODP and PTA.⁵² Before the URAA, PTA did not exist, and courts relied on the patent's issuance date to assess whether a patentee attempted to improperly prolong the seventeen-year exclusivity period. The URAA's statutory changes raised a fundamental question: should issuance dates remain relevant in an ODP analysis, now that patent term is based on the filing date? Addressing this mismatch, *Gilead Sciences, Inc. v. Natco Pharma Ltd.* (“*Gilead*”) and *AbbVie v. Mathilda & Terence Kennedy Institute of Rheumatology Trust* (“*AbbVie*”) set the scene for the use of expiration dates in a post-URAA world to determine ODP outcomes and

47. Stephanie Plamondon Bair, *Adjustments, Extensions, Disclaimers, and Continuations: When Do Patent Term Adjustments Make Sense*, 41 CAP. U. L. REV. 458, 486 (2013).

48. *Id.* at 486.

49. *Id.*

50. *Id.*

51. *See, e.g., In re Collect, LLC*, 81 F.4th 1216, 1224–28 (Fed. Cir. 2023); Petition for a Writ of Certiorari at *15, *Collect, LLC v. Vidal*, (May 20, 2024) (No. 23-1231), 2024 WL 2379649; Brief for the respondent in opposition at *13–14, *Collect, LLC v. Vidal*, (Aug. 21, 2024) (No. 23-1231), 2024 WL 3914202; *see also Abiomed, Inc. v. Maquet Cardiovascular LLC*, 2023 WL 4038564, at *33–34 (D. Mass. 2023). In *In re Collect*, *Collect* contended that “PTA and PTE should be factored into an ODP analysis in the same way” because they have similar statutory limitations, legislative intent, and precedents. The USPTO, however, argued that the statutory language and precedents support treating PTA and PTE differently from each other in an ODP analysis. The Federal Circuit in *Collect* ultimately agreed with the USPTO on their treatment of PTA and PTE when analyzing ODP.

52. *See generally Magna Elecs., Inc. v. TRW Auto. Holdings Corp.*, 2015 WL 11430786, at *3–6 (W.D. Mich. 2015); *Mitsubishi Tanabe Pharma Corp. v. Sandoz, Inc.*, 533 F. Supp. 3d 170 (D.N.J. 2021); *Abiomed*, 2023 WL 4038564, at *33–34; *Collect*, 81 F.4th 1216; *Allergan*, 111 F.4th 1358.

contextualize the courts' concerns about patentee gamesmanship.⁵³ The implementation of the URAA also triggers a series of double patenting scenarios due to the statutory change in patent term calculations—particularly in transitional cases where one patent application was filed before the passage of the URAA and another after it. Cases such as *Novartis Pharmaceuticals Corp. v. Breckenridge Pharmaceutical Inc.* (“*Breckenridge*”) and *Novartis AG v. Ezra Ventures LLC* (“*Ezra*”) emphasized that expiration dates are not always dispositive in an ODP analysis and offered analogous perspectives to ODP cases with statutorily-granted term modification mechanisms.⁵⁴ Finally, *Collect* brought the interaction between ODP and PTA to the forefront, and *Allergan* began to refine the legal contours set by *Collect*.⁵⁵ This Section reviews these ODP legal precedents and rationales in detail to further contextualize *Allergan*.

1. *Gilead Leads the Transition from Issuance Dates to Expiration Dates as an ODP Proxy, with the Intent to Curb Gamesmanship*

Prior to *Gilead Sciences, Inc. v. Natco Pharma Ltd.*, the Federal Circuit had used patent issuance dates as a benchmark to determine whether a patentee was improperly extending her patent term in an ODP analysis.⁵⁶ This was a result of a pre-URAA world, where the patent term was seventeen years from the issuance date.⁵⁷ Thus, an earlier-issued patent would generally expire earlier and could often be used as an ODP reference to invalidate a later-issued, later-expiring patent.⁵⁸ Most of the time, an earlier-issued patent was also filed earlier, so double patenting practically only posed a problem for the later-filed and later-issued patent.⁵⁹

However, in a post-URAA world, where a patent's issuance date is no longer tied to its expiration date, double patenting issues persist when the later-issued but earlier-expiring patent now serves as an ODP reference. This raises the question: can a later-expiring but earlier-issued patent be invalidated for ODP by an earlier-expiring but later-issued patent?

Gilead addresses this question in an ODP scenario involving two post-URAA patents from separate chains of priorities.⁶⁰ It considers whether a patent that was filed before, issued after, but expiring before another patent

53. See *Gilead*, 753 F.3d 1208, 1215–16 (2014); *AbbVie*, 764 F.3d 1366, 1373–74 (2014).

54. See generally *Breckenridge*, 909 F.3d 1355 (2018); *Ezra*, 909 F.3d 1367 (2018).

55. See generally *Collect*, 81 F.4th 1216; *Allergan*, 111 F.4th 1358.

56. See *Gilead*, 753 F.3d at 1208.

57. See Uruguay Round Agreements Act, *supra* note 34.

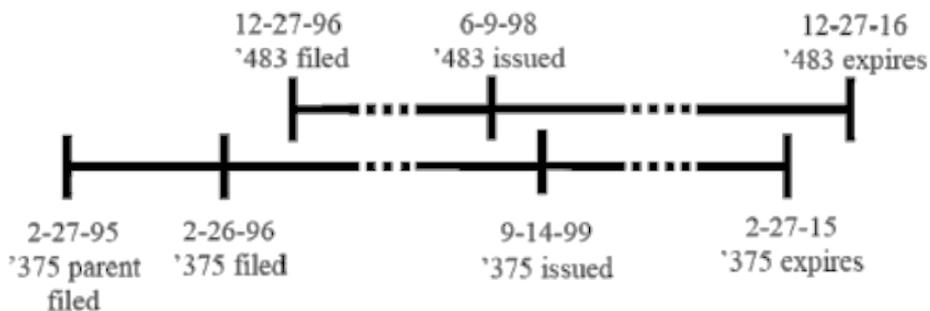
58. Daniel Kazhdan, *Obviousness-Type Double Patenting: Why It Exists and When It Applies*, 53 AKRON L. REV. 1017, 1029 (2019).

59. *Id.*

60. *Gilead*, 753 F.3d at 1208.

qualifies as an ODP reference.⁶¹ Gilead's patents at issue, the '483 and '375 patents, do not claim priority to a common patent application, and thus, have different expiration dates.⁶² Natco argued that the '483 patent should be invalidated for ODP over the '375 patent since the '483 patent expired after the '375 patent.⁶³ Gilead asserted that the '375 patent could not serve as an ODP reference against the '483 patent because the '483 patent was issued before the '375 patent.⁶⁴ Figure 1 depicts the relationships between these patents and their respective filing, issuance, and expiration dates.

Figure 1: Filing, issuance, and expiration dates for *Gilead* patents⁶⁵



The Federal Circuit in *Gilead* addressed ODP in relation to issuance dates and expiration dates.⁶⁶ In *Gilead*, the Federal Circuit asserted that the issuance date is only a “stand-in for the date that really matter[s]—patent expiration.”⁶⁷ Rejecting Gilead's emphasis on the issuance date, the Federal Circuit instead held that only the expiration date is relevant in an ODP analysis to prevent improper extensions of exclusivity.⁶⁸ Thus, the *Gilead* court held that an earlier-expiring patent could be used as a reference against the later-expiring patent, even though the later-expiring patent had been issued first.⁶⁹ This decision was grounded in the principle that, upon patent expiration, the public should be free to use an invention and its obvious modifications.⁷⁰

61. *Id.*

62. *Id.* at 1209.

63. *Id.* at 1210.

64. *Id.* at 1209.

65. *Id.* at 1210.

66. *Id.* at 1214–17.

67. *Id.* at 1215.

68. *Id.* at 1215–16.

69. *Id.* at 1217.

70. *Id.* at 1214.

The *Gilead* decision also emphasized the role of patentee misconduct in an ODP analysis. Gilead had crafted two separate chains of applications with different priority dates.⁷¹ The court noted that “if the double patenting inquiry was limited by issuance date, inventors could routinely orchestrate patent term extensions by (1) filing serial applications on obvious modifications of an invention, (2) claiming priority to different applications in each, and then (3) arranging for the application claiming the latest filing date to issue first. If that were to occur, inventors could obtain additional patent term exclusivity for obvious variants of their inventions while also exploring the value of an earlier priority date during prosecution.”⁷² The *Gilead* court held that focusing on the expiration date “guarantees a stable benchmark that preserves the public’s right to use the invention . . . when that patent expires.”⁷³

2. *AbbVie Reaffirms the Applicability of the ODP Coctrine and its Public Policy Goals Under the URAA*

AbbVie v. Mathilda & Terence Kennedy Institute of Rheumatology Trust followed *Gilead* in 2014 and resolved the question of whether the doctrine of ODP still applied post-URAA.⁷⁴ In *AbbVie*, the Federal Circuit made *Gilead* explicit by holding that ODP continued to apply to prevent gamesmanship, where two patents were directed to claims that were not patentably distinct but had different expiration dates.⁷⁵ Like *Gilead*, the Mathilda and Terrance Kennedy Institute of Rheumatology Trust (Kennedy) owned two related post-URAA patents filed in separate priority chains.⁷⁶ Filed on August 1, 1996, the first patent was the ’766 patent, which claimed priority to a 1992 application through a continuation-in-part.⁷⁷ The second patent, the ’442 patent, claimed priority to the date the ’766 patent was filed, August 1, 1996.⁷⁸ The ’442 patent also had 750 days of PTA, and thus was set to expire six years after the expiration of the ’766 patent (Figure 2).⁷⁹

71. *Id.* at 1210.

72. *Id.* at 1215.

73. *Id.* at 1216.

74. *AbbVie*, 764 F.3d at 1374.

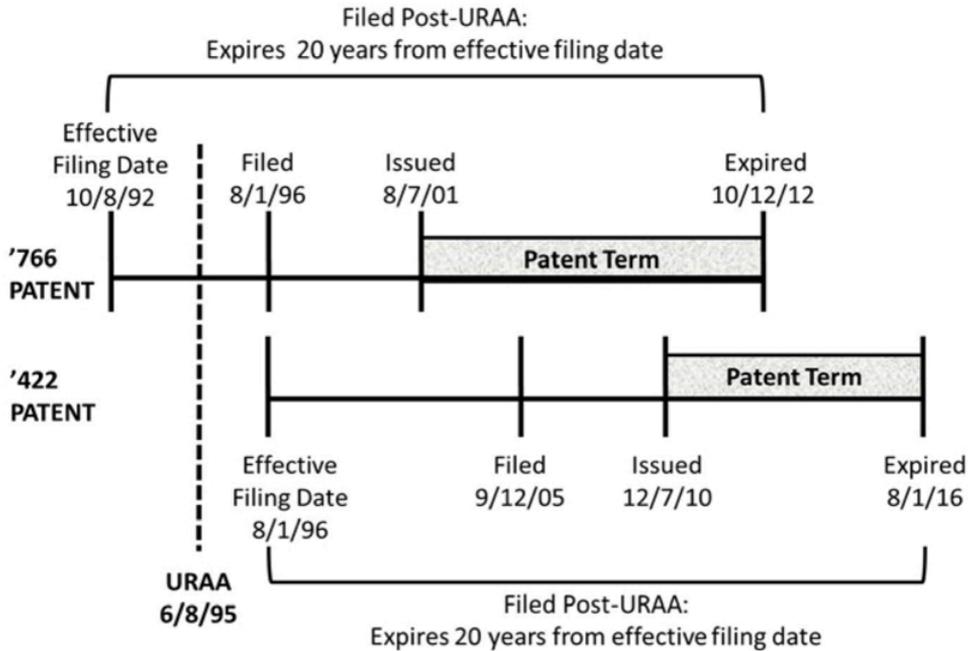
75. *Id.*; see also *Acadia Pharms. Inc. v. Aurobindo Pharma Ltd.*, 706 F. Supp. 3d 477, 488 (D. Del. 2024) (stating that “*AbbVie* applied the *Gilead* rationale, making clear that the availability of OTDP remained viable to prevent gamesmanship in certain narrow instances.”).

76. *AbbVie*, 764 F.3d at 1368–71.

77. *Id.* at 1369.

78. *Id.* at 1370.

79. *Id.*

Figure 2: Filing, issuance, and expiration dates for *AbbVie* patents⁸⁰

AbbVie licensed the '766 patent but not the '442 patent.⁸¹ Unwilling to secure an additional license for the '442 patent, AbbVie sued Kennedy for a declaratory judgment that the '442 patent was invalid for ODP over the '766 patent.⁸² Following a bench trial, the district court held that the '442 patent was invalid for ODP.⁸³ The Federal Circuit affirmed the district court's finding and invalidated the '442 patent against the '766 patent under ODP.⁸⁴

While *AbbVie* did not directly address PTA, the *AbbVie* court noted in passing that ODP remains relevant post-URAA, particularly when separate applications claiming overlapping subject matter have different expiration dates due to examination delays at the PTO or different priority dates.⁸⁵ Some

80. See *id.*; Kevin E. Noonan, *Novartis Pharmaceuticals Corp. v. Breckenridge Pharmaceutical Inc.* (Fed. Cir. 2018), PATENT DOCS (Dec. 11, 2018), <https://www.patentdocs.org/2018/12/novartis-pharmaceuticals-corp-v-breckenridge-pharmaceutical-inc-fed-cir-2018.html>.

81. *AbbVie*, 764 F.3d at 1368.

82. *Id.* at 1370.

83. *AbbVie Inc. v. Mathilda & Terence Kennedy Inst. of Rheumatology Tr.*, 956 F. Supp. 2d 429, 429 (S.D.N.Y. 2013).

84. *AbbVie*, 764 F.3d at 1381.

85. *Id.* at 1373 (stating that "[ODP] is designed to prevent an inventor from securing a second, later expiring patent for the same invention. That problem still exists [post-URAA]. Patents claiming overlapping subject matter that were filed at the same time still can have different patent terms due to examination delays at the PTO . . . When such situations arise,

have interpreted the *AbbVie* court's commentary as suggesting that a PTA-extended patent term is a scenario in which ODP may apply and override.⁸⁶

3. *Ezra and Breckenridge Refine the Use of Expiration Dates in an ODP Analysis After Gilead*

The *Gilead* and *AbbVie* courts held that a patent's expiration date serves as a proper benchmark in an ODP analysis—in the specific context of patentably indistinct applications filed in separate priority chains that naturally result in different expiration dates.⁸⁷ The courts, however, left open whether ODP should apply when the difference in expiration dates arises from other circumstances. In the aftermath of *Gilead* and *AbbVie*, patent infringement defendants have sought to extend *Gilead's* reasoning to other situations. Patents were brought under scrutiny and challenged for ODP even when Congress explicitly granted a longer patent term, such as through patent term extension (PTE)⁸⁸ or through the URAA's intervening change in law.

Novartis AG v. Ezra Ventures LLC further clarified the scope of *Gilead* and addressed the relationship between ODP and PTE.⁸⁹ In *Ezra*, a pre-URAA patent was challenged under ODP because its PTE caused it to expire after a later-issued post-URAA patent (Figure 3).⁹⁰ The Federal Circuit held that ODP does not invalidate a validly obtained PTE if the claims are otherwise valid under its pre-PTE expiration date.⁹¹ In making this determination, the court pointed out that it is the earlier-filed, earlier-issued patent that has the later expiration date due to PTE.⁹² The court asserted that *Ezra* does not raise the traditional ODP concern of a patentee trying to extend her patent exclusivity through a “later-filed patent that [is] not patentably distinct from claims in the earlier-filed patent.”⁹³ The court also noted that, unlike *Gilead*, *Ezra* did not present the same risks of “gamesmanship” through the structuring of priority dates.⁹⁴ More importantly, the *Ezra* court held that ODP, as a “judge-made

the doctrine of obviousness-type double patenting ensures that a particular invention (and obvious variants thereof) does not receive an undue patent term extension.” (citations omitted)).

86. *See Magna Elecs.*, 2015 WL 11430786, at *1.

87. *See Gilead*, 753 F.3d at 1212, 1217; *AbbVie*, 764 F.3d at 1374.

88. *See* discussion *supra* Section II.B.2 for patent term extension (PTE) in 35 U.S.C. § 156 and its purposes.

89. *Ezra*, 909 F.3d at 1369.

90. *Id.* at 1369–70.

91. *Id.* at 1374.

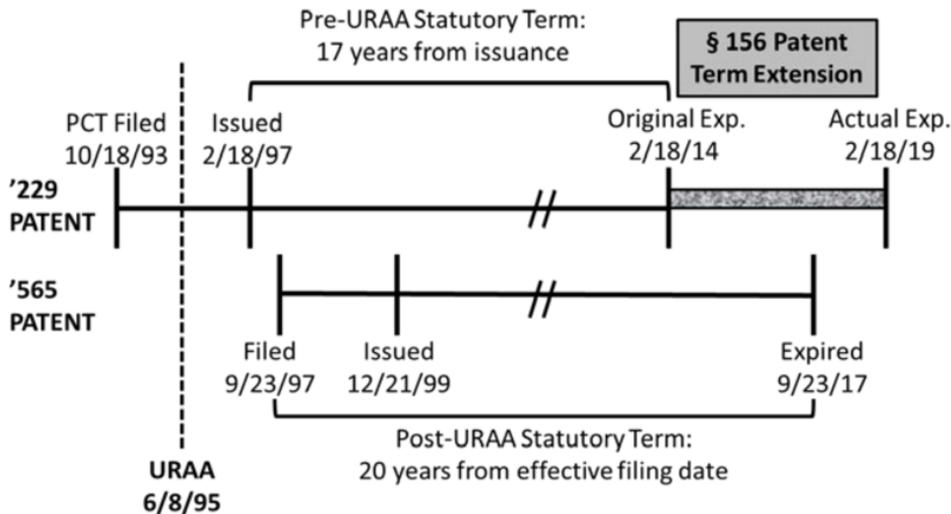
92. *Id.*

93. *Id.* (emphasis added).

94. *Id.*

doctrine,” cannot cut off “a statutorily authorized time extension,” such as PTE.⁹⁵

Figure 3: Filing, issuance, and expiration dates for *Ezra* patents⁹⁶



Novartis Pharmaceuticals Corp. v. Breckenridge Pharmaceutical Inc. provides another instance where the implementation of the URAA’s new patent term law by Congress caused an earlier-filed, earlier-issued, pre-URAA patent to expire before a later-filed, later-issued, post-URAA patent (Figure 4), creating an ODP issue.⁹⁷ In a ruling issued on the same date as *Ezra*, the Federal Circuit emphasized that an earlier-expiring post-URAA patent is not a proper ODP reference against a later-expiring pre-URAA patent.⁹⁸ The court acknowledged that the pre-URAA patent expires after the post-URAA patent not because of “prosecution gamesmanship,” but because of “happenstance of an intervening change in patent term law.”⁹⁹ The court clarified that its holding in *Gilead* applies only to post-URAA patents, and that a change in patent term law should not truncate the default, statutorily assigned term in the pre-URAA patent.¹⁰⁰ More importantly, the court held that expiration dates alone are not always dispositive in an ODP analysis.¹⁰¹

95. *Id.* at 1375.

96. *Id.* at 1370.

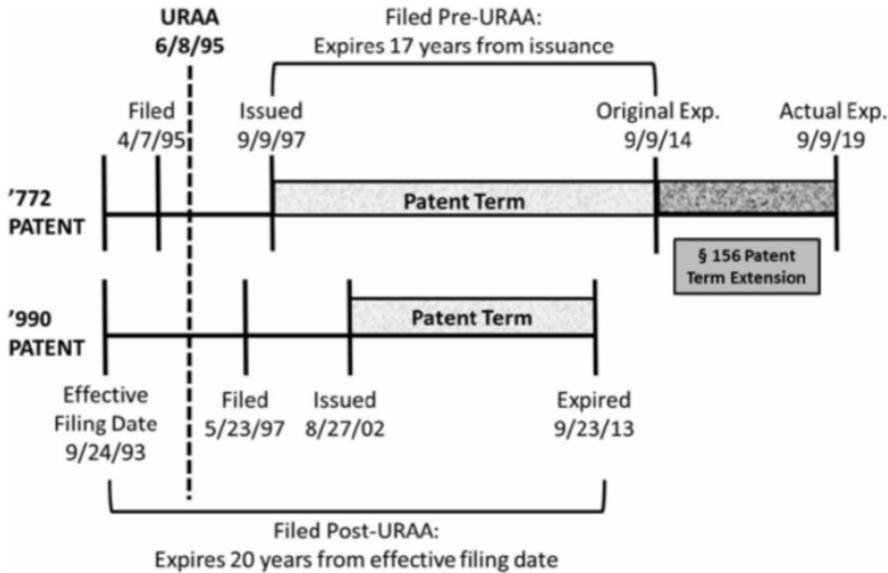
97. *Breckenridge*, 909 F.3d at 1357–58.

98. *Id.* at 1358, 1362.

99. *Id.* at 1364.

100. *Id.* at 1358.

101. *Id.* at 1362–64.

Figure 4: Filing, issuance, and expiration dates for *Breckenridge* patents¹⁰²

Both *Ezra* and *Breckenridge* pushed back against efforts to use ODP to cut short statutorily guaranteed patent terms. In both cases, the Federal Circuit rejected the use of an earlier-expiring patent to invalidate a later-expiring patent under ODP, when the difference in expiration dates was not the result of prosecution gamesmanship, but rather of mandated legislative mechanisms.¹⁰³ Although transitional cases involving pre- and post-URAA patents are now rare—pre-URAA applications had to be filed before June 7, 1995, and are largely obsolete today¹⁰⁴—the underlying rationale in *Ezra* and *Breckenridge* remains relevant to a more common scenario of post-URAA patents. For patents with PTA that extend expiration dates beyond those of other patents, a key question lingers: in what circumstances can an earlier-expiring patent serve as an ODP reference against a later-expiring patent? Just as the earlier-filed, earlier-issued patent in *Ezra* received more PTE due to extended FDA review, an earlier-filed, earlier-issued patent may accrue more PTA due to USPTO prosecution delays, thus expiring later than other patents. While *Ezra* temporarily put an end to post-*Gilead* ODP challenges related to

102. *Id.* at 1360.

103. *See Ezra*, 909 F.3d at 1374; *Breckenridge*, 909 F.3d at 1358.

104. Kazhdan, *supra* note 58, at 1046.

PTE, courts have provided inconsistent guidance on the interaction of ODP and PTA.

4. *District Courts Grappled with the Interaction of ODP and PTA Before Collect and Allergan*

Long before *Collect* and *Allergan*, district courts grappled with ODP cases involving PTA. In *Magna Electronics, Inc. v. TRW Automotive Holdings Corp.*, the U.S. District Court for the Western District of Michigan applied ODP to two patents in the same family with different expiration dates because one of them accrued PTA while the other did not.¹⁰⁵ Both patents had the same priority date, and without PTA, both would have expired on the same date.¹⁰⁶ Following *Gilead's* instruction of looking to the expiration dates in an ODP analysis, the court used the later-filed, later-issued, but earlier-expiring patent (without PTA) as the ODP reference to invalidate the later-expiring, but earlier-filed, earlier-issued patent (with PTA).¹⁰⁷ In other words, the court ruled that the earlier-expiring patent without PTA qualified as an ODP reference—effectively invalidating the later-expiring patent and eliminating its PTA in the process.¹⁰⁸

However, some district courts have refused to invalidate patents based on ODP, where the only difference in expiration dates came from PTA. In *Mitsubishi Tanabe Pharma Corp. v. Sandoz, Inc.* (“*Mitsubishi?*”), the District Court for the District of New Jersey found that the later-expiring patent with PTA was not a proper ODP reference to invalidate the earlier-expiring patent without PTA.¹⁰⁹ The court found that “[t]his case does not raise the traditional concern with obviousness-type double patenting” and that “the granting of a PTA does not present the potential for gamesmanship by inventors to secure a second, later expiring patent for the same invention.”¹¹⁰ The defendant later appealed the district court’s decision to the Federal Circuit.¹¹¹ The case was remanded to the district court for modification of the final judgment consistent with the district court’s indicative ruling in favor of the patentees.¹¹²

105. *Magna Elecs.*, 2015 WL 11430786, at *3–6 (W.D. Mich. 2015).

106. *Id.*

107. *Id.*

108. *Id.* at *4.

109. *Mitsubishi*, 533 F. Supp. 3d 170 (D.N.J. 2021).

110. *Id.* at 214.

111. Notice of Appeal to the Federal Circuit, *Mitsubishi Tanabe Pharma Corp. v. Sandoz, Inc.*, 533 F. Supp. 3d 170 (D.N.J. 2021) (No. 3:17-cv-05319).

112. Text Order terminating Motion, *Mitsubishi Tanabe Pharma Corp. v. Sandoz, Inc.*, 533 F. Supp. 3d 170 (D.N.J. 2021) (No. 3:17-cv-05319).

Abiomed, Inc. v. Maquet Cardiovascular LLC (“*Abiomed*”) followed *Mitsubishi* and reached a similar outcome.¹¹³ In *Abiomed*, the first-filed patent with 407 days of PTA was challenged on the grounds of ODP by a second patent, which claimed priority to the first patent. The second patent was filed ten years later, received only ninety-eight days of PTA, and thus expired before the first patent.¹¹⁴ The District Court for the District of Massachusetts held that ODP did not invalidate the first patent in this case.¹¹⁵ *Abiomed* had attempted to distinguish itself from *Ezra*, but the district court found the arguments unpersuasive.¹¹⁶ The court drew a comparison between PTA and PTE and found the case analogous to *Ezra*, where there were no gamesmanship concerns underlying the ODP doctrine by the applicant.¹¹⁷ In addressing PTA, the court emphasized that “[e]ven if . . . such an extension is unfair to the public, the statutory text commits the task of correcting that unfairness to Congress, not courts applying a judicially-created doctrine.”¹¹⁸ *Abiomed* is currently on appeal at the Federal Circuit.¹¹⁹

5. Collect *Spotlights the Interplay Between ODP and PTA, Putting PTA-Extended Patents at Risk in an ODP Challenge*

While the muddy interaction between ODP and PTA had occasionally surfaced in district court cases, *In re Collect* thrust this issue into the spotlight.¹²⁰ In an ex parte reexamination, the USPTO determined that the claims in four of Collect’s patents were invalid based on ODP over a reference patent and issued a rejection.¹²¹ Each of these four challenged patents shared the same effective filing date as the reference patent.¹²² Each of the challenged patents

113. *Abiomed*, 2023 WL 4038564, at *33–34.

114. *Id.* at 33.

115. *Id.* at 34.

116. *Id.* at 33–34 (Abiomed attempted to distinguish itself from *Ezra* by contending in three ways. First, it contended that the term extension by the first patent is unfair to the public (“failing to apply the ODP doctrine here would allow patentees to obtain varying, extended terms for multiple patents that claim obvious variations of the same invention.”) Second, it contended that the statutory language of 35 U.S.C. § 154 suggests that “any patent extended by § 154 cannot be extended past another patent claiming overlapping subject matter.” Third, it contended that 35 U.S.C. § 154 and 35 U.S.C. § 156 have different statutory purposes.).

117. *Id.* at 33.

118. *Id.*

119. Notice of Appeal to the Federal Circuit, *Abiomed, Inc. v. Maquet Cardiovascular LLC*, 2023 WL 4038564, at *33–34 (D. Mass. 2023) (No 1:16-CV-10914); *Abiomed, Inc. v. Maquet Cardiovascular LLC* (Fed. Cir. 2023) (No. 24-01062).

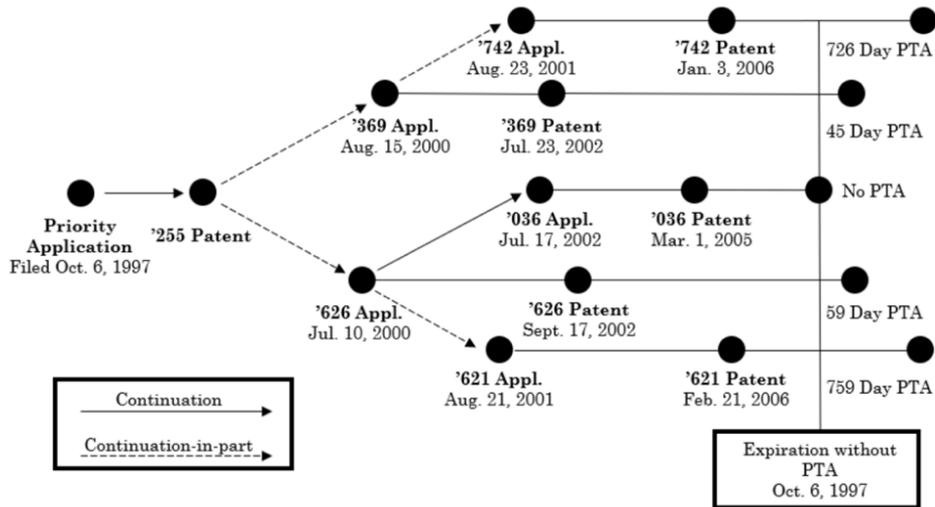
120. See discussion *supra* Section II.C.5 for district court cases dealing with the interaction of ODP and PTA.

121. *Collect*, 81 F.4th at 1219.

122. *Id.* at 1219–20. The four challenged patents are part of a complex patent family and are all interrelated. The ODP reference patents to invalidate these four challenged patents

was filed before the reference patent; however, each of them also accrued PTA and thus expired later than the reference patent, which had no PTA (Figure 5).¹²³ None of the challenged patents were subject to a terminal disclaimer, as they had never been rejected under ODP during their original prosecution.¹²⁴

Figure 5: Filing, issuance, and expiration dates for *In re Collect* patents¹²⁵



Collect first appealed the Examiner's rejections to the Patent Trial and Appeal Board (PTAB). The PTAB agreed with the Examiner's rejections and held that ODP should be based on the patent's adjusted expiration date, including PTA.¹²⁶ Collect then appealed to the Federal Circuit. The Federal Circuit affirmed the PTAB's findings and concluded that ODP is determined based on a patent's expiration date *after* PTA has been added.¹²⁷ In arriving at this ruling, the court pointed out that the statutory provisions for PTA and PTE have different rationales and purposes.¹²⁸

form a network across four ex parte reexamination proceedings. However, all invalidated claims can be traced back to the '036 patent, the only family member that did not receive PTA and shared the same priority date with the four patents.

123. *Id.*

124. *Id.* at 1219.

125. *Id.* at 1220.

126. *Id.* at 1221–22.

127. *Id.* at 1229.

128. *Id.* at 1227–28.

Collect filed an en banc petition seeking a rehearing at the Federal Circuit in January 2024, but the court denied the petition.¹²⁹ In May 2024, Collect filed a petition for a writ of certiorari with the U.S. Supreme Court.¹³⁰ Several brand-name and generic drug companies, industry groups, and bar associations have since filed amicus briefs in response to the writ of certiorari to voice their opinions and policy justifications.¹³¹ However, in October 2024, the Supreme Court denied Collect's petition for a writ of certiorari, allowing the rulings of the Federal Circuit to stand.¹³²

III. ALLERGAN V. MSN

Following *Collect*, district courts were left to continue navigating the interaction between ODP and PTA on their own. This has proven challenging. Courts have taken divergent approaches, interpreting the *Collect* decision differently and issuing conflicting rulings in PTA-related ODP cases. The confusion is most pronounced in the District of Delaware, which hears many patent cases.¹³³ In *Acadia Pharmaceuticals Inc. v. Aurobindo Pharmaceuticals Ltd.* (“*Acadia*”) and *Allergan*, two judges in the District of Delaware reached opposing conclusions on whether ODP can invalidate an earlier-filed patent that expires later due to PTA, despite the cases having similar fact patterns.¹³⁴ In *Acadia*, the district court held that “only earlier-filed patents are proper [ODP] references.”¹³⁵ The court asserted that “the claims in the challenged

129. Petition for Rehearing En Banc, *Collect*, 81 F.4th 1216 (Fed. Cir. 2023) (Nos. 22-1293, 22-1294, 22-1295, 22-1296).

130. Petition for a Writ of Certiorari, *denied*, *Collect, LLC v. Vidal*, 145 S. Ct. 153 (Oct. 7, 2024) (No. 23-1231).

131. *See generally* Brief Amicus Curiae of The New York Intell. Prop. L. Assoc., *Collect, LLC v. Vidal*, 2024 WL 2798145 (May 28, 2024) (No. 23-1231); Brief Amicus Curiae of Intell. Prop. L. Assoc., *Collect, LLC v. Vidal*, 2024 WL 3162077 (June 20, 2024) (No. 23-1231); Brief Amicus Curiae of Teige P. Sheehan, *Collect, LLC v. Vidal*, 2024 WL 3179564 (June 21, 2024) (No. 23-1231); Brief Amici Curiae of Pharm. Rsch. & Mfrs. of Am., et al., *Collect, LLC v. Vidal*, 2024 WL 3179568 (June 21, 2024) (No. 23-1231); Brief Amici Curiae of Sonos, Inc., et al., *Collect, LLC v. Vidal*, 2024 WL 3179567 (June 21, 2024) (No. 23-1231); Brief Amicus Curiae of Am. Intell. Prop. L. Assoc., *Collect, LLC v. Vidal*, 2024 WL 3179569 (June 21, 2024) (No. 23-1231); Brief Amici Curiae of Sanofi, et al., *Collect, LLC v. Vidal*, 2024 WL 3179565 (June 21, 2024) (No. 23-1231); Brief Amicus Curiae of Inari Agric., Inc., *Collect, LLC v. Vidal*, 2024 WL 3936689 (Aug. 21, 2024) (No. 23-1231).

132. Petition for a Writ of Certiorari, *denied*, *Collect, LLC v. Vidal*, 2024 WL 2379649 (May 20, 2024) (No. 23-1231).

133. *Delaware Disclosure Debauché Depressed District's NPE Filings in 2024*, RPX (Feb. 26, 2025), <https://www.rpxcorp.com/data-byte/delaware-disclosure-debauché-depressed-districts-npe-filings-in-2024/> (finding that District of Delaware was in second place for overall patent litigation in 2024).

134. *See Acadia*, 706 F. Supp. 3d 477, 489 (D. Del. 2023); *Allergan*, 694 F. Supp. 3d at 590.

135. *Acadia*, 706 F. Supp. 3d at 487.

patent were earlier-filed and thus are entitled to their full term, including the PTA.”¹³⁶ However, in *Allergan*, the district court went one step further and invalidated the first-filed, first-issued patent under ODP solely because it had PTA and expired later, stating that the “first-filed, first-issued distinction [was] immaterial.”¹³⁷ The Federal Circuit later reversed the district court’s decision and held that ODP cannot cut short the term of a first-filed, first-issued patent based on later-filed family members with less or no PTA.¹³⁸ This Part delineates *Allergan*’s background and procedural history from the district court to the Federal Circuit.

A. CASE BACKGROUND

Allergan markets and sells eluxadoline tablets under the brand name Viberzi, following FDA approval in 2015.¹³⁹ The first patent application covering eluxadoline, assigned to Janssen, was U.S. Patent Application No. 11/079,647.¹⁴⁰ This application was filed on March 14, 2005, and issued on June 22, 2010 as U.S. Patent No. 7,741,356 (“the ’356 patent”).¹⁴¹ Due to delays during prosecution at the USPTO, the ’356 patent received a PTA of 1,107 days.¹⁴² It also received an additional 1,068 days of PTE to compensate for the FDA’s delay in approving Viberzi.¹⁴³ As part of obtaining PTE after FDA approval, Janssen disclaimed all but 467 days of the awarded PTA.¹⁴⁴ Thus, the ’356 patent will expire on June 24, 2026, after accounting for PTA.¹⁴⁵

Janssen owns two other patents relevant to this case, U.S. Patent No. 8,344,011 (“the ’011 patent”) and 8,609,709 (“the ’709 patent”).¹⁴⁶ These patents claim priority from the March 14, 2005 filing date of the ’356 patent, and are related to the ’356 patent as continuations.¹⁴⁷ Both the ’011 and the ’709 patents did not receive any PTA and will expire on March 14, 2025, twenty years from their priority dates.¹⁴⁸ Because all three patents share a priority date, all would have expired on the same day.¹⁴⁹ However, because the ’356 patent

136. *Id.*

137. *Allergan*, 694 F. Supp. 3d at 540.

138. *Allergan*, 111 F.4th at 1369.

139. *Id.* at 1362.

140. *Id.*; U.S. Patent App. No. 11/079,647 (filed Mar. 14, 2005).

141. *Allergan*, 111 F.4th at 1362.

142. *Id.* at 1363.

143. *Id.*

144. *Id.*

145. *Id.*

146. *Id.*

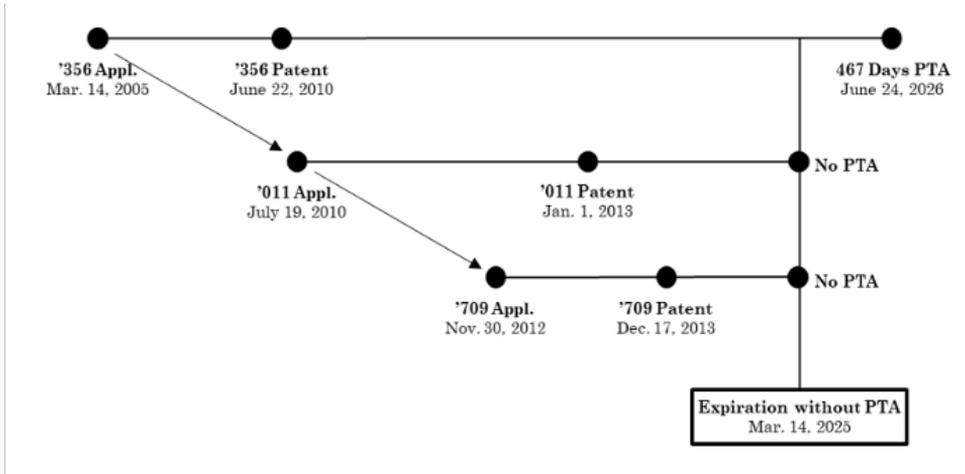
147. *Id.*

148. *Id.*

149. *Id.* at 1364.

had accrued an additional 467 days of PTA, it now expires later than the '011 and the '709 patents.¹⁵⁰ Figure 6 depicts the relationships between these patents and their respective filing, issuance, and PTA-adjusted expiration dates.

Figure 6: Filing, issuance, and expiration dates for *Allergan* patents¹⁵¹



In July 2019, Sun Pharmaceutical Industries (Sun) filed an Abbreviated New Drug Application (ANDA) to the FDA, seeking approval to sell a generic version of Allergan's Viberzi.¹⁵² Per the ANDA filing requirements under the Hatch-Waxman Act, Sun submitted a Paragraph IV certification, asserting that the claims in Allergan's '356 patent were invalid or not infringed by the manufacture, use, or sale of Sun's generic product.¹⁵³ On October 8, 2020, Sun notified Allergan of its certification via a notice letter.¹⁵⁴

Three weeks later, Allergan filed a complaint against Sun for directly infringing claim 40 of its '356 patent.¹⁵⁵ As part of its defense strategy, Sun contended that claim 40 of the '356 patent was invalid for ODP over certain claims in Allergan's '011 patent and '709 patents.¹⁵⁶ Sun asserted that the '356 patent was invalid for ODP because it had accrued PTA, and thus, expired after the '011 and '709 patents, and because the claims are not patentably

150. *Id.*

151. *Id.*

152. *Id.* at 1364–65.

153. *Id.* at 1365.

154. *Id.*

155. *Id.*

156. *Id.*

distinct.¹⁵⁷ In response, Allergan argued that ODP was not applicable because the '356 patent was the first eluxadoline patent to be filed and issued.¹⁵⁸ Allergan did not contest that claim 40 was not patentably distinct from the reference claims.¹⁵⁹

B. PROCEDURAL HISTORY

1. *District of Delaware*

The district court sided with Sun, finding claim 40 of the '356 patent invalid for ODP.¹⁶⁰ Allergan had argued that, as the first-filed, first-issued patent for eluxadoline, the '356 patent should not be subject to ODP over the later-filed, later-issued reference patents.¹⁶¹ The district court, however, deemed this “first-filed, first-issued” distinction “immaterial.”¹⁶² Instead, the court emphasized the use of patent expiration dates for ODP, citing *Gilead*'s holding that ODP is determined by comparing “patent expiration dates, rather than filing or issuance dates.”¹⁶³ The court also relied on the Federal Circuit's recent decision in *Collect*, which established that “ODP for a patent that has received [patent-term adjustment (PTA)], regardless [of] whether or not a terminal disclaimer is required or has been filed, must be based on the expiration date of the patent after PTA has been added.”¹⁶⁴ As a result, the court invalidated claim 40 of the '356 patent because its PTA-adjusted expiration date extended beyond that of the '011 and '709 patents, despite being filed and issued first.¹⁶⁵ The court also noted that ODP should not be influenced by equitable concerns, a line of reasoning that *Collect* had previously rejected.¹⁶⁶

2. *Federal Circuit*

After the district court's ruling, Allergan appealed to the Federal Circuit.¹⁶⁷ On August 13, 2024, the Federal Circuit, which consisted of the same three-judge panel that decided *In re Collect*, reversed the district court's decision and

157. *Id.*

158. *Id.*

159. *Id.*

160. *Id.*

161. *Id.*

162. *Allergan*, 694 F. Supp. 3d at 540.

163. *Id.* (citing *Gilead*, 753 F.3d at 1215–17).

164. *Id.* at 540, 522 (citing *Collect*, 81 F.4th at 1229).

165. *Id.* at 541.

166. *Id.* at 540; *see also Collect*, 81 F.4th at 1230 (The Federal Circuit in *Collect* held that “an applicant's ability to show that it did not engage in gamesmanship in obtaining a grant of PTA is not sufficient to overcome a finding that it has received an unjust timewise extension of term.”).

167. *Allergan*, 111 F.4th at 1366.

held that “a first-filed, first-issued, later-expiring claim cannot be invalidated by a later-filed, later-issued, earlier-expiring reference claim having a common priority date.”¹⁶⁸ In other words, the “first-filed, first-issued patent in [the] family” establishes “the maximum period of exclusivity for the claimed subject matter.”¹⁶⁹ The Federal Circuit provided four key rationales for its decision.

First, the Federal Circuit addressed the district court’s reliance on *Collect*. To reconcile its seemingly contrasting decisions in *Collect* and *Allergan*, the Federal Circuit clarified that *Collect* was not applicable in this case as it addressed a different question related to ODP.¹⁷⁰ Specifically, the Federal Circuit pointed out that *Collect* “does not address, let alone resolve, any variation of the question presented here—namely, under what circumstances can a claim properly serve as an ODP reference.”¹⁷¹ In other words, *Collect* did not resolve any question as to what patents can and cannot serve as ODP reference patents. The patentee in *Collect* never disputed whether the asserted reference patents were appropriate ODP references, instead arguing only that (i) ODP can never be invoked to negate a PTA and (ii) that ODP should not apply in that case on equitable grounds because there was no strategic manipulation of patent term or risk of separate ownership.¹⁷² Because the patentee in *Collect* did not raise the question of whether the ODP reference was appropriate, they waived these arguments, allowing the court to subsequently use the unvetted reference in an ODP analysis without addressing its propriety.¹⁷³

The Federal Circuit in *Allergan* explained that, while *Collect* requires consideration of a PTA-adjusted expiration date in an ODP analysis, this does not mean that the ’356 patent must be invalidated by the child patents simply because it expires later.¹⁷⁴ Distinguishing from *Collect*, the Federal Circuit further held that the ’011 and ’709 patents were not proper ODP references because they were both filed and issued after the ’356 patent.¹⁷⁵ Citing *Miller v. Eagle Manufacturing Co.*, the court reiterated that the purpose of ODP is to prevent inventors from improperly extending the term of the *first* patent by

168. *Id.* at 1369.

169. *Id.*

170. *Id.* at 1368–69.

171. *Id.*

172. *Collect*, 81 F.4th at 1222, 1229–30.

173. *See Acadia*, 706 F. Supp. 3d at 487 (stating that “Collect opted not to challenge the availability of the reference patents being used in an OTDP challenge, and ‘instead focused its argument on whether or not [OTDP] could cut short a grant of PTA’ (quoting *In re Collect*, 81 F.4th at 1222).”).

174. *Allergan*, 111 F.4th at 1368.

175. *Id.* at 1369.

obtaining a *second* patent for a non-distinct invention.¹⁷⁶ Here, the court held that the '356 patent was the *first* eluxadoline patent—whether measured by filing date or issuance date.¹⁷⁷ Because the applications for the '011 and '709 patents were filed after the '356 patent had already been issued, both of these patents were “unquestionably ‘*second*’ to [the '356] patent.”¹⁷⁸ As such, it was improper to use them in an ODP analysis to invalidate the earlier-issued '356 patent.¹⁷⁹ The court concluded that as the “first-filed, first-issued patent in its family,” the '356 patent “sets the maximum period of exclusivity for the claimed subject matter.”¹⁸⁰

Second, the Federal Circuit asserted that its conclusion aligned with established case law.¹⁸¹ Referencing *Ezra*, the court explained that “the traditional concern with obviousness-type double patenting” does not apply when “the earlier-filed, earlier issued . . . patent, not the later-filed, later-issued . . . patent, (. . .) has the later expiration date.”¹⁸² The court also cited *Breckenridge*, noting that an earlier-filed, earlier-issued, pre-URAA patent that expires after a later-filed, later-issued, post-URAA patent should not be invalidated for ODP due to changes in statutory patent term law.¹⁸³

Third, the Federal Circuit addressed the district court’s use of patent expiration dates for ODP in light of *Gilead*. In *Gilead*, the Federal Circuit had established that an ODP analysis must rely on the expiration dates, rather than the previously used issuance dates.¹⁸⁴ However, *Gilead* involved a situation where the asserted patent, though issued first, had a later filing and priority date, resulting in it expiring after the reference claims.¹⁸⁵ As a result, by focusing on the expiration dates, *Gilead* held that a later-issued, earlier-expiring patent can serve as an ODP reference to invalidate an earlier-issued, later-expiring patent.¹⁸⁶ The post URAA scenario contemplated in *Gilead* can give rise to gamesmanship, where an inventor claims obvious variants in unrelated applications and improperly extends the patent term.¹⁸⁷

176. *Id.* (citing *Miller v. Eagle Mfg. Co.*, 151 U.S. 186, 198 (1894)).

177. *Id.*

178. *Id.* (emphasis added).

179. *See id.*

180. *Id.*

181. *Id.* at 1370.

182. *Id.* (citing *Ezra*, 909 F.3d at 1374).

183. *Id.* (citing *Breckenridge*, 909 F.3d at 1366).

184. *Id.* (see *Gilead*, 753 F.3d at 1215–17).

185. *Id.*

186. *Id.*

187. *Id.*

Unlike in *Gilead*, here, the '356 patent was both filed and issued before the '011 and '709 patents.¹⁸⁸ All three of Allergan's patents shared the same priority date, and the difference in expiration dates was solely due to PTA of the challenged patent.¹⁸⁹ Thus, the risk of gamesmanship was minimal. The Federal Circuit highlighted this distinction and clarified that *Gilead* "did not address the role of filing dates."¹⁹⁰ Consequently, the court concluded that because the '356 patent was the first patent in its family to be filed and issued, it did not "extend . . . the monopoly . . . beyond the period allowed by law."¹⁹¹

Finally, the Federal Circuit acknowledged that the prosecution of "a first-of-its-kind invention" typically requires "greater time and effort by the applicant and examiner alike."¹⁹² Thus, first-filed applications are more likely to receive PTA than later-filed continuing applications covering modifications of that invention, which "proceed[s] much more efficiently through prosecution."¹⁹³ As a result, child patents generally receive little to no PTA and often expire "no later than the parent patent."¹⁹⁴ Therefore, no improper patent term lengthening can reasonably result from the child patents.¹⁹⁵ The parent patent also cannot be said to improperly extend the term of a child patent that might not have even existed when the parent was issued.¹⁹⁶ As such, the court concluded that invalidating a first-filed, first-issued parent patent with PTA based on a later-filed, later-issued child patent "would not only run afoul of the fundamental purposes of ODP, but effectively abrogate the benefit Congress intended to bestow on patentees when codifying PTA."¹⁹⁷ In other words, such a decision would force patent owners to disclaim any PTA awarded to the parent patent to match the term of the child patent, effectively negating any benefits Congress intends to provide with PTA and guaranteed statutory term.¹⁹⁸

Following the Federal Circuit's opinions, Sun filed a combined petition for panel rehearing and rehearing en banc.¹⁹⁹ Citing *Collect* and *Gilead* in its petition, Sun contended that the Federal Circuit's decision conflicted with these cases

188. *Id.*

189. *Id.*

190. *Id.*

191. *Id.* (citing *Miller*, 151 U.S. at 198).

192. *Id.* at 1371.

193. *Id.*

194. *Id.*

195. *Id.*

196. *Id.*

197. *Id.*

198. *Id.*

199. Combined Petition for Panel Rehearing and Rehearing En Banc, Allergan USA, Inc. v. MSN Lab's Priv. Ltd., 111 F.4th 1358 (Fed. Cir. 2024) (No. 24-1061).

and that the Federal Circuit lacked the authority to “create exceptions to this Court’s precedent.”²⁰⁰ In November 2024, Sun withdrew its rehearing petition.²⁰¹

IV. *ALLERGAN* PROVIDES A NECESSARY CLARIFICATION FOR THE INTERACTION BETWEEN ODP AND PTA

Part IV examines the Federal Circuit’s reasoning for its precedential decision in *Allergan* and argues that *Allergan* is consistent with ODP case law, equitable doctrine, congressional intent behind PTA, and current patent practice. This Part also discusses how *Allergan* will affect ODP scenarios with PTA moving forward and explores how patentees can best navigate these scenarios.

A. *ALLERGAN* CLARIFIES SCOPES OF ODP POST-*CELLECT*

The Federal Circuit’s decision in *Collect* and the district court’s decision in *Allergan* put patent families with PTA at risk of invalidation due to ODP. More than four hundred thousand patents issued over the past twenty years could face ODP invalidation due to one family member having PTA, and thus, a longer patent term.²⁰² Many of these at-risk patents are first-filed, first-issued patents that expire later than their continuations due to PTA.²⁰³ The Federal Circuit’s decision in *Allergan* provides reassurance for the patent community in this critical scenario by holding that a first-filed, first-issued, later-expiring patent cannot be invalidated for ODP by a later-filed, later-issued, earlier-expiring patent having a common priority date.²⁰⁴ This Section contends that this decision aligns with the equitable concerns underlying the ODP doctrine and clarifies previous courts’ use of patent expiration dates in an ODP analysis.

200. *Id.* at 4–5 (stating that “[r]egardless of the merits, the panel cannot create exceptions to this Court’s precedent: ‘In this Circuit, a later panel is bound by the determinations of a prior panel, unless relieved of that obligation by an en banc order of the court or a decision of the Supreme Court.’ *Deckers Corp. v. United States*, 752 F.3d 949, 959 (Fed. Cir. 2014).”)

201. Unopposed Motion for Withdrawal of Combined Petition for Panel Rehearing and Rehearing En Banc, *Allergan USA, Inc. v. MSN Lab’s Priv. Ltd.*, 111 F.4th 1358 (Fed. Cir. 2024) (No. 24-1061).

202. Dennis Crouch, *Collect: Unveiling the Potential Impact on Patent Term Adjustment*, PATENTLY-O (July 8, 2024), <https://patentlyo.com/patent/2024/07/unveiling-potential-adjustment.html>.

203. *Id.*

204. *Allergan*, 111 F.4th at 1369.

1. *Allergan Addresses the Equitable Concerns Under Which ODP Doctrine Was Established*

The Federal Circuit rightly decided *Allergan*, as the decision is consistent with the equitable concerns and circumstances underlying the ODP doctrine. Historically, ODP was established to prevent a patentee from extending their “exclusive rights to an invention through claims in a *later-filed* patent that are not patentably distinct from claims in the earlier[-]filed patent.”²⁰⁵ The purpose of ODP is to prevent a patent owner from “*extending* the exclusivity rights over his invention *beyond a full patent term*.”²⁰⁶ This ensures that “the public gets the benefit of the invention after the *original period* of monopoly expires.”²⁰⁷ A patent represents a bargain struck with the public: in exchange for fully disclosing an invention, the inventor obtains patent exclusivity for a period of time, after which the public is free to use the invention.²⁰⁸ The prohibition on double patenting prevents a patentee from “extend[ing] or prolong[ing] the monopoly beyond the period allowed by law.”²⁰⁹ Courts have consistently reinforced this foundational principle, prohibiting patentees from extending their monopolies through obvious variants of the original invention.²¹⁰

In this historical context, the first-filed, first-issued patent is the patent that defines the original monopoly period and the inventor’s agreement with the public, establishing when the invention becomes freely available for public use. The first-filed patent cannot be the one with which the patentee tries to improperly extend this term, because it sets the original term.²¹¹ In other words, there is no previously claimed subject matter to double patent, nor any monopoly to extend, until the first-filed patent issues.²¹² Moreover, patentees cannot file terminal disclaimers on a first-filed patent at the time of issuance, as later-filed patents do not yet exist.²¹³ Thus, in *Allergan*, the alleged reference patents were inappropriate ODP references to the first-filed patents, because they are continuations filed years later.²¹⁴ They expire earlier merely due to the variations in the timing of their prosecution by the USPTO. Therefore, ODP

205. *Procter & Gamble Co. v. Teva Pharm. USA, Inc.*, 566 F.3d 989, 999 (Fed. Cir. 2009) (emphasis added).

206. *Breckenridge*, 909 F.3d at 1367 (emphasis added).

207. *AbbVie*, 764 F.3d at 1373 (emphasis added).

208. *Gilead*, 753 F.3d at 1212.

209. *Miller*, 151 U.S. at 198.

210. *See id.*; *AbbVie*, 764 F.3d at 1373; *Gilead*, 753 F.3d at 1214–15; *Ezra*, 909 F.3d at 1374.

211. *See* Brief for Plaintiffs-Appellants, *Allergan USA, Inc. v. MSN Lab’ys Priv. Ltd.*, 111 F.4th 1358 (Fed. Cir. 2024) (No. 24-1061).

212. *Id.*

213. *Id.* at 5.

214. *Allergan*, 111 F.4th at 1368.

cannot apply in such circumstances, as there is no inequity concern in preserving the full term of the first-filed patent. The inventor's bargain with the public remains intact.²¹⁵ Thus, *Allergan* confirms ODP as an equitable doctrine as precedents require.

2. *Rigid Application of Expiration Dates for ODP Analysis Has Never Been Some Previous Courts' Intent*

A closer reading of the Federal Circuit's opinion in *Collect* suggests that the court likely did not intend to subject the first-filed, first-issued patent in the family to ODP if it expires earlier than the later-filed, later-issued patents. However, the district court in *Allergan* mechanically applied *Collect*, holding that any earlier-expiring patent could serve as an ODP reference patent.²¹⁶ The Federal Circuit in *Allergan* reversed, and to reconcile two seemingly contrasting rulings in *Collect* and *Allergan*, it clarified that *Collect* did not address which patents can serve as ODP references.²¹⁷ Because the patentee in *Collect* waived this issue, the court never had the opportunity to determine which "earlier-filed" patents could be properly used as ODP references.²¹⁸ In fact, *Allergan* is, in some ways, consistent with *Collect*. The *Collect* court stated that "claims in . . . challenged patents are entitled to their full term, including the duly granted PTA, unless they are found to be *later-filed* obvious variations of *earlier-filed*, commonly owned claims."²¹⁹ The court in *Collect* also repeatedly emphasized that ODP "limits the term of a patent or, at least, ties *later-filed*, commonly owned, obvious variations to the expiration date of an *earlier-filed reference patent*."²²⁰ Moreover, the court asserted that "ODP determination depends on an assessment of obviousness, i.e., whether the claims of a *later-expiring* patent would have been obvious over the claims of an *earlier-expiring* patent owned by the same party."²²¹ Thus, the *Collect* court never likely intended to invalidate a first-filed, first-issued patent for ODP based on a later-filed, later-issued patent.

Allergan is also consistent with precedents set before *Collect*. Following the *Collect* decision, the district court in *Allergan* rigidly applied a rule that any earlier-expiring patent can serve as an ODP reference patent.²²² A closer

215. See, e.g., *AbbVie*, 764 F.3d at 1372–73; *Ezra*, 909 F.3d at 1374 (The "traditional concern" of "extending his exclusive rights" is not implicated where "it is the earlier-filed, earlier-issued" patent "that has the later expiration date.").

216. See *Allergan*, 694 F. Supp. 3d at 511.

217. *Allergan*, 111 F.4th at 1368–69.

218. *Acadia*, 706 F. Supp. 3d at 487–88.

219. *Collect*, 81 F.4th at 1230 (emphasis added).

220. *Id.* at 1226 (emphasis added).

221. *Id.* (emphasis added).

222. See generally *Allergan*, 694 F. Supp. 3d.

reading of *Gilead* and *Breckenridge* indicates that the court never intended the use of a proxy date for ODP to be as rigid and absolute as *Collect* implies. The court did not aim to rely solely on a simplistic comparison of either expiration dates or issuance dates (pre-URAA) in an ODP analysis. Instead, these dates originate from the unique circumstances arising from changes in patent term law, as well as the specific fact patterns of the case.²²³ For instance, the *Gilead* court stated that it was deciding only the “narrow question” of “[c]an a patent that issues after but expires before another patent qualify as a [ODP] reference for that other patent,” and held only that, “under the circumstances of this case . . . it *can*.”²²⁴ In other words, previous courts have made it clear that using issuance dates or expiration dates is not a bright-line rule in an ODP analysis.

In *Gilead*, the patentee had received the full statutory term for the first-filed patent, but continued to extend its monopoly by pursuing patentably indistinct claims in a separate chain of application.²²⁵ The Federal Circuit in *Gilead* reasoned that relying solely on the issuance date in an ODP analysis in a post-URAA world would allow applicants to engage in “significant gamesmanship during prosecution.”²²⁶ The *Gilead* court then limited its holding to the circumstances of the case to prevent gamesmanship when issuance dates are used in an ODP analysis.²²⁷ Thus, the Federal Circuit’s rationale for moving away from the issuance dates stems from its intent to curtail gamesmanship, where patentees could file multiple applications with different filing dates and allow the latest filed to issue first.²²⁸ In post-URAA cases like *Allergan*, when two patents share the same priority date, the risk of unjustified term extension is reduced since both patents are expected to expire simultaneously—unless a term extension is granted by Congress, such as through PTA or PTE.

Similarly, the Federal Circuit in *Breckenridge* made it clear that ODP should not be determined solely by a mechanical comparison of expiration dates.²²⁹ There, the Federal Circuit held that an earlier-expiring post-URAA patent could not be used to invalidate a later-expiring pre-URAA patent.²³⁰ Although *Breckenridge* addressed whether a later-issued, earlier-expiring post-URAA patent could serve as an ODP reference against an earlier-issued, later-expiring

223. *Gilead*, 753 F. 3d at 1211–12, 1217.

224. *Id.* (“We therefore hold that an earlier-expiring patent *can* qualify as an [ODP] reference for a later-expiring patent *under the circumstances here.*”) (emphasis added).

225. *Id.* at 1210.

226. *Id.* at 1215.

227. *Id.* at 1212, 1217.

228. *See id.* at 1215–16.

229. *Breckenridge*, 909 F.3d at 1364–67.

230. *Id.* at 1366.

pre-URAA patent, the same reasoning applies in *Allergan*. The court in *Breckenridge* noted that “[h]ere, critically, [the patentee] did *not seek to extend its patent rights* over its . . . invention beyond one patent term.”²³¹ Similar to *Allergan*, *Breckenridge* merely sought to preserve its original monopoly period—the first-filed “patent’s statutorily-granted 17-year patent term.”²³² The court emphasized that “[t]o find that [ODP] applies here because a post-URAA patent expires earlier would abrogate [the patentee’s] right to enjoy one full patent term on its invention.”²³³ Thus, ODP cannot shorten the statutorily guaranteed term of a first-filed, first-issued patent.

B. *ALLERGAN* REFLECTS DEFERENCE TO CONGRESS’S LEGISLATIVE INTENT IN CREATING PTA

ODP thwarts any unjustified timewise extension of the original patent term beyond what is warranted. The passage of the URAA and the codification of PTA under 35 U.S.C. § 154(b) did not change this core principle.²³⁴ Thus, the Federal Circuit’s decision in *Allergan* reflects deference to congressional intent to compensate diligent applicants for USPTO prosecution delays.

For a long time, the term of a U.S. patent was seventeen years from the date of issuance. On December 8, 1994, Congress enacted the URAA, which changed the patent term to twenty years from the earliest effective U.S. filing date.²³⁵ This change in the patent term law was driven by two major factors. First, it aligned the U.S. patent term with international standards, as most foreign jurisdictions had already adopted a twenty-year term from the earliest filing date standard.²³⁶ Second, the change reduced incentives for patentees to prolong prosecution and create so-called “submarine patents.”²³⁷ Under the old seventeen-year rule, where the patent term was based on the issuance date, patentees could game the system by keeping their related patents pending at the USPTO for extended periods, thereby delaying the start of their patent term. This strategy allowed patentees to continuously update their patent

231. *Id.* at 1367 (emphasis added).

232. *Id.*

233. *Id.*

234. *See, e.g., AbbVie*, 764 F.3d at 1374; *Breckenridge*, 909 F.3d 1355.

235. Uruguay Round Agreements Act, *supra* note 34.

236. This change was required for member nations of the World Trade Organization that entered into the General Agreement on Tariffs and Trade (GATT) treaty during the Uruguay Round and the Trade-Related Aspects of Intellectual Property Rights (TRIPS) Agreement.

237. Analogous to a submarine, submarine patents could lurk for an extended period, only to surface unexpectedly and torpedo the market. *See* Mark A. Lemley, *An Empirical Study of the Twenty-Year Patent Term*, 22 AIPLA Q.J. 369, 377–80 (1994); Patricia Montalvo, *How Will the New Twenty-Year Patent Term Affect You? A Look at the Trips Agreement and the Adoption of a Twenty-Year Patent Term*, 12 SANTA CLARA HIGH TECH. L.J. 139, 156–57 (1996).

applications with new technological developments, wait for market conditions to mature, and then surprise competitors with enforceable rights over supposedly “new” technology.²³⁸ One notorious submarine patent case involved a patentee who kept his applications pending at the USPTO for forty years.²³⁹ Such submarine patents not only delayed public access to technological developments but also disrupted industry innovation and investment.²⁴⁰ Thus, setting the patent term to twenty years from the filing date curbed the incentives to engage in submarine patenting, because every day spent in prosecution reduced the enforceable term of a patent. As a result, patentees are motivated to expedite prosecution.

The change to the new patent term regime was highly controversial when it was first introduced.²⁴¹ The new law took effect on June 8, 1995, prompting a surge of patent filings at the USPTO in the weeks leading up to the deadline.²⁴² Inventors rushed to file patent applications, fearing that the new law might reduce their guaranteed seventeen years of protection under the previous system.²⁴³ As a result, the USPTO experienced a huge influx of patent applications, leading to a significant backlog.²⁴⁴ Under the previous regime, using the issuance date to calculate the term of a patent meant that any delays in prosecution by the USPTO did not affect the overall patent term. The patent term only began once the patent was issued. With the new law regime, patents filed on or after June 8, 1995 would face greater disadvantages because they would be subject to a longer pendency period and lose patent term from USPTO delays.²⁴⁵

Faced with mounting concerns that the change in patent term law could shorten patent terms due to prosecution delays—often lasting three or more years—Congress enacted the American Inventors Protection Act (AIPA) in 1999.²⁴⁶ The AIPA included the Patent Term Guarantee Act, incorporating

238. Montalvo, *supra* note 237, at 156–57.

239. *See, e.g.*, *Symbol Tech., Inc. v. Lemelson*, 277 F.3d 1361, 1363 (Fed. Cir. 2002); *see also* Montalvo, *supra* note 237, at 157; Lemley, *supra* note 237, at 379.

240. Montalvo, *supra* note 237, at 156–57.

241. Lemley, *supra* note 237, at 376; *see also* Montalvo, *supra* note 237, at 159–62; *see, e.g.*, Dana Rohrabacher, *Pennies for Thoughts: How GATT Fast Track Harms American Patent Applicants*, 11 ST. JOHN’S J. LEGAL COMMENT. 491 (1996); Dana Rohrabacher & Paul Grilly, *The Case for a Strong Patent System*, 8 HARV. J.L. & TECH. 263, 265 (1995). Critics of this change, including universities and biotechnology industry, raised concerns that the new patent term regime might not only shorten the life of their patents but also increase opportunity for foreign competitors.

242. Montalvo, *supra* note 237, at 162.

243. *Id.* at 162–63.

244. *Id.* at 163.

245. *Id.*

246. Lemley & Reinecke, *supra* note 13, at 686–87.

protections into the statute to guarantee a minimum seventeen-year patent term for diligent applicants—consistent with the pre-URAA framework. That guaranteed protection was implemented in the form of patent term adjustment (PTA).²⁴⁷

Indeed, the legislative history of PTA reinforces Congress’s intent to provide guaranteed term extensions and maintain the benefits of the previous seventeen-year term system. PTA is necessary because even a diligent patentee can “lose years of effective patent term due to delays in the PTO and other circumstances beyond [their] control.”²⁴⁸ Representative Dana Rohrabacher, one of the PTA bill’s co-sponsors, emphasized that the goal of PTA was to “assure a minimum patent term of 17 years from the date a patent is granted” via the “guarantee that the PTO will extend the patent term as necessary to assure a term of 17 years from filing for non-dilatory applicants . . . essentially giv[ing] back to the non-dilatory patent holder . . . a guaranteed 17 year patent term.”²⁴⁹

The *Allergan* decision thus reflects judicial deference to Congress’s legislative intent and statutory authority. Allowing a later-filed patent to cut short Allergan’s first-filed patent solely based on their expiration dates would mean that the first-filed patent would receive only fourteen years, nine months, and two days of statutory patent term—despite Congress’s guarantee of a minimum seventeen-year term.²⁵⁰ Moreover, under the doctrine of separation of powers, a judge-made rule such as ODP cannot override a statutory mandate.²⁵¹ Allowing such judicial doctrine to do so would “give judges a ‘legislation-overriding’ role that is beyond the Judiciary’s power.”²⁵² Indeed, the Constitution empowers Congress to enact legislation governing patents, and “it is the province of the legislative branch of the government to say when a patent to an inventor shall expire.”²⁵³ This principle applies directly here, where Congress has established a minimum PTA-adjusted statutory term under 35

247. Uruguay Round Agreements Act, *supra* note 34; 35 U.S.C. § 154(b)(1).

248. See H.R. REP. NO. 106-287, pt. 1, at 33, 49, 50 (1999); *id.* at 49–50 (stating that the Patent Term Guarantee Act amendments “compensate patent applicants for certain reductions in patent term that are *not the fault* of the applicant,” and penalize only “those who purposely manipulate the system”) (emphasis added).

249. 145 CONG. REC. H6944 (daily ed. Aug. 3, 1999).

250. See Brief for Plaintiffs-Appellants, *supra* note 211, at 15.

251. U.S. CONST. art. 1, § 1.3.1; see also *Ezra*, 909 F.3d at 1375 (“[A] judge-made doctrine” cannot “cut off a statutorily-authorized time extension.”).

252. See Brief for Plaintiffs-Appellants, *supra* note 211, at 43 (citing to *SCA Hygiene Prods. Aktiebolag v. First Quality Baby Prods., LLC*, 580 U.S. 328, 335 (2017) and quoting *Petrella v. Metro-Goldwyn-Mayer, Inc.*, 572 U.S. 663, 680 (2014)).

253. U.S. CONST. art. 1, § 8, cl. 8 (“[The Congress shall have Power] To promote the Progress of Science and useful Arts, by securing for limited Times to Authors and Inventors the exclusive Right to their respective Writings and Discoveries.”); *Bate Refrigerating Co. v. Sulzberger*, 157 U.S. 1, 43 (1895).

U.S.C. § 154(a)(2) and § 154(b)(1). Using ODP to undermine this statutory framework would unduly encroach upon legislative power.

Additionally, when enacting the Patent Term Guarantee Act, Congress acknowledged that patentees may still need to file terminal disclaimers for later-filed applications if an earlier patent had already exhausted the monopoly for that invention.²⁵⁴ Congress codified this principle into 35 U.S.C. § 154(b)(2)(B), which states that “[n]o patent the term of which has been disclaimed beyond a specified date may be adjusted under this section beyond the expiration date specified in the disclaimer.”²⁵⁵ In *Collect*, the Federal Circuit interpreted the statutory language in § 154(b)(2)(B) to hold that both ODP and terminal disclaimers should be applied *after* PTA is added to a patent’s expiration date.²⁵⁶ In other words, terminal disclaimers can cut short PTA, and a grant of PTA cannot extend beyond the expiration date set by a terminal disclaimer.²⁵⁷ However, the statutory language in 35 U.S.C. § 154(b)(2)(B) is also clear that this limitation only applies to a patent whose term “has been disclaimed”—a condition that does not apply to a first-filed, first-issued patent, such as the challenged patent in *Allergan*.²⁵⁸ Patentees cannot file terminal disclaimers on a first-filed patent upon its issuance, as no other patents from the same family exist at that time to justify such a disclaimer. Thus, § 154(b)(2)(B) cannot apply to first-filed patents, and PTA for first-filed patents should not be cut off by terminal disclaimers or ODP, as the Federal Circuit concluded in *Allergan*.²⁵⁹

C. *ALLERGAN* IS CONSISTENT WITH WELL-ESTABLISHED PATENT PRACTICE

A patent is part of an ongoing continuum of innovation. Technology often advances in incremental, interconnected steps. In many industries, the first fundamental invention is just the foundation for further applications and improvements. The doctrine of double patenting encourages incremental secondary innovations and follow-on research in continuation applications by presenting a trade-off between patent term and patent scope.²⁶⁰ In exchange for broader patent claim coverage and a lead over competitors researching

254. 35 U.S.C. § 154(b)(2)(B).

255. *Id.*

256. *Collect*, 81 F.4th at 1226–29.

257. *See id.*

258. *See id.*

259. *See Allergan*, 111 F.4th at 1371.

260. ROBERT PATRICK MERGES & JOHN FITZGERALD DUFFY, PATENT LAW AND POLICY: CASES AND MATERIALS 1165 (8th ed. 2021).

similar improvements, the patentee must forfeit any additional patent term that might come with the later-filed applications.²⁶¹

The *Collect* ruling calls on inventors to preemptively file terminal disclaimers to avoid unforeseen ODP challenges.²⁶² The Federal Circuit's decision in *Collect* introduces uncertainty into the continuation application practice, a common and longstanding practice under 35 U.S.C. § 120 that allows inventors to protect the full scope of their inventions.²⁶³ The risk of ODP-based invalidation after *Collect* affects patentees who file continuation applications that share the same priority date as the original patent. In fact, in the aftermath of *Collect*, terminal disclaimer filings increased by fifty percent from 2022 to 2023.²⁶⁴

In contrast, the *Allergan* decision better aligns with continuation practices and addresses post-*Collect* concerns from patentees. ODP originated before the URAA, when patent terms were calculated from the issuance date, allowing for submarine patenting and gamesmanship to delay the issuance of a patent and improperly extend its term. ODP, therefore, was designed to prevent an abuse of continuation practice.²⁶⁵ However, after the URAA, the term of a patent is now twenty years from its earliest filing date.²⁶⁶ As a result, continuations under the new law generally do not result in any additional patent term, as they typically share the same priority date as the original application. Continuation practices ensure rapid disclosure of follow-on research, since the inventor does not need to keep the original patent pending through claim amendments as new developments emerge.²⁶⁷ In practice,

261. MERGES & DUFFY, *supra* note 260.

262. Robert S. Rigg, Daniel H. Shulman & Sudip K. Mitra, *In re Collect: The Federal Circuit Alters Terminal Disclaimer Strategy*, VEDDERPRICE (Sep. 2023), <https://www.vedderprice.com/in-re-collect-the-federal-circuit-alters-terminal-disclaimer-strategy>.

263. 35 U.S.C. § 120; *see also* Stephen T. Schreiner & Patrick A. Doody, *Patent Continuation Applications: How the PTO's Proposed New Rules Undermine an Important Part of the U.S. Patent System with Hundreds of Years of History*, 88 J. PAT. & TRADEMARK OFF. SOC'Y 556, 559–70 (2006) (stating that “[c]ontinuation practice has been statutorily recognized for more than 50 years since the passage of the Patent Act of 1952.” The authors also noted that “[c]ontinuation applications are important because they allow the inventor to secure patent coverage for the various aspects of the invention that are not captured in the first patent” and listed reasons why the first patent might not provide sufficient coverage.).

264. *See* Dennis Crouch, *Terminal Disclaimers: A Growing Concern in Patent Practice*, PATENTLY-O (May 10, 2024), <https://patentlyo.com/patent/2024/05/terminal-disclaimers-practice.html>.

265. *See AbbVie*, 764 F.3d 1366, 1373 (Fed. Cir. 2014); *Ricoh Co., Ltd. v. Nashua Corp.*, 185 F.3d 884, No. 97–1344, slip op. at *3 n.3 (Fed. Cir. 1999).

266. Uruguay Round Agreements Act, *supra* note 34; *see* discussion *infra* Section IV.B for a legislative history behind the change in U.S. patent term and introduction of PTA after the passage of the URAA.

267. MERGES & DUFFY, *supra* note 260.

inventors frequently file multiple patents for the same technology, with an initial application that discloses, but may not claim, related inventions.²⁶⁸ An inventor might also accept narrow initial claims to expedite the issuance of a first foundational patent. However, if inventors fear losing patent terms due to ODP, they may be compelled to file applications with broad claim scope from the beginning. These broader applications would take longer to draft and process, thus overburdening the USPTO. As noted in *In re Braithwaite*, “all [the patentee] is getting from this [later-filed] application—and for only the remainder of the same term—are additional, more specific claims which would serve as a second line of defense if the dominating claims should prove to be vulnerable.”²⁶⁹ Discouraging patentees from prosecuting such continuations “would principally serve to deprive the public of the knowledge contained in the added disclosures.”²⁷⁰

D. TWO-PRONG INQUIRY TO DETERMINE OUTCOMES FOR ODP SCENARIOS WITH PTA

While *Allergan* has limited *Collect* in a critical scenario for the patent community, courts have yet to address several other ODP scenarios involving PTA post-*Collect*. This Section first clarifies what has been implicitly assumed in ODP jurisprudence by proposing a two-prong approach to ODP analysis—one that considers both the propriety of the alleged ODP reference and any equitable concerns. It then examines other ODP scenarios involving PTA that were not covered by *Allergan*—specifically when the patents share the same priority date and the only difference in expiration dates is due to PTA granted to the challenged patent. Applying the two-prong approach in these scenarios, this Section shows that a prior patent can still invalidate a later patent if traditional ODP concerns are present, because such a prior patent would qualify as a proper ODP reference.²⁷¹ Finally, this Section identifies measures patentees can take to reduce ODP risks in these scenarios.

268. *Id.*

269. *In re Braithwaite*, 379 F.2d 594, 601 (C.C.P.A. 1967).

270. *Id.*

271. This Section uses “first” versus “second” and “earlier” or “prior” versus “later” interchangeably to denote the order of the filing, issuance, and expiration dates of the patents in the scenario analysis. The main point is to consider any patents that might extend the *original* patent monopoly. Strictly speaking, using “earlier” or “prior” versus “later” offers a broader, more generalized description. In *Allergan*, the court strictly limited its language and decision to the “first-filed, first-issued” patent that was challenged, but did not address other broader scenarios.

1. *An ODP Analysis Requires a Dual Approach that Considers Both ODP Reference Propriety and Traditional Concerns, and an Assessment of Effective Filing Dates and Expiration Dates*

The recent *Allergan* decision suggests that courts may need to adopt a combined approach—analyzing both the effective filing dates and the expiration dates—to assess whether an alleged ODP reference is proper. Examining patent expiration dates is crucial to ensure that there is no unjustified term extension, which is the core concern of ODP. As explained in *Gilead*, “[p]ermitting any earlier expiring patent to serve as a double patenting reference for a patent . . . guarantees a stable benchmark that preserves the public’s right to use the invention (and its obvious variants) that are claimed in a patent when that patent expires.”²⁷²

However, considering effective filing dates as part of the analysis helps prevent situations like the one in *Allergan*. For patents with different effective filing dates (e.g., patents from different families), this combined approach allows for a straightforward ODP reference determination: an earlier-filed patent, with or without PTA, can serve as an ODP reference for a later-filed patent. In such cases, ODP rejections would only apply to the later-filed patent, preserving the equitable purpose of ODP. For patents with the same effective filing dates (e.g., continuations in a family), looking at the effective filing dates would create a tie between the two patents. In that case, a two-prong analysis may be necessary: first, to determine whether an alleged reference is a proper ODP reference (i.e., ODP reference propriety) (Prong One), and second, to determine whether the challenged patent raises any traditional ODP equitable concerns (i.e., unjustified timewise extension of a patent monopoly based on later obvious variations of the same invention) (Prong Two). If both conditions are met, ODP may still cut off the PTA-extended term of the challenged patent. Courts have implicitly used this two-prong approach in traditional ODP jurisprudence. However, in complex ODP cases involving concurrent term modification mechanisms, this inquiry becomes particularly vital and warrants an emphasis.

Allergan presents an ideal example to apply this two-prong inquiry. Under Prong One, the later-filed, later-issued patent in *Allergan* would be an improper ODP reference for the first-filed, first-issued patent. Under Prong Two, no traditional concerns with ODP would arise in this case, as there is no unjustified timewise extension of patent monopoly. Thus, *Allergan* fails both tests: the term of the challenged patent can be extended via PTA. Further, there are other ODP scenarios involving PTA that remain unresolved by

272. *Gilead*, 753 F.3d at 1216.

Allergan. In such cases, the joint analysis of effective filing dates and expiration dates might prove inconclusive. The following Section explores these scenarios and further demonstrates how this two-prong approach can be applied to achieve fair and consistent outcomes.

2. ODP Scenarios with PTA Not Covered by *Allergan*

Figure 7 illustrates five common post-URAA ODP scenarios involving PTA. Scenarios 1 and 2 in this Figure represent the typical ODP fact pattern, where two patents have different effective filing dates and, thus, different expiration dates. Consistent with the holding in *Gilead*, which involved patents from separate priority chains, the earlier-expiring patent in these two scenarios qualifies as a proper ODP reference for the later-expiring patent. Any PTA granted to the later-expiring patent would only further shift its expiration date, and ODP could still truncate the PTA-lengthened term.

Allergan narrowed *Collect* in one specific instance: it protects *first-filed, first-issued* patents that receive PTA, shielding them from ODP challenges by later-filed continuations that share the same priority date (depicted broadly as Scenario 5 in Figure 7).²⁷³ In other words, a first-filed patent is immune from an ODP challenge posed by a later-filed but earlier-expiring patent within the same family. Now that *Collect*'s writ of certiorari to the Supreme Court has been denied, several other ODP scenarios remain unresolved.

First, the *Allergan* court confined its holding to “first-filed, first-issued” challenged patents,²⁷⁴ rather than adopting broader language such as “earlier-filed, earlier-issued.” Thus, *Allergan* might be interpreted as narrowly applicable to this exact fact pattern—namely, a patent issuing from the first nonprovisional application in a family cannot be invalidated by later-filed, later-issued patents. It is unclear whether continuation patents filed and issued within the priority chain, other than the first-filed, first-issued patents, would remain vulnerable to ODP challenges.

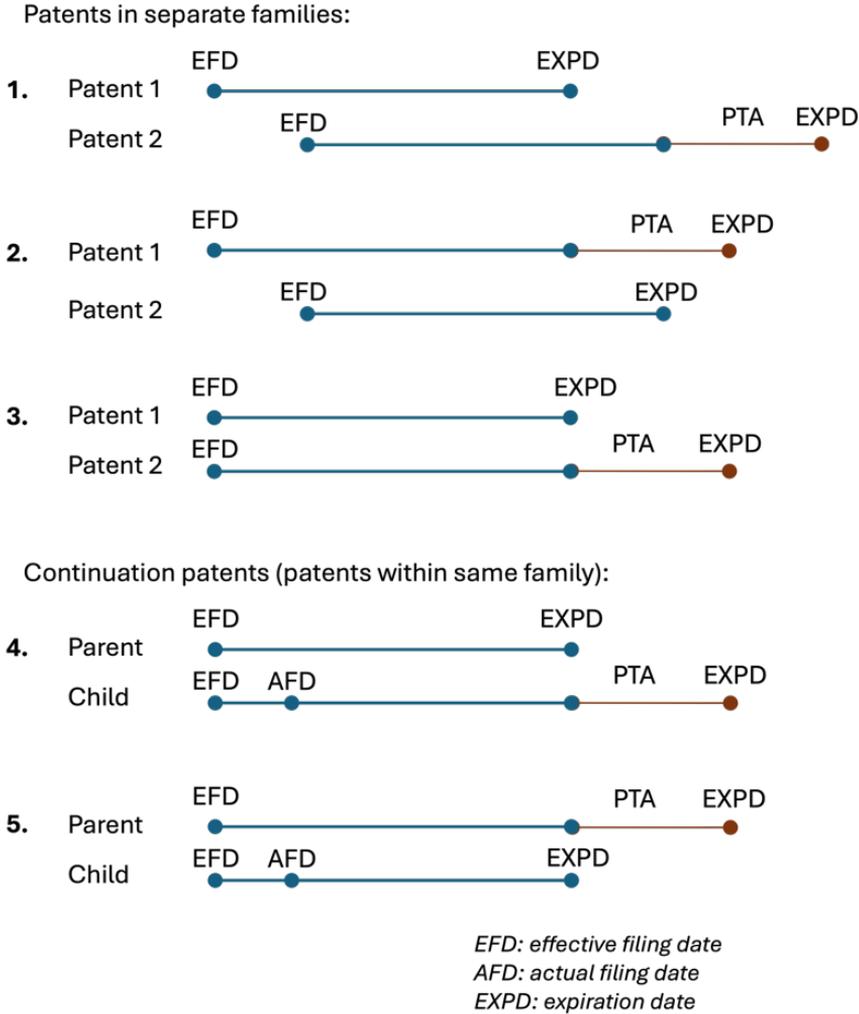
Second, *Allergan* did not address scenarios where two patents share the same effective filing dates, but the second patent—either a child continuation or another patent from a separate family—receives PTA (Scenarios 3 and 4 in Figure 7). This Section describes these two scenarios and emphasizes that the ODP doctrine will still apply to invalidate the second patent and cut off its PTA. To analyze the ODP outcomes in these two scenarios, this Section uses the two-prong approach outlined above and demonstrates that a prior patent can still invalidate a later patent, even when the sole factor causing their

273. See generally *Allergan*, 111 F.4th.

274. *Id.*

expiration dates to differ is the PTA granted to the later patent.²⁷⁵ The following Section then outlines strategies that patentees could implement to minimize ODP risks.

Figure 7: Five main post-URAA ODP scenarios with PTA



275. See discussion *supra* Section IV.D.1 for the proposed two-prong approach to determine outcomes for ODP scenarios with PTA.

a) Scenario 1: The Parent and Child Patents Have the Same Effective Filing Dates, and the Child Patent Receives PTA

In *Allergan*, the Federal Circuit clarified its previous decision in *Collect*, rejecting the interpretation that a first-filed patent with PTA could be invalidated for ODP by a later-filed child patent that expires earlier and does not have PTA.²⁷⁶ However, an open question remains: should a child patent expiring later than its parent due to PTA also be immune from an ODP challenge (Scenario 4 in Figure 7)?

Although courts have not addressed this specific scenario, it is common in the pharmaceutical industry to file continuations that result in a PTA-extended term for a child patent. An example of this scenario is when an earlier patent covers broad (genus) claims while a later patent focuses on narrower (species) claims. The first step a court will take in assessing an ODP challenge is determining whether the alleged reference patent qualifies as a proper ODP reference.²⁷⁷ This is “a threshold issue.”²⁷⁸ Once the court has determined whether a reference is proper, it then proceeds with the substantive ODP analysis.²⁷⁹ Thus, the central question in this scenario is whether the parent patent qualifies as an ODP reference for the child patent with PTA.

ODP jurisprudence has indicated that this is possible. *Allergan* confirms that only earlier-filed patents are proper ODP references. Historically, ODP has always been about challenging the “second” patent (see Table 1).²⁸⁰ By definition, a child patent is the “second” patent. This rationale for the double patenting doctrine is rooted in anticipation, as seen in *Miller v. Eagle Manufacturing Co.*, the first case where the Court gave definitive justification for the ODP doctrine.²⁸¹ The Court said that “[w]hen a patentee anticipates himself, he cannot, in the nature of things, give validity to the second patent.”²⁸² The Court invalidated the second patent with a simple rationale: if a *prior* patent to a *different party* can invalidate a *later* patent to the same invention, then a *prior* patent issued to the *same party* can also invalidate the *later* patent.²⁸³ The Court said:

276. See generally *Allergan*, 111 F.4th.

277. See *Acadia*, 706 F. Supp. 3d at 487; *Ezra*, 909 F.3d at 1375 n.4.

278. *Acadia*, 706 F. Supp. 3d at 487; see also *Ezra*, 909 F.3d at 1375 n.4 (“Because we find that the ’565 patent is not a double patenting reference for the ’229 patent, we need not address Ezra’s arguments as to whether the ’229 patent is patentably indistinct from the ’565 patent.”).

279. *Acadia*, 706 F. Supp. 3d at 487; see *Breckenridge*, 909 F.3d 1355, 1359 (Fed. Cir. 2018).

280. *Acadia*, 706 F. Supp. 3d at 487.

281. See *Miller*, 151 U.S. at 196–98.

282. *Id.* at 197.

283. See *id.* at 196–98.

Under these circumstances can it be held that the second patent has any validity, or must it be treated as having been *anticipated* by the grant of the 1879 patent? If, upon a proper construction of the two patents, which presents a question of law to be determined by the court, (*Heald v. Rice*, 104 U. S. 749,) and which does not seem to have been passed upon and decided by the court below, they should be considered as covering the same invention, then the later must be declared void, under the well-settled rule that two valid patents for the *same invention* cannot be granted either to the *same* or to a *different party*.²⁸⁴

Indeed, the ODP doctrine exists to prevent an inventor from receiving an undue patent term extension by securing a *second, later-expiring* patent for the same invention.²⁸⁵ The doctrine ensures that “the power to create a monopoly is exhausted by the *first* patent,” so that “a new and later patent for the same invention” does not “operate to extend or prolong the monopoly beyond the period allowed by law.”²⁸⁶ In numerous ODP decisions, courts have reiterated that the purpose of ODP is to “ensure[] that the public gets the benefit of the invention after the *original* period of monopoly expires,”²⁸⁷ and to “prevent a patent owner from extending his exclusive rights to an invention through claims in a *later-filed* patent that are not patentably distinct from claims in the *earlier-filed* patent.”²⁸⁸ Therefore, in this scenario, a parent patent qualifies as an ODP reference for a child patent—regardless of whether the child patent has PTA. As U.S. Circuit Judge Giles Rich noted in the *In re Zickendraht* decision:

Where there are in fact two inventions, whether or not they are patentable, this statute would seem to be inapplicable and the second patent has to be denied, if it is denied on some other ground. The ground one finds stated in the cases is to the effect that the second invention must be patentable on its own account, over the invention claimed in the issued patent, just as though the invention so claimed were in the prior art, and tested (since 1953) by the unobviousness requirement of 35 U.S.C. § 103.²⁸⁹

Now that Prong One—assessing whether the alleged ODP reference is proper—courts may proceed to Prong Two to apply the equitable doctrine of

284. *Id.* at 196–97 (emphasis added).

285. *See id.* at 196–98.

286. *Id.* at 198; *see* *Odiorne v. Amesbury Nail Factory*, 18 F. Cas. 578, 579 (C.C.D. Mass. 1819).

287. *AbbVie*, 764 F.3d at 1373 (emphasis added).

288. *Procter & Gamble*, 566 F.3d 989, 999 (emphasis added); *see also Collect*, 81 F.4th at 1226 (stating that ODP “limits the term of a patent or, at least, ties *later-filed* commonly owned, obvious variations to the expiration date of an *earlier-filed* reference patent.”) (emphasis added).

289. *Application of Zickendraht*, 50 C.C.P.A. 1529, 1536 n.4 (1963).

ODP. This analysis could lead to the invalidation of the child patent—regardless of whether it has PTA—if courts identify traditional inequitable concerns or signs of gamesmanship associated with ODP. In these instances, a child patent might not be entitled to its PTA if granting PTA would result in an improper extension of patent term. In other words, if the timewise extension introduces opportunities for gamesmanship or other inequitable outcomes that ODP is meant to prevent, the granted PTA in a later-filed, later-issued patent could still be cut off.

Indeed, courts have invalidated child patents with term adjustments or extensions under ODP over the past years. In *AbbVie*, the Federal Circuit applied ODP to invalidate a challenged child patent, thereby eliminating not only part of its 20-year patent term but also the 750-day PTA it had been granted.²⁹⁰ In *Boehringer*, a child patent was awarded over 1,500 days of PTE, but was later challenged for ODP over a parent patent.²⁹¹ *Boehringer* argued that it did not enjoy any unjustified advantage or unentitled rights as it had lawfully obtained PTE under 35 U.S.C. § 156.²⁹² However, the court disagreed, ruling that the rights enjoyed by a patentee during the original term of a patent are not the same rights enjoyed by a patentee during the term of an extension under § 156.²⁹³ The court emphasized that “[t]he fundamental reason for the rule [of obviousness-type double patenting] is to prevent unjustified timewise extension of the right to exclude granted by a patent *no matter how the extension is brought about*.”²⁹⁴ These outcomes reflect broader public policy concerns applicable to all continuations and child patents filed from a parent patent, regardless of whether PTA is involved. In other words, if courts identify a risk of gamesmanship, they may cut off PTA in the child patents.

However, in the second step, if the case does “not raise the traditional concern with [ODP]” and “there is no potential gamesmanship issue through structuring of priority claims,”²⁹⁵ then term adjustments and extensions for a child patent may still be justified and permissible, as the Federal Circuit recognized in *Ezra*. Following precedent in *Merck & Co. v. Hi-Tech Pharmacal Co.*, the *Ezra* court held that “a PTE pursuant to § 156 is valid so long as the extended patent is otherwise valid *without the extension*.”²⁹⁶ One example the

290. *AbbVie*, 764 F.3d 1366.

291. *Boehringer Ingelheim Intern. GmbH v. Barr Lab’s, Inc.*, 592 F.3d 1340, 1345 (Fed. Cir. 2010).

292. *Id.* at 1349.

293. *Id.*

294. *Id.* at 1347 (quoting *In re Van Ornum*, 686 F.2d 937, 943–44 (C.C.P.A. 1982)) (emphasis added).

295. *Ezra*, 909 F.3d at 1374.

296. *Id.* at 1375 (emphasis added).

court provided where ODP may invalidate a patent is “a patent, under its original expiration date without a PTE that should have been (but was not) terminally disclaimed.”²⁹⁷ However, the court also asserted that “if a patent, under its pre-PTE expiration date, is valid under all other provisions of law, then it is entitled to the full term of its PTE.”²⁹⁸ Since *Collect*, the comparison between PTA and PTE statutes and their respective purposes has sparked debates. However, until further guidance is provided, it remains uncertain how courts will interpret PTA in these scenarios. It is important to recognize that in some ODP cases, defendants rarely contested the non-obviousness of the claims. An ODP rejection arises only when the claims are very similar or obvious to each other. It is easy to solely focus on patent term and overlook the fundamental principle of ODP: one should not obtain a second patent with extended term for obvious variants of the same invention. As stated in *In re Braat*, “only if the extension of patent right is *unjustified* is a double patenting rejection appropriate. There are situations where the extension is justified.”²⁹⁹

297. *Id.* at 1374.

298. *Id.*

299. *In re Braat*, 937 F.2d 589, 595 (Fed. Cir. 1991).

Table 1: Past cases at the Federal Circuit concerning the interaction of ODP and patent term modifiers (e.g., PTA, PTE, and changes in patent term law), demonstrating that only earlier-filed patents are proper ODP references.³⁰⁰

Cases	Same v. Different Patent Families	Same v. Different Priority Dates	Challenged Patent(s)	Patent Used To Invalidate	Invalid Under ODP?
<i>Gilead</i>	Different	Different	Second-filed First-issued Second-expired	First-filed Second-issued First-expired	Yes
<i>AbbVie</i>	Same	Different	Second-filed Second-issued Second-expired (PTA)	First-filed First-issued First-expired	Yes
<i>Ezra</i>	Different	Different	First-filed (pre-URAA) First-issued Second-expired (PTE)	Second-filed (post-URAA) Second-issued First-expired	No
<i>Breckenridge</i>	Same	Same	First-filed (pre-URAA) Second-issued Second-expired (PTE)	Second-filed (post-URAA) Second-issued First-expired	No
<i>Collect</i>	Same	Same	Four interrelated challenged patents, all later-expired (PTA)	Later-filed Earlier-expired	Yes
<i>Allergan</i>	Same	Same	First-filed First-issued Second-expired (PTA)	Second-filed Second-issued First-expired	No

300. Transitional cases involving pre- and post-URAA patents include *Ezra* and *Breckenridge*, as noted within Table 1. The remaining cases involve post-URAA patents. Additionally, the term “filed” in this Table, used to describe the challenged patents and the alleged reference patent, refers to the actual filing dates of these patents. With the exception of *Collect*, these exemplary cases have shown that only the earlier-filed patents (e.g., first-filed) can be used to invalidate the challenged patents under ODP.

b) Scenario 2: Two Patents in Separate Families Have the Same Effective Filing Date, and One of the Patents Receives PTA

Another ODP scenario not covered by *Allergan* involves two patents from different families sharing the same effective filing date, where one of the patents receives PTA due to prosecution delays (Scenario 3 in Figure 7). The two patents would ordinarily have expired on the same day because they share the same filing date, but the granted PTA results in one of the patents expiring later. This scenario can be common in pharmaceutical patents, which often involve large, intricate patent portfolios spanning multiple families with related technologies. For example, one patent family might claim a new compound while discussing its method of using that compound in the specification, while another family might claim a method of using or manufacturing that new compound.³⁰¹ If these inventions are not filed within the same patent, a restriction requirement will not be triggered,³⁰² but instead, the patents may be interpreted as obvious over one another.

Based on ODP jurisprudence, it is entirely possible that the earlier-expiring patent can invalidate the later-expiring patents with PTA. An ODP rejection can only occur if the two inventions are deemed obvious over one another. This hypothetical scenario closely mirrors the fact patterns in *Gilead* and would satisfy both steps in the two-prong analysis. The patents in *Gilead*, despite being similar, did not belong to the same patent family and were not considered by the same examiner.³⁰³ Instead, Gilead crafted separate chains of applications, resulting in patents with different priority dates and, consequently, different expiration dates.³⁰⁴ The Federal Circuit in *Gilead* addressed whether “a patent that issues after but expires before another patent qualif[ies] as a double patenting reference for that other patent.”³⁰⁵ The court held that “an earlier-expiring patent can qualify as an obviousness-type double patenting reference for a later-expiring patent” in this scenario.³⁰⁶ The main concern in *Gilead*, and also in this hypothetical scenario, was the potential for “significant gamesmanship during prosecution.”³⁰⁷ In other words, allowing applicants to structure their filings this way would enable them to “obtain additional patent term exclusivity for obvious variants of their inventions while also exploring the value of an earlier priority date during prosecution.”³⁰⁸ This

301. See generally *AbbVie*, 764 F.3d at 1366.

302. See discussion *infra* Section IV.D.3 for restriction requirements.

303. *Gilead*, 753 F.3d at 1210.

304. *Id.*

305. *Id.* at 1211–12.

306. *Id.* at 1217.

307. *Id.* at 1215.

308. *Id.*

rationale applies to any patent—regardless of whether it has PTA—and a term adjustment can be valid so long as the patent is valid without the adjustment.

AbbVie further reinforced the *Gilead* rationale, holding that an ODP analysis must consider the potential for applicant gamesmanship.³⁰⁹ The *AbbVie* court emphasized that ODP remains viable “where, as here, the applicant chooses to file separate applications for overlapping subject matter and to claim different priority dates for the applications.”³¹⁰ Indeed, the court outright asserted:

We now make explicit what was implicit in *Gilead*: the doctrine of obviousness-type double patenting continues to apply where two patents that claim the same invention have different expiration dates. We hold that Kennedy is not entitled to an extra six years of monopoly solely because it filed a separate application unless the two inventions are patentably distinct.³¹¹

3. Strategies for Patentees to Minimize ODP Risks

Given the ongoing risks of ODP invalidation for patents with PTA and the evolving complexity of ODP jurisprudence, patentees must proactively address ODP risks. The following Section outlines strategies available to patentees to mitigate potential ODP risks.

Allergan establishes protection for the first-filed, first-issued patent in a family against ODP challenges.³¹² This decision is likely to influence patent portfolio strategies to cover the most critical subject matter and secure the maximum PTA for first-filed patents. Patentees may prioritize broader claims in the initial patent rather than seeking a quick issuance for an initial patent.³¹³ Given the value of PTA and the likelihood of a first-filed patent obtaining some PTA, patentees should also prosecute patents diligently to avoid any PTA penalty that may reduce the amount of PTA awarded. Pending additional judicial guidance, patent owners should also actively and thoroughly review their patent portfolios and identify patents that could face ODP challenges due to varying expiration dates caused by PTA. It is also important to note that an ODP rejection may not be issued during prosecution. As seen in *Collect*, examiners may not raise ODP concerns during prosecution at the USPTO, leaving the patentee vulnerable to future ODP challenges in

309. *Acadia*, 706 F. Supp. 3d at 487; see also *AbbVie*, 764 F.3d at 1374.

310. *AbbVie*, 764 F.3d at 1373.

311. *Id.* at 1374.

312. See generally *Allergan*, 111 F.4th 1358.

313. Dennis Crouch, *Family Planning Patent Style: Allergan, Collect, and the ODP Maze*, PATENTLY-O (Aug. 13, 2024), <https://patentlyo.com/patent/2024/08/family-planning-patent-style-allergan-collect-and-the-odp-maze.html>.

litigation.³¹⁴ Enhanced IP due diligence is critical to mitigate ODP risks early and avoid post-grant invalidation.

One common prosecution strategy is to force a restriction requirement for the first-filed patent. This approach allows for later divisional applications from the first-filed patent to be protected against any ODP challenges, under what is known as the “safe harbor” provision of 35 USC § 121.³¹⁵ Section 121 creates an exception to the ODP doctrine, by providing that “a patent issuing on an application with respect to which a requirement for restriction . . . has been made, or on an application filed as a result of such a requirement, shall not be used as a reference . . . against a divisional application or against the original application.”³¹⁶ The USPTO issues a restriction requirement when an examiner determines that a patent application claims more than one distinct and independent invention. In such cases, the patentee must elect a single, claimed invention for examination, while the other claims may be pursued in a later divisional application. For instance, if the patent application has both composition and method claims within the same application, the examiner may require the patentee to elect one set of claims to move forward with the current application, while the other claims can be filed in a later divisional application.³¹⁷ Section 121 thus exists to prevent an unfair outcome where the USPTO requires an applicant to divide claims into separate patents to comply with the restriction requirements, only for them to later use the original application to issue a double patenting rejection for the later-filed application.³¹⁸ The safe harbor provision addresses “difficulties created by restriction requirements imposed by the [USPTO] during examination, followed by double patenting challenges in the courts.”³¹⁹

To trigger the requirement restriction in a first-filed patent application, patentees can present multiple claim types (e.g., composition versus method claims) or claims from independent, distinct inventions. Once the divisional applications are filed, safe harbor protections can be invoked against ODP rejections. However, patentees must meet specific requirements to qualify for the safe harbor protection. First, divisional applications must be filed as a result of restriction requirements.³²⁰ Continuation or continuation-in-part (CIP)

314. *See Collect*, 81 F.4th at 1219.

315. 35 U.S.C. § 121; *see also Acadia*, 706 F. Supp. 3d at 482.

316. 35 U.S.C. § 121.

317. *Id.*

318. *Id.*; Pub. L. No. 82-593, 66 Stat. at 800–01 (1952).

319. *St. Jude Med., Inc. v. Access Closure, Inc.*, 729 F.3d 1369, 1376–77 (Fed. Cir. 2013).

320. 35 U.S.C. § 121; *see also Bristol-Myers Squibb Co. v. Pharmachemie B.V.*, 361 F.3d 1343, 1347–48 (Fed. Cir. 2004) (“[the patentee] is entitled to invoke the statutory prohibition against the use of the [reference] patent ‘as a reference’ against the divisional application that

applications are not entitled to the ODP safe harbor.³²¹ In fact, courts have consistently invalidated continuation patents challenged with ODP that failed to be designated as divisional applications.³²² Patentees should ensure that the filings are correct as divisional applications—not continuations. Second, the claims in the divisional applications must maintain “consonance” with the restriction requirements. The doctrine of consonance “requires that the line of demarcation between the ‘independent and distinct inventions’ that prompted the restriction requirement be maintained.”³²³ In other words, consonance ensures that the claims in the divisional applications adhere to the original boundaries set by the restriction. Claims must not overlap with inventions elected in the parent application.³²⁴

Lastly, when facing an ODP rejection, patentees can argue that the claims are patentably distinct or amend the claims to obviate the ODP rejection for the child patent.³²⁵ Patentees can also file terminal disclaimers for later-filed patents, sacrificing the child patent’s term to preserve PTA for another family member with more valuable claims.³²⁶ A terminal disclaimer can only overcome an ODP rejection if the earlier patent has not yet expired.³²⁷ Patentees should assess the validity of an ODP rejection before submitting a terminal disclaimer. Terminal disclaimers carry certain implications, as not only

resulted in the [challenged] patent only if the *divisional application was filed as a result of a restriction requirement* and is consonant with that restriction requirement.” (emphasis added)).

321. See, e.g., *In re Janssen Biotech, Inc.*, 880 F.3d 1315 (Fed. Cir. 2018); see also *Pfizer, Inc. v. Teva Pharms. USA, Inc.*, 518 F.3d 1353, 1362 (Fed. Cir. 2008) (“[T]he protection afforded by section 121 to applications (or patents issued therefrom) filed as a result of a restriction requirement is limited to divisional applications.”).

322. See, e.g., *Pfizer*, 518 F.3d at 1359–63 (holding that safe harbor does not apply to patents issued from continuation-in-part (CIP) applications); see also *Amgen Inc. v. F. Hoffman-La Roche Ltd.*, 580 F.3d 1340, 1352–53 (Fed. Cir. 2009) (holding that safe harbor does not apply to patents issued from continuation applications).

323. *Gerber Garment Tech., Inc. v. Lectra Sys., Inc.*, 916 F.2d 683, 688 (Fed. Cir. 1990); see also *Geneva Pharm., Inc. v. GlaxoSmithKline PLC*, 349 F.3d 1373, 1381 (Fed. Cir. 2003) (“Section 121 shields claims against a double patenting challenge if consonance exists between the divided groups of claims and an earlier restriction requirement.”); MPEP § 804.02 (9th ed. Rev. 1, 2024).

324. *Gerber Garment Tech.*, 916 F.2d 683, 687 (stating that “a divisional application filed as a result of a restriction requirement may not contain claims drawn to the invention . . . in the parent application.”).

325. MPEP § 804 (9th ed. Rev. 1, 2024).

326. 35 U.S.C. § 253; MPEP § 1490 (9th ed. Rev. 1, 2024).

327. See *Boehringer*, 592 F.3d 1340 (Fed. Cir. 2010); *In re Lonardo*, 119 F.3d at 965 (Fed. Cir. 1997) (“With obviousness-type double patenting, . . . a terminal disclaimer may overcome that basis for unpatentability, assuming that the first patent has not expired. In this case, the [patent] over which the claims have been rejected . . . has expired, so a terminal disclaimer cannot cure these rejections.”) (emphasis added).

do they tie the terms of the patents together, but they may also link the patents for licensing purposes when a common owner is involved.³²⁸ Further, if ownership of the patents is later divided, the disclaimed patents may become unenforceable.³²⁹

V. CONCLUSION

Double patenting, though seemingly straightforward, remains a complicated and unsettled area of patent law. In *Allergan*, the Federal Circuit reached an outcome that was both equitable and consistent with the foundational principles of the ODP doctrine and double patenting jurisprudence. The ruling clarifies what qualifies as a proper ODP reference, while reinforcing PTA's original purpose—a statutory safeguard to compensate diligent applicants, rather than a tool for exposing patents to ODP invalidation.

Unfortunately, prosecution delays at the USPTO are here to stay, and PTA and ODP continue to remain in each other's crosshairs. From October 2023 until now, only thirty-two percent of patent applications received their first action within fourteen months of filing.³³⁰ Addressing the unresolved ODP scenarios with PTA post-*Allergan*, this Note offers a systematic approach for analyzing ODP outcomes—one that balances the propriety of ODP references with traditional equitable concerns. In the meantime, while Sun has withdrawn its en banc rehearing petition and *Allergan* has narrowed *Collect* in one acute instance, other cases involving ODP and PTA remain on appeal at the Federal Circuit.³³¹ These future appeals will provide the court further opportunities to refine its view on the interaction between PTA and ODP. Until the courts provide a definitive clarification, the interplay between PTA and ODP will continue to leave this area of law ambiguous and unsettled.

328. Gary Maze & Jeffrey Wendt, *Prosecution and Litigation Implications of Subsequent Patent Applications (Part IV)*, IPWATCHDOG (Dec. 28, 2020), <https://ipwatchdog.com/2020/12/28/prosecution-litigation-implications-subsequent-patent-applications-part-iv/id=128451/>.

329. 37 C.F.R. § 1.321(c)(3); see also *Email Link Corp. v. Treasure Island, LLC*, 2012 WL 4482576, at *4 (D. Nev. 2012); *Voda v. Medtronic, Inc.*, No. CIV-09-95-L, 2011 WL 10820070, at *3 (W.D. Okla. 2011).

330. *Patent Term Adjustment Data August 2024*, USPTO PATENTS DASHBOARD, <https://www.uspto.gov/dashboard/patents/patent-term-adjustment-new.html> (last visited Nov. 17, 2024).

331. See, e.g., *Abiomed*, 2023 WL 4038564, at *33–34 (D. Mass. 2023); *Acadia*, 706 F. Supp. 3d at 487 (as of April 20, 2025, both cases are under appeal at the Federal Circuit).

FOREIGN CONDUCT AS A MEASURE OF PATENT DAMAGES AFTER *BRUMFIELD V. IBG*

William R. Clark[†]

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I. INTRODUCTION

As the world’s economy grows ever more connected, products made in the United States are commonly sold elsewhere. This poses a question for U.S. patent laws: to what extent may a patentee recover damages for sales of an infringing product that occur abroad?

In recent years, the Supreme Court and the Federal Circuit have struggled with this question. At first, the Supreme Court sought to strongly limit the application of United States laws to activities inside its borders. There was a customary “presumption against extraterritoriality”: a strong thumb on the

scales against applying our patent laws to conduct outside the United States' borders unless the statute said otherwise.¹ If a plaintiff failed to rebut this presumption, then its claims had to involve a “domestic application” of the statute.”²

But then companies began manufacturing components in the United States and only assembling them into systems that infringed United States patents when they left the country. Putting the infringing behavior out of the territorial reach of United States courts circumvented the U.S.'s patent laws. Accordingly, Congress amended the Patent Act in 1984 to add 35 U.S.C. § 271(f) to forbid this behavior,³ and the Supreme Court sought to stymie the exploitation of this loophole.⁴ Decades later, the Supreme Court ruled that patentees can recover for foreign sales in the narrow circumstances that a defendant infringes under § 271(f).⁵ This ruling created a crack in the presumption against extraterritoriality, suggesting that the United States' patent laws do not *only* consider domestic behavior.

Trying to make sense of the territorial bounds of U.S. patent law, the Federal Circuit recently heard the case of *Brumfield v. IBG*.⁶ There, the Federal Circuit ruled that, if closely connected to domestic infringement, foreign conduct can be used to increase a reasonable-royalty award, so long as it has the “the needed causal relationship” to making the accused products in the United States.⁷ This Note seeks to make sense of *Brumfield*, its “causal relationship” requirement, and its relationship with previous case law.

Part II provides the legal background, laying out the case law that precipitates *Brumfield*.

Part III then discusses *Brumfield* in detail, pointing out the questions that it leaves open. What does this ruling mean for lost profit damages? How can courts apply this ruling to be consistent with existing law on reasonable-royalty awards? And will other patent damages doctrines come under extraterritorial scrutiny?

Part IV seeks to answer these questions. Section IV.A parses the tensions between *Brumfield* and its predecessors to suggest that foreign conduct should only be used as a measure of the value of domestic infringement. Section IV.B

1. *RJR Nabisco, Inc. v. Eur. Cmty.*, 579 U.S. 325, 337 (2016).

2. *Id.*

3. Patent Law Amendments Act of 1984, Pub. L. No. 98-622, 98 Stat. 3383 (Nov. 8, 1984).

4. *WesternGeco LLC v. ION Geophysical Corp.*, 585 U.S. 407, 411 (2018) [hereinafter *WesternGeco II*].

5. *Id.*

6. *Brumfield v. IBG LLC*, 97 F.4th 854 (Fed. Cir. 2024) [hereinafter *Brumfield II*].

7. *Id.* at 878.

argues that *Brumfield*'s "causal relationship" should be scrutinized closely in the lost-profits context, only authorizing recovery of money that the infringer's domestic infringement accrued abroad. Section IV.C suggests that *Brumfield* should be implemented in the reasonable-royalty context through the existing *Georgia-Pacific* framework. And Section IV.D outlines the uncertainty that *Brumfield* creates in the arena of willful infringement and enhanced damages based on foreign bad acts. At each turn, this Note suggests that foreign conduct should only be used as a *measure* of damages, as opposed to a cause of legal injury. Part V briefly concludes.

II. LEGAL BACKGROUND

Brumfield is the culmination of an ongoing conversation between the Federal Circuit and the Supreme Court about the territorial scope of the U.S.'s patent laws. This Part lays out recent installments in that conversation, as well as other relevant background on other areas of patent damages, proceeding in four Sections.

Section II.A outlines the conduct that United States patent laws regulate, discussing what does and does not constitute infringement. Section II.B outlines the different types of patent damages awards: lost profits, reasonable royalties, and enhancements. Section II.C discusses *Power Integrations v. Fairchild Semiconductor*, the last time the Federal Circuit aimed to constrain the reach of United States patent damages to domestic conduct.⁸ *Brumfield* partially overruled this case, but its guidance remains useful. Section II.D discusses *WesternGeco v. ION Geophysical*, where the Supreme Court first expanded the ability of courts to consider money earned abroad to calculate the damages caused by patent infringement.⁹ Understanding this ruling is crucial because the court in *Brumfield* interprets it to have created the new framework for the consideration of foreign conduct, which it then applies to new types of damages and infringement.

A. PATENT INFRINGEMENT

Because the inquiry established in *Brumfield* inspects the causal connection between damages and infringement, understanding what does—and does not—constitute patent infringement is essential. Section 271(a) of the Patent Act defines direct infringement to include making, using, selling, offering to sell, or importing into the United States any patented invention.¹⁰ By the plain

8. *Power Integrations, Inc. v. Fairchild Semiconductor Int'l, Inc.*, 711 F.3d 1348 (Fed. Cir. 2013).

9. *WesternGeco II*, 585 U.S. at 407.

10. 35 U.S.C. § 271(a).

language of the statute, these actions constitute infringement only when they occur “in the United States.”¹¹ As a general rule, making or selling a U.S. patented product in another country is not infringement because § 271’s provisions all describe conduct in, into, or from “the United States.”¹²

But there is an exception.¹³ Section 271(f) of the Patent Act provides that infringement *does* occur when one “suppl[ies] . . . from the United States,” for “combination” abroad, a patented invention’s “components.”¹⁴ Even if the components themselves do not infringe the patent, the act of supplying the components for combination into an infringing system abroad is an act of patent infringement.¹⁵

B. TYPE OF PATENT DAMAGES

After infringement is proven, courts award damages under Title 35 of the U.S. Code.¹⁶ Section 284 outlines different types of damages, which are the subjects of the following Sections. The first two Sections describe compensatory damages. Section II.B.1 discusses lost profit damages, the subject of the cases that precede *Brumfield*. Section II.B.2 provides background on reasonable-royalty awards, the object of *Brumfield*’s ruling. Section II.B.3 previews the law of willful infringement and enhanced damages, an area of patent law that may face substantial uncertainty as a result of *Brumfield*.

1. Lost Profits

Section 284 of the Patent Act provides that “the court shall award the claimant damages adequate to compensate for the infringement.”¹⁷ Patent holders sometimes seek to recover the profits they lost as a result of the infringement as damages.¹⁸ Courts require a patentee to show a “reasonable probability” that “but for the infringement,” the patentee would have made

11. *Id.*; see also *Ortho Pharm. Corp. v. Genetics Inst., Inc.*, 52 F.3d 1026, 1033–34 (Fed. Cir. 1995) (holding “a U.S. patent grants rights to exclude others from making, using and selling the patented invention only in the United States.”).

12. *Microsoft Corp. v. AT & T Corp.*, 550 U.S. 437, 445 (2007); see also 35 U.S.C. § 271(a).

13. *Microsoft Corp.*, 550 U.S. at 437 (describing § 271(f) as an “exception”).

14. 35 U.S.C. § 271(f)(1).

15. *See id.*

16. 35 U.S.C. § 284.

17. *Id.*

18. ROBERT A. MATTHEWS, JR., 4 ANNOTATED PATENT DIGEST § 30:20 (Oct. 2024) [hereinafter MATTHEWS PATENT DIGEST].

the infringer's sales.¹⁹ Lost profits, as a measure of compensatory damages, are intended to make the party whole—not to punish the infringer.²⁰

2. Reasonable-Royalty Awards

Section 284 of the Patent Act provides that the “damages adequate to compensate for the infringement,” shall be “in no event less than a reasonable royalty for the use made of the invention by the infringer.”²¹ Therefore, instead recovering the actual damages of a particular act of infringement, a patentee may instead seek a reasonable royalty for the infringer's use of the patented technology.²² Lost-profit awards intend to compensate the patent holder for profits lost as a result of the infringement.²³ A reasonable royalty, while also a compensatory award, is intended to compensate the patentee for the value of the patented technology itself—not how profitable its use actually was.²⁴

A reasonable-royalty award typically requires establishing a royalty rate and a royalty base.²⁵ The royalty base is the number of times the infringing product was made, sold, used, or otherwise infringed.²⁶ A royalty rate is a per-unit dollar amount.²⁷ The reasonable-royalty award is calculated by multiplying the royalty rate times the royalty base.²⁸

Absent evidence of prior licensing rates, a royalty rate is based on the amount the infringer would have agreed to pay to engage in the activity constituting the infringement.²⁹ To determine this amount, courts imagine the outcome of a hypothetical negotiation, conducted on the date of first infringement.³⁰ Royalty rates are often determined by considering fifteen factors set forth in *Georgia-Pacific Corp. v. U.S. Plywood Corp.*³¹ In relevant part for this Note, these factors include:

19. MATTHEWS PATENT DIGEST, *supra* note 18, § 30:20.

20. *See WesternGeco II*, 585 U.S. at 417 (quoting *Gen. Motors Corp. v. Devex Corp.*, 377 U.S. 648, 655 (1983)).

21. 35 U.S.C. § 284.

22. *See id.*

23. *See WesternGeco II*, 585 U.S. at 417 (quoting *Gen. Motors Corp.*, 377 U.S. at 655).

24. *Warsaw Orthopedic, Inc. v. NuVasive, Inc.*, 778 F.3d 1365, 1375 (Fed. Cir. 2015).

25. MATTHEWS PATENT DIGEST, *supra* note 18, § 30:89.

26. *Id.*

27. *Id.*

28. *Id.*

29. *Lucent Techs., Inc. v. Gateway, Inc.*, 580 F.3d 1301, 1324–25 (Fed. Cir. 2009).

30. MATTHEWS PATENT DIGEST, *supra* note 18, § 30:86.10.

31. *Georgia-Pacific Corp. v. U.S. Plywood Corp.*, 318 F. Supp. 1116, 1120 (S.D.N.Y. 1970), *modified on appeal*, 446 F.2d 295 (2d Cir. 1971); *see also* MATTHEWS PATENT DIGEST, *supra* note 18, § 30:84.

3. The nature and scope of the license, as exclusive or non-exclusive; or as restricted or non-restricted in terms of territory or with respect to whom the manufactured product may be sold . . .
5. The commercial relationship between the licensor and licensee, such as, whether they are competitors in the same territory in the same line of business; or whether they are inventor and promoter.
6. The effect of selling the patented specialty in promoting sales of other products of the licensee; that existing value of the invention to the licensor as a generator of sales of his non-patented items; and the extent of such derivative or convoyed sales . . .
8. The established profitability of the product made under the patent; its commercial success; and its current popularity . . .
11. The extent to which the infringer has made use of the invention; and any evidence probative of the value of that use.³²

Each of these factors gives a reason that the infringer would agree to pay more to license the patent.³³

3. *Enhanced Damages*

According to the Federal Circuit, willful infringement “arises upon deliberate disregard for the property rights of the patentee,” like knowing a patent exists and copying the invention anyway.³⁴ After a jury returns a finding of willful infringement, the court has discretion to punish the infringer by awarding enhanced damages.³⁵ An infringer’s subjective intent—the presence or absence of deliberate disregard—is commonly proven through circumstantial evidence.³⁶ As enumerated in *Read v. Portec*, such considerations include:

1. whether the infringer deliberately copied
2. whether the infringer had a good-faith belief in noninfringement or invalidity
3. the infringer’s behavior as a party to the litigation

32. *Georgia-Pacific*, 318 F. Supp. at 1120; MATTHEWS PATENT DIGEST, *supra* note 18, § 30:84.

33. See MATTHEWS PATENT DIGEST, *supra* note 18, § 30:84.

34. *Vulcan Eng’g Co., Inc. v. Fata Aluminium, Inc.*, 278 F.3d 1366, 1378 (Fed. Cir. 2002).

35. See 35 U.S.C. § 284.

36. See *Gustafson, Inc. v. Intersystems Indus. Prods., Inc.*, 897 F.2d 508, 510–11 (Fed. Cir. 1990) (finding “[w]hether an act is ‘willful’ is by definition a question of the actor’s *intent*, the answer to which must be inferred from all the circumstances.”).

4. the infringer's size and financial condition
5. closeness of the case
6. duration of the infringer's misconduct
7. remedial action by the infringer
8. the infringer's motivation for harm
9. whether the infringer attempted to conceal its misconduct.³⁷

Courts must not award increased damages just to rectify “an inadequacy in the compensatory damages awarded.”³⁸

C. UNDER *POWER INTEGRATIONS*, COMPENSATORY DAMAGES COULD NOT INCLUDE FOREIGN SALES

Power Integrations v. Fairchild is the first in the duo of cases that led to *Brumfield*. The Federal Circuit held that U.S. patent damages cannot compensate the patentee for the infringer's use of the patent abroad.³⁹ In *Power Integrations*, both parties agreed that Fairchild directly infringed Power Integrations's patents under § 271(a) by making or selling infringing circuits in the United States.⁴⁰ But, the parties disagreed over the proper damages amount.⁴¹

Plaintiff Power Integrations argued that Fairchild's domestic patent infringement caused Power Integrations to lose sales in foreign markets.⁴² Power Integrations advanced both broad and narrow damages theories for lost profits.⁴³ On the broadest side, Power Integrations alleged that Fairchild's infringement in the United States “would cause Power Integrations to lose all sales . . . both inside and outside the U.S.”⁴⁴ But Power Integrations also pointed to more specific damages, such as Fairchild supplanting Power Integrations as the provider of 40 percent of Samsung's chips.⁴⁵

37. *Read Corp. v. Portec, Inc.*, 970 F.2d 816, 827 (Fed. Cir. 1992) (citation modified).

38. *Beatrice Foods Co. v. New England Printing & Lithographing Co.*, 923 F.2d 1576, 1579 (Fed. Cir. 1991).

39. *Power Integrations, Inc. v. Fairchild Semiconductor Int'l, Inc.*, 711 F.3d 1348, 1371 (Fed. Cir. 2013).

40. *Id.* at 1376.

41. *Id.*

42. *Id.* at 1370.

43. *See generally* Brief for Plaintiff-Cross Appellant at 46, *Power Integrations*, 711 F.3d 1348 (Nos. 2011-1218, 2011-1238), 2011 WL 2827447, at *46.

44. *Id.*

45. *Id.*

Power Integrations argued that damages for these actions were recoverable because of their causal connection with Fairchild’s domestic infringement.⁴⁶ Specifically, Power Integrations alleged that no company would buy any of the defendant’s infringing components unless the resulting products could be sold in the United States.⁴⁷ Accordingly, a jury awarded “worldwide damages” for the lost sales that Power Integrations would have had around the world but for Fairchild’s domestic infringement.⁴⁸

The Federal Circuit held that this jury award was incorrect as a matter of law.⁴⁹ The Federal Circuit acknowledged that United States patent laws allow for “damages adequate to compensate for the infringement.”⁵⁰ The court explained that patent laws do not compensate for the foreign exploitation of a patented invention, “which is not infringement at all.”⁵¹ The Federal Circuit emphasized that foreign conduct cannot constitute infringement because the entirely extraterritorial use or sale of a patented invention breaks the chain of causation initiated by an act of domestic infringement.⁵² Under this reasoning, foreign conduct is irrelevant to calculating “damages adequate to compensate for the infringement” because foreign conduct is not infringement.⁵³ Accordingly, the court ruled that Power Integrations was not entitled to “compensatory damages” for the exploitation of the patented invention outside the United States.⁵⁴

After *Power Integrations*, the rule was clear: U.S. patent laws do not compensate a patentee for an infringer’s actions abroad—even if those actions would constitute patent infringement if performed in the United States.

D. UNDER *WESTERNGECO*, A LOST-PROFIT AWARD CAN INCLUDE LOST FOREIGN PROFITS IN NARROW CIRCUMSTANCES

Next came *WesternGeco v. ION Geophysical Corp* in 2018, where the Supreme Court created the initial crack in the rule against extraterritoriality that *Brumfield* would widen: A lost-profit award can include lost foreign profits when the patent owner proves infringement under § 271(f)(2).⁵⁵

46. *See generally id.*

47. *Id.*

48. *Power Integrations*, 711 F.3d at 1370.

49. *Id.* at 1372.

50. *Id.* at 1371 (quoting 35 U.S.C. § 284).

51. *Id.*

52. *Id.* at 1372.

53. *See id.* at 1370–72.

54. *Power Integrations*, 711 F.3d at 1371.

55. *WesternGeco II*, 585 U.S. at 417.

Plaintiff WesternGeco owned patents that claimed systems for surveying the ocean floor.⁵⁶ A jury found that ION infringed these patents by manufacturing components of patent-claimed systems and exporting them abroad, where they were assembled in infringing systems.⁵⁷ Specifically, the jury found infringement under 35 U.S.C. § 271(f), and awarded lost-profit damages for the sale of ocean-surveying services outside the United States.⁵⁸

Consistent with its ruling in *Power Integrations*, the Federal Circuit held the award of lost-profit damages for foreign sales to be an impermissible extraterritorial application of U.S. patent law.⁵⁹ WesternGeco argued that *Power Integrations*'s ruling was limited to infringement under § 271(a), and therefore its ruling could not limit the damages recoverable from ION's § 271(f) infringement.⁶⁰ In response, the Federal Circuit reasoned that WesternGeco's reading impermissibly broadened the reach of patent damages.⁶¹ Because someone selling a patented invention in the United States is not liable for the use of the product abroad, the exporter of "the component parts cannot be liable for use of the infringing article abroad."⁶²

The Supreme Court reversed, holding that courts can award lost-profit damages based on foreign conduct when the underlying infringement involved exporting components that are assembled into an infringing system abroad.⁶³ The Court did not address the Federal Circuit's reasoning or its application of *Power Integrations*—a loose thread that *Brumfield* addresses later.⁶⁴ Instead, the Court analyzed the case as a matter of extraterritoriality: could the Patent Act be applied to ION's conduct outside the United States?⁶⁵

To answer this question, the Court applied the conventional test for extraterritoriality. When claims involve foreign conduct, courts only have power to hear the claims under two conditions. First, a court could find that the text of the statute itself rebuts the presumption against extraterritoriality.⁶⁶ Second, the court could find that the case involves a "domestic application" of the statute.⁶⁷ In *WesternGeco*, the Court declined to address whether the

56. *Id.* at 411.

57. *Id.*

58. *Id.*

59. *WesternGeco LLC v. ION Geophysical Corp.*, 791 F.3d 1340, 1350–51 (Fed. Cir. 2015) [hereinafter *WesternGeco I*].

60. *Id.* at 1351.

61. *Id.*

62. *Id.*

63. *WesternGeco II*, 585 U.S. at 417.

64. *Brumfield II*, 97 F.4th at 871.

65. *WesternGeco II*, 585 U.S. at 412.

66. *Id.* at 413 (citing *RJR Nabisco*, 579 U.S. at 337).

67. *Id.* (citing *RJR Nabisco*, 579 U.S. at 337).

presumption against extraterritoriality applied to the patent damages statute or if it had been rebutted.⁶⁸ Instead, the Court focused its analysis on determining whether there was a “domestic application” of the statute in the award against ION.⁶⁹

To determine if awarding lost foreign profits was a “domestic application” of the statute, the Court asked if the “conduct relevant to [the statute’s] focus occurred in United States territory.”⁷⁰ The Court identified that § 284’s remedies focused on “the infringement.”⁷¹ Through this lens, the damages provisions of § 284 were “merely the means” by which the statute remedies infringement.⁷² ION’s act of infringement was exporting components from the United States in violation of § 271(f), which regulates the domestic act of supplying components from the United States.⁷³ The Court reasoned that the focus of the statute’s application was ION’s domestic act of supplying.⁷⁴ Because this conduct occurred in the United States, the Court held that the lost-profit award was a domestic application of § 284.⁷⁵ Therefore, the Court upheld the jury award.⁷⁶

Justice Gorsuch’s dissent in *WesternGeco* expressed fear that the majority had authorized damage awards for any use of a patented invention abroad as long as one of its components was supplied from the United States.⁷⁷ Justice Gorsuch argued that the majority’s ruling would allow greater recovery when a defendant exports a component of an invention than when a defendant exports the entire invention.⁷⁸ The majority responded that this position “wrongly conflates legal injury with the damages arising from that injury.”⁷⁹ Without further elaboration on the difference between legal injury and damages in the patent context, the majority concluded that “taken together, § 271(f)(2) and § 284 allow[ed] the patent owner to recover for lost foreign profits.”⁸⁰

68. *WesternGeco II*, 585 U.S. at 413.

69. *Id.*

70. *Id.*

71. *Id.* at 414.

72. *Id.* at 416.

73. *Id.* at 415.

74. *WesternGeco II*, 585 U.S. at 415.

75. *Id.* at 416.

76. *Id.*

77. *Id.* at 423–24 (Gorsuch, J., dissenting).

78. *Id.* at 423 (Gorsuch, J., dissenting).

79. *Id.* at 417.

80. *WesternGeco II*, 585 U.S. at 417.

III. *BRUMFIELD V. IBG*

In *Brumfield*, the Federal Circuit extended *WesternGeco*'s ruling beyond lost-profit damages for infringement under § 271(f). The district court excluded a damages theory that claimed worldwide damages. The Federal Circuit upheld the exclusion, creating three notable shifts to the doctrine. First, the Federal Circuit allowed courts to consider foreign conduct when awarding reasonable-royalty damages. Second, the Federal Circuit expanded the consideration of foreign conduct when the underlying infringement is direct infringement. Finally, the Federal Circuit interpolated *WesternGeco* to recognize a causation requirement for patent damages.

A. DISTRICT COURT OPINION

Trading Technologies (“TT”) owned patents directed to computer interfaces for commodity trading and methods for placing trade orders using those interfaces.⁸¹ TT sued IBG for patent infringement in the Northern District of Illinois, alleging that IBG provided traders with software that infringed TT’s patents.⁸² TT asserted patent claims directed to methods and computer readable mediums (“CRMs”).⁸³ A jury found IBG directly infringed TT’s patent claims under § 271(a).⁸⁴

Instead of lost-profit damages, TT asked IBG to pay a reasonable royalty for its infringing behaviors.⁸⁵ TT’s reasonable-royalty damages theory included “foreign damages” for “making the accused products in the United States.”⁸⁶ Specifically, TT’s damages expert opined that TT was entitled to worldwide damages for the foreseeable and but-for results of IBG’s domestic infringement.⁸⁷

The District of Northern Illinois excluded this damages theory.⁸⁸ Noting that *WesternGeco*, which concerned lost-profit damages, “is of limited value” to a case involving reasonable-royalty damages, the court forbade the damages expert from including foreign users of the accused products in the royalty base.⁸⁹ The court also emphasized that this case involved infringement under

81. *Brumfield II*, 97 F.4th at 859.

82. *Id.*

83. *Id.* at 867.

84. *Brumfield v. IB LLC*, 586 F. Supp. 3d 827, 840 (N.D. Ill. 2022) [hereinafter *Brumfield I*].

85. *Brumfield II*, 97 F.4th at 865.

86. *Id.*

87. *Id.* at 866.

88. *Brumfield I*, 586 F. Supp. 3d at 840.

89. *Id.*; see also Order on Daubert Motion, *Brumfield I*, 586 F. Supp. 3d 827, Dkt. No. 1984.

§ 271(a), unlike *WesternGeco*, which involved infringement under § 271(f).⁹⁰ Because § 271(f) explicitly contemplates foreign activities that are actionable in the United States, and § 271(a) does not, the court declined to extend *WesternGeco*.⁹¹ The court also noted that *WesternGeco* had not explicitly overruled *Power Integrations*, which concerned damages for foreign conduct in a § 271(a) case.⁹² Therefore, the court applied the rule from *Power Integrations* instead of extending the reasoning in *WesternGeco* to § 271(a) infringement.⁹³ Accordingly, the court excluded TT's damages theory, holding TT was not entitled to worldwide damages.⁹⁴

B. FEDERAL CIRCUIT OPINION

On appeal, Brumfield, a trustee of TT,⁹⁵ argued that the district court erred by not applying the *WesternGeco* framework to determine whether the jury award was impermissibly extraterritorial.⁹⁶ The Federal Circuit agreed, but even applying *WesternGeco*, the court affirmed the exclusion of the worldwide damages theory.⁹⁷

1. *The Federal Circuit Extended the WesternGeco Framework to Reasonable-Royalty Awards for Direct Infringement*

The Federal Circuit clarified that district courts should apply the *WesternGeco* framework in extraterritoriality analysis instead of looking to *Power Integrations*.⁹⁸ First, when deciding if the application of the patent damages statute is impermissibly extraterritorial, courts must first identify the “statute’s focus.”⁹⁹ Then, the court should ask “whether the conduct relevant to the statutory focus in this case is domestic.”¹⁰⁰ Last, the court should ask if the infringement has “the needed causal relationship to the foreign conduct” that is the basis of the damages theory.¹⁰¹

First, the court justified expanding the *WesternGeco* framework to cover damages theories to compensate for direct infringement under § 271(a).¹⁰²

90. *Brumfield I*, 586 F. Supp. 3d at 840.

91. *Id.*

92. *Id.*

93. *Id.*

94. *Id.*

95. *Brumfield II*, 97 F.4th at 859.

96. *Id.* at 870.

97. *Id.* at 871.

98. *Id.* at 871.

99. *Id.* at 873 (citing *RJR Nabisco*, 579 U.S. at 337).

100. *Id.* at 873 (citing *WesternGeco II*, 585 U.S. at 414).

101. *Brumfield II*, 97 F.4th at 878.

102. *Id.* at 874–75.

Brumfield's software directly infringed in the United States, unlike *WesternGeco*, where components were exported from the United States and assembled into an infringing system abroad.¹⁰³ The Federal Circuit afforded little analysis to this difference, going so far as to say "nothing about the *WesternGeco* analysis . . . is altered when the infringement at issue is infringement under § 271(a) rather than § 271(f)."¹⁰⁴

Second, the court discussed why courts should use the *WesternGeco* framework to determine whether foreign conduct is a proper basis for a reasonable-royalty award.¹⁰⁵ The Federal Circuit noted that the *WesternGeco* Court did not distinguish between forms of damages in its extraterritoriality analysis, so its ruling could be extended to a different form of damages.¹⁰⁶ The Federal Circuit cautioned that the royalty base for a damages award "cannot include activities that do not constitute patent infringement."¹⁰⁷ However, the court held that a patentee may use foreign conduct that is not itself infringing to increase its reasonable-royalty rate through "show[ing] why that foreign conduct increases the value of the domestic infringement itself."¹⁰⁸

Finally, the Federal Circuit interpolated *WesternGeco* to recognize a causation requirement for all patent damages. While silent on the necessary level of proof for a lost-profit award, the Federal Circuit ruled that a patentee seeking a reasonable-royalty award can use foreign conduct to increase the value of the award if it explains why the royalty established at the hypothetical negotiation "would have properly been increased to reflect . . . prospective [conduct] abroad."¹⁰⁹

2. *Applying the WesternGeco Framework, the Federal Circuit Upheld the Exclusion of TT's Damages Theory*

Applying these three principles to the allegations against IBG, the Federal Circuit affirmed the exclusion of TT's foreign damages theory.¹¹⁰ According to the court, the damages theory lacked "the needed causal relationship" to making the accused products in the United States.¹¹¹

103. *Id.* at 875.

104. *Id.*

105. *Id.*

106. *Id.*

107. *Brumfield II*, 97 F.4th at 876 (quoting *AstraZeneca AB v. Apotex Corp.*, 782 F.3d 1324, 1343 (Fed. Cir. 2015)).

108. *Id.* at 877. The Federal Circuit also offers an example of such an increase if the domestic infringement "enables and is needed to enable otherwise-unavailable profits from conduct abroad." *Id.*

109. *Id.* at 880.

110. *Id.* at 879.

111. *Id.*

The jury found IBG liable for making, using, offering to sell, selling, or importing a claimed method and a claimed CRM under § 271(a).¹¹² However, the damages theory only claimed compensation for “making the accused products.”¹¹³ The Federal Circuit noted that “making the accused product” cannot describe infringing a method claim because methods are practiced, not made.¹¹⁴ In the case of a CRM claim, the domestic act of infringement is “making an individual memory-device unit.”¹¹⁵ For the CRM claims, the Federal Circuit found that the damages expert failed to tie the overseas purchase and usage of IBG’s software to a domestic act of infringement.¹¹⁶

TT’s damages expert opined that distributing the infringing software to customers outside the United States was the result of being designed and programmed in the United States.¹¹⁷ But designing and programming the software did not “make a CRM,” such as an individual memory-device unit, so the court found these actions did not constitute domestic acts of infringement.¹¹⁸ Instead of tying the damages theory to making a CRM, the damages expert focused on the use of the software itself, which the patent claims did not protect.¹¹⁹ The damages expert failed to connect the overseas purchase and usage of IBG’s software to a domestic act of infringement, so the Federal Circuit found that the district court correctly excluded her testimony.¹²⁰

After this holding, the Federal Circuit continued to outline the deficiencies of the excluded damages theory.¹²¹ This criticism is instructive of the requirements of a damages theory that includes foreign conduct in its reasonable-royalty calculation. Any such damages theory must present a “focused, coherent explanation of the required causal connection” between the foreign conduct and domestic infringement.¹²² In the reasonable-royalty context, a patentee needs to explain why the royalty established at the hypothetical negotiation would have been increased to reflect prospective conduct abroad.¹²³ Lastly, the Federal Circuit also acknowledged that such a

112. *See id.*

113. *Brumfield II*, 97 F.4th at 879.

114. *Id.*

115. *Id.*

116. *Id.*

117. *Id.* at 880.

118. *See id.*

119. *Brumfield II*, 97 F.4th at 879.

120. *Id.*

121. *Id.* at 880.

122. *Id.* at 881.

123. *Id.* at 880.

damages theory must apportion the value of the foreign conduct that is attributable to the claimed invention.¹²⁴

IV. ANALYSIS OF *BRUMFIELD V. IBG*

In *Brumfield*, the Federal Circuit ruled that the *WesternGeco* framework displaced *Power Integrations* as the required framework of analysis for a case involving 35 U.S.C. § 271(a) and a reasonable royalty.¹²⁵ But the Federal Circuit declined to “parse *Power Integrations* to identify which particular sentences are now superseded by *WesternGeco*.”¹²⁶ The court also explicitly declined to explore whether the facts of *Power Integrations* would have supported the same ruling under the *WesternGeco* framework.¹²⁷ Additionally, the court in *Brumfield* was silent on the role of foreign conduct in other patent damage awards. These questions are explored in the following Sections.

Section IV.A proposes a way to read *Power Integrations*, *WesternGeco*, and *Brumfield* to be consistent with one another by using foreign conduct as a tool to measure the proper amount of damages. The following three Sections explore how foreign conduct functions as a measure in three different damages contexts. First, Section IV.B examines the impact of *Brumfield* on lost-profit awards, arguing that foreign conduct must only be used to measure the amount of money that the infringer’s domestic infringement accrued abroad. Then, Section IV.C cautions that foreign conduct has no place in a royalty *base*, but foreign conduct may be considered in harmony with the *Georgia-Pacific* factors to determine the royalty *rate*. Lastly, Section IV.D discusses the potential for courts to use foreign conduct as a measure of willfulness in deciding whether to award enhanced damages.

A. PARSING *POWER INTEGRATIONS*, *WESTERNGECO*, AND *BRUMFIELD* TO CREATE A FRAMEWORK IN WHICH FOREIGN CONDUCT MEASURES, BUT DOES NOT PRODUCE, PATENT DAMAGES

The outcomes of *WesternGeco* and *Brumfield* seem to contradict *Power Integrations*. *Power Integrations* held that a patentee is not entitled to “*compensatory damages* for injury caused by infringing activity that occurred outside the territory of the United States.”¹²⁸ But *Brumfield* and *WesternGeco* involve two compensatory damages awards that considered activity that occurred outside

124. *Id.*

125. *Brumfield II*, 97 F.4th at 871.

126. *Id.*

127. *Id.*

128. *Power Integrations*, 711 F.3d at 1371 (emphasis added).

the United States.¹²⁹ *Brumfield* held that a patentee seeking a reasonable-royalty award could use foreign conduct to increase the value of the award if it explains why the royalty rate “would have properly been increased to reflect . . . prospective [conduct] abroad.”¹³⁰ *WesternGeco* held that a lost-profit award could “include lost foreign profits when the patent owner proves infringement under § 271(f)(2).”¹³¹

These cases can be synthesized into a single doctrine. Take *Brumfield* to establish a general rule for reasonable-royalty awards, *Power Integrations* to establish a general rule for lost-profits awards, and *WesternGeco* to be an exception to *Power Integrations*’s rule.

Viewed through this lens, some of *Power Integrations* remains good law. Indeed, the Federal Circuit declined to “parse *Power Integrations* to identify which particular sentences are now superseded by *WesternGeco*.”¹³² Thereby, the court suggested that some parts of *Power Integrations* are no longer binding, but that some parts still may be.

The following Sections identify two important principles from *Power Integrations* that *WesternGeco* may affect. Section IV.A.1 outlines that *Brumfield* does not address whether *Power Integrations*’s claim that foreign conduct cuts off the chain of causation from domestic infringement is still good law.¹³³ On the contrary, Section IV.A.2 argues that *WesternGeco* and *Brumfield* necessarily refute *Power Integrations*’s claims regarding compensatory damages. By this token, this Note proposes that the correct way to apply *Power Integrations*, *WesternGeco*, and *Brumfield* is through using foreign conduct to measure the value of domestic infringement.

1. The “Chain of Causation” Clause of Power Integrations May Remain Good Law

Power Integrations held that “the entirely extraterritorial production, use, or sale of an invention patented in the United States is an independent, intervening act that, under almost all circumstances, cuts off the chain of causation initiated by an act of domestic infringement.”¹³⁴ The Federal Circuit offered this as bright-line guidance on the scope of an infringer’s liability. The *Brumfield* court explicitly declined to comment on the extent to which proximate causation and foreseeability limit the scope of foreign liability.¹³⁵

129. See *Brumfield II*, 97 F.4th at 880; *WesternGeco II*, 585 U.S. at 417.

130. *Brumfield II*, 97 F.4th at 880.

131. *WesternGeco II*, 585 U.S. at 417.

132. *Brumfield II*, 97 F.4th at 871.

133. *Power Integrations*, 711 F.3d at 1371–72.

134. *Id.*

135. *Brumfield II*, 97 F.4th at 878.

The applicability of these doctrines in the context of patent damages has been the subject of debate,¹³⁶ and it is outside the scope of this Note, which analyzes the *new* open questions after *Brumfield*. Because *Brumfield* passed on this question, practitioners may still anchor their arguments in *Power Integrations* when advancing these arguments.

2. *The “Compensatory Damages” Clause of Power Integrations Must Be Construed Narrowly*

Power Integrations held that a patentee is not entitled to “compensatory damages for injury caused by infringing activity that occurred outside the territory of the United States.”¹³⁷ In light of *WesternGeco* and *Brumfield*, *Power Integrations*’s language about “compensatory damages” must be clarified not to extend to reasonable-royalty awards. Reasonable-royalty awards are compensatory damages.¹³⁸ *Brumfield* makes clear that damages may be awarded based on activity outside the United States.¹³⁹

A defendant may argue that the “compensatory damages” language remains good law, but that interpretation is misguided. Recall that *Power Integrations* prohibited “compensatory damages for injury caused by infringing activity that occurred outside the territory of the United States.”¹⁴⁰ A defendant, seeking to minimize its foreign liability, may argue that *Power Integrations* prohibited compensation for injury that occurs abroad. Because *Brumfield* did not discuss foreign injury—as the hypothetical negotiation that determines the royalty rate occurs before *any* infringement occurs—a defendant could therefore argue that *Power Integrations*’s prohibition on compensatory damages awards for foreign infringement remains binding even over *Brumfield*.¹⁴¹

A plaintiff may easily counter this textualist reading of *Power Integrations*. Activities outside the United States do not infringe patent rights,¹⁴² so conduct occurring outside the United States cannot be called “infringing activity.”¹⁴³ Therefore, prohibiting compensatory damages for injury caused by infringing activity that occurred outside the territory of the United States would be a

136. See, e.g., Nicolas E. Calcaterra, *The Supreme Court Denies Rebuttal: WesternGeco and Salvaging Extraterritorial Bars to Patent Liability*, 34 BERKELEY TECH. L.J. 925, 949 (2019) (discussing multiple viewpoints on the role of foreseeability in patent damages).

137. *Power Integrations*, 711 F.3d at 1371 (emphasis added).

138. See *Minks v. Polaris Indus., Inc.*, 546 F.3d 1364, 1372 (Fed. Cir. 2008) (referring to a “reasonable royalty” as a “compensatory award”).

139. *Brumfield II*, 97 F.4th at 880.

140. *Power Integrations*, 711 F.3d at 1371.

141. See MATTHEWS PATENT DIGEST, *supra* note 18, § 30:86.10.

142. See *Brown v. Duchesne*, 60 U.S. 183, 195–96 (1856).

143. *Contra Power Integrations*, 711 F.3d at 1371.

trivial rule: there is no such thing as infringing activity outside of the United States, so it can cause no injury, and so there is nothing to compensate.

But even supposing that such foreign injury from foreign infringement did exist, *WesternGeco* already rejected this hypothetical defendant's argument. Justice Gorsuch's dissent in *WesternGeco* expressed fears that the majority had authorized damage awards for any use of a patented invention abroad, as long as one of its components was supplied from the United States.¹⁴⁴ The majority responded that this position "wrongly conflates legal injury with the damages arising from that injury."¹⁴⁵ By this token, the foreign use of the patent is not independently actionable; foreign conduct does not produce new harm or injury. Rather, foreign conduct is merely the measure of how much the patentee has suffered as a result of the infringement.

But *how* should courts use foreign conduct as a measure of harm? The following Sections illustrate the answer through discussing how foreign conduct is a measure of the proper amount of damages in three different contexts: lost profits, reasonable royalties, and enhanced damages.

B. FOREIGN CONDUCT AS A MEASURE OF LOST-PROFIT AWARDS

The *Brumfield* court declined to speculate if *Power Integrations* would stand up under the *WesternGeco* framework.¹⁴⁶ Exploring this question will illustrate the effects of the *WesternGeco* framework on the determination of lost-profit awards. The discussion below illuminates a fork in the road: foreign conduct could be used as either a broad or narrow measure of lost-profit awards.

Recall how *Brumfield* describes the *WesternGeco* framework. First, when deciding if the application of a statute is impermissibly extraterritorial, courts must first identify the statute's focus.¹⁴⁷ Then, the court should ask whether the conduct relevant to the statute's focus is "domestic."¹⁴⁸ Last, the court should ask if the infringement has "the needed causal relationship" to the foreign conduct that is the basis of the damages theory.¹⁴⁹

Applying the *WesternGeco* framework to *Power Integrations*, the first two steps are unlikely to exclude the consideration of foreign conduct. *WesternGeco* and *Brumfield* clearly establish that the focus of § 284 is "the infringement."¹⁵⁰ *Power Integrations* involved direct infringement under § 271(a).¹⁵¹ Reading § 271(a)

144. *WesternGeco II*, 585 U.S. at 423–24 (Gorsuch, J., dissenting).

145. *Id.* at 417.

146. *Brumfield II*, 97 F.4th at 871.

147. *Id.* at 873 (citing *RJR Nabisco*, 579 U.S. at 337).

148. *Id.* (citing *WesternGeco II*, 585 U.S. at 414).

149. *Id.* at 874, 878.

150. *WesternGeco II*, 585 U.S. at 414.

151. *Power Integrations*, 711 F.3d at 1376.

into the focus, § 284 provides a remedy for the act of making, using, selling, or importing any patented invention within the United States.¹⁵² As another scholar has noted, this trivially shows a domestic application of the statute.¹⁵³

Therefore, the last element, analysis of the “needed causal relationship,” will almost always be dispositive.¹⁵⁴ After *Brumfield*, the reasonable royalty argument needs to show that the hypothetically negotiated royalty would have been increased to reflect prospective conduct abroad.¹⁵⁵ The *Brumfield* court did not offer explicit guidance on the required causal connection for a lost-profit award, so applying the *WesternGeco* to *Power Integrations* poses a choice. Courts could apply this principle to lost-profit awards under two potential frameworks.

First, courts could apply the causation principle loosely when using foreign conduct to measure lost profits. The question guiding the damages award under that framework would be: What amount of money did the infringer make in *foreign sales* that the patentee should have instead made through its *domestic practice* of the patent?

Alternatively, the court could apply this causation principle more narrowly when using foreign conduct to measure lost profits. The question guiding the damages award under that framework would be: What amount of money did the infringer’s *domestic infringement* accrue abroad?

The following Sections discuss the application of each interpretation, suggesting that the latter interpretation is more consistent with Federal Circuit case law.

1. *When Using Foreign Conduct as a Measure of Injury, Courts Should Not Focus on the Disgorgement of Foreign Profits*

The generous reading of *WesternGeco* suggests that an infringer should be disgorged for the foreign sales of patented products that the patentee would have otherwise made through its domestic practice of the patent.¹⁵⁶ In this view, the foreign sales constitute unjust enrichment, which should be disgorged from the defendant. However, this view is misguided. In synthesizing the new doctrine of foreign patent damages, *Power Integrations* should be read to reject this damage theory.

WesternGeco and *Brumfield* both agree that patent damages should be “the difference between [the patentee’s] pecuniary condition after the infringement,

152. 35 U.S.C. § 271(a).

153. Calcaterra, *supra* note 136, at 949.

154. *See generally Brumfield II*, 97 F.4th at 880.

155. *Id.*

156. *See generally WesternGeco II*, 585 U.S. at 407.

and what [its] condition would have been if the infringement had not occurred.”¹⁵⁷ This frames the issue as expectation damages, where the patentee should be provided the benefits they expected to receive had the infringement not occurred.¹⁵⁸ One such expected benefit is the sale of their patented products on a global marketplace. By this token, if a domestic infringer made sales that, absent the infringement, otherwise would have been the patentee’s—isn’t the patentee entitled to those lost profits? This damages theory could be said to remain domestic because it focuses on the domestic conduct that the patentee would have profited from if not for the infringer.

This generous reading, however, is difficult to reconcile with *Power Integrations*, where the Federal Circuit prohibited a similar damage theory.¹⁵⁹ Power Integrations originally supplied 100 percent of the controller chips for Samsung cellphone chargers, and after beginning to sell infringing chips, Fairchild took on 40 percent of Samsung’s business.¹⁶⁰ Noting that selling a patented invention abroad is not infringement, the Federal Circuit rejected Power Integrations’s claim to these profits.¹⁶¹ Some of Fairchild’s sales to Samsung occurred abroad, but absent Fairchild’s infringement, Power Integrations alleged that it would have sold Samsung the chips in the United States.¹⁶² A disgorgement framework, therefore, would condone this damages theory, because Fairchild’s foreign sales should have been Power Integrations’s domestic ones.

A disgorgement theory’s focus on unjust enrichment threatens to expand the scope of liability for patent infringement to be broader than ever before—even for domestic conduct. An infringer would not only be unjustly enriched through stolen profits, but also through avoided research and development (R&D) costs. Courts do not disgorge infringers of their avoided costs in patent cases.¹⁶³ This framework’s eye toward disgorgement also confuses the purposes of compensatory and punitive damages. Disgorgement “is assessed in part for punitive purposes, and in many cases, the award is not

157. *Brumfield II*, 97 F.4th at 874; *WesternGeco II*, 585 U.S. at 414–15.

158. *See* Fifth Third Bank v. United States, 518 F.3d 1368, 1374 (Fed. Cir. 2008) (discussing the nature of expectation damages).

159. Recall that *Brumfield* held that *Power Integrations*’s legal framework was superseded by *WesternGeco*, but *Brumfield* did not cast doubt on the court’s ultimate ruling to exclude the damages theory. *Brumfield II*, 97 F.4th at 871.

160. Brief for Plaintiff-Cross Appellant, *Power Integrations*, *supra* note 43, at 46.

161. *Power Integrations*, 711 F.3d at 1372.

162. *See* Brief for Plaintiff-Cross Appellant, *Power Integrations*, *supra* note 43, at 46.

163. *Prism Techs. LLC v. Sprint Spectrum L.P.*, 849 F.3d 1360, 1375 (Fed. Cir. 2017) (permitting evidence of an infringer’s avoided costs insofar as they were probative of the royalty rate the infringer would have agreed to pay, but not as an independent basis of damages).

compensatory.”¹⁶⁴ But § 284 authorizes only compensatory awards: “damages adequate to compensate for the infringement.”¹⁶⁵

2. *Using Foreign Conduct as a Measure of Injury Should Instead Focus on the Amount of Money That the Infringer’s Domestic Conduct Accrues Abroad*

Even before *Brumfield*, the Eastern District of Texas interpreted *WesternGeco* to authorize lost-profit damages for foreign sales if and only if the sales were the result of domestic infringement.¹⁶⁶ In 2019, *Plastronics* extended the holding of *WesternGeco* to a lost-profits case based on § 271(a) infringement.¹⁶⁷ The court characterized *WesternGeco* as holding “a plaintiff could recover foreign damages that resulted from domestic acts of infringement,” regardless of the type of damages sought or nature of underlying infringement.¹⁶⁸ The court also correctly cautioned, in accordance with *WesternGeco*, that a plaintiff cannot recover under § 271(a) for purely foreign manufacturing, use, or sales because these acts do not constitute infringement under § 271(a).¹⁶⁹

Helpfully, the *Plantronics* court offered examples of foreign activity coupled with domestic infringement that can authorize lost profit awards, e.g., an infringing product made in the United States that was sold abroad, or a product imported into the United States that was subsequently sold internationally.¹⁷⁰ The court noted that each of these instances involved conduct from a defendant that constituted infringement under § 271(a), and thus, under the reasoning of *WesternGeco*, was compensable even if the sale causing damage ultimately occurred abroad.¹⁷¹ By this token, foreign profits measure the patentee’s harm because they were where the domestic infringement finally accrued a measurable benefit.

WesternGeco, viewed through this lens, is consistent with the proposition that lost-profit awards must only compensate for the *domestic* actions of the infringer.¹⁷² ION’s infringement was shipping components of a patented invention overseas to be assembled.¹⁷³ The *WesternGeco* jury found that because

164. Liu v. Sec. & Exch. Comm’n, 591 U.S. 71, 76 (2020).

165. 35 U.S.C. § 284.

166. See generally *Plastronics Socket Partners, Ltd. v. Dong Weon Hwang*, No. 218CV00014JRGRSP, 2019 WL 4392525 (E.D. Tex. June 11, 2019), *report and recommendation adopted*, No. 218CV00014JRGRSP, 2019 WL 2865079 (E.D. Tex. July 3, 2019).

167. *Id.* at *4.

168. *Id.*

169. *Id.* at *5 (citing *WesternGeco II*, 585 U.S. at 410).

170. *Id.* at *5.

171. *Id.*

172. See *WesternGeco II*, 585 U.S. at 409.

173. *Id.*

ION supplied components to companies abroad, ION won ten contracts worth over \$90 million.¹⁷⁴ The jury found that absent ION's shipping of components, WesternGeco would have obtained, performed, and profited from these contracts.¹⁷⁵ Accordingly, the relevant "lost profits" were not merely for sales of ION's components, but instead the value of overseas contracts that WesternGeco lost to competitors as a result of ION's infringement.¹⁷⁶

This framework has the benefit of easier administration. *Power Integrations* ruled that no company would buy any of the Fairchild's infringing chips unless the resulting products could be sold in the United States.¹⁷⁷ This theory is a disgorgement theory because it argues that all of Fairchild's foreign profits should instead have been Power Integrations' domestic profits. But proving a blanket statement on the consumption of foreign consumers is inadministrable. In contrast, WesternGeco pointed to ten contracts and proved that they would have obtained, performed, and profited from these contracts.¹⁷⁸ This has a level of specificity that makes the causation requirement easier to satisfy.

C. FOREIGN CONDUCT AS A MEASURE OF REASONABLE-ROYALTY AWARDS

How should courts use foreign conduct to measure the proper amount that an infringer would have paid to engage in the infringing conduct, and how may practitioners argue that foreign conduct should increase a reasonable-royalty rate? Section IV.C.1 examines one court's misunderstanding of *Brumfield* to authorize the consideration of non-infringing conduct in a royalty base. Section IV.C.2 illustrates how foreign conduct may increase reasonable-royalty rates through the already-existing *Georgia-Pacific* factors.

174. Brief for Petitioner at 14, 25, *WesternGeco II*, 585 U.S. 407 (No. 16-1011), 2018 WL 1083739, at *14, *25; accord Brief for Respondent at 8, *WesternGeco II*, 585 U.S. 407 (No. 16-1011), 2018 WL 1517869, at *8.

175. Brief for Petitioner, *WesternGeco II*, *supra* note 174, at 14.

176. Compare *WesternGeco II*, 585 U.S. at 417 (affirming damages amount), with Brief for Petitioner, *WesternGeco II*, *supra* note 174, at 14, 25 (discussing amount and calculation of original damages amount).

177. Brief for Plaintiff-Cross Appellant, *Power Integrations*, *supra* note 43, at 46.

178. Brief for Petitioner, *WesternGeco II*, *supra* note 174, at 14.

1. *Patentees Should Not Include Foreign Conduct in Their Royalty Bases*

The *WesternGeco* dissent expressed fear that companies would interpret the causation requirement as broadening, not limiting, damages.¹⁷⁹ Expanding *WesternGeco*, then, also raises this fear, particularly that courts will include foreign conduct in a royalty base. District courts should be careful to apply the rule of *Brumfield* only as a measure of how much the infringer would agree to pay per use of the infringing product.

Recall that the royalty base is generally the number of times the infringing product was made, sold, used, or otherwise infringed.¹⁸⁰ And recall that making, selling, or using a patented product in another country is not infringement.¹⁸¹

IPA Technologies, the first district court opinion to cite *Brumfield*, curiously interpreted *Brumfield* to support the consideration of non-infringing *domestic* conduct in a royalty base.¹⁸² IPA Technologies sued Microsoft, alleging that servers embedded in Windows 10 infringed its patent.¹⁸³ IPA's proposed reasonable-royalty base included all sales of Windows 10¹⁸⁴ on the rationale that the infringing servers "can only be accessed by Windows 10 and can only serve Windows 10."¹⁸⁵ Microsoft moved for summary judgment on this damages theory, arguing that sales of Windows 10 could not form the royalty base because Windows 10 did not infringe, only the accused servers did.¹⁸⁶ Microsoft insisted that the damages calculation "must be tied to actual consumer usage of the accused server code," not of Windows 10 as a whole.¹⁸⁷ The District of Delaware denied Microsoft's motion of summary judgment to exclude this damages theory, finding that using Windows 10 as the royalty base was a "reasonable way of measuring" the impact of the infringement.¹⁸⁸

After *Brumfield*, Microsoft petitioned the court for reconsideration.¹⁸⁹ Citing *Brumfield*, Microsoft argued that "the royalty base for reasonable-royalty

179. *WesternGeco II*, 585 U.S. at 423 (Gorsuch, J., dissenting) ("[S]upplying a single infringing product from the United States would make ION responsible for any foreseeable harm its customers cause by using the product to compete against WesternGeco worldwide").

180. MATTHEWS PATENT DIGEST, *supra* note 18, § 30:89.

181. *Microsoft Corp.*, 550 U.S. at 437.

182. Memorandum Order, *IPA Techs., Inc. v. Microsoft Corp.*, No. CV 18-1-RGA, 2024 WL 1962070, at *1 (D. Del. May 2, 2024).

183. *Id.* at *2.

184. Memorandum Opinion at 40, *IPA Techs.*, No. CV 18-1-RGA (D. Del. May 2, 2024), Dkt. No. 247.

185. Memorandum Order, *IPA Techs.*, *supra* note 182, at *2.

186. Memorandum Opinion, *IPA Techs.*, *supra* note 184, at 42.

187. *Id.* at 46.

188. *Id.* at 39.

189. Memorandum Order, *IPA Techs.*, *supra* note 182, at *2.

damages cannot include activities that do not constitute patent infringement, like Windows 10.”¹⁹⁰ Curiously, the District of Delaware understood Microsoft to argue that damages theories cannot include consideration of any non-infringing product.¹⁹¹ The court cited *Brumfield* to support the opposite proposition: a non-infringing product may be considered when it “enables and is needed to enable otherwise-unavailable profits” from the non-infringing activity.¹⁹² Without addressing Microsoft’s narrower argument about Windows 10 as a royalty *base*, the court ruled that IPA Technologies’s proposed reasonable-royalty *rate* did not “capture more than the value of what was taken.”¹⁹³ Thereupon, the district court declined reconsideration and upheld the damages theory.¹⁹⁴ At trial, the jury found that IPA Technologies was entitled to \$242 million in reasonable-royalty damages.¹⁹⁵ After verdict, the parties dismissed the case pursuant to a settlement agreement, so the court’s characterization of *Brumfield* escaped appellate review.¹⁹⁶

IPA Technologies exists in a curious tension with *Brumfield*. The *Brumfield* court indeed held that a non-infringing product may be considered when it enables and is needed to enable profits from the non-infringing activity.¹⁹⁷ But it explicitly stated that this consideration cannot be in the royalty *base*, which “cannot include activities that do not constitute patent infringement.”¹⁹⁸ *Brumfield* explicitly forecloses a damages theory like IPA Technologies’s. There should be no compensation specifically for the sale of Windows 10, “which is not infringement at all.”¹⁹⁹ The District of Delaware seemed to not want to disturb a damages award that it considered proper,²⁰⁰ but it muddled its analysis in its ruling.

Instead, the better consideration of Windows 10 would be in the royalty rate. *Brumfield* supports a damages theory that technological integration with Windows 10 “increase[d] the value” of the domestically infringing servers.²⁰¹

190. *Id.* (citing *Brumfield II*, 97 F.4th at 876); see also Microsoft Corporation’s Opening Brief in Support of Its Partial Motion for Reconsideration at 3, *IPA Techs.*, No. CV 18-1-RGA (D. Del. Apr. 26, 2024), Dkt. No. 348.

191. Memorandum Order, *IPA Techs.*, *supra* note 182, at *1.

192. *Id.*

193. *Id.* at *3 (emphasis added).

194. *Id.*

195. Jury Verdict, *IPA Techs.*, No. CV 18-1-RGA (D. Del. May 10, 2024), Dkt. No. 371.

196. Joint Stipulation of Dismissal with Prejudice, *IPA Techs.*, No. CV 18-1-RGA (D. Del. June 20, 2024), Dkt. No. 407.

197. *Id.* at *1.

198. *Brumfield II*, 97 F.4th at 876 (quoting *AstraZeneca*, 782 F.3d at 1343).

199. See *id.* at 866.

200. Memorandum Order, *IPA Techs.*, *supra* note 182, at *2.

201. See *Brumfield II*, 97 F.4th at 877.

By this token, Microsoft may have been willing to pay more per use of the allegedly infringing servers—a higher royalty rate. The following Section outlines the proper ways to consider foreign conduct in consonance with *Brumfield*. Foreign conduct may be considered in the royalty base only to the extent that it would be the proper basis for a lost profit award.

2. *Brumfield Is Consistent with the Georgia-Pacific Factors*

Having clarified that foreign conduct may be considered in the royalty rate and not the royalty base, this Section outlines how foreign conduct may “increase the value of the domestic infringement.”²⁰² Practitioners should include these arguments in their existing analysis of the *Georgia-Pacific* factors, each of which embody a reason that an infringer would have agreed to pay a higher royalty rate.²⁰³ The following Sections discuss how foreign conduct fits into several of the existing *Georgia-Pacific* factors.

a) Factor 3: The Scope of the License

The third *Georgia-Pacific* factor is “[t]he nature and scope of the license, as exclusive or non-exclusive; or as restricted or non-restricted in terms of territory or with respect to whom the manufactured product may be sold.”²⁰⁴ This factor explicitly contemplates that the territorial scope of a license influences a royalty rate.²⁰⁵ Here, it is possible that a prospective infringer would pay more for a license that permits international sales from the United States than it would for one that only authorizes sales in the United States. This possesses the “required causal connection” because the sales abroad result from the domestic infringement: making the infringing product in the United States.²⁰⁶

b) Factor 5: The Commercial Relationship Between the Licensor and Licensee

The fifth *Georgia-Pacific* factor is “[t]he commercial relationship between the licensor and licensee, such as, whether they are competitors in the same territory in the same line of business.”²⁰⁷ Suppose a patentee and infringer are competitors in markets outside of the United States. A patentee will be less

202. *Brumfield II*, 97 F.4th at 877. The Federal Circuit also offers the example of such an increase if the domestic infringement “enables and is needed to enable otherwise-unavailable profits from conduct abroad.” *Id.*

203. *See supra* Section II.B.2.

204. *Georgia-Pacific*, 318 F. Supp. at 1120.

205. *See id.*

206. *See Brumfield II*, 97 F.4th at 880.

207. *Georgia-Pacific*, 318 F. Supp. at 1120.

willing to license to its competitor—especially if it competes in the market for the patented product *outside* the United States—leading to a higher royalty rate. After all, a company that buys the licensed product from the competitor in the United States may be more likely to also buy it from the competitor abroad. As above, this theory possesses the “required causal connection” because the sales abroad result from the domestic infringement of making the infringing product in the United States.²⁰⁸

c) Factor 6: Promotion of Sales of Non-Patented Items

The sixth *Georgia-Pacific* factor is “[t]he effect of selling the patented specialty in promoting sales of other products of the licensee; that existing value of the invention to the licensor as a generator of sales of his non-patented items.”²⁰⁹ Running with the same hypothetical from above, a company that buys the licensed product from the competitor in the United States may be more likely to also buy the competitor’s other products abroad. The potential sales boost to non-patented items outside of the United States may make the competitor more willing to pay a higher price to practice the patent in the United States. Therefore, the royalty established at the hypothetical negotiation could be increased to reflect prospective conduct abroad.²¹⁰

d) Factor 8: Established Profitability

The eighth *Georgia-Pacific* factor is “[t]he established profitability of the product made under the patent; its commercial success; and its current popularity.”²¹¹ If the competitor or patentee has a proven record of high profits from selling the product abroad, then the competitor would pay more to license the patent in the United States. Therefore, the royalty established at the hypothetical negotiation could be increased to reflect prospective conduct abroad.²¹²

e) Factor 11: Value of Invention to the Infringer

The eleventh *Georgia-Pacific* factor is “[t]he extent to which the infringer has made use of the invention; and any evidence probative of the value of that use.”²¹³ This factor does not reference the use of the invention in the United States, so it could cover prior use abroad. Suppose that prior to infringing in the United States, a competitor used the patented method to manufacture

208. See *Brumfield II*, 97 F.4th at 880.

209. *Georgia-Pacific*, 318 F. Supp. at 1120.

210. See *Brumfield II*, 97 F.4th at 880.

211. *Georgia-Pacific*, 318 F. Supp. at 1120.

212. See *Brumfield II*, 97 F.4th at 880.

213. *Georgia-Pacific*, 318 F. Supp. at 1120.

widgets abroad, to great success. A patentee may offer evidence that is probative of the value of that foreign use to suggest that the competitor would have paid more to license the patent to use the method for manufacturing in the United States.

D. FOREIGN CONDUCT AS A MEASURE OF WILLFUL INFRINGEMENT

Section IV.B.1 proposes that courts reject the disgorgement interpretation of *WesternGeco*'s causation framework in the context of lost-profit awards. But this is not to say that damages awards may never be increased to disgorge a defendant for their foreign bad acts. Indeed, it makes sense to increase damages awards to punish or deter wrongdoing, but this must be done by using foreign conduct as a measure of willfulness. Thereby, foreign conduct fits neatly into the existing framework of enhanced damages awards.

Section IV.D.1 illustrates a real-life scenario where enhanced damages based on foreign misconduct may be proper. Then, Section IV.D.2 applies the *WesternGeco* framework to the enhanced damages provision of § 284, arguing that it could render such an award impermissibly extraterritorial. Therefore, courts must be careful in applying *WesternGeco*.

1. Case Study: Power Integrations II

Interestingly, an example of seeking enhanced damages based on bad acts abroad is *Power Integrations II*.²¹⁴ On remand, after the Federal Circuit had excluded the evidence of foreign sales in a lost-sales award, Power Integrations instead argued that Fairchild had willfully infringed its patent.²¹⁵ The District of Delaware ruled that the Federal Circuit's *Power Integrations* decision did not prohibit punitive damages for foreign conduct, even though it prohibited compensatory damages for foreign conduct.²¹⁶ Specifically, the District of Delaware found that Fairchild's extraterritorial conduct "is relevant to assessing Fairchild's intent, and, hence, it may be considered as part of a record supporting a finding of willfulness."²¹⁷ Accordingly, the District of Delaware found that the infringement was willful.²¹⁸ However, the court ultimately declined to award enhanced damages because the patent invalidity ruling was too close of a call.²¹⁹ Nonetheless, *Power Integrations II* illustrates that foreign bad acts can establish willful infringement.

214. *Power Integrations, Inc. v. Fairchild Semiconductor Int'l, Inc.*, No. CV 04-1371-LPS, 2017 WL 6206382, at *13 (D. Del. Dec. 8, 2017) [hereinafter *Power Integrations II*].

215. *Id.*

216. *Id.* at *10.

217. *Id.* at *10.

218. *Id.* at *11.

219. *Id.* at *9.

2. *WesternGeco Does Not Prohibit Using Foreign Conduct as the Basis of Willful Infringement*

Brumfield is silent on the issue of extraterritoriality in enhanced damages awards.²²⁰ And to the extent that *Power Integrations* remains good law, its focus is on compensatory, not punitive awards.²²¹ Is considering foreign conduct in awarding enhanced damages—augmenting the actual damages to punish or deter wrongdoers—impermissibly extraterritorial? As *Power Integrations II* illustrates, courts already consider foreign conduct in determining whether infringement was willful, and *Brumfield* should not change that.

As *Brumfield* dictates, the *WesternGeco* framework guides how a court must determine the permissibility of considering foreign conduct as the basis of willful infringement awards.²²² As in *WesternGeco*, the relevant statute is § 284, but this time the relevant provision allows courts to “increase the damages up to three times the amount found or assessed.”²²³

The first step of the *WesternGeco* framework requires identifying the “statute’s focus.”²²⁴ The Supreme Court and Federal Circuit both found the focus of § 284 to be providing patent owners “complete compensation for infringements.”²²⁵ But they focused on the compensatory damages provision of the statute, not the enhanced damages provision.²²⁶ Just as the *WesternGeco* Court looked to jurisprudence to determine the focus of the first provision of § 284,²²⁷ determining the purpose of the enhanced damages provision requires analyzing case law. Federal Circuit case law explains that the two *focuses* of enhanced damages are punishment and deterrence.²²⁸

The next step of the *WesternGeco* framework requires asking if the conduct relevant to the statutory focus in this case is domestic.²²⁹ *WesternGeco* found that the conduct relevant to § 271(f)(2) was “the domestic act of supply[ing] in

220. See generally *Brumfield II*, 97 F.4th at 871.

221. *Power Integrations*, 711 F.3d at 1371.

222. *Brumfield II*, 97 F.4th at 871 (holding that the *WesternGeco* framework governs the “determination whether patent damages are properly awarded in a particular case based partly on conduct abroad”).

223. 35 U.S.C. § 284.

224. *Brumfield II*, 97 F.4th at 873 (citing *RJR Nabisco*, 579 U.S. at 337).

225. *Id.* (citing *WesternGeco II*, 585 U.S. at 408).

226. *WesternGeco II*, 585 U.S. at 414.

227. *Id.*

228. *See* *Avia Grp. Int’l, Inc. v. L.A. Gear Cal., Inc.*, 853 F.2d 1557, 1566 (Fed. Cir. 1988) (holding that “[o]ne purpose of an increased damage award is to deter willful patent infringement by punishing the willful infringer.”); *see also* *SRI Int’l, Inc. v. Advanced Tech. Lab’ys, Inc.*, 127 F.3d 1462, 1468 (Fed. Cir. 1997) (holding that “the remedy of enhancement of damages” is “primar[ily] punitive/deterr[ence]”).

229. *Brumfield II*, 97 F.4th at 873 (citing *WesternGeco II*, 585 U.S. at 414).

or from the United States.”²³⁰ *Brumfield* framed this inquiry as focusing on the “object of [the statute’s] solicitude, which can include the conduct it seeks to regulate, as well as the parties and interests it seeks to protect or vindicate.”²³¹ This poses a choice: do enhanced damages awards deter and punish foreign activity, or the willful infringement itself?²³²

This choice is dispositive of the framework’s outcome. If a court interpreted the award of enhanced damages to be concerned with regulating foreign conduct, then the application of § 284 could not be said to be domestic. But if the court interpreted the award of enhanced damages to be concerned with the willful domestic infringement itself, by the same token as *Brumfield*, the application of § 284 would be domestic.

Courts should carefully consider the evidentiary issues of proving willful infringement when considering whether the conduct relevant to § 284’s focus is domestic. The Federal Circuit instructs that the “tort of willful infringement arises upon deliberate disregard for the property rights of the patentee.”²³³ The evidence of an infringer’s subjective intent—the presence or absence of deliberate disregard—is commonly proven through careful consideration of the circumstances of the infringement.²³⁴ Through this lens, foreign conduct is merely a *measure* of willfulness, not the bad act that *itself* deserves punishment. The factors outlined in *Read v. Portec* are circumstantial evidence of subjective intent, not bad acts in themselves.²³⁵

Last in the *WesternGeco* framework is an inquiry into whether willful infringement “ha[s] the needed causal relationship to the foreign conduct.”²³⁶ In compensatory damages awards, courts ask how the foreign conduct increases the value of the domestic infringement.²³⁷ By this token, courts should ask if the foreign conduct increases the likelihood that, when the infringer committed domestic infringement, it acted knowingly or with

230. *Id.* (citing *WesternGeco II*, 585 U.S. at 415).

231. *Id.*

232. *See* 35 U.S.C. § 284.

233. *Vulcan Eng’g Co., Inc. v. Fata Aluminium, Inc.*, 278 F.3d 1366, 1378 (Fed. Cir. 2002).

234. *Gustafson, Inc. v. Intersystems Indus. Prods., Inc.*, 897 F.2d 508, 510–11 (Fed. Cir. 1990) (holding “[w]hether an act is ‘willful’ is by definition a question of the actor’s *intent*, the answer to which must be inferred from all the circumstances.”).

235. *See supra* Section II.B.3.

236. *Brumfield II*, 97 F.4th at 874, 878.

237. *Id.* at 877. The Federal Circuit also offers the example of such an increase if the domestic infringement “enables and is needed to enable otherwise-unavailable profits from conduct abroad.” *Id.*

deliberate disregard. As with compensatory damages awards, this will be a fact-specific inquiry.²³⁸

Accordingly, courts should consider that foreign bad acts can justify increasing damages awards. But consistent with *Power Integrations*, courts should not disgorge lost foreign profits that lack a causal connection to domestic infringement.²³⁹ Instead, courts should consider whether the foreign conduct makes it more likely that, at the time the defendant infringed in the United States, it acted with willful disregard for the patent.

V. CONCLUSION

Now more so than ever before, juries and judges are authorized to consider foreign conduct when determining the amount of damages that an infringer owes. Amidst the changing doctrine, courts should be careful not to make foreign bad acts independently actionable. Foreign activity can be a measure of injury, but it must not be mistaken for a cause of injury.

It is unclear what tactical advantage the expansion of foreign conduct will give to litigants. Perhaps patent plaintiffs, eager to get damning facts before the jury, will use foreign conduct damages theories to argue the relevance of foreign exploitation of the invention. Perhaps defendants, worried about the possibly increased scope of their liability, will be more willing to reach a settlement.

It is likely that international companies risk more by infringing in the United States. Now that the Supreme Court and Federal Circuit have expanded the ability of patent owners to recover for foreign conduct, offshore profits are not immune from damages awards. Businesses may begin to protect these offshore assets by creating American subsidiaries. Ultimately, sophisticated companies will structure themselves to minimize the scope of their risk, and the growing territorial reach of United States patent law threatens to expand it.

Only time will tell what the impact of *Brumfield* on lost-profit and enhanced damages awards will be. District courts should construe the impact of *Brumfield* on lost-profit awards narrowly because foreign bad acts are sometimes better punished through enhanced damages rather than disgorgement. Instead, lost-profit awards should focus on the amount of money that an infringer's domestic infringement accrues abroad—a measure, not a cause, of damages.

238. *See supra* Section II.B.3.

239. *Id.*

DESIGNING AROUND OBVIOUSNESS: THE IMPLICATIONS OF *LKQ V. GM GLOBAL*

Tyler Kotchman[†]

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I. INTRODUCTION

Design patents not only play a crucial role in safeguarding the unique visual and ornamental features of industrial products, but they can be worth millions and even shape the future of entire industries. A prime example is *Apple v. Samsung*, where Apple's design patents on the iPhone's iconic look were central to a multibillion-dollar lawsuit.¹ This case highlighted the immense financial value of design patents, underscoring their importance in maintaining a company's competitive edge and brand identity in fiercely competitive markets.

In the automotive industry, car manufacturers use design patents as a key tool to safeguard the aesthetic features of their vehicles from third-party suppliers and other manufacturers. However, the utilization of design patent protections also allows car manufacturers to maintain a monopoly over their automotive crash parts, such as bumpers, fenders, and mirrors, which has sparked significant legal and economic debates. Some critics argue that design patent protections allow manufacturers to inflate repair costs and limit

1. *Apple, Inc. v. Samsung Elecs. Co.*, 678 F.3d 1314, 1317–19 (Fed. Cir. 2012).

consumer choice.² Proponents of design patents assert that these protections incentivize innovation and ensure high-quality replacements.³

LKQ Corp. v. GM Global Technology Operations LLC involved a third-party supplier, LKQ, attempting to invalidate General Motors's design patent so LKQ could continue to sell their third-party parts after losing their license to the design patent.⁴ LKQ challenged the obviousness of the design patent, and spurred the Federal Circuit to address the question pending for over a decade and a half: whether the Supreme Court's determination for the standard of obviousness for utility patents applied to design patents.⁵ Obviousness is a key requirement for patents that prevents the granting of a patent that lacks apparent innovation.⁶ In the context of design patents, which protect the ornamental features of an article rather than its function, the obviousness inquiry asks whether the claimed design would have been obvious to an ordinary designer considering the prior art.⁷ Obviousness was extended to design patents through the Patent Act of 1952 under § 103 utilizing the same framework as utility patents.⁸ Applying the utility patent framework to design patents has caused confusion about which designs are protectable because there are no written claims in design patents. After § 103 was established, both design and utility patents developed through case law their own rigid but predictable way to determine eligibility based on obviousness.⁹ However, the Supreme Court shifted its opinion to disfavor a rigid obviousness test for utility patents. It reemphasized the more relaxed factors that it had established to determine obviousness but did not speak on design patents.¹⁰ Since the Supreme Court's determination on the standard for utility patent obviousness, the design patent community has been unsure if the rigid standard still applies to design patents.¹¹ In *LKQ*, the Federal Circuit determined that the relaxed factors reemphasized by the Supreme Court applied to design patents and

2. See, e.g., *Promoting Automotive Repair, Trade, and Sales (PARTS) Act of 2015: Hearing on H.R. 1057 Before the Subcomm. on Cts., Intell. Prop., & the Internet, 114th Cong.* 16 (2016) [hereinafter *Hearings*] (statement of Jack Gillis, Dir. of Pub. Affs., Consumer Fed'n of Am.) (arguing that the lack of competition for repair parts due to design patent protections allow car companies to charge monopolistic prices).

3. See, e.g., *Hearings, supra* note 2, at 8 (statement of Hon. Jerrold Nadler) (arguing that design protections create incentives for automakers to create innovative designs).

4. 102 F.4th 1280, 1287–88 (Fed. Cir. 2024).

5. See *id.* at 1293; *KSR Int'l Co. v. Teleflex Inc.*, 550 U.S. 398 (2007).

6. See 35 U.S.C. § 103.

7. *Id.*

8. Janice M. Mueller & Daniel Harris Bream, *Overcoming the "Impossible Issue" of Nonobviousness in Design Patents*, 99 KY. L.J. 419, 465 (2011).

9. *LKQ*, 102 F.4th at 1287.

10. *KSR*, 550 U.S. at 427–28.

11. *LKQ*, 102 F.4th at 1287.

eliminated the rigid framework.¹² The consequences of shifting from a rigid to a relaxed framework exposes up to four hundred thousand U.S. design patents to substantial uncertainty.¹³

A uniform standard to determine obviousness for design and utility patents can clean up the law most effectively because it offers a single set of factors to consider for any § 103 obviousness analysis. Still, the uniform standard that *LKQ* established fails to acknowledge the inherent differences between design and utility patents because *LKQ*'s design patent framework erroneously incorporates functional elements into a nonfunctional, or design-focused, analysis. This Note suggests that courts should filter out non-protectable functional elements under this new framework for obviousness before considering the difference between the prior art and the claimed design.¹⁴ Filtering out unprotectable functional elements, similar to how courts apply copyright law, ensures design patents protect what they intend to.

This Note examines the Federal Circuit's reasoning in *LKQ Corp. v. GM Global Technology Operations* and its consequences. Part II provides the legal background and history of design patent obviousness. Part III summarizes *LKQ Corp. v. GM Global Technology Operations*. Part IV analyzes the Federal Circuit's ruling, discusses the potential implications of utilizing the relaxed framework in the nonobviousness determination for design patents, evaluates the Patent Trial and Appeals Board's (PTAB) attempts to implement this ruling, and proposes additional considerations to better protect against functional elements receiving design protection. Part V provides concluding thoughts.

II. LEGAL BACKGROUND

The Federal Circuit's decision in *LKQ Corp.* reconciled how the nonobviousness standard for design patents, as established in § 103, aligns with the Supreme Court's holding in *KSR International Co. v. Teleflex Inc.* Section II.A describes the history of nonobviousness in utility patents and the establishment of the *Graham* factors to guide the courts in their determination. This Section also discusses the Supreme Court's rejection of a more rigid interpretation of § 103 for utility patents in *KSR*. Section II.B outlines the history of design patent nonobviousness and the Federal Circuit's *Rosen-Durling*

12. *Id.* at 1295.

13. Brief of Amicus Curiae Am. Intell. Prop. L. Ass'n in Support of Neither Party, *LKQ*, 102 F.4th 1280 (No. 21-2348), 2023 WL 5748137, at *26 [hereinafter AIPLA Brief].

14. *See LKQ*, 102 F.4th at 1298.

test to guide district courts in their nonobviousness determination for design patents.

A. HISTORY OF OBVIOUSNESS IN UTILITY PATENTS

Congress established an obviousness standard in § 103 for utility and design patents in the Patent Act of 1952.¹⁵ A claimed invention or design is not eligible for a patent unless it is determined to be nonobvious over prior art.¹⁶ However, lawmakers wrote § 103 with utility patents in mind. Section II.A.1 discusses the establishment of the *Graham* factors, which are factual inquiries to guide courts in making nonobviousness determinations. Section II.A.2 discusses the Supreme Court's rejection of the Federal Circuit's Teaching, Suggestion, or Motivation (TSM) test to determine the nonobviousness of design patents.

1. *Establishment of the Graham Factors, 1966*

The Supreme Court established a modern framework for obviousness analysis in *Graham v. John Deere Co.* In this case, the Court established four basic factual inquiries collectively known as the *Graham* factors for courts, the USPTO, and the PTAB to consider in their obviousness analysis.¹⁷ The first factor the courts need to determine is the scope and content of the prior art.¹⁸ There is a two-part test to determine the scope of analogous art for utility patents: “(1) whether the art is from the same field of endeavor as the claimed invention; and (2) if the reference is not within the field of the inventor's endeavor, whether the reference still is reasonably pertinent to the particular problem with which the endeavor is involved.”¹⁹ After establishing the scope, the second factor requires courts to determine the differences between the prior art and the claims of the current invention.²⁰ The third factor evaluates the level of ordinary skill in the pertinent art.²¹ The fourth and final factor allows for secondary considerations “to give light to the circumstances surrounding the origin of the subject matter sought to be patented.”²² The Court acknowledged commercial success, long-felt but unsolved needs, and failure of others as some potential secondary considerations.²³ The Court also was careful to note that the new test did not change the overall strictness courts

15. 23 A.L.R. Fed. 326 § 2[a] (1975).

16. 35 U.S.C. § 103.

17. *See generally* *Graham v. John Deere Co. of Kansas City*, 383 U.S. 1, 1 (1966).

18. *Id.* at 17.

19. *LKQ*, 102 F.4th at 1297.

20. *Graham*, 383 U.S. at 17.

21. *Id.*

22. *Id.*

23. *Id.*

previously applied § 103 and retained the relaxed standard of § 103 to determine obviousness.²⁴

2. *Introduction and Demise of the Teaching, Suggestion, or Motivation Test*

The broad *Graham* factors continued to guide the obviousness analysis until the Federal Circuit sought to answer obviousness questions with more uniformity and consistency due to lower courts' varying interpretations of the flexible *Graham* factors.²⁵ Courts applying the second *Graham* factor would look at the prior art of a claimed invention, and would combine multiple prior arts to demonstrate each element was independently known and the claimed invention was therefore obvious.²⁶ However, most new inventions rely upon the building blocks of previous innovations and are combinations of what is already known.²⁷ To address this, the court began employing a more rigid Teaching, Suggestion, or Motivation test that was still in line with the *Graham* factors but imposed additional requirements to lead to more predictable obviousness determinations.²⁸ This test added the requirement that a patent claim "is only proved obvious if 'some motivation or suggestion to combine the prior art teachings' can be found in the prior art, the problem's nature, or the knowledge of a person having ordinary skill in the art."²⁹

The Federal Circuit's TSM test dominated utility patent's obviousness analysis until the Supreme Court overruled it in the 2007 *KSR International Co. v. Teleflex Inc.* decision.³⁰ In *KSR*, Teleflex accused KSR of infringing its patent by adding an electric sensor to one of KSR's previously designed accelerator pedals.³¹ KSR counterclaimed that Teleflex's patent was invalid under § 103 because it was obvious.³² The Federal Circuit held that Teleflex's patent was nonobvious because, after applying the TSM test, the prior art would not have led a person of ordinary skill to put a sensor on a pedal like Teleflex did.³³ On writ of certiorari, the Supreme Court held that the TSM test was incompatible with its holding in *Graham* because it "transform[ed] the general principle into a rigid rule that limit[ed] the obviousness inquiry."³⁴ After overruling the TSM test, the Court determined Teleflex's patent claim was invalid as obvious

24. *Id.* at 19.

25. *KSR Int'l Co. v. Teleflex Inc.*, 550 U.S. 398, 407 (2007).

26. *Id.* at 418.

27. *Id.* at 418–19.

28. *Id.*

29. *Id.*

30. *Id.* at 427–28.

31. *Id.* at 406.

32. *Id.*

33. *Id.* at 413–14.

34. *Id.* at 419.

because combining an available sensor to a pedal was not an inventive step.³⁵ A person of ordinary skill in the relevant art was capable of, and the benefit of doing so was obvious.³⁶

The Supreme Court clearly refuted the rigid TSM test for obviousness in utility patents in *KSR*. The Court expressed concern about granting a patent based on the combination of the prior art, which is the principal reason for declining patents for obvious inventions.³⁷ A rigid test like TSM allowed for a patent to be granted by combining two prior art references, a pedal and an electric sensor. With the TSM test, the courts and patent examiner focused on the problem the patentee was trying to solve and limited the scope of their obvious analysis to elements of prior art designed to solve the same problem.³⁸ However, an obviousness analysis is not limited to the prior art of the same problem.³⁹ A person of ordinary skill would be able to fit the teachings of multiple patents together to solve a different problem and, therefore, required the Court to step in to prevent similar occurrences.⁴⁰ In its decision, the Court did not address whether the obviousness holding presented in *KSR* extended to design patents.⁴¹

B. ORIGIN AND HISTORY OF OBVIOUSNESS IN DESIGN PATENTS

Since the creation of design patents in 1842, courts have struggled to apply the utility patent framework seamlessly to design patent protections, particularly after the concept of nonobviousness was introduced in the Patent Act of 1952. This led to the creation of the *Rosen-Durling* test by the Federal Circuit. Section II.B.1 examines early cases from the Supreme Court and the Court of Customs and Patent Appeals (C.C.P.A.) that laid the groundwork for the court's decisions in *Rosen* and *Durling*. Section II.B.2 discusses the court's decisions on design patent obviousness in *Rosen* and *Durling* and the creation of the two-part test to determine nonobviousness in design patents. Section II.B.3 discusses the Federal Circuit's application of applying the *Rosen-Durling* test to assess the nonobviousness of a design patent.

1. *Development of Obviousness in Design Patents prior to Rosen-Durling*

As industrial design emerged in America, Congress sought to protect these designs with the first design patent statute in 1842, utilizing the framework of

35. *Id.* at 424.

36. *Id.*

37. *Id.* at 415–16.

38. *Id.* at 420.

39. *Id.*

40. *Id.* at 420–21.

41. *See generally id.*

the already-created utility patents.⁴² More than a century later, the passage of the Patent Act of 1952 introduced the nonobviousness requirement of § 103 into design patentability.⁴³ However, the drafters of the 1952 Act did not envision that design patents would require a standard for nonobviousness to determine eligibility and intentionally set aside the “problem” of designs for later attention.⁴⁴ Because this issue was never addressed by Congress, it was left to the courts to best interpret how § 103 applied to design protections.

The following Sections discuss how courts historically have interpreted design patent protections and how they apply § 103 to design protections. Section II.1.a discusses a landmark Supreme Court case about the combination of prior art. Section II.1.b discusses the C.C.P.A. and its decisions on design patent obviousness prior to the establishment of the *Rosen-Durling* Test, the standard that *LKQ* overturned.

a) Supreme Court on Design Patentability: *Smith v. Whitman Saddle Co.* (1893)

The Supreme Court addressed the patentability of designs in *Smith v. Whitman Saddle Co.*⁴⁵ in the late nineteenth century, prior to the establishment of an obviousness standard in patents.⁴⁶ In *Whitman Saddle Co.*, the Supreme Court focused on the skill involved in making the product embodying the design, stating “[n]othing more was done in this instance [. . .] than to put the two halves of these saddles together in the exercise of the ordinary skill of workmen of the trade, and in the way and manner ordinarily done.”⁴⁷ In *Whitman Saddle Co.*, the Supreme Court focused on a design’s patentability from a saddler’s perspective and not just as an unskilled or ordinary observer.⁴⁸ The required viewpoint perspective of a workman in the trade established in *Whitman Saddle Co.* carried over to the modern § 103 standard of obviousness, “a person having ordinary skill in the art to which the claimed invention

42. See Jason J. Du Mont & Mark D. Janis, *The Origins of American Design Patent Protection*, 88 IND. L.J. 837, 843 (2013).

43. Mueller & Bream, *supra* note 8, at 465–66.

44. *The Industrial Innovation and Technology Act: Hearing on S. 791 Before the Subcomm. on Patents, Copyrights & Trademarks of the S. Comm. on the Judiciary*, 100th Cong. 8 (1987) (statement of Hon. Giles S. Rich, Fed. Cir.) (“[W]hen we wrote the 1952 Patent Act, protection of designs was known to be a somewhat difficult problem. The [1952] Patent Act was primarily a codification, and we deliberately laid aside the whole problem of design legislation to be taken up at a later date.”).

45. *Smith v. Whitman Saddle Co.*, 148 U.S. 674 (1893).

46. See *id.*

47. *Id.* at 681.

48. See *id.*

pertains.”⁴⁹ The Court had not provided further guidance on design patentability since.

b) The Court of Customs and Patent Appeals on Nonobviousness

The C.C.P.A. began to restrict the prior art that could be used while conducting an obviousness analysis of a design. From 1929 until the establishment of the Federal Circuit in 1982, the C.C.P.A. had jurisdiction over direct appeals from the patent office.⁵⁰ The court in *In re Jennings* held that when determining the patentability of a design, the design must be viewed as a whole and compared to something in existence that could be created by combining features of different pieces of prior art.⁵¹ This case demonstrates the restriction the court begins to place on prior art by only allowing the current design to be compared to something in existence, and goes against the determination in *Whitman Saddle Co.*⁵² The Court in *Whitman Saddle Co.* determined that the combination of two different saddles, although not currently in existence, would be obvious to a workman in the trade.⁵³

However, the court in *In re Glavas*, clarified its position by allowing the combination of analogous art if the art “are so related that the appearance of certain ornamental features in one would suggest the application of those features to the other.”⁵⁴ This decision aligns with *Whitman Saddle Co.* by allowing the combination of ornamental features in prior art if they are so related.⁵⁵ But *Glavas* left open the question of what prior art would be so related that it would suggest the application of the features in the other.⁵⁶

2. *The Federal Circuit’s Establishment of the Two-Part Rosen-Durling Test*

Two notable cases, *In re Rosen* and *Durling v. Spectrum Furniture Co.*, continued to shape the legal framework for determining obviousness.⁵⁷ In *Rosen*, the court established a stringent requirement for evaluating design patent obviousness, mandating that a primary reference must be “basically the same” as the claimed design.⁵⁸ The rule significantly narrowed the scope of prior art that could be considered in the obviousness analysis, thereby

49. *See id.*; 35 U.S.C. § 103.

50. Mueller & Bream, *supra* note 8, at 469–70.

51. 182 F.2d 207, 208 (C.C.P.A. 1950).

52. *See id.*; *Whitman Saddle Co.*, 148 U.S. at 681.

53. *Whitman Saddle Co.*, 148 U.S. at 681.

54. 230 F.2d 447, 450 (C.C.P.A. 1956).

55. *See Whitman Saddle Co.*, 148 U.S. at 681–82.

56. *See Glavas*, 230 F.2d at 450.

57. *In re Rosen*, 673 F.2d 388, 389–90 (C.C.P.A. 1982); *Durling v. Spectrum Furniture Co.*, 101 F.3d 100, 102 (Fed. Cir. 1996).

58. *Rosen*, 673 F.2d at 391.

providing broader protection for design patents.⁵⁹ The Federal Circuit in *Durling* further expanded the framework by introducing a two-part test: first, a primary reference must be identified, or the analysis ends, and second, secondary references must be so closely related that their ornamental features suggest applying them to the primary reference.⁶⁰ Together, these decisions set the stage for the legal landscape regarding design patent obviousness until the 2024 *LKQ* decision, which marked a pivotal shift in the standard.

a) *In re Rosen*: Requirement of a Primary Reference That is “Basically the Same”

The C.C.P.A. attempted to define the lines of what prior art could be considered in determining the obviousness of a design in *In re Rosen*.⁶¹ In *In re Rosen*, a patent examiner rejected a claimed design for a coffee table because the combination of prior art references would have been obvious to a person of ordinary skill in the art (Figure 1).⁶² On appeal, the court reversed the patent office decision because there was not a single reference that was the same as the claimed design to support a holding of nonobvious.⁶³ The court turned to its prior holding in *In re Jennings*, where it held, “[i]n considering patentability of a proposed design the appearance of the design must be viewed as a whole [. . .] and compared with something in existence—not with something that might be brought into existence by selecting individual features from prior art and combining them.”⁶⁴ The court rejected the petitioner’s “regrouping” of furniture elements and imposed a requirement for a primary reference that was currently in existence (Figure 2).⁶⁵ The court’s holding required the design characteristics of the primary reference to be “basically the same” as the claimed design.⁶⁶ If no primary reference could be provided, then the obviousness inquiry ended without further consideration.⁶⁷ This primary reference is commonly referred to as the Rosen reference in § 103 obviousness cases.⁶⁸

59. *See id.*

60. *Durling*, 101 F.3d at 103.

61. *Rosen*, 673 F.2d at 390–91.

62. *Id.* at 389–90.

63. *Id.* at 390–91.

64. *Id.* at 391 (quoting *In re Jennings*, 182 F.2d 207, 208 (C.C.P.A. 1950)).

65. *Id.*

66. *Id.*

67. *See id.*

68. *LKQ Corp. v. GM Glob. Tech. Operations LLC*, 102 F.4th 1280, 1289 (Fed. Cir. 2024).

Figure 1: The Claimed Design of the Coffee Table

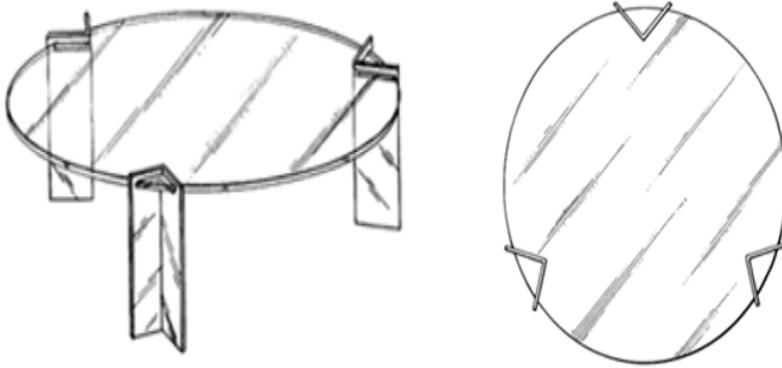
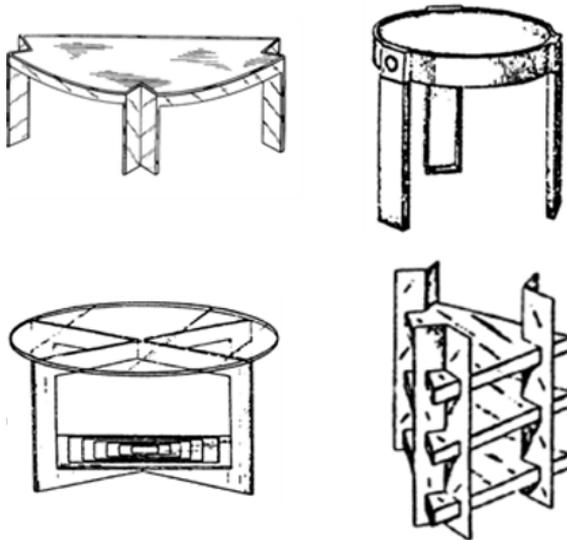


Figure 2: The Four Claimed Prior Arts with Elements of the Claimed Design



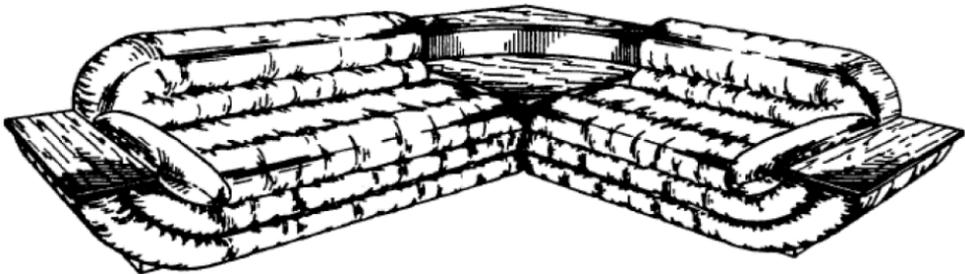
In re Rosen introduced a very rigid requirement to the obviousness analysis of design patents. Requiring a primary reference that is “basically the same” as the claimed design severely limited the prior art available to invalidate a patent and allowed designers to freely combine elements from previous designs as long as there is no prior art that could be considered “basically the same.”⁶⁹

69. *See id.*

b) *Durling v. Spectrum Furniture Co.*: Determining the Scope of Secondary References

The Federal Circuit addressed the permissible scope of prior art that may supplement a *Rosen* Reference in *Durling v. Spectrum Furniture Co.*⁷⁰ In this case, Durling sued Spectrum for infringing on their design patent for a sofa.⁷¹ Spectrum defended itself by arguing that Durling's design patent was not eligible because it was obvious.⁷² The district court relied on Durling's concession that a different sofa manufactured by Schweiger Furniture Industries Inc. was the closest prior art for the primary reference and found that the differences between the Durling sofa and the Schweiger sofa were insignificant (Figures 3 and 4).⁷³ In addition to a secondary consideration of the lack of commercial success of Durling's sofa, the district court found Durling's design patent invalid for obviousness.⁷⁴

Figure 3: Claimed Design: Durling's Sofa



70. *Durling v. Spectrum Furniture Co.*, 101 F.3d 100, 103 (Fed. Cir. 1996).

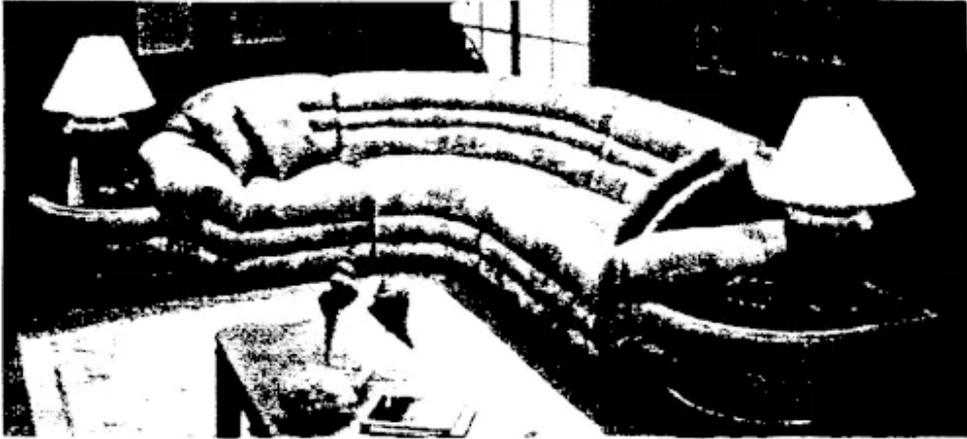
71. *Id.* at 101–02.

72. *Id.* at 102.

73. *Id.*

74. *Id.*

Figure 4: Prior Art: Schweiger's Sofa



On appeal, however, the Federal Circuit did not agree that the differences between the two sofas were insignificant.⁷⁵ The Federal Circuit stated a two-part test to determine obviousness. The first part confirmed the decision in *Rosen*, requiring a single prior art reference currently in existence with basically the same design characteristics as the claimed design.⁷⁶ For the second part of the test, the court held that once a primary reference was found, secondary references must be “so related [to the primary reference] that the appearance of certain ornamental features in one would suggest the application of those features to the other.”⁷⁷

The court then applied its two-factor test to the facts before it. The Federal Circuit found that the district court improperly interpreted Durling’s design claims as more general abstract design concepts rather than looking at the actual overall appearance.⁷⁸ The court found no prior art that would create basically the same overall impression as the claimed Durling design, and therefore it was improper to invalidate the design patent on the grounds of obviousness.⁷⁹

The Federal Circuit criticized the district court for looking at Durling’s claimed design too broadly by just describing the claimed design as a sectional sofa with end tables.⁸⁰ The Federal Circuit pointed out all the differences between Durling’s design and the Schweiger sofa and noted that the significant

75. *Id.* at 103.

76. *Id.*

77. *Id.* at 103 (internal citations omitted).

78. *Id.*

79. *Id.* at 104.

80. *Id.*

differences could not create basically the same visual impression.⁸¹ *Durling* further confirmed the high threshold for a primary reference established by *Rosen* and further established that any secondary reference must be “so related” to the primary reference that the appearance of certain ornamental features in one would suggest the application of those features to the other.”⁸² The *Rosen-Durling* test in the Federal Circuit guided all obviousness analyses for design patents from the *Durling* decision in 1996 until it was overturned in *LKQ* in 2024.⁸³ The high threshold requirement of a *Rosen* reference made it extremely difficult to invalidate patents on obviousness grounds because of the difficulty in finding a primary reference that is “basically the same.”⁸⁴

3. Court Opinion Under the *Rosen-Durling* Test

Titan Tire Corp. v. Case New Holland, Inc. provides an example of the Federal Circuit applying the *Rosen-Durling* test.⁸⁵ In this case, Titan Tire filed a motion for a preliminary injunction to prohibit Case New Holland from selling its allegedly infringing tires.⁸⁶ However, the trial court found that Case New Holland was likely to succeed on its invalidity claim (obviousness) against Titan Tire’s design (Figure 5) and did not grant the injunction.⁸⁷ In applying the first part of the *Rosen-Durling* test, the Federal Circuit confirmed the trial court’s finding that the primary reference, Ram Maxi-Trac tires (Figure 6), had design characteristics that are basically the same as Titan Tire’s patented design.⁸⁸ Moving to the second part of the *Rosen-Durling* test, the Federal Circuit again confirmed the trial court’s finding that secondary references, which had the hexagonal lug heads that the primary reference was missing, could be combined to create the same overall appearance as Titan Tire’s claimed design.⁸⁹ The court found that both parts of the *Rosen-Durling* test were satisfied. It upheld the trial court’s denial of the motion because of the likelihood that the design patent would be found invalid as obvious.⁹⁰

81. *Id.*

82. *Id.* (cleaned up).

83. *See LKQ Corp. v. GM Glob. Tech. Operations LLC*, 102 F.4th 1280, 1287 (Fed. Cir. 2024).

84. *See Durling*, 101 F.3d at 103.

85. *Titan Tire Corp. v. Case New Holland, Inc.*, 566 F.3d 1372, 1383 (Fed. Cir. 2009).

86. *Id.* at 1375.

87. *Id.* at 1385.

88. *Id.* at 1381.

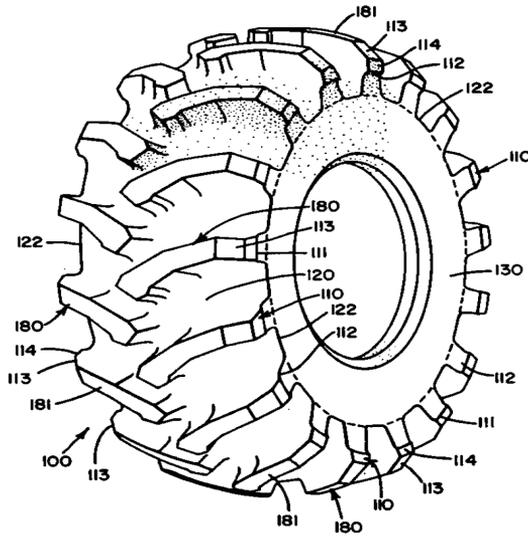
89. *Id.* at 1383.

90. *Id.* at 1385.

Figure 5: Titan Tire's Claimed Design



Figure 6: Primary Reference Ram Maxi-Trac Tires



In this case, the Federal Circuit explicitly chose not to address whether the recently decided Supreme Court case *KSR International Co. v. Teleflex, Inc.* applied to design patents.⁹¹ The court did note that it was not clear whether the Supreme Court meant to exclude design patents from the reach of *KSR*, but since the trial court's decision did not rely on *KSR*, the Federal Circuit chose not to address it.⁹² It would take until *LKQ*, fifteen years later, for the court to revisit if *KSR* applied to design patents.

III. *LKQ CORPORATION V. GM GLOBAL TECHNOLOGY OPERATIONS*

In *LKQ Corporation v. GM Global Technology Operations*, the Federal Circuit sitting en banc overruled the *Rosen-Durling* test for determining obviousness in design patents. The en banc panel concluded that the rigid requirements of the *Rosen-Durling* test were inconsistent with the flexible standard of § 103 and prior Supreme Court decisions, including *KSR* and *Whitman Saddle Co.*⁹³ The court set forth a new framework for design patent obviousness analysis that utilizes the *Graham* factors from utility patents. Section III.A gives the background on LKQ's obviousness claim and summarizes the PTAB and Federal Circuit's decisions. Section III.B discusses the en banc panel's decision and reasoning and discusses how the court applied the *Graham* factors to design patents. It also discusses the remaining open questions after applying the *Graham* factors to design patents, including the scope of analogous art and secondary considerations. Section III.C discusses the USPTO's current guidance to examiners for design patent obviousness determinations and how the guidance addressed the remaining open questions.

A. BACKGROUND ON LKQ'S OBVIOUSNESS CLAIM AND THE PTAB'S AND FEDERAL CIRCUIT'S DECISION

LKQ Corporation and Keystone Automotive (collectively, LKQ) filed a petition for an *inter partes* review against GM Global Technology Operations, Inc. (GM) for a design patent on a "vehicle's front fender."⁹⁴ LKQ asserted that the challenged claim was unpatentable under 35 U.S.C. § 103 based on the previous fender alone or as modified by a promotional brochure depicting the design of the front fender on the 2010 Hyundai Tucson (Figure 7).⁹⁵ Looking

91. *Id.* at 1384–85.

92. *Id.*

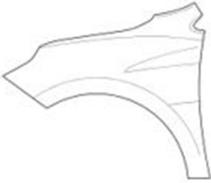
93. *LKQ Corp. v. GM Glob. Tech. Operations LLC*, 102 F.4th 1280, 1294 (Fed. Cir. 2024).

94. *Id.* at 1288.

95. *Id.*

at LKQ’s obviousness claim, the PTAB applied the long-standing *Rosen-Durling* test and found that LKQ had failed to identify a *Rosen* reference that was “basically the same.”⁹⁶ Since there was no *Rosen* reference, the PTAB ended its obviousness analysis, finding that GM’s design patent would not have been obvious.⁹⁷

Figure 7: GM’s Claimed Design and LKQ’s Proposed Prior Art

'625 PATENT CLAIMED DESIGN	LIAN PRIMARY REFERENCE	TUCSON SECONDARY REFERENCE
		

LKQ appealed this decision, contending that the Supreme Court had implicitly overruled the *Rosen-Durling* test in their *KSR* decision.⁹⁸ As a panel, the Federal Circuit could not overrule *Rosen* or *Durling*; the court needed to hear the case en banc to overrule its precedent.⁹⁹ So, the court was bound to apply the existing law, and it was unclear if the Supreme Court overruled the *Rosen-Durling* test for design patents in *KSR*.¹⁰⁰

96. *Id.* at 1289.

97. *Id.*

98. *LKQ Corp. v. GM Glob. Tech. Operations LLC*, No. 2021-2348, 2023 WL 328228, at *2 (Fed. Cir. Jan. 20, 2023), *reh'g en banc granted, opinion vacated*, 71 F.4th 1383 (Fed. Cir. 2023), and *on reh'g en banc*, 102 F.4th 1280 (Fed. Cir. 2024).

99. *See LKQ*, 102 F.4th at 1290; *see also Deckers Corp. v. United States*, 752 F.3d 949, 965 (Fed. Cir. 2016) (explaining panels are “bound by prior panel decisions until they are overruled by the court en banc or the Supreme Court”).

100. *LKQ*, 102 F.4th at 1290; *see also Deckers Corp.*, 752 F.3d at 965 (explaining panels are “bound by prior panel decisions until they are overruled by the court en banc or the Supreme Court”).

B. EN BANC PANEL'S DECISION, REASONING, AND UTILIZATION OF THE *GRAHAM* FACTORS FOR DETERMINING OBVIOUSNESS IN DESIGN PATENTS

To answer whether *KSR* overruled *Rosen* or *Durling*, the Federal Circuit vacated the panel opinion and granted a hearing en banc.¹⁰¹ The en banc panel determined that the § 103 statute for obviousness along with the Supreme Court's precedents in *Whitman Saddle Co.*, *Graham*, and *KSR*, all suggested a more flexible approach than the current *Rosen-Durling* test.¹⁰² First, the en banc panel turned to the language of § 103 and determined that it set forth an expansive and flexible approach for assessing obviousness.¹⁰³ *Rosen's* rigid requirement limiting a primary reference to designs that are "basically the same" as the claimed design—and abruptly ending the obvious analysis if one could not be identified—was at direct odds with the broad and flexible standard in § 103.¹⁰⁴

Next, the panel found that *Rosen's* "basically the same" requirement was at odds with the Supreme Court's analysis in *Whitman Saddle Co.* The panel noted that in *Whitman Saddle Co.*, the Court did not ask if the prior art was "basically the same."¹⁰⁵ Instead, the Court acknowledged that the claimed design combined the front and the rear of two prior arts, which was a customary combination for saddlers to make.¹⁰⁶ The panel held that *Whitman Saddle Co.* opposed *Rosen's* "one-size-fits all approach" because finding a single reference that discloses nearly every aspect of the claimed design would not fit all obviousness scenarios.¹⁰⁷ The *Rosen* requirement would not find it obvious to combine two ends of a saddle even though it is a common and customary practice for saddlers.¹⁰⁸

Additionally, the panel found that the strict *Rosen* reference requirement conflicted with the Supreme Court's guidance in *KSR*. The Supreme Court explained that "[w]hen a court transforms [a] general principle into a rigid rule that limits the obviousness inquiry . . . it errs."¹⁰⁹ The Court in *KSR* emphasized the "expansive and flexible approach" outlined in § 103 and *Graham* and reiterated the need for caution in granting a patent based on the combination

101. *LKQ*, 102 F.4th at 1290.

102. *Id.* at 1293.

103. *Id.* at 1294.

104. *Id.*

105. *Id.*

106. *Id.*

107. *Id.*

108. *See* *Smith v. Whitman Saddle Co.*, 148 U.S. 674, 681 (1893).

109. *KSR Int'l Co. v. Teleflex Inc.*, 550 U.S. 398, 419 (2007).

of elements in the prior art.¹¹⁰ The panel noted that the flexible approach the Court emphasized, in addition to the need for caution in granting a patent that claims an obvious combination of elements, is directly at odds with the rigid requirement for a *Rosen* reference.¹¹¹

Next, considering the second part of the *Rosen-Durling* test, the en banc panel found that the “so related” requirement added a restriction that was at odds with the broad standard for prior art in § 103.¹¹² Section 103 required comparing the claimed design to the prior art to determine if the claimed design as a whole would have been obvious to a person having ordinary skill in the relevant field.¹¹³ The panel held that nothing in the statute would indicate that the secondary prior art references must be “so related” to the primary that it creates its own motivation to combine them.¹¹⁴

Additionally, the panel found the “so related” requirement too rigid and analogous to the rigid application of the TSM test that the Supreme Court rejected in *KSR*.¹¹⁵ The panel also found the second part of the test inconsistent with the Supreme Court’s decision in *Whitman Saddle Co.* In *Whitman Saddle Co.*, the Court relied on the knowledge and practice of a saddler or ordinary workman in the trade, determining that putting two halves of saddles together was an exercise of ordinary skill and in the way and manner customarily done.¹¹⁶ The Court did not rely on a “so related” requirement to combine prior art references but instead on the knowledge of a person of ordinary skill in the relevant field, consistent with the framework the Court laid out in *Graham*.¹¹⁷

To replace the *Rosen-Durling* test, the panel turned to the *Graham* factors, finding that obviousness for design patents should be determined on factual criteria similar to tests developed for reviewing the validity of a utility patent under § 103.¹¹⁸ Applying the *Graham* factors in a design patent context, the panel held that the fact finder should consider the “scope and content of the prior art” that is within the knowledge of an ordinary designer in the field of design.¹¹⁹

As in *Graham*, to reign in the scope of prior art and prevent hindsight after dismissing the “so related” requirement, the panel applied the analogous art

110. *Id.* at 415.

111. *LKQ*, 102 F.4th at 1294.

112. *Id.* at 1294–95.

113. 35 U.S.C. § 103.

114. *LKQ*, 102 F.4th at 1295.

115. *Id.*

116. *Smith v. Whitman Saddle Co.*, 148 U.S. 674, 681 (1893).

117. *LKQ*, 102 F.4th at 1295.

118. *Id.*

119. *Id.* at 1295–96.

requirement to the obviousness of design patents.¹²⁰ As stated previously, there is a two-part test to determine the scope of analogous art for utility patents: “(1) whether the art is from the same field of endeavor as the claimed invention; and (2) if the reference is not within the field of the inventor’s endeavor, whether the reference still is reasonably pertinent to the particular problem with which the endeavor is involved.”¹²¹ The panel applied the first part of the test to design patents, straightforwardly stating that “analogous art for a design patent includes art from the same field of endeavor as the article of manufacture of the claimed design.”¹²² The panel acknowledged that the second part of the test does not apply directly to design patents since they do not articulate a particular problem involving the inventor or designer.¹²³ Although the second part of the test would not apply to design patents, the panel declined to define the full contours of the analogous art test. It left the question to be addressed on a case-by-case basis and for future cases to develop a standard.¹²⁴

Applying the second *Graham* factor to design patents, a court must assess the differences between the visual appearances of the claimed design and the prior art designs from the perspective of the ordinary designer in the field of the article of manufacture.¹²⁵ The panel likened this factor to design patent infringement, where the visual appearance of the claimed design is compared to that of the allegedly infringing design—but, instead of comparing the claimed design to an infringing design, it is compared to prior art designs.¹²⁶

The panel interpreted the third *Graham* factor in the design patent context as assessing the obviousness of a design from the viewpoint of an ordinary designer in the related field of the design.¹²⁷

For the final *Graham* factor, the panel acknowledged the requirement to assess secondary considerations when evidence of considerations is

120. *Id.* at 1296.

121. *Id.* at 1297.

122. *Id.*

123. *Id.*

124. *Id.* at 1297–98.

125. *Id.* at 1298; *see* *Apple, Inc. v. Samsung Elecs. Co.*, 678 F.3d 1314, 1329 (Fed. Cir. 2012) (characterizing obviousness as whether “one of ordinary skill would have combined teachings of the prior art to create the same overall visual appearance as the claimed design” (quoting *Titan Tire Corp. v. Case New Holland, Inc.*, 566 F.3d 1372, 1381 (Fed. Cir. 2009))).

126. *LKQ*, 102 F.4th at 1298; *see* *Egyptian Goddess, Inc. v. Swisa, Inc.*, 543 F.3d 665, 676 (focusing on the “overall appearance of the design” in assessing design patent infringement).

127. *LKQ*, 102 F.4th at 1298–99; *In re Nalbandian*, 661 F.2d 1214, 1216 (C.C.P.A. 1981) (holding that “[i]n design cases we will consider the fictitious person identified in § 103 as ‘one of ordinary skill in the art’ to be the designer of ordinary capability who designs articles of the type presented in the application,” which is consistent with the third *Graham* factor).

presented.¹²⁸ Prior cases involving secondary considerations confirmed that at least commercial success, industry praise, and copying could be used to indicate the nonobviousness of design patents.¹²⁹ The panel left it to future cases to decide if other considerations, such as a long-felt but unsolved need, failure of others, or any other potential secondary considerations apply in the design patent context.¹³⁰

C. OPEN QUESTIONS AFTER *LKQ* AND THE USPTO'S GUIDANCE TO EXAMINERS

Although the en banc panel walked through how the *Graham* factors would apply in the design patent space, it still acknowledged that there were some open questions, including the scope of the prior art that should be considered and any additional secondary considerations, to be answered on a case-to-case basis.¹³¹ After the Federal Circuit's decision in *LKQ*, the USPTO released a memo with updated guidance and examination instructions for determining the obviousness of design patent claims.¹³² The guidance does not bind the courts and is used to assist examiners in the obviousness analysis.¹³³ The updated guidance addressed but did not answer the remaining two open questions. The USPTO addressed the first question of how to determine whether a prior art design outside the field of endeavor of the article of manufacture is analogous.¹³⁴ Examiners were directed to consider the degree to which an ordinary skilled designer would be motivated to consider other fields.¹³⁵ Additionally, the USPTO advised examiners to confer with their supervisory patent examiner or look at examples of what has been determined to be analogous.¹³⁶ The guidance did not effectively answer the open question of the scope of analogous art. It still leaves it open to the examiner to consider a broad scope of analogous art to invalidate design patents on obviousness

128. *LKQ*, 102 F.4th at 1300.

129. *See, e.g.*, *Campbell Soup Co. v. Gamon Plus, Inc.*, 10 F.4th 1268, 1276–79 (Fed. Cir. 2021) (considering evidence of commercial success, industry praise, and copying); *MRC Innovations, Inc. v. Hunting Mfg., LLP*, 747 F.3d 1326, 1335–36 (Fed. Cir. 2014) (considering evidence of commercial success, copying, and acceptance by others).

130. *LKQ*, 102 F.4th at 1300.

131. *See id.* at 1297–1300.

132. *See generally* Memorandum from Katherine K. Vidal, Dir., U.S. Pat. & Trademark Off., to P.T.A.B., Updated Guidance and Examination Instructions for Making a Determination of Obviousness in Designs in Light of *LKQ Corp. v. GM Global Technology Operations LLC* (May 22, 2024) [hereinafter PTO Guidance].

133. *In re Rudy*, 956 F.3d 1379, 1383 (Fed. Cir. 2020) (holding that the Federal Circuit is not bound by USPTO guidance).

134. PTO Guidance, *supra* note 132, at 2.

135. *Id.*

136. *See id.*

grounds.¹³⁷ If the scope is vast, as it could be hard to determine the exact field a designer operates in and allow for hindsight, then the continued precedent and examples that the examiner will continue to consider will lead to potentially more patents being found invalid on obviousness grounds.

The new USPTO guidance also did not address the potential for any new secondary considerations. It focused on the considerations outlined by the panel of commercial success, industry praise, and copying.¹³⁸ Secondary considerations can be powerful enough to overturn a *prima facie* case of obviousness, so there remains the potential that new secondary considerations may still be introduced that could influence the examiner's final decision on obviousness.¹³⁹

IV. IMPLICATIONS OF UTILIZING THE *GRAHAM* FACTORS AND AN OPPORTUNITY TO FILTER OUT UNPROTECTABLE FUNCTIONAL ELEMENTS FROM OBVIOUSNESS ANALYSIS

The fallout from shifting to utilizing the *Graham* factors for design patent obviousness analysis will lead to a major change in what designs are considered obvious to a court or examiner. Section IV.A discusses the potential implications of this ruling, one being the increased difficulty of receiving and enforcing design patents, using repair parts in the automotive industry as an example. In addition, it discusses the implications of *LKQ* from the PTAB's most recent ruling in *Next Step Group, Inc. v. Deckers Outdoor Corp.*¹⁴⁰ Section IV.B analyzes *why* the Federal Circuit would choose to make this ruling and align the design patent obviousness factors to utility patents. Section IV.C explores how applying the second *Graham* factor could be used to filter out unprotectable functional elements. Utilizing an abstraction, filtration, and comparison test similar to the Second Circuit's copyright infringement test will allow examiners and courts to filter out functional elements of a design and focus on the ornamental elements that design patents are intended to protect.

137. See Brief for Appellee, *LKQ Corp. v. GM Glob. Tech. Operations LLC*, 102 F.4th 1280 (Fed. Cir. 2024) (No. 21-2348), 2023 WL 6879814, at *48–49 (arguing that an analysis without the *Rosen-Durling* framework will take away guideposts and leave fact finders rudderless in judging particular subsets of obviousness).

138. See PTO Guidance, *supra* note 132; see MPEP § 1504.03 (9th ed. Rev. 1, Jan. 2024).

139. See MPEP § 2145 (9th ed. Rev. 1, Jan. 2024).

140. IPR2024-00525, Paper 16, 2 (P.T.A.B. Aug. 6, 2024).

A. POTENTIAL IMPLICATIONS OF UTILIZING *GRAHAM* FACTORS

The panel's decision in *LKQ* reshaped the analysis for design patent obviousness and will have several potential implications. Section IV.A.1 discusses the potential drawbacks of applying the *Graham* factors to design patents, including increased uncertainty, the possibility of more successful invalidity claims, and the increased potential to allow hindsight analysis affect the obviousness determination. Section IV.A.2 explores how the *Graham* factors might make obtaining and enforcing design patents more difficult. Section IV.A.3 examines the specific implications of the *Graham* factors on the automotive repair parts industry, where design patents are critical to maintaining market control and higher prices. Finally, Section IV.A.4 discusses the PTAB's application of the *Graham* factors in a recent case, demonstrating that while the new approach offers flexibility, a high threshold remains to prove obviousness.

1. *Criticism for a Uniform Test with Utility Patents*

Utilizing the *Graham* factors to determine obviousness for design patents has the benefit of a uniform test with utility patents. However, the *Graham* factors can be criticized and may also lead to more successful invalidity claims due to obviousness. Eliminating the established *Rosen-Durling* framework, which has been in place since 1996, exposes up to four hundred thousand U.S. design patents to substantial uncertainty as they can now be challenged in court under the new obviousness standard.¹⁴¹ The flexibility of utilizing the *Graham* factors could leave fact finders without the proper guidelines to conduct the obviousness analysis.¹⁴² The *Graham* factors can lead to unpredictable results on what is considered obvious and what is not because, unlike utility patents, there are no written claims and just a drawing of the claimed design.¹⁴³ Casting aside the “so related” step from *Durling* could allow hindsight because it removes the step to ensure that the patent challenger identifies why an ordinary designer would modify the primary reference because of another design.¹⁴⁴ The current ambiguous state of the first *Graham* factor could allow a challenger to successfully use hindsight to identify and combine elements that had no role in the design to challenge a design patent on obviousness grounds.¹⁴⁵

141. AIPLA Brief, *supra* note 13, at *26.

142. Brief for Appellee, *LKQ*, 102 F.4th 1280 (No. 21-2348), 2023 WL 6879814, at *13.

143. *Id.* at *16.

144. *See id.* at *23.

145. *See* Brief for Ford Motor Co. as Amici Curiae Supporting Appellee, *LKQ*, 102 F.4th 1280 (No. 21-2348), at *11.

2. *The Graham Factors Can Make It Harder to Receive and Then Enforce Design Protections*

Another implication of utilizing the *Graham* factors in the design patent space is that it could be harder to receive design protection and enforce it once it is obtained. Basic design elements such as a straight line, a curve, and a spline can be found in virtually any prior art reference and combined because they are simple design elements.¹⁴⁶ With the *Graham* factors' flexibility, patent examiners can see the repeated design elements and decide that the combination of the elements is obvious. The uncertainty of receiving design protection will also carry over to enforcing design protection. The unpredictability of design protection may embolden copycats to flood the markets with knockoffs that could harm the brand's value, knowing it is uncertain if the design patent holder will be able to enforce their design protections.¹⁴⁷ The uncertainty whether a design may receive protections combined with the uncertainty that it may be enforced against counterfeits may impact the future of product innovation by diminishing the value of industrial design and disincentivizing innovation in industrial design.¹⁴⁸ However, this disincentivizing could conversely increase innovation in industrial design due to a diminished fear that a design will be found to be infringing.¹⁴⁹

Although the *Graham* factors are a more flexible approach to determining obviousness for design, there is still the potential that there will be no overall change because obviousness is an objective test done through the eyes of the examiner or fact finder. The Federal Circuit reasoned that a more flexible approach would allow fact finders to use common sense that a rigid rule would limit.¹⁵⁰ However, even utilizing common sense, a fact finder can still find an obviousness determination that reaches the same outcome the *Rosen-Durling* test would have produced.¹⁵¹ A patent examiner looking at a new design could still limit the scope of their analogous prior art that is still "so related" even though it is no longer required.¹⁵² They could also look for a primary reference

146. Corrected Brief of Amicus Curiae Indus. Designers Soc'y of Am. in Support of Appellee and Affirmance, *LKQ*, 102 F.4th 1280 (No. 21-2348), 2023 WL 7183956, at *13 [hereinafter Amicus Brief of IDSA].

147. Corrected Brief for Amicus Curiae Apple Inc. in Support of Appellee GM Global Technology Operations LLC, *LKQ*, 102 F.4th 1280 (No. 21-2348), 2023 WL 7296931, at *28.

148. Amicus Brief of IDSA, *supra* note 146, at *13.

149. See Mueller & Bream, *supra* note 8, at 511 (noting that blindly applying KSR to design patents could be devastating to the field of design).

150. *LKQ*, 102 F.4th at 1291–92; see *KSR Int'l Co. v. Teleflex Inc.*, 550 U.S. 398, 420–21 (2007).

151. See *LKQ*, 102 F.4th at 1291–92; *KSR*, 550 U.S. at 420–21.

152. See *LKQ*, 102 F.4th at 1295.

that is “basically the same” and ignore the combination of multiple prior arts as obvious.¹⁵³ Until more cases demonstrate the application of the *Graham* factors in the design patent space, there is no way to fully predict its effect on the ability to obtain and enforce design patents.¹⁵⁴

3. *Impact on the Automobile Parts Industry*

One market in which the *Graham* factors for obviousness could have the most significant impact is automobile parts because manufacturers rely on design patents to maintain market dominance on repair parts. Automotive manufacturers control more than 70 percent of the market for repair parts and can charge up to 80 percent more for their repair parts due to design patent protection.¹⁵⁵ Automakers can effectively block competition for crash parts, leading to higher repair costs, which insurers pass to the consumer as higher auto insurance premiums.¹⁵⁶ An automaker blocking a third-party parts manufacturer was the crux of the *LKQ* case, with an auto part supplier (LKQ) contesting the validity of an automotive manufacturer’s (GM) design patent on a fender so they cannot be excluded from the market.¹⁵⁷

This issue of car manufacturers excluding third-party suppliers has also been at the forefront of discussion in Congress, most recently with the introduction of the Save Money on Auto Repair Transportation (SMART) Act. This Act would create a carve-out for design patent infringement if the purpose of the infringing design is to provide a part for the repair of a motor vehicle and restore it to its original appearance.¹⁵⁸ However, due to lack of congressional support, the SMART Act faces an uphill battle. If the flexibility of the *Graham* factors leads courts to find more design patents invalid on obviousness grounds and makes it more difficult to obtain and enforce design protection, then the goals of the SMART Act would be realized.¹⁵⁹ Auto part makers will be able to enter the market without worry of exclusion by a design patent, and the increase in competitors beyond just the original equipment manufacturers will drive the repair price down, leading to lower insurance rates for the consumer.¹⁶⁰

153. *See id.* at 1294.

154. *See id.* at 1300.

155. *Hearings, supra* note 3, at 16 (statement of Jack Gillis, Dir. of Pub. Affs., Consumer Fed’n of Am.).

156. *Id.*

157. *See generally LKQ*, 102 F.4th 1280.

158. *See* Save Money on Auto Repair Transportation (SMART) Act, H.R. 1707, 188th Cong. § 2 (2023).

159. *See id.*

160. *See Hearings, supra* note 3, at 16 (statement of Jack Gillis, Dir. of Pub. Affs., Consumer Fed’n of Am.) (arguing that the lack of competition for repair parts due to design patent

4. *The PTAB's First Final Written Decision Since LKQ: Next Step Group Inc. v. Deckers Outdoor Corporation*

On August 6, 2024, the PTAB issued its first final written decision applying the *Graham* factors as the test for the obviousness of design patents.¹⁶¹ This case demonstrated the early implications of *LKQ* and showed that the PTAB still required petitioners to be detailed in their explanation of any combinations or modifications of prior art that achieved the claimed design.¹⁶² In this case, Next Step Group, Inc. (NSG) asserted ten unpatentability grounds, including eight obviousness theories against a boot design patent owned by Deckers Outdoor Corporation.¹⁶³ However, the PTAB determined that their obviousness theories were not reasonably likely to prevail and declined to initiate an *inter partes* review.¹⁶⁴

The PTAB criticized NSG for not being more detailed about the prior art and for not explaining why combining or modifying it would have been obvious.¹⁶⁵ NSG needed to provide an adequate reason why a designer would select particular elements from all possible design options, and they needed to sufficiently address all the differences in the overall appearance of the claimed design and the prior art.¹⁶⁶ The PTAB criticized NSG for not addressing all the subtle differences in the design of the prior art boots, including “the ratio of the length of the foot opening to the length of the boot, the pull tab, and the sloping top line.”¹⁶⁷ Although the *Graham* factors provided a more flexible approach, as seen in this case, a high threshold remains to invalidate a design patent for obviousness.¹⁶⁸

The removal of the *Rosen* reference and the relaxation of the *Durling* “so related” requirement may make it easier to provide relevant prior art. However, the PTAB is still looking for petitioners to explain every aspect of a claimed

protections allows car companies to charge monopolistic prices, leading to higher repair costs and auto insurance premiums).

161. Connor Scholes & John Evans, *PTAB Issues First Post-LKQ Design Patent Decision*, PTAB LITIG. BLOG (Oct. 13, 2024), <https://www.ptablitigationblog.com/ptab-issues-first-post-lkq-design-patent-decision/>.

162. *See* Next Step Grp., Inc. v. Deckers Outdoor Corp., IPR2024-00525, 2024 WL 3678413, at *17 (P.T.A.B. Aug. 6, 2024) (“Petitioner does not offer adequate reasoning why a designer would select, from all the possible design options, the specifically configured pull tab of the claimed design.”).

163. *Id.* at *2.

164. *Id.* at *1.

165. Next Step Grp., Inc. v. Deckers Outdoor Corp., IPR2024-00525, Paper 16, 45 (P.T.A.B. Aug. 6, 2024).

166. *Id.*

167. *Id.* at 50.

168. *Id.* at 45.

design and any combinations or modifications to the prior art that achieve the claimed design.¹⁶⁹ This first determination from the PTAB demonstrates that the new obviousness standard may not affect the ability to receive a design patent. It is yet to be seen if a district court will require the same detailed explanation the PTAB required in future cases or if they will accept general assertions of obviousness like NSG put forward. If the PTAB is looking for an obvious explanation for differences in even slight, trivial variations, such as the shape of a line or the height-to-width ratio, that could be an incredibly high threshold to prove obviousness with available prior art.

B. WHY ALIGN WITH THE UTILITY PATENT STANDARD IF DESIGN PATENTS ARE DIFFERENT? WHY NOT KEEP SEPARATE STANDARDS LIKE INFRINGEMENT?

If the *Rosen-Durling* test has been the controlling rule to determine obviousness since 1996, why did the Federal Circuit decide to upend its precedent by applying a Supreme Court decision that occurred fifteen years ago? GM and supporting amici briefs criticized the need to upend the *Rosen-Durling* framework, which the public has come to rely on and the USPTO has developed a body of jurisprudence around.¹⁷⁰ The Federal Circuit established a separate standard to determine infringement in design patents from utility patents, knowing that the utility patent infringement framework would not apply to design patents.¹⁷¹

One of the most straightforward explanations is that the Federal Circuit did not want to be overruled by the Supreme Court on its test for design patent obviousness. This concern arose because they had previously been overruled on their TSM test for utility patent obviousness. In Judge Stark's concurrence-in-part during the panel decision, he acknowledged that there was "at minimum, substantial tension between the Supreme Court's holding in KSR and our [. . .] test."¹⁷² He noted that the *Rosen* reference requirement and the "so related" *Durling* requirement were the types of limiting rules similar to the

169. Scholes & Evans, *supra* note 161; see *Next Step Grp.*, IPR2024-00525, 2024 WL 3678413, at *17 ("Petitioner does not offer adequate reasoning why a designer would select, from all the possible design options, the specifically configured pull tab of the claimed design.").

170. See Brief for Appellee, *LKQ Corp. v. GM Glob. Tech. Operations LLC*, 102 F.4th 1280 (Fed. Cir. 2024) (No. 21-2348), 2023 WL 6879814, at *43–44; AIPLA Brief, *supra* note 13, at *26.

171. See Mark A. Lemley & Mark P. McKenna, *Design Patents Aren't Patents (and It's a Good Thing Too)*, 92 GEO. WASH. L. REV. 811, 818–31 (2024) (discussing the differences between design and utility patents).

172. *LKQ Corp. v. GM Glob. Tech. Operations LLC*, No. 2021-2348, 2023 WL 328228, at *13 (Fed. Cir. Jan. 20, 2023) (Stark, J., concurring in part and concurring in judgment).

TSM rule that *KSR* faulted.¹⁷³ However, Judge Lourie presented additional views that differed, acknowledging that although § 103 applies to all patents, the considerations involved in determining obviousness between design and utility patents differ.¹⁷⁴ To settle the differences of opinions on the panel for *LKQ*, and since there was no clear direction from the Supreme Court if *KSR* applied to design patents, the Federal Circuit made the rare decision to hear *LKQ* en banc.

The *LKQ* en banc opinion acknowledges that the *KSR* Court emphasized that § 103 and *Graham* “set forth an expansive and flexible approach” and that rigid factors are not consistent with their case law.¹⁷⁵ There are significant differences between design and utility patents, but they are governed by § 103 for obviousness.¹⁷⁶ The Federal Circuit, keen to avoid being overruled again for applying strict rules that limit the flexible approach of § 103, removed the *Rosen-Durling* test before the Supreme Court could potentially overturn them.

Another reason the Federal Circuit could have chosen to adopt the *Graham* factors is because they are more in line with how designers approach a new design. The *Graham* factors can be adjusted for design patents easily.¹⁷⁷ With the previous *Rosen* reference requirement, the majority of designs that made a trivial change to a current design were found to be protectable. However, designers often draw from various sources and combine different design concepts.¹⁷⁸ Utilizing the *Graham* factors, fact finders can now find specific designs that combine multiple elements to be obvious if they are based on known principles of design and what designers would do.¹⁷⁹ Because the Federal Circuit was easily able to apply the *Graham* factors to design patents in conjunction with how they are closely related to how designers operate, it made sense for the court to keep the standard the same as utility patents rather than come up with a new standard that would fit § 103.

Additionally, the court in *LKQ* explicitly stated that the standard for design obviousness in the third *Graham* factor was to be viewed through the lens of a

173. *Id.*

174. *Id.* at *8 (Lourie, J., filing additional views).

175. *LKQ Corp. v. GM Glob. Tech. Operations LLC*, 102 F.4th 1280, 1300 (Fed. Cir. 2024).

176. *See* Lemley & McKenna, *supra* note 171, at 819–22 (discussing the three major differences between design patent and utility patent infringement analysis: (1) design patents are claimed visually rather than verbally, (2) design patent infringement has no all-elements rule, and, lastly, (3) the difference in the perspective between design and utility patents from which the comparisons are made).

177. *See LKQ*, 102 F.4th at 1295–1300 (discussing how the *Graham* factors will apply to design patents).

178. Lemley & McKenna, *supra* note 171, at 844.

179. *See id.*

designer with skill in the field to which the claimed design pertains as a person having ordinary skill in the art.¹⁸⁰ This requirement that the standard for obviousness is from a designer's viewpoint will benefit the obviousness analysis to design patents specifically because it requires a holistic inquiry focused on what designers would do and look at.¹⁸¹ This potentially will also be a higher standard than a PHOSITA in utility patents, where a person with a mechanical engineering degree can be considered a PHOSITA for a mechanical utility patent even if they are not a practicing engineer. The standard the court defines for design patents is "the designer of ordinary capability who designs articles of the type presented in the application."¹⁸² The higher standard—requiring a designer who works in the relevant field rather than someone with only a design education—may lead courts to find more designs obvious. Practicing designers are aware of more design elements and know how those elements are combined and modified in their field.

C. THE SECOND *GRAHAM* FACTOR SHOULD FILTER OUT FUNCTIONAL ELEMENTS AT THE NONOBVIOUSNESS VALIDITY STAGE

The *Graham* factor analysis presents an opportunity for the courts to fix one of the most significant issues that plague design patents: the inclusion of unprotectable functional elements.¹⁸³ The Federal Circuit's decision in *Apple, Inc. v. Samsung Electronics Co.* reinforced the narrow framework of interpreting ornamentality and non-functionality established in *L.A. Gear, Inc. v. Thom McAn Shoe Co.*¹⁸⁴ In *L.A. Gear*, the Federal Circuit held that the availability of alternative designs—in this case, alternative designs for a shoe—means the design of the shoe cannot be solely dictated by function.¹⁸⁵ The Federal Circuit has treated designs for which there are alternatives as non-functional, which has allowed manufacturers such as Apple to use design patents to protect functional elements of their designs as long as there are suitable alternatives.¹⁸⁶ This opposes the 1902 Design Patent Act, where Congress clarified that they were limited to ornamental attributes and did not extend to functional attributes.¹⁸⁷ Utilizing the *Graham* factors for obviousness presents the

180. *LKQ*, 102 F.4th at 1298–99.

181. See Lemley & McKenna, *supra* note 171, at 844.

182. *LKQ*, 102 F.4th at 1299 (citing *In re Borden*, 90 F.3d 1570 (Fed. Cir. 1996)).

183. See Peter S. Menell & Ella Corren, *Design Patent Law's Identity Crisis*, 36 BERKELEY TECH. L.J. 1, 115 (2021).

184. *Id.*; see *Apple, Inc. v. Samsung Elecs. Co.*, 678 F.3d 1314 (Fed. Cir. 2012); *L.A. Gear, Inc. v. Thom McAn Shoe Co.*, 988 F.2d 1117 (Fed. Cir. 1993).

185. *L.A. Gear*, 988 F.2d at 1123.

186. See Menell & Corren, *supra* note 183, at 115.

187. See Act of May 9, 1902, ch. 783, sec. 4929, 32 Stat. 193 (amending R.S. 4929, relating to design patents).

opportunity to first filter out non-protectable functional elements before considering the difference between the prior art and the claimed design.

The court should look to copyright law and the abstraction, filtration, and comparison test to identify the best way to filter out unprotectable elements. That framework helps determine which elements are protectable by copyright and which are infringed. In *Computer Associates International v. Altai, Inc.*, the Second Circuit devised the abstraction, filtration, and comparison test and applied it to computer code. The first step of abstraction for copyright law involves separating the unprotectable ideas from the protectable elements of expression.¹⁸⁸ Applying this step to design patents would separate the non-protectable elements from the protectable ornamental elements. The second step, filtration, requires separating the protectable expression from the non-protectable material.¹⁸⁹ For design patents, this would mean filtering out any functional elements and leaving just the ornamental elements.¹⁹⁰ The final step, comparison, requires comparing the remaining protectable elements and determining if there is substantial similarity between the alleged infringing work and the protected work.¹⁹¹ Applying this step to design patents to determine obviousness would require moving to the third *Graham* factor and viewing the remaining elements as a whole of the claimed design and prior art from the perspective of a designer who works in the field.¹⁹² Then, it must be determined if it would have been obvious to a designer in the field—if the designer would have been motivated to modify the remaining elements of the prior art to create the same overall visual appearance of the remaining elements of the claimed design.¹⁹³

Utilizing the abstraction-filtration-comparison test during the second *Graham* factor will help prevent companies from using design patents to receive protection for functional elements. In the case of *LKQ*, any unprotectable functional elements, such as the aerodynamic sculpting of the fender, the wheel arch shape, and the door cut line, would be filtered out during the abstraction obviousness analysis. These are also elements that the PTAB concluded were key differences between the prior art and the claimed

188. *Comput. Assocs. Int'l, Inc. v. Altai, Inc.*, 982 F.2d 693, 706 (2d Cir. 1992); *see Oracle Am., Inc. v. Google Inc.*, 750 F.3d 1339, 1357 (Fed. Cir. 2014) (discussing endorsement of the abstraction-filtration-comparison test in the Ninth and Tenth Circuit courts).

189. *Altai*, 982 F.2d at 707.

190. *See id.*

191. *Id.* at 710.

192. *See LKQ Corp. v. GM Glob. Tech. Operations LLC*, 102 F.4th 1280, 1298–99 (Fed. Cir. 2024).

193. *Id.*

design.¹⁹⁴ With these major functional elements removed, a designer in the field will likely find it obvious to modify the prior art design to create the same overall visual appearance of the remaining elements in the claimed design and invalidate the design patent.

The ability to filter out unprotectable functional elements at the obviousness phase will allow design patents to be granted only for unique ornamental designs; however, the issue of determining what is considered functional remains. In *L.A. Gear*, the Federal Circuit determined that “when there are several ways to achieve the function of an article of manufacture, the design of the article is more likely to serve a primarily ornamental purpose.”¹⁹⁵ This standard means a design element could not be considered functional if the claimed design can point to other alternatives to achieve the same function. This current standard allows designers a back door for functional design protection—as long as they can point to alternative designs, then the design itself is not “dictated by function” and can be granted a design patent.¹⁹⁶

The Federal Circuit should turn to the Third Circuit’s opinion in *Ezaki Glico Kabushiki Kaisha v. Lotte International America Corp.* to close this loophole and prevent backdoor design protection for functional elements. Although this case concerns trade dress protection and not design patents, it still involves filtering out unprotectable functional elements. The Third Circuit determined that a feature of a particular design is functional if it is “useful,” even if it is not essential to the product’s function.¹⁹⁷ The court also held that evidence could show that the design is functional even with alternatives.¹⁹⁸

Applying this standard to the design patents in *Apple v. Samsung*, a court could likely find the rounded edges of Apple’s design useful because they better distribute the impact during drops and prevent screen cracking.¹⁹⁹ Although alternative designs exist for the corners, which are not essential to the phone’s function, under the standard set forth by the Third Circuit, the rounded edges would be deemed functional and, therefore, not protectable.²⁰⁰

Taking elements from copyright and trademark protections may seem like a radical step to prevent design patents from protecting functional aspects; however, it will also bring the United States closer to the current E.U. design

194. *LKQ Corp. v. GM Glob. Tech. Operations LLC*, No. 2021-2348, 2023 WL 328228, at *2 (Fed. Cir. Jan. 20, 2023).

195. *L.A. Gear, Inc. v. Thom McAn Shoe Co.*, 988 F.2d 1117, 1123 (Fed. Cir. 1993).

196. Menell & Corren, *supra* note 183, at 122–24.

197. *Ezaki Glico Kabushiki Kaisha v. Lotte Int’l Am. Corp.*, 986 F.3d 250, 256–57 (3d Cir. 2021).

198. *Id.* at 260.

199. *See Apple, Inc. v. Samsung Elecs. Co.*, 678 F.3d 1314, 1318 (Fed. Cir. 2012).

200. *See id.*; *Lotte*, 986 F.3d at 256–60.

protections. In 1998, the European Parliament adopted the European Directive on the Legal Protection of Design to establish an E.U.-wide design protection regime.²⁰¹ Just like in U.S. design patents, the E.U. Designs Regulation and Directive expressly exclude from design protection features of appearance of a product which are “solely dictated by its technical function.”²⁰²

The Court of Justice of the European Union (CJEU) clarified the test to determine what design features are solely dictated by technical function in *Doceram GmbH v. CeramTec GmbH*.²⁰³ The CJEU rejected the multiplicity of forms test, similar to the standard *LA Gear* outlined in the United States, that the availability of alternative designs means it cannot be solely dictated by function.²⁰⁴ The EU Design Regulation also authorizes the filtration of features within a multicomponent product by excluding features that are not eligible for protection.²⁰⁵ If U.S. courts are to adopt the proposed changes by adding an abstraction, filtration, and comparison step similar to copyright and a functionality determination identical to the Third Circuit’s opinion in *Lotte* during the second *Graham* factor, the United States will be closer to the design protection regulations in the European Union.

V. CONCLUSION

The Federal Circuit’s determination in *LKQ* removed the rigid *Rosen-Durling* test and replaced it with the *Graham* factors for obviousness analysis in design patents. This opinion brought the obviousness analysis in line with utility patents and could lead to more invalidated design patents on obviousness grounds with a more flexible standard. However, the factors do not apply directly to design patents and will rely on future case law to shape the scope of the prior art and any additional secondary conditions. With the subjectiveness of determining nonobviousness, there remains a possibility that using the flexible *Graham* factors will affect patent eligibility in the future. Using the *Graham* factors also presents an opportunity to fix an issue plaguing design patents by preventing the protection of functional elements of design. Implementing an abstraction, filtration, and comparison test to remove any functional elements will prevent designers or inventors from obtaining

201. Peter S. Menell, *Navigating the Trans-Atlantic Design Protection Quandary*, in HARMONIZING INTELLECTUAL PROPERTY LAW FOR A TRANS-ATLANTIC KNOWLEDGE ECONOMY 333–34 (Péter Mezei, Anett Pogácsás & Hannibal Travis eds., 2023).

202. *Id.* at 334–35.

203. *Id.* at 336.

204. *Id.* at 328–29.

205. *Id.* at 334–35; see also *Samsung Elecs. (UK) Ltd. v. Apple Inc.* [2012] EWHC (Pat) 1882 [64], [91]–[176] (applying filtration analysis to all the design features relied on by the potential infringing design).

backdoor design patents to protect functional designs. Although *LKQ* represents a welcomed change to design patents by potentially limiting eligibility, the significant issues of design patents remain until there is a defined process to filter out unprotectable functional elements.

“ARE APPS PRODUCTS?”: CONSUMER SOFTWARE AND PRODUCTS LIABILITY

Karina A. Sanchez[†]

ABSTRACT

Products liability law is unclear on whether apps are products. Trial courts are faced with an increasing number of products liability cases brought against companies that create apps offering a blend of technology, content, and services. Without guiding authority, trial courts inconsistently conclude that apps are or are not products. Although many scholars have posed products liability as a mechanism to promote safety in the development of emerging digital technology such as autonomous vehicles and AI, the threshold question of whether software is a product and remains unanswered.

The court in *In re Social Media Adolescent Addiction/Personal Injury Products Liability Litigation* sought to streamline the analysis of whether an app is a product by looking at functionality within the app rather than the app as whole. To further promote administrability and consistency, this Note advocates extending *In re Social Media*'s framework: an app or a feature should be considered a product when it has a user experience or user interface intended for consumer use.

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I. INTRODUCTION

For many of us, consumer apps, such as TikTok, Facebook, and ChatGPT, are part of daily life. Given the digital nature of apps, it seems far-fetched that they could hurt us. Unfortunately, we are beginning to see the tangible and nefarious harms that apps can pose to society and especially to children. In October 2024, fourteen-year-old Sewell Seltzer III used Character.ai’s chatbot, became severely emotionally distressed, and then tragically took his own life.¹ The Seltzer family has since brought products liability claims against Character.ai for the defective design of its chatbot.² If the trial court assessed

1. Kevin Roose, *Can A.I. Be Blamed for a Teen’s Suicide?*, N.Y. TIMES (Oct. 23, 2024), <https://www.nytimes.com/2024/10/23/technology/characterai-lawsuit-teen-suicide.html>.

2. Complaint, Garcia v. Character Techs., Inc., No. 6:24-CV-01903 (M.D. Fla. Oct. 22, 2024).

claims against Character.ai under traditional products liability law, the court could dismiss them because an AI chatbot is not a tangible product. The court could hold that Character.ai is not subject to products liability claims at all without addressing whether Character.ai's chatbot malfunctioned, had insufficient warnings, or lacked reasonable safety features.

Throughout American history, the law has confronted new technologies that endanger consumers. Motorized transportation is a safe and ubiquitous part of modern life, but trains and cars malfunctioned and injured citizens often when they first became available. To balance the benefits and risks of new transportation technology, courts created products liability law. As Judge Cardozo said in the 1916 landmark case *MacPherson v. Buick Motor Co.*, the principle that manufacturers of technology should be liable for harms caused by defects “does not change, but the things subject to the principle do change. They are whatever the needs of life in a developing civilization require them to be.”³

This principle adapted over the past century to provide injured consumers relief from harm caused by anything from medical devices to power tools, water heaters, and more.⁴ The next frontier is to apply products liability to consumer software. Many scholars believe that products liability should apply to software. For example, John Villasenor of the Brookings Institute stated, “if implemented with appropriate frameworks, products liability law represents an important mechanism to mitigate possible [AI] harms.”⁵ But, under the existing legal framework, consumer software is not neatly classifiable as a product. As opposed to a medication or mechanical device, which are canonically considered products under the existing products liability framework, consumer software often blurs the line between software's services and content. No American appeals court—state or federal—has directly addressed whether consumer software is a product for the purposes of products liability. Some international governments explicitly define when products liability applies to consumer software, such as AI.⁶ However, the United States does not have a governance framework that guides courts on how to address products liability claims against consumer software. Based on

3. 217 N.Y. 382, 391 (1916).

4. See RESTATEMENT (SECOND) OF TORTS § 402A cmt. d (A.L.I. 1965).

5. John Villasenor, *Products Liability Law as a Way to Address AI Harms*, BROOKINGS (Oct. 31, 2019), <https://www.brookings.edu/articles/products-liability-law-as-a-way-to-address-ai-harms/>.

6. See, e.g., TAMBIA MA DIEGA, EUR. PARL. RSCH. SERV., ARTIFICIAL INTELLIGENCE LIABILITY DIRECTIVE (2023) (stating that the EU products liability directive applies to harm caused by AI-driven devices).

existing case law, the answer to the question of whether consumer software is a “product” under products liability is “remarkably unclear and unsettled.”⁷ As a result, trial courts struggle to determine when consumer software is a product and often reach inconsistent conclusions.

In a recent products liability case brought against social media companies for psychological harm, District Judge Yvonne Gonzalez Rogers offered a new approach.⁸ In *In re Social Media*, the court analyzed whether social media apps were products overall and examined whether individual functionalities within the apps were products.⁹ The court consolidated the common law requirements of a “product” into a multi-step inquiry that the court applied to the social media apps as a whole and to the accused functionalities within the apps.¹⁰ The court concluded that certain features of social media apps—such as making it difficult for users to delete their accounts—were products for products liability purposes.¹¹ Multiple trial courts have since cited *In re Social Media*’s framework to determine that apps like Uber and Grindr are also products.¹²

The issue of whether consumer apps are products has not been addressed extensively in modern scholarship, leaving courts to engage in guesswork as to whether plaintiffs can sustain products liability claims against consumer software companies. In 1992, Michael R. Maule argued that the application of strict products liability to software would be desirable, but challenging because software is not neatly classifiable as a traditional product or service.¹³ In 2018, Professor Karni Chagal-Feferkorn explored whether and when products liability law should apply to an autonomous system.¹⁴ In 2022, Ian Wardell noted the active debate on whether artificial intelligence (AI) and machine

7. Ketan Ramakrishnan, Gregory Smith & Conor Downey, *U.S. Tort Liability for Large-Scale Artificial Intelligence Damages*, RAND GLOB. & EMERGING RISKS 27 (2024).

8. *See In re Soc. Media Adolescent Addiction/Pers. Inj. Prods. Liab. Litig.*, 702 F. Supp. 3d 809, 842–54 (N.D. Cal. 2023).

9. *Id.*

10. *Id.* at 842.

11. *Id.* at 849–54.

12. *See In re Uber Techs., Inc., Passenger Sexual Assault Litig.*, 2024 WL 4211217 (N.D. Cal. Aug. 15, 2024) (holding that the Uber app was a product for the purposes of products liability because it was sufficiently analogous to tangible personal property); *T.V. v. Grindr, LLC*, 2024 WL 4128796 (M.D. Fla. Aug. 13, 2024) (holding that the Grindr app was a product for the purposes of products liability because plaintiff alleged harm from Grindr’s app design choices and because Grindr was in the best position to prevent such harm).

13. Michael R. Maule, *Applying Strict Products Liability to Computer Software*, 27 TULSA L. REV. 735, 755 (1992).

14. *See generally* Karni A. Chagal-Feferkorn, *Am I an Algorithm or a Product? When Products Liability Should Apply to Algorithmic Decision-Makers*, 30 STAN. L. & POL’Y REV. 61 (2019).

learning (ML) are products or services, but did not analyze the issue extensively.¹⁵ In 2023, Professor Nina Brown argued that chatbots powered by AI should be considered products for the purposes of products liability and examined how plaintiffs might bring a manufacturing defect, design defect, or failure to warn claims for defective chatbots.¹⁶ In 2024, Retired Justice John G. Browning noted that courts are increasingly finding that products liability claims against social media and dating apps are not barred by § 230.¹⁷

Building on *In re Social Media's* holding, this Note argues that a consumer app—or functionality within the app—is a product if it has a consumer-facing user interface or user experience. Part II summarizes the relevant historical and legal background of products liability law, the existing legal definitions of a “product,” and how consumer software fits those definitions. Part III analyzes the *In re Social Media* framework for determining whether consumer software is a product and how it has been applied in other trial courts. Part IV analyzes the strengths and weaknesses of *In re Social Media's* framework and suggests a modification that will further the policy goals of products liability law: determining whether an app or feature is a product by its user interface or user experience.

II. BACKGROUND

A products liability claimant must show that the allegedly defective object that injured them is a product, as opposed to a service or content.¹⁸ Part II of this Note will examine the legal framework that determines whether consumer software is a product:¹⁹ (A) an overview of products liability law, including its

15. See generally Ian A. Wardell, *Product Liability Applied to Automated Decisions*, SETON HALL L. STUDENT WORKS (2022).

16. See generally Nina Brown, *Bots Behaving Badly: A Products Liability Approach to Chatbot-Generated Defamation*, 3 J. FREE SPEECH 389 (2023).

17. See generally John G. Browning, *A Product by Any Other Name? The Evolving Trend of Product Liability Exposure for Technology Platforms*, 16 ELON L. REV. 181 (2024).

18. See *Brooks v. Eugene Burger Mgmt. Corp.*, 215 Cal. App. 3d 1611, 1626 (1989).

19. Some scholars analyze the treatment of software as a “good” under Article 2 of the Uniform Commercial Code (UCC) to argue that software should be a product for the purposes of products liability. See, e.g., Lori A. Weber, *Bad Bytes: The Application of Strict Products Liability to Computer Software*, 66 ST. JOHN'S L. REV. 469 (1992); Lawrence B. Levy & Suzanne Y. Bell, *Software Product Liability: Understanding and Minimizing the Risks*, 5 HIGH TECH. L.J. 1 (1990). This Note will not address Article 2 because cases that analyze whether software is a good under the UCC typically involve contracts for enterprise software. See, e.g., *RRX Indus. v. Lab-Con, Inc.*, 772 F.2d 543, 546 (9th Cir. 1985) (holding that a hybrid transaction for medical lab software was a contract for the sale of goods); *Triangle Underwriters, Inc. v. Honeywell, Inc.*, 604 F.2d 737, 742–43 (2d. Cir. 1979) (holding that a hybrid transaction for an enterprise

historical roots and policy goals; (B) the legal definitions of a product under the Second and Third Restatements of Torts; (C) the scope of § 230 immunity in the context of products liability claims; and (D) the technical, business, and legal background of consumer apps.

A. PRODUCTS LIABILITY LAW

Under modern products liability law, a seller of products is liable for physical harm caused by a defective product.²⁰ A product is defective when it contains a manufacturing defect, design defect, or has inadequate instructions or warnings.²¹ Section II.A (1) provides historical background on the innovation-driven purpose of products liability law; and (2) explains that products liability's policy goals are allocative efficiency, deterrence, and administrability.

1. *The Historical Purpose of Products Liability Is to Balance Innovation and Safety*

Products liability law is a policy-driven legal framework developed in response to technological change.²² In the nineteenth century, the privity requirement mandated that a consumer had to have a contractual relationship with the manufacturer to sue the manufacturer for an injury caused by a defective product.²³ At the time the privity requirement was developed, goods were produced by consumers themselves, family members, or local craftsmen.²⁴ After the Industrial Revolution, manufacturers sent their goods to networks of distributors and retailers who in turn sold the products to consumers.²⁵ By the turn of the twentieth century, the privity requirement made it nearly impossible for consumers of defective products to sue manufacturers for injuries because consumers and manufacturers lacked direct

computer system was a contract for the sale of goods because the goods predominated the transaction).

20. RESTATEMENT (THIRD) OF TORTS: PRODS. LIAB. § 1 (A.L.I. 1998).

21. *Id.* § 2.

22. See Donald G. Gifford, *Technological Triggers to Tort Revolutions: Steam Locomotives, Autonomous Vehicles, and Accident Compensation*, 11 J. TORT L. 71, 117 (2018).

23. See *Winterbottom v. Wright*, 152 Eng. Rep. 402, 405 (Ct. Exch. 1842) (holding that a plaintiff cannot sustain claims for negligent performance of a contract if the plaintiff lacks privity of contract with the defendant).

24. Gifford, *supra* note 22, at 116.

25. *Id.*; see also *Escola v. Coca Cola Bottling Co.*, 24 Cal. 2d. 453, 467 (1944) (Traynor, J., concurring) (“As handicrafts have been replaced by mass production with its great markets and transportation facilities, the close relationship between the producer and consumer of a product has been altered.”).

contractual relationships.²⁶ In response, courts abolished the privity requirement and instead concluded that a manufacturer owes a duty of care to consumers whenever its products are “reasonably certain to place life and limb in peril when negligently made,” regardless of whether a contractual relationship existed.²⁷

2. *The Goals of Products Liability Are Allocative Efficiency, Deterrence, and Administrability*

Products liability has three concurrent policy goals: allocative efficiency, deterrence, and administrability.²⁸ The allocative efficiency theory of products liability aims to place the burden of injury on the manufacturer, who is in a better position than an injured consumer to prevent accidents and spread costs.²⁹ By reallocating injury costs onto the manufacturer, products liability aims to replicate market functions and achieve a socially-optimal level of product accidents that rational consumers and manufacturers would bargain for.³⁰

Second, the deterrence theory of products liability aims to incentivize manufacturers to place safe goods into the stream of commerce where the market fails to do so.³¹ Product manufacturers have an informational advantage over consumers because they have more knowledge about product design, production, and potential alternatives.³² Because it is often impossible for plaintiffs to know all the ways manufacturers are negligent, a negligence-only framework incentivizes manufacturers to bypass safety measures whenever doing so reduces costs.³³ In contrast, holding products manufacturers strictly liable for harm caused by their products prevents

26. Gifford, *supra* note 22, at 116.

27. *MacPherson v. Buick*, 217 N.Y. at 389.

28. See KEITH N. HYLTON, TORT LAW: A MODERN PERSPECTIVE 335 (2016); *Escola*, 24 Cal. 2d. at 464–68 (Traynor, J., concurring).

29. See John E. Montgomery & David G. Owen, *Reflections on the Theory and Administration of Strict Tort Liability for Defective Products*, 27 S.C.L. REV. 803, 809 (1976).

30. See RESTATEMENT (THIRD) OF TORTS: PRODS. LIAB. § 2 cmt. a (A.L.I. 1998) (stating that the goal of products liability is to “achieve optimal levels of safety in designing and marketing products”); MARSHALL S. SHAPO, SHAPO ON THE LAW OF PRODUCTS LIABILITY 7-42–43 (7th ed. 2017) (stating that the allocative efficiency rests on “the idea that rational, bargaining sellers and purchasers will achieve together the general level of accidents that is optimal”).

31. See SHAPO, *supra* note 30, at 7–43 (noting that deterrence “does not necessarily imply an optimizing feature” and that some courts “would like to see an absolute reduction in the level of personal injuries, even if that level falls below what the market would support”).

32. HYLTON, *supra* note 28, at 335.

33. See *id.*

manufacturers from exploiting this informational advantage and encourages a greater investment in product safety than a negligence framework.³⁴ Therefore, products liability law's strict liability regime deters manufacturers from bypassing safety measures.³⁵

Third, the administrability theory of products liability aims to streamline litigation. Products liability eliminates the elements of duty and breach and therefore “avoids complicated doctrinal rules that either serve no useful purpose or take us to the same conclusion.”³⁶ In contrast, negligence is fact-specific, unpredictable, and involves complicated rules that often divert liability away from manufacturers.³⁷ Therefore, products liability aims to create consistent litigation outcomes that put defendants on notice of potential liability.³⁸

B. DEFINITION OF A PRODUCT

Unless an alternative definition is provided by statute,³⁹ the question of whether something is a product is always a question of law determined by the court.⁴⁰ “When the applicable definition fails to provide an unequivocal answer, decisions regarding whether a ‘product’ is involved are reached in light of the public policies behind the imposition of strict liability in tort.”⁴¹ Section II.B outlines definitions of a product under (1) the Second Restatement of Torts and (2) the Third Restatement of Torts.

1. *The Second Restatement of Torts Defines Products as Tangible Personal Property and Not Content, Ideas, and Expression*

The American Law Institute incorporated products liability in the first volume of the Second Restatement of Torts in 1965.⁴² Although the Second

34. *Id.*

35. *See id.*

36. *Id.* at 336.

37. *See* GUIDO CALABRESI, THE COSTS OF ACCIDENTS: A LEGAL AND ECONOMIC ANALYSIS 47–64 (1970); *see also* RESTATEMENT (THIRD) OF TORTS: PRODS. LIAB. § 2 cmt. a (A.L.I. 1998) (“[B]y eliminating the issue of manufacturer fault from plaintiff’s case, strict liability reduces the transaction costs involved in litigating that issue.”).

38. *See* CALABRESI, *supra* note 37, at 47–64.

39. *See, e.g.*, RESTATEMENT (THIRD) OF TORTS: PRODS. LIAB. § 19 cmt. a (A.L.I. 1998) (providing statutory definitions of a “product” under Maryland, Ohio, and Tennessee law) (internal citations omitted); RWCA 7.72.010(3) (providing a definition of a “product” under Washington state law).

40. RESTATEMENT (THIRD) OF TORTS: PRODS. LIAB. § 19 cmt. a (A.L.I. 1998).

41. *Id.* at Reporters’ Note.

42. *See* Lana Barnett, *Restatement to the Rescue*, HARV. L. BULL. (May 3, 2024), <https://hls.harvard.edu/today/restatement-to-the-rescue/> (“Each Restatement aims to organize and

Restatement did not define a “product,” comment d of Section 402A provided some guidance:

“The rule stated in this Section . . . extends to any product sold in the condition . . . in which it is expected to reach the ultimate user or consumer. Thus the rule stated applies to an automobile, a tire, an airplane, a grinding wheel, a water heater, a gas stove, a power tool, a riveting machine, a chair, and an insecticide.”⁴³

Courts have interpreted the list of tangible items provided in comment d to imply that products liability law only applies to tangible items under the Second Restatement.⁴⁴ In *Winter v. G.P. Putnam’s Sons*, the Ninth Circuit used the implied tangibility requirement to hold that products liability law does not apply to content, ideas, and expression.⁴⁵ In that case, the Ninth Circuit also noted that “[c]omputer software that fails to yield the result for which it was designed” may be considered a product.⁴⁶

2. *The Third Restatement of Torts Expands the Second Restatement’s Definition of a “Product” to Include Intangibles and Exclude Services*

The American Law Institute published the Third Restatement of Torts: Products Liability in 1998.⁴⁷ In response to the ambiguity created by the Second Restatement, the Third Restatement provided an explicit definition of a product in Section 19: (a) a product is tangible personal property or other intangible items, such as electricity, “when the context of their distribution and use is sufficiently analogous” to the distribution and use of tangible personal property; and (b) services are not products.⁴⁸

First, consistent with the Second Restatement, the Third Restatement’s definition of a product states that “most but not necessarily all products are tangible personal property.”⁴⁹ Tangible items considered products under the Second Restatement, such as automobiles, tires, planes, water heaters, power tools, and insecticides, are also products under the Third Restatement.⁵⁰ The

present in a systematic manner the legal rules and principles in a particular area of law, such as . . . torts.”); *see generally* RESTATEMENT (SECOND) OF TORTS (A.L.I. 1965).

43. RESTATEMENT (SECOND) OF TORTS § 402A cmt. d (A.L.I. 1965).

44. *See, e.g.*, *Winter v. G.P. Putnam’s Sons*, 938 F.2d 1033, 1034 (9th Cir. 1991) (“The American Law Institute clearly was concerned with including all physical items but gave no indication that the doctrine should be expanded beyond that area.”).

45. *Id.* at 1036.

46. *Id.*

47. *See generally* RESTATEMENT (THIRD) OF TORTS: PRODS. LIAB. (A.L.I. 1998).

48. *Id.* § 19(a)–(b).

49. *Id.* § 19 cmt. b.

50. *See* RESTATEMENT (SECOND) OF TORTS § 402A cmt. d (A.L.I. 1965).

Third Restatement also expanded the Second Restatement's definition of a product to include some forms of intangible property.⁵¹ Section 19(a) states that intangibles are products for the purposes of products liability "when the context of [their] distribution and use is sufficiently analogous to the distribution and use of tangible personal property."⁵² One example is the transmission of intangible forces, such as electricity, which a majority of courts have held "becomes a product when it passes through the customer's meter and enters the customer's premises."⁵³ Embodying *Winter v. G.P. Putnam's Sons*, comment d explains that intangible content, expression, and ideas are not a valid basis for a products liability claim.⁵⁴

Second, the Third Restatement provides that products liability law does not apply to services.⁵⁵ Those who sell services are not liable in the absence of negligence or intentional misconduct.⁵⁶ In hybrid transactions that involve products and services, the plaintiff must show that the "primary objective was to acquire ownership or use of a product" and not "to obtain a service" to maintain a strict products liability claim.⁵⁷

C. SECTION 230 DOES NOT BAR PRODUCTS LIABILITY CLAIMS AGAINST INTERNET COMPANIES

Section 230⁵⁸ "provides internet companies with immunity from certain claims" in order to "promote the continued development of the Internet and other interactive computer services."⁵⁹ Under *Barnes v. Yahoo!, Inc.*, § 230 shields an internet company from liability if the company is "(1) a provider or user of an interactive computer service (2) whom a plaintiff seeks to treat, under a state law cause of action, as a publisher or speaker (3) of information provided by another information content provider."⁶⁰

51. *See id.* (stating that intangible property may be products in some cases).

52. RESTATEMENT (THIRD) OF TORTS: PRODS. LIAB. § 19(a) (A.L.I. 1998).

53. *Id.*; *see also* *Pierce v. Pac. Gas & Elec. Co.*, 212 Cal. Rptr. 283, 292 (Ct. App. 1985) (holding that electricity is a product when it is in the "stream of commerce" and "expected to be a marketable voltage"); *Hou. Lighting & Power Co. v. Reynolds*, 765 S.W.2d 784, 785 (Tex. 1988) (holding that electricity is a product (citing *Pierce*, 212 Cal. Rptr. at 290)).

54. RESTATEMENT (THIRD) OF TORTS: PRODS. LIAB. § 19 cmt. d (A.L.I. 1998).

55. *Murphy v. E.R. Squibb & Sons, Inc.*, 40 Cal. 3d 672, 677 (1985).

56. *Gagne v. Bertran*, 43 Cal. 2d 481, 487 (1989).

57. *Hennigan v. White*, 199 Cal. App. 4th 395, 403 (2011) (citing *Ferrari v. Grand Canyon Dorics*, 32 Cal. App. 4th 248, 258 (1995)).

58. *See generally* 47 U.S.C. § 230(c)(1).

59. *HomeAway.com, Inc. v. City of Santa Monica*, 918 F.3d 676, 681 (9th Cir. 2019) (quoting 47 U.S.C. § 230(b)(1)).

60. 570 F.3d 1096, 1100–01 (9th Cir. 2009).

Retired Justice John G. Browning notes that there is a growing trend of courts upholding products liability claims against consumer apps when faced with § 230 defenses.⁶¹ When plaintiffs bring products liability claims for allegedly defective technology, defendants do not have § 230 immunity because plaintiffs seek to hold defendants liable as manufacturers and therefore fail the second prong of the *Barnes* test.⁶² When plaintiffs bring products liability claims for harmful content posted by third parties,⁶³ § 230 bars their claims because they imply that the app has a publishing duty to monitor and censor user-generated content.⁶⁴ This Note reserves the question of how § 230 impacts products liability claims brought against consumer apps for future scholarship. However, the question of what app features are content and whether those features are first or third-party content is critical to determining whether products liability claims are barred by § 230.

D. WHETHER SOFTWARE IS A PRODUCT

Under existing jurisprudence, it is unclear if and how products liability applies to consumer software.⁶⁵ Because mutual understanding between technical and legal scholarship creates effective interdisciplinary solutions,⁶⁶ it is important to understand the technical and business context of consumer software. Section II.D of this Note (1) defines technical terms essential for understanding consumer apps; (2) provides business context behind the development of consumer apps; and (3) summarizes the challenges trial courts face in classifying consumer apps as products for the purposes of products liability.

61. See generally Browning, *supra* note 17.

62. See *Lemmon v. Snap, Inc.*, 995 F.3d 1085, 1093 (9th Cir. 2021) (holding that § 230 did not bar plaintiffs' negligent design claims against Snap for the defective design of its content filters and in-app reward system).

63. Even without § 230, content-based does not form a valid basis for products liability claims. See *Winter v. G.P. Putnam's Sons*, 938 F.2d at 1036.

64. *Herrick v. Grindr, LLC*, 765 F. App'x 586, 591 (2d Cir. 2019) (holding that § 230 barred products liability claims brought against a dating app for harassment caused by the plaintiff's ex-boyfriend posting fake profiles of the plaintiff).

65. Ramakrishan et. al., *supra* note 7, at 27.

66. See Ryan Calo, *Robotics and the Lessons of Cyberlaw*, 103 CAL. L. REV. 513, 561 (2015) (stating that "the legally and technically savvy will need to be in constant conversation" to provide effective legal solutions to the burgeoning robotics industry).

1. *Defining Consumer Apps*

Tech industry professionals use the term “product” to describe software built and maintained to satisfy user needs.⁶⁷ Tech companies may build software for businesses or the public, called enterprise software and consumer software respectively.⁶⁸ Users might derive value from the technology embodied in the app itself or from content, goods, or services that the app makes available. For example, users on marketplace apps, such as Amazon, Etsy, and Airbnb, derive value from transactions for goods and services that the apps facilitate.⁶⁹ On the other hand, users of ChatGPT derive value from the ability to use OpenAI’s large language model (LLM)—an algorithm that understands and generates human language using AI.⁷⁰

User experience—or “UX” for short—is a tech industry term referring to the user’s overall experience with the app or website.⁷¹ User experience is a broad term that includes the app’s visual display on the screen as well as the data and algorithms that make the app work. The user interface—or “UI”—is a subset of the user experience that refers strictly to the interactivity, look, and feel of an app or website as embodied in the visual elements.⁷² Consider Apple’s feature that allows users to automatically fill in one-time verification codes sent via text to log in to websites on their iPhones.⁷³ Apple’s user experience is better for the user because it allows for quick verification without the difficulty of remembering the verification code or switching back and forth between texts and the web browser. The user experience for this feature includes the entire process of signing in, starting with you signing into a website on your iPhone, receiving a text message with your verification code,

67. See, e.g., Anna Grigoryan, *What Is a Software Product?*, WRIKE, <https://www.wrike.com/product-management-guide/software-product/> (last visited Nov. 16, 2024).

68. Sid Nasnodkar, *Enterprise vs Consumer Product Management*, PROD. SCH. (Jan. 24, 2024), <https://productschool.com/blog/product-fundamentals/enterprise-vs-consumer-product-management>.

69. See *Marketplaces vs. Platforms: What’s the Difference Between Them?*, STRIPE (Oct. 1, 2023), <https://stripe.com/resources/more/marketplaces-vs-platforms> (defining a marketplace as “a digital platform or ecommerce hub where a diverse array of goods, services, or digital content is bought, sold, and exchanged”).

70. *Models*, OPENAI PLATFORM, <https://platform.openai.com/docs/models> (last visited Nov. 16, 2024).

71. *What Is the Difference Between UI and UX?*, FIGMA, <https://www.figma.com/resource-library/difference-between-ui-and-ux/> (last visited Nov. 16, 2024).

72. *Id.*

73. *Automatically Fill in SMS Passcodes on iPhone*, IPHONE USER GUIDE, <https://support.apple.com/guide/iphone/automatically-fill-in-sms-passcodes-iphc89a3a3af/ios> (last visited Nov. 16, 2024).

seeing a window that asks if you want to use the code, and auto-filling the texted code to log in.⁷⁴ The user interface for this feature is only the pop-up window and buttons that appear on your screen.⁷⁵

2. *The Business of Consumer Apps and Product Management*

It is industry standard to hire product managers to oversee software development.⁷⁶ Product managers collaborate with business stakeholders to prioritize business problems and design new features in apps to solve them.⁷⁷ The new features are tied to a success metric, or key performance indicator (KPI), that is often tied to the business's profitability.⁷⁸ For example, a product manager for an eCommerce app may be asked to oversee the development of a feature that increases conversion rate—i.e., “the percentage of website visitors who complete a desired action (like make a purchase).”⁷⁹ The product manager will oversee the design and development of a new feature that will convert more visitors into customers.⁸⁰ Once the feature is completed by software engineers, the product manager will measure changes to the conversion rate with monitoring software built into the app that tracks user behavior.⁸¹ If the feature shows changes to the conversion rate that aligns with business goals during the monitoring phase, the product manager will launch the feature; otherwise, the product manager will revert the app to its original state and brainstorm an alternative solution.⁸² Insofar as products liability aims to use market forces to incentivize companies to place safe technology into the stream of commerce,⁸³ we should expect that tech companies will respond

74. *See id.*

75. *See id.*

76. Christopher Selden, *Product Management Process: Stages, Tips & Diagrams*, AMPLITUDE (Aug. 27, 2024), <https://amplitude.com/blog/product-management-process>.

77. *Id.*

78. *See* Carlos González De Villaumbrosia, *20+ Key Metrics for Product Management*, PROD. SCH. (Apr. 3, 2024), <https://productschool.com/blog/analytics/metrics-product-management> [<https://perma.cc/YG7F-CBSB>] (defining KPIS as “key indicators of performance over time” and noting that a KPI for an eCommerce business might be conversion rate, which “measures the percentage of website visitors who complete a desired action (like making a purchase)”).

79. *Id.*

80. *See id.*

81. *See id.*; Sam Tardif, *What Every Product Manager Needs to Know About Product Analytics*, ATLISSIAN, <https://www.atlassian.com/agile/product-management/product-analytics> (last visited Nov. 16, 2024).

82. *See* Tardif, *supra* note 81.

83. *See supra* text accompanying notes 29–30.

accordingly given the sophisticated economic analysis that drives the production of new consumer software features.

3. *How Courts Have Viewed Whether Consumer Software Is a Product*

In the context of consumer software, trial courts have found that apps are not tangible personal property,⁸⁴ but that finding does not preclude finding that consumer software is a product.⁸⁵ As discussed, *supra*, in Section II.B, under the Third Restatement, an intangible can still be a product if it is sufficiently analogous to tangible personal property in the context of its distribution and use, it is not a service, and it is not akin to content, ideas, and expression.⁸⁶ Courts have not extensively addressed the question of whether software is sufficiently analogous to tangible personal property to constitute a product for the purposes of products liability.⁸⁷ The case law shows that (a) plaintiffs cannot maintain a products liability action if their harm was caused by content, ideas, or expression contained in digital media; and (b) it is unclear whether consumer apps are products under the Third Restatement.

a) Plaintiff Cannot Bring Products Liability Claims Based on Harm Caused by Content in Apps

There is substantial case law establishing that harmful digital media cannot form the basis of a products liability claim. For example, in *James v. Meow Media, Inc.*, the Sixth Circuit cited *Winter v. G.P. Putnam's Sons* to determine that video games, movies, and internet sites were not sufficiently tangible to be considered products under the Second Restatement of Torts.⁸⁸ Plaintiffs brought products liability claims alleging that defendants' video games, movies, and internet sites contained violent content that caused a third party to shoot and kill three high school students.⁸⁹ Although the cartridges, cassettes, and internet transmissions were tangible, the Sixth Circuit found that plaintiffs' alleged harm was caused by the communicative properties rather than the

84. *See, e.g.*, *Jackson v. Airbnb, Inc.*, 639 F. Supp. 3d 994, 1011 (C.D. Cal. 2022) (finding that plaintiff's products liability claims failed for lack of a tangible product because they were not seeking to hold Airbnb liable based on the house as the end product); *Doe v. Uber Techs., Inc.*, 2020 WL 13801354, at *6 (Cal. Super. Nov. 30, 2020) ("The Uber App is not tangible personal property").

85. *See* RESTATEMENT (THIRD) OF TORTS: PRODS. LIAB. § 19(a) (A.L.I. 1998).

86. *See id.* § 19(a)–(b) cmt. d; *Winter v. G.P. Putnam's Sons*, 938 F.2d at 1036.

87. *See, e.g.*, *Doe v. Uber*, 2020 WL 13801354, at *7 (stating, without analysis, that the Uber app is not analogous to tangible personal property).

88. 300 F.3d 683, 701 (6th Cir. 2002).

89. *Id.* at 687.

tangible properties of the video games, movies, and internet sites.⁹⁰ Therefore, the Sixth Circuit concluded that the communicative content in the video games, movies, and internet sites were not “products” for the purposes of products liability.⁹¹

In *Estate of B.H. v. Netflix, Inc.*, the Northern District of California also cited *Winter v. G.P. Putnam’s Sons* to conclude that content contained in a show produced, distributed, and recommended by Netflix could not form the basis of a products liability claim.⁹² Plaintiffs brought products liability claims against Netflix for distributing a TV show containing depictions of suicide that caused a young girl to take her own life.⁹³ The court noted that “[w]ithout the content, there would be no claim” and granted the defendant’s motion to dismiss on the ground that the plaintiff’s harm was caused by Netflix’s expressive content.⁹⁴ Therefore, harmful content is not a valid basis for a products liability action. However, similarly to the § 230 analysis, the line between content-based harm and product-based harm can be blurry.⁹⁵

b) Courts Come to Inconsistent Conclusions as to Whether Apps Are Products

Trial courts are divided on whether apps are products—eligible for products liability claims—or services—precluded from products liability claims.⁹⁶ Some courts hold that consumer apps are services.⁹⁷ Other courts hold that apps are products.⁹⁸ In fact, they often come to opposite conclusions on the same app. For example, Snapchat is an app that allows users to communicate with each other by sending and receiving messages, photos, and

90. *Id.* (“Certainly if a video cassette exploded and injured its user, we would hold it a ‘product’ and its producer strictly liable for the user’s physical damages.”).

91. *Id.*

92. 2022 WL 551701, at *3 (N.D. Cal. Jan. 12, 2022).

93. *Id.*

94. *Id.*

95. *See supra* Section II.C.

96. *See Murphy v. E.R. Squibb & Sons*, 40 Cal. 3d at 677.

97. *See, e.g., Doe v. Uber*, 2020 WL 13801354, at *7 (holding that plaintiffs could not maintain a products liability claim against Uber because “the Uber App was used to gain a service: a ride”); *Jackson v. Airbnb*, 639 F. Supp. 3d at 1010–11 (holding that Airbnb is not a product because it is used to provide services); *Jacobs v. Meta Platforms, Inc.*, 2023 WL 2655586, at *4 (Cal. Super. Mar. 10, 2023) (“Facebook is a service for the purposes of the products liability analysis.”).

98. *See, e.g., Brookes v. Lyft, Inc.*, 2022 WL 19799628, at *2 (Fla. Cir. Ct. Sep. 30, 2022) (holding that the Lyft app is a product for the purposes of Florida products liability law).

videos.⁹⁹ In *Zeincik v. Snap*, plaintiffs claimed products liability based on Snapchat's alleged failure to respond to alerts of threatening messages.¹⁰⁰ The court concluded that "Snapchat is more like a service than a product," and plaintiffs could therefore not sustain products liability claims.¹⁰¹ In *Lemmon*, the Ninth Circuit implied the opposite conclusion.¹⁰² The Ninth Circuit found that plaintiffs' negligent design claims against Snapchat for its speed filter¹⁰³ and internal reward system¹⁰⁴ "treat[ed] Snap as a products manufacturer."¹⁰⁵

Two trial courts also came to conflicting conclusions as to whether the Uber app was a product. In *Doe v. Uber*, plaintiffs brought products liability claims against Uber, alleging that "fake driver[s]" displayed the Uber decal in their vehicle to trick victims into entering their vehicle and then committing sexual assault.¹⁰⁶ The California Superior Court concluded, without analysis, that the Uber app is not analogous to tangible personal property in the context of its distribution and use.¹⁰⁷ The court reasoned that because the Uber app was downloaded to obtain a service, it could not be subject to products liability claims.¹⁰⁸ In *In re Uber*, plaintiffs claimed products liability based on an alleged failure to implement specific safety features into the Uber app that resulted in the sexual assault of passengers.¹⁰⁹ But here, the Northern District of California concluded that the Uber app was sufficiently analogous to the distribution and use of tangible personal property and held that the Uber app was a product.¹¹⁰

99. *Zeincik v. Snap, Inc.*, 2023 WL 2638314, at *1 (N.D. Cal. Feb. 3, 2023); *Lemmon v. Snap*, 995 F.3d at 1088.

100. *Zeincik*, 2023 WL 2638314, at *1–2.

101. *Id.* at *4.

102. *See Lemmon*, 995 F.3d at 1092.

103. Snapchat's speed filter is a content filter that allows users to overlay the speed the user is traveling at (ex. "20.1mph") onto a photo or video that they take on Snapchat. *Id.* at 1088–89.

104. Plaintiffs alleged that Snap created an incentive system within Snapchat that "encouraged its users to pursue certain unknown achievements and rewards." *Id.* at 1091.

105. *Id.* at 1092. There is disagreement in trial courts as to whether the Ninth Circuit implicitly recognized Snapchat as a product in *Lemmon*. Compare *Jacobs v. Meta Platforms*, 2023 WL 2655586, at *3 (holding that the Ninth Circuit did not recognize Snapchat as a product), with *In re Soc. Media*, 702 F. Supp. 3d at 846 ("the Ninth Circuit [in *Lemmon*] assumed (perhaps because they found it obvious) that plaintiffs adequately alleged a product-based negligence claim against Snap").

106. 2020 WL 13801354, at *1.

107. *Id.* at *6.

108. *Id.* at *6–7.

109. *In re Uber*, 2024 WL 4211217, at *1.

110. *Id.* at * 22.

In the case of rival rideshare app Lyft, the trial court in *Brookes v. Lyft* concluded that the Lyft app was a product for the purposes of products liability when the plaintiff alleged she was hit by a driver because the app was designed to take drivers' eyes off the road.¹¹¹ Referencing the allocative efficiency goals of torts, the court reasoned that "Lyft is the designer and sole distributor of the Lyft application."¹¹² Although the Lyft app was designed to provide a service, the court analogized the Lyft app to commercial laundry machines.¹¹³ "If Lyft had designed commercial laundry machines and mass distributed them to laundromats operated by third-parties to provide a laundry service, Lyft could not credibly argue that the laundry machine was a service and not a product."¹¹⁴ The court found "no rational basis to distinguish" the Lyft app from tangible products "just because it involves enhanced technology."¹¹⁵ In *Lemmon*, *In re Uber*, and *Brookes*, the courts were all inclined to find that the accused apps were products when the plaintiffs alleged a defect in an app's user experience or user interface. In contrast, in *Zeincik* and *Doe v. Uber*, the courts did not find that the accused apps were products when the plaintiffs alleged problems with the defendant tech companies' business practices.

Ideally, courts would consistently find that the same app is or is not a product across all cases. However, as the preceding examples illustrate, trial courts can view an app as a product or a service depending on the plaintiffs' allegations. When faced with products liability claims against tech companies that are clearly unsupported by the allegations, courts sometimes sidestep the issues of defect and causation by concluding that the defendants' apps are not products. For example, in *Jackson v. Airbnb, Inc.*, the court concluded that Airbnb was not a product in a case involving the shooting and death of a boy on an Airbnb property.¹¹⁶ A trial court cited *Jackson* in *Jacobs v. Meta Platforms, Inc.* to hold that Facebook was not a product in a case involving the shooting and death of a security guard at a federal courthouse.¹¹⁷ In both cases, the courts shortcut the analysis of plaintiffs' products liability claims by categorizing Airbnb and Facebook as services.¹¹⁸

111. 2022 WL 19799628, at *1–2.

112. *Id.* at *2.

113. *Id.* at *5.

114. *Id.*

115. *Id.*

116. 639 F. Supp. 3d 994, 1000–11 (C.D. Cal. 2022).

117. 2023 WL 265586, at *4.

118. *Jackson*, 639 F. Supp. 3d at 1011 (dismissing products liability claims because plaintiffs failed to adequately allege a product); *Jacobs*, 2023 WL 265586, at *4 (finding that because Facebook was a service and not a product, plaintiffs products liability claims "cannot proceed beyond the threshold question").

III. IN RE SOCIAL MEDIA

District Judge Yvonne Gonzalez Rogers noticed trial courts' inconsistent conclusions on whether consumer apps are products.¹¹⁹ In *In re Social Media*, she offered a new approach to create consistent outcomes in software products liability cases. Part III of this Note (A) provides the procedural history and background of *In re Social Media*; (B) examines the analysis of *In re Social Media*'s holding that features within social media apps were products rather than the apps as a whole; and (C) examines how trial courts apply *In re Social Media*.

A. PROCEDURAL HISTORY AND BACKGROUND

In 2022, the Judicial Panel on Multidistrict Litigation (JPML) created MDL No. 3047, centralizing twenty civil actions from courts across the country that alleged psychological harm to children as a result of social media use.¹²⁰ MDL No. 3047 consolidated cases brought by individuals, school districts, and state Attorneys General against social media apps¹²¹ operated by Meta (Facebook and Instagram), Google (YouTube), ByteDance (TikTok), and Snap (Snapchat).¹²² After filing a master amended complaint, plaintiffs identified five priority claims.¹²³ Four of those claims were products liability.¹²⁴

Plaintiffs alleged that the social media apps allowed users to search for and share content and that the apps “determine[d] when and to whom certain content is shown.”¹²⁵ Because the social media apps relied on revenue from advertisements, “profits from these [apps] are highly dependent on the number

119. *In re Soc. Media*, 702 F. Supp. 3d at 838 (noting that “[c]ases exist on both sides of the questions posed by this litigation”).

120. *In re Soc. Media Adolescent Addiction/Pers. Inj. Prods. Liab. Litig.*, 637 F. Supp. 3d 1377 (U.S. Jud. Pan. Mult. Lit. 2022).

121. Per industry usage, a software “product” is software that is intended to be used directly by end-users, while a software “platform” is intended to be built upon by other software developers and support integrations. *What's the Difference Between a Software Product and a Platform?*, FORBES (Mar. 17, 2015), <https://www.forbes.com/sites/adrianbridgwater/2015/03/17/whats-the-difference-between-a-software-product-and-a-platform/>. Although the court and defendants refer to the social media apps as “platforms,” this Note will refer to them as “apps” to avoid confusion between the legal and technical industry definitions of the term “product” and “platform.” See generally *In re Soc. Media*, 702 F. Supp. 3d at 809; Defendants' Joint Motion to Dismiss, *In re Soc. Media*, 702 F. Supp. 3d at 809; Defendants' Joint Supplemental Motion to Dismiss, *In re Soc. Media*, 702 F. Supp. 3d at 809.

122. *In re Soc. Media*, 702 F. Supp. 3d at 817.

123. *Id.* at 818.

124. *Id.* at 817 (noting that plaintiffs prioritized claims of design defect, failure to warn, negligent design, negligent failure to warn, and negligence *per se*).

125. *Id.* at 818.

of users, the amount of time each user spends on the [app], and the amount of information a user provides, directly or indirectly, to the [app] about themselves.”¹²⁶ Plaintiffs alleged that defendants designed their apps to “appeal and addict” child users and that the apps facilitated sexual exploitation of children.¹²⁷ Examples of alleged design defects included:

- failure to implement robust age verification and parental controls;
- failure to assist users in limiting screen time;
- creating barriers to account deletion and deactivation;
- making filters available to alter content;
- failing to label filtered content; and
- failure to provide processes for reporting suspected child sexual abuse materials (CSAM).¹²⁸

Defendants filed two motions to dismiss: one addressing plaintiffs’ priority claims¹²⁹ and the other addressing § 230 immunity and First Amendment defenses.¹³⁰ In the former motion to dismiss, the defendants argued that their apps were services and that the plaintiff’s allegations concerned content that could not form the basis of a products liability claim.¹³¹ Plaintiffs argued in response that the alleged cause of harm was the defendants’ software design choices.¹³² The court granted in part and denied in part the motions to dismiss, with some of the products liability claims surviving.¹³³ Defendants moved for interlocutory appeal to contest, amongst other things, that their apps are not products.¹³⁴ The court denied the motion for untimeliness.¹³⁵

B. JUDGE GONZALEZ ROGERS’S FRAMEWORK FOR DETERMINING PRODUCT STATUS

In re Social Media established a two-step framework for determining whether an app is a product under the Third Restatement: (1) choosing to analyze the app as a whole or as individual features within the app, and (2)

126. *Id.* at 819.

127. *Id.*

128. *Id.* at 839.

129. Defendants’ Joint Motion to Dismiss, *In re Soc. Media*, 702 F. Supp. 3d at 809.

130. Defendants’ Joint Supplemental Motion to Dismiss, *In re Soc. Media*, 702 F. Supp. 3d at 809.

131. *In re Soc. Media*, 702 F. Supp. 3d at 838.

132. *Id.*

133. *Id.* at 862–63. The court held that § 230 barred a subset of plaintiffs’ products liability claims. *See id.* at 829.

134. *See* Defendants’ Motion to Certify Appeal, *In re Soc. Media*, 702 F. Supp. 3d at 809.

135. Order, *In re Soc. Media*, 702 F. Supp. 3d at 809.

determining whether the app or feature meets the common law requirements of a product under the Third Restatement.¹³⁶

1. *Choosing the “All-or-Nothing” Approach, “Defect-Specific” Approach, or Both*

Whereas prior cases evaluated the product status of apps as a whole, Judge Gonzalez Rogers recognized that the parties’ analyses of the app as a whole were “overly simplistic and misguided.”¹³⁷ The court recognized that trial courts come to inconsistent conclusions as to whether consumer apps are products because “it is the *functionalities* of the alleged products that must be analyzed.”¹³⁸ The court held that plaintiffs alleging products liability claims for app-caused harm can survive a motion to dismiss if they adequately allege a product at either or both of (1) the app level using the “all-or-nothing” approach; and (2) the functionality level using the “defect-specific approach.”¹³⁹

2. *The Third Restatement Multi-Step Inquiry*

Judge Gonzalez Rogers also consolidated the common law requirements of a product into a multi-step inquiry.¹⁴⁰ The Second Restatement of Torts established that tangible personal property can form the basis of a products liability and that content, ideas, and expression cannot.¹⁴¹ The Third Restatement of Torts expanded this definition to include items analogous to tangible property in the context of their distribution and use and exclude services.¹⁴² Therefore, the court held that in order to analyze whether something is a product under the Third Restatement of Torts, courts must assess whether the accused object or instrumentality is: (a) tangible or analogous to tangible personal property; (b) a service; and/or (c) akin to content, ideas, or expression.¹⁴³

136. *See In re Soc. Media*, 702 F. Supp. 3d at 842.

137. *Id.* at 838 (stating that the parties’ approaches that analyze the apps as a whole “are overly simplistic and misguided”).

138. *Id.*

139. *Id.* at 843–53.

140. *See supra* Section II.B.

141. *See supra* Section II.B.1.

142. *See supra* Section II.B.2.

143. *In re Soc. Media*, 702 F. Supp. 3d at 842. The court also considered the arguments that software is a product because software is sometimes considered a “good” under the Uniform Commercial Code. *Id.* The court noted “there may be a workable analogy” to the treatment of software under the UCC, but that “plaintiffs have not identified it.” *Id.* at 848.

C. APPLYING THE FRAMEWORK TO DETERMINE WHETHER SOCIAL MEDIA APPS ARE PRODUCTS

The court analyzed the merits of plaintiffs' claims at both the app and feature levels. For each level of analysis, the court applied the multi-step inquiry to determine if the app or feature was a product under the Third Restatement: (a) was the app or feature tangible or analogous to tangible property?; (b) was the app or feature akin to a service?; and (c) was the app or feature akin to content, ideas, or expression?¹⁴⁴

1. *Under the "All-or-Nothing" Approach, Plaintiffs Failed to Adequately Allege that Apps Were Products*

First, the court analyzed whether the apps as a whole were: (a) tangible or analogous to tangible personal property; (b) services; or (c) akin to ideas, content, and expression.¹⁴⁵

a) *Social Media Apps Are Not Tangible or Analogous to Tangible Property*

The court found that the defendants' social media apps were neither tangible nor analogous to tangible personal property.¹⁴⁶ The court found that the connection between the defendants' apps and haptics—such as noises, vibrations, notifications, and user interface prompts—was too attenuated to consider the apps tangible.¹⁴⁷ Second, the court reasoned that the defendants' apps as a whole were not sufficiently analogous to tangible personal property.¹⁴⁸ The court reasoned that buying a tangible good in a store was not sufficiently analogous to downloading an app from an online marketplace, because the app could be accessed through websites and on certain integrated devices as well.¹⁴⁹ The plaintiffs attempted to analogize social media apps to a container, stating, without analysis, that "[t]here is no functional difference between downloading an app from the App Store and using it on your phone, and buying a container from the Container Store and using it on your counter top."¹⁵⁰ The court did not find this analogy persuasive.¹⁵¹

144. *Id.*

145. *Id.* at 842.

146. *Id.* at 843.

147. *Id.* at 843–44.

148. *Id.* at 843.

149. *Id.*

150. *Id.* (internal citations omitted).

151. *Id.*

b) Social Media Apps Are Not Services

Although the court acknowledged that the accused social media apps facilitated users' interactions with other users and content, the court was not persuaded that the apps as a whole were services.¹⁵² However, the court also did not declare that the apps were products as a whole, noting that the parties' "global arguments" did not resolve the issue.¹⁵³ The court noted that cases classifying apps as products or services "offered minimal, if any, rationale for such classifications."¹⁵⁴ The court also noted that hiring product managers to work on a social media app and referring to a social media app as a product, without more, did not render the app a product for legal purposes.¹⁵⁵

c) Social Media Apps Are Not Akin to Ideas, Content, and Expression

The court found that the defendants' apps as a whole were not akin to ideas, content, and expression.¹⁵⁶ The court distinguished "between products liability claims that are focused on content (and thus, were not cognizable) and those focused on design (which are cognizable)."¹⁵⁷ For example, the court noted that the plaintiffs' claims in *Estate of B.H. v. Netflix* were not cognizable because they were based on harmful depictions of suicide in a television show.¹⁵⁸ On the other hand, the court noted that the plaintiffs' claims were cognizable in *Lemmon v. Snap*, which alleged a negligently designed speed filter that encouraged dangerous behavior, and *Brookes v. Lyft*, which alleged a defectively designed app that encouraged drivers to take their eyes off the road.¹⁵⁹

2. Under the "Defect-Specific" Approach, Plaintiffs Adequately Alleged That Functionalities of Apps Are Products

After finding that plaintiffs failed to establish that the defendants' apps were products as a whole, the court analyzed whether the accused

152. *Id.*

153. *Id.*

154. *Id.*; see also *id.* at 843 n.36 (collecting cases).

155. *Id.* at 843; see also *id.* at 843 n.37 ("it is surely not the case that hiring 'Product Managers' to work on a [app] makes that [app] a product in a legal sense").

156. *Id.* at 847.

157. *Id.* at 846–47.

158. *Id.* at 845 (citing *Estate of B.H. v. Netflix*, 2022 WL 551701, at *1–3).

159. *Id.* at 846–47 (citing *Brookes v. Lyft*, 2022 WL 19799628, at *1–3; *Lemmon v. Snap*, 995 F.3d at 1093).

functionalities within the apps were products.¹⁶⁰ The court found that the following features met the legal definition of a “product”:

- Defective parental controls and age verification;
- Failure to assist users in limiting in-app screen time;
- Creating barriers to account deactivation and/or deletion;
- Failure to label edited content; and
- Making filters available to users to manipulate content.¹⁶¹

For each accused feature, the court asked the same questions as it did when it examined the apps as a whole: is the feature tangible or analogous to tangible property?; is the feature a service?; and, is the feature analogous to ideas, content, and expression?¹⁶² The court concluded that the plaintiffs sufficiently showed that each feature was a product to survive a motion to dismiss.¹⁶³ The court reasoned that (a) parental controls, age verification, and screen time limitations were sufficiently analogous to tangible property; (b) account deletion was not a service; and, (c) filters and content labels were not akin to content.

a) Parental Controls, Age Verification, and Screen Time Limitations
Are Analogous to Tangible Property

The court found that defective parental controls, age verification, and failure to implement screen time limitations were products.¹⁶⁴ Applying a strict interpretation of the tangibility requirement in Section 19(a) of the Third Restatement of Torts,¹⁶⁵ the court noted that both features had analogous physical products. Parental controls and age verifications were analogous to child-proof locks on prescription medication bottles and parental controls on televisions.¹⁶⁶ Screen time limitations were analogous to timers, alarms, and smartphones with screen time limitation software.¹⁶⁷ The court therefore concluded that the accused features were “akin to user interface/experience choices” and therefore were products.¹⁶⁸

160. *Id.* at 849.

161. *Id.* at 849–54. In addition to the listed features, the court also held that functionality for reporting child sexual abuse material (“CSAM”) was a product. *Id.* at 853.

162. *Id.* at 849.

163. *Id.* at 853.

164. *Id.* at 849–51.

165. *See supra* text accompanying notes 124–126.

166. *In re Soc. Media*, 702 F. Supp. 3d at 849.

167. *Id.* at 850.

168. *Id.* at 849–50.

b) Account Deletion is Not a Service

The court analyzed whether alleged barriers to account deactivation and deletion were a product or a service.¹⁶⁹ The court noted that “in some senses, account deletion and deactivation may be analogized to interactions a consumer might have with a service provider (such as closing an account with a bank or a credit card company, for instance).”¹⁷⁰ The distinction in this case is that account deactivation and deletion was a process directed by the user.¹⁷¹ Unlike closing an account with a bank, the defendants’ employees were not involved in processing user requests to delete or deactivate accounts.¹⁷² Therefore, the court concluded that plaintiffs adequately alleged that barriers to account deactivation and deletion were a product.¹⁷³

c) Filters and Content Labels Are Not Akin to Content, Ideas, or Expression

The court analyzed whether making filters available and failing to label edited content were either products or content, ideas, and expression.¹⁷⁴ In doing so, the court noted a meaningful distinction between “a ‘tool,’ or functionality, that permit[s] users to manipulate the content and the content itself.”¹⁷⁵ The filters fell into the former category because they were tools to modify expression.¹⁷⁶ The court also concluded that labeling edited or filtered content “does not alter the underlying photo as much as it guides the user in better understanding how to interpret that photo.”¹⁷⁷ Therefore, the court concluded that filters and labeling edited content were both products.¹⁷⁸

D. APPLICATION IN OTHER TRIAL COURTS

As explained, *supra*, in Section III.B, the *In re Social Media* framework has two steps: (1) deciding to analyze product status at the app level (the “all-or-nothing” approach), at the feature level (the “defect-specific” approach), or at both levels; and (2) applying a multi-step inquiry to determine whether the app or feature is a product under the Third Restatement by asking (a) is the

169. *Id.* at 851.

170. *Id.*

171. *Id.*

172. *Id.*

173. *Id.*

174. *Id.* at 851–53.

175. *Id.* at 852.

176. *Id.*

177. *Id.*

178. *Id.* at 852–53.

software a service?; (b) is the software tangible or analogous to tangible property?; and, (c) is the software akin to content, ideas, and expression?¹⁷⁹ Recently, trial courts cite *In re Social Media* to assess whether consumer apps are products for the purposes of products liability.

1. *In re Uber Technologies, Inc., Passenger Sexual Assault Litigation*

For example, in *In re Uber Technologies, Inc., Passenger Sexual Assault Litigation*, District Judge Charles R. Breyer held that the Uber app and features of the Uber app are products under the Third Restatement of Torts using both the “defect-specific” and “all-or-nothing” approaches.¹⁸⁰ In October 2023, the Judicial Panel on Multidistrict Litigation (JPML) created MDL No. 3084, centralizing twenty-two actions from courts across the country concerning the sexual misconduct of Uber drivers.¹⁸¹ Plaintiffs brought products liability claims for Uber’s failure to implement features in its app to prevent sexual misconduct of Uber drivers.¹⁸²

The court applied the “all-or-nothing” and “defect-specific” approaches to hold that the Uber app was a product under the Third Restatement of Torts.¹⁸³ Under the “all-or-nothing” approach, the court reasoned that the Uber app was designed and distributed by Uber¹⁸⁴ and the app as a whole was analogous to tangible personal property.¹⁸⁵ The court cautioned that “it does not follow from [the conclusion that the Uber app is a product] that strict liability applies to everything that might go wrong in relation to the use of the app.”¹⁸⁶

The court also found that the allegedly defective functionality was analogous to tangible products under the “defect-specific” approach.¹⁸⁷ The court asked whether the accused functionality was specific to the product, the Uber app, or was an issue with Uber’s services or business practices.¹⁸⁸ Alleged defects that were product-specific included failure to implement video or audio

179. *Id.* at 847–54.

180. 2024 WL 4211217, at *22–23.

181. *In re Uber Techs., Inc., Passenger Sexual Assault Litig.*, 669 F. Supp. 3d. 1396, 1400–01 (U.S. Jud. Pan. Mult. Lit. Oct. 4, 2023).

182. *In re Uber*, 2024 WL 4211217, at *1.

183. *Id.* at *22.

184. *Id.*

185. *Id.* (reasoning that the Uber app is analogous to a tangible mobile phone accessory that could summon an Uber ride to the user’s location).

186. *Id.* at *24.

187. *Id.* (reasoning that the alleged defective GPS alerting system was analogous to GPS-based alerting in an Apple AirTag).

188. *Id.* at *23–25.

monitoring of rides, GPS-based safety alert systems, and biometric scanning for identity verification of drivers.¹⁸⁹ On the other hand, alleged defects that were service-specific and therefore not subject to strict products liability included failure to offer support during unsafe rides, failure to background check drivers, failure to enact and enforce a zero-tolerance policy towards drivers with histories of inappropriate behavior, and failure to monitor rides.¹⁹⁰

2. *T.V. v. Grindr, LLC*

Another case citing *In re Social Media* was *T.V. v. Grindr*.¹⁹¹ Magistrate Judge Patricia D. Barksdale used the “all-or-nothing” approach to determine that the Grindr app was a product.¹⁹² In 2022, T.V. sued Grindr in federal court under Florida state law on behalf of the estate of A.V. claiming, among other things, products liability.¹⁹³ Grindr is a dating app marketed to gay, bisexual, transgender, and queer people.¹⁹⁴ The plaintiff’s child, A.V., allegedly used Grindr while he was a minor, was exposed to adult Grindr users, and engaged in sexual relationships and activities with adult Grindr users.¹⁹⁵ A.V.’s use of Grindr resulted in severe emotional distress and bodily injuries, culminating in A.V. taking his own life.¹⁹⁶ T.V. alleged that the design of the Grindr app facilitated sexual relationships between adults and minors through features such as ineffective age verification and “Grindr Tribes,” which made it easier for adult users to narrow their search to minor users.¹⁹⁷

Grindr filed a motion to dismiss T.V.’s complaint, contending that the Grindr app was not a product.¹⁹⁸ Citing *In re Social Media*, the court analyzed the Grindr app using the “all-or-nothing” approach but not the “defect-specific” approach. First, the court concluded that Grindr was not a service provider because it designed and distributed the Grindr app, “putting Grindr in the best position to control the risk of harm associated with the Grindr app.”¹⁹⁹ The court further held that the alleged defects did not seek to hold Grindr liable for users’ communications, but rather Grindr’s design choices in

189. *Id.* at *25.

190. *Id.* at *24.

191. 2024 WL 4128796, at *21–26.

192. *Id.* at *26.

193. *Id.* at *1.

194. *Id.*

195. *Id.* at *6.

196. *Id.*

197. *Id.* at *4–5.

198. *Id.* at *17.

199. *Id.* at *26.

its app.²⁰⁰ Applying just the “all-or-nothing” approach, the court concluded that the Grindr app was a product.²⁰¹

IV. EXTENDING *IN RE SOCIAL MEDIA* PROMOTES THE POLICY GOALS OF PRODUCTS LIABILITY LAW

Does the *In re Social Media* framework advance products liability law’s policy goals of allocative efficiency, deterrence, and administrability? Prior to *In re Social Media*, trial courts had to determine whether apps were products as a whole—even when the accused apps embodied a mixture of content, services, and technology. As a result, trial courts arrived at conflicting conclusions. In Section IV.A, this Note argues that *In re Social Media*’s “defect-specific” and “all-or-nothing” approaches promote the policy goals of products liability law, but *In re Social Media*’s multi-step inquiry does not. In Section IV.B, this Note advocates for an extension of *In re Social Media*’s approach to determining whether an app or feature is a product under the Third Restatement of Torts: the user experience (UX)/user interface (UI) approach.

A. CRITIQUE OF *IN RE SOCIAL MEDIA*

Section IV.A of this Note argues that: (1) *In re Social Media*’s “defect-specific” and “all-or-nothing” approaches promote administrability and (2) *In re Social Media*’s multi-step inquiry is not administrable and does not deter companies from putting unsafe consumer software into the stream of commerce.

1. “Defect-Specific” and “All-or-Nothing” Approach

As discussed in Section II.D.1 *supra*, consumer apps have varying and multifaceted purposes.²⁰² Users on some apps, such as marketplace and social media apps, interact with technology, services, and content simultaneously.²⁰³ Users on other apps, such as generative AI apps that leverage LLMs, only interact with technology.²⁰⁴ Before *In re Social Media*, these varied purposes made it difficult for trial courts to determine whether consumer apps were products.²⁰⁵ This Note argues that *In re Social Media* eliminates this difficulty because (a) the “defect-specific” approach eliminates zero-sum outcomes for

200. *Id.*

201. *Id.*

202. *See supra* Section II.D.1.

203. *See supra* text accompanying notes 72–74.

204. *See supra* text accompanying note 71.

205. *See supra* Section II.D.3.

apps that are used to access goods, services, and content and (b) the “all-or-nothing” approach is more administrable for apps that are used for technology alone, as opposed to apps that are used for accessing content or services.

a) Defect-Specific Approach

The “defect-specific” approach is well suited to apps that are used to access goods, services, and content, such as marketplace and social media apps. Under existing products liability law, courts may find that these apps are not products for two reasons. First, the user downloads the app to consume content or obtain services.²⁰⁶ Second, most of the products liability litigation against tech companies thus far concerns harm caused by third parties rather than harm caused directly by the defendant’s technology, and therefore claims against the defendant tech companies would clearly fail for causation.²⁰⁷ Rather than reaching the fact-intensive question of causation, courts may have chosen to dispose of unmeritorious claims quickly by holding that defendants’ apps were not products as a matter of law.²⁰⁸

Determining whether an app is a product as a whole when it encompasses technology, content, and services puts courts in a catch twenty-two. Holding that an app is not a product insulates defendants from products liability claims even when harm arises from the app’s technology and there is an obvious defect.²⁰⁹ In the reverse scenario, holding that an app as a whole is a product allows plaintiffs to sustain products liability claims for *any* injury caused by the app.²¹⁰ This includes injuries defendants are not in a position to mitigate through the design of their apps, such as harm caused by third-party content or services. This zero-sum outcome makes products liability litigation of consumer apps very unpredictable. For example, as noted, *supra*, in Section

206. See, e.g., STRIPE, *supra* note 69.

207. See, e.g., *Doe v. Uber*, 2020 WL 13801354, at *1 (alleging sexual assault by individuals pretending to be Uber drivers); *Jackson v. Airbnb*, 639 F. Supp. 3d at 1000 (alleging that the plaintiff’s son was shot and killed at an Airbnb rental property).

208. The act of a third party does not automatically disclaim a defendant from tort liability; a defendant can be the proximate cause of harm if the third party’s conduct was foreseeable. See *Brauer v. New York Cent. & H.R.R. Co.*, 103 A. 166, 167 (1918) (internal citations omitted). Whether third-party harm is foreseeable is a question of fact that must be decided by the jury, while the question of whether something is or is not a product is a question of law. See Restatement (Third) of Torts: Prods. Liab. § 19 cmt. a (A.L.I. 1998).

209. See *Brookes v. Lyft*, 2022 WL 19799628, at *3 (stating that “Lyft should be responsible for any harm caused by its digital application in the same way the designer of any defective physical product is held accountable”).

210. See *In re Uber*, 2024 WL 4211217, at *24 (noting that it does not follow from the conclusion that the Uber app is a product “that strict liability applies to everything that might go wrong in relation to the use of the app”).

II.D.3, two trial courts came to the exact opposite conclusion on the question of whether the Uber app was a product or a service.²¹¹

The “defect-specific” approach avoids zero-sum outcomes. The question of whether certain functionality constitutes a product is far simpler than whether an entire marketplace or social media app is a product. As a result, courts will accurately classify products liability claims at a higher rate, leading to greater predictability for courts and litigants. This simplified analysis promotes the administrability goals of products liability law.

b) All-or-Nothing Approach

The “all-or-nothing” approach is well suited to apps that are used for technology alone. One example of apps that are used for their technology and not for third-party content or services are generative AI apps powered by LLMs.²¹² Because applied AI and generative AI are major focuses of the tech industry,²¹³ we will likely see an uptick in future products liability litigation against AI apps. The judiciary will need a products liability framework adaptable to AI.

As explained, *supra*, in Section II.A.2.c, one purpose of products liability law is to simplify complicated doctrinal rules that produce the same result.²¹⁴ Taking the “all-or-nothing” approach in the case of apps used for the technology alone—such as generative AI apps—does exactly that. Courts can use the “all-or-nothing” approach to make a quick and simple determination that a consumer app is a product as a whole.²¹⁵ Functionality-level analysis is not necessary because users are not interacting with content, services, or other users at all. Therefore, the “all-or-nothing” approach increases the efficiency of products liability litigation and promotes administrability when analyzing apps used for their technology alone. Having the option of implementing the “defect-specific” approach, “all-or-nothing” approach, or both gives courts the tools to efficiently address a wide variety of consumer technologies, including generative AI apps that may face products liability claims in the future.

211. *See Doe v. Uber*, 2020 WL 13801354, at *7 (holding that the Uber app is not a product); *In re Uber*, 2024 WL 4211217, at *22 (holding that the Uber app is a product for the purposes of products liability under the Third Restatement of Torts).

212. *See supra* text accompanying note 65.

213. Lareina Yee, Michael Chui & Roger Roberts, *McKinsey Technology Trends Outlook 2024*, MCKINSEY (July 16, 2024), <https://www.mckinsey.com/capabilities/mckinsey-digital/our-insights/the-top-trends-in-tech>.

214. HYLTON, *supra* note 28, at 336.

215. *See id.*

2. *Third Restatement's Multi-Step Inquiry*

The second step of the *In re Social Media* framework reconciles the test for whether something is a product under the Third Restatement into a single multi-step inquiry. This multi-step inquiry is not adaptable to consumer apps because (a) the question of whether software is a service or akin to content, expression, or ideas allows defendants to exploit their informational advantage over plaintiffs and (b) software does not need a tangible analog to be considered a product under the Third Restatement.

a) Asking Whether Software is a Service or Akin to Content Allows Defendants to Exploit their Informational Advantage

As required by the Third Restatement, software cannot be a product if it is a service or akin to content, expression, and ideas.²¹⁶ This analysis may be simple in some cases. For example, in *In re Social Media*, the court found that plaintiffs adequately alleged that filters and labels for edited content were products and not content.²¹⁷ The court also found that plaintiffs adequately alleged that barriers to account deletion and deactivation were products and not services.²¹⁸

But it may sometimes be impossible for plaintiffs to know when a tech company acts as a manufacturer of their apps, as opposed to a content creator or service provider. In *In re Social Media*, the court did not analyze whether the accused infinite scroll user interface was a product.²¹⁹ Infinite scroll is a user interface convention that automatically displays new content to users as they scroll.²²⁰ On its face, this feature may seem akin to content or a service that generates content, but it is a deliberate product design choice. There are many user interfaces companies can use to display content. For example, pagination is a user interface technique that loads a discrete set of content at a time.²²¹ When the user reaches the end of that discrete set of content, the user must

216. See RESTATEMENT (THIRD) OF TORTS: PRODS. LIAB. § 19 (A.L.I. 1998); *supra* Section II.B.2.

217. See *supra* Section III.C.2.c).

218. See *supra* Section III.C.2.b).

219. See *In re Soc. Media*, 702 F. Supp. 3d at 819–20 (noting that the plaintiffs accused “endless feeds” of causing mental and psychological harm to children). Judge Gonzalez Rogers found that this claim was barred by § 230 because it sought to hold defendants liable as a content publisher. See *id.* at 831.

220. Tim Neussesser, *Infinite Scrolling: When to Use It, When to Avoid It*, NEILSON NORMAN GRP. (Sep. 4, 2022), <https://www.nngroup.com/articles/infinite-scrolling-tips/>.

221. See Jakob Nielsen, *Users' Pagination Preferences and “View All,”* NEILSON NORMAN GRP. (Apr. 28, 2013), <https://www.nngroup.com/articles/item-list-view-all/>.

prompt the app to show them additional content.²²² Reaching the end of the content provides a natural stopping point for users and serves as a psychological trigger to get off the app.²²³ Infinite scroll is intentionally designed without a natural stopping point to psychologically manipulate users into maximizing their screen time, allowing social media apps to gain additional revenue from displaying ads to users.²²⁴ In light of infinite scroll's exploitative design, potential alternatives, and business goals, it is more akin to a design choice in product manufacturing than to content or service.

Defendant tech companies are the ones with access to information regarding their apps' design and the availability and feasibility of alternative designs. In fact, it is industry practice for product managers to document and test their design choices to maximize business performance.²²⁵ Such documentation is not available to the public because it contains sensitive business information and trade secrets.²²⁶ Therefore, plaintiffs are often unaware of the design choices in defendants' apps and the availability of alternative designs.²²⁷ In sum, plaintiffs are at an informational disadvantage because they do not know all the ways how defendant tech companies act as manufacturers of their apps.²²⁸

b) Software is Analogous to Tangible Personal Property Even If It Does Not Have a Tangible Analog

In *In re Social Media*, the court sought to satisfy the Third Restatement's tangibility requirement by asking whether the accused app or functionality has a physical analog.²²⁹ Despite the plaintiffs' unconvincing arguments, the court's

222. *See id.*

223. *See id.*

224. *See* Sanzana Karim Lora, Sadia Afrin Purba, Bushra Hossain, Tanjina Oriana & Ashek Seum, *Infinite Scrolling, Finite Satisfaction: Exploring User Behavior and Satisfaction on Social Media in Bangladesh*, ARXIV (2024).

225. *See supra* Section II.D.2; Carlos González De Villambrosia, *The Only Product Requirements Document (PRD) Template You Need*, PROD. SCH. (May 19, 2024), <https://productschool.com/blog/product-strategy/product-template-requirements-document-prd> (noting that product managers write PRDs to communicate what features they are building and provide a guide to develop and launch the features).

226. Anesi Igebu, *How to Write a Product Requirements Document*, LINKEDIN (Nov. 18, 2020), <https://www.linkedin.com/pulse/how-write-product-requirements-document-anesi-igebu/> (noting that products requirements documents are confidential).

227. *See id.*

228. *See* HYLTON, *supra* note 28, at 335 (noting that products liability prevents manufacturers from exploiting their informational advantage).

229. *See supra* Section C.1.a; *see also In re Uber*, 2024 WL 4211217, at *22 (reasoning that the Uber app is analogous to a tangible mobile phone accessory that could summon an Uber

conclusion that social media apps were not sufficiently analogous to tangible personal property rested on a misinterpretation of the Third Restatement of Torts. The court interpreted electricity and intangibles that are sufficiently analogous to tangible property as two separate categories of products.²³⁰ The court therefore determined that an intangible can be considered a product if it has an analogous tangible product.²³¹ However, the Third Restatement provides electricity as an *example* of an intangible that is sufficiently analogous to tangible personal property.²³² An intangible does not need a tangible analog to be considered a product; for example, electricity is considered a product even though it does not have a tangible analog.²³³

Additionally, the physical analog requirement creates an upper limit on the applicability of products liability law that technology is already surpassing. Many emerging technologies do not have clear physical analogs. For example, are autonomous vehicles analogous to a remote-controlled vehicle (product) or a taxi ride (service)? The same question arises for AI: is a chatbot powered by AI analogous to a question-answering robot (product), an omniscient person hired to answer questions (service), or the works of an author (ideas, expression, and content)? AI's physical analog is at best strained and at worst nonexistent.

Requiring an app or feature to have a tangible analog to be considered a product is contrary to the goals of products liability law for two reasons. First, it will disincentivize tech companies from investing in the safety of emerging technologies without tangible analogs. If courts find that technologies such as AI or autonomous vehicles do not have tangible analogs, manufacturers of these technologies will be immune from products liability claims. This contradicts products liability's goal of incentivizing safety in innovation. Second, the question of whether an app or feature has a physical analog is subjective and will vary from judge to judge. For example, the court in *In re Social Media* concluded that social media apps were not analogous to tangible containers and therefore not products as a whole.²³⁴ On the other hand, in *In*

ride to the user's location and that an allegedly defective GPS alerting system was analogous to GPS-based alerting in an Apple AirTag).

230. *In re Soc. Media*, 702 F. Supp. 3d at 841.

231. *Id.*

232. See RESTATEMENT (THIRD) OF TORTS: PRODS. LIAB. § 19 (A.L.I. 1998) ("Other items, *such as* . . . electricity, are products when the context of their distribution and use is sufficiently analogous to the distribution and use of tangible personal property that it is appropriate to apply the rules stated in this Restatement." (emphasis added)).

233. See RESTATEMENT (THIRD) OF TORTS: PRODS. LIAB. § 19 cmt. d. (A.L.I. 1998).

234. *In re Soc. Media*, 702 F. Supp. 3d at 843.

re Uber the court concluded that the Uber app was a product as a whole because it was analogous to a tangible mobile phone accessory that could summon an Uber ride to the user's location.²³⁵ The question of whether an app or feature has a physical analog is a subjective determination made at a trial judge's discretion. This will lead to inconsistent outcomes in courts, contrary to the administrability goals of products liability.²³⁶

B. THE USER EXPERIENCE (UX)/USER INTERFACE (UI) APPROACH

In parts of the *In re Social Media* decision, Judge Gonzalez Rogers hints that user experience and user interface choices are more likely to be products for the purposes of products liability.²³⁷ This Note argues that this factor is determinative for analyzing the product status of consumer software. Section IV.B of this Note: (1) contends that instead of applying the *In re Social Media* multi-step inquiry, courts can determine whether an app or feature is a product under the Third Restatement of Torts by the app's user experience or user interface; (2) explains why the UX/UI approach promotes the policy goals of products liability law; and, (3) shows that implementing UX/UI approach is unlikely to cause chilling effects on the tech industry.

1. *An App or Feature Is a Product under the Third Restatement If It Has a Consumer-Facing User Experience (UX) or User Interface (UI)*

In re Social Media's "all-or-nothing" and "defect-specific" approaches promote administrability and prevent zero-sum outcomes in consumer app products liability. *In re Social Media's* multi-step inquiry fails to promote the administrability and deterrence goals of products liability. Building upon the "all-or-nothing" and "defect-specific" approaches, this Note proposes the UX/UI approach as an alternative to *In re Social Media's* multi-step inquiry:

1. Under the "all-or-nothing" approach, a consumer app should be considered a product if the user experience only involves the defendant's technology and the user never interacts with human-provided services or human-generated content.
2. Under the "defect-specific" approach, an accused feature is a product if the plaintiff can visually identify a defective user interface element within the defendant's app.

235. *In re Uber*, 2024 WL 4211217, at *22.

236. See CALABRESI, *supra* note 37, at 47–64.

237. See *In re Soc. Media*, 702 F. Supp. 3d at 849–53 (concluding that defective parental controls and age verification and failure to implement CSAM reporting were products because they were user interface/experience choices).

The UX/UI approach is advantageous because it provides a bright-line rule that courts can consistently apply. The UX/UI approach meets the requirements of the Third Restatement of Torts because (a) tech companies are manufacturers of their user experiences and user interfaces but not of services and content and (b) user experiences and user interfaces are analogous to tangible personal property.

a) Tech Companies Are Manufacturers of User Experiences and User Interfaces in Their Apps

Any company that builds consumer apps should be considered a manufacturer of the user experiences and user interfaces in their apps. The software product development process involves data-driven design and distribution.²³⁸ Even the most minuscule features of an app are designed to influence user behavior and increase revenue.²³⁹ Each new feature is monitored to ensure it is promoting the business's goals.²⁴⁰ Therefore, the role tech companies play in designing, building, and testing the user experiences and user interfaces in their apps is analogous—if not identical—to the role manufacturers play in designing, building, and testing conventional products.²⁴¹ Furthermore, tech companies are capable of sophisticated, automated monitoring to improve their products in a way that surpasses the capabilities of conventional manufacturers.²⁴² Therefore, tech companies should be considered manufacturers of user experiences and user interfaces in their consumer apps.

If and when companies replace manual tasks performed by human employees with AI automation in consumer apps, it will become more important to view tech companies as manufacturers of user experiences and user interfaces. For example, a company's choice to use an AI chatbot instead of a human employee is regarded as a user experience choice because it impacts the user's overall experience within the app—perhaps by eliminating wait times for customer service. The user could also identify visible user interface elements, such as harmful messages from the chatbot or a label on the screen indicating that the user is interacting with an AI. Under the UX/UI approach, the use of a chatbot in lieu of a human employee is a UX design choice and therefore would be a product for the purposes of products liability. A harmed plaintiff can show that the use of a chatbot is a product by showing that their

238. *See supra* Section II.D.2.

239. *See id.*

240. *See id.*

241. *See id.*

242. *See supra* text accompanying note 76.

UX did not involve human-generated content or services, or by identifying a specific UI component that caused their harm. Therefore, under the UX/UI approach, a company will be liable under products liability for harm caused by AI chatbots but liable for the conduct of human employees only in the case of negligence. This is consistent with a simple principle of tort law: companies should be liable under negligence for harm caused by their employees²⁴³ and liable under products liability for harm caused by their technology.²⁴⁴

b) Use Experiences and User Interfaces Are Sufficiently Analogous to Tangible Personal Property

User experiences and user interfaces meet the Third Restatement of Tort's definition of a product because they are sufficiently analogous to tangible personal property in the context of their distribution and use.²⁴⁵ While Judge Gonzalez Rogers points out in *In re Soc. Meda* that apps are not tangible products in the same way a water heater or a power tool are tangible products,²⁴⁶ the Third Restatement imposes no such requirement to achieve product status.²⁴⁷ The text of Section 19(a) provides that “[o]ther items, such as real property and electricity, are products when the *context of their distribution and use is sufficiently analogous to the distribution and use of tangible personal property* that it is appropriate to apply the rules stated in this Restatement.”²⁴⁸ This text does not require an app or feature to have an analogous tangible product.²⁴⁹

For example, electricity is a product for the purposes of products liability even though it does not have a tangible analog.²⁵⁰ In *In re Uber*, Judge Breyer notes that electricity becomes a product once it enters a consumer's home, even though it is “not quite tangible and requires a massive background infrastructure to be useful.”²⁵¹ Judge Breyer suggests further that “[a]n analogy can be drawn [between electricity and] Uber's software, which may not be a product just in itself, but sensibly recognized as a product when a user downloads the frontend interface onto their own device.”²⁵² Experts in

243. See *Gagne v. Bertran*, 43 Cal. 2d at 487.

244. See *supra* Section II.A.

245. See RESTATEMENT (THIRD) OF TORTS: PRODS. LIAB. § 19(a) (A.L.I. 1998).

246. See *supra* Section II.B.1.b.

247. See RESTATEMENT (THIRD) OF TORTS: PRODS. LIAB. § 19(a) (A.L.I. 1998).

248. *Id.*

249. See *id.*

250. See *id.* § 19 cmt. d.

251. *In re Uber*, 2024 WL 4211217, at *22 n.15.

252. *Id.*

cyberlaw emphasize that analogies such as Judge Breyer's are critical to developing effective legal solutions for emerging technologies.²⁵³

Like electricity, consumer software should be considered a product when it flows through devices that users interact with.²⁵⁴ Software that exists on a server before a user downloads an app or accesses a web page is analogous to electricity that has not flowed through a customer's meter because it has "not yet been sold or otherwise distributed."²⁵⁵ Just as electricity is sufficiently analogous to tangible property when a user flips a light switch or turns on an appliance, consumer software is sufficiently analogous to tangible property when users interact with it through a mobile app or web page.²⁵⁶ A simple way for courts and litigants to tell when consumer software has become sufficiently analogous to tangible property is to have plaintiffs identify a user experience or user interface that they interacted with.²⁵⁷ For example, in *Lemmon v. Snap* the plaintiffs could have satisfied their burden to show that the speed filter was a product by identifying the UI element corresponding to the filter: the font showing the user's speed that appears on top of the user's photo or video.²⁵⁸ Therefore, the UX/UI approach satisfies the requirements of the Third Restatement.²⁵⁹

2. *The UX/UI Approach Promotes the Policies of Tort Law*

The UX/UI approach promotes allocative efficiency, deterrence, and administrability. First, the UX/UI approach places the burden of product accidents on the party best able to prevent harm, because tech companies are in a superior position to control the design of their apps. Although tech companies are not always able to control third-party services and content facilitated by their apps, the UX/UI approach will not hold tech companies liable for harm resulting from services or content.

Second, the UX/UI approach promotes deterrence by encouraging tech companies to invest in product safety. Although the physical analog requirement fails to incentivize safety in emerging technologies such as AI,²⁶⁰ the UX/UI approach considers that AI apps are products if the AI app has a

253. See Calo, *supra* note 66, at 559.

254. See *id.*

255. See RESTATEMENT (THIRD) OF TORTS: PRODS. LIAB. § 19 cmt. d (A.L.I. 1998) (internal quotations omitted).

256. See *id.*

257. See *supra* text accompanying notes 66–67.

258. See *Lemmon v. Snap*, 995 F.3d at 1089.

259. See RESTATEMENT (THIRD) OF TORTS: PRODS. LIAB. § 19(a) (A.L.I. 1998).

260. See *supra* Section IV.A.2.

consumer-facing user experience or user interface. As many scholars would agree, this is a desirable outcome.²⁶¹ On top of the existing proof problems plaintiffs face in bringing design defect claims against product manufacturers,²⁶² AI's "black box problem" amplifies proof problems because engineers themselves do not understand how some AI models make their decisions.²⁶³ Placing the burden on plaintiffs to show a lack of reasonable care and causation will preclude negligence claims against AI companies because no one—not even a reasonable AI developer—can explain the inner workings of certain AI models.²⁶⁴ By recognizing AI and other technologies without obvious tangible analogs as products, the UX/UI approach incentivizes safety in innovation and prevents tech companies from exploiting their informational advantage.

Finally, the UX/UI approach will be more administrable for courts than the *In re Social Media*'s multi-step inquiry. As explained above, the UX/UI approach is a bright-line rule that produces the same result as the subjective and complicated multi-step inquiry.²⁶⁵ Additionally, the UX/UI approach will help trial courts come to consistent conclusions about what apps and features are products.²⁶⁶

3. *The UX/UI Approach Will Not Create Chilling Effects on the Tech Industry*

One potential concern regarding the UX/UI approach is that it will lower the barrier for plaintiffs claiming products liability against defendant tech companies. There are unlikely to be significant chilling effects on tech companies due to the many additional hurdles plaintiffs face in products liability cases. Just because a court determines that a consumer app is a product does not mean that the defendant is liable for all resulting harm. Once a plaintiff satisfies their burden to show that a consumer software app or feature is a product, they must also demonstrate defect, harm, and causation.²⁶⁷ Additionally, in claims for design defect and insufficient warnings the plaintiff

261. See Villasenor, *supra* note 5; Ramakrishan et. al., *supra* note 7, at 27.

262. See *id.*

263. See Lou Blouin, *AI's Mysterious 'Black Box' Problem, Explained*, U. MICH.-DEARBORN NEWS (Mar. 6, 2023), <https://umdearborn.edu/news/ais-mysterious-black-box-problem-explained> (defining the "black box problem" as the "inability for us to see how deep learning systems make their decisions").

264. See HYLTON, *supra* note 28, at 335.

265. See *supra* Section IV.A.2.

266. See *supra* Section II.D.3.

267. See RESTATEMENT (THIRD) OF TORTS: PRODS. LIAB. §§ 1–2 (A.L.I. 1998).

must also show that their harm was foreseeable and could have been prevented with a reasonable alternative design or reasonable warnings or instructions.²⁶⁸

Furthermore, products liability only provides redress for physical harm.²⁶⁹ Given the digital nature of apps, it is unlikely that defects will often result in direct physical harm. Many of the products liability cases involving defective apps only allege psychological harm.²⁷⁰ Even if physical harm results, plaintiffs must overcome the additional hurdle of proximate causation. Courts may dismiss products liability cases against apps for insufficient causation when third parties cause the intentional tort to harm plaintiffs.²⁷¹ Plaintiffs' own conduct could be an independent intervening cause of harm because users make a conscious choice to use consumer apps.²⁷² Furthermore, the defendant has an additional opportunity to assert defenses, such as misuse and subsequent mishandling.²⁷³

Given the other barriers plaintiffs have to establish a successful products liability claim, the UX/UI approach is not likely to open the floodgates of products liability litigation.²⁷⁴ Nonetheless, the UX/UI approach will incentivize tech companies to invest in product safety to avoid litigation in the

268. *See id.* § 2(b) (stating that a product has a design defect “when the foreseeable risks of harm posed by the product could have been reduced or avoided by the adoption of a reasonable alternative design . . . and the omission of the alternative design renders the product not reasonable safe”); Ramakrishnan et. al., *supra* note 7, at 33 (predicting that liability determinations for AI developers will largely be the same under the risk-utility test and traditional negligence doctrines).

269. *See* RESTATEMENT (THIRD) OF TORTS: PRODS. LIAB. § 1(A.L.I. 1998).

270. *See, e.g., In re Soc. Media*, 702 F. Supp. 3d at 819 (alleging mental health harm and addiction); *T.V. v. Grindr*, 2024 WL 4128796, at *6 (alleging severe emotional distress and suicide).

271. *Brauer*, 103 A. at 167 (holding that unforeseeable third-party intervention is an independent intervening cause of harm); *See also, e.g., Jackson v. Airbnb*, 639 F. Supp. 3d at 1000 (alleging that plaintiff's son was shot and killed on an Airbnb property); *In re Uber*, 2024 WL 4211217, at *1–2 (alleging that Uber drivers engaged in sexual misconduct).

272. *See* RESTATEMENT (THIRD) OF TORTS: PHYS. & EMOT. HARM § 34 (2010) (“When a force of nature or an independent act is also a factual cause of harm, an actor's liability is limited to those harms that result from the risks that made the actor's conduct tortious.”).

273. *See* RESTATEMENT (SECOND) OF TORTS § 402A cmt. g (A.L.I. 1998) (noting that a product is not defective if it the harm results from subsequent mishandling or from abnormal handling or misuse by the consumer).

274. *See* Gary Wilson, Vincent Moccio & Daniel O. Fallon, *The Future of Products Liability in America*, 27 WM. MITCHELL L. REV. 85, 88–101 (2000) (noting that statutes of repose, damages caps, and federal preemption heightened requirements for the reliability of expert testimony under *Daubert*, and the advent multi-district litigation made it more difficult for individual plaintiffs to maintain products liability suits).

first place and provide an avenue for redress for app-caused harm to plaintiffs with meritorious claims.

V. CONCLUSION

The purpose of products liability is to strike the optimal balance between innovation and safety.²⁷⁵ This is just as true for consumer software as it was for the first passenger vehicles.²⁷⁶ Courts are struggling to determine when consumer software is a product and sometimes arrive at opposite conclusions on the very same app.²⁷⁷ In an attempt to address the unique complexity of consumer software and avoid these zero-sum outcomes, *In re Social Media* created a new framework to analyze the product status of consumer software using the “all-or-nothing” and “defect-specific” approaches and then applying the Third Restatement of Torts through a multi-step inquiry.²⁷⁸ Although *In re Social Media*’s approach is better than the baseline, replacing the multi-step inquiry with the UX/UI approach further simplifies the analysis of whether consumer apps are products and creates consistent, administrable litigation.²⁷⁹

Products liability law still has many unanswered questions concerning consumer software. First, this Note does not address § 230 Immunity. Although internet companies are not insulated from products liability claims under § 230,²⁸⁰ what constitutes protected expression in user experiences and user interfaces of consumer apps is a difficult question to answer.²⁸¹ Although courts have historically provided internet companies with immunity for harms caused by their algorithms,²⁸² the Third Circuit held in *Anderson v. TikTok, Inc.* that § 230 did not shield TikTok from liability for its recommendation algorithm.²⁸³ The interplay between § 230 and products liability in the context of consumer software warrants further scholarship. Second, additional investigation is needed to clarify the line between the expressive and functional

275. See SHAPO, *supra* note 30, at 7-42-43.

276. See *MacPherson v. Buick*, 217 N.Y. at 389.

277. See *supra* Section II.D.3.b.

278. See *supra* Section III.B.

279. See *supra* Section IV.B.

280. *Lemmon v. Snap*, 995 F.3d at 1093. Note that the Ninth Circuit did not directly address the question of whether Snapchat is a product. See *id.*

281. Max Del Real, *Breaking Algorithmic Immunity: Why Section 230 Immunity May Not Extend to Recommendation Algorithms*, 99 WASH. L. REV. 1, 1 (noting that “recommendation algorithms pose an especially tricky challenge for Section 230 analyses”).

282. *Id.* at 3.

283. 116 F.4th 180, 184 (3d Cir. 2024) (holding that § 230 did not protect TikTok from liability for harm caused by its recommendation algorithm because the recommendation algorithm is TikTok’s own expression rather than the expression of a third party).

attributes of user interfaces and user experiences. It may be very difficult for courts to draw the line between technology and content, ideas, and expressions in the context of specific design elements. Finally, this Note does not address how other products liability rules apply in the context of consumer software, such as what constitutes a manufacturing or design defect in a consumer app.

In conclusion, the existing products liability framework can address harm caused by emerging consumer software technology. Although courts would benefit from adopting the UX/UI approach in lieu of the multi-step inquiry, *In re Social Media* shows that courts are already moving in the right direction to adapt products liability law to meet the needs of modern consumers.

IMMUNIZING THE ALGORITHM ONLY AS MUCH AS IT NEEDS: RETHINKING HOW COURTS ANALYZE ALGORITHMS UNDER SECTION 230

Andra Cernavskis[†]

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I. INTRODUCTION

Anyone who has used social media—whether that's TikTok, Instagram, YouTube, or any other popular platform—has engaged with “the algorithm.”¹

1. In 2022, seven out of ten Americans used social media in some capacity. Lee Rainie, Cary Funk, Monica Anderson & Alec Tyson, *Mixed Views About Social Media Companies Using Algorithms to Find False Information*, PEW RSCH. CTR. (Mar. 17, 2022), <https://>

Social media users often talk about the algorithm’s role in their lives and social media experiences, and many have tried to understand how it works or why particular content appears on their social media feeds. Whether people like it or not, the algorithm has a lot of power in modern society. It helps inform spending habits, what news users consume, what opinions people are exposed to, and even what hobbies or interests people adopt. This all happens through a type of algorithm known as a recommendation system. As Michael Schrage notes, “[m]uch as steam engines energized the Industrial Age, recommendation engines are the prime movers digitally driving 21st-century advice worldwide.”² The algorithm is often characterized as an obscure, all-powerful deity that perhaps knows a person better than they know themselves.³ That is to say, the algorithm has taken on a life of its own in the modern world.

However, “the algorithm” is not just one all-knowing, powerful entity, even if it sometimes feels like that might be the case. Companies that use algorithms—which extend far past social media companies and include online marketplaces like Amazon, streaming services like Netflix, and beyond⁴—all have their own individual algorithms that their own engineers built and maintain.⁵ On top of that, all major companies use many different algorithms to perform different functions and reach different goals.⁶ For example, one company may use one algorithm (or group of algorithms) for recommending content to a user while using another algorithm to filter out spam-type content from entering people’s feeds.⁷

In its most simple form, algorithms are “a list of rules to follow in order to complete a task or solve a problem.”⁸ By this definition, recipes or directions

www.pewresearch.org/internet/2022/03/17/mixed-views-about-social-media-companies-using-algorithms-to-find-false-information/.

2. Michael Schrage, *The Recommender Revolution*, MIT TECH. REV. (Apr. 27, 2022), <https://www.technologyreview.com/2022/04/27/1048517/the-recommender-revolution/>.

3. See generally Eleanor Cummins, *The Creepy TikTok Algorithm Doesn’t Know You*, WIRED (Jan. 3, 2022), <https://www.wired.com/story/tiktok-algorithm-mental-health-psychology/>.

4. See Rachel Metz, *Algorithms Are Everywhere. Here’s Why You Should Care*, CNN (Nov. 19, 2021), <https://www.cnn.com/2021/11/19/tech/algorithm-explainer/index.html>; see also Larry Hardesty, *The History of Amazon’s Recommendation Algorithm*, AMAZON SCI. (Nov. 22, 2019), <https://www.amazon.science/the-history-of-amazons-recommendation-algorithm>.

5. See Arvind Narayana, *Understanding Social Media Recommendation Algorithms*, KNIGHT FIRST AMEND. INST. AT COLUM. U. (Mar. 9, 2023), <https://knightcolumbia.org/content/understanding-social-media-recommendation-algorithms>.

6. See generally Rainie et al., *supra* note 1.

7. See generally *id.*

8. *What Is an Algorithm?*, BBC, <https://www.bbc.co.uk/bitesize/articles/z3whpv4> (last visited May 5, 2025).

to a friend's house are all algorithms.⁹ These are classic, rule-based algorithms, and these types of algorithms can and do exist on digital platforms.¹⁰ However, rule-based algorithms are difficult to scale because they are largely hand-coded. While hand-coding algorithms makes the algorithm easier to understand and therefore troubleshoot when needed, it also means that if individual developers' were to create rule-based algorithms to fuel social media feeds, the engineers' assumptions about what people want to see online would be baked into the rules of those algorithms, whether those assumptions are correct or not.¹¹

Therefore, most of the algorithms that now fuel the modern online experience are machine-learning recommendation algorithms, which are also known as recommender systems.¹² These algorithms all share at least one feature in that they are built using advanced machine-learning models that are trained on massive data sets that effectively teach the system how to make predictions based on that data or classify data in an organized way.¹³ In this way, recommender systems are a lot more complex than rule-based algorithms. In fact, experts often accuse these types of algorithms as being black boxes because of the nearly impossible task of understanding how and why they work the way they do.¹⁴

For many users, recommendation systems make their social media experience more pleasurable, offering up entertaining or educational content related to their specific interests. However, it is no secret that there is a dark side to social media companies' use of recommendation systems. The world discovered this after the 2016 U.S. presidential election, when whistleblowers and researchers shined a light on how these types of algorithms manipulated voter behavior and spread election misinformation.¹⁵ Since then, social media companies that use recommendation algorithms have been accused of

9. *See id.*

10. *See* Chris Meserole, *How Do Recommender Systems Work on Digital Platforms?*, BROOKINGS (Sep. 21, 2022), <https://www.brookings.edu/articles/how-do-recommender-systems-work-on-digital-platforms-social-media-recommendation-algorithms/>.

11. *See id.*

12. *See id.*

13. *See* Simson L. Garfinkel, *A Peek at Proprietary Algorithms*, AM. SCIENTIST, <https://www.americanscientist.org/article/a-peek-at-proprietary-algorithms>.

14. *See* Cynthia Rudin & Joanna Radin, *Why Are We Using Black Box AI When We Don't Need To? A Lesson from an Explainable AI Competition*, HARV. DATA SCI. REV. (Nov. 22, 2019), <https://hdsr.mitpress.mit.edu/pub/f9kuryi8/release/8>.

15. *See generally* Carole Cadwalladr & Emma Graham-Harrison, *Revealed: 50 Million Facebook Profiles Harvested for Cambridge Analytica in Major Data Breach*, GUARDIAN (Mar. 17, 2018), <https://www.theguardian.com/news/2018/mar/17/cambridge-analytica-facebook-influence-us-election>.

radicalizing terrorists, promoting eating disorders to at-risk, young girls, spreading more dangerous misinformation, and promoting hate speech.¹⁶

Despite the extreme power and influence that recommendation algorithms hold in modern society, the companies responsible for building and maintaining these algorithms have been able to do so with very little oversight or government regulation. This is all because of one federal law that is often credited with creating the internet as we know it today in the United States: § 230.¹⁷ Congress passed § 230 in 1996 when it saw a growing need to encourage the creation and development of internet companies.¹⁸ While § 230 has many components, there are twenty-six words that carry the most weight and have received the most attention: “[n]o provider or user of an interactive computer service shall be treated as the publisher or speaker of any information provided by another information content provider.”¹⁹ These are the words that have allowed multitudes of internet companies to invoke statutory immunity as a defense when a plaintiff seeks damages for harms related to content posted by third parties on websites, including content that was promoted by the company’s own recommendation algorithms.²⁰

While it was relatively uncontroversial at the time of its enactment, § 230 has remained statutorily unchanged since 1996. This is despite both the facts that the internet looks completely different than it did in 1996 and that § 230 arguably finished its intended job in promoting innovation and U.S. internet company growth. The companies that the law originally sought to help are now some of the wealthiest and most powerful corporations in the world.²¹ Despite

16. See John Schultz, *The Drivers of Platform Harm*, BELFER CTR. FOR SCI. & INT’L AFFS. (June 5, 2023), <https://www.belfercenter.org/publication/drivers-platform-harm>; *Deadly By Design: TikTok Pushes Harmful Content Promoting Eating Disorders and Self-Harm Into Users’ Feeds*, CTR. FOR COUNTERING DIGIT. HATE (Dec. 2022), https://counterhate.com/wp-content/uploads/2022/12/CCDH-Deadly-by-Design_120922.pdf; *Five Things About the Role of the Internet and Social Media in Domestic Radicalization*, NAT’L INST. JUST. (Dec. 18, 2023), <https://nij.ojp.gov/topics/articles/five-things-about-role-internet-and-social-media-domestic-radicalization>; see generally Pilar M. Hoye, *Down the Alt-Right Rabbit Hole: The Role of Social Media Platforms in the Radicalization of Domestic Right-Wing Terrorists*, 33 S. CAL. INTERDISC. L.J. 161 (2023).

17. See Stephen Engelberg, *Twenty-Six Words Created the Internet. What Will It Take to Save it?*, PROPUBLICA (Feb. 9, 2021), <https://www.propublica.org/article/nsu-section-230>.

18. See VALERIE C. BRANNON & ERIC N. HOLMES, CONG. RSCH. SERV., R46751, SECTION 230: AN OVERVIEW 2 (2024).

19. 47 U.S.C. § 230(c)(1).

20. Alan Z. Rozenshtein, *Interpreting the Ambiguities of Section 230*, BROOKINGS (Oct. 26, 2023), <https://www.brookings.edu/articles/interpreting-the-ambiguities-of-section-230/#liability-for-algorithmic-amplification-754>.

21. See Letter from William P. Barr, Att’y Gen., United States, to Michael R. Pence, President, United States Senate (Sep. 23, 2020), <https://www.justice.gov/ag/media/1093246/>

modern realities, both legislative and judicial branches in the United States have had a difficult time adapting the 1996 law to a rapidly changing internet. As such, § 230 has remained a consistent shield for large internet companies to protect them from liability for harmful content on their platforms, which now includes content that may connect individuals with terrorist organizations or help convince a young girl to develop an eating disorder. As the internet has grown and developed in the decades since Congress passed § 230, the question of what § 230 continues to protect has taken center stage with one of the most important questions currently being: Does § 230 apply to recommendation algorithms?²² Furthermore, the question of how far § 230 will go is becoming ever more critical in the face of the rapid technological advancements being made with generative AI.

On top of § 230 remaining unchanged in the light of modern realities, U.S. courts have also overgeneralized the function of social media platforms and algorithms under § 230. Throughout many of the cases that address how § 230 applies to social media companies' algorithms, federal courts have treated these algorithms as one, monolithic entity that works roughly the same way across and within companies. This results in an all-or-nothing approach in which algorithms, as a single concept, are determined to either violate § 230 or not. This all-or-nothing approach leaves little room for courts to consider that some algorithms may violate § 230, while others do not. Instead, courts should consider taking a much narrower, more fact-intensive approach to determining § 230 immunity and liability. This new approach should examine each individual algorithm separately from other algorithms on the same or different platforms. If this individualized approach is taken, courts can assess a single algorithm under the law and find it to be outside the scope of § 230 immunity without over-implicating other algorithms within the same platform or across platforms.

Part II of this Note will first examine the legislative and judicial background of § 230 and why recommendation algorithms have posed a unique challenge for courts when examining § 230 as a defense. Part III will

dl?inline= [https://perma.cc/R42E-A2TE]; see also Engelberg, *supra* note 17 (referring to the title of Jeff Kosseff's book, *The Twenty-Six Words That Created the Internet*); Andrea Murphy & Matt Schiffrin, *The Global 2000 2024*, FORBES (June 6, 2024), <https://www.forbes.com/lists/global2000/>; Alina Sekyukh, *Section 230: A Key Legal Shield for Facebook, Google Is About to Change*, NPR (Mar. 21, 2018), <https://www.npr.org/sections/alltechconsidered/2018/03/21/591622450/section-230-a-key-legal-shield-for-facebook-google-is-about-to-change>.

22. Other important debates involve § 230's role in protecting free speech and promoting thoughtful content moderation practices. Jennifer Stisa Granick, *Is This the End of the Internet as We Know It*, ACLU (Feb. 22, 2023), <https://www.aclu.org/news/free-speech/section-230-is-this-the-end-of-the-internet-as-we-know-it>.

then expand on some of the key appellate and Supreme Court cases that have characterized algorithms either in a § 230 analysis or otherwise.²³ Part IV will address faults with the courts' broad characterizations of algorithms, propose a new, more fact-intensive and individualized approach for courts to take that will result in more satisfying outcomes for plaintiffs and defendants alike, and address potential concerns with the new approach (such as the potential for chilling speech and how the new approach might be implemented). Finally, Part V will conclude and suggest how the new approach introduced in Part IV could be helpful in future cases that surely will involve new and developing technologies beyond the recommendation algorithm.

II. THE DEVELOPMENT OF SECTION 230

Part II will first address the legislative and early judicial history of § 230, paying special attention to key cases that have helped shape appellate courts' broad understandings of the statutory language. Part II will then examine more recent appellate court cases that have either limited the initial broad interpretation of § 230 over the years or helped define a test for how to apply § 230 to various claims against internet companies. Lastly, Part II will address why § 230 poses a unique challenge when it comes to emerging technologies that did not exist when Congress passed the statute, namely recommendation algorithms.

A. SECTION 230

Section II.A will first examine the legislative history and goals of § 230 in the context of the 1990s internet. Section II.A will also address the debates that have arisen because § 230 has remained unchanged for nearly 30 years. The discussion will then turn to the early judicial interpretation of § 230 in *Zeran v. America Online, Inc.*, decided shortly after Congress passed § 230.²⁴ In *Zeran*, the Fourth Circuit broadly interpreted how much immunity internet companies should receive under the statute when it was presented with a case in which a plaintiff was seeking to hold AOL accountable for harmful content posted by a third-party user.²⁵ *Zeran's* broad interpretation of § 230 has since influenced courts' § 230 analysis for decades, for better or worse.²⁶

23. If the Supreme Court decides to take up the § 230 issue of how the law is applied to algorithms, the Court's already-existing characterization of algorithms could influence its future decisions.

24. See generally *Zeran v. Am. Online, Inc.*, 129 F.3d 327 (4th Cir. 1997).

25. See generally *id.*

26. See Rozenshtein, *supra* note 20.

1. *Legislative History*

The internet has changed dramatically since it started to become widely available to the public in the 1990s. Section 230 passed at a time when the internet was beginning to take off. For example, in the year prior to § 230's enactment, only 21 percent of people in the U.S. had used the internet.²⁷ A year later, that number grew to 73 percent.²⁸ Congress passed § 230, in part, to promote the growth of the technology industry and shield internet companies from lawsuits that could potentially put them out of business.²⁹ Known as “the twenty-six words that created the internet,”³⁰ § 230 of the Communications Decency Act (CDA) has been highly impactful ever since Congress passed it in 1996.

Congress initially passed § 230 as part of a group of measures meant to amend the Communications Act of 1934.³¹ The group of new measures was collectively known as the CDA and was largely enacted to protect children on the internet from pornography and obscene materials.³² Section 230, however, stood apart from many of the other sections of the CDA. While the Supreme Court quickly struck down most of the CDA on First Amendment grounds, § 230 remains the only constitutionally sound part of the CDA.³³

Congress passed § 230 largely in response to a 1995 New York state court decision in *Stratton Oakmont, Inc. v. Prodigy Services Co.*, which held that an internet company was liable for libelous statements a user had posted to its message boards.³⁴ Congress wanted to provide immunity to internet companies like Prodigy Services from liability for third-party content posted on their platforms.³⁵ The idea was that if companies were embattled in endless litigation over the legality of third-party content, they would not be able to grow and innovate in any meaningful way.³⁶ The provision granting internet companies immunity for third-party content can mostly be found in subsection (c)(1) of § 230, which states, “[n]o provider or user of an interactive computer

27. *News Attracts Most Internet Users: Online Use*, PEW RSCH. CTR. (Dec. 16, 1996), <https://www.pewresearch.org/politics/1996/12/16/online-use/>.

28. *Id.*

29. JEFF KOSSEFF, *THE TWENTY-SIX WORDS THAT CREATED THE INTERNET* 57–78 (2019).

30. Engelberg, *supra* note 21 (referring to the title of Jeff Kosseff's book, *The Twenty-Six Words That Created the Internet*).

31. See BRANNON, *supra* note 18, at 1.

32. *Id.*

33. *See id.*

34. *See Stratton Oakmont, Inc. v. Prodigy Servs. Co.*, 1995 WL 323710 *5 (N.Y. Sup. Ct. May 24, 1995).

35. See BRANNON, *supra* note 18, at 7.

36. See Barr, *supra* note 21.

service shall be treated as the publisher or speaker of any information provided by another information content provider.”³⁷ Subsection (c)(1) is also the focus of the debates surrounding § 230.³⁸

Another important goal of § 230 was to allow internet companies to moderate the content on their websites without fear of liability if they act “in good faith.”³⁹ As Jeff Kosseff, a well-known proponent of § 230, says, “[t]oday it protects both from liability for user posts as well as liability for any claims for moderating content.”⁴⁰

There is an ongoing debate about whether § 230 remains a necessary law, given modern realities. Although often with different motives, elected officials and politicians from across the aisle have argued that § 230 has run its course and that social media companies are abusing the law in order to protect themselves in situations where they should be held liable.⁴¹ As such, many have recently called for § 230 reform or for its repeal entirely.⁴² So far, none of these efforts have been effective.⁴³ Proponents of § 230 continue to argue that without the law in its current form, the internet we know today could not exist.⁴⁴ Regardless of where one stands on § 230, one thing is clear: it has remained on the books since 1996 fairly unscathed.

2. *Early Judicial Interpretation in Zeran v. America Online, Inc. (1997)*

In the years and decades since 1996, many have attempted to use the courts to hold internet companies responsible, at least in part, for disseminating and potentially contributing to harmful content on their platforms. However, these efforts have had little success because judges often find that § 230 bars

37. 47 U.S.C. § 230(c)(1).

38. Danielle Draper, *Summarizing the Section 230 Debate: Pro-Content Moderation vs. Anti-Censorship*, BIPARTISAN POL’Y CTR. (July 5, 2022), <https://bipartisanpolicy.org/blog/summarizing-the-section-230-debate-pro-content-moderation-vs-anti-censorship/>.

39. 47 U.S.C. § 230(c)(2)(a); Barbara Ortutay, *What You Should Know About Section 230, The Rule That Shaped Today’s Internet*, PBS (Feb. 21, 2023), <https://www.pbs.org/newshour/politics/what-you-should-know-about-section-230-the-rule-that-shaped-todays-internet>.

40. Ortutay, *supra* note 39.

41. E.g., Sara Morrison, *Section 230, The Internet Law That’s Under Threat, Explained*, VOX (Feb. 23, 2023), <https://www.vox.com/recode/2020/5/28/21273241/section-230-explained-supreme-court-social-media>.

42. ERIC N. HOLMES, CONG. RSCH. SERV., R47753, LIABILITY FOR ALGORITHMIC RECOMMENDATIONS 14 (2023).

43. *Id.*

44. *Section 230*, ELEC. FRONTIER FOUND., <https://www.eff.org/issues/cda230> (last visited Dec. 18, 2024); Granick, *supra* note 22.

plaintiffs' claims.⁴⁵ This is due largely to the early judicial interpretation of § 230, which construed immunity under the statute to be very broad.⁴⁶

Zeran v. America Online, Inc. was the first case to interpret § 230 in 1997, shortly after the CDA passed.⁴⁷ The Fourth Circuit decided in favor of AOL, ruling that § 230(c) “creates a federal immunity to any cause of action that would make service providers liable for information originating with a third-party user of the service.”⁴⁸ The case involved an unknown America Online user who had tried to sell t-shirts containing offensive slogans referring to the Oklahoma City bombing. The unidentified user’s post provided the phone number of plaintiff Zeran as a way for people to order the shirts. Zeran received threatening telephone calls because of this user’s post, and he consequently sued AOL for defamation.⁴⁹

The Fourth Circuit, interpreting the legislative intent of § 230 and the plain language of the statute, said that § 230(c)(1) makes it so that any “computer service provider” is “plainly immunize[d]” from being held liable for “information that originates with third parties.”⁵⁰ While later opinions noted that subsection (c)(1) does not mention the term “immunity,” the Fourth Circuit interpreted (c)(1) to provide broad immunity for internet companies when it comes to hosting third-party content on their websites.⁵¹ That is, most internet companies would not be held liable for any third-party content posted on their websites, according to *Zeran*.⁵² Importantly, § 230(c)(1) does not protect internet companies from claims based on the company’s own, original content.⁵³

The *Zeran* opinion also weighed in on the term “publisher” included in § 230(c)(1). It said § 230 “precludes courts from entertaining claims that would place a computer service provider in a publisher’s role.”⁵⁴ The Fourth Circuit further defined what it means to serve a publishing role, saying that it includes “traditional editorial functions . . . such as deciding whether to publish, withdraw, postpone or alter content.”⁵⁵ Here, the Fourth Circuit opined that

45. See generally *Zeran*, 129 F.3d.

46. See generally *id.*

47. *Id.*

48. *Id.* at 330.

49. *Id.* at 328–29.

50. *Id.* at 330.

51. *Barnes v. Yahoo! Inc.*, 570 F.3d 1096, 1100 (9th Cir. 2009); Chi. Laws.’ Comm. for C.R. Under L., Inc. v. Craigslist, Inc., 519 F.3d 666, 669 (7th Cir. 2008).

52. See *Zeran*, 129 F.3d at 335.

53. BRANNON, *supra* note 18, at 16.

54. *Zeran*, 129 F.3d at 330.

55. *Id.*

without this type of publisher immunity, internet companies would be disincentivized to self-regulate.⁵⁶ It noted that Congress passed § 230 in part to allow companies to self-regulate third-party content—what is referred to today as “content moderation”—without fear of liability for those decisions.⁵⁷ Since *Zeran*, other courts of appeal have largely adopted the Fourth Circuit’s broad interpretation of § 230(c)(1) and its explanation of the term “publisher.”⁵⁸

B. IMPORTANT SECTION 230 CASES POST-ZERAN

Section II.B will discuss two landmark Ninth Circuit cases that qualified the broad § 230 immunity established in *Zeran: Fair Housing Council v. Roommates.com* and *Barnes v. Yahoo!*.⁵⁹ These two cases established the two most important tests courts now use in analyzing § 230 immunity against claims. *Roommates.com* established the material contribution test, which says that for a company to be held liable for unlawful content posted to their platforms, that company must have helped co-develop that content in a way that contributes to its illegality.⁶⁰ *Barnes* established a namesake three-part test that plaintiffs’ claims must meet to survive a motion to dismiss against a § 230 immunity defense.⁶¹ Courts now almost exclusively rely on these tests when determining § 230 immunity. Section II.B will lastly explain how these tests work together.

1. Fair Housing Council v. Roommates.com (2008)

Fair Housing Council v. Roommates.com was the one of the first cases to qualify the broad § 230 immunity established in *Zeran* over twenty years after *Zeran*. The Ninth Circuit held that *Roommates.com* was liable under § 230 for third-party content posted to its website that it had in part developed.⁶² Plaintiffs successfully alleged that the website had violated aspects of the Fair Housing

56. *See id.* at 331.

57. BRANNON, *supra* note 18, at 16.

58. *See, e.g.,* Force v. Facebook, Inc., 934 F.3d 53 (2d Cir. 2019); *Barnes*, 570 F.3d at 1096. *But see* BRANNON, *supra* note 18, at 11 (noting that “some jurists have expressed skepticism about the Fourth Circuit’s approach. In a statement written to accompany a denial of certiorari in a § 230 case, U.S. Supreme Court Justice Clarence Thomas suggested, contrary to the holding in *Zeran*, that § 230(c)(1) might not limit distributor liability. Two federal appellate judges concurring in separate § 230 cases also questioned whether *Zeran*’s definition of ‘publisher’ interpreted § 230(c)(1) beyond its intended scope. In addition to the skepticism expressed by individual jurists, a 2022 Fourth Circuit opinion appeared to narrow *Zeran*’s conception of ‘publisher’ activity without disturbing its basic ruling on distributor liability.”)

59. *See generally* Fair Hous. Council of San Fernando Valley v. Roommates.com, 521 F.3d 1157 (9th Cir. 2008); *Barnes*, 570 F.3d.

60. *See Roommates.com*, 521 F.3d at 1168.

61. *See Barnes*, 570 F.3d at 1100–01.

62. *See Roommates.com*, 521 F.3d at 1175.

Act when it asked its users to fill out a questionnaire in which they answered questions based on legally protected characteristics and subsequently displayed those answers on users' profiles.⁶³ The Ninth Circuit decided that the answers displayed on the users' profiles were not entirely third-party content because Roommates.com had helped develop, at least in part, the content and contributed to what made that content illegal.⁶⁴ This meant that Roommates.com could be held liable for illegal content in which it helped in part create: in this case the answers to the discriminatory questions published on users' profiles.⁶⁵

The Ninth Circuit's decision created an important test. Chief Judge Kozinski articulated the appropriate test, holding: "a website helps to develop unlawful content . . . if it contributes materially to the alleged illegality of the conduct."⁶⁶ Following *Roommates.com*, the Ninth Circuit continued to clarify what has come to be known as the material contribution test in other opinions, including stating that the test "draw[s] the line at the 'crucial distinction between, on the one hand, taking actions (traditional to publishers) that are necessary to the display of unwelcome and actionable content and, on the other hand, responsibility for what makes the displayed content illegal or actionable."⁶⁷

The Ninth Circuit looked to the statutory text of § 230(f)(3) in forming the material contribution test.⁶⁸ Section 230(f)(3) defines "information content provider" as "any person or entity that is responsible, in whole or in part, for the creation or development of information provided through the Internet or any other interactive computer service."⁶⁹ Section 230(f)(3)'s definition of "information content provider" has led to courts, when analyzing third-party content, largely "focus[ing] on the defendant's role in the 'creation or development' of the content."⁷⁰ The Ninth Circuit noted in *Roommates.com* that only holding companies liable when they are co-developers of third-party content ignores the "in part" phrasing of the passage in the statute that reads "creation or development in whole or in part."⁷¹ The Ninth Circuit stated that

63. *See id.* at 1161.

64. *See id.* at 1172.

65. *See id.* at 1175.

66. *Id.* at 1168.

67. *Kimzey v. Yelp! Inc.*, 836 F.3d 1263, 1269 n.4 (9th Cir. 2016) (quoting *Jones v. Dirty World Ent. Recordings LLC*, 755 F.3d 398, 413–14 (6th Cir. 2014)).

68. *Roommates.com*, 521 F.3d at 1166.

69. 47 U.S.C. § 230(f)(3).

70. BRANNON, *supra* note 18, at 16.

71. Max Del Real, Note, *Breaking Algorithmic Immunity: Why Section 230 Immunity May Not Extend to Recommendation Algorithms*, 99 WASH. L. REV. ONLINE 1, 18 (2024); *Roommates.com*, 521 F.3d at 1167 (quoting 47 U.S.C. § 230(f)(3)).

when platforms act as “passive conduits,” they should receive § 230 immunity for any third-party content posted to their sites.⁷² However, full immunity does not always extend to co-developers, especially when they “materially contribute” and therefore “in part” develop the offending content.⁷³ The Ninth Circuit also said that when platforms provide “neutral tools” to users, it does not mean that the platform itself is acting as a developer of content, and the platform should therefore still receive § 230 immunity for third-party content it might display through these neutral tools.⁷⁴ The court defined “neutral tools” to be those that are “identically applied in all contexts.”⁷⁵

The court’s decision in *Roommates.com* was truly ground-breaking in how it interpreted § 230 and its willingness to draw a line when it comes to extending the statute’s immunity for different types of content. Under the material contribution test, platforms can be held liable more often than they had been prior to the *Roommates.com* opinion.⁷⁶

2. Barnes v. Yahoo! (2009)

Shortly after *Roommates.com* established the material contribution test, another Ninth Circuit opinion established a now widely used three-part legal test to determine if a defendant is liable under § 230. In *Barnes v. Yahoo!*, the Ninth Circuit held that § 230 barred the plaintiff’s claims because Yahoo! performed traditional publishing functions when it hosted and failed to take down third-party content posted by the plaintiff’s ex-boyfriend as a means of revenge.⁷⁷ The plaintiff, Barnes, wanted to hold the internet company that hosted the content, Yahoo!, liable under Oregon tort law for what the Ninth Circuit synthesized as “negligent undertaking.”⁷⁸

The Ninth Circuit found that § 230 does not “declare[] a general immunity from liability deriving from third-party content,” which was what Yahoo! argued.⁷⁹ With this sentiment established, the Ninth Circuit interpreted both § 230(c)(1) and § 230(e)(3) to develop what is now widely known as the *Barnes* test.⁸⁰ The test states that “(c)(1) *only* protects from liability (1) a provider or user of an interactive computer service (2) whom a plaintiff seeks to treat,

72. *Roommates.com*, 521 F.3d at 1167.

73. *Id.*

74. *See id.* at 1169.

75. Del Real, *supra* note 71, at 20.

76. *See* G.S. Hans, *Revisiting Roommates.com*, 36 BERKELEY TECH. L.J. 1227, 1230 (2021).

77. *See Barnes*, 570 F.3d at 1103.

78. *Id.* at 1099 (discussing the unclear nature of plaintiffs’ negligence claim under Oregon tort law).

79. *Id.* at 1100.

80. *Id.* at 1100–01.

under a state law cause of action, as a publisher or speaker (3) of information provided by another information content provider.”⁸¹

Courts now almost ubiquitously rely on *Barnes*, or the three-part immunity test, and material contribution tests to dismiss claims on § 230 grounds. For a claim to pass the three prongs of the *Barnes* test and therefore receive § 230 immunity, plaintiffs need to prove that one of the three prongs is not satisfied: (1) the defendant is an interactive computer provider or user (2) whom the plaintiff seeks to treat as a publisher or speaker (3) of information provided by a third-party information content provider.⁸² Once the court finds that the test has been met, no additional factfinding occurs.⁸³ In terms of the material contribution test and neutral tools framework established in *Roommates.com*, they are best understood as working in tandem with Prong Three of the *Barnes* test.⁸⁴ An internet company’s § 230 defense is likely to fail Prong Three of the *Barnes* test if two conditions are met. The first condition is met when an internet company is found to materially contribute to the third-party, offending content in question. The second condition is met when a platform is found to have encouraged the third party’s posting of illegal content rather than hosting all content neutrally.⁸⁵ If the content in question meets both of these conditions, it is unlikely to pass Prong Three of the *Barnes* test, and the company therefore is likely to be held liable for the offending content under § 230.⁸⁶

C. RECOMMENDATION ALGORITHMS AND SECTION 230

As internet companies have grown and developed since 1996, in no small part due to the freedom from litigation that § 230 has afforded them, they have developed increasingly sophisticated tools that interact with third-party content. These new tools have posed novel and challenging questions about how far § 230 immunity extends. One of these tools is recommendation systems. Recommendation systems are now a common type of algorithm used by companies to predict and sort content that is presented to users. They are the algorithms that this Note will mostly address.

Recommendation systems are based on machine-learning models that “use[] data to help predict, narrow down, and find what people are looking for

81. *Id.* (emphasis added).

82. *Lemmon v. Snap, Inc.*, 995 F.3d 1085, 1091 (9th Cir. 2021).

83. *Del Real*, *supra* note 71, at 9.

84. *See Gonzalez v. Google LLC*, 2 F.4th 871, 892–93 (9th Cir. 2021).

85. *Id.*

86. *Id.*

among an exponentially growing number of options.”⁸⁷ The data that recommendation systems (also known as recommendation algorithms) use to train themselves to better understand individual users can include demographic information, search history, a user’s engagement with other content on a platform, and other various factors.⁸⁸ By using these various inputs from individual users, an algorithm teaches itself what a user might like and attempts to provide users with, as the name suggests, recommendations for more of what they like or what the machine thinks they might like.⁸⁹ While most recommendation algorithms are built on the above-discussed premise, there are many different types of recommendation algorithms that use different inputs and prioritize different filtering systems to provide individuals with personalized recommendations.⁹⁰ For example, Instagram’s “Feed” has traditionally prioritized content posted by users that someone has actively chosen to follow, whereas TikTok’s For You Page famously does not prioritize content from users someone has chosen to follow.⁹¹ Additionally, each of these recommendation systems—Instagram’s “Feed,” TikTok’s For You Page, and all the comparable tools on other platforms—is made up of many different algorithms that accomplish different goals.⁹² Computer scientists refer to the collection of individual algorithms that fuel each of the systems mentioned above as “recommender systems.”⁹³

As more internet companies build algorithms or systems of algorithms and as those algorithms or systems become more complex, courts have had to increasingly contend with whether companies should be held legally liable for recommending content through recommendation systems.⁹⁴ For the purposes of this paper, “recommendation systems” and “recommendation algorithms” will mean the same thing in that they will both refer to the system of algorithms that makes up an overall recommending experience. As such, the algorithms that make up each recommendation system can be considered individual parts of the larger system.

87. *Recommendation System*, NVIDIA, <https://www.nvidia.com/en-us/glossary/recommendation-system/> (last visited Dec. 18, 2024).

88. *Id.*

89. *Id.*; Schrage, *supra* note 2.

90. *Recommendation System*, *supra* note 87.

91. HOLMES, *supra* note 42, at 3.

92. *See, e.g.*, Karen Hao, *The Facebook Whistleblower Says Its Algorithms Are Dangerous. Here’s Why*, MIT TECH. REV. (Oct. 5, 2021), <https://www.technologyreview.com/2021/10/05/1036519/facebook-whistleblower-frances-haugen-algorithms/>.

93. HOLMES, *supra* note 42, at 3.

94. *Id.* at Summary.

III. RECOMMENDATION ALGORITHMS IN THE COURTS

Part III will examine how two appellate courts came to the same decision about recommendation algorithms' role in assisting in terrorism. Both courts applied the *Barnes* and material contribution tests to recommendation algorithms and barred plaintiffs' claims under § 230, setting the stage for other courts' analysis of recommendation algorithms and § 230 immunity. Part III will then examine how the Supreme Court has characterized algorithms in two opinions outside of the § 230 context, which has already influenced how lower courts characterize algorithms within the § 230 context. Lastly, Part III will examine how one appellate court recently came to a different conclusion from the other appellate courts when examining recommendation algorithms under § 230, signaling a circuit split.

A. *FORCE V. FACEBOOK* (2019)

The Second Circuit's opinion in *Force v. Facebook* is one of the most important cases covering recommendation algorithms under § 230.⁹⁵ It is important because the decision was the first federal appellate decision to hold that § 230 bars civil terrorism claims against social media companies' use of recommendation algorithms.⁹⁶ The case centered on a series of terrorist attacks executed by Hamas against five Americans in Israel from 2014 to 2016.⁹⁷ Plaintiffs alleged that Facebook violated federal anti-terrorism laws both by allowing Hamas to post content that encouraged the attacks and also by recommending that Hamas-created content to the people who carried out the attacks through its recommendation algorithm.⁹⁸ Plaintiffs further alleged that Facebook contributed to Hamas's content through its recommendation algorithm.⁹⁹ Facebook, in turn, argued that § 230 barred all the claims against it, including ones involving its algorithm.¹⁰⁰ The Second Circuit agreed with Facebook and held that § 230 barred plaintiffs' claims that Facebook went beyond its role as publisher through the use of its algorithms and materially contributed to the offending content through its algorithm.¹⁰¹

95. See generally *Force*, 934 F.3d.

96. Sophia Cope & Aaron Mackey, *Second Circuit Rules That Section 230 Bars Civil Terrorism Claims Against Facebook*, ELEC. FRONTIER FOUND. (Aug. 7, 2019), <https://www.eff.org/deeplinks/2019/08/second-circuit-rules-section-230-bars-civil-terrorism-claims-against-facebook>.

97. *Force*, 934 F.3d at 57.

98. *Id.* at 59.

99. *Id.* at 62.

100. See *id.* at 57.

101. See *id.* at 70–71.

The Second Circuit examined Hamas’s content on Facebook through the *Barnes* test.¹⁰² The second prong of the *Barnes* test asks: does a plaintiff seek to treat the defendant as a publisher or speaker?¹⁰³ Under this second prong, the Second Circuit decided that plaintiffs’ claims treated Facebook as a publisher, even when plaintiffs were arguing the opposite, because they were seeking to hold Facebook liable for performing traditional publishing activities.¹⁰⁴ Even though plaintiffs argued that Facebook did not act as a publisher when it came to its use of recommendation algorithms, the Second Circuit found that Facebook acted as a publisher when employing a recommendation algorithm because of the algorithm’s traditional publishing functions of “arranging and distributing third-party information.”¹⁰⁵

Additionally, under the third prong of the *Barnes* test and, consequently, the material contribution test, the Second Circuit held that Facebook did not materially contribute to the content Hamas posted, even when it recommended that content to potential Hamas recruits through its algorithm.¹⁰⁶ The Second Circuit said that Facebook merely displayed the objectionable content rather than played a role in what made that displayed content illegal or objectionable.¹⁰⁷ The Second Circuit stated that if Facebook were to have done something like instruct Hamas on how to target its content to relevant audiences who were likely to carry out attacks, the platform might fail the material contribution test.¹⁰⁸ Thus, the Second Circuit found that plaintiffs’ claims did not pass the *Barnes* and material contribution tests, and Facebook was shielded from liability under § 230.

While the Second Circuit extended § 230 immunity to Facebook’s recommendation algorithm, Chief Judge Katzmann concurred in part and dissented in part, as he ultimately disagreed about whether § 230 immunity should extend to all of Facebook’s algorithms.¹⁰⁹ While Chief Judge Katzmann agreed with the outcome of the majority’s opinion, he specifically dissented on the majority’s treatment of Facebook’s “suggestion algorithms.”¹¹⁰ The Chief Judge presented a scenario that challenged the majority’s opinion that

102. *Id.* at 65.

103. *Barnes*, 570 F.3d at 1100–01.

104. *Forve*, 934 F.3d at 65.

105. *Id.* at 66.

106. *Id.* at 69 (2d Cir. 2019) (holding the difference between displaying illegal content and playing a role in what makes the displayed content illegal or actionable).

107. *See id.* at 70.

108. Different appellate courts took similar stances in other cases. *See generally* Dyroff v. Ultimate Software Grp., Inc., 934 F.3d 1093 (9th Cir. 2019).

109. *Forve*, 934 F.3d at 76. (Katzmann, C.J., concurring in part and dissenting in part).

110. *Id.*

Facebook acts as a publisher and that its algorithm is simply an extension of its role as a publisher in sorting and displaying the content posted to the website. He wrote:

Suppose that you are a published author. One day, an acquaintance calls. ‘I’ve been reading over everything you’ve ever published,’ he informs you. ‘I’ve also been looking at everything you’ve ever said on the Internet. I’ve done the same for this other author. You two have very similar interests; I think you’d get along.’ The acquaintance then gives you the other author’s contact information and photo, along with a link to all her published works. He calls back three more times over the next week with more names of writers you should get to know.¹¹¹

Chief Judge Katzmann said that he would not find the acquaintance to be a “publisher” in this scenario.¹¹² Given that the acquaintance’s activities mimic those of a recommendation algorithm, Chief Judge Katzmann argued that social media companies should not be treated as publishers when it comes to their recommendation algorithms performing similarly to the acquaintance in the hypothetical.¹¹³

In fact, Chief Judge Katzmann wrote extensively that he would not extend § 230 immunity to Facebook’s recommendation algorithm, which he called the “friend- and content-suggestion algorithm.”¹¹⁴ He suggested that while some aspects of social media platforms are like some aspects of traditional publishers, not all actions the platforms take should be considered to be similar to those a publisher takes.¹¹⁵ He argued that § 230 “limits liability based on the function the defendant performs, not its identity.”¹¹⁶ Section 230, he argued, only immunizes social media companies from those activities that resemble traditional publisher functions but not the whole range of activities it engages in.¹¹⁷ He also invoked the material contribution test and neutral tools framework as established in *Roommates.com* and directly quoted from that decision to suggest Facebook “does not merely provide a framework that could be utilized for proper or improper purposes; rather, [Facebook’s] work in developing’ the algorithm and suggesting connections to users based on their prior activity on Facebook, including their shared interest in terrorism, ‘is

111. *Id.*

112. *Id.*

113. *Id.* at 77. (Katzmann, C.J., concurring in part and dissenting in part).

114. *Id.*

115. *Id.* at 81–82 (Katzmann, C.J., concurring in part and dissenting in part).

116. *Id.* at 81 (Katzmann, C.J., concurring in part and dissenting in part).

117. *Id.*

directly related to the alleged illegality of the site.”¹¹⁸ Chief Judge Katzmann thus presented an alternative way to view algorithms in relation to § 230 in his dissent.

B. *GONZALEZ V. GOOGLE* (2021)

Gonzalez v. Google is another case that dealt with a plaintiff seeking to hold a social media company liable for aiding and abetting acts of terrorism through its recommendation algorithm.¹¹⁹ Like the Second Circuit in *Forve*, the Ninth Circuit held that § 230 barred plaintiffs’ claims because Google acted as a publisher and did not materially contribute to the offending content.¹²⁰ The Supreme Court granted certiorari in *Gonzalez* but side-stepped the § 230 issues present in the case by issuing an opinion in a companion case, *Twitter v. Taamneh*, which resolved the terrorism-related torts claims without addressing § 230 immunity.¹²¹ The discussion here will focus on the Ninth Circuit’s decision, which did address the § 230 issues present in the case.

Gonzalez, like *Forve*, dealt with claims that attempted to hold social media platforms responsible for their alleged roles in terrorist attacks under the Anti-Terrorism Act, and plaintiffs in both cases made the argument that platforms’ recommendation algorithms “helped advance the cause of terrorist groups using the platforms.”¹²² In *Gonzalez*, plaintiffs sued Google, Twitter, and Facebook for alleged violations of the Anti-Terrorism Act, claiming the platforms had “allowed ISIS to post videos and other content to communicate the terrorist group’s message, to radicalize new recruits, and to generally further its mission.”¹²³ The plaintiffs were family members of people who were executed in an ISIS terrorist attack in Paris.¹²⁴

Much like the Second Circuit in *Forve*, the Ninth Circuit used the *Barnes* test in *Gonzalez* to find that § 230 immunity extended to YouTube’s recommendation algorithm, owned by Google.¹²⁵ In its relatively quick Prong Two analysis, the Ninth Circuit relied on *Forve* to hold that Google is a publisher under the *Barnes* test.¹²⁶ The Ninth Circuit then spent considerably more time on Prong Three and the material contribution test, ultimately holding that recommendation algorithms are afforded § 230 immunity

118. *Id.* at 83 (Katzmann, C.J., concurring in part and dissenting in part).

119. *See generally Gonzalez*, 2 F.4th.

120. *See generally Forve*, 934 F.3d; *see also Gonzalez*, 2 F.4th at 892–97.

121. *Twitter, Inc. v. Taamneh*, 137 HARV. L. REV. 402 (2023).

122. BRANNON, *supra* note 18, at 9.

123. *Gonzalez*, 2 F.4th at 880.

124. *Id.* at 880–82.

125. *See id.* at 891–93.

126. *See id.* at 891.

because, by recommending third-party content to users, they are not materially contributing to the content in question.¹²⁷ The Ninth Circuit likened the Google video-sharing platform's (YouTube) recommendation algorithm to a traditional search engine.¹²⁸ While the court admitted that recommendation algorithms are "more sophisticated than traditional search engine[s] . . . the core principle is the same."¹²⁹ The court used this logic to suggest that Google "provide[s] a neutral platform that did not specify or prompt the type of content to be submitted, nor determine particular types of content its algorithms would promote."¹³⁰

However, the concurrence in *Gonzalez* is worth noting for its similarities to the dissent in *Force*. In both the concurrence and dissent, Judge Berzon and Judge Gould explicitly invoked Chief Judge Katzmann's analysis in the *Force* dissent. Judge Berzon made it clear that the only reason she concurred with the judgement is because she found that the Ninth Circuit is "bound by [] precedent compelling the outcome in this case."¹³¹ She urged the court to reconsider its precedent so that the "term" publisher under § 230 does not extend to machine-learning algorithms and "activities that promote or recommend content or connect content users to each other."¹³² Judge Gould's dissent agreed with Judge Berzon's concurrence, arguing that Google "amplified and in part developed the terrorist message by encouraging similar views to be given to those already determined to be most susceptible to the ISIS cause."¹³³ Judge Gould argued that § 230 should not shield the defendant companies from liability for these activities.¹³⁴ Judge Gould also argued that the algorithms in question in *Gonzalez* are not neutral. He said that they may be "seemingly neutral," but in reality they are "a force to intensify and magnify a message."¹³⁵ Thus, both Judge Berzon and Judge Gould agreed that the internet companies in question should not be held liable for content merely published to their platforms and other activities that fall squarely within the role of a "publisher" defined under § 230, but that the activities of the

127. *See id.* at 892–93.

128. *Id.* at 895.

129. *Id.*

130. *Id.*

131. *Id.* at 913 (Berzon, J., concurring).

132. *Id.*

133. *Id.* at 922 (Gould, J., concurring in part and dissenting in part).

134. *See id.*

135. *Id.* at 921 (Gould, J., concurring in part and dissenting in part).

recommendation algorithms go far beyond normal publishing activities and therefore should not receive § 230 immunity.¹³⁶

C. RECENT SUPREME COURT CASES: *TWITTER V. TAAMNEH* (2023) AND *MOODY V. NETCHOICE* (2024)

The Supreme Court has recently characterized recommendation algorithms in two cases outside of the § 230 context.¹³⁷ It is important to have a brief understanding of these cases, however, because lower courts have started to use at least the *Moody* opinion’s characterization of recommendation algorithms to question the extent of § 230 immunity.¹³⁸

In *Twitter v. Taamneh*, the Supreme Court collapsed the issues presented in *Gonzalez* with the issues presented in *Taamneh* as they both involved social media platforms sued for allegedly aiding and abetting acts of terrorism.¹³⁹ In *Taamneh*, the Court ruled in favor of the social media companies, holding that they did not aid and abet terrorists under 18 U.S.C. § 2333, which provides a cause of action to plaintiffs injured by “an act of international terrorism.”¹⁴⁰ The difference between *Taamneh* and *Gonzalez* is that the former did not raise § 230 concerns.¹⁴¹ Despite the Court avoiding the § 230 concerns in its *Taamneh* decision, Justice Thomas briefly discussed recommendation

136. See *id.* at 913, 922 (Berzon, J., concurring; Gould, J., concurring in part and dissenting in part).

137. See generally *Twitter, Inc. v. Taamneh*, 598 U.S. 471 (2023); *Moody v. NetChoice, LLC*, 144 S. Ct. 2383 (2024).

138. See *Anderson v. TikTok, Inc.*, 116 F.4th 180, 183–84 (3d Cir. 2024).

139. *Twitter, Inc. v. Taamneh*, *supra* note 121.

140. See generally *Taamneh*, 598 U.S. at 506; 18 U.S.C. § 2333(d)(2).

141. Before the Supreme Court filed its decision in *Taamneh* and *Gonzalez*, many believed *Gonzalez* would be the first time the Supreme Court would address the scope of § 230 and, specifically, if immunity extends to recommendation algorithms. *Google v. Gonzales LLC*, ACLU (May 18, 2023), <https://www.aclu.org/cases/google-v-gonzales-llc>. Some commentators agreed with the Court’s decision to avoid the § 230 issue. Aaron Mackey, *The Internet Dodges Censorship by the Supreme Court*, ELEC. FRONTIER FOUND. (May 18, 2023), <https://www.eff.org/deeplinks/2023/05/internet-dodges-censorship-supreme-court>. Justice Kagan herself noted that the Justices are “not, like, the nine greatest experts on the internet.” Vittoria Elliott & Dell Cameron, *The US Supreme Court Doesn’t Understand the Internet*, WIRED (Feb. 22, 2023), <https://www.wired.com/story/the-supreme-court-section-230-the-internet/>. In ruling the way they did, the Court avoided making an “erroneous judgment on a technical question with far-reaching consequences” and left to Congress the job of defining the scope of § 230 if it so chooses. *Twitter, Inc. v. Taamneh*, *supra* note 121. Others, however, wanted the Court to finally address § 230 and provide some workable guidelines for lower courts on how to address claims allegedly barred by § 230. *Id.* As one scholar noted that “[g]iven the ubiquity of algorithms and their importance to the operation of many websites, less guidance on the question means that lower courts and social media platforms will continue to wrestle with uncertainties about legal liability.” *Id.*

algorithms in the context of torts in his opinion.¹⁴² Justice Thomas disagreed with the plaintiffs' assertion that recommendation algorithms "go beyond passive aid and constitute active, substantial assistance."¹⁴³ Instead, he wrote, "algorithms appear agnostic as to the nature of the content, matching any content . . . with any user who is more likely to view that content. The fact that these algorithms matched some ISIS content with some users thus does not convert defendants' passive assistance into active abetting."¹⁴⁴ While the Court did not address § 230 in *Taamneh*, its understanding of what an algorithm is, even if not explicitly connected to the § 230 issue, could have implications for future § 230 litigation. As Daphne Keller, the Director of Platform Regulation at Stanford's Cyber Policy Center has said, "[the Court's] broad statements about platform passivity will give future litigants a lot of jurisprudential spaghetti to throw at the wall."¹⁴⁵

In *Moody v. NetChoice*, the Court vacated and remanded two judgements from the Eleventh and Fifth Circuits that challenged the constitutionality of two statutes that aimed to regulate large social media companies.¹⁴⁶ The Texas law in question required, among other things, that large social media companies make certain disclosures about the content they remove and establish complaint procedures for those who had content removed from the platform.¹⁴⁷ The Florida law was similar in that it established a violation when social media companies removed political candidates from their platforms and mandated requirements for when social media companies restrict users' speech.¹⁴⁸ Plaintiffs challenged both laws on First Amendment grounds. The Fifth Circuit and Eleventh Circuit came to opposite conclusions about the constitutionality of the laws. The Supreme Court vacated and remanded both judgements because neither circuit adequately analyzed the facial First Amendment challenge to the statutes.¹⁴⁹

However, the Court took an opportunity in *Moody* to establish that content moderation policies are platforms' expressive content and are therefore protected under the First Amendment.¹⁵⁰ In doing so, the Court discussed how

142. *Taamneh*, 598 U.S. at 499.

143. *Id.*

144. *Id.*

145. Daphne Keller, *Carriage and Removal Requirements for Internet Platforms: What Taamneh Tells Us*, 4 J. FREE SPEECH L. 87, 93 (2023).

146. *See Moody*, 603 U.S. at 745.

147. *See id.* at 717–18.

148. *See id.*

149. *See id.* at 734–35.

150. *See id.* at 744.

algorithms factor into content moderation.¹⁵¹ The Court was very careful in its analysis of algorithms and made clear that there are multiple types of algorithms. For example, the Court held that algorithms guided by platform standards establishing the type of permissible content are expressive content.¹⁵² In one footnote, the Court made clear that it “do[es] not deal here with feeds whose algorithms respond solely to how users act online—giving them the content they appear to want, without any regard to independent content standards.”¹⁵³ In her concurrence, Justice Barrett stated that algorithms that “present[] automatically to each user whatever the algorithm thinks the user will like,” might not receive the same First Amendment protections as those algorithms guided by platform standards and policies.¹⁵⁴

D. *ANDERSON V. TIKTOK* (2024)

A Third Circuit decision that came down in August 2024 has made it clear that the issue of § 230 immunity and its relationship to recommendation algorithms is not going away. In *Anderson*, the Third Circuit examined whether § 230 barred state claims against TikTok’s For You Page for promoting content to a young girl that resulted in her accidentally killing herself.¹⁵⁵ The Third Circuit held that § 230 did not bar these claims.¹⁵⁶ The case centered on a ten-year-old girl, Nylah Anderson, who saw videos on TikTok’s personally curated For You Page that depicted what is known as the “Blackout Challenge.”¹⁵⁷ The viral challenge encouraged users to post videos of themselves taking part in self-asphyxiation. Anderson’s mother sued TikTok for violations of state law after Anderson attempted the challenge and unintentionally hung herself.¹⁵⁸

Instead of using the ubiquitous *Barnes* test to examine TikTok’s For You Page under § 230, the Third Circuit did something unexpected and instead relied on the Supreme Court’s characterization of algorithms in *Moody* to make its § 230 determination.¹⁵⁹ The Third Circuit determined that TikTok could not invoke § 230 immunity against the claims because TikTok’s For You Page algorithm is TikTok’s own expressive activity.¹⁶⁰ The Third Circuit held that

151. *See id.* at 734–35.

152. *See id.* at 735–38.

153. *See id.* at 736 n.5.

154. *Id.* at 746 (Barrett, J., concurring).

155. *See Anderson*, 116 F.4th at 181.

156. *Id.*

157. *Id.*

158. *Id.*

159. *See id.* at 183.

160. *Id.* at 184.

§ 230 immunity only extends to information “provided by another” and not a platform’s own expressive activity.¹⁶¹

E. WHERE COURTS STAND NOW

With the Third Circuit’s opinion in *Anderson*, there is now a circuit split with how appellate courts interpret § 230 applying to recommendation algorithms. The Third Circuit held that § 230 does not bar a plaintiff’s claim that a recommendation algorithm played a role in her daughter’s death because TikTok’s recommendation algorithm can be considered the platform’s own content.¹⁶² This stands in stark contrast to the decisions in *Forve* and *Gonzalez*, which are still precedent in the Second and Ninth Circuits.

Many criticized the Third Circuit’s reasoning in *Anderson*, pointing out that applying *Moody* was faulty because *Moody* dealt with First Amendment issues and therefore was an inappropriate precedent to apply to a § 230 case.¹⁶³ TikTok petitioned the Third Circuit for a rehearing and a rehearing en banc.¹⁶⁴ The Third Circuit has denied this petition.¹⁶⁵ It is not yet known whether the Supreme Court will grant certiorari in this case. However, this circuit split indicates a need for the Court to finally settle the issue of how lower courts should analyze algorithms under § 230.¹⁶⁶

161. *See id.* at 183–84.

162. *Id.* at 184.

163. Ryan Calo, *Courts Should Hold Social Media Accountable—But Not By Ignoring Federal Law*, HARV. L. REV. (Sep. 10, 2024), <https://harvardlawreview.org/blog/2024/09/courts-should-hold-social-media-accountable-but-not-by-ignoring-federal-law/>; Eric Goldman, *Bonkers Opinion Repeals Section 230 In the Third Circuit—Anderson v. TikTok*, TECH. & MKTG. L. BLOG (Aug. 29, 2024), <https://blog.ericgoldman.org/archives/2024/08/bonkers-opinion-repeals-section-230-in-the-third-circuit-anderson-v-tiktok.html>.

164. Emily Field, *TikTok Won’t Get 3rd Cir. Rehearing of Section 230 Ruling*, LAW360 (Oct. 24, 2024), <https://www.law360.com/articles/2251176>.

165. *Id.*

166. In February 2025, the circuit split over recommendation algorithms deepened when the Fourth Circuit held that § 230 barred a plaintiff’s state tort law claims against Meta (Facebook’s parent company) that sought to hold Meta liable for the way it prioritizes content to users of its platform. *M.P. by and through Pinckney v. Meta Platforms Inc.*, 127 F.4th 516, 521 (4th Cir. 2025). The plaintiff’s father had been killed by Dylann Roof in a mass shooting in a South Carolina church. *Id.* Plaintiff alleged Meta’s recommendation algorithms were in part to blame for radicalizing Roof because the company allows “racist, harmful content to appear on its platform and directs that content to likely receptive users to maximize Facebook’s profits.” *Id.* at 525. The Fourth Circuit noted that there was no meaningful disagreement between the parties on the first and third prongs of the *Barnes* test. *Id.* at 524. However, the Fourth Circuit found that Facebook served as a publisher under the second prong of the *Barnes* test despite the fact that Facebook boosts certain content for the sake of raising engagement. *Id.* at 526. The Fourth Circuit said that using an algorithm to maximize engagement and profits “does not change the underlying nature of the act that it is performing.

IV. CHALLENGING THE COURTS' CURRENT APPROACH

While Part III described how appellate courts and the Supreme Court have examined algorithms both inside and outside the context of § 230, Part IV will first explain how the appellate courts' approach thus far in performing a *Barnes* test analysis on algorithms has been overbroad and flawed. The second component of Part IV will then propose a new, individualized, and fact-intensive approach to assessing algorithms under § 230. Under this new approach, any analysis of algorithms under Prongs Two and Three of the *Barnes* test should examine each algorithm on its own, separate from the other algorithms used within the same company or across companies. Part IV will then apply this narrow, individual tools analysis to the *Anderson* case to show how this proposed approach could lead to a similar outcome in that case without the Third Circuit's use of ill-fitting precedent. Part IV will lastly tackle some challenges to implementing this new approach and offer solutions.

A. APPELLATE COURTS' CURRENT APPROACH TO ANALYZING ALGORITHMS UNDER THE *BARNES* TEST SHOULD BE RECONSIDERED

Section IV.A will discuss how many social media platforms create and maintain tools that do not serve publishing functions, which is an important consideration for a Prong Two analysis under the *Barnes* test. Similarly, Section IV.A will also examine how different algorithms within and across social media platforms can differ from one another, which is critical for a Prong Three analysis under the *Barnes* test. Section IV.A will then suggest that various courts' methods in analyzing algorithms have been overbroad, flawed, or both because the methods are seemingly based on the notion that social media platforms act as publishers in a general sense and that all algorithms are the same.

1. *Not All Activities of Social Media Platforms Mimic Traditional Publisher Functions, and Not All Algorithms Are the Same*

Many of the companies that are implicated in the court cases involving algorithms are massive entities that offer users and customers many different types of experiences and products.¹⁶⁷ There is no doubt that social media platforms can be considered publishers of third-party content. However, many

Decisions about whether and how to display certain information provided by third parties are traditional editorial functions of publishers, notwithstanding the various methods they use in performing that task." *Id.*

167. *See, e.g.*, GOOGLE, https://about.google/intl/ALL_us/products/ (last visited Nov. 14, 2024); *see* META, <https://business.meta.com/> (last visited Nov. 14, 2024); META, <https://www.meta.com/> (last visited Nov. 14, 2024).

of these companies also engage in a wide range of activities that have nothing to do with publishing. For example, a quick look at the list of Google's products will immediately present tools that are used primarily for data storage, like One, or data organization, like Google Sheets.¹⁶⁸ Likewise, Meta is developing what it calls the Metaverse, a new artificial world in which people from around the physical world can be connected in a virtual world.¹⁶⁹ Both companies have also built and continue to develop their own generative artificial intelligence tools and platforms.¹⁷⁰ These newer products, or tools, will seemingly be entirely different than many of the tools for which Meta is currently known like direct messaging over WhatsApp or buying and selling on Facebook Marketplace. While this may seem obvious to anyone who uses the internet today, it is important, for the purposes of this Note and any *Barnes* Prong Two analysis, to highlight the wide variety of tools that can exist on any given platform.

In addition to social media platforms offering many different types of tools for many different types of functions, each individual platform uses different types of algorithms for different purposes across its internal tools and systems.¹⁷¹ Technically speaking, recommendation systems or algorithms can be based on a variety of different machine-learning models like primary ranking models, peripheral ranking models, and auxiliary models.¹⁷² Each of these models serves different functions. Primary ranking models suggest relevant content to users.¹⁷³ Peripheral ranking models suggest accounts to follow or surface advertisements.¹⁷⁴ Auxiliary models generally perform content moderation tasks.¹⁷⁵ In addition to using machine models to develop recommendation systems, companies also apply manual, rule-based models to the machine-modeled recommendation systems to help refine how content is

168. See GOOGLE, *supra* note 167.

169. See Eric Ravenscraft, *What Is the Metaverse, Exactly?*, WIRED (June 15, 2023), <https://www.wired.com/story/what-is-the-metaverse/>; Mike Isaac, *Meta Unveils New Smart Glasses and Headsets in Pursuit of the Metaverse*, N.Y. TIMES (Sep. 25, 2024), <https://www.nytimes.com/2024/09/25/technology/meta-products-artificial-intelligence.html>.

169. See generally META AI, www.meta.ai (last visited Oct. 2, 2025); META GOOGLE GEMINI, gemini.google.com (last visited Oct. 2, 2025).

171. Kristian Lum & Tomo Lazovich, *The Myth of The Algorithm: A System-Level View of Algorithmic Amplification*, KNIGHT FIRST AMEND. INST. AT COLUM. U. (Sep. 13, 2023), <https://knightcolumbia.org/content/the-myth-of-the-algorithm-a-system-level-view-of-algorithmic-amplification>.

172. See *id.*

173. See *id.*

174. See *id.*

175. See *id.*

displayed to the user in a way that aligns with different business goals.¹⁷⁶ For example, engineers will manually change algorithms so that certain content does not appear next to certain brands' advertisements or to make sure that users' feeds are not too repetitive.¹⁷⁷

Furthermore, different algorithms can have different objectives and purposes across a platform's different tools. For example, some algorithms prioritize exploiting content, like Google search, while others are built more for exploration, like Instagram's Explore tab.¹⁷⁸ Some algorithms try to accomplish both goals at the same time, which is what TikTok's primary recommender system, the For You Page, does.¹⁷⁹

Additionally, there can even be different algorithms with different objectives that fuel the same recommendation algorithm or system. Engineering teams with varying goals can and do apply different algorithms to the same recommendation system, like Facebook's newsfeed.¹⁸⁰ Facebook uses hundreds if not thousands of algorithms to rank content in its newsfeed alone.¹⁸¹ Some of those algorithms are designed with recommending content in mind and are therefore based on data gathered from user inputs and preferences, while other algorithms are built to serve as detection tools for "bad content" that the company wants to make sure is demoted in users' feeds.¹⁸²

2. *Appellate Courts Overgeneralize Platforms' Publisher Status and Ignore Important Differences Among Algorithms, Leading to Flawed Analyses Under the Barnes and Material Contribution Tests*

Most appellate court cases that have examined algorithms have used an overbroad and flawed approach that has created an idea that extending § 230 immunity to algorithms must be an all-or-nothing inquiry. This approach is flawed because it does not consider the different functions platforms have beyond that of traditional publishing or the differences among algorithms. The all-or-nothing approach, therefore, likely extends § 230 immunity past where it should be extended under the established *Barnes* and material contribution tests.

176. *See id.*

177. *See id.*

178. See Jonathan Stray, Luke Thorburn & Priyanjana Bengani, *What's the Difference Between Search and Recommendation?*, TECH POL'Y PRESS (Oct. 16, 2023), <https://www.techpolicy.press/whats-the-difference-between-search-and-recommendation/>.

179. *See id.*

180. *See* Hao, *supra* note 92.

181. *Id.*

182. *Id.*

In *Force* and *Gonzalez*, the Second and Ninth Circuits examined social media platforms as a whole when determining their roles as publishers under Prong Two of the *Barnes* test.¹⁸³ Even when it addressed how “Facebook’s algorithm” could place it outside the role of a publisher, the Second Circuit suggested that Facebook was either a publisher or not for the purposes of Prong Two. However, categorizing all the entire Facebook product experience as a publisher is overly simplistic and creates a situation in which the entire Facebook application is conflated with one out of many of its specific tools. Facebook, or Meta, offers dozens, if not hundreds, of different tools. A user can post on their own page, send private messages to friends, play games, buy goods on the marketplace, plan an event, join groups relevant to their interests, and peruse their “newsfeed.”¹⁸⁴ The better question is whether or not Facebook’s individual tools, like its newsfeed or instant messaging service, serve publishing functions, not whether Facebook as a whole is a publisher.

Additionally, in *Force* and *Gonzalez*, the Second and Ninth Circuits overgeneralized the way in which Facebook’s and Google’s algorithms work. For example, while the *Force* opinion noted that there are different algorithms used across the platform, much of the language and reasoning of the opinion suggested that the algorithms use similar inputs of data and work in fundamentally the same way.¹⁸⁵

However, there is evidence that Facebook’s various algorithms can differ widely from one another. Based on interviews with Facebook executives, current and former employees, and experts, an MIT Technology Review Investigation found that “Facebook decides how to target ads and rank content based on hundreds, perhaps thousands, of algorithms.”¹⁸⁶ The report also found that engineers on different teams with different business objectives “develop and add their own machine-learning models into the mix, based on their team’s objectives.”¹⁸⁷ Furthermore, multiple teams across Facebook contribute to just its newsfeed recommendation system.¹⁸⁸ This creates a situation in which one system can be so “complex and unwieldy that no one can keep track anymore of all of its different components.”¹⁸⁹ This description

183. See *Force*, 934 F.3d at 65; *Gonzalez*, 2 F.4th at 892.

184. See generally FACEBOOK, www.facebook.com (last visited Dec. 18, 2024).

185. *Force*, 934 F.3d at 70.

186. Hao, *supra* note 92; see Karen Hao, *How Facebook Got Addicted to Spreading Misinformation*, MIT TECH. REV. (Mar. 11, 2021), <https://www.technologyreview.com/2021/03/11/1020600/facebook-responsible-ai-misinformation/>.

187. Hao, *supra* note 92.

188. *Id.*

189. *Id.*

of Facebook’s algorithms is a far cry from the Second Circuit’s characterization of Facebook’s algorithms in *Force*.¹⁹⁰

The Ninth Circuit, in turn, compared Google’s algorithms to search engines—which are completely different tools that serve a different purpose than a recommendation system—and other algorithms at issue in earlier cases, suggesting Google’s algorithms function the same way as these other tools or algorithms.¹⁹¹ The Ninth Circuit used the similarities it found between search engines and recommendation algorithms to argue that the plaintiffs’ complaints fail Prong Three of the *Barnes* test.¹⁹² Thus, the Ninth Circuit implied that search engines and recommendation systems are the same under Prong Three of *Barnes*.¹⁹³ This is a flawed analysis because while both tools are built using algorithms, there is ample evidence to show that search engines are different than recommendation algorithms in function, build, and purpose.¹⁹⁴

The Third Circuit’s opinion in *Anderson* arguably moved closer to singling out individual recommendation systems than the previous decisions had. The Third Circuit recognized TikTok’s For You Page as a singular tool across the opinion. The Third Circuit did this in part by noting the particular features of the algorithm behind TikTok’s For You Page. These features included “curat[ing] and recommend[ing] a tailored compilation of videos . . . based on a variety of factors, including the user’s age and other demographics, online interactions, and other metadata.”¹⁹⁵ On its face, the Third Circuit’s description of TikTok’s For You Page is similar to the Second Circuit’s description of Facebook’s algorithms, but the key difference in *Anderson* is that the Third Circuit examined the For You Page on its own without implicating multiple tools in one overbroad analysis.¹⁹⁶ The Third Circuit occasionally used somewhat broad language. For example, it uses the term “TikTok’s algorithm” many times when discussing the For You Page. However, it is clear by the way the opinion is written that the Third Circuit was consistently discussing the For You Page algorithm specifically without suggesting the For You Page is

190. See *Force*, 934 F.3d at 70 (“The algorithms take the information provided by Facebook users and ‘match’ it to other users—again, materially unaltered—based on objective factors applicable to any content, whether it concerns soccer, Picasso, or plumbers. Merely arranging and displaying others’ content to users of Facebook through such algorithms—even if the content is not actively sought by those users—is not enough to hold Facebook responsible as the ‘develop[er]’ or ‘creat[or]’ of that content. See, e.g., *Marshall’s Locksmith*, 925 F.3d at 1269–71; *Roommates.Com*, 521 F.3d at 1169–70.”).

191. See *Gonzalez*, 2 F.4th at 895.

192. See *id.* at 896.

193. See *Stray*, *supra* note 178.

194. See generally *id.*

195. *Anderson*, 116 F.4th at 182.

196. See generally *Force*, 934 F.3d at 69–70; *Anderson*, 116 F.4th at 181.

similar or dissimilar to other algorithms within TikTok or across other platforms.

However, the Third Circuit's *Anderson* decision is flawed for other reasons. It relied on and mischaracterized the Supreme Court's decision in *Moody*.¹⁹⁷ The *Moody* decision recognized that different types of algorithms serve different functions even within one platform.¹⁹⁸ The Court made it clear that it was only looking at algorithms that are guided by the platform's content standards and policies.¹⁹⁹ The Court made a point to suggest that the content-moderation algorithms with which they were most concerned are not necessarily the same as algorithms that focus mostly on presenting relevant content to users like that which is at issue in *Anderson*.²⁰⁰ Therefore, the Third Circuit applied the Court's reasoning in *Moody* to the exact type of algorithm the Court said was not implicated in its analysis in the *Moody* opinion, effectively mischaracterizing and watering down the Supreme Court's nuanced assessment of algorithms in *Moody*.

3. *The Supreme Court Also Ignored Differences Among Algorithms in Taamneh but Acknowledged Them in Moody*

While the Supreme Court has not yet addressed whether § 230 extends to algorithms, they recently used a broad, sweeping approach to characterize algorithms in *Taamneh* but seemingly showed a more nuanced understanding of algorithms in *Moody* as discussed, *supra*, Section III.C.

In *Taamneh*, the Court described algorithms as “passive” when establishing whether social media platforms played a role in aiding and abetting a terrorist attack and could therefore be held liable under federal law.²⁰¹ This characterization of algorithms is overbroad and seems to suggest that all algorithms, regardless of the platform, have this “passive” quality. However, in *Moody*, the Court seemed to take a different approach to characterizing algorithms than in *Taamneh* by suggesting that different types of algorithms may be subject to different legal protections.²⁰² For example, the Court was only willing to grant First Amendment rights to platforms' algorithms that were designed with content policies in mind.²⁰³ The Court suggested that they

197. See generally *Anderson*, 116 F.4th at 183–84.

198. See *Moody*, 603 U.S. at 735–38.

199. *Id.*

200. *Id.* at 746 (Barrett, J., concurring).

201. *Taamneh*, 598 U.S. at 499.

202. See generally *Moody*, 603 U.S. at 735.

203. *Id.*

would not address whether these same rights would be extended to other algorithms the platform may use for other purposes.²⁰⁴

It is unclear why the Supreme Court characterized algorithms in such different ways in the *Taamneh* and *Moody* decisions. It is likely that the Court did so because the cases themselves presented very different issues. *Taamneh* examined social media platforms' role in aiding and abetting terrorism, while *Moody* looked at social media companies' First Amendment rights in relation to their content moderation policies. The way the Court characterized algorithms in each decision likely had to do with supporting a desired outcome in each case.

Even though the Court addressed the nature of algorithms outside the § 230 context, its characterization of algorithms in *Moody* has already implicated a case that involves § 230: *Anderson*. If TikTok petitions for and the Court decides to grant certiorari in the *Anderson* case, the Court could correct its overbroad characterization of algorithms in *Taamneh* and continue down the path it started on in *Moody*. The Court should ultimately establish an analytical approach that examines each specific algorithm at issue in a case narrowly.

B. A DIFFERENT APPROACH: A NARROW, FACT-INTENSIVE EXAMINATION OF INDIVIDUAL ALGORITHMS UNDER SECTION 230

Section IV.B will propose a different approach than the overgeneralized ones most courts have taken when addressing social media platforms' algorithms. This new approach is called “the individual tools approach” and should be applied during an analysis of Prongs Two and Three of the *Barnes* test and the material contribution test. Section IV.B will then apply the proposed approach to *Anderson* and show how using this approach could result in a similar outcome without relying on *Moody*. Lastly, Section IV.B will examine the challenges in implementing this new approach and propose some solutions. Challenges include how plaintiffs might get past a motion to dismiss stage with limited evidence, the fact that machine-learning algorithms are black boxes, and general free speech concerns.

1. *Courts Should Focus on As Specific a Tool As Possible When Conducting an Analysis Under Prongs Two and Three of the Barnes Test*

As established, *supra*, in Section IV.A, many social media platforms serve multiple functions and provide many tools beyond ones that could be considered “publishing” tools. Under the individual tools approach, there is a difference between being a publisher and using tools that serve publishing

204. *See id.* at 736 n.5.

functions. The former suggests that a social media company can be considered a publisher in its entirety. The latter acknowledges the reality that companies may serve publishing functions through specific tools while also recognizing that many of these companies are not categorically publishers. Under this approach, companies won't be able to hide behind generalizations of their function in society to escape liability.

Under the individual tools approach, once the individual tool in question—whether that be an individual algorithm that is part of a larger recommendation system, an entire recommendation system itself, a search engine for users to explore content, an ads builder, a direct messaging system, etc.—has been identified, an analysis of Prong Two should then ask: is this specific tool functioning in a way that can be compared to traditional publishing?

Take Facebook's newsfeed, for example. As discussed, *supra*, Sections IV.A.1 and IV.A.2, it is a recommendation system that uses multiple algorithms to supply users with content in a way that is completely unique to that system. Facebook's parent company Meta also has, as discussed previously, a plethora of other tools that are separate from its newsfeed: some that use algorithms and some that do not and some that might behave similarly to a traditional publisher and some that unquestionably do not.²⁰⁵ Under the new approach, the question for the second prong of the *Barnes* test can focus on whether the entire recommendation system or even just one of the specific algorithms that creates that larger system serves a traditional publishing function, not whether Meta in its entirety is comparable to a traditional publisher.

The analysis for whether an individual algorithm or system of algorithms should be considered to serve publishing functions can then mimic the analysis of whether the platform as a whole should be considered a publisher. This analysis was introduced in *Zeran* and discussed in subsequent appellate decisions.²⁰⁶ In *Zeran*, the Fourth Circuit said § 230 precludes claims that originate from “traditional editorial functions . . . such as such as deciding whether to publish, withdraw, postpone, or alter content.”²⁰⁷ The Second Circuit in *Forve* said that it and other courts have examined the ordinary meaning of the term “publisher” in § 230(c)(1), which is “one that makes

205. See META, <https://business.meta.com/> (last visited Nov. 14, 2024); META, <https://www.meta.com/> (last visited Nov. 14, 2024).

206. See *Forve*, 934 F.3d at 64; *Gonzalez*, 2 F.4th at 892–93.

207. *Zeran*, 129 F.3d at 330.

public,”²⁰⁸ “the reproducer of a work intended for public consumption,”²⁰⁹ and “one whose business is publication.”²¹⁰ Drawing on the opinions in *Roommates.com* and *Barnes*, the Ninth Circuit largely mimicked the *Zeran* approach in examining the publisher question in *Gonzalez*, stating that publishing includes “reviewing, editing, and deciding whether to publish or to withdraw from publication third-party content.”²¹¹

Courts can ask several questions to determine whether the individual tool in question is serving a publishing function based on the Second and Ninth Circuits’ understanding of what it means to be a publisher. The example of Facebook’s newsfeed is again illustrative. The purpose of that system, on its face, is to recommend and suggest content to users based on user signals, like previous content they have liked.²¹² A court could first ask whether that activity mimics that of a traditional publisher. While this arguably goes beyond the mere function of “making something public,” it could be possible for a court to decide that recommending content to users fits more into the “reviewing, editing, and deciding whether to publish” function.²¹³

The next question might become: Do traditional publishers actively promote biased content to change user’s behavior and beliefs and to increase the amount of time users spend on the platform? The answer to this question is currently unclear and might be difficult to ascertain without plaintiffs being able to gather more information during the pleading stage.²¹⁴ It is hard to imagine any traditional publisher behaving in such an extreme fashion, but that is an inquiry the courts can make with sufficient information. For example, studies have shown that Facebook’s newsfeed takes some actions in how it organizes content that could be considered to go beyond the role of a traditional publisher.²¹⁵ Courts will likely need evidentiary support about how

208. *Forve*, 934 F.3d at 65 (citing *Klayman v. Zuckerberg*, 753 F.3d 1354, 1359 (D.C. Cir. 2014)).

209. *Forve*, 934 F.3d at 65 (citing *Fed. Trade Comm’n v. LeadClick Media, LLC*, 838 F.3d 158, 175 (2d Cir. 2016)).

210. *Id.*

211. *Gonzalez*, 2 F.4th at 892 (quoting *Barnes*, 570 F.3d at 1102).

212. See Sam Lauron, *2025 Facebook Algorithm: Tips and Expert Secrets to Succeed*, HOOTSUITE (Feb. 3, 2025), <https://blog.hootsuite.com/facebook-algorithm/>.

213. *Gonzalez*, 2 F.4th at 892.

214. Most of the cases in which a § 230 claim does not survive the *Barnes* test are decided on a motion to dismiss. How to survive a motion to dismiss will be discussed later in this Note.

215. See Huo Jingnan & Shannon Bond, *New Study Shows Just How Facebook’s Algorithm Shapes Conservative and Liberal Bubbles*, NPR (July 27, 2023), <https://www.npr.org/2023/07/27/1190383104/new-study-shows-just-how-facebooks-algorithm-shapes-conservative-and-liberal-bub>; see also Will Oremus, Chris Alcantara, Jeremy B. Merrill & Artur Galocha, *How*

individual algorithms work to draw a line somewhere between when an algorithm functions similarly to a traditional publisher and when it does not. While that line is not yet known,²¹⁶ it will be a lot easier for courts to establish that line if they are able to work off clear evidence about how individual algorithms work and subsequently single out each individual algorithm in their Prong Two analysis. Once each algorithm is singled out, courts can decide which algorithms pass a Prong Two analysis and which ones fail that same analysis.

Similar to singling out individual tools in a Prong Two analysis, courts should also conduct fact-specific determinations about each algorithm in question during the Prong Three analysis in order to avoid making sweeping generalizations about all algorithms. As stated earlier, while algorithms share many similarities, there are ample differences among them across different platforms, within the same platform, and even within the same recommendation system.²¹⁷ Under this new approach, once an individual algorithm has been identified and isolated, the question courts need to answer under Prong Three and the material contribution test is if that algorithm developed, co-developed, or materially contributed to the offending content. Taking this approach will protect the integrity of § 230 and avoid extending liability or immunity further than necessary. In other words, if one algorithm is found to have failed Prong Three of the *Barnes* test, other algorithms separate from or even within the same recommendation system will not be implicated and can presumably continue to function as they always have.

Take X (formerly “Twitter”)’s “For you” tab as an illustrative example. It has been reported that current X owner, Elon Musk, asked engineers to promote his content so that it was higher in users’ feeds shortly after he took

Facebook Shapes Your Feed, WASH. POST (Oct. 23, 2021), <https://www.washingtonpost.com/technology/interactive/2021/how-facebook-algorithm-works/>.

216. Even in *Anderson*, the court did not address the publisher issue, instead conducting essentially a Prong Three analysis. See *Anderson*, 116 F.4th at 183–84.

217. See generally Akos Lada, *How Does New Feed Predict What You Want to See?*, FACEBOOK NEWSROOM (Jan. 26, 2021), <https://about.fb.com/news/2021/01/how-does-news-feed-predict-what-you-want-to-see/>; see Nima Noorshams, Saurabh Verma & Aude Hofleitner, *Leveraging Online Social Interactions for Enhancing Integrity at Facebook*, META RSCH. BLOG (Aug. 26, 2022), <https://research.facebook.com/blog/2020/8/leveraging-online-social-interactions-for-enhancing-integrity-at-facebook/>; *The Facebook Algorithm Explained*, BRANDWATCH (May 7, 2021), <https://www.brandwatch.com/blog/the-facebook-algorithm-explained/>; *Explained: The Algorithms that Run Facebook*, ECON. TIMES (Oct. 26, 2021), <https://economictimes.indiatimes.com/tech/trendspotting/explained-the-algorithms-that-run-facebook/articleshow/87282136.cms?from=mdr>.

over the company.²¹⁸ If a court were to examine X’s “For you” recommendation system under Musk’s influence, it is likely that they could find that the “For you” tab does not pass Prong Three. This is because X’s engineers arguably co-developed and possibly even materially contributed to the content published on the “For you” tab by actively promoting Elon Musk’s content to all users regardless of whether they wanted to follow him or not. If a court were to make this determination, the algorithm responsible for promoting Elon Musk’s post would not receive § 230 immunity. However, the other algorithms fueling the “For you” page, like those which show users content related to their proven interests, could remain untouched by that decision, as would all other algorithms on X and other platforms unless separately challenged and tested under the individual tools approach. In this way, the individual, fact-intensive approach can make it so that § 230 immunity only extends to as narrow a group of algorithms as is absolutely necessary under the law without implicating every algorithm or system of algorithms that exist.

In the cases discussed, *supra*, in Parts III and IV of this Note, neither plaintiffs nor defendants have argued that courts should take this more individualized approach when analyzing algorithms. Plaintiffs’ claims tend to overgeneralize algorithms when challenging their status under the last two prongs of the *Barnes* test, and defendants tend to respond in kind. This is likely due to a lack of available evidence at the pleading stage. The closest a court or party has come to suggesting a more individualized approach to examining algorithms comes from Chief Judge Katzmann of the Second Circuit in the *Force* dissent.²¹⁹ He argued that precedent does not suggest that publishers should be immune under § 230 for every activity in which they engage.²²⁰ He said, “Facebook may be immune under the CDA from plaintiffs’ challenge to its allowance of Hamas accounts, since Facebook acts solely as the publisher of the Hamas users’ content. That does not mean, though, that it is also immune when it conducts statistical analyses of that information and delivers a message based on those analyses.”²²¹

If courts were to use the individual tools approach, the outcome may be that § 230 immunity is applied appropriately to protect the parts of the internet it was intended to protect while holding companies liable for conduct that

218. Faiz Siddiqui & Jeremy B. Merrill, *Elon Musk Reinvents Twitter for the Benefit of a Power User: Himself*, WASH. POST (Feb. 16, 2023), <https://www.washingtonpost.com/technology/2023/02/16/elon-musk-twitter/>.

219. *See generally Force*, 934 F.3d (Katzmann, C.J., concurring in part and dissenting in part).

220. *Force*, 934 F.3d at 81 (Katzmann, C.J., concurring in part and dissenting in part).

221. *Id.* at 83 (Katzmann, C.J., concurring in part and dissenting in part).

surpasses what § 230 seemingly meant to protect. With this narrower, fact-intensive approach, courts can decide about whether a specific recommendation system or an individual algorithm that is part of that larger system is subject to § 230 without making a judgement about whether every single recommendation system, algorithm, search engine, or any other type of tool is subject to the same immunity or liability. This would benefit both plaintiffs and defendants because plaintiffs would likely receive damages for harms caused by tools that should not be protected by § 230, while defendants would only be held liable for as small a portion of their technology as necessary under the law.

2. *Applying the Individual Tools Approach to Anderson*

As discussed, *supra*, in Section III.D, the Third Circuit in *Anderson* decided that TikTok's For You Page did not qualify for § 230 immunity because it determined that the For You Page was TikTok's own "expressive activity" under *Moody*.²²² The Third Circuit did not complete a full *Barnes* test analysis in its opinion but rather focused on the plain language of the statute, which states that § 230 only immunizes information "provided by another."²²³ That analysis is essentially a Prong Three analysis because Prong Three explicitly looks at who is providing the content in question, but the Third Circuit ultimately used a case that many find to be unrelated to the question at hand, *Moody*, to make its determination.²²⁴

Section IV.B.2 applies the individual tools approach under the *Barnes* test to analyze Anderson's claims against TikTok. Section IV.B.2 shows how this analysis would likely lead to a similar conclusion as was made by the Third Circuit without relying on caselaw that focuses on a different legal question or by making sweeping statements about how all algorithms function with § 230 as the Second and Ninth Circuits did in *Force* and *Gonzalez*.

a) Does TikTok's For You Page Function as a Traditional Publisher Under Prong Two of *Barnes*?

While the first inquiry in a *Barnes* test analysis is whether the defendant is an interactive computer provider, that question is rarely disputed, particularly in cases like *Anderson* that implicate a well-established social media company.²²⁵ Accordingly, a *Barnes* analysis really begins at the second prong. Under the individual tools approach, the question is: does TikTok's For You Page, as an

222. *Anderson*, 116 F.4th at 183–84.

223. *Id.* at 184 (citing 47 U.S.C. § 230(c)(1)).

224. Calo, *supra* note 163; Goldman, *supra* note 163.

225. See *Force*, 934 F.3d at 69; see also *Gonzalez*, 2 F.4th at 891.

individual tool, function like a traditional publisher? The question is not the one many courts currently ask under Prong Two: Is TikTok a publisher as a whole?

To answer whether TikTok's For You Page functions as a traditional publisher, one first must consider whether the For You Page fits the definition: "one that makes public,"²²⁶ "the reproducer of a work intended for public consumption,"²²⁷ and "one whose business is publication."²²⁸ Much like Facebook's newsfeed discussed, *supra*, in Section IV.B.1, on its face TikTok's For You Page recommends new content to users based on previous content that they have engaged with. This function might fall into the definition of a traditional publisher. However, additional evidence might persuasively prove to the Supreme Court, if it grants certiorari in *Anderson*, that the For You Page goes beyond the function of a traditional publisher.

For example, there is evidence that TikTok's For You Page provides users with content the company believes that specific user wants to see, rather than content the user actually wants to see. In other words, the evidence suggests that the recommendation system promotes content that the platform thinks the user will watch.²²⁹ While this behavior may not initially seem different to how other platforms' recommendation systems function, there is an important distinction to make between TikTok's For You Page and other potentially similar systems. In focusing on what the user will watch rather than what they have indicated they might want to watch, the algorithm can prey on people's vulnerabilities. For example, a teenager showing signs of depression may not want to watch depressing content, but when presented that content, they will likely watch it.²³⁰ This is part of what is thought to make TikTok's For You Page distinct from other platforms' recommendation systems.²³¹ TikTok itself has seemingly recognized that this particular recommendation system can cause harm and has claimed to have attempted to put various safety measures

226. *Forve* 934 F.3d at 65 (citing *Klayman*, 753 F.3d at 1359).

227. *Id.* (citing *LeadClick*, 838 F.3d at 175).

228. *Id.*

229. Sara Morrison, *TikTok Won't Stop Serving Me Horror and Death*, VOX (Oct. 26, 2022), <https://www.vox.com/recode/2022/10/26/23423257/tiktok-for-you-page-algorithm>.

230. *Id.*

231. Sara Morrison, *TikTok Is Confusing by Design*, VOX (July 5, 2023), <https://www.vox.com/technology/23780112/tiktok-internet-design-algorithm-for-you-page-ux-ui>.

in place to mitigate that harm.²³² However, evidence suggests that these efforts have been futile and unsuccessful.²³³

Given the evidence that exists about TikTok's For You Page, it is possible that a court would find that the specific recommendation system performs in a way that surpasses what a traditional publisher might do. For example, it is difficult to imagine a traditional publisher recognizing someone has a psychological disorder and providing that person content that makes that disorder worse for the sake of keeping them on their platform longer. In other words, if the facts surrounding how TikTok's algorithm is built suggest that it is purposefully designed to manipulate user behavior in a way that encourages people to watch content about self-harm, a court could use those facts about TikTok's algorithm to decide that it does not fall under § 230 protections. However, a court could decide the other way after a fact-intensive and individualized inquiry into how TikTok's For You Page operates. Under the individual tools approach, the publishing status will only apply to TikTok's For You Page and not to any of the other tools TikTok provides, like its "Following" or "Explore" tools, unless separately challenged and found to also fail the individual tools approach. The status will also not apply to other companies' recommendation systems unless it can be proved those systems also fail the newly proposed test.

b) Does TikTok's For You Page Develop, Co-develop, or Materially Contribute to the Offending Content Under Prong Three of *Barnes*?

The third and last inquiry made under the *Barnes* test is whether the algorithm that promoted the offending content developed, co-developed, or materially contributed to that content.²³⁴ In this case the offending content is the Blackout Challenge videos that appeared on Nylah's For You Page.²³⁵ An inquiry under the individual tools approach will only implicate the specific algorithm responsible for promoting these videos on Nylah's For You Page. To make its determination, a court will need to look at the facts surrounding the specific algorithm to make its determination.

Once again, it is possible that the Supreme Court, if it grants certiorari, could find that TikTok's For You Page does co-develop and materially contribute to the offending content. As discussed, *supra*, in Section IV.B.2.a,

232. Olivia Carville, *TikTok's Algorithm Keeps Pushing Suicide to Vulnerable Kids*, BLOOMBERG (Apr. 19, 2023), <https://www.bloomberg.com/news/features/2023-04-20/tiktok-effects-on-mental-health-in-focus-after-teen-suicide>.

233. *Id.*

234. *See Barnes*, 570 F.3d at 1100–01.

235. *See Anderson*, 116 F.4th at 181.

there is evidence to suggest that the For You Page provides users content that they never wanted to watch in the first place.²³⁶ The For You Page instead promotes content that the user will likely watch, which can be very different than content users actually desire. Additionally, it has been suggested that TikTok’s “[a]lgorithmic processes . . . gamify harmful content” to make it seem like entertainment to young people.²³⁷ If a user does, in fact, watch novel and unexpected content, the algorithm will feed them more of that content. Thus, a strong argument could be made for considering this process to be one that materially contributes to the development of the offending content, even if TikTok itself did not create any Blackout Challenge videos.

There are also other possible outcomes under the individual tools analysis. First, it is entirely possible that one of the many algorithms that create the entire system of algorithms that is the For You Page is to blame for pushing nefarious content for the sake of increasing engagement. It is possible that a court would find that specific portion of the larger system is what makes the company liable for the offending content. Second, it is possible that a court could find that TikTok’s For You Page does not in part develop the harmful content at all. Regardless of the decision a court might make regarding a Prong Three analysis of TikTok’s For You Page, that decision will only apply to the specific, offending algorithm found responsible for promoting the Blackout Challenge on Nylah’s For You Page under the individual tools approach.

3. *Potential Challenges or Concerns About the Individual Tools Approach*

a) *Implementing the Individual Tools Approach Under the Federal Rules of Civil Procedure*

One of the challenges courts will have in implementing the individual tools approach is that the rules of federal civil procedure make it very difficult for plaintiffs to gather enough evidence during the pleading stage to survive a motion to dismiss for failure to state a claim. As can be seen throughout the cases examined in this Note, plaintiffs often made broad accusations about the algorithms they sought to hold liable because the plaintiffs only had so much information available to them about how the algorithms. Furthermore, the *Barnes* and material contribution tests put the burden of proof on the plaintiff to prove that the defendant’s conduct should not be barred by § 230.²³⁸

236. See Morrison, *supra* note 229.

237. Sally Weale, *Social Media Algorithms ‘Amplifying Misogynistic Content’*, GUARDIAN (Feb. 5, 2024), <https://www.theguardian.com/media/2024/feb/06/social-media-algorithms-amplifying-misogynistic-content>; Cummins, *supra* note 3.

238. See *generally* *Forve*, 934 F.3d; *Gonzalez*, 2 F.4th.

One solution to this problem is putting the burden on defendants instead of plaintiffs to prove that their algorithms pass the *Barnes* test. Another solution would be to allow plaintiffs to plead insufficient information under FRCP Rule 11(b)(3).²³⁹ Rule 11(b) generally imposes certain requirements attorneys must meet in making any pleading, written motion, or other paper to avoid any pleading or other document that might cause “improper, frivolous, harassing, unnecessarily delayed, and unnecessarily expensive litigation.”²⁴⁰ Rule 11(b)(3) allows plaintiffs to make claims that “will likely have evidentiary support after a reasonable opportunity for further investigation or discovery.”²⁴¹ While “[s]imply guessing or speculating that there may be a claim is not enough,” plaintiffs can invoke 11(b)(3) during the pleading stage if they can “articulate at least some facts as to why it is reasonable to believe there is infringement.”²⁴² In the context of gathering enough evidence to get past a motion to dismiss after a defendant has invoked a § 230 defense, plaintiffs would need to articulate some facts about the inner workings of an algorithm to show that the algorithm might not pass the *Barnes* test. If plaintiffs succeed with 11(b)(3) and can show that they have some facts that indicate an algorithm may not pass the *Barnes* test, they can then engage in further investigation or discovery to gather the evidence needed to prove their case.

b) Implementing the Individual Tools Approach Given the Black Box Methods of Machine-learning Algorithms

One argument social media companies are likely to make against the individual tool approach is that even if plaintiffs could gather more evidence about recommendation algorithms, many machine-learning algorithms are black boxes.²⁴³ That is, no one understands why they work the way they do.²⁴⁴ As experts note, “even those who design them, cannot understand how variables are being combined to make predictions. Even if one has a list of the input variables, black box predictive models can be such complicated functions of the variables that no human can understand how the variables are jointly related to each other to reach a final prediction.”²⁴⁵ Additionally, companies have a financial interest in creating black box models because it gives them a

239. FED R. CIV. P. 11(b)(3).

240. *Elan Microelectronics v. Apple*, No. C 09–01531, 2009 WL 2972374, at *3 (N.D. Cal. Sep. 14, 2009).

241. FED R. CIV. P. 11(b)(3).

242. *Elan*, No. C 09–01531, 2009 WL 2972374, at *4.

243. See generally Rudin, *supra* note 14.

244. *Id.*

245. *Id.*

competitive advantage over other companies given that no one can crack a particularly successful model, including the competitor.²⁴⁶

However, these same experts suggest that it is possible to design machine-learning models with interpretability constraints, which would mean that the models are built to be able to give people a better sense of how the system's predictions are actually made.²⁴⁷ These models are technically equivalent to black box models but arguably much more ethical.²⁴⁸

For the individual tools analysis to ultimately be successful, a law that requires companies to build more interpretable tools might first be required.

c) Free Speech and Content Moderation Concerns If Any Company Is Found to Be Liable for Offensive Content Due to an Algorithm

Whenever § 230's scope is debated, one argument in favor of maintaining § 230's broad reach is that any effort to cut off platform immunity will both chill free speech and hamper content moderation policies.²⁴⁹ The idea, in terms of chilling free speech, is that platforms will be afraid of being held liable for any content on their platforms and will end up censoring more content than is necessary in an effort to avoid lawsuits.²⁵⁰ Another similar argument is that § 230 actually allows companies to moderate the content that exists on their platforms already without fear that they will be held liable for the decisions they make or for any content that falls through the gaps of their moderation practices and policies.²⁵¹

While the free speech and content moderation concerns are something to take seriously when considering the scope of § 230, the individual tools approach makes it so platforms can adjust their recommendation algorithms to look something more like a traditional publisher or take a less active approach in prioritizing certain types of content without implicating all algorithms across the industry. For example, a company that is consistently being found liable for a recommendation system that fails either one or multiple prongs of the *Barnes* test could change or remove one of the many algorithms that comprise that recommendation system to make it so that it passes a *Barnes* test analysis. That same company could also switch to a system that posts content in a chronological order and from accounts that have only

246. *See id.*

247. *See id.*

248. *See id.*

249. Granick, *supra* note 22.

250. Draper, *supra* note 38.

251. Granick, *supra* note 22.

a few degrees of separation from accounts a user already follows. Changes like these would mean users are still allowed to post whatever speech they want. That speech may just find its way to other users in more organic ways than it currently does under certain algorithmic designs.²⁵²

Additionally, if it is important for business metrics to keep recommendation algorithms as they are, companies do have tools at their disposal to make their algorithms safer.²⁵³ For example, companies take significant measures to prevent child pornography from appearing on their platforms. Those same measures can be taken to prevent other harmful or unlawful content from not only appearing but also being prioritized on people's feeds. In these ways, companies can still allow as much speech as they want on their platforms and continue to moderate content without fear of liability.

V. CONCLUSION

The internet has changed immensely since § 230 of the Communications Decency Act was enacted in 1996. In passing § 230, no one could have predicted the power of tools like recommendation systems and the individual algorithms that fuel them. The companies that wield these algorithms have a vested interest in continuing to use § 230 as a defense can to avoid liability, particularly when it comes to claims that implicate their most powerful tools. As discussed, many courts have handed social media platforms victories by suggesting that recommendation algorithms qualify for § 230 immunity under Prongs Two and Three of the *Barnes* test. The Third Circuit is the only court that has denied this immunity to a recommendation system. However, most of the decisions were based on an overbroad characterization of algorithms that take an all-or-nothing approach to applying § 230 to algorithms, setting unhelpful precedents for both plaintiffs and defendants.

If the Supreme Court grants certiorari for a case like *Anderson v. TikTok*, the Court has an opportunity to apply a more nuanced approach when examining how § 230 should apply to algorithms. It is what this Note has termed “the individual tools approach.” Through examining each individual tool—whether that be looking at a recommendation system as a whole or one specific algorithm that helps run that larger system—on its own when doing a

252. See generally William J. Brady, Joshua Conrad Jackson, Björn Lindström & M. J. Crockett, *Algorithm-Mediated Social Learning in Online Social Networks*, 27 TRENDS IN COGNITIVE SCIS. 947 (2023).

253. Danielle Draper & Sabine Neschke, *The Pros and Cons of Social Media Algorithms*, BIPARTISAN POL'Y CTR. (Oct. 2023), https://bipartisanpolicy.org/download/?file=/wp-content/uploads/2023/10/BPC_Tech-Algorithm-Tradeoffs_R01.pdf.

Barnes test analysis, § 230 immunity can be applied to the narrowest set of tools needed. This approach would protect the integrity of § 230 and would also protect defendants by making it so that similar tools across and within platforms would not be needlessly implicated. In turn, the tools that are found to fall outside the bounds of § 230 immunity could be appropriately held liable, benefitting plaintiffs and those who are at the mercy of social media companies' decisions.

Furthermore, the individual tools approach will be useful for courts analyzing how § 230 should be applied to even newer tools and technologies like those that are backed by generative AI. There has been much debate and speculation over how courts will interpret § 230 as it applies to AI-backed tools.²⁵⁴ Under the individual tools approach, courts could single out AI tools from the other tools offered on social media platforms and assess how § 230 immunity relates to that specific, AI-backed tool without implicating other tools on the platform.

254. PETER J. BENSON & VALERIE C. BRANNON, CONG. RSCH. SERV., LSB11097, SECTION 230 IMMUNITY AND GENERATIVE ARTIFICIAL INTELLIGENCE 3 (2023); Noor Waheed, *Section 230 and Its Applicability to Generative AI: A Legal Analysis*, CTR. FOR DEMOCRACY & TECH. (Sep. 4, 2024), <https://cdt.org/insights/section-230-and-its-applicability-to-generative-ai-a-legal-analysis/>.

AI EXPORT CONTROLS: SAFEGUARD OR A STRAITJACKET?

Siwen D. Cremean[†]

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I. INTRODUCTION

Artificial intelligence (AI) is an emerging technology that is reshaping global power dynamics and presenting countries with opportunities to define the next global order. As AI transforms warfare, commerce, and daily life, policymakers must balance innovation, technological advantage, and security. Export controls under the Export Control Reform Act (ECRA) lie at the heart of this issue.

Export controls are federal regulations that restrict the cross-border movement of goods, services, technology, information, and money; for example, American export controls might restrict the transfer of AI-related information and products to foreign countries and people.¹ AI technology can improve American warfighting and economic capabilities; simultaneously, adversaries and competitors can use AI created in the United States to advance foreign military and economic power.² Overzealous export controls can reduce

1. Cornell University, *Export Controls: Regulations and Overview*, RESEARCH & INNOVATION SERVS., <https://researchservices.cornell.edu/policies/export-controls-regulations-and-overview> [https://perma.cc/4PDD-HE2R] (last visited Apr. 6, 2025).

2. William A. Reinsch, *Export Control: Too Much or Too Little*, CTR. FOR STRATEGIC & INT'L STUDS. (Oct. 17, 2022), <https://www.csis.org/analysis/export-control-too-much-or-too-little> [https://perma.cc/82DP-R7ZS].

American overseas revenue, impede global supply chains, harm allied relationships, and reduce American market dominance.³ Simultaneously, inadequate regulations may heighten the risk of uncontrolled international weapons proliferation and competition with American businesses.⁴ How the government chooses to calibrate its commercial export controls can tip the U.S. economy and military toward either dominance or decline.

Countries around the world recognize AI as a transformative technology with strategic advantages.⁵ Historically, power has rested with rich countries equipped with large, well-funded, and technologically sophisticated militaries. AI, however, offers widespread, procurable, and inexpensive opportunities to augment unsophisticated military technologies, potentially levelling the playing field.⁶ This unprecedented growth in military technology, stemming from AI, combined with a shift towards limited multipolarity, may affect future alliances between the East and West.⁷

Over the last decade, China's ideological views and rise as a technological powerhouse have intensified great power competition with the United States, leading to what some believe to be a new bipolar world order with eastern and western hegemons.⁸ Former Secretary of State Antony Blinken has called the Sino-American relationship the "most consequential" relationship of the twenty-first century.⁹ How both countries elect to use AI, the next technological frontier, will determine the future of warfare and commerce.

Technology underpins both economic and military spheres; thus, AI technologies sold by commercial companies affect both commercial and military interests.¹⁰ Traditionally, export controls had a military focus—the United States employed export controls as levers to manage the proliferation

3. *Id.*

4. *Id.*

5. JAMES JOHNSON, ARTIFICIAL INTELLIGENCE AND THE FUTURE OF WARFARE: THE USA, CHINA, AND STRATEGIC STABILITY 60–62 (Manch. Univ. Press 2021).

6. *Id.* at 69–70.

7. See Emma Ashford & Evan Cooper, *Yes, the World is Multipolar*, FOREIGN POL'Y (Oct. 5, 2023), <https://foreignpolicy.com/2023/10/05/usa-china-multipolar-bipolar-unipolar/> [https://perma.cc/VWR7-CPUR].

8. JOHNSON, *supra* note 5, at 69–70.

9. See Graham T. Allison, Jash M. Cartin, Elizabeth Economy, Susan A. Thornton, Ryan Hass, Patricia M. Kim & Emilie Kimball, *Is the US-China Relationship the Most Consequential Relationship for America in the World?*, BROOKINGS (Feb. 6, 2024), <https://www.brookings.edu/articles/is-the-us-china-relationship-the-most-consequential-relationship-for-america-in-the-world/> [https://perma.cc/HK9D-DJWD].

10. See 50 U.S.C. § 4811(1)–(3). U.S. commercial export law explicitly recognizes both economic and military considerations as elements of the national security umbrella, used to protect Americans and further foreign policy and international obligations.

of high-end weapons.¹¹ Commercial export controls are a more recent invention, yet given the weaponizing capabilities of many commercial technologies today, they are equally important.¹² Export controls of commercial products with military applications—products like AI-augmented drones, nuclear technology, or satellite internet—stem from nonproliferation philosophies that were historically applied to weapons exports; however, these nonproliferation-focused models often prove impractical when commercial sales also have societal and statecraft-related benefits.¹³ Many companies want to sell beneficial AI products on a global scale to advance society and maintain market dominance. The government must balance these beneficial sales with AI's dual-use warfighting capabilities, lest these ordinary companies turn into proverbial weapons dealers.¹⁴

The United States enacted ECRA in 2018 as its most recent attempt to reform the commercial export system and control sales of commercial dual-use emerging technologies.¹⁵ ECRA enables the Department of Commerce to regulate emerging technologies, both through explicit, list-based controls as well as catch-all controls. ECRA defines dual-use technologies as those that

11. See PAUL K. KERR & CHRISTOPHER A. CASEY, CONG. RSCH. SERV., R46814, THE U.S. EXPORT CONTROL SYSTEM AND THE EXPORT CONTROL REFORM ACT OF 2018 2–6 (2021). Export controls were historically limited to foreign military sales, expanding to commercial sales during World War II (WWII). After WWII, the United States created a commercial export regime to regulate foreign demand of U.S. products. Since then, the United States has adjusted commercial export controls accordingly—export controls were stricter during the Cold War to prevent international theft of U.S. technology and more lenient in the years that followed to keep up with global technological competition (to maintain global market share in the face of European, Japanese, and now Chinese competitors).

12. See *id.*

13. See *id.*

14. See Amritha Jayanti, *Starlink and the Russia-Ukraine War: A Case of Commercial Technology and Public Purpose?*, BELFER CTR. FOR SCI. AND INT'L AFFS., HARV. KENNEDY SCH. (Mar. 9, 2023), <https://www.belfercenter.org/publication/starlink-and-russia-ukraine-war-case-commercial-technology-and-public-purpose>; see also Tara Brown, *Can Starlink Satellites Be Lawfully Targeted?*, WEST POINT LIEBER INST. (Aug. 5, 2022), <https://lieber.westpoint.edu/can-starlink-satellites-be-lawfully-targeted/> [<https://perma.cc/4WVA-GK66>]; ANDURIL, <https://www.anduril.com/article/anduril-s-lattice-a-trusted-dual-use-commercial-and-military-platform-for-public-safety-security/> [<https://perma.cc/H5Q2-FFEC>] (last visited Feb. 22, 2025). At the onset of the Russo-Ukraine War in 2022, SpaceX sent 5,000 terminals to Ukraine. Starlink was reappropriated for combat. To avoid being complicit in major acts of war (Starlink was a lawful target), SpaceX stopped sending Starlink terminals to Ukraine. The U.S. Government created a hasty Government contract for “Starshield” to continue providing Ukraine with wartime communication products. Similarly, Anduril’s Lattice OS combines AI with drone technology for commercial and military uses from undersea power infrastructure inspection to military intelligence and reconnaissance. Such commercial technology sold for nonmilitary purposes has wartime applications.

15. See KERR & CASEY, *supra* note 11, at 1.

have “civilian applications and military, terrorism, weapons of mass destruction, or law-enforcement-related applications.”¹⁶ Because AI has broad commercial and military dual-uses, many AI-related sales fall under ECRA. Policymakers deliberately drafted ECRA broadly to allow expansive agency interpretation, particularly mindful of emerging and foundational technologies in Sino-American relations.¹⁷

In the six years since ECRA’s enactment, the United States has been slow to implement explicit, list-based AI export controls despite flagging AI as a high-risk emerging technology.¹⁸ To date, AI controls have focused primarily on the hardware used to power and run AI software—such as components found in data centers (semiconductors, quantum computing technologies, etc.).¹⁹ Existing AI software controls are narrowly written and exclusively target niche, closed-weight AI.²⁰

This Note argues that current export controls for AI hardware provide limited benefits, even if implemented efficiently. Many controls on AI software would be ineffective, which is why agencies operating under ECRA have declined to impose substantial software controls to date. ECRA provides guidelines for regulatory agencies to determine the effectiveness of future AI controls.²¹ Based on ECRA’s balancing considerations, and given AI’s rapid growth and uncertainty, responsible AI related regulations must limit their scope. Even though AI controls, at present, have limited benefits, regulators should continue to analyze AI under ECRA’s balancing factors, as the evolving AI landscape may necessitate future list-based controls.²² Any future AI

16. War and Nat’l. Def., Exp. Control Reform Act, 50 U.S.C. § 4801(2) (2018).

17. See KERR & CASEY, *supra* note 11, at 1.

18. JON BATEMAN, U.S.-CHINA TECHNOLOGICAL “DECOUPLING”: A STRATEGY AND POLICY FRAMEWORK 18 (Carnegie Endowment for International Peace 2022).

19. Export Administration Regulations, 15 C.F.R. § 774 (2025); see Giovanna M. Cinelli, Kenneth J. Nunnenkamp & JiaZhen Guo, *US Expands Controls on Quantum, Semiconductor Tech to Secure Industry Leadership*, MORGAN LEWIS (Sep. 18, 2024), <https://www.morganlewis.com/pubs/2024/09/us-expands-controls-on-quantum-semiconductor-tech-to-secure-industry-leadership> [https://perma.cc/DS7K-N7XM].

20. See Josephine I. Aiello LeBeau & Anne E. Seymour, *Artificial Intelligence Software Controlled for Export, Including to Foreign National Employees*, WILSON SONSINI (Jan. 10, 2020), <https://www.wsgr.com/en/insights/artificial-intelligence-software-controlled-for-export-including-to-foreign-national-employees.html> [https://perma.cc/58EH-JDZU]; Neena Shenai, Barry J. Hurewitz, Lauren Mandell, Leslie A. Harrelson, Stephanie Hartmann, Alexandra Maurer & Anh H. Do, *BIS Issues Long-Awaited Export Controls on AI*, WILMERHALE (Feb. 5, 2025), <https://www.wilmerhale.com/en/insights/publications/20250205-bis-issues-long-awaited-export-controls-on-ai> [https://perma.cc/M7JC-B2EJ].

21. See 50 U.S.C. § 4817(a)(2)(B)(i)–(iii).

22. See *id.*

controls should be narrowly written, balancing economic and military development with nonproliferation.

Part II introduces ECRA, discusses the geopolitical tensions motivating its development, and describes the current AI export landscape. Part III explains judicial treatment of export regulations and highlights sections of ECRA that expanded upon previous export law. Part IV provides examples of applying ECRA's balancing considerations to AI. Part V concludes.

II. LAYING THE FRAMEWORK FOR THE EXPORT CONTROL REFORM ACT (ECRA) AND AI

Part II builds a framework for understanding how and why ECRA expanded upon past export law, and how these expansions relate to AI. Section II.A reviews the contours of the U.S. export system, the scope of ECRA's jurisdiction within this system, and discusses why commercial AI falls under ECRA. Section II.B then takes the reader through history to the present day, explaining ECRA's origin story, the geopolitical factors that spur modern-day considerations, and current regulations that affect AI.

A. ECRA AUTHORIZES EXPORT CONTROLS FOR DUAL-USE TECHNOLOGIES LIKE COMMERCIAL AI

The following Sections define AI and explain why AI falls under the ECRA. Section II.A.1 explains ECRA's place within the U.S. export regime and ECRA's objective—to regulate dual-use technology. Section II.A.2 explains how AI can augment weapons systems. Section II.A.3 provides examples of how commercial AI can be used in unconventional warfare. Section II.A.4 explains how the open-source nature of many foundational AI algorithms further complicates the American national security posture.

1. *ECRA Controls the Exports of Dual-Use Technologies*

The United States imposes export controls to advance U.S. national security objectives, promote regional stability, and prevent the proliferation of weapons used in warfare, terrorism, and human rights abuses.²³ Under federal statutory authority, government agencies collaborate to regulate exports through controls, directives, and penalties.²⁴

In the United States, export controls have clear lines of authority. The Department of the Treasury's Office of Foreign Assets Control (OFAC)

23. U.S. Dep't of State, *Overview of U.S. Export Control System*, U.S. DEP'T. OF STATE: A RES. ON STRATEGIC TRADE MGMT. AND EXP. CONTROLS, <https://2009-2017.state.gov/strategictrade/overview/index.htm> [<https://perma.cc/3Z38-46F9>] (last visited Apr. 6, 2025).

24. *Id.*

enforces asset freezes, trade sanctions, and travel bans targeting foreign countries, narcotics traffickers, and terrorists.²⁵ The Arms Export Control Act of 1976 (AECA) authorizes the Department of State to regulate arms exports and weapons sales.²⁶ Finally, ECRA authorizes the Department of Commerce, via the Bureau of Industry and Security (BIS), to oversee export licensing and enforcement of commercial items with weaponization potential.²⁷ Just as AECA gives rise to the International Traffic in Arms Regulations (ITAR), ECRA provides authority for the Export Administration Regulations (EAR).²⁸ A core component of the EAR is the Commerce Control List (CCL), which lists export-restricted items under export control classification numbers (ECCNs).²⁹ When people think of export controls, they generally think of ECCNs. However, even if an item is not explicitly listed on CCL under an ECCN, if it is of U.S. origin, it remains subject to EAR's end-user and end-use controls—discussed further, *infra*, in Section III.D.³⁰

25. U.S. Dep't of Treasury, *OFAC Consolidated Frequently Asked Questions*, OFF. OF FOREIGN ASSETS CONTROL (Aug. 21, 2024), <https://ofac.treasury.gov/faqs/all-faqs> [<https://perma.cc/G93K-9YDX>].

26. CHRISTINA L. ARABIA, NATHAN J. LUCAS & MICHAEL J. VASSALOTTI, CONG. RSCH. SERV., R46337, TRANSFER OF DEFENSE ARTICLES: U.S. SALE AND EXPORT OF U.S.-MADE ARMS TO FOREIGN ENTITIES 1–2 (2023).

27. KERR & CASEY, *supra* note 11, at 1.

28. *Id.* at 6–13.

29. *Id.* at 6–7.

30. *Id.* at 30.

Table 1: United States Export Control Regime

	Sanctions-Related	Export-Related	
Purpose	Economic and Trade Sanctions (restrictions on trade, foreign taxes, asset seizures, etc.)	Export of Dual-Use Commercial Articles (non-weapons with weaponization potential)	Export of Defense Articles (weapons)
Congressional Statute	International Emergency Economic Powers Act (IEEPA)	Export Control Reform Act (ECRA) **We are here.	Arms Export Control Act (AECA)
Executive Agency	Department of the Treasury	Department of Commerce	Department of State
Executive Sub-Agency	Office of Foreign Assets Control (OFAC)	Bureau of Industry and Security (BIS)	Bureau of Political Military Affairs, Directorate of Defense Trade Controls (DDTC)
Regulation	Regulations Relating to Money and Finance	Export Administration Regulations (EAR)	International Traffic in Arms Regulations (ITAR)
Export List	Sanctions List Service (SLS); Specially Designated Nationals List (SDN)	Commerce Control List (CCL)	United States Munitions List (USML)
Compare/ Contrast	Focuses on the parties involved in the transaction; can apply sanctions to noncompliant countries and companies to enforce export decisions.	Focuses on limiting the exports of certain dual-use commercial goods.	Focuses on limiting the exports of weapons.

Although both ECRA and AECA regulate sensitive technologies, they serve distinct functions. AECA authorizes Department of State decisions, whereas ECRA authorizes Department of Commerce decisions. Because the Department of Commerce enforces ECRA, ECRA includes more economic balancing considerations than AECA.³¹ The AECA regulates items specifically designed for military use, such as fighter jets, tanks, missiles, satellite systems, etc., while ECRA controls items primarily designed for commercial use, albeit with some warfighting function.³² ECRA-controlled dual-use technologies include everyday commercial products that can be converted for military use, such as encryption technologies or semiconductors.³³ Even microchips from mundane items like refrigerators, washing machines, and breast pumps can be reused in weapons.³⁴

An item's commercial versus military impact often lies in the eye of the beholder. Technologies with civilian applications may nevertheless be subject to AECA, while technologies with serious warfighting implications may fall under ECRA. For example, computer chips designed to run software on commercial laptops and tablets (under ECRA) can also be used to power advanced weapons systems.³⁵ Global positioning systems (GPS), originally created for military use (under AECA), were dithered in the 1990s for civilian travel.³⁶ The designation of dual-use, alone, is not always enough to justify ECRA treatment, just as some weaponizing potential is not always enough to justify AECA treatment.³⁷ Because a product's regulatory footprint, exposure to penalties, and end market often depends on whether it is designated under the Department of State or Department of Commerce, and because dual-use designation can be ambiguous, determining whether a product is governed by AECA or ECRA is a critical step in controlling the risk, customer base, and potential profitability of a product.³⁸ This Note will focus on those dual-use AI products whose civilian use cases are significant enough to warrant ECRA, as opposed to AECA, treatment.

31. See KERR & CASEY, *supra* note 11, at 10–13; see also 50 U.S.C. §§ 4811–4822.

32. See KERR & CASEY, *supra* note 11, at 11–14, 18–23.

33. *Id.* at 7.

34. See Alberto Nardelli, Bryce Baschuk & Marc Champion, *Putin Stirs Worry That Russia Is Stripping Home-Appliance Imports for Arms*, TIME (Oct. 29, 2022), <https://time.com/6226484/russia-appliance-imports-weapons/> [<https://perma.cc/NST8-RJAY>].

35. *Id.*

36. Andrew Young, Christina Rogawski & Stefaan Verhulst, *United States Opening GPS Data for Civilian Use: Creating a Global Public Utility*, GOVLAB (Jan. 2016), <https://odimpact.org/case-united-states-opening-gps-data-for-civilian-use.html> [<https://perma.cc/L7YH-T8QE>].

37. See 50 U.S.C. § 4801(2); 15 C.F.R. § 730.3.

38. See 50 U.S.C. § 4801(2); 15 C.F.R. § 730.3; see also KERR & CASEY, *supra* note 11, at 6–14.

2. *AI is a Tool That Can Augment Weapons Systems*

AI broadly refers to computer software that can perform complex, automated tasks traditionally requiring human intelligence.³⁹ AI can perform these tasks with little to no human oversight.⁴⁰ Most AI is currently limited to narrow subsets of tasks rather than general functions.⁴¹ These narrow tasks include image processing and identification, ranking and prioritization, and language processing.⁴²

AI models, algorithms, and code-based automated systems (“AI software”) require certain, sometimes specialized computing equipment to run them (“AI hardware”). Semiconductors, quantum computers, and other physical hardware are connected within data centers and supercomputing facilities to train large AI models.⁴³ Energy efficient semiconductors with large computing power, memory, and parallel processing capabilities are optimal for AI.⁴⁴ Quantum computers are capable of performing multiple calculations simultaneously, accelerating AI algorithms that require heavy data processing.⁴⁵ Together, these technologies can help remove limitations in data size, complexity, and problem-solving speed that inhibit AI’s ability to perform complex functions.⁴⁶

AI is not a weapon per se but rather a tool that can augment warfare at strategic, operational, and tactical levels.⁴⁷ Conventional weapons, such as precision-strike munitions,⁴⁸ autonomous wingmen,⁴⁹ air-to-air missiles,⁵⁰

39. JOHNSON, *supra* note 5, at 20.

40. *Id.*

41. *Id.* at 18.

42. *Id.* at 19 fig. 1.1.

43. Shweta Surender, *The Convergence of AI Chips and Quantum Computing: Future Possibilities*, MARKETSANDMARKETS (Sep. 16, 2024), <https://www.marketsandmarkets.com/blog/SE/the-convergence-of-ai-chips-and-quantum-computing-future-possibilities> [<https://perma.cc/US25-LVRE>].

44. *Id.*

45. *Id.*

46. *Id.*

47. JOHNSON, *supra* note 5, at 17.

48. *See* AEON, <https://www.aeonindustrial.com/what-we-do> [<https://perma.cc/DK6H-GXEL>] (last visited Feb. 22, 2025).

49. *See* Stephen Losey, *New in 2024: Air Force Plans Autonomous Flight Tests for Drone Wingmen*, DEFENSENEWS (Dec. 30, 2023), <https://www.defensenews.com/air/2023/12/30/new-in-2024-air-force-plans-autonomous-flight-tests-for-drone-wingmen/> [<https://perma.cc/8CJJ-4GZA>].

50. *See* Vanessa Montalbano, *Skunk Works Tests AI in Air-to-Air Combat*, INSIDE DEF. (June 6, 2024), <https://insidedefense.com/insider/skunk-works-tests-ai-air-air-combat> [<https://perma.cc/3EHP-7R72>].

sentry guns,⁵¹ battlefield command and control systems,⁵² and the like, often integrate AI. AECA governs AI that is directly integrated into weapons systems, placing them beyond the scope of this Note. Other types of AI integration, such as self-driving cars, light-show drones, facial recognition, generative pre-trained transformers (GPTs),⁵³ cybersecurity tools, geospatial intelligence, and home surveillance systems, have both commercial and wartime applications and fall under ECRA—these are the focus of this Note.

3. *Regulators Must Balance Unconventional Commercial AI Applications with Practicality*

There are many examples of how commercial AI technologies might be converted for military use. Self-driving cars, manufacturing robots, and surgical assistance robots, for example, may be converted into unmanned ground vehicles for bomb disposal, reconnaissance, obstacle detection, and mine detection.⁵⁴ Autonomous drones, such as those used in crop monitoring, package delivery, and aerial lightshows may conduct reconnaissance, surveillance, precision strikes, and drone swarms.⁵⁵ Facial recognition, commonly used in unlocking smartphones, public safety, and personal shopping, may identify enemy combatants, acquire targets, conduct mass surveillance, monitor dissidents, and even enforce border security.⁵⁶ GPTs that help design drugs by finding new protein combinations may also help design

51. See Alexander Velez-Green, *The Foreign Policy Essay: The South Korean Sentry—A “Killer Robot” to Prevent War*, LAWFARE (Mar. 1, 2015), <https://www.lawfaremedia.org/article/foreign-policy-essay-south-korean-sentry%e2%80%94killer-robot-prevent-war> [https://perma.cc/J57K-DTFK].

52. See Wes Haga & Courtney Crosby, *AI’s Power to Transform Command and Control*, NATIONAL DEF. (Nov. 13, 2020), <https://www.nationaldefensemagazine.org/articles/2020/11/13/ais-power-to-transform-command-and-control> [https://perma.cc/CQ4Q-AKVV].

53. See *What is GPT?*, AMAZON WEB SERVICES, <https://aws.amazon.com/what-is/gpt/> [https://perma.cc/3MQJ-ZKHN] (last visited Feb. 22, 2025).

54. See Mindy Support, *Autonomous Vehicles are Making Their Way into the Military*, MINDY SUPPORT (Apr. 1, 2024), <https://mindy-support.com/news-post/autonomous-vehicles-are-making-their-way-into-the-military/> [https://perma.cc/3GU8-8RND].

55. See Zachary Kallenborn, *InfoSwarms: Drone Swarms and Information Warfare*, 52 U.S. ARMY WAR COLL. Q. 87, 88 (2022).

56. See Donna Ferguson, *Police Urged to Double Use of Facial Recognition Software*, GUARDIAN (Oct. 28, 2023), <https://www.theguardian.com/technology/2023/oct/29/uk-police-urged-to-double-use-of-facial-recognition-software> [https://perma.cc/5ZSM-3KTU]; see also Nicol Turner Lee & Caitlin Chin-Rothmann, *Police Surveillance and Facial Recognition: Why Data Privacy is Imperative for Communities of Color*, BROOKINGS INST. (Apr. 12, 2022), <https://www.brookings.edu/articles/police-surveillance-and-facial-recognition-why-data-privacy-is-an-imperative-for-communities-of-color/> [https://perma.cc/5LB6-GEPS].

biochemical weapons.⁵⁷ Geospatial intelligence services used in environmental monitoring, urban planning, and disaster response may assist with battlefield mapping and target identification.⁵⁸ Cybersecurity tools used for threat detection may be flipped for hacking purposes.⁵⁹

The ease with which commercial technologies can be adapted for military purposes magnifies the potential risks of further development. AI algorithms with similar use-cases and coding structures can be modified or retrained to different use-cases—this can be done with a couple of lines of new code and readily available open-source data.⁶⁰ For example, an AI that recognizes benign flying objects may be retrained with different data to recognize incoming missiles. Thus, the government has repeatedly sought to proactively identify and create controls for AI.⁶¹

Yet not every commercially available, potentially weaponizable technology warrants rigorous export controls. For example, fertilizers that contain ammonium nitrate can be mixed with fuel to create improvised explosive devices (IEDs).⁶² Even so, ammonium nitrate is still a common component in commercial fertilizers and can be produced either in America and exported, or developed overseas and imported.⁶³ Put differently, just because an adversary can weaponize any number of commercially available items does not automatically justify rigorous export controls. ECRA must balance commercial value with the likelihood of misuse, and weigh those factors against whether

57. See Ailin Zhao & Yijun Wu, *Future Implications of ChatGPT in Pharmaceutical Industry: Drug Discovery and Development*, 14 FRONTIERS IN PHARMACOLOGY (2023), <https://pmc.ncbi.nlm.nih.gov/articles/PMC10390092/> [<https://doi.org/10.3389/fphar.2023.1194216>].

58. See Brandi Vincent, *AI Will “Revolutionize” the Way NATO Looks at Geospatial Intelligence, Leader Says*, DEFENSESCOOP (May 7, 2024), <https://defensescoop.com/2024/05/07/nato-geoai-revolutionize-geoint-scott-bray/> [<https://perma.cc/D2VL-NBF7>].

59. See Sangfor Techs., *Defining AI Hacking: The Rise of AI Cyber Attacks*, SANGFOR (Aug. 13, 2024), <https://www.sangfor.com/blog/cybersecurity/defining-ai-hacking-rise-ai-cyber-attacks> [<https://perma.cc/F7WP-KM67>].

60. See Steve Sewell, *Training Your Own AI Model Is Not as Hard as You (Probably) Think*, BUILDER.IO (Nov. 22, 2023), <https://www.builder.io/blog/train-ai> [<https://perma.cc/3ZD9-ZAJB>].

61. Scott A. Jones, *Trading Emerging Technologies: Export Controls Meet Reality*, 31 BRILL NIJHOFF SEC. & HUM. RTS. 47, 51 (2020), https://brill.com/view/journals/shrs/31/1-4/article-p47_47.xml?language=en [<https://doi.org/10.1163/18750230-31010004>].

62. *IED Attack: Improvised Explosive Devices*, DEP’T. OF HOMELAND SEC. & THE NAT’L. ACAD., https://www.dhs.gov/xlibrary/assets/prep_ied_fact_sheet.pdf [<https://perma.cc/9LY5-ASD6>] (last visited Feb. 22, 2025).

63. ENCYCLOPEDIA OF TOXICOLOGY 209–11 (Philip Wexler et al. eds., 3d ed. 2014).

such items, even if controlled, would still be available through other channels, including the black market.⁶⁴

Nevertheless, commercially available AI, embedded in a commercial product, can serve a military purpose. For example, inexpensive and readily available AI, combined with inexpensive commercial drones, have been used in drone swarms on the battlefields of Ukraine.⁶⁵ However, these same products have significant commercial benefits, i.e., similar drones can be used in search and rescue and firefighting operations.⁶⁶ The beneficial uses warrant further research, development, and sales.

Further, even if the United States limits domestic AI development, the United States cannot curtail similar development outside its jurisdiction; case in point, the use of drone swarms in the Russo-Ukraine war developed without U.S. oversight.⁶⁷ This increasingly blurred line between commercial and military-grade AI applications, and the complex geopolitical relationships at play, makes it difficult to predict the second and third order effects of technological development in offensive and defensive warfare, terrorism, and human rights abuses.⁶⁸ In determining the scope of AI exports, policymakers must weigh AI's economic and societal benefits against its development in international markets and its likelihood of shaping battlespaces.

64. See Sujai Shivakumar, Charles Wessner & Thomas Howell, *Balancing the Ledger: Export Controls on U.S. Chip Technology to China*, CTR. FOR STRATEGIC & INT'L STUDS. (Feb. 21, 2024), <https://www.csis.org/analysis/balancing-ledger-export-controls-us-chip-technology-china> [<https://perma.cc/X5AW-C83T>].

65. See Kallenborn, *supra* note 55, at 87–88; Kateryna Bondar, *Ukraine's Future Vision and Current Capabilities for Waging AI-Enabled Autonomous Warfare*, CTR. FOR STRATEGIC & INT'L STUDS. (Mar. 6, 2025), <https://www.csis.org/analysis/ukraines-future-vision-and-current-capabilities-waging-ai-enabled-autonomous-warfare> [<https://perma.cc/2W4H-WUNK>]; David Kirichenko, *The Rush for AI-Enabled Drones on Ukrainian Battlefields*, LAWFARE (Dec. 5, 2024), <https://www.lawfaremedia.org/article/the-rush-for-ai-enabled-drones-on-ukrainian-battlefields> [<https://perma.cc/NGA9-7CPM>].

66. Zacc Dukowitz, *Search and Rescue Drones: A Guide to How SAR Teams Use Drones in Their Work*, UAV COACH (June 14, 2024), <https://uavcoach.com/search-and-rescue-drones> [<https://perma.cc/BG85-JXKJ>].

67. See *supra* note 65 and accompanying text; discussion *infra* Section IV.A.2.

68. Christopher Kuner & Gabriela Zanfir-Fortuna, *Geopolitical Fragmentation, the AI Race, and Global Data Flows: The New Reality*, FUTURE OF PRIV. FORUM (Feb. 26, 2025), <https://fpf.org/blog/geopolitical-fragmentation-the-ai-race-and-global-data-flows-the-new-reality> [<https://perma.cc/XY5M-QHVV>].

4. *The Open-Source Nature of AI Software Adds Complication*

AI is further categorized as either open- or closed-source, which further complicates its controllability.⁶⁹ Currently, as much as 76 percent of AI codebases contain open-source components, and some experts think the percentage might be higher.⁷⁰

The open-source AI movement took off in the early 2000s, when companies realized that globally adopted foundational algorithms permitted widespread AI development and innovation.⁷¹ In the beginning, the international community collaborated on open-source AI models to accelerate the growth of the AI ecosystem.⁷² Democratic, open-source research and development (R&D) allowed smaller startups to assist with AI development rather than concentrating power in a handful of well-resourced technology companies.⁷³ This accelerated AI innovation and safety, as more helping hands identified vulnerabilities, flaws, and biases.⁷⁴ Companies built trust in AI systems by developing AI standards that ensured high-quality training and auditability, but for these standards to be effective, they required global adoption.⁷⁵ As a result, companies often released the outputs of their AI development for free as “open-source” or “open weight” models.⁷⁶ With time, however, companies also started safeguarding some of their proprietary source code, giving rise to “closed-source” models.⁷⁷

Open-source AI models publicly share their source code, while closed-source AI models maintain proprietary source code, trading flexibility and shared innovation for increased security of intellectual property (IP).⁷⁸ Many companies build products with open-source code, then customize those

69. *Emerging AI: Open vs Closed Source*, CTR. FORWARD (Dec. 16, 2024), <https://center-forward.org/basic/emerging-ai-open-vs-closed-source/> [<https://perma.cc/UM3V-6DRJ>].

70. Tyler Weitzman, *The Rise of Open Artificial Intelligence: Open-Source Best Practices*, FORBES (Mar. 8, 2024), <https://www.forbes.com/councils/forbesbusinesscouncil/2024/03/08/the-rise-of-open-artificial-intelligence-open-source-best-practices> [<https://perma.cc/Z6QP-6K4S>].

71. See David Cain, *The Rise of Open-Source AI*, LINKEDIN (Jan. 12, 2024), <https://www.linkedin.com/pulse/rise-open-source-ai-david-cain-gymoc> [[https://perma.cc/Z7N\]-YZZE](https://perma.cc/Z7N]-YZZE)].

72. *Id.*

73. *Id.*

74. *Id.*

75. *Id.*

76. See Kyle Miller, *Open Foundation Models: Implications of Contemporary Artificial Intelligence*, CTR. FOR SEC. AND EMERGING TECH. (Mar. 12, 2024), <https://cset.georgetown.edu/article/open-foundation-models-implications-of-contemporary-artificial-intelligence> [<https://perma.cc/G642-APEC>].

77. CTR. FORWARD, *supra* note 69.

78. *Id.*

products with closed-source code.⁷⁹ To continue an example from the previous Section, a software engineer can customize a closed-source model that identifies incoming missiles from a foundational open-source AI that recognizes flying objects.

Open-weight models are a middle ground between open- and closed-source models.⁸⁰ Open-weight models do not share their underlying source code, training data, and architecture, but nevertheless allow users to fine-tune the model to their personal specifications and deploy these models privately.⁸¹ This private deployment of open-weight models assuages the creator companies' data-sharing concerns.⁸² AI companies then permit such open-source and open-weight models to underpin future products.⁸³ When other companies subscribe to these "product packages," which they originally received for free, the creator company gains market share.⁸⁴

Even though open-weight and closed-source models safeguard their proprietary code more so than open-source models, they are still prone to theft because they can be reverse engineered from existing open-source options.⁸⁵ Open-weight models release their entire set of model parameters (weights) for download, which allows foreign software engineers to analyze these

79. See Dan Leszkowicz, *AI Decision Series | Part 1: Open-Source Versus Closed-Source Models*, PIENSO (Oct. 24, 2023), <https://pienso.com/blog/ai-decision-series-part-1-open-source-versus-closed-source-models> [https://perma.cc/MG3F-85TD].

80. Aruna Kolluru, *Exploring the World of Open Source and Open Weights AI*, MEDIUM (Mar. 29, 2024), <https://medium.com/@aruna.kolluru/exploring-the-world-of-open-source-and-open-weights-ai-aa09707b69fc> [https://perma.cc/4V87-RD9R].

81. *Id.*; Miller, *supra* note 76.

82. See Miller, *supra* note 76; John Weil, *AI for the Edge: Why Open-Weight Models Matter*, SEMICONDUCTOR ENG'G (Apr. 3, 2025), <https://semiengineering.com/ai-for-the-edge-why-open-weight-models-matter> [https://perma.cc/ZP5H-BGT6].

83. See Marketplace Tech, *Will DeepSeek Disrupt American AI's First-Mover Advantage?*, MARKETPLACE, at 11:20 (Feb. 13, 2025), <https://www.marketplace.org/episode/2025/02/13/will-deepseek-disrupt-american-ais-first-mover-advantage> [https://perma.cc/3CY7-4AQE]; see also CFI Team, *First Mover Advantage*, CFI, <https://corporatefinanceinstitute.com/resources/management/first-mover-advantage/> [https://perma.cc/Q9H3-FCLM] (last visited Apr. 8, 2025). Businesses gain a first mover advantage when it is the first to introduce a new product or service to the market. The company then establishes brand recognition, customer loyalty, and potentially captures market share before other competitors. For example, Chinese AI company DeepSeek created a usable, advanced, open-weight, and inexpensive AI model, and in being first to publicly release that product, it may have a first to market advantage (see discussion *infra* Section IV.A.3). It can then use this advantage—customer loyalty and brand recognition—to sell future products.

84. See *supra* note 83 and accompanying text.

85. Matt Marshall, *The Enterprise Verdict on AI Models: Why Open Source Will Win*, VENTUREBEAT (Oct. 24, 2024), <https://venturebeat.com/ai/the-enterprise-verdict-on-ai-models-why-open-source-will-win/> [https://perma.cc/ZFX9-MR9H].

architectures, inputs, and outputs until they successfully replicate the model.⁸⁶ In contrast, a closed-source AI model has a proprietary system owned and managed by a private company.⁸⁷ Its code, structure, and training are kept private.⁸⁸ However, hackers can easily copy and distribute a few lines of code.⁸⁹ AI training code is unusual in that only a short snippet of code can represent mathematical innovations that lead to significantly improved performance.⁹⁰ These short snippets are easier to steal, and adversary countries can acquire this code through hacking or black market smuggling operations.⁹¹

Due to competing priorities, there is a security question of whether export safeguards can effectively protect national security. Open-source models are readily available for anyone to use, thus, it is impossible to subject these models to export controls.⁹² Any person with the requisite engineering knowledge can take generic, basic open-source models and combine them with other generic technology, like basic commercial drones, to create potentially lethal battlespace tools, and this adds another layer of complexity to modern warfare.⁹³ Open-weight and closed-weight models are slightly more protected, but not by much.⁹⁴ Adversaries without the requisite engineering knowledge can still steal or reverse engineer these types of AI for nefarious uses.⁹⁵ Beyond the battlefield, foreign companies can build upon existing open-source, open-weight, and even closed-source AI to create comparable products that compete with U.S. offerings and destabilize the U.S. economic posture.⁹⁶

86. See Manikandan Palani, *How to Reverse Engineer Open AI's of 1 With Less Powerful Models?*, LINKEDIN (Sep. 15, 2024), <https://www.linkedin.com/pulse/how-reverse-engineer-open-ais-of-1-less-powerful-models-palani-sbkie> [<https://perma.cc/SZ9J-2X2Y>].

87. Leszkowicz, *supra* note 79.

88. *Id.*

89. Marin Ivezic & Luka Ivezic, *The Dark Art of Model Stealing: What You Need to Know*, SECURING.AI (Nov. 13, 2019), <https://securing.ai/ai-security/ai-model-stealing/> [<https://perma.cc/5Z59-GX3L>].

90. Programmers use snippets of code to encapsulate a calculation or act of data manipulation within an AI program. It is a way of transcribing a mathematical process. The innovation lies in the math, which can be transcribed succinctly and elegantly in short snippets of code.

91. Devin McCormick, *Why Regulating AI Is a Losing Battle*, LIBERTAS INST. (Aug. 30, 2024), <https://libertas.institute/op-eds/why-regulating-ai-is-a-losing-battle/> [<https://perma.cc/T69F-2NPX>].

92. Miller, *supra* note 76.

93. See *supra* note 65 and discussion *supra* Sections II.A.2, II.A.3.

94. McCormick, *supra* note 91.

95. See discussion *supra* Sections II.A.2, II.A.3.

96. See Jowi Morales, *Chinese AI Built Off Open-Source Code Matches American Tech in Chatbot Benchmark Tests*, TOM'S HARDWARE (July 27, 2024), <https://www.tomshardware.com/tech-industry/artificial-intelligence/chinese-ai-built-off-open-source-code-matches-american-tech-in-chatbot-benchmark-tests> [<https://perma.cc/65ZU-AYYU>].

Simultaneously, many customers prefer using open-weight models that they can fine-tune independently, and it would be foolish for the United States not to participate and try to gain the “first mover advantage” in these markets.⁹⁷ As a result, a bright-line export control that satisfies one stakeholder often negatively affects another.

B. ECRA RESPONDS TO EMERGING GEOPOLITICAL THREATS.

The following Sections explain the history of the U.S. commercial export regime, the contemporary great power competition that spurred ECRA’s development, and current regulatory developments.

1. *The U.S. Commercial Export Regime Evolved in Response to National Security Concerns*

The United States’ commercial export regime originated during World War II. Initially focused on military equipment and munitions, export controls expanded in the 1940s to include exports of civilian goods.⁹⁸ After World War II, countries devastated by war relied heavily on U.S. imports.⁹⁹ Congress continued its commercial export control policy to reduce inflation caused by foreign demand.¹⁰⁰ For the first time, export controls were used to regulate peacetime markets.¹⁰¹ In 1949, Congress officially established a three-pronged commercial export policy that (1) protected the domestic economy, (2) protected national security, and (3) furthered foreign policy.¹⁰² These goals still underlie modern commercial export policy.

In the early 1950s, the onset of the Cold War strained United States-Soviet relations. The U.S. defense strategy became increasingly centered on technological supremacy, leading Congress to adopt embargo-like export controls as part of its containment strategy.¹⁰³ By the late 1960s, however, the United States and its allies recognized the importance of global trade in bolstering their own economies.¹⁰⁴ Policymakers and industry leaders feared that strict export controls would economically disadvantage U.S. companies relative to European and Japanese competitors.¹⁰⁵ Thus, Congress passed the

97. *See Open vs. Closed: The Fine-Tuning Divide in AI Models*, SHOUT, <https://www.shoutdigital.com/insights/open-vs-closed-the-fine-tuning-divide-in-ai-models> [<https://perma.cc/4DJQ-QJWM>] (last visited Apr. 6, 2025); *see also supra* note 83.

98. KERR & CASEY, *supra* note 11, at 2.

99. *Id.*

100. *Id.*

101. *Id.*

102. *Id.* at 3.

103. *Id.*

104. *Id.*

105. *Id.* at 4.

Export Administration Act of 1969, which relaxed certain export restrictions.¹⁰⁶

From the 1970s through 1990s, Congress continued to relax export controls, even allowing subsequent EAAs to lapse.¹⁰⁷ However, by the 2010s, emerging geopolitical concerns centered on technological supremacy and great power competition—this time with China—renewed the focus on regulating commercial exports.¹⁰⁸ In 2018, amid concerns of commercial technology misappropriation for military use, Congress enacted ECRA.¹⁰⁹ ECRA provides statutory authorization for executive regulations on commercial technologies with military applications, recognizing economic policy as a sub-prong of national security and providing greater coverage over dual-use technologies.¹¹⁰ Unlike previous export acts, ECRA has no expiration date.¹¹¹ Because AI has both commercial and military applications, many commercial AI exports fall under ECRA.¹¹²

2. *Great Power Competition with China Shaped U.S. Policies*

Many countries openly recognize AI as an indispensable tool that will allow militaries to achieve battlespace dominance through increased speed, surprise, focus, and boldness.¹¹³ These factors propel great power competition, particularly the ongoing rivalry between the United States and China. China is currently the United States' primary competitor, and technology is the new arena for interstate struggle.¹¹⁴

Although ECRA outlines heightened controls for many countries, the United States has intensified export restrictions against China in response to the superpower's state-led industrial efforts, to which China has responded in kind.¹¹⁵ Currently, the U.S. government levies export controls against China

106. *Id.*

107. *Id.*

108. *See id.* at 6.

109. *Id.* at 1.

110. 50 U.S.C. §§ 4811, 4822.

111. KERR & CASEY, *supra* note 11, at 20.

112. *See* discussion *supra* notes 19 and 20.

113. JOHNSON, *supra* note 5, at 60–62.

114. BATEMAN, *supra* note 18, at 2–5.

115. *Id.* at 1–2; *see* CHRISTOPHER A. CASEY & KAREN M. SUTTER, CONG. RSCH. SERV., IF11627, U.S. EXPORT CONTROLS AND CHINA 1–2 (2022); James K. Wholey, *Defense Technology Companies Targeted by Latest Chinese Trade Ruling*, PHILLIPS LYTTLE LLP (Jan. 7, 2025), <https://phillipslytle.com/update-to-u-s-china-trade-relations-china-adds-u-s-companies-to-new-restricted-list/> [https://perma.cc/9M7F-CDFS].

through the Entity List and other methods.¹¹⁶ Many of the export controls discussed in this Note focus on China.

3. *Regulations for AI Continue to Develop*

When Congress enacted ECRA, BIS published an Advanced Notice of Proposed Rulemaking (ANPRM) signaling possible future controls on fourteen emerging technology categories, including AI.¹¹⁷ The public responded negatively to the ANPRM, arguing in favor of specific technologies over blanket categories of technologies not yet evaluated for their national security impacts.¹¹⁸ Therefore, to date, BIS has issued few direct export controls on AI software, instead focusing on AI-adjacent hardware to curtail foreign progress.¹¹⁹

On October 7, 2022, BIS released controls prohibiting exports of cutting-edge chips, chip design software, chip manufacturing equipment, and U.S.-built components of manufacturing equipment (“October 2022 Semiconductor Controls”).¹²⁰ These measures were focused on restricting Chinese access to advanced semiconductor technology and to chill, if not freeze, China’s AI developmental capability.¹²¹ On September 6, 2024, BIS imposed export controls on quantum computers, quantum computing components, quantum software, advanced semiconductors, and gate all around field effect transistors (GAAFETs)—a type of multi-gate integrated circuit that can be used to develop supercomputers.¹²² Though these controlled technologies are not themselves AI, they underpin AI software and related areas of research where the United States believes it has a technological lead.¹²³ On January 13, 2025, BIS released a new interim final rule that imposes export controls on certain closed-weight AI as well as semiconductor

116. See BATEMAN, *supra* note 18, at 19–20; see discussion *infra* Section III.D.2.

117. Jones, *supra* note 61, at 51.

118. *Id.* at 56; BATEMAN, *supra* note 18, at 18.

119. 15 C.F.R. § 774; see Cinelli et al., *supra* note 19; LeBeau & Seymour, *supra* note 20.

120. Emily Benson, *Updated October 7 Semiconductor Export Controls*, CTR. FOR STRATEGIC AND INT’L STUDS. (Oct. 18, 2023), <https://www.csis.org/analysis/updated-october-7-semiconductor-export-controls> [<https://perma.cc/F4R5-C496>].

121. See Shivakumar et al., *supra* note 64.

122. Cinelli et al., *supra* note 19.

123. See Congressional Testimony by Gregory C. Allen, *China’s Pursuit of Defense Technologies: Implications for U.S. and Multilateral Export Control and Investment Screening Regimes*, CTR. FOR STRATEGIC & INT’L. STUDS. (Apr. 13, 2023), <https://www.csis.org/analysis/chinas-pursuit-defense-technologies-implications-us-and-multilateral-export-control-and> [<https://perma.cc/6BDX-7E8F>].

manufacturing clusters used to train AI.¹²⁴ This Note will center its discussion on concerns related to semiconductor controls and AI software controls.

III. ANALYSIS OF ECRA AND WHY COURTS DEFER TO IT

Section III.A uses past judicial decisions to illustrate why courts are likely to uphold ECRA. The remainder of Part III explains how ECRA has expanded the definition of national security, created explicit jurisdiction over emerging and foundational technology, and created a three-prong test to evaluate future regulations.

A. COURTS WILL UPHOLD EXPORT-RELATED AGENCY DECISIONS

Courts typically uphold export-related decisions, not only because they have historically applied a deferential standard for agency decisions, but also because judicial precedent supports agency decisions grounded in a national security rationale. Therefore, even though few explicit export controls currently exist for AI, courts will likely uphold those controls that do exist.¹²⁵

Courts apply a deferential standard to export laws, recognizing that sensitive, national-security decisions require expert analysis.¹²⁶ They follow an “arbitrary and capricious” standard, examining agency decisions for rationality and procedure.¹²⁷ As long as an agency demonstrates a rational basis and correctly implements an export control, courts uphold the attached penalty.

Additionally, cases involving export decisions under ECRA’s predecessors typically required two elements to trigger government liability: (1) a civilian plaintiff needed either a waiver of sovereign immunity or an *ultra vires* claim to pursue action against the government; and even if the case went to court, (2)

124. Shenai et al., *supra* note 20.

125. *See* Glimp v. Dep’t. of Com.’s Bureau of Indus. & Sec., No. 22-CV-02708-GPG-KAS, 2023 WL 6622736, at *3–5 (D. Colo. Oct. 10, 2023) (granting a motion to dismiss for failure to identify a waiver of sovereign immunity); *see also* United States v. Shih, 73 F.4th 1077, 1094 (9th Cir. 2023) (holding that “rated for operation” is not unconstitutionally vague); United States v. Lachman, 387 F.3d 42, 48–50 (1st Cir. 2004) (holding that the term “specially designed” was not unconstitutionally vague); United States v. Geissler, 731 F. Supp. 93, 98–101 (E.D.N.Y. 1990) (holding that the export regulation applied to unlicensed export of F-14 aircraft tires to Iran was not “unconstitutionally vague”); United States v. Gregg, 829 F.2d 1430, 1436 (8th Cir. 1987) (showing that the defendant likely understood the export regulation); United States v. Mechanic, 809 F.2d 1111, 1112–14 (5th Cir. 1987) (upholding the President’s constitutional power to “prohibit or curtail” the export of technology to protect national security); United States v. Helmy, 951 F.2d 988, 993–95 (9th Cir. 1991) (holding that lack of statutory opportunity for defendants to challenge regulations is not a due process violation).

126. 15 C.F.R. § 766.21.

127. 15 C.F.R. § 766.21(a)(4).

to win, the civilian party had to prove the government violated a fundamental right.¹²⁸ Generally, civilian parties alleged a due process violation based on “unconstitutional vagueness” in existing export law.¹²⁹ Even if the civilian party survived step one, the civilian party almost never won on Fifth Amendment grounds.¹³⁰ Most cases ended either when the court granted the government’s motion to dismiss or affirmed the government’s allegation of civilian wrongdoing.¹³¹

Since ECRA’s enactment, its application has been challenged in only one case, *Fed. Express Corp. (“FedEx”) v. U.S. Department of Commerce*. The government imposed strict liability fines on FedEx for shipping packages that contained export-restricted items. FedEx sued in an *ultra vires* claim, arguing that the regulations forced FedEx to “police the content of its packages on an almost infinitely broad scale,” to which FedEx’s “sophisticated proprietary risk-based compliance system” could not perfectly conform.¹³² These restrictions required FedEx to stop business activities with certain foreign entities or risk penalties, depriving FedEx of “liberty and property.”¹³³ The trial court dismissed in favor of the government, holding FedEx strictly liable in “aiding and abetting” illegal exports within individual shipments of mail.¹³⁴ FedEx then lost again on appeal.¹³⁵ The court applied to *FedEx* the same playbook as previous courts in previous export decisions.

The court held that the “strictly economic burdens” of FedEx’s shipping enterprise did not implicate fundamental, constitutional rights.¹³⁶ Under the arbitrary and capricious standard, the court then evaluated only whether ECRA and its ensuing regulations were “rationally related to a legitimate

128. *See Glimp*, 2023 WL 6622736, at *3–5 (granting a motion to dismiss for failure to identify a waiver of sovereign immunity); *see also Shib*, 73 F.4th at 1094 (holding that “rated for operation” is not unconstitutionally vague); *Lachman*, 387 F.3d at 48–50 (holding that the term “specially designed” was not unconstitutionally vague); *Geissler*, 731 F. Supp. at 98–101 (holding that the export regulation applied to unlicensed export of F-14 aircraft tires to Iran was not “unconstitutionally vague”); *Gregg*, 829 F.2d at 1436 (showing that the defendant likely understood the export regulation); *Mechanic*, 809 F.2d at 1112–14 (holding that export controls did not exceed executive authority under the Export Administration); *Helmy*, 951 F.2d at 993–95 (holding that lack of statutory opportunity for defendants to challenge regulations is not a due process violation).

129. *See supra* note 125.

130. *See id.*

131. *See id.*

132. *Fed. Express Corp. v. U.S. Dep’t of Com.*, 486 F. Supp. 3d 69, 74 (D.D.C. 2020), *aff’d sub nom.*, 39 F.4th 756 (D.C. Cir. 2022).

133. U.S. CONST. amend. V.

134. 50 U.S.C. § 4811(1).

135. *Fed. Express Corp.*, 486 F. Supp. 3d at 72.

136. *Id.* at 75.

government interest.”¹³⁷ Because the export regulations promoted “national security and foreign policy interests,” the court found them to be legitimate.¹³⁸ Moreover, the court held that it was not irrational for the government to create a strict liability regime that held common carriers, like FedEx, to a higher standard.¹³⁹ This decision underscores that ECRA grants expansive regulatory authority—courts generally will uphold export decisions that advance a legitimate national security interest. ECRA’s powers are vast.

B. ECRA’S ECONOMIC FOCUS EXPANDS AND LIMITS EXISTING LAW

Although courts will generally uphold agency decisions regarding exports, AI regulations must still fall within ECRA’s scope. Sections III.B, III.C, III.D, and III.E discuss specific provisions of ECRA that pertain to AI export controls.

1. *ECRA Emphasizes Economic Considerations in Addition to the Nonproliferation of Military Technology*

Historically, export controls primarily restricted adversary military capabilities and limited domestic inflation.¹⁴⁰ However, ECRA recognizes the increasingly globalized nature of worldwide manufacturing and emphasizes market leadership as a national security consideration, thereby expanding upon what is deemed an appropriate economic consideration under export law.¹⁴¹ Whereas before, export controls were enacted in war or to protect against the inflationary effects of foreign demand,¹⁴² they can now be enacted whenever U.S. market leadership is threatened.

For dual-use technology, which inherently has commercial elements, ECRA must balance national security concerns with market interests. ECRA recognizes that national security requires maintaining technological leadership and that U.S. technological leadership is predicated on U.S. supremacy in global markets.¹⁴³ 50 U.S.C. § 4811(3) states the following:¹⁴⁴

137. *Id.*; *Empresa Cubana Exportadora de Alimentos y Productos Varios v. U.S. Dep’t of Treasury*, 638 F.3d 794, 800 (D.C. Cir. 2011).

138. 15 C.F.R. § 730.6.

139. *Fed. Express Corp.*, 486 F. Supp. 3d at 76.

140. *See* Export Administration Act of 1979, Pub. L. No. 96-72, 93 Stat. 503, at 503–505; *see* discussion *supra* Section II.B.1.

141. KERR & CASEY, *supra* note 11, at 4 (showing how Congress liberalized export controls to compete with foreign competitors in global markets).

142. *See* discussion *supra* Section II.B.1.

143. David H. McCormick, Charles E. Luftig & James M. Cunningham, *Economic Might, National Security, and the Future of American Statecraft*, 3 TEX. NAT’L SEC. REV. 51, 53 (2020).

144. 50 U.S.C. refers to the section of the United States Code where ECRA is codified.

The national security of the United States requires that the United States maintain its leadership in the science, technology, engineering, and manufacturing sectors Such leadership requires that United States persons are competitive in global markets. The impact of [export controls] on such leadership and competitiveness must be evaluated on an ongoing basis . . . to avoid negatively affecting such leadership.¹⁴⁵

As stated above, under § 4811(3), U.S. technological leadership, economic competitiveness, security, and broader economic health are pillars of national security strategy.¹⁴⁶ Market factors must be evaluated against military deterrence-related constraints to ensure export controls balance economic and security priorities.¹⁴⁷

For emerging technologies, well-balanced controls are still speculative.¹⁴⁸ Although controls can proactively prevent the proliferation of dangerous dual-use technologies that affect the physical security of the American people, controls can also place excessive emphasis on applications that may never prove militarily practicable while failing to consider how such controls might affect American competitiveness in global markets.¹⁴⁹

ECRA provides regulatory agencies with broad latitude to balance control intensity, evaluating security and nonproliferation against economic flexibility and global competitiveness.¹⁵⁰ When placing controls on AI, regulators must balance economic and military concerns and determine whether such controls, on balance, are reasonable.

2. *Economic Considerations Restrain ECRA's Power*

Although courts generally uphold ECRA-based decisions, ECRA's expanded national security outlook is not limitless. ECRA aims to restrict dual-use items only when necessary to *significantly* protect national security or further foreign policy, with an eye on contributions to foreign military potential, economic impact, and international obligations.¹⁵¹ 50 U.S.C. § 4811(1) states the following:

145. 50 U.S.C. § 4811(3).

146. *Id.*

147. *Id.*

148. Jones, *supra* note 61, at 57–59.

149. See P.R. Rajeswari, *Economics of Export Controls: A Study of US Export Control Mechanism*, 23 COLUM. U.: STRATEGIC ANALYSIS (1999), https://ciaotest.cc.columbia.edu/olj/sa/sa_99rap02.html [<https://perma.cc/45C5-G6J6>].

150. See Jones, *supra* note 61, at 56–57; Allen, *supra* note 123.

151. 50 U.S.C. § 4811(1).

The purpose of ECRA is “to use export controls only after full consideration of the impact on the economy of the United States and only to the extent necessary—[] to restrict the export of items which would make a significant contribution to the military potential of any other country or combination of countries which would prove detrimental to the national security of the United States; and [] to restrict the export of items if necessary to further significantly the foreign policy of the United States or to fulfill its declared international obligations.”¹⁵²

Thus, ECRA prefers restraint, authorizing export controls only as necessary to meet national security threats.¹⁵³ Before imposing export controls, ECRA requires regulators to consider the economic effects of the action and to only (1) restrict the capability of a foreign military or (2) enforce an obligation to an international ally.¹⁵⁴ Consequently, controls on AI should account for these factors and only be implemented after conducting an economic impact assessment. The government in 2018 lacked the requisite data to adequately assess AI for its economic and national security impacts, however, renewed interest in 2024 and 2025 has resulted in more regulations.¹⁵⁵

C. ECRA EXPANDED ITS JURISDICTION OVER EMERGING AND FOUNDATIONAL TECHNOLOGIES

ECRA also expanded prior export law by emphasizing the importance of emerging and foundational technologies in national security. Although ECRA has explicit jurisdiction to curtail transfers of emerging and foundational technologies, the government nevertheless must limit controls of these technologies to maintain market dominance in key sectors.

1. *ECRA Expanded its Focus on Emerging and Foundational Dual-Use Technologies*

Under § 4817(a)(1), regulators must “identify [and control] emerging and foundational technologies . . . that are essential to the national security of the United States.”¹⁵⁶ However, Congress did not define what constitutes an “emerging and foundational technology.”¹⁵⁷ Emerging technologies are

152. *Id.*

153. *Id.*

154. *Id.*

155. See Jones, *supra* note 61, at 56–57; Shenai et al., *supra* note 20.

156. 50 U.S.C. § 4817(a)(1).

157. Emma Rafaelof, *Unfinished Business: Export Control and Foreign Investment Reforms*, U.S.-CHINA ECON. & SEC. REV. COMM’N 4 (June 1, 2021), https://www.uscc.gov/sites/default/files/2021-06/Unfinished_Business-Export_Control_and_Foreign_Investment_Reforms.pdf [<https://perma.cc/32MH-6Y9N>].

typically defined as those with the potential to transform society, have a growing role in the economy, give rise to subfields with breakthroughs, and give way to trends that further contribute to growth.¹⁵⁸ Many iterative technologies are both emerging and mature.¹⁵⁹ For example, graphics processing units (GPUs) are uniquely suited for AI software because they have parallel processing capabilities, which are necessary for simultaneously managing large data sets and performing complex mathematical computations.¹⁶⁰ GPUs continue to develop and improve; however, GPUs have been available since 1999.¹⁶¹

Foundational technologies refer to core technological infrastructures that support and drive product development.¹⁶² They are technologies that provide a base upon which to build digital products or advance other scientific fields.¹⁶³ AI hardware is foundational as it runs AI software. AI software is foundational if it is used to advance fields like machine learning, computer vision, among other fields.

Although the U.S. government continues to define “emerging and foundational” technology, GPUs and other AI-related hardware such as field-programmable gate arrays (FPGAs),¹⁶⁴ application-specific integrated circuits (ASICs),¹⁶⁵ and more recently, GAAFETs¹⁶⁶ are currently considered “emerging and foundational.”¹⁶⁷ AI software is likewise both emerging and foundational. AI software is rapidly developing (emerging), and its core

158. Daniele Rotolo, Diana Hicks & Ben R. Martin, *What Is an Emerging Technology?*, 44 RSCH. POL'Y, 1827, 1827–30 (2015).

159. *Id.*

160. *Id.*

161. Audrey Reznik, Troy Nelson, Kaitlyn Abdo & Christina Xu, *Why GPUs Are Essential for AI and High-Performance Computing*, RED HAT DEV. (Nov. 21, 2022), <https://developers.redhat.com/articles/2022/11/21/why-gpus-are-essential-computing> [<https://perma.cc/RKT4-PJGG>].

162. Colin Dowling, *How Foundational Technology Accelerates Product Development*, APOLLO21, <https://www.apollo21.io/transmissions/how-foundational-technology-accelerates-product-development> [<https://perma.cc/2TNQ-XXF4>] (last visited Feb. 22, 2025).

163. *Id.*

164. *See What Is an FPGA?*, LATTICE SEMICONDUCTOR, <https://www.latticesemi.com/en/What-is-an-FPGA> [<https://perma.cc/68RC-44VF>] (last visited Feb. 22, 2025).

165. *See* BAE SYSTEMS, *What are ASICs?*, <https://www.baesystems.com/en-us/definition/what-are-asics> [<https://perma.cc/QNK4-QZQX>] (last visited Feb. 22, 2025).

166. *See Gate-All-Around FET (GAA FET)*, SEMICONDUCTOR ENG'G, https://semiengineering.com/knowledge_centers/integrated-circuit/transistors/3d/gate-all-around-fet [<https://perma.cc/PD4E-E3VU>] (last visited Feb. 22, 2025). GAAFETs have a special transistor design that enables AI software.

167. MICHAELA D. PLATZER, EMILY G. BLEVINS & KAREN M. SUTTER, CONG. RSCH. SERV., R46581, SEMICONDUCTORS: U.S. INDUSTRY, GLOBAL COMPETITION, AND FEDERAL POLICY 3 (2020).

algorithms can be applied to many technologies and underpin a multitude of disparate applications (foundational).¹⁶⁸ Therefore, AI software is also within ECRA's regulatory scope.

2. *Economic Considerations Restrain ECRA's Emerging & Foundational Dual-Use Focus*

Despite ECRA's explicit authorization to control broad swaths of "emerging and foundational technologies," these dual-use technologies are sold in global markets and involve significant economic considerations. "Emerging and foundational technologies" are inherently research-intensive, and such research depends on domestic and international funding.¹⁶⁹ ECRA must therefore balance dual-use technology controls with the realities of the global marketplace.¹⁷⁰

The computer age and globalized supply chains have created powerful commercial technologies, independent of government-funded research.¹⁷¹ Companies developing "emerging and foundational technologies" fund their R&D more often through product sales than through government contracts.¹⁷² Although the U.S. government remains the world's top R&D spender, devoting \$806 billion to R&D in 2021 alone, many companies prefer to obtain R&D funds from global sales as these funds come with fewer restrictions and avoid years of bureaucratic red tape.¹⁷³ Commercial growth in computers and AI has, for decades, surpassed government-funded growth.¹⁷⁴

Commercially funded R&D for items with military applications creates unprecedented export issues. Items produced by commercially funded research fall under ECRA's more lenient provisions rather than AECA's stricter weapons sales laws.¹⁷⁵ The United States must allow companies to fund

168. *What Are Foundational Models?*, AMAZON WEB SERVS., <https://aws.amazon.com/what-is/foundation-models> [<https://perma.cc/76ED-84ZZ>] (last visited Feb. 22, 2025); Dowling, *supra* note 162.

169. See Francisco Moris & Alexander Rhodes, *R&D: U.S. Trends and International Comparisons*, NAT'L SCI. BOARD: SCI. AND ENG'G INDICATORS 2024 1, 7 (May 21, 2024), <https://nces.nsf.gov/pubs/nsb20246> [<https://perma.cc/2UGA-EVFP>].

170. See discussion *supra* Sections III.B.2.

171. Paul Scharre & Ainikki Riikonen, *Defense Technology Strategy*, CTR. FOR NEW AM. SEC. 1, 6–7 (2020), <https://www.cnas.org/publications/reports/defense-technology-strategy> [<https://perma.cc/X67N-WG5X>].

172. See MARCY E. GALLO, CONG. RSCH. SERV., R45403, *THE GLOBAL RESEARCH AND DEVELOPMENT LANDSCAPE AND IMPLICATIONS FOR THE DEPARTMENT OF DEFENSE* 4–6 (2021).

173. Moris & Rhodes, *supra* note 169, at 7.

174. *Id.*

175. See *International Traffic in Arms Regulations*, 22 C.F.R. § 120.41 (2025). Items specially designed for military use fall under the AECA/ITAR. Commercially funded products

R&D through commercial sales because it helps the United States maintain market dominance—more commercial sales translate to more American presence in global markets.¹⁷⁶ Simultaneously, licensing agreements allow the military to benefit from modern technology without spending military money—they reduce military R&D expenditures.¹⁷⁷ However, when the government does not develop militarily applicable products, the government has less control over the product. Historically, the government could curtail the proliferation of military-use technologies because (1) it directly funded their development, and (2) it did not have to directly compete with commercial companies' need for market dominance.¹⁷⁸ Today, the government must consider the economic effects of commercial export controls on global market dominance and U.S. innovation, balancing companies' R&D needs with military risks.¹⁷⁹ This economic accounting limits export controls on many “emerging and foundational technologies.”¹⁸⁰

D. ECRA HAS OVERSEAS REACH VIA CATCH-ALL CONTROLS AND THE FOREIGN DIRECT PRODUCT RULE

Under ECRA, BIS can expand unilateral U.S. export regulations to activities in foreign countries. Through catch-all controls and the Foreign Direct Product Rule (FDPR), BIS extends U.S. jurisdiction to items neither produced in nor passing through the United States. In this way, the United States controls not just physical items but also the activities of people using those items, both domestically and internationally.

1. *Section 4817(b) Gives Authority for U.S. Regulatory Bodies to Extend Export Jurisdiction to Foreign Countries*

ECRA is a unilateral export law that asserts U.S. regulatory jurisdiction abroad.¹⁸¹ Under § 4817(b)(1), ECRA authorizes BIS to “establish appropriate

are generally not “specifically designed” for military use, especially if the creator intends to sell that product in commercial markets. These products therefore fall under ECRA/EAR.

176. Christopher S. Chivvis & Ethan B. Kapstein, *U.S. Strategy and Economic Statecraft: Understanding the Tradeoffs*, CARNEGIE ENDOWMENT FOR INT'L PEACE (Apr. 28, 2022), <https://carnegieendowment.org/research/2022/04/us-strategy-and-economic-statecraft-understanding-the-tradeoffs?lang=en> [<https://perma.cc/F44N-9AGS>].

177. See Thomas Mulkern & Troy Carter, *Private Sector Helps Army and National Economy*, U.S. ARMY (Feb. 15, 2018), https://www.army.mil/article/200705/private_sector_helps_army_and_national_economy [<https://perma.cc/WKQ9-9GTF>].

178. See Robert Kuttner, *How 'National Security' Hurts National Competitiveness*, HARVARD BUSINESS REVIEW (Jan.–Feb. 1991), <https://hbr.org/1991/01/how-national-security-hurts-national-competitiveness> [<https://perma.cc/8Q3W-G9XS>].

179. Compare discussion *supra* Section III.B.1, with discussion *supra* Section III.C.2.

180. Compare discussion *supra* Section III.B.1, with discussion *supra* Section III.C.2.

181. 50 U.S.C. § 4817.

controls [under EAR] on the *export, reexport, or in-country transfer of technology*.¹⁸² Therefore, § 4817(b) grants BIS authority to impose controls not only on exports leaving the United States, but also on any U.S. item that is reexported or transferred within a foreign country.¹⁸³ ECRA's jurisdiction extends to any country and any person or company (regardless of citizenship) that exports items incorporating U.S.-origin products and software.¹⁸⁴ Moreover, if the foreign product contains a *de minimis* percentage (usually 25 percent) of a U.S. product, the foreign product (and the originating country or company) is also subject to U.S. export controls.¹⁸⁵

2. *The Export Control Reform Act Expanded Upon the Authority of Catch-All Rules*

Typically, export controls fall into two categories: list-based controls and catch-all controls.¹⁸⁶ ECRA gives EAR the power to create lists of controlled items that are pre-identified by the U.S. government as export threats.¹⁸⁷ ECRA also permits the United States to create lists of military end-users and end-uses to whom exporters may not ship sensitive items.¹⁸⁸ The explicit controls described, *supra*, in Section II.B.3 are such list-based controls.

Ex ante, list-based controls simplify the export process by proactively identifying risky technologies; however, these lists cannot anticipate every potential harmful use.¹⁸⁹ Moreover, list-based controls risk overregulating items whose benefits outweigh their harms. Catch-all controls address gaps by “catching” harmful exports not flagged by explicit lists or directed toward sanctioned countries.¹⁹⁰ Even though few explicit AI-related list-based controls exist, catch-all controls still apply to AI.

In the 1990s, the United States created catch-all controls, providing a legal basis to require export licenses even for previously uncontrolled “weapons.”¹⁹¹

182. 50 U.S.C. § 4817(b) (emphasis added).

183. *Id.*

184. Emily S. Weinstein & Kevin Wolf, *For Export Controls on AI, Don't Forget the “Catch-All” Basics*, CTR. FOR SEC. AND EMERGING TECH. (July 5, 2023), <https://cset.georgetown.edu/article/dont-forget-the-catch-all-basics-ai-export-controls/> [<https://perma.cc/F8S4-GGM6>].

185. See BATEMAN, *supra* note 18, at 20.

186. Weinstein & Wolf, *supra* note 184.

187. *Id.*

188. 15 C.F.R. § 744.21.

189. Weinstein & Wolf, *supra* note 184.

190. *Id.*

191. U.S. Dep't of State, *Catch-All Controls*, U.S. DEPARTMENT OF STATE: A RESOURCE ON STRATEGIC TRADE MANAGEMENT AND EXPORT CONTROLS, <https://2009->

ECRA and EAR create a net of catch-all controls that extend U.S. export jurisdiction to exports potentially used for nefarious purposes, regardless of whether an explicit list-based control exists. The remainder of this Section discusses specific catch-all controls relevant to Part IV.

a) End-User & End-Use Controls

If the supplier knows or has reason to know that their export may be sold to a prohibited end-user or for a prohibited end-use, the sale is subject to export controls and may require a license.¹⁹² Under 15 C.F.R. § 744.6(b), military end-users include individuals who “support” prohibited uses.¹⁹³ The term “support” is broadly defined, encompassing not only direct export actions but also any “facilitation” of shipments, contracts, or services that might enable a prohibited end-use.¹⁹⁴ Therefore, foreign individuals might be subject to U.S. export laws and penalties if they facilitate the sale of foreign-made items that contain more than a *de minimis* amount of U.S.-origin components.¹⁹⁵

Under 15 C.F.R. § 744.1(b)(1) and § 744.3(b), even if an end-user is not on an end-user list, an exporter is still liable if they “know or have reason to know” that the exported item may be used improperly.¹⁹⁶ Typically, the government interprets “to know” broadly, so if an exporter had reason to be aware (i.e., should have known) that the exported item could be used for prohibited purposes, they can be subject to U.S. sanctions.¹⁹⁷ For example, in *FedEx*, BIS imposed strict liability on FedEx, despite FedEx lacking direct knowledge of each parcel’s content.¹⁹⁸ The court held that FedEx’s institutional knowledge allowed for application of a stricter standard than that for the average person.¹⁹⁹ According to the court, FedEx should have been aware that their packages could contain export-limited items.

b) Entity List

To help streamline licensing procedures, BIS administers the Entity List, an end-user-based list that targets foreign companies considered to have

2017.state.gov/strategictrade/practices/c43179.htm [https://perma.cc/Z6N4-D7RM] (last visited Feb. 22, 2025).

192. See 50 U.S.C. §§ 4813(a)(4), 4813(2), 4817(b)(1).

193. 15 C.F.R. § 744.6(b); see Weinstein & Wolf, *supra* note 184.

194. See Weinstein & Wolf, *supra* note 184.

195. See *id.*; BATEMAN, *supra* note 18, at 20.

196. 15 C.F.R. §§ 744.1(b)(1), 744.3(b).

197. See *Fed. Express Corp. v. U.S. Dep’t of Com.*, 486 F. Supp. 3d 69, 80–82 (D.D.C. 2020), *aff’d sub nom.*, 39 F.4th 756 (D.C. Cir. 2022).

198. *Id.*

199. *Id.* at 76.

interests counter to those of the United States.²⁰⁰ An entity need not be on the Entity List to be subject to U.S. export controls, but the Entity List expedites the review process.²⁰¹ From 2018 to 2022, the share of Chinese companies with military affiliations on the Entity List grew from 14 percent (130 entries) to 29 percent (532 entries).²⁰² To export to listed entities—for example, Chinese technology companies that create AI-adjacent products—companies must obtain a license from the U.S. government, subject to a presumption of denial.²⁰³

c) Deemed Exports

Finally, EAR § 734.13(b) states that “[a]ny release in the United States of ‘technology’ or source code to a foreign person is a deemed export to the foreign person’s most recent country of citizenship or permanent residency.”²⁰⁴ In other words, any transfer of information or software source code to a non-U.S. citizen is considered an export and can be subject to export law if that foreigner is a citizen of a restricted country.

In sum, catch-all controls broadly apply to any domestic export or foreign reexport that may go toward any “foreseeable” prohibited end-user or end-use.²⁰⁵ ECRA’s catch-all rules give the executive branch the power to regulate the activities of a person (American citizen or not) who assists with the sale of any U.S.-origin “emerging or foundational technology” that *could be* used in a foreign weapon (which is almost all such technologies).²⁰⁶ These rules emphasize the export act or the exporter’s citizenship rather than the item itself, regardless of whether the exporter predicted the final end-use of the item.²⁰⁷ Thus, U.S. companies must proactively supervise their market to prevent U.S. government sanctions for potential, even unintended, end-uses.

Because most AI products have foreseeable warfighting end-uses, nearly all American-developed AI software and hardware could be subject to ECRA’s catch-all controls. Thus, any seller—American or not—who supports the sale of an American-origin AI could be investigated or penalized by the U.S.

200. See BATEMAN, *supra* note 18, at 19–20.

201. *Id.*; Weinstein & Wolf, *supra* note 184.

202. BATEMAN, *supra* note 18, at 19–20.

203. 15 C.F.R. § 742.4(b)(7)(i) (stating that for certain countries such as Burma, Cambodia, China, or Venezuela, “[t]here is a presumption of denial for license applications to export[,] reexport, or transfer items that would make a material contribution to the ‘development,’ ‘production,’ maintenance, repair, or operation of weapons systems . . .”); see also BATEMAN, *supra* note 18, at 19–20.

204. 15 C.F.R. § 734.13.

205. See Weinstein & Wolf, *supra* note 184.

206. *Id.*

207. *Id.*

government if it can be proven that enough of that American-origin AI was found in prohibited weaponry or used by an enemy combatant.

3. *The Foreign Direct Product Rule Further Expands Upon Catch-All Rules in Foreign Countries*

ECRA authorizes EAR to enforce the Foreign Direct Product Rule (FDPR).²⁰⁸ The FDPR is a narrowly tailored regulatory regime with broad consequences.²⁰⁹ There are eight versions of FDPR, each listing new ECCNs, countries, and criteria.²¹⁰ The FDPR restricts the transfer of certain ECCNs to specific end-users, even if the product contains no U.S.-origin content or has never entered the United States, *because its production involved U.S.-origin software or equipment*.²¹¹ In this way, FDPR extends the United States' jurisdiction to certain foreign products (if they fall within a listed ECCN) even if they fall below *de minimis* export thresholds.²¹² Unlike catch-all rules, which apply only if products contain at least 25 percent U.S.-origin components, FDPR applies even when products do not contain any U.S.-made subcomponents because the products were created with U.S. software or equipment. FDPR's goal is to impose controls on every part of a supply chain, to use export controls to choke both U.S. and foreign flow of certain ECCNs, preventing the global proliferation of certain ECCNs at a near embargo.²¹³ This ensures that no trickle of water escapes the metaphorical "dam."²¹⁴

Figure 1: Example of U.S. Jurisdiction Under Foreign Direct Product Rule

208. 15 C.F.R. § 734.9.

209. See *Understanding the Foreign Direct Product Rule*, EXPORT COMPLIANCE TRAINING INST. (Dec. 20, 2022), <https://www.learnexportcompliance.com/understanding-the-foreign-direct-product-rule/> [<https://perma.cc/K7WY-8NT8>].

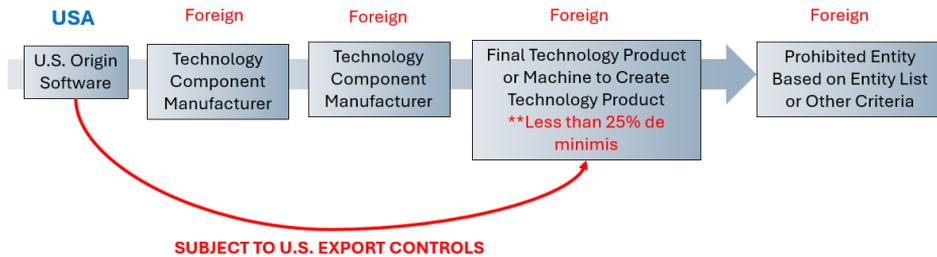
210. *Id.*

211. *Id.*

212. *Id.*

213. *Id.*; Matthew Schleich & Thibault Denamiel, *Why US Semiconductor Export Controls Backfire*, DIPLOMAT (May 23, 2024), <https://thediplomat.com/2024/05/why-us-semiconductor-export-controls-backfire> [<https://perma.cc/7CJD-Z8GT>].

214. *Id.*



For example, FDPR 7.0 and 8.0 impose controls on ECCNs related to advanced computing products, including semiconductors, going to China.²¹⁵ As a result, in 2020, Huawei Technologies Co., Ltd., a Chinese telecommunications and consumer electronics company that also develops AI chips, needed permission from the U.S. government to import chip-related technology made with U.S. software.²¹⁶ The United States used FDPR to prevent ASML, a Dutch photolithography manufacturer, from selling microchip manufacturing equipment to Huawei because U.S.-origin software was used to build ASML’s semiconductor manufacturing equipment somewhere in ASML’s multi-country supply chain.²¹⁷

Typically, FDPR only applies to items that are (1) listed under certain ECCNs and (2) destined for certain countries or companies; however, FDPR can, under EAR99, apply to any direct product of U.S. technology—products that, at some stage of manufacturing, involve U.S.-origin technology or equipment.²¹⁸ These include emerging technologies such as closed-weight AI models and quantum computing.²¹⁹

FDPR has significant consequences for non-U.S. companies.²²⁰ Successful application of FDPR requires international coordination between the United

215. EXPORT COMPLIANCE TRAINING INST., *supra* note 209.

216. *Id.*

217. *Id.*

218. Ishan V. Nagpal, *Decoding the Foreign Direct Product Rule (FDPR)*, SUBSTACK: COMPLIANCE IN AN INTEGRATED NETWORK (Feb. 11, 2025), https://ishanvnagpal.substack.com/p/decoding-the-foreign-direct-product?utm_campaign=post&utm_medium=web [<https://perma.cc/2PJL-4X48>].

219. *Id.*

220. See Jane Lee & Stephen Nellis, *Explainer: What Is “FDPR” and Why Is the U.S. Using It to Cripple China’s Tech Sector?*, REUTERS (Oct. 8, 2022), <https://www.reuters.com/technology/what-is-fdpr-why-is-us-using-it-cripple-chinas-tech-sector-2022-10-07/> [<https://perma.cc/K3GD-ZZ8P>].

States and affected U.S. allies.²²¹ Countries whose supply chains involve U.S. products must preemptively disclose their entire supply chain, often many layers deep, to ensure compliance.²²² U.S. allies must obey U.S. export restrictions whenever a U.S. software touches their manufacturing process, even if the foreign product has no other relation to the United States.²²³

An embargo of U.S. products against one country can effectively backfire into an embargo against the United States, as allied countries may forego U.S. imports in favor of less cumbersome foreign offerings.²²⁴ FDPR constrains allied countries' ability to sell products in international markets, forcing allies to choose between using U.S. supply chains, subject to U.S.-imposed limitations, or declining certain U.S. products in favor of less restrictive, and potentially less expensive foreign products.²²⁵ Overly restrictive FDPR provisions—which operate as an “us versus them” demand—can cause the United States to lose market share not just to those embargoed countries or companies, but also to allied countries that sell products to embargoed countries.²²⁶ Thus, the United States could lose export revenue at every step of the supply chain.

Because FDPR extends to advanced computing products, FDPR applies to technologies that enable AI.²²⁷ Overseas companies that create AI hardware and software must consider their relationships with the United States at every

221. Schleich & Denamiel, *supra* note 213; CHRISTOPHER A. CASEY, CONG. RSCH. SERV., R47684, EXPORT CONTROLS—INTERNATIONAL COORDINATION: ISSUES FOR CONGRESS 6–7 (2023).

222. See EXPORT COMPLIANCE TRAINING INSTITUTE, *supra* note 209; Patrick Kurniawan, *YL Blog #71 – China’s Pursuit of Semiconductor Independence: US Foreign Direct Product Rule (FDPR) in Effect*, PACIFIC FORUM (June 27, 2024), <https://pacforum.org/publications/yl-blog-71-chinas-pursuit-of-semiconductor-independence-us-foreign-direct-product-rule-fdpr-in-effect> [<https://perma.cc/7DJG-SKP5>].

223. See Schleich & Denamiel, *supra* note 213; Kurniawan, *supra* note 222.

224. See Robert D. Atkinson, *Stronger Semiconductor Export Controls on China Will Likely Harm Allied Semiconductor Competitiveness*, INFO. TECH. & INNOVATION FOUND. (Oct. 12, 2023), <https://itif.org/publications/2023/10/12/stronger-semiconductor-export-controls-on-china-will-likely-harm-allied-semiconductor-competitiveness/> [<https://perma.cc/3435-2CRT>].

225. *Id.*

226. See Jack Whitney, Matthew Schleich & William Alan Reinsch, *The Double-Edged Sword of Semiconductor Export Controls* 3–12, CTR. FOR STRATEGIC & INT’L STUDS. (Oct. 4, 2024), https://csis-website-prod.s3.amazonaws.com/s3fs-public/2024-10/241004_Whitney_Export_Controls.pdf?VersionId=1333avUXqn8.aHkwy1hPw2PQzPHU.UG [<https://perma.cc/F9TW-5QXW>].

227. See Foreign-Produced Direct Product Rule Additions, and Refinements to Controls for Advanced Computing and Semiconductor Manufacturing Items, 89 Fed. Reg. 96790 (Dec. 5, 2024) (to be codified at 15 C.F.R. pts. 732, 734, 736, 740, 742, 744, 746, 758, 762, 772, 774).

point of their supply chain.²²⁸ U.S. companies must also consider whether their products could, at any point, be used in manufacturing an AI-adjacent product, and if so, how that affects their global market sales.

E. EXPORT REGULATIONS FOR ARTIFICIAL INTELLIGENCE ARE SUBJECT TO A THREE-PRONG TEST

In considering whether to create list-based and explicit export controls for AI, regulators use a three-prong test to assess whether a given technology is suitable for export controls. Under 50 U.S.C. § 4817(a)(2)(B), executive agencies consider (1) the development of an AI technology outside the United States; (2) the effect of an export control on the development of an AI technology in the United States; and (3) the effectiveness of an export control in limiting the proliferation of an AI technology outside the United States.²²⁹ Section 4817(a)(2)(B) requires that executive agencies consider the following:

- (i) the development of emerging and foundational technologies in foreign countries; (ii) the effect export controls imposed pursuant to this section may have on the development of such technologies in the United States; and (iii) the effectiveness of export controls imposed pursuant to this section on limiting the proliferation of emerging and foundational technologies to foreign countries.²³⁰

This three-prong test, provided by law, is the balancing test to ascertain whether a certain AI can and should be subject to U.S. export controls. Part IV applies this three-prong test to AI hardware and software.

IV. EVALUATING AI UNDER ECRA

Part IV combines the technological and geopolitical considerations discussed in Part II with the statutory considerations discussed in Part III to consider whether explicit controls for AI are effective or advisable. Section 4817(a)(2)(B)'s three-prong test provides the framework for evaluating the benefits and drawbacks of explicitly regulating AI under ECRA. This evaluation concludes that export controls should be narrowly written and consider the second and third order effects of each action. The lack of AI regulation is not an ECRA problem, but a problem with the ripeness of AI technology.

228. *Id.*

229. 50 U.S.C. § 4817(a)(2)(B)(i)–(iii).

230. *Id.*

A. EXPORT CONTROLS OF AI, UNDER SECTION 4817(A)(2)(B), AT BEST, HAVE MARGINAL BENEFITS AND AT WORST, ARE COUNTERPRODUCTIVE

Section IV.A evaluates AI under the § 4817(a)(2)(B) three-prong balancing test. Applying the three-prong balancing test to AI hardware and software counsels against broad export controls.

1. *Under Section 4817(a)(2)(B), Export Controls of AI Hardware Might Have Marginal Short-Term Benefits, but May Be Counterproductive Overall*

This analysis focuses primarily on semiconductor-related controls, particularly those restricting exports to China. These conclusions may provide insight into the potential effects of exports on other, more recently controlled AI hardware, such as quantum computers, GAAFETs, and additive manufacturing technology.²³¹

a) Export Controls Must Consider the Development of AI Hardware in Foreign Countries

Section 4817(a)(2)(B)(i) requires the United States, before imposing export controls, to consider the foreign development of “emerging and foundational technologies.”²³² For semiconductors, the United States and other U.S.-allied countries have a developmental advantage over China.²³³

According to the Semiconductor Industry Association (SIA), in 2023, the United States controlled 50.2 percent of global semiconductor industry sales and market share, whereas South Korea accounted for 18.8 percent, the European Union for 12.7 percent, Japan for 9 percent, Taiwan for 7 percent, and China for 7 percent.²³⁴ U.S.-allied nations also have a virtual monopoly on semiconductor manufacturing equipment, with the United States producing 47 percent, Japan producing 30 percent, the Netherlands producing 17 percent, South Korea producing less than 3 percent, and Germany producing less than 3 percent of semiconductor manufacturing equipment.²³⁵ These

231. See Cinelli et al., *supra* note 19.

232. 50 U.S.C. § 4817(a)(2)(B)(i).

233. Allen, *supra* note 123.

234. Stephen Ezell, *How Innovative Is China in Semiconductors?*, INFO. TECH. & INNOVATION FOUND. (Aug. 19, 2024), <https://itif.org/publications/2024/08/19/how-innovative-is-china-in-semiconductors> [<https://perma.cc/X5JP-3YMY>].

235. Carrick Flynn, *Recommendations on Export Controls for Artificial Intelligence*, CTR. FOR SEC. & EMERGING TECH. 1, 7 (Feb. 2020), <https://cset.georgetown.edu/wp-content/uploads/Recommendations-on-Export-Controls-for-Artificial-Intelligence-1.pdf> [<https://perma.cc/PJ9M-6NAC>].

statistics show that U.S.-allied nations likely control over 90 percent of semiconductor and associated technologies.

Although China currently relies on western computer chips, the Chinese government has prioritized its domestic semiconductor sector, seeking self-sufficiency while building its own competitive products.²³⁶ Although Chinese semiconductor firms lag behind U.S.-allied countries, they appear to be catching up in certain pockets through a mix of both innovation and replication.²³⁷ The Chinese government has considered semiconductors one of the country's key long-term innovation priorities.²³⁸ China recognizes semiconductors as a foundational technology that underpins its economy and national security posture and aims to gain self-sufficiency in this sector.²³⁹

In the last decade, China has increased its chip manufacturing and design industry manifold and is projected to account for the most significant share of available chip-making capacity within the next several years.²⁴⁰ China currently outpaces the United States in semiconductor R&D spending, semiconductor patent applications, and is on par with the United States in the volume and quality of semiconductor-related research publications.²⁴¹ China's chip subsidies artificially lower prices and have helped the Chinese gain market share at the expense of non-Chinese firms.²⁴² Although the United States and its allies currently hold a significant lead, the long-term sustainability of this advantage will largely depend on the pace and effectiveness of China's innovation and self-sufficiency efforts.

b) Export Controls Must Consider the Effects of Those Controls on AI Hardware Development in the United States

In addition to considering the development of emerging technologies abroad, ECRA requires BIS to consider the effect of export controls on the development of "emerging and foundational technologies," such as AI, in the United States.²⁴³ Currently, semiconductor exports impede Chinese AI development while reinforcing domestic semiconductor capabilities.²⁴⁴

236. Ezell, *supra* note 234.

237. *Id.*

238. *Id.*

239. *Id.*

240. *Id.*

241. *Id.*

242. *Id.*

243. 50 U.S.C. § 4817(a)(2)(B)(ii).

244. Allen, *supra* note 123.

However, these restrictions might deny U.S. firms the profits and market share needed for U.S. semiconductor growth.²⁴⁵

China is the largest semiconductor market in the world, accounting for 31.4 percent of global semiconductor purchases, with U.S. firms supplying 53.4 percent of those sales.²⁴⁶ Export controls not only cause U.S. firms to lose direct revenue from China but, due to the catch-all rules, may also disrupt U.S. revenue streams from other countries that have sales relationships with China, compounding losses.²⁴⁷ Lost revenue leads to lost stock market capitalization and undermines economies of scale that offset the upfront costs of semiconductor manufacturing and R&D.²⁴⁸ Semiconductor manufacturing and research are expensive, and many of these costs cannot be borne by the government alone.²⁴⁹ Chip sales bolster revenues that sustain research for better products.²⁵⁰

Proponents of semiconductor controls argue that these controls buy the United States time to strengthen its domestic semiconductor fabrication abilities and maintain a lead over Chinese AI development.²⁵¹ The United States can capitalize on this newfound “breathing room” to improve its onshore manufacturing capabilities, reduce supply chain dependency on foreign suppliers, ensure a steady supply of advanced chips needed for AI software applications, and further its AI-related military research.²⁵² Meanwhile, export controls prevent adversaries from using U.S. chip

245. *Id.*

246. Kirti Gupta, Chris Borges & Andrea Leonard Palazzi, *Collateral Damage: The Domestic Impact of U.S. Semiconductor Export Controls*, CTR. FOR STRATEGIC & INT’L STUDS. (July 9, 2024), <https://www.csis.org/analysis/collateral-damage-domestic-impact-us-semiconductor-export-controls> [<https://perma.cc/BW36-D3JQ>].

247. *See* discussion *supra* Sections III.D.2, III.D.3.

248. *Id.*

249. *See* Gallo, *supra* note 172, at 1 (showing that in 1960, the U.S. Government funded twice as much R&D as businesses, but now businesses fund 71% of R&D).

250. *See* Gupta et al., *supra* note 246.

251. Owen J. Daniels & Will Hunt, *Sustaining and Growing the U.S. Semiconductor Advantage: A Primer*, CTR. FOR SEC. & EMERGING TECH. 5 (2022), <https://cset.georgetown.edu/wp-content/uploads/CSET-Sustaining-Growing-US-Semiconductor-Advantage-A-Primer.pdf> [<https://doi.org/10.51593/20220006>].

252. *See* Vishnu Kannan & Jacob Feldgoise, *After the CHIPS Act: The Limits of Reshoring and Next Steps for U.S. Semiconductor Policy*, CARNEGIE ENDOWMENT FOR INT’L PEACE (Nov. 22, 2022), <https://carnegieendowment.org/research/2022/11/after-the-chips-act-the-limits-of-reshoring-and-next-steps-for-us-semiconductor-policy?lang=en> [<https://perma.cc/4A5S-P39R>]; Justin Badlam, Stephen Clark, Suhrid Gajendragadkar, Adi Kumar, Sara O’Rourke & Dale Swartz, *The CHIPS and Science Act: Here’s What’s in It*, MCKINSEY & CO. (May 16, 2024), <https://www.mckinsey.com/industries/public-sector/our-insights/the-chips-and-science-act-heres-whats-in-it> [<https://perma.cc/YG5E-MATJ>].

technologies to develop competing products.²⁵³ The CHIPS and Science Act (CHIPS), enacted at the same time as the October 2022 Semiconductor Controls, is intended to work in concert with these controls, providing funding to improve semiconductor production within the United States.²⁵⁴

Critics of semiconductor export controls argue that they are “a double-edged sword.”²⁵⁵ Although controls can stifle technological advancement of U.S. competitors, they can also “strain the very businesses that propelled the United States into technological leadership” by causing the United States and allied businesses to lose market share.²⁵⁶ Semiconductor export controls can deny domestic firms access to export-affected markets without providing adequate alternatives to compensate for their lost profits.²⁵⁷

Since the October 2022 Semiconductor Controls, affected U.S. firms have terminated relationships with Chinese firms but have not formed equally profitable relationships elsewhere.²⁵⁸ After the October 2022 Semiconductor Controls, U.S. semiconductor firms saw a 2.5 percent drop in stock market valuation that persisted for 20 days, translating to an aggregate loss of \$130 billion in market capitalization.²⁵⁹ Additionally, the chilling effect on the market seems to have extended beyond the semiconductor industry, with businesses in unrelated sectors becoming wary of new relationships that may, in the future, be subject to restrictions.²⁶⁰

c) Export Controls Must Consider the Effectiveness of Such Controls in Limiting the Proliferation of AI Hardware in Foreign Countries

ECRA requires the United States to consider the effectiveness of export controls on “limiting the proliferation of emerging and foundational technologies to foreign countries.”²⁶¹ Through catch-all controls and FDP, the United States believes it can touch almost every part of the semiconductor supply chain and throttle Chinese AI development, preventing Chinese access

253. Daniels & Hunt, *supra* note 251, at 5.

254. H.R. 4346, 117th Cong. (2022).

255. Schleich & Denamiel, *supra* note 213.

256. *Id.*

257. Gupta et al., *supra* note 246.

258. *Id.*

259. Matteo Crosignani, Lina Han, Marco Macchiavelli & André F. Silva, *Securing Technological Leadership? The Cost of Export Controls on Firms*, FED. RES. BANK OF N.Y. (Feb. 2025), https://www.newyorkfed.org/research/staff_reports/sr1096 [<https://doi.org/10.59576/sr.1096>].

260. Gupta et al., *supra* note 246.

261. 50 U.S.C. § 4817(a)(2)(B)(iii).

to foundational technologies and thereby “cooling” the competitive landscape.²⁶²

For U.S. export controls to be effective, allies must willingly comply with U.S. controls. The United States currently maintains compliance agreements with its allies, but some allies have pushed back.²⁶³ When the United States imposed unilateral controls on semiconductor manufacturing equipment in 2022, its allies hesitated to comply.²⁶⁴ In the months that followed, U.S. controls barred U.S. firms from selling to China while Dutch and Japanese companies delivered the same products to China in record quantities, anticipating future restrictions.²⁶⁵

It was not until the United States applied pressure that these companies stopped gaining market share at the United States’ expense.²⁶⁶ Although Japan and the Netherlands eventually implemented similar controls, Chinese firms like Huawei and SMIC—major Chinese semiconductor foundries—had already acquired large amounts of semiconductor manufacturing equipment, and they now use these machines to produce their own semiconductors.²⁶⁷ Without international collaboration, unilateral export controls do little to limit the proliferation of emerging technologies, such as AI semiconductors in competitor economies.²⁶⁸

Many of the United States’ Asian allies, such as South Korea, Japan, and Taiwan, have historic trading relationships with China.²⁶⁹ South Korea is the world’s second-largest exporter of semiconductor products after the United States.²⁷⁰ Japan and the Netherlands both have lynchpin semiconductor industries, and they also sell semiconductor manufacturing machines to China.²⁷¹ When U.S. export controls undermine allied interests or challenge established trade relationships, the economic costs of allyship can outweigh the benefits of continued cooperation with the United States.²⁷² Allies may,

262. See EXPORT COMPLIANCE TRAINING INSTITUTE, *supra* note 209; Allen, *supra* note 123.

263. Nisarg Jani, *The ‘Fab 4’ Allies Are Pushing Back on US Export Controls on China*, DIPLOMAT (Oct. 29, 2024), <https://thediplomat.com/2024/10/the-fab-4-allies-are-pushing-back-on-us-export-controls-on-china> [<https://perma.cc/FJ32-BS9F>].

264. Schleich & Denamiel, *supra* note 213.

265. *Id.*

266. *Id.*

267. *Id.*

268. *Id.*

269. See André Brunel, *A Proposal for a Semiconductor Export Control Treaty*, 19 J. BUS. & TECH. L. 1, 25 (2023).

270. Ezell, *supra* note 234.

271. Shivakumar et al., *supra* note 64.

272. See Jani, *supra* note 263.

instead, prefer to step into the United States' vacated market position, increasing their market share at the United States' expense.²⁷³ As the SIA noted, "companies not affected by U.S. export controls are . . . able to use that income for research and development to out-compete those companies affected by the unilateral controls. They are also delivering to the restricted country or end-user the exact technology the U.S. has intended to restrict, undermining the national security objectives the U.S. government set out to achieve."²⁷⁴

Semiconductor export controls remain effective if adversaries cannot obtain comparable technology elsewhere.²⁷⁵ This requires the United States and its allies to adhere to unilateral American export controls—controls subject to complicated catch-all rules and FDPR.²⁷⁶ Export controls will be ineffective if allies fail to maintain a united front or if they fail to prevent black market chip sales.²⁷⁷

Finally, export controls will be ineffective if adversary countries can rely on expanding Chinese markets that create comparable and inexpensive semiconductor products.²⁷⁸ The Chinese government has responded to recent U.S. export controls by pouring money into export-limited sectors.²⁷⁹ Reports show that China has invested billions in state-backed chipmaking entities.²⁸⁰ If the Chinese find ways to accelerate the development of their own domestic alternatives, they will be able to capitalize on the United States' self-imposed ban and fill the United States' vacated market position.²⁸¹ Semiconductor export controls can therefore propel Chinese innovation and advancement at the expense of American firms, who lose substantial sales from China, one of the world's largest semiconductor customers.

273. Semiconductor Industry Assoc., *Comments of the Semiconductor Industry Association on The Interim Final Rule Entitled "Additional Export Controls: Certain Advanced Computing and Semiconductor Manufacturing Items; Supercomputer and Semiconductor End Use, Entity List Modification"*, SEMICONDUCTOR INDUS. ASSOC. 1, 6 (2023), <https://www.semiconductors.org/wp-content/uploads/2024/07/SIA-Comments-to-BIS-on-October-2022-IFR.pdf> [<https://perma.cc/P9J2-26A6>].

274. *Id.*

275. Brunel, *supra* note 269, at 25–26.

276. *See* Schleich & Denamiel, *supra* note 213.

277. John Villasenor, *The Tension Between AI Export Control and U.S. AI Innovation*, BROOKINGS INST. (Sep. 24, 2024), <https://www.brookings.edu/Articles/the-tension-between-ai-export-control-and-u-s-ai-innovation/> [<https://perma.cc/TVB7-GRBX>].

278. Flynn, *supra* note 235, at 8.

279. *See* Shivakumar et al., *supra* note 64.

280. *Id.*

281. *See* Gupta et al., *supra* note 246.

There are multiple historic examples where American exports reinforce Chinese innovation and market dominance. In 2016, export controls prevented Intel from shipping Xeon processors to China for use in the Sunway TaihuLight supercomputer.²⁸² China later locally designed Sunway SW26010 processors, which they used as a substitute.²⁸³ The TaihuLight supercomputer was the fastest supercomputer for two years.²⁸⁴ Here, export controls forced Chinese companies to design around the control and, as a result, accelerated Chinese innovation.

Given China's decade-long innovation focus on computing technologies, even if export controls on tangible technologies have short-term benefits in stemming Chinese production, they may not have long-term use cases. Peter Wennick, CEO of ASML, a Dutch semiconductor lithography firm, said in 2021 "if you shut out the Chinese with export control measures, you'll force them to strive toward tech sovereignty, in their case real tech sovereignty . . . In 15 years' time, they'll be able to do it all by themselves—and [Western equipment suppliers'] market . . . will be gone."²⁸⁵ Tudor Brown, former director at Semiconductor Manufacturing International Corporation (SMIC), concurred, stating that semiconductor controls "will slow [China] down for two to five years, not 10."²⁸⁶

In sum, U.S. semiconductor controls constrain China, but they also risk harming American and allied semiconductor companies. Among the allied nations that comply with export controls to China, any country that breaks ranks stands to benefit significantly.²⁸⁷ Alternatively, even if all allies remain united, China can innovate around the issue and gain market share at the expense of those countries constrained by shared agreements.²⁸⁸ Thus, overly restrictive semiconductor export controls can backfire.

282. Flynn, *supra* note 235, at 8.

283. *Id.*

284. *Id.*

285. Sujai Shivakumar, Charles Wessner & Thomas Howell, *A Seismic Shift: The New U.S. Semiconductor Export Controls and the Implications for U.S. Firms, Allies, and the Innovation Ecosystem*, CTR. FOR STRATEGIC & INT'L. STUDS. (Nov. 14, 2022), <https://www.csis.org/analysis/seismic-shift-new-us-semiconductor-export-controls-and-implications-us-firms-allies-and> [<https://perma.cc/V7QD-K4XY>].

286. *Id.*

287. See discussion *supra* Section IV.A.

288. *Id.*

2. *Under Section 4817(a)(2)(B), Export Controls for AI Software Have Limited Effectiveness*

Section IV.A.2 applies § 4817(a)(2)(B) to AI software. To date, there are few AI software controls. BIS has imposed a list-based software control for “Deep Convolutional Neural Network[s] [that] automate geospatial imagery and point cloud analysis.”²⁸⁹ On January 13, 2025, BIS announced new export controls on advanced closed-weight AI models.²⁹⁰ Even in these narrow cases, BIS imposes controls only when the software meets highly specific functional criteria.²⁹¹ Nevertheless, it appears that the United States is moving toward stricter AI software controls, and regulators should evaluate further controls under § 4817(a)(2)(B)’s three-prong balancing test.

a) *Export Controls Must Consider the Development of AI Software in Foreign Countries*

Section 4817(a)(2)(B)(i) requires the United States to consider the development of AI software in foreign countries before imposing export controls.²⁹² AI software poses unique challenges for export controls because many AI models are open-source, intangible, and globally accessible, which inherently circumvent control mechanisms. Export controls are ineffective for open-source models where data is, by definition, freely shared.²⁹³ The very open-source, intangible nature of many models makes AI development from these models available to both allies and adversaries.²⁹⁴

Open-weight and closed-source models are likewise difficult to control. Competitors can reverse engineer open-weight models.²⁹⁵ Closed-weight code is subject to theft.²⁹⁶ Unlike nuclear or other weapons systems, software cannot be counted and inventoried—software is information that can be copied, retrained, and easily appropriated by competitor countries and black market smugglers.²⁹⁷ Export controls for these types of models may not entirely stem the flow of information to foreign countries; instead, they focus on fining

289. LeBeau & Seymour, *supra* note 20.

290. Shenai et al., *supra* note 20.

291. *See supra* note 20.

292. 50 U.S.C. § 4817(a)(2)(B)(i).

293. Claudia Wilson & Emmie Hine, *Export Controls on Open-Source Models Will Not Win the AI Race*, JUST SEC. (Feb. 25, 2025), <https://www.justsecurity.org/108144/blanket-bans-software-exports-not-solution-ai-arms-race> [<https://perma.cc/4248-Z5HA>].

294. *Id.*

295. *See discussion supra* Section II.A.4.

296. *Id.*

297. Eric Schmidt, *AI, Great Power Competition & National Security*, 151 J. AM. ACAD. ARTS & SCIS.: DÆDALUS 288, 295 (2022), <https://www.amacad.org/publication/daedalus/ai-great-power-competition-national-security> [https://doi.org/10.1162/daed_a_01916].

American companies, shifting the policing burden to these American companies.²⁹⁸

The reality is that countries around the world prioritize AI development.²⁹⁹ Currently, most—but not all—of them are American allies.³⁰⁰ As AI offerings become more internationally pervasive, these AI products will also become more difficult to track and enforce.

b) Export Controls Must Consider the Effects of Such Controls on AI Software Development in the United States

Just as with hardware, ECRA requires regulators to consider how AI software controls affect domestic AI development.³⁰¹ Export controls might, as some policymakers believe, buy time for lagging domestic capabilities to improve.³⁰² Proponents of these policies, however, fail to recognize that AI development in the United States is interconnected with international and open-source research.³⁰³

American AI benefits from international collaboration.³⁰⁴ U.S. companies have built popular and expansive open-source libraries for general-purpose AI software.³⁰⁵ These open-source ecosystems advance U.S. economic interests while also fostering communities of like-minded experimenters whose contributions further fuel American AI innovation.³⁰⁶ Export controls risk damaging this ecosystem, undermining the United States' ability to develop, disseminate, control, and profit from its open-source and open-weight AI.³⁰⁷

The United States is currently the world's undisputed leader in AI research and draws talent from around the world.³⁰⁸ Researchers regularly share information and code with international colleagues, but export controls limit

298. See discussion *supra* Sections II.A.4, III.D.

299. See Stanford HAI Staff, *Global AI Power Rankings: Stanford HAI Tool Ranks 36 Countries in AI*, STAN. U.: HUMAN-CENTERED A.I. (Nov. 21, 2024), <https://hai.stanford.edu/news/global-ai-power-rankings-stanford-hai-tool-ranks-36-countries-in-ai> [<https://perma.cc/L6HC-C4T9>].

300. *Id.*

301. 50 U.S.C. § 4817(a)(2)(B)(ii).

302. Allen, *supra* note 123.

303. Flynn, *supra* note 235, at 4.

304. Clara Boothby & Benjamin Schneider, *International Collaboration in Selected Critical and Emerging Fields: COVID-19 and Artificial Intelligence*, NAT'L. CTR. FOR SCI. & ENG'G STATS. (Apr. 11, 2024), <https://nces.nsf.gov/pubs/nsf24323> [<https://perma.cc/YYE6-PVJ8>].

305. Yujian Tang, *23 Open Source AI Libraries for 2023*, MEDIUM (May 11, 2023), <https://medium.com/plain-simple-software/23-open-source-ai-libraries-for-2023-6d697010d3e7> [<https://perma.cc/A4RW-E998>].

306. Flynn, *supra* note 235, at 4.

307. *Id.*

308. See Schmidt, *supra* note 297, at 291.

this type of collaboration; foreign researchers are subject to catch-all rules on “deemed exports.”³⁰⁹ Deemed exports restrict the information and software code that U.S. researchers can share with non-U.S. colleagues that are working on the same AI projects.³¹⁰ In AI companies, where research is shared between employees to improve algorithmic outcomes and prevent bias, export controls prevent hiring and retaining diverse, foreign candidates.³¹¹

Finally, as with AI hardware, export controls on AI software can reduce international sales that facilitate AI innovation and research.³¹² Most American AI investment comes from private companies that fund research through product sales (and investors).³¹³ Export controls can trigger a “death spiral” for U.S. firms, reducing competitiveness and revenue, which in turn curtails R&D investment and further slows competitiveness and revenue.³¹⁴ Export controls could harm U.S. innovation while China, ranked second in AI development, leaps ahead.³¹⁵

c) Export Controls Must Consider the Effectiveness of Such Controls in Limiting the Proliferation of AI Software in Foreign Countries

Controls for AI software must also consider the effectiveness of limiting the proliferation of AI weapons.³¹⁶ As discussed, *supra*, in Section IV.A.2.a, the use of open-source code in many proprietary AI products makes export regulation inherently difficult.³¹⁷ Government-imposed catch-all controls also apply.³¹⁸ Firms whose AI software is used by prohibited end-users for prohibited end-uses are still subject to U.S. export penalties.³¹⁹ BIS may be able to rely on existing catch-all controls to achieve this objective.

It is important to tailor export controls to prioritize specific goals while recognizing export controls’ inherent limitations. Adversaries need not have the most advanced AI to do damage—just as commercially available fertilizer

309. 15 C.F.R. § 734.13; BATEMAN, *supra* note 18, at 20.

310. 15 C.F.R. § 734.13; *see* Villasenor, *supra* note 277.

311. BATEMAN, *supra* note 18, at 20.

312. Flynn, *supra* note 235, at 4.

313. *See* Gupta et al., *supra* note 246.

314. Reuters, *California Democrats Fear US Tech Firm “Death Spiral” With More China Curbs*, REUTERS (Aug. 14, 2024), <https://www.reuters.com/technology/california-democrats-fear-us-tech-firm-death-spiral-with-more-china-curbs-2024-08-14/> [<https://perma.cc/7XUH-PYQZ>].

315. *See* Flynn, *supra* note 235, at 5; Gupta et al., *supra* note 246.

316. 50 U.S.C. § 4817(a)(2)(B)(iii).

317. *See* discussion *supra* Section IV.A.2a).

318. *See* discussion *supra* Section III.D.

319. *Id.*

is an ingredient for explosives, relatively basic AI software, combined with other readily available commercial technologies, can wreak havoc.³²⁰ Export controls, here, would be ineffective because foreign offerings can likely supply these ingredients.³²¹ Instead, the United States should dominate the market for these basic technologies, keeping these technologies open-weight to achieve widespread global adoption of these American products to increase American market share.³²² However, for AI that can be used in high-level warfighting strategy, or for highly technical AI breakthroughs unlikely to be found outside of the United States, the United States may still want to regulate its proprietary IP.³²³ The United States must assess the advancement of comparative AI software through every angle to determine whether the control will undermine U.S. innovation and market superiority.³²⁴

Therefore, although most AI software controls are likely ineffective most of the time, they can still provide an overarching policy that prevents the sale of exceedingly complex, niche, and closed-source AI, such as deep convolutional neural networks for geospatial imagery.³²⁵ Indeed, BIS's new rules pertaining to closed-weight AI models appear to support this sentiment.³²⁶ Policymakers should continue to consider AI controls on a case-by-case basis.

3. *DeepSeek is an Ongoing Case Study on the Efficacy of AI Export Controls*

In January 2025, Chinese AI company DeepSeek released “r1,” a large language model that appears to match or surpass U.S. equivalents.³²⁷ Alongside its main language model, DeepSeek released smaller distillations that perform much of the same work as top U.S. models at a fraction of the price.³²⁸

320. See *supra* note 65. Low-cost kamikaze drones, which used readily available drones outfitted with basic AI, operate in networks of drone swarms that identify targets and map terrain with relatively little human input.

321. Ukraine sources its drone swarms through domestic production, the UK, and Latvia, among other international sources.

322. Christina Knight, *Why U.S. Leadership in AI Necessitates Global Collaboration*, LAWFARE (Apr. 2, 2025), <https://www.lawfaremedia.org/article/why-u.s.-leadership-in-ai-necessitates-global-collaboration> [<https://perma.cc/83ZX-UUVR>].

323. See *supra* note 20.

324. See Knight, *supra* note 322.

325. See Flynn, *supra* note 235, at 6; LeBeau & Seymour, *supra* note 20.

326. See *supra* note 20.

327. Dean W. Ball, *What DeepSeek r1 Means—And What It Doesn't*, LAWFARE (Jan. 28, 2025), <https://www.lawfaremedia.org/article/what-deepseek-r1-means-and-what-it-doesn-t> [<https://perma.cc/6ZXM-ZLN5>].

328. *Id.*

In response to DeepSeek's announcement, Nvidia (an American company that currently owns between 70 to 95 percent of the global GPU market³²⁹) experienced an immediate stock selloff, losing nearly \$600 billion in market capitalization.³³⁰ After the October 2022 Semiconductor Controls, the U.S. government restricted exports of Nvidia's most powerful GPUs (A100 and H100s) to China.³³¹ As a workaround, Nvidia introduced modified, lower-performance versions of these chips (A800, H800, and H20) specifically for sale in Chinese markets.³³² Despite these limitations, DeepSeek achieved equivalent performance (compared with leading U.S. models) on lower-performance GPUs, triggering the kneejerk stock selloff.³³³ This ongoing case study raises two main questions: (1) why, after two and a half years of AI hardware export controls, Chinese companies are able to remain on par with American counterparts, and (2) whether American export controls have in fact spurred Chinese innovation.

On the one hand, it may take more time for the effects of U.S.-imposed AI hardware controls to become apparent. Prior to the October 2022 Semiconductor Controls, DeepSeek acquired a cache of A100 chips from Nvidia.³³⁴ DeepSeek also had access to H800 chips and H100 chips.³³⁵ If the export controls were too little and too late, stricter controls could resource-constrain future Chinese developments. DeepSeek openly acknowledges that its primary obstacle is low computing power caused by U.S. export controls.³³⁶ Assuming companies like Huawei cannot replicate advanced GPUs, continued American efforts to throttle China's computing power, even for a short period, could translate into a durable lead for the United States.³³⁷

On the other hand, scarcity and necessity fuel innovation. DeepSeek's detailed white papers, which are well-regarded by the scientific community,

329. Kif Leswing, *Nvidia Dominates the AI Chip Market, But There's More Competition Than Ever*, CNBC (June 2, 2024), <https://www.cnbc.com/2024/06/02/nvidia-dominates-the-ai-chip-market-but-theres-rising-competition.html> [https://perma.cc/EN8H-PLG8].

330. *Id.*; Steve Kopack, *Nvidia Loses Nearly \$600 Billion in Market Value After Chinese AI Startup Bursts Onto Scene*, NBC NEWS (Jan. 27, 2025), <https://finance.yahoo.com/news/nvidia-loses-more-500-billion-193121486.html> [https://perma.cc/UT9B-FSSY].

331. Dylan Patel, AJ Kourabi, Doug O'Laughlin & Reyk Knuhtsen, *DeepSeek Debates: Chinese Leadership on Cost, True Training Cost, Closed Model Margin Impacts*, SEMIANALYSIS (Jan. 31, 2025), <https://semianalysis.com/2025/01/31/deepseek-debates> [https://perma.cc/CA69-S7Q8].

332. *Id.*

333. Ball, *supra* note 327.

334. Patel et al., *supra* note 331.

335. Ball, *supra* note 327; Patel et al., *supra* note 331.

336. Ball, *supra* note 327; Patel et al., *supra* note 331.

337. Dario Amodei, *On DeepSeek and Export Controls*, DARIO AMODEI (Jan. 2025), <https://darioamodei.com/on-deepseek-and-export-controls> [https://perma.cc/D7AZ-H2HN].

demonstrate that it has created a cutting-edge AI that uses less money and less computing power, despite U.S.-imposed limitations.³³⁸ DeepSeek's computational advancements establish China as more than just an imitator—China is emerging as an innovator that has improved AI efficiency.³³⁹ DeepSeek's ability to acquire A100 and H100 chips also proves that so long as alternative product streams exist, whether via other countries, the black market, or even pre-export control caches, such streams will continue to undermine U.S. export controls.

Finally, DeepSeek's rise raises questions about the American AI strategy. DeepSeek is an open-weight AI model that developed proprietary code from an open-source foundation.³⁴⁰ In contrast, American AI firms have, in recent years, shifted toward closed-source, proprietary models to safeguard IP and maintain technological advances.³⁴¹ DeepSeek's open-weight approach not only democratizes AI advancement, permitting researchers from around the world to reverse engineer DeepSeek's contributions, but also establishes DeepSeek as a cost-effective, reliable, and transparent alternative to American offerings, whose low cost and availability may prove advantageous in global markets.³⁴² Because r1's open-weight structure allows companies to run it on their own GPU clusters, organizations can process data locally without sending their inputs to third-party AI companies.³⁴³ Thus, DeepSeek's choice to open its weights may be a tactical move to have a stronger competitive edge against closed-weight American AI labs, thereby giving DeepSeek greater reach in global markets.³⁴⁴ This may be useful for companies that want to keep their inputs private, such as medical companies that store sensitive information.

In sum, as DeepSeek has acknowledged, U.S. export controls tangibly limit Chinese computing power and may, in time, prove effective.³⁴⁵ However, Chinese companies have time and again actively and successfully innovated around U.S. controls.³⁴⁶ Export controls are predicated on U.S. superiority—they matter only when the United States has something worthy of protecting. If open-source algorithms can achieve comparable, if not superior, results compared to closed-source models, the United States faces a critical question:

338. Ball, *supra* note 327.

339. Amodei, *supra* note 337.

340. Ball, *supra* note 327.

341. *Id.*

342. *See supra* note 83 and accompanying text.

343. *See* Kolluru, *supra* note 80; Miller, *supra* note 76; Weil, *supra* note 82.

344. *See* Ball, *supra* note 327.

345. *See* Ball, *supra* note 327; Patel et al., *supra* note 331.

346. *See* discussion *supra* Section IV.A.1.

(1) whether the U.S. government can realistically control AI, and (2) if not, whether American hubris will lead to its decline.

B. AI EXPORT CONTROLS MUST BE NARROWLY WRITTEN AND SUBJECT TO BALANCING CONSIDERATIONS

Weakness and strength are relative in interconnected markets. An action intended to weaken another country may weaken the initiating country more, ultimately leading to the relative strength of the second. U.S. efforts to gain technological supremacy could trigger a cycle of diminishing economic leverage.³⁴⁷ As the United States contemplates its appropriate role in world governance, it must consider whether excessive intervention in the fickle global ecosystem could lead to outsized and negative consequences. If China outmaneuvers the United States in the global technology race, it will establish a digital foundation on which to challenge the U.S.-led geopolitical order on both military and economic grounds.³⁴⁸ This scenario could become reality if the United States loses market dominance through overly strict export policies that destroy its current sales relationships.

Based on the § 4817(a)(2)(B) three-prong test, U.S. regulators can draw a few conclusions. First, list-based export controls for commercial AI may be counterproductive if the controls are overly broad and apply a one-size-fits-all approach.³⁴⁹ AI is a multi-domain product with multiple applications across different industries, varying levels of complexity, and diverse IP structures.³⁵⁰ Broad AI export controls may disqualify U.S. companies from selling commercially desirable products and could prove difficult to enforce. They can restrict U.S. businesses, prevent foreign innovation and investment in the United States, and prevent foreign sales of U.S. products.³⁵¹ Export controls that prevent commercial sales not only reduce revenue, but also restrain companies from controlling the market for that product.³⁵² Such controls therefore have a negative impact on national security.

Broad catch-all controls can transform reasonable restrictions into detrimental ones. Far-reaching catch-all controls on broad swaths of AI products can disincentivize foreign companies from buying and using such products in their supply chains.³⁵³ Products subject to broad catch-all controls carry with them the stink of current or future restrictions, creating a myriad of

347. See discussion *supra* Sections III.B, III.D, IV.A.

348. Schmidt, *supra* note 297, at 296.

349. Flynn, *supra* note 235, at 4–5.

350. See discussion *supra* Sections II.A.2, II.A.3, II.A.4.

351. See discussion *supra* Section IV.A.

352. See Knight, *supra* note 322.

353. See Jani, *supra* note 263; Schleich & Denamiel, *supra* note 213.

second- and third-order effects—considerations that require extensive rule parsing by global legal teams and affect the size of the product’s end market.³⁵⁴ Overly strict controls can also alienate allies, who in turn undermine U.S. priorities.³⁵⁵ Therefore, narrow controls for specific AI products, subject to narrowly applied catch-all controls, is good policy.

List-based controls for AI should be narrowly written, have short-term goals, and be limited only to those sectors where the technology’s military uses outweigh its civilian uses. A good example of this is geospatial analysis AI—AI that uses satellite imagery combined with deep neural networks to create insights about the locations of certain targets, presumably anywhere in the world, and can tell an adversary where a U.S. military asset is at any place and time.³⁵⁶ Imagine if such an AI were combined with a long-range missile system to identify and neutralize high-value targets in real-time: there would be nowhere in the world left to hide. Even if there were an equivalent civilian use-case for such technology, it would pale in comparison to its military applications. Here, a narrowly written export control for this specific technology limits foreign access to a highly dangerous, technical, and exclusive AI; it is reasonably likely that an export control can limit the proliferation of this technology, moreover, the reasons for nonproliferation outweigh the benefits of widespread commercial sales.

All AI export controls should be assessed for effectiveness before enactment. The success of list-based controls hinges on two main factors: (1) securing foreign cooperation and enforcement mechanisms in an interdependent, global economy,³⁵⁷ and (2) preventing adversaries from accessing alternative supply chains, stealing IP, or developing comparable AI products.³⁵⁸ The former requires the United States to negotiate plurilateral agreements, which is generally feasible.³⁵⁹ The latter is difficult to execute,

354. See discussion *supra* Section III.D.

355. See discussion *supra* Section III.D.

356. *AI for GIS: Unlocking New Possibilities in Geospatial Analysis*, PRIUS INTELLI (Sep. 8, 2023), <https://priusintelli.com/ai-for-gis-unlocking-new-possibilities-in-geospatial-analysis> [https://perma.cc/UD38-3L3H].

357. See discussion *supra* Sections IV.A.1, IV.A.2.

358. See Shivakumar et al., *supra* note 64.

359. See Peter L. Flanagan, Kimberly A. Strosnider, Peter Lichtenbaum, Eric Carlson, Stephen Rademaker, Corinne A. Goldstein, Eric Sandberg-Zakian, Stephen C. Bartenstein, Joshua N. Williams, A. Seth Atkisson & Lisa Ann Johnson, *U.S. Implements Plurilateral Export Controls Framework and Additional Controls on Semiconductor, Quantum, and Additive Manufacturing Items*, COVINGTON & BURLING (Sep. 9, 2024), <https://www.cov.com/en/news-and-insights/insights/2024/09/us-implements-plurilateral-export-controls-framework-and-additional-controls> [https://perma.cc/M9TH-5934].

especially for intangible strings of software code that can be copied and redistributed.³⁶⁰

If these two factors weigh against export controls—i.e., allies are unwilling to comply with catch-all controls and FDPR, or competitors have a high likelihood of innovating around the control, or otherwise circumventing the control via the black market—the United States should consider whether the export control will affect U.S. market share.³⁶¹ If the control affects market share, the second and third order effects of lost market share might be unreasonably detrimental to U.S. innovation and R&D.³⁶² Where export controls are unlikely to be effective and may even prove to be dangerous—typically because the controlled item has become widely available—the United States should reverse course and seek to dominate the market for that product. In this situation, export controls are no longer preventing proliferation—it has happened. When nonproliferation is no longer a balancing consideration, then market dominance is the only remaining option.³⁶³ Market clout, used as leverage in economic statecraft, becomes the last line of defense.³⁶⁴ Here, the United States should seek to control the availability of the product, not by preventing sales, but by encouraging sales, dominating the market, and then controlling those products that enter the market.

For AI software products, regulators should consider additional factors, such as the extent to which closed-source, proprietary AI can be replicated with open-source options.³⁶⁵ Controls should also consider human capital in areas that conduct AI research, for example, the percentage of AI engineers who are dual-citizens or on work visas, who may be considered “deemed exports.”³⁶⁶ If, on balance, these considerations weigh against stricter list-based controls, the government should redirect its focus on relationship building between AI companies and the Department of Defense, focusing on deterrence—via economic statecraft—over nonproliferation.

If the United States chooses to pursue a short-term export control on a particular item to stem adversary innovation while creating domestic “breathing room,” it must couple these controls with an achievable, benchmark-oriented domestic innovation strategy that revitalizes U.S. productivity in critical areas.³⁶⁷ For example, the CHIPS and Science Act

360. See discussion *supra* Sections II.A.4, IV.A.2a).

361. See Shivakumar et al., *supra* note 64.

362. See discussion *supra* Sections IV.A.1, IV.A.2.

363. See discussion *supra* Section III.B.

364. See Chivvis & Kapstein, *supra* note 176.

365. See discussion *supra* Section IV.A.2.

366. See discussion *supra* Section IV.A.2; 15 C.F.R. § 734.12.

367. See Schmidt, *supra* note 297, at 296.

complemented the October 2022 Semiconductor Controls to fund U.S.-based semiconductor manufacturing.³⁶⁸ It remains to be seen whether the CHIPS Act will prove effective; nevertheless, other AI export controls should have similar push-pull levers. Because export controls are often a double-edged sword, they must be tailored for specific outcomes.³⁶⁹ Any attempts to restrict foreign development, at the expense of U.S. companies, should include equally tailored R&D incentive structures to catalyze domestic military and economic capacities.³⁷⁰ In other words, using export controls to stall overseas AI development must have the effect of a well-placed timeout used to call a game-winning play. Failure to adequately leverage the temporary pause created by export controls will only prolong domestic mediocrity, while previously successful U.S. companies lose market share.³⁷¹

In the long term, U.S. export controls and sanctions are unlikely to cripple Chinese innovation and may, in fact, accelerate it.³⁷² Self-imposed trade embargos create opportunities for Chinese market expansion.³⁷³ When American export controls inadvertently accelerate Chinese innovation in disputed fields, they not only trigger deeper geopolitical tensions but also further decouple the two nations' economies.³⁷⁴ Successful Chinese innovations could escalate the ongoing AI race by reducing both countries' economic bargaining leverage.³⁷⁵ This may push the United States and China toward militarized, rather than economic, use of force to settle conflict.³⁷⁶ Regardless of which country started the cycle of economic decoupling and who is more at fault, U.S. policymakers must consider whether export controls drive both countries closer to heightened conflict.

C. REGULATORS SHOULD CONTINUE TO CONSIDER AI EXPORT CONTROLS UNDER ECRA

Even though the U.S. export control regime has its share of shortfalls, policymakers have struggled to find better alternatives. Historically, export law

368. See Kannan & Feldgoise, *supra* note 252.

369. See discussion *supra* Section IV.A.

370. See Cindy Levy, Matt Watters, Shubham Singhal, Bryce Bittner, Isabella Bennett & Doron Hindin, *Restricted: How Export Controls Are Reshaping Markets*, MCKINSEY & CO. (Apr. 3, 2025), <https://www.mckinsey.com/capabilities/geopolitics/our-insights/restricted-how-export-controls-are-reshaping-markets> [<https://perma.cc/2DYY-MQLQ>]; Badlam et al., *supra* note 252.

371. See discussion *supra* Section IV.A.1c).

372. See discussion *supra* Section IV.A.1.

373. See discussion *supra* Section IV.A.1.

374. BATEMAN, *supra* note 18, at 50–52.

375. *Id.*

376. *Id.* at 57–60.

has managed great power relationships by using ex ante nonproliferation principles to complement military deterrence.³⁷⁷ However, proactive and ex ante controls are speculative, unrealistic, and can cause outsized economic harm.³⁷⁸ Reactive, ex post controls arrive too late, after disaster has struck.³⁷⁹ Dual-use technologies do not fit cleanly under traditional nonproliferation concepts because they carry economic consequences that preclude harsh nonproliferation measures; simultaneously, dual-use technologies have destructive wartime applications.³⁸⁰

Dual-use technologies must account not only for the militaristic elements in a country's national security posture but also for the role economic statecraft plays in regional stability.³⁸¹ ECRA expanded upon previous export laws, increasing government control of commercial products for national security reasons.³⁸² However, ECRA is neither fully military nor fully commercial.³⁸³ Instead, ECRA balances economic and military nonproliferation factors, requiring policymakers to continuously weigh the effectiveness and validity of export decisions.³⁸⁴ This tricky middle ground between "avoiding protectionism and compromising national security"³⁸⁵ means that ECRA must choose the lesser evil while appeasing no one.

Export controls, in some form or another, must exist to provide centralized frameworks that curtail risky, profit-driven business practices. ECRA, EAR, and other parts of the U.S. export regime create a framework under which businesses can align their common export practices and avoid ambiguity.³⁸⁶ Catch-all controls, although painful for companies and foreign allies alike, are decentralizing controls that shift enforcement responsibilities to companies, by providing a framework under which companies must understand their market and self-police.³⁸⁷ Catch-all controls allow the

377. Hosuk Lee-Makiyama & Badri Narayanan Gopalakrishnan, *Economic Costs of Ex Ante Regulations*, EUR. CTR. FOR INT'L. POL. ECON. (Oct. 2020), <https://ecipe.org/publications/ex-ante/> [<https://perma.cc/26GA-JQQ2>].

378. See discussion *supra* Sections II.B, IV.A.

379. CFI Team, *Ex-Ante vs. Ex-Post*, CORP. FIN. INST., <https://corporatefinanceinstitute.com/resources/equities/ex-ante-vs-ex-post/> [<https://perma.cc/VW2L-6Q58>] (last visited Feb. 22, 2025).

380. See discussion *supra* Sections IV.A.1, IV.A.2, IV.B.

381. See discussion *supra* Sections III.B, III.C.

382. See discussion *supra* Section III.

383. *Id.*

384. *Id.*

385. Maria Shagina, *The Role of Export Controls in Managing Emerging Technology*, in *THE IMPLICATIONS OF EMERGING TECHNOLOGIES IN THE EURO-ATLANTIC SPACE* 57, 58 (Julia Berghofer et al. eds., 2023).

386. See discussion *supra* Section III.

387. See discussion *supra* Section III.D.

government to provide a centralized command option while deferring to companies' decentralized control.³⁸⁸ Because evolving technologies are difficult to capture on control lists, controls that regulate an activity, rather than a product, are better for AI, which often changes form and function.³⁸⁹

Even though ECRA's balancing test currently shows that most AI should not be expressly regulated, regulators should continue considering AI controls under ECRA's framework, particularly for dangerous or destabilizing commercial AI. ECRA's limitations stem not from shortfalls in the law but from uncertainties in AI.³⁹⁰ On a case-by-case basis, with deference to ECRA's balancing factors, narrowly crafted AI regulations may not only be reasonable, but also justified. Conversely, in many cases, existing government authorities sufficiently address AI risks, and examining existing laws can save time, reduce costs, and avert regulatory overreach.³⁹¹ Regulations not on AI itself, but on adjacent technology might bypass broad AI regulations while still achieving the same objectives.

V. CONCLUSION

The United States currently leads the world in AI innovation because it has some of the best technical talent, a good reputation in global markets, and a flourishing and decentralized open-source software ecosystem that fosters experimentation. However, export controls risk driving away domestic talent, preventing international research-sharing, and damaging revenue streams that fuel the United States' R&D investment. ECRA authorizes broad and far-reaching controls that fully encompass AI, but these controls are subject to balancing factors that consider potential export harms. Based on these considerations, BIS has enacted AI regulations sparingly. Future AI regulations should continue to balance potential economic and military risks.

Looming in the background is the great power competition between the United States and China. Focused decoupling in certain sectors may reduce unacceptable vulnerabilities, curb IP theft, and limit the development of unconstrained and destructive military capabilities.³⁹² Extensive regulations, however, can harm U.S. development while further deepening tensions,

388. See Clint Hinote, *Centralized Control and Decentralized Execution: A Catchphrase in Crisis?*, AIR FORCE RSCH. INST. 1, 13–18 (Mar. 2009), https://media.defense.gov/2017/Jun/19/2001764937/-1/-1/0/AP_0006_HINOTE_CENTRALIZED_CONTROL_DECENTRALIZED_EXECUTION.PDF [<https://perma.cc/M9P5-2VY4>].

389. See discussion *supra* Section III.D.2.

390. See discussion *supra* Section IV.A.

391. Weinstein & Wolf, *supra* note 184.

392. Schmidt, *supra* note 297, at 296.

drawing both countries toward a near-peer conflict between two highly technical militaries. Failure to correctly navigate these controls in either direction could tip the international community into a global conflict of catastrophic proportions.

HYTER-RITORIALITY: THE PROPER EXTRATERRITORIAL SCOPE OF THE DEFEND TRADE SECRETS ACT

Ben Clifner[†]

ABSTRACT

In *Motorola Solutions v. Hytera Communications Corp.*, the Seventh Circuit held that a single “act in furtherance” of trade secret misappropriation in the United States exposes a misappropriator to liability for its worldwide conduct under the 2016 Defend Trade Secrets Act (DTSA)—even if the extraterritorial damages do not stem from the domestic act. This Note argues that the Seventh Circuit arrived at this result by misconstruing the statute and assigning identical meaning to two different terms: “offense” and “misappropriation.” Interpreting the term “offense” to mean improper acquisition of trade secrets properly limits the extraterritorial application of the DTSA. Beyond a textual error, the Seventh Circuit’s sweeping extraterritorial application of the DTSA also contravenes Congressional intent in enacting the statute. The legislative history of the DTSA presents a wealth of evidence that Congress understood the importance of extraterritorial protection for trade secrets but intended this protection to be much more limited in scope than what the Seventh Circuit’s holding established.

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I. INTRODUCTION

Imagine an Italian corporation illicitly copying trade secret files from a Spanish competitor’s server in France, manufacturing products embodying the misappropriated trade secrets in Germany, and selling 60 percent of those products in the United Kingdom and the remaining 40 percent across other European markets. Ordinarily, a case involving conduct spanning multiple jurisdictions could raise complex legal questions—even for an experienced transnational litigator—about which nation’s laws would protect the trade secret owner and which nation’s courts would be amenable to hearing the dispute. Making the wrong choice about where to file a lawsuit or even waiting too long could result in the plaintiff losing out on some, most, or even all recoverable damages. If there were a single forum where that Spanish trade secret owner could recover for all its European losses, that would be the obvious choice. However, the Italian corporation’s widely distributed conduct makes finding such a forum difficult, if one even exists. Yet, under current U.S. trade secret law, if the misappropriator also sold some misappropriated products in the United States, the Spanish trade secret owner could recover worldwide damages in American courts under American law. The owner could even, potentially, recover worldwide damages if the misappropriator failed to make any *sales* in the United States, but still marketed its products at U.S. trade

shows. In fact, they could *still* recover worldwide damages if the misappropriator merely registered for a trade show, even if it did not actually participate.

In *Motorola Solutions. v. Hytera Communications Corp.*, the Seventh Circuit held that the 2016 Defend Trade Secrets Act (DTSA) “does not require a completed act of misappropriation, nor does it impose a specific causation requirement” to impose extraterritorial liability.¹ The ruling in *Hytera* relied on § 1837(2) of Title 18,² which provides that Chapter 90—where the DTSA is codified—applies to conduct outside the United States if “an act in furtherance of the offense [is] committed in the United States.”³ This language comes from the Economic Espionage Act of 1996 (EEA), and, for decades, commentators have suggested that § 1837(2) could impose extraterritorial liability for acts as inconsequential as visiting websites or using email services hosted on servers located in America.⁴

Hytera’s holding could impose global liability under American law if a foreign misappropriator so much as sends an email⁵ or places a phone call⁶ that touches the United States. If trade secrets protected under the DTSA are to align with other intellectual property (IP) rights, extraterritoriality under the DTSA should bear some resemblance to principles governing other federal IP regimes. Copyright, patent, and trademark laws are territorially limited and require a strong nexus between foreign and domestic conduct to impose extraterritorial liability.⁷ The Seventh Circuit’s decision in *Hytera* held that the “offense” required to invoke extraterritorial protection under § 1837(2) “in the context of the DTSA private cause of action, is the misappropriation.”⁸ However “offense” and “misappropriation” are distinct terms and should not be treated interchangeably. This Note argues that the text of the statute supports a narrower reading: “offense” should refer only to the improper

1. *Motorola Sols., Inc. v. Hytera Commc’ns Corp. Ltd. (Hytera II)*, 108 F.4th 458 (7th Cir. 2024), *reh’g dismissed*, No. 22-2370, 2024 WL 4416886 (7th Cir. Oct. 4, 2024).

2. *Hytera II*, 108 F.4th at 486.

3. 18 U.S.C. § 1837(2).

4. See Robin J. Effron, *Secrets and Spies: Extraterritorial Application of the Economic Espionage Act and the Trips Agreement*, 78 N.Y.U. L. REV. 1475, 1513 (2003) (presenting a hypothetical where internet activity connected to servers in America can support prosecution for extraterritorial conduct under the EEA).

5. See *id.*

6. See *United States v. Stewart*, 878 F.2d 256 (8th Cir. 1989) (holding that a phone call, even routed through a jurisdiction, constitutes an act in furtherance committed within that jurisdiction).

7. See *infra* Section II.B.2.

8. *Hytera II*, 108 F.4th at 483 (quoting *Motorola Sols., Inc. v. Hytera Commc’ns Corp. (Hytera I)*, 436 F. Supp. 3d 1150, 1163 (N.D. Ill. 2020), *aff’d*, 108 F.4th 458 (7th Cir. 2024)).

acquisition of trade secrets. This narrower reading—imposing civil liability for extraterritorial conduct only when a misappropriator commits an act in furtherance of the acquisition of trade secrets in the United States—better aligns with Congressional intent as reflected by the statute’s legislative history. By confining the DTSA’s scope to trade secret theft occurring in the United States, the statute can still protect the role and value of trade secrets in the American economy while also respecting the territorial limits of U.S. law and preventing American courts from becoming venues for foreign disputes.

Part II of this Note provides the necessary background information to understand the significant expansion of trade secret law under the Seventh Circuit’s holding in *Hytera*. Part III discusses the facts of *Hytera*, the reasoning the district court and Seventh Circuit used in determining the extraterritorial scope of the DTSA, the arguments *Hytera* presented in its petition for certiorari, and the consequences of the Seventh Circuit’s holding. Part IV argues that courts should interpret the DTSA with a much more limited extraterritorial application than the Seventh Circuit’s holding in *Hytera* condones.

II. LEGAL BACKGROUND

The Seventh Circuit’s ruling in *Hytera* dramatically expands extraterritorial liability under American trade secret law—this Part provides the necessary context to appreciate its overbreadth. Section II.A provides a brief historical overview of trade secret protection in the United States. Section II.B discusses the extraterritorial application of American law. Section II.C considers the breadth and flexibility of the “act in furtherance” concept as derived from criminal conspiracy law.

A. A BRIEF HISTORY OF TRADE SECRET PROTECTION IN THE UNITED STATES UNDER STATE AND FEDERAL LAW

Before the passage of the DTSA, trade secret protection in the United States lacked uniformity.⁹ The EEA made trade secret theft a federal crime, but only state law provided a civil remedy for trade secret owners.¹⁰ Congress understood the importance of a federal civil remedy when drafting the EEA, but believed the “proposal needed to be vetted on its own terms,” rather than hastily added to a criminal statute.¹¹ After passing the EEA, however, Congress

9. See H.R. REP. NO. 114-529, at 4 (2016).

10. See generally Economic Espionage Act of 1996, Pub. L. No. 104-294 (the EEA, imposing criminal penalties in several sections, and only an injunction as a civil remedy).

11. *Trade Secrets: Promoting and Protecting American Innovation, Competitiveness and Market Access in Foreign Markets: Hearing Before the Subcomm. on Cts., Intell. Prop., and the Internet of the H.*

shifted its focus to other pressing issues and did not return to the creation of a federal civil remedy for trade secret misappropriation.¹² In the absence of a unified federal trade secret law, forty-nine states adopted the Uniform Trade Secrets Act (UTSA) to standardize trade secret protections.¹³ While the UTSA aimed to provide uniform trade secret protection across states,¹⁴ states were free to adopt, adapt, or amend the UTSA as they desired, undermining its goal of nationwide uniformity.¹⁵ The DTSA was meant to address this deficiency by providing a federal remedy for trade secret misappropriation applicable in every state.¹⁶ To that end, Congress enacted the DTSA as an amendment to Chapter 90 of Title 18, United States Code, originally the EEA.¹⁷

18 U.S.C. § 1836 created the long-awaited federal civil remedy for trade secret owners, allowing courts to grant injunctions to prevent misappropriation and award damages to plaintiffs for harm caused by misappropriation.¹⁸ Section 1839 spells out the scope of the trade secret rights, using definitions for “trade secret” and “misappropriation” that are “substantively similar” to those found in the UTSA.¹⁹ Section 1839(3) defines the term “trade secret” broadly, covering almost any information the owner keeps secret as long as the owner can derive value from its continued secrecy.²⁰ “Misappropriation” as defined by § 1839(5) means:

(A) acquisition of a trade secret of another by a person who knows or has reason to know that the trade secret was acquired by improper means; or

Comm. on the Judiciary, 113th Cong. 8 (2014) [hereinafter *Hearing Before the House Judiciary Committee*].

12. *Id.*

13. MELVIN F. JAGER & BRAD LANE, *TRADE SECRETS LAW* § 3:29 (2024). As of November 2025, New York is the only state that has not adopted the UTSA.

14. *Why States Should Adopt the UTSA*, UNIF. L. COMM'N, <https://www.uniformlaws.org/HigherLogic/System/DownloadDocumentFile.ashx?DocumentFileKey=f0fd9607-5912-9945-85e2-7cea5015447d&forceDialog=0> [https://perma.cc/XLF7-UGT5] (last visited May 4, 2025).

15. *See, e.g.*, R. Mark Halligan, *Protection of U.S. Trade Secret Assets: Critical Amendments to the Economic Espionage Act of 1996*, 7 J. MARSHALL REV. INTELL. PROP. L. 656, 670 (2008).

16. *See infra* Section IV.C.2.a.

17. *See* Defend Trade Secrets Act of 2016, Pub. L. No. 114-153.

18. 18 U.S.C. § 1836(b)(3).

19. Danielle A. Duszczyszyn, Ph.D & Daniel F. Roland, *Three Years Later: How the Defend Trade Secrets Act Complicated the Law Instead of Making It More Uniform*, FINNEGAN, <https://www.finnegan.com/en/insights/articles/three-years-later-how-the-defend-trade-secrets-act-complicated-the-law-instead-of-making-it-more-uniform.html> [https://perma.cc/B83K-QNJT] (last visited Dec. 20, 2024).

20. 18 U.S.C. § 1839(3).

(B) disclosure or use of a trade secret of another without express or implied consent.²¹

The DTSA does not define the “use” of a trade secret. However, courts interpreting state laws modeled on the UTSA have relied on the Restatement of Unfair Competition, which asserts that “use” covers a broad range of conduct and includes “any exploitation of the trade secret” that is likely to harm the trade secret owner or enrich the misappropriator.²² The Restatement (Third) of Unfair Competition explicitly names certain conduct as uses of trade secrets:

[M]arketing goods that embody the trade secret, employing the trade secret in manufacturing or production, relying on the trade secret to assist or accelerate research or development, or soliciting customers through the use of information that is a trade secret (see § 42, Comment f) all constitute “use.”²³

A misappropriator necessarily acquires trade secret information by improper means,²⁴ meaning that any action taken with that information is also improper. This expansive definition of “use” strengthens trade secret protection by imposing liability on misappropriators for anything they do with information they should never have had in the first place.

In drafting the DTSA, Congress sought to modernize trade secret protection given the frequency of trade secret theft occurring “across state and international boundaries.”²⁵ According to the International Trade Commission report *China: Effects of Intellectual Property Infringement and Indigenous Innovation Policies on the U.S. Economy*, U.S. businesses lost an estimated \$1.1 billion due to Chinese trade secret misappropriation in 2009 alone.²⁶ Congress enacted the DTSA to uniformly protect American trade secret owners, but they took special care to highlight the threat of foreign misappropriation, stating:

It is the sense of Congress that—

- (1) trade secret theft occurs in the United States and around the world;

21. 18 U.S.C. § 1839(5).

22. RESTATEMENT (THIRD) OF UNFAIR COMPETITION § 40 cmt. c. For the proposition that some state trade secret laws derived their definition of “use” from this Restatement, see *Hytera I*, 436 F. Supp. 3d at 1164.

23. RESTATEMENT § 40 cmt. c.

24. See 18 U.S.C. § 1839(3).

25. *Hearing Before the House Judiciary Committee*, *supra* note 11, at 38.

26. *China: Effects of Intellectual Property Infringement and Indigenous Innovation Policies on the U.S. Economy*, Inv. No. 332-519, USITC Pub. 4226 (May 2011) (Final).

- (2) trade secret theft, wherever it occurs, harms the companies that own the trade secrets and the employees of the companies.²⁷

The scope of remedies available under the DTSA for trade secret misappropriation occurring worldwide was at issue in *Hytera*. Title 18 expressly covers certain conduct outside of the United States—18 U.S.C. § 1837 provides that:

This chapter also applies to conduct occurring outside the United States if—

...

- (2) an act in furtherance of the offense was committed in the United States.²⁸

This extraterritoriality provision was originally enacted with the EEA²⁹ and left unamended by the DTSA.³⁰ The statute does not, however, expressly define the terms “act in furtherance” or “offense,” leaving the question of the proper extraterritorial bounds of the DTSA up to interpretation by the courts.³¹

B. THE PRESUMPTION AGAINST EXTRATERRITORIALITY URGES RESTRAINT IN APPLYING UNITED STATES LAW TO CONDUCT IN FOREIGN COUNTRIES

Section IV.B.2.a of this Note argues that the DTSA was designed to provide trade secrets the same level of legal protection afforded to copyrights, patents, and trademarks. Understanding where the DTSA fits into the federal intellectual property regime requires an understanding of how other intellectual property laws address domestic and extraterritorial infringement. Section II.B.1 covers the Supreme Court’s jurisprudence on the presumption against extraterritoriality in American law. Section II.B.2 discusses how this presumption is applied to copyright, patent, and trademark law.

1. *The Presumption as a Canon of Construction*

Extraterritoriality refers to the application of a nation’s law to conduct occurring outside its own borders.³² The U.S. Supreme Court has long applied

27. Defend Trade Secrets Act of 2016, Pub. L. No. 114-153, § 5.

28. 18 U.S.C. § 1837.

29. Economic Espionage Act of 1996, Pub. L. No. 104-294, § 1837.

30. *See* Defend Trade Secrets Act of 2016, Pub. L. No. 114-153.

31. *See* 18 U.S.C. § 1837.

32. William S. Dodge, *A Primer on Extraterritoriality*, TRANSNAT’L LITIG. BLOG, <https://tblog.org/a-primer-on-extraterritoriality/> [<https://perma.cc/393T-XSGB>] (last visited Dec. 20, 2024).

a presumption against the extraterritorial application of American law³³ on the principle that “United States law governs domestically but does not rule the world.”³⁴ This does not mean that Congress lacks the power to enact legislation that applies extraterritorially. In fact, Congress has the power to extend U.S. laws beyond domestic borders.³⁵ The Restatement (Fourth) of Foreign Relations Law explains that nations may enact laws with extraterritorial effect if there is a “genuine connection” between the nation and the conduct implicated.³⁶ The presumption against extraterritoriality is simply a canon of statutory construction; it urges courts to ask not whether Congress has the *power* to give a statute extraterritorial effect, but rather whether it had the *intent* to do so.³⁷ While courts have historically proceeded with caution in extending U.S. law to foreign jurisdictions, they have lacked a single test to apply across different areas of law—until recently.³⁸

In a series of four decisions, the Supreme Court has attempted to create a standardized extraterritoriality framework.³⁹ The first two cases, *Morrison v. National Australia Bank*⁴⁰ and *Kiobel v. Royal Dutch Petroleum Co.*,⁴¹ marked a shift toward a “focus” test for determining whether a statute applies extraterritorially, but they did not establish a definitive rule for other cases.⁴² In *RJR Nabisco v. European Community*, the Supreme Court formulated a two-step test for extraterritoriality.⁴³ In step one, the presumption against extraterritoriality can be rebutted if the language in the statute “gives a clear, affirmative indication that it applies extraterritorially.”⁴⁴ If a statute fails step one, the court then looks to step two, where it “determine[s] whether the case

33. See generally William S. Dodge, *The New Presumption Against Extraterritoriality*, 133 HARV. L. REV. 1582 (2020).

34. *Microsoft Corp. v. AT&T Corp.*, 550 U.S. 437, 454 (2007).

35. *Steele v. Bulova Watch Co.*, 344 U.S. 280, 282 (1952) (“Congress in prescribing standards of conduct for American citizens may project the impact of its laws beyond the territorial boundaries of the United States.”).

36. RESTATEMENT (FOURTH) OF FOREIGN RELS. L. § 407.

37. See *Morrison v. Nat’l Austl. Bank Ltd.*, 561 U.S. 247, 255 (2010) (“This principle represents a canon of construction, or a presumption about a statute’s meaning, rather than a limit upon Congress’s power to legislate.”).

38. See Dodge, *supra* note 33, at 1585–86.

39. See Timothy R. Holbrook, *Is There a New Extraterritoriality in Intellectual Property?*, 44 COLUM. J.L. & ARTS 457, 479–84 (2021).

40. *Morrison*, 561 U.S. at 247.

41. *Kiobel v. Royal Dutch Petroleum Co.*, 569 U.S. 108 (2013).

42. Holbrook, *supra* note 39, at 481.

43. Dodge, *supra* note 33, at 1603; see *RJR Nabisco v. Eur. Cmty.*, 579 U.S. 325 (2016).

44. *RJR Nabisco*, 579 U.S. at 337 (2016).

involves a domestic application of the statute . . . by looking to the statute's 'focus.'"⁴⁵

In *WesternGeco LLC v. ION Geophysical Corp.*, the fourth and final case in the series, the Court for the first time reached the second step of the *RJR Nabisco* test and applied it to patent statutes.⁴⁶ There, defendant ION Geophysical Corp. ("ION") manufactured the components of plaintiff WesternGeco LLC's ("WesternGeco") patented system in the United States, before shipping them abroad for assembly.⁴⁷ WesternGeco sued to recover foreign lost profits under 35 U.S.C. § 271(f), but the Federal Circuit reasoned that § 271(f) did not apply extraterritorially.⁴⁸ After granting certiorari, the Court held that the case presented a permissible domestic application of the Patent Act.⁴⁹ The trial court examined damages under the general patent damages statute, 35 U.S.C. § 284, which provides patent owners compensation for infringement but does not itself define patent infringement.⁵⁰ The Court applied the *RJR Nabisco* test and determined the "focus" of § 284 was "the infringement," as defined by 35 U.S.C. § 271(f).⁵¹ Section 271(f) defines infringement as the exportation of uncombined components of patented devices "in such manner as to actively induce the combination of such components outside of the United States."⁵² The Court held that the recovery of foreign lost profits was a permissible domestic application of § 284, attaching liability to the domestic act of infringement defined by § 271(f).⁵³ Because § 271(f) defined infringement as the domestic act of exportation, the Court found the defendant liable for exportation and measured its liability by its foreign profits.⁵⁴

2. *Application of the Presumption Against Extraterritoriality to Intellectual Property Law Requires a Strong Connection to Domestic Activity to Impose Liability for Extraterritorial Conduct*

The presumption against extraterritoriality, as established in *RJR Nabisco*, applies across all substantive areas of U.S. law. This Note, however, focuses on its application to intellectual property law and the differing extraterritorial

45. *Id.*

46. *WesternGeco LLC v. ION Geophysical Corp.*, 585 U.S. 407 (2018).

47. *Id.*

48. *Id.*

49. *Id.*

50. *Id.* at 408.

51. *Id.* at 414–15.

52. 35 U.S.C. § 271(f)(1).

53. *WesternGeco*, 587 U.S. at 415–16.

54. *Id.* at 416.

scope of each intellectual property regime. Section II.B.2.a examines extraterritoriality in copyright law. Section II.B.2.b examines extraterritoriality in patent law. Section II.B.2.c examines extraterritoriality in trademark law.

a) Copyright's Predicate Act Doctrine Requires Domestic Infringement to Impose Extraterritorial Liability

Extraterritoriality in copyright law follows the “predicate act” doctrine, which allows a copyright holder to recover damages for foreign infringement only if the damage stems from a completed act of infringement committed within the United States.⁵⁵ In 1939, the Second Circuit created the predicate act doctrine and awarded damages for foreign screenings of a movie because the infringer had copied the film in the United States and the foreign damages necessarily stemmed from that domestic act of copying.⁵⁶ The predicate act doctrine likely survives the *RJR Nabisco* test, but few courts have rigorously applied the test.⁵⁷ The Seventh Circuit, in *Hytera II*, briefly referenced *RJR Nabisco* while addressing Motorola's copyright infringement claims but ultimately found no domestic act of infringement, devoting little analysis to the doctrine's continued validity.⁵⁸ In *Hytera I*, the district court ruled that the predicate act doctrine survived the Court's tetralogy of extraterritoriality decisions because the doctrine “holds similarities to the Supreme Court's recent analysis in *WesternGeco*” without further explanation.⁵⁹

The D.C. Circuit has used the *RJR Nabisco* test in a few copyright cases, finding that the Copyright Act did not rebut the presumption against extraterritoriality.⁶⁰ The court has accordingly examined which types of border-crossing activities constitute a domestic act of infringement.⁶¹ In *Spanski Enterprises, Inc. v. Telewizja Polska, S.A.*, the court held that although the infringer uploaded the copyrighted work in Poland, users in the United States accessed and viewed the content, creating liability for copyright infringement in the United States.⁶² The D.C. Circuit distinguished *Spanski* in *IMAPizza, LLC v. At Pizza Ltd.*, finding that downloading pictures from U.S. servers to U.K. computers was not U.S. copyright infringement because the legally

55. Holbrook, *supra* note 39, at 470.

56. *Sheldon v. Metro-Goldwyn Pictures Corp.*, 106 F.2d 45, 52 (2d Cir. 1939), *aff'd*, 309 U.S. 390 (1940).

57. Holbrook, *supra* note 39, at 494.

58. *Id.*

59. *Hytera I*, 436 F. Supp. 3d at 1168.

60. *See Spanski Enters., Inc. v. Telewizja Polska, S.A.*, 883 F.3d 904 (D.C. Cir. 2018); *IMAPizza, LLC v. At Pizza Ltd.*, 965 F.3d 871 (D.C. Cir. 2020).

61. *Spanski*, 883 F.3d at 914; *IMAPizza*, 965 F.3d at 877.

62. *Spanski*, 883 F.3d at 914.

defined copying took place where the images became fixed, in the United Kingdom.⁶³ Both cases involved digital downloads of copyrighted content and concluded that infringement occurs in the country where the download took place—not in the country containing the server from which the copyrighted content was accessed.⁶⁴ Conversely, the district court in *Hytera I* found that the predicate act doctrine could apply where copyrighted software was downloaded from a U.S. server to a user in Malaysia, finding the infringing download to occur in the country of the server rather than the user.⁶⁵ While the Seventh Circuit ultimately reversed the district court's finding of domestic copyright infringement, it did so on factual grounds, holding Motorola failed to prove the downloads actually originated from a domestic server.⁶⁶ In fact, the Seventh Circuit expressly stated that U.S. copyright law can reach infringers downloading documents abroad, stating “[i]f a copyright owner hopes to prove infringement based solely on the illicit download of copyrighted material but has stored identical copies of that material in servers abroad, it must be prepared to show that the unauthorized download was made from a U.S.-based server.”⁶⁷ Although the Seventh Circuit did not pass on the question of infringement by domestic users downloading from foreign servers, its conflict with the D.C. Circuit's holding that only the location of the user governs under the predicate act doctrine suggests the courts in *Hytera I* and *Hytera II* may have been overeager in imposing extraterritorial liability.

b) Patent Law Requires a Showing of Domestic Infringement
Causing Extraterritorial Harm to Impose Extraterritorial Liability

Before the Supreme Court formulated the rule of extraterritoriality in *RJR Nabisco*, patent law was highly territorial.⁶⁸ While recent amendments to the Patent Act have expanded its extraterritorial protections,⁶⁹ the Supreme Court has historically held that “infringement of [a patent] right cannot be predicated [on] acts wholly done in a foreign country.”⁷⁰ In *WesternGeco*, as briefly discussed, *supra*, Section II.A, the Supreme Court held that 35 U.S.C. § 271(f) allows for extraterritorial damages because it defines infringement as the domestic manufacture of components to be exported and assembled into a

63. *IMAPIZZA*, 965 F.3d at 877.

64. *See Spanski*, 883 F.3d at 907; *IMAPIZZA*, 965 F.3d at 874.

65. *Hytera I*, 436 F. Supp. 3d at 1168.

66. *Hytera II*, 108 F.4th at 475.

67. *Id.*

68. *See Holbrook*, *supra* note 39, at 472.

69. *See id.*; 35 U.S.C. § 271(f), (g); Timothy R. Holbrook, *Territoriality Waning? Patent Infringement for Offering in the United States to Sell an Invention Abroad*, 37 U.C. DAVIS L. REV. 701, 720–22 (2004).

70. *Dowagiac Mfg. Co. v. Minn. Moline Plow Co.*, 235 U.S. 641, 650 (1915).

patented device.⁷¹ The Court held that damages could be measured by foreign conduct, provided that liability stemmed from a domestic act of infringement.⁷² More recently, however, the Federal Circuit expanded patent extraterritoriality in *Brumfield, Trustee for Ascent Trust v. IBG LLC*, holding that damages for extraterritorial sales are allowed under 35 U.S.C. § 271(a) if a plaintiff can show a domestic act of infringement connected to those foreign sales.⁷³ This is an expansion of extraterritoriality in patent law because § 271(a), unlike § 271(f), does not include the concept of exports in its definition of the term “infringement.”⁷⁴ However, the Federal Circuit cabined its ruling by stressing that “causation is a necessary part” of the patent infringement inquiry.⁷⁵ A plaintiff must prove that extraterritorial damages were actually caused by the domestic infringement to recover any damages.

c) Trademark Requires a Domestic Use in Commerce Before Imposing Extraterritorial Liability

In *Abitron Austria GmbH v. Hetronic International, Inc.*, the Supreme Court resolved a circuit split over the extraterritorial scope of the Lanham Act.⁷⁶ Previously, all circuits applied a test based on *Steele*,⁷⁷ the seminal case on trademark extraterritoriality. The *Steele* test focused on whether the alleged infringement had a “substantial effect” on U.S. commerce, though circuits differed in the exact standards they applied.⁷⁸ In *Abitron*, the Court held that the Lanham Act applies only to domestic “use in commerce,”⁷⁹ but declined to define the “precise contours of that phrase.”⁸⁰ Although the decision left ambiguity regarding where the territorial line should be drawn, it significantly narrowed extraterritoriality in trademark law. *Abitron* makes it more difficult for trademark owners to recover damages for acts of infringement committed abroad, as a “use in commerce” seems more territorially limited than an “effect on commerce.”⁸¹

71. *WesternGeco*, 585 U.S. at 415.

72. *Id.*

73. *Brumfield v. IBG LLC*, 97 F.4th 853, 870–71 (Fed. Cir. 2024).

74. *See* 35 U.S.C. § 271(a), (f).

75. *Brumfield*, 97 F.4th at 877.

76. *Abitron Austria GmbH v. Hetronic Int’l, Inc.*, 600 U.S. 412, 417 (2023).

77. *Steele*, 344 U.S. at 280.

78. *See* Holbrook, *supra* note 39, at 465.

79. *Abitron*, 600 U.S. at 415.

80. *Id.* at 428 n.6.

81. Joyce Liou & Jack William Haisman, *U.S. Supreme Court Eliminates Extraterritorial Applications of the Lanham Act*, MORRISON FOERSTER, <https://www.mofo.com/resources/insights/230706-us-supreme-court-eliminates-extraterritorial-applications-lanham-act> [<https://perma.cc/T8MV-USJ2>] (last visited Nov. 5, 2024).

C. CONSPIRACY LAW: THE “ACT IN FURTHERANCE”

The DTSA’s extraterritoriality provision is derived from § 1837 of the EEA, which requires a domestic “act in furtherance of the offense” before allowing for extraterritorial application of U.S. trade secret law.⁸² While neither the EEA nor the DTSA defines the term “act in furtherance,” the “overt act in furtherance” is a familiar concept in criminal conspiracy law.⁸³ The principles of statutory interpretation suggest that Congress chose this language intentionally to import the same requirements to the domestic hook of the EEA and DTSA.⁸⁴

In criminal conspiracy law, the “act in furtherance” is an umbrella term that captures a wide range of possible acts.⁸⁵ An overt act need not be unlawful, the substantive offense charged, or even an element of the substantive offense to create liability.⁸⁶ Courts have interpreted the term broadly, stating it may be “an act so near the completion of the offense as to constitute an attempt, or an act so remote as not to amount to an attempt; but at least it must be a step towards execution.”⁸⁷ Supreme Court precedent has further clarified that an overt act must “manifest that the conspiracy is at work,” distinguishing the conspiracy from both completed acts and mere ideas not yet put into action.⁸⁸

A small selection of cases illustrates the breadth of the concept and its applications. In *In re Terrorist Bombings of U.S. Embassies in East Africa*, the Second Circuit upheld a conviction for conspiracy to bomb American embassies in Kenya and Tanzania.⁸⁹ The Second Circuit noted that the defendant had committed multiple overt acts in furtherance of this conspiracy, but only specifically mentioned perjury as an overt act sufficient to support the conviction.⁹⁰ With larger conspiracies and criminal organizations, like in the terrorist bombing case, it may be difficult to identify a single “step towards execution,”⁹¹ but much easier to show that perjury, in keeping the plans under wraps, “manifest[s] the conspiracy is at work.”⁹²

82. 18 U.S.C. § 1837(2).

83. *See generally Developments in the Law: Criminal Conspiracy*, 72 HARV. L. REV. 920 (1959).

84. ANTONIN SCALIA & BRYAN A. GARNER, *READING LAW: THE INTERPRETATION OF LEGAL TEXTS* 320 (2012).

85. CHARLES DOYLE, CONG. RSCH. SERV., R41223, *FEDERAL CONSPIRACY LAW: A BRIEF OVERVIEW* (2020).

86. *Id.*

87. *Tillinghast v. Richards*, 225 F. 226, 232 (D.R.I. 1915).

88. *Yates v. United States*, 354 U.S. 298, 334 (1957).

89. *In re Terrorist Bombings of U.S. Embassies in E. Afr.*, 552 F.3d 93 (2d Cir. 2008).

90. *Id.* at 114.

91. *Tillinghast*, 225 F. at 232.

92. *Yates*, 354 U.S. at 334; *see In re Terrorist Bombings*, 552 F.3d at 114.

The act in furtherance can also act as a jurisdictional hook. In *United States v. Stewart*, the Eighth Circuit affirmed a conspiracy charge based on a phone call in furtherance of that conspiracy.⁹³ As part of a drug conspiracy, the defendant in Colorado called a North Dakota phone number, which automatically forwarded the calls to Minnesota.⁹⁴ The court held that venue was proper for the conspiracy charge in North Dakota because even though the calls originated from Colorado and were automatically rerouted to Minnesota, they still constituted acts in furtherance of the conspiracy in North Dakota.⁹⁵

III. MOTOROLA V. HYTERA

Section III.A summarizes the factual and procedural history of the dispute between Motorola and Hytera. Section III.B analyzes the district court's opinion in *Hytera I* to understand how the court found a permissible extraterritorial application of the DTSA. Section III.C analyzes the Seventh Circuit opinion in *Hytera II*, highlighting the portions of the district court's opinion it affirmed and the areas where it expanded its reasoning in response to Hytera's arguments on appeal. Section III.D analyzes the arguments Hytera made in its petition for Supreme Court review.

A. FACTUAL AND PROCEDURAL HISTORY

The dispute between Motorola and Hytera began in the 2000s, during which time Hytera plainly acted in bad faith.⁹⁶ From the 1980s through the 2000s, Motorola developed and patented the standard software for digital mobile radio (DMR) products.⁹⁷ It also developed a high-end line of DMR products, which it protected as trade secrets, to differentiate its offerings from competing products using the same communications standard.⁹⁸ Hytera and Motorola were the two main global competitors in the two-way radio systems market.⁹⁹ Internal Hytera documents from 2006 show that Hytera struggled to develop its own line of high-end DMR products to compete with Motorola.¹⁰⁰ Rather than continuing to invest in its own research and development, Hytera opted to steal Motorola's trade secrets and incorporate them into its competing

93. *Stewart*, 878 F.2d 256 (8th Cir. 1989).

94. *Id.* at 257.

95. *Id.* at 258.

96. *Hytera II*, 108 F.4th at 468.

97. *Id.*

98. *Id.*

99. *Id.* at 469.

100. *Id.*

products.¹⁰¹ In 2007, Hytera’s president and CEO recruited a Motorola Malaysia engineer, offering him stock compensation worth roughly \$2.5 million at Hytera’s IPO.¹⁰² After joining Hytera, this engineer facilitated the hiring of two other Motorola engineers, one of whom secretly began working for Hytera while still employed at Motorola.¹⁰³ Together, these two engineers downloaded more than ten thousand technical documents from Motorola’s servers in Malaysia, including Motorola’s proprietary DMR source code.¹⁰⁴ Hytera copied this source code directly into its own products, even preserving identical coding errors.¹⁰⁵ Between 2010 and 2014, Hytera launched a line of high-end DMR products that were “functionally indistinguishable” from Motorola’s.¹⁰⁶ Hytera continued selling these high-end DMR products globally for years—including in the United States—and regularly attended trade shows in the United States to market its infringing products.¹⁰⁷

In 2017, Motorola filed a lawsuit against Hytera in the Northern District of Illinois under the DTSA and Illinois Trade Secret Act, later amending its complaint to include claims under the Copyright Act as well.¹⁰⁸ Under the DTSA, Motorola sought damages for Hytera’s worldwide sales beginning on May 11, 2016, the effective date of the DTSA.¹⁰⁹ The district court awarded a nine-figure damages award to Motorola under the DTSA, including \$135.8 million in compensatory damages and \$271.6 million in punitive damages.¹¹⁰ On appeal in *Hytera II*, the Seventh Circuit affirmed this award and resoundingly endorsed the district court’s DTSA analysis.¹¹¹ Notably, at least 80 percent of the damages award was based on Hytera’s foreign sales.¹¹² The case marked the first time the Seventh Circuit—or any circuit court—directly addressed the extraterritorial scope of the DTSA.¹¹³ While other courts have previously recognized the DTSA’s extraterritorial reach, they have done so with minimal analysis. For example, in *Amyndas Pharmaceuticals*, the First Circuit noted in dicta that the DTSA, in both its text and legislative history, indicates

101. *Id.*

102. *Id.*

103. *Id.*

104. *Id.*

105. *Id.* at 469–70.

106. *Id.* at 470.

107. *Id.*

108. *Id.*

109. *Id.*

110. *Id.*

111. *See generally id.*

112. Brief for Defendant-Appellant at 41, *Hytera II*, 108 F.4th 458 (Nos. 22-2370, 22-2413), 2022 WL 17217059.

113. *Hytera II*, 108 F.4th at 480.

that “Congress was concerned with the theft of American trade secrets abroad and intended the DTSA to have extraterritorial reach.”¹¹⁴ Likewise, numerous district courts have also decided, without much analysis, that the DTSA applies extraterritorially.¹¹⁵ Hytera petitioned the Supreme Court for certiorari, arguing this extraterritorial application of the DTSA conflicted with Supreme Court precedent interpreting Title 18.¹¹⁶ The Supreme Court denied the petition.¹¹⁷

B. THE DISTRICT COURT FOUND HYTERA WAS LIABLE FOR ITS EXTRATERRITORIAL CONDUCT BECAUSE “OFFENSE” MEANS “MISAPPROPRIATION” UNDER THE DTSA

The Northern District of Illinois, in *Hytera I*, was the first to provide a thorough analysis of the DTSA’s extraterritorial application.¹¹⁸ While other district courts had assumed, without much discussion, that the DTSA applied extraterritorially,¹¹⁹ the district court declined “to simply join the chorus” without its own analysis.¹²⁰ The court examined the text and legislative history of the DTSA to apply the *RJR Nabisco* test for extraterritoriality, ultimately finding that the DTSA overcomes the presumption against extraterritoriality.¹²¹

Proceeding through *RJR Nabisco*’s two-step framework, the district court found language in the statute that explicitly rebutted the presumption against

114. *Amyndas Pharms., S.A. v. Zealand Pharma A/S*, 48 F.4th 18, 35 (1st Cir. 2022).

115. *See, e.g., Luminati Networks Ltd. v. BIScience Inc.*, No. 2:18-CV-00483-JRG, 2019 WL 2084426, at *9–10 (E.D. Tex. May 13, 2019); *Austar Int’l Ltd. v. AustarPharma LLC*, No. CV198356KMMAH, 2019 WL 6339848, at *11 (D.N.J. Nov. 27, 2019); *ProV Int’l Inc. v. Lucca*, No. 8:19-CV-978-T-23AAS, 2019 WL 5578880, at *3 (M.D. Fla. Oct. 29, 2019); *MACOM Tech. Sols. Inc. v. Litrinium, Inc.*, No. SACV19220JVSJDEX, 2019 WL 4282906, at *4 (C.D. Cal. June 3, 2019); *Vendavo, Inc. v. Price f(x) AG*, No. 17-CV-06930-RS, 2018 WL 1456697, at *3 (N.D. Cal. Mar. 23, 2018); *Micron Tech., Inc. v. United Microelectronics Corp.*, No. 17-CV-06932-MMC, 2019 WL 1959487, at *8 (N.D. Cal. May 2, 2019).

116. Petition for Writ of Certiorari at 12, *Hytera Commc’ns Corp. v. Motorola Sols., Inc.*, 2025 WL 581667 (Feb. 24, 2025) (No. 24-725).

117. *Hytera Commc’ns Corp. v. Motorola Sols., Inc.*, No. 24-725, 2025 WL 581667 (Feb. 24, 2025).

118. *Hytera I*, 436 F. Supp. 3d at 1159.

119. *See id.; see also Luminati*, 2019 WL 2084426, at *9–10 (“The DTSA ‘applies to conduct occurring outside the United States if . . . an act in furtherance of the offense was committed in the United States.’ 18 U.S.C. § 1837(2).”); *Austar Int’l Ltd.*, 2019 WL 6339848, at *11 (holding, with limited analysis, that the DTSA applies extraterritorially); *ProV Int’l Inc.*, 2019 WL 5578880, at *3 (same); *MACOM Tech. Sols. Inc.*, 2019 WL 4282906, at *4 (same); *Vendavo, Inc.*, 2018 WL 1456697, at *3 (same); *Micron Tech., Inc.*, 2019 WL 1959487, at *8 (“Micron has a substantial interest in trying the case in the United States, as federal law provides for jurisdiction over misappropriation occurring outside the United States, *see* 18 U.S.C. § 1837.”).

120. *Hytera I*, 436 F. Supp. 3d at 1159.

121. *Id.* at 1157.

extraterritoriality.¹²² The court held that § 1837, enacted with the original EEA in 1996, clearly rebuts the presumption against extraterritoriality where it states that “[t]his chapter also applies to conduct occurring outside the United States.”¹²³ However, the court thought it necessary to devote more effort to the question of whether or not this extraterritoriality also extended to the private right of action created by the DTSA in § 1836.¹²⁴ Because Congress passed the DTSA to create a private right of action for trade secret misappropriation and not just to change an existing judicial interpretation of the EEA, the court felt “the chapter . . . should be read as a cohesive whole.”¹²⁵ The court interpreted Congress’s choice to leave § 1837 intact as an intent to create a private right of action to redress extraterritorial harms.¹²⁶ The court further cited language enacted in the DTSA to show that Congress expressly addressed trade secret theft occurring outside the United States, recognizing both the threat it posed and how it might be prevented in the text of the DTSA.¹²⁷

122. *Id.*

123. *Id.* at 1159.

124. *Id.*

125. *Id.* at 1158.

126. *Id.* at 1159.

127. *Id.* at 1159–60:

Moreover, the actual law passed by Congress, Pub. L. 114-253, includes numerous references to extraterritorial conduct that were absent in the previous versions of the statute. For example, Pub. L. 114-153 states:

It is the sense of Congress that—

- (1) trade secret theft occurs in the United States and around the world;
- (2) trade secret theft, wherever it occurs, harms the companies that own the trade secrets and the employees of the companies;
- (3) chapter 90 of title 18, United States Code (commonly known as the “Economic Espionage Act of 1996”), applies broadly to protect trade secrets from theft;

...

Additionally, Pub. L. 114-153, § 4(b) contains new reporting requirements for the Attorney General, absent in either the original EEA or in an earlier amendment in 2012, requiring the Attorney General prepare reports on a biannual basis about, inter alia:

- (1) The scope and breadth of the theft of the trade secrets of United States companies occurring outside of the United States.
- (2) The extent to which theft of trade secrets occurring outside of the United States is sponsored by foreign governments, foreign instrumentalities, or foreign agents.
- (3) The threat posed by theft of trade secrets occurring outside of the United States.

After establishing that § 1837, in principle, allowed for extraterritorial civil actions under § 1836, the court rejected Hytera's argument that "offense" only applied to criminal violations. Citing *Black's Law Dictionary*, the court determined that the term "offense" sometimes carries a "criminal connotation," but ultimately held that its definition as "a 'violation of the law' . . . encompasses a violation of a civil statute."¹²⁸ The district court then declared that "the misappropriation of a trade secret" constituted an offense under the DTSA, stressing that its conclusion was "clear through the plain language of the statute."¹²⁹

The court then examined Hytera's conduct to see if it had committed a qualifying "act in furtherance" of its offense to impose extraterritorial liability under § 1837 and found that it did.¹³⁰ The parties focused their briefings on the acquisition of the trade secrets as the relevant offense,¹³¹ but the court dismissed their arguments because the acquisition took place before the effective date of the DTSA.¹³² Affirmatively holding that "offense" includes more than just acquisition, the court stressed that misappropriation can also be premised on a "theory of disclosure or use."¹³³ While the DTSA does not define the term "use," the court looked to decisions on state trade secret law imposing liability for "use" and the Restatement (Third) of Unfair Competition to support an interpretation that "any exploitation of the trade secret that is likely to result in injury to the trade secret owner or enrichment to the defendant is a 'use.'"¹³⁴ This includes "marketing goods that embody the trade secret."¹³⁵ The DTSA does not define the term "act in furtherance," but the district court adopted an interpretation from federal conspiracy law.¹³⁶ The court agreed with a Texas district court's holding in *Luminati Networks Ltd. v. BIScience Inc.*,¹³⁷ holding that an "act in furtherance of the offense of trade secret misappropriation . . . must 'manifest that the [offense] is at work.'"¹³⁸ The

(4) The ability and limitations of trade secret owners to prevent the misappropriation of trade secrets outside of the United States, to enforce any judgment against foreign entities for theft of trade secrets, and to prevent imports based on theft of trade secrets overseas.

128. *Id.* at 1162.

129. *Id.* at 1163.

130. *Id.*

131. *Id.*

132. *Id.* at 1163–64.

133. *Id.* at 1164 (internal quotations omitted).

134. RESTATEMENT (THIRD) UNFAIR COMPETITION § 40 cmt. c.

135. *Id.*; *Hytera I*, 436 F. Supp. 3d at 1165.

136. *Id.*

137. *Luminati*, 2019 WL 2084426, at *9.

138. *Id.* at *10 (quoting *Yates*, 354 U.S. at 334).

court determined that Hytera committed a qualifying act in furtherance of its “use” of Motorola’s trade secrets by “advertis[ing], promot[ing], and market[ing] products embodying” those trade secrets “domestically at numerous trade shows.”¹³⁹

C. THE SEVENTH CIRCUIT HELD THE DTSA DOES NOT REQUIRE A SHOWING OF CAUSATION TO IMPOSE EXTRATERRITORIAL LIABILITY

On appeal, the Seventh Circuit fully endorsed the district court’s reasoning and even expanded upon it to address Hytera’s appellate counterarguments. As in the district court proceedings, Hytera again argued that the term “offense” encompassed only criminal violations.¹⁴⁰ On this point, Hytera raised interesting arguments on appeal, but only in the eleventh hour, and thus insufficiently developed its arguments to limit the extraterritorial application of the DTSA.¹⁴¹ In challenging the district court’s construction of the term “offense,” Hytera’s appellate brief emphasized that “Congress did not amend § 1837 or re-define its operative term ‘offense.’ Rather, it used a new term for the conduct prohibited by the DTSA: ‘misappropriation.’”¹⁴² Making a related point, Hytera cited *Kellogg Brown & Root Servs., Inc. v. United States ex rel. Carter*,¹⁴³ a case decided before the enactment of the DTSA, for the proposition that the term “offense,” as used in Title 18, applied only to criminal conduct.¹⁴⁴ Hytera further argued that because Congress used “misappropriation” elsewhere in the DTSA, “the term ‘offense’ in § 1837 can only have been meant to refer to those acts that the Economic Espionage Act made criminal.”¹⁴⁵ Hytera also argued that its “participation [in] U.S. trade shows certainly was not an ‘act in furtherance’ of . . . purely extraterritorial sales,” suggesting that the DTSA’s “act in furtherance” standard should require a showing of causation.¹⁴⁶ Additionally, Hytera made a policy argument that it would be “anomalous” for the DTSA to have such wide extraterritorial reach when other intellectual property regimes do not.¹⁴⁷

The Seventh Circuit dismissed these arguments. The court agreed with the district court’s construction that the “offense, in the context of the DTSA

139. *Hytera I*, 436 F. Supp. 3d at 1165.

140. Brief for Defendant-Appellant, *supra* note 112, at 53.

141. Plaintiffs’ Response to Defendants’ Motion to Preclude Motorola from Relying on Extraterritorial Damages at 1, *Hytera I*, 436 F. Supp. 3d 1150 (No. 17-cv-01973), 2019 WL 7839046.

142. Brief for Defendant-Appellant, *supra* note 112, at 53–54.

143. 575 U.S. 650 (2015).

144. Brief for Defendant-Appellant, *supra* note 112, at 20.

145. *Id.* at 53.

146. *Id.* at 60.

147. *Id.* at 55.

private cause of action, is the misappropriation of a trade secret.”¹⁴⁸ It reached this conclusion based on the plain meaning of “offense,” which “reach[es] both criminal and civil violations.”¹⁴⁹ It then correctly noted that § 1837(2) does not impose a causation requirement through its “act in furtherance” standard.¹⁵⁰ The court drew out the proper bounds of an “act in furtherance” based on its origins in conspiracy law.¹⁵¹ Because the DTSA imposes liability “for any foreign conduct related to ‘the offense,’” the court concluded that the domestic act in furtherance need not directly cause extraterritorial harm to impose liability for extraterritorial conduct.¹⁵² Thus, a single act in furtherance of misappropriation in the United States entitled Motorola to damages from Hytera’s sales worldwide “regardless of where in the world the remainder of Hytera’s illegal conduct occurred.”¹⁵³ While Hytera’s participation in United States trade shows was itself a completed act of misappropriation, the Seventh Circuit made sure to emphasize that “section 1837(2) does not *require* a completed act.”¹⁵⁴ While the common law definition of an act in furtherance implies possible liability for conduct other than completed misappropriation, the Seventh Circuit’s express confirmation here leaves little doubt that the DTSA can impose worldwide liability for conduct only tangentially connected to the United States.¹⁵⁵ The court also dismissed Hytera’s arguments based on *Kellogg*.¹⁵⁶ While the Supreme Court in *Kellogg* held that the term “offense” only referred to criminal violations in Title 18, the Seventh Circuit reasoned that “[t]he Court’s statement that the term was not used that way in [T]itle 18 was a description of [T]itle 18 in 2015, not a sweeping command that the word may never be used in [T]itle 18 to refer to a civil violation.”¹⁵⁷ The court finally disposed with Hytera’s policy argument because the “issue for [the court] is statutory interpretation, not the public policy choices.”¹⁵⁸

D. HYTERA RELIED MORE HEAVILY ON *KELLOGG* IN ITS PETITION TO THE SUPREME COURT

Hytera refreshed familiar arguments against the DTSA’s extraterritoriality in its certiorari petition, but it changed its perspective on *Kellogg* to present a

148. *Hytera II*, 108 F.4th at 483 (quoting *Hytera I*, F. Supp. 3d at 1163).

149. *Id.*

150. *Id.* at 487.

151. *Id.*

152. *Id.*

153. *Id.* at 488.

154. *Id.* at 487 (emphasis added and omitted).

155. *See* Effron, *supra* note 4, at 1513.

156. *Id.* at 485.

157. *Id.* at 485–86.

158. *Id.* at 486

more compelling argument to limit the definition of “offense.”¹⁵⁹ In its petition, Hytera argued that because *Kellogg* was decided before the enactment of the DTSA, Congress’s failure to amend § 1837 incorporated *Kellogg*’s reading of “offense” into the DTSA.¹⁶⁰ Hytera reasoned that Congress did not “silently change[]” the meaning of the term “offense” by leaving § 1837 unamended.¹⁶¹ Specifically, Hytera proposed that when Congress “enacted the DTSA against the backdrop of the one-year-old *Kellogg* decision, Congress had every reason to expect that courts would continue to read ‘offense’ in § 1837 to mean what it (undisputedly) had always meant.”¹⁶² Hytera also pointed to the fact that §§ 3 and 4 of the DTSA explicitly addressed the problem of extraterritorial trade secret theft (with solutions other than extraterritorial liability) to argue that it was improper to read implied extraterritorial application into other sections of the law.¹⁶³

IV. THE PROPER EXTRATERRITORIAL REACH OF THE DTSA

This Part argues that courts should interpret the DTSA with a more limited extraterritorial effect, reading the term “offense” to extend only to trade secret acquisition and not to misappropriation under theories of disclosure or use. Section IV.A considers the negative consequences of the Seventh Circuit’s holding in *Hytera II*. Section IV.B presents a textual argument that a proper construction of § 1837 distinguishes the terms “offense” and “misappropriation” such that the DTSA does not create a remedy for trade secret theft occurring abroad. Section IV.C examines the legislative intent of the DTSA to argue that Congress intended only to remedy extraterritorial injury resulting from domestic trade secret theft.

A. THE RULE OF *HYTERA* IMPOSES EXTRATERRITORIAL LIABILITY DISPROPORTIONATE TO THE DOMESTIC CONDUCT PROVIDING JURISDICTION

The Seventh Circuit’s holding in *Hytera II* expands liability disproportionately to the domestic conduct providing jurisdiction. The court correctly applied the arguments before it, but such an expansive reading of the DTSA creates global liability for conduct minimally connected to the United States—perhaps a single act as innocuous as phone call or email to the United

159. Petition for Writ of Certiorari, *supra* note 116, at 12.

160. *Id.* at 13–14.

161. *Id.*

162. *Id.* at 14.

163. *Id.* at 17.

States.¹⁶⁴ The Seventh Circuit's statement that § 1837(2) does not require a completed act confirms the rule of *Hytera II* may impose worldwide liability for conduct that is not by itself wrongful. This sweeping interpretation also breaks trade secret law from other intellectual property regimes. For example, copyright and patent law require proof that a domestic act of infringement directly caused extraterritorial damage,¹⁶⁵ while trademark law requires a showing of domestic harm through domestic use in commerce.¹⁶⁶ By eliminating any causation inquiry to invoke extraterritoriality under the DTSA, the Seventh Circuit's holding places trade secret protection in a category of its own.

This broad extraterritoriality also lacks meaningful guardrails, potentially making the United States a magnet for international forum-shoppers seeking to litigate foreign trade secret disputes. Some commentators have suggested that personal jurisdiction and *forum non conveniens* doctrines sufficiently mitigate this problem,¹⁶⁷ but this is unconvincing. Because § 1837(2) already requires a domestic act connected to the misappropriation, courts can readily find specific jurisdiction over foreign defendants for their misappropriation, even with minimal U.S. contact.¹⁶⁸ While *forum non conveniens* dismissals may keep some foreign disputes out of American courts, the doctrine's discretionary nature means it is not a reliable or consistent solution for international forum-shopping. Instead, it may simply drive foreign litigants to specific states with plaintiff-friendly courts. The Texas Constitution, for example, requires that “[a]ll courts . . . be open, and every person . . . have remedy by due course of law.”¹⁶⁹ Because *forum non conveniens* is discretionary, it will likely fail to keep some foreign disputes out of American courts, especially where state constitutional provisions favor access to judicial remedies.¹⁷⁰

164. See *Stewart*, 878 F.2d at 258; see also Effron, *supra* note 4, at 1513 (hypothesizing that 18 U.S.C. § 1837(2) might be used to supply jurisdiction over foreign actors for conduct such as using American email services or accessing American websites).

165. See *supra* Sections II.B.2.a, b.

166. See *supra* Section II.B.2.c.

167. See Elizabeth A. Rowe & Giulia C. Fariior, *Revisiting Trade Secret Extraterritoriality*, 25 B.U. J. SCI. & TECH. L. 431, 449–50 (2019).

168. See *Burger King Corp. v. Rudzewicz*, 471 U.S. 462 (1985).

169. TEX. CONST. art. I, § 13.

170. See *Chick Kam Choo v. Exxon Corp.*, 486 U.S. 140, 149 (1988) (proposing that international forum-shopping is okay in state courts, at least where the state court's *forum non conveniens* analysis is “significantly different” than that of federal courts).

B. THE STATUTORY TEXT LIMITS LIABILITY FOR EXTRATERRITORIAL CONDUCT TO CASES OF DOMESTIC ACQUISITION OF TRADE SECRETS

The DTSA's text does not create a remedy for extraterritorial harms resulting from extraterritorial trade secret theft. Section IV.B.1 presents a textual argument that the term "offense" should be construed as referring only to trade secret acquisition, distinguishing it from the general term "misappropriation." Section IV.B.2 explains why textual references to foreign trade secret theft do not support the conclusion that the DTSA provides a remedy for trade secret theft occurring abroad.

1. "Offense" Does Not Mean "Misappropriation" or "Violation of the Law"

The DTSA's language best supports a limited construction of § 1837(2), where the term "offense" means the acquisition of a trade secret, as distinct from "misappropriation," which extends to the acquisition, disclosure, and use of trade secrets. Throughout Chapter 90, Congress differentiates between "offense" and "misappropriation," implying that the two should not be read interchangeably.¹⁷¹ The district court construed "offense" to include any misappropriation because, according to *Black's Law Dictionary*, "an 'offense' . . . is a 'violation of the law.'"¹⁷² This construction, however, cannot stand. Section 1833 of Title 18, both as enacted in the EEA and as amended by the DTSA, refers to neither "offenses" nor "misappropriations," but rather to "violation[s] of law."¹⁷³ Congress chose to use three different terms in different sections of the statute, and it would be improper to read them with overlapping meanings.¹⁷⁴ "Violation of the law" is an umbrella term, but "offense" and "misappropriation" have a narrower scope as used in Title 18.

The term "offense" appears only in §§ 1831, 1832, and 1837 of Title 18.¹⁷⁵ Section 1831 is a criminal provision enacted by the EEA that proscribes only the acquisition of trade secrets and uses the term "offense" to refer only to the acquisition of trade secrets:

171. See SCALIA & GARNER, *supra* note 84, at 170 (on the "presumption of consistent usage" and its corollary that "where the document has used one term in one place, and a materially different term in another, the presumption is that the different term denotes a different idea").

172. *Hytera I*, 436 F. Supp. 3d at 1162.

173. 18 U.S.C. § 1833; see Economic Espionage Act of 1996, Pub. L. No. 104-294, § 1833; Defend Trade Secrets Act of 2016, Pub. L. No. 114-153, § 1833.

174. See SCALIA & GARNER, *supra* note 84, at 170.

175. 18 U.S.C. §§ 1831, 1832, 1837.

(a) In General.—Whoever, intending or knowing that **the offense** will benefit any foreign government, foreign instrumentality, or foreign agent, knowingly—

(1) **steals**, or without authorization **appropriates, takes, carries away**, or conceals, or by fraud, artifice, or deception **obtains a trade secret**;

(2) without authorization **copies, duplicates, sketches, draws, photographs, downloads, uploads, alters, destroys, photocopies, replicates, transmits, delivers, sends, mails, communicates, or conveys a trade secret**;

(3) **receives, buys, or possesses a trade secret**, knowing the same to have been **stolen or appropriated, obtained, or converted** without authorization;

(4) attempts to commit any **offense described in any of paragraphs (1) through (3)**; or

(5) conspires with one or more other persons to commit any **offense described in any of paragraphs (1) through (3)**.¹⁷⁶

Section 1832 is another criminal provision enacted by the EEA that proscribes the same conduct as § 1831 with a different intent requirement. It also uses the term “offense” only in reference to the acquisition of trade secrets:

(a) Whoever, with **intent to convert a trade secret**, that is related to a product or service used in or intended for use in interstate or foreign commerce, to the economic benefit of anyone other than the owner thereof, and intending or knowing that **the offense** will, injure any owner of that trade secret, knowingly—

(1) **steals**, or without authorization **appropriates, takes, carries away**, or conceals, or by fraud, artifice, or deception **obtains such information**;

(2) without authorization **copies, duplicates, sketches, draws, photographs, downloads, uploads, alters, destroys, photocopies, replicates, transmits, delivers, sends, mails, communicates, or conveys such information**;

(3) **receives, buys, or possesses such information**, knowing the same to have been **stolen or appropriated, obtained, or converted** without authorization;

176. 18 U.S.C. § 1831(a)(1)–(5) (emphasis added).

(4) attempts to commit any **offense described in paragraphs (1) through (3)**; or

(5) conspires with one or more other persons to commit any **offense described in paragraphs (1) through (3)**.¹⁷⁷

Title 18 does not expressly define the term “offense” in any section, but §§ 1831 and 1832 are the only provisions that use the term “offense” to describe specific conduct.¹⁷⁸ In other words, the only conduct Congress directly references with the term “offense” in Title 18 is the improper acquisition of trade secrets.¹⁷⁹ By contrast, § 1836, which created the private right of action, authorizes suit and provides remedies for “misappropriation,” not the “offense”:

(b) Private Civil Actions.—

(1) In general.—

An owner of a trade secret that is **misappropriated** may bring a civil action under this subsection

...

(3) Remedies.—In a civil action brought under this subsection with respect to the **misappropriation** of a trade secret, a court may—

(A) grant an injunction—

(i) to prevent any actual or threatened **misappropriation**

...

(B) award—

(i)

(I) damages for actual loss caused by the **misappropriation** of the trade secret; and

(II) damages for any unjust enrichment caused by the **misappropriation** of the trade secret that is not addressed in computing damages for actual loss; or

(ii) in lieu of damages measured by any other methods, the damages caused by the **misappropriation** measured by imposition of liability for a reasonable royalty.¹⁸⁰

177. 18 U.S.C. § 1832(a)(1)–(5) (emphasis added).

178. *See* 18 U.S.C. §§ 1831–39.

179. *See id.*

180. 18 U.S.C. § 1836(b)(1), (3)(A), (B) (emphasis added).

When Congress enacted the DTSA in 2016, it defined “misappropriation” to include the improper acquisition, disclosure, and use of trade secrets,¹⁸¹ but did not amend § 1837 to replace the term “offense” with “misappropriation.”¹⁸² These terms should thus have different meanings. This is not to say that Hytera was right in arguing that “offense” in § 1837 refers exclusively to criminal violations. Its reliance on *Kellogg* in its certiorari petition is misplaced. Hytera seems to rely on a presumption of legislative acquiescence, arguing Congress would have expected courts to continue interpreting “offense” in Title 18 consistently with the *Kellogg* decision.¹⁸³ The Seventh Circuit of course could not address these arguments directly in *Hytera II*, but nonetheless provided a basis that weakened Hytera’s arguments in its certiorari petition. In *Hytera II*, the Seventh Circuit noted that the Supreme Court’s reasoning in *Kellogg* was based, at least in part, on its failure to find any provision in Title 18 that labeled a civil wrong as an “offense.”¹⁸⁴ The court speculated that, had the Supreme Court decided *Kellogg* after the enactment of the DTSA, the statute “would have provided the ‘single provision of that title’” describing a civil wrong as an “offense.”¹⁸⁵ Although Hytera argued in its certiorari petition that, with this holding, the Seventh Circuit concluded that “Congress *silently changed* the meaning of ‘offense,’” this is not so.¹⁸⁶ The Seventh Circuit concluded that the Supreme Court did not use *Kellogg* to issue an authoritative interpretation of the term “offense,” but rather to provide a descriptive account of how it had been used.¹⁸⁷ By enacting for the first time a robust civil remedy in Title 18, Congress changed the usage of the term “offense” and gave it a different scope.

Chapter 90 uses the term “offense” to include both civil and criminal wrongs, but not so broadly as to reach *any* civil or criminal wrongs. Rather, § 1832 describes “offense” using language that contemplates both civil and criminal wrongs, proscribing acquisition “with intent to convert a trade secret.”¹⁸⁸ Although Chapter 90 of Title 18 does not define “conversion,” it is a familiar concept in both criminal and tort law, meaning that § 1832 should carry “the cluster of ideas” attached to conversion.¹⁸⁹ *Black’s Law Dictionary* defines conversion in both tort and criminal law as:

181. 18 U.S.C. § 1839(5).

182. See Defend Trade Secrets Act of 2016, Pub. L. No. 114-153.

183. See Petition for Writ of Certiorari, *supra* note 116, at 14.

184. *Hytera II*, 108 F.4th at 486.

185. *Id.*

186. Petition for Writ of Certiorari, *supra* note 116, at 13–14.

187. *Hytera II*, 108 F.4th at 485–86.

188. 18 U.S.C. § 1832(a).

189. *Morissette v. United States*, 342 U.S. 246, 263 (1952).

The wrongful possession or disposition of another's property as if it were one's own; an act or series of acts of willful interference, without lawful justification, with an item of property in a manner inconsistent with another's right, whereby that other person is deprived of the use and possession of the property.¹⁹⁰

Salmond on the Law of Torts further elaborates on the term, enumerating three ways in which someone can be “guilty of a conversion and liable in an action for trover—(1) by wrongly taking [property], (2) by wrongly detaining it, and (3) by wrongly disposing of it.”¹⁹¹ *Black’s Law Dictionary* defines trover as “[a] common-law action to recover damages for the conversion of personal property, the damages generally being measured by the property’s value.”¹⁹²

Supreme Court precedent on statutory interpretation holds that Congress “presumably kn[ew] and adopt[ed]” this long-established “cluster of ideas” from the common law when it included “intent to convert” in § 1832.¹⁹³ Thus, the “offense” required to invoke extraterritoriality under § 1837(2) can extend to the civil wrong of trade secret misappropriation, but only under a theory of acquisition, akin to tortious conversion. Courts should recognize Congress’s deliberate decision to leave the language of § 1837 unamended and therefore assign materially distinct meanings to the materially different terms “offense” and “misappropriation.”¹⁹⁴ The Supreme Court has repeatedly held that “where Congress includes particular language in one section of a statute but omits it in another section of the same Act, it is generally presumed that Congress acts intentionally and purposely in the disparate inclusion or exclusion.”¹⁹⁵ Had Congress intended the DTSA to apply extraterritorially to *any* act in furtherance of misappropriation—including “acquisition,” “disclosure,” and “use”¹⁹⁶—it could have: (1) amended § 1837(2) to require a domestic “act in furtherance of misappropriation,” or (2) added a definition of “offense” to encompass misappropriation as “disclosure” or “use,” as defined by § 1839.¹⁹⁷ Congress did not make these amendments when it enacted the DTSA, so courts should not infer such a dramatic expansion of extraterritorial reach without sufficient textual evidence.

190. *Conversion*, BLACK’S LAW DICTIONARY (12th ed. 2024).

191. *Id.* (quoting R.F.V. HEUSTON, *Salmond on the Law of Torts* 94 (17th ed. 1977)).

192. *Trover*, BLACK’S LAW DICTIONARY (12th ed. 2024).

193. *Morissette*, 342 U.S. at 263.

194. *See* SCALIA & GARNER, *supra* note 84, at 170.

195. *Russello v. United States*, 464 U.S. 16, 23 (1983) (citing *United States v. Wong Kim Bo*, 472 F.2d 720, 722 (5th Cir. 1972)).

196. 18 U.S.C. § 1839(5).

197. 18 U.S.C. § 1839(5)(B).

The district court in *Hytera I* may have considered the plain meaning of “offense” as a generic “violation of the law” to hold that “offense” and “misappropriation” mean the same thing. This construction, however, is incorrect. It cannot be a proper construction of the statute to ignore completely the choice of Congress to use “offense” in some sections, “violation of the law” in others, and “misappropriation” in others still by assigning the same meaning to each. Assigning the same meaning to both terms contradicts both the “presumption that identical words used in different parts of the same act are intended to have the same meaning,”¹⁹⁸ and its corollary that a “different term denotes a different idea.”¹⁹⁹ Accordingly, the “offense” required by § 1837(2) should be interpreted as the same conduct described by §§ 1831 and 1832: the improper acquisition of a trade secret.²⁰⁰ The district court’s error was not in noting that an offense can be a civil violation, but in failing to consider that Congress intentionally distinguished between “offense” and “misappropriation.”

At most, the potential overlap between these terms suggests that the statute is ambiguous as to what precisely is meant by “offense” in § 1837(2). Courts should thus look to the DTSA’s legislative history for clarification rather than simply collapsing the distinct definitions of “offense,” “violation of the law,” and “misappropriation.” “[C]lear evidence of congressional intent may illuminate ambiguous text,”²⁰¹ and Section IV.C.2 will argue that the DTSA’s legislative history presents clear evidence that Congress intended a much more limited extraterritorial application of the statute than the Seventh Circuit’s holding allows.²⁰²

2. *The Text of the DTSA Does Not Sufficiently Support the Creation of a Remedy for Trade Secret Theft Occurring Abroad*

The district court cited sections of Public Law 114–153 that impose neither civil liability nor criminal penalty to support its conclusion that Congress intended the DTSA to create a remedy for “trade secret theft ‘wherever it occurs.’”²⁰³ However, these sections are better understood as serving a purpose entirely separate from the DTSA’s private right of action. While the text confirms that Congress was concerned about trade secret theft occurring abroad, it does not clearly establish that Congress intended the DTSA to

198. *See* *Atl. Cleaners & Dyers v. United States*, 286 U.S. 427, 433 (1932).

199. SCALIA & GARNER, *supra* note 84, at 170.

200. *See* 18 U.S.C. §§ 1831–32.

201. *Milner v. Dep’t of Navy*, 562 U.S. 562, 572 (2011).

202. *See infra* Section IV.C.2.

203. *Hytera I*, 436 F. Supp. 3d at 1162 (citing *Defend Trade Secrets Act*, Pub. L. No. 114-153).

remedy or prevent such theft in foreign countries. The district court misread the statutory text, mistaking Congress's mere *acknowledgment* of the problem for the creation of a *remedy* addressing it.

To support its interpretation that Congress intended the DTSA to apply extraterritorially, the district court first cited § 5 of Public Law 114–153,²⁰⁴ which states Congress's understanding that:

- (1) trade secret theft occurs in the United States and around the world;
- (2) trade secret theft, wherever it occurs, harms the companies that own the trade secrets and the employees of the companies;
- (3) chapter 90 of title 18, United States Code (commonly known as the “Economic Espionage Act of 1996”), applies broadly to protect trade secrets from theft.²⁰⁵

While this language does show that Congress was aware of the threat posed by foreign trade secret theft when drafting the DTSA, it does not necessarily establish that Congress intended the DTSA to solve this problem. Section IV.C.2, *infra*, will later argue that Congress's purpose in acknowledging foreign trade secret theft was distinct from creating an extraterritorial remedy.²⁰⁶ Accordingly, § 5 should not be read as Congress declaring its intent to combat trade secret theft all around the world. Because § 5 declares the “sense” rather than the intent of Congress, its language is insufficient to overcome Congress's choice to draft § 1837(2) with a domestic acquisition requirement.²⁰⁷

The district court also cited § 4(b) of Public Law 114–153,²⁰⁸ which requires the Attorney General to submit reports about a wide range of issues related to foreign trade secret theft.²⁰⁹ A selection of key topics suggests that Congress did not expect the DTSA to remedy trade secret theft occurring outside the United States:

the Attorney General . . . shall submit . . . a report on the following:

- (1) The scope and breadth of the theft of the trade secrets of United States companies occurring outside of the United States.

. . .

204. *Hytera I*, 436 F. Supp. 3d at 1160.

205. Defend Trade Secrets Act of 2016, Pub. L. No. 114-153, § 5(1)–(3).

206. *See infra* Section IV.C.2.

207. Defend Trade Secrets Act of 2016, Pub. L. No. 114-153, § 5.

208. *Hytera I*, 436 F. Supp. 3d at 1160.

209. Defend Trade Secrets Act of 2016, Pub. L. No. 114-153, § 4(b).

(4) The ability and limitations of trade secret owners to prevent the misappropriation of trade secrets outside of the United States . . .

(5) A breakdown of the trade secret protections afforded United States companies by each country that is a trading partner of the United States and enforcement efforts available and undertaken in each . . .

. . .

(7) Specific progress made under trade agreements and treaties, including any new remedies enacted by foreign countries, to protect against theft of trade secrets of United States companies outside of the United States.²¹⁰

If “offense” were synonymous with “misappropriation,” the DTSA would undermine part of its own purpose. Subsections (5) and (7) reference trade secret protections enacted by other countries,²¹¹ and subsection (5) explicitly addresses the enforcement efforts available in foreign jurisdictions.²¹² Reports on the enforcement of foreign trade secret law in foreign courts would have little value if U.S. courts could impose liability for foreign trade secret theft under the DTSA, as permitted by the holding in *Hytera II*. Hytera noted this in its petition for certiorari, suggesting that the “provision for ongoing factfinding . . . suggests that Congress did *not* expect the DTSA to be the last word—i.e., the complete solution to the problem of global trade secret theft.”²¹³ Thus, this provision again shows that Congress was concerned about the problem of foreign trade secret theft, but did not intend the DTSA to create a universal remedy.

C. THE LEGISLATIVE HISTORY OF THE DTSA SHOWS CONGRESSIONAL INTENT TO PROVIDE A REMEDY FOR DOMESTIC TRADE SECRET THEFT CAUSING WORLDWIDE INJURY

The legislative history of the DTSA supports a narrow reading of the term “offense,” such that only domestic acts in furtherance of the acquisition of trade secrets are sufficient to invoke the extraterritorial protection provided by § 1837(2). Section IV.C.1 demonstrates that Congress intended the DTSA to provide an adequate remedy when trade secrets were stolen within the U.S. and taken abroad. Section IV.C.2 demonstrates a complementary view that Congress did not intend the DTSA to provide a remedy for trade secret theft that originated outside the United States.

210. *Id.*

211. *Id.* § 4(b)(5), (7).

212. *Id.* § 4(b)(5).

213. Petition for Writ of Certiorari, *supra* note 116, at 17.

1. *Congress Intended the DTSA to Have Limited Extraterritorial Effect*

The DTSA's legislative history confirms that Congress intended to provide a remedy for worldwide harm resulting from domestic trade secret theft but not for trade secret theft occurring abroad. Congressional committee reports are "the authoritative source for finding the Legislature's intent."²¹⁴ Committee reports on the DTSA demonstrate that Congress was aware of the threat of global trade secret misappropriation but intended to address only the theft or acquisition of trade secrets when it occurred in the territorial boundaries of the United States.²¹⁵ The House Judiciary Committee's report on the Trade Secrets Protection Act of 2014—the predecessor of the DTSA,²¹⁶ containing substantially similar language—emphasized the need for legislation to "keep a trade secret thief from boarding a plane and taking the secret beyond the reach of American law."²¹⁷ The Committee's 2016 report on the DTSA reiterated this concern.²¹⁸ Reports from both the House and Senate Judiciary Committee praised the DTSA's ability to "stop trade secrets from winding up being disseminated" and emphasized the urgency of a federal remedy for trade secret owners "fac[ing] threats . . . both at home and abroad."²¹⁹ These reports also both described the DTSA as "narrowly drawn legislation."²²⁰ Taken together, these statements confirm that Congress was primarily concerned with providing a remedy for the harm that flowed from the domestic acquisition of trade secrets. In this "narrowly drawn" conception of the DTSA, it is unlikely that Congress ever imagined the sweeping extraterritoriality interpretation adopted in *Hytera II*.

Senate floor statements from the DTSA's sponsors and other legislators all echo the concern about foreign actors acquiring trade secrets in the United States and taking them abroad. Senator Amy Klobuchar, a DTSA cosponsor, spoke in favor of its passage, warning that advancements in technology had made trade secret theft "as easy as clicking a button or touching a screen," necessitating "21st century solutions" to protect American intellectual

214. *Garcia v. United States*, 469 U.S. 70, 76 (1984).

215. *See generally* H.R. REP. NO. 113-657 (2014); H.R. REP. NO. 114-529 (2016); S. REP. NO. 114-220 (2016).

216. *See* John Cannan, *A Legislative History of the Defend Trade Secrets Act of 2016*, IP WATCHDOG, <https://ipwatchdog.com/2016/05/20/a-legislative-history-of-the-defend-trade-secrets-act-of-2016/id=69082/> [<https://perma.cc/JV87-WDL9>] (last visited Nov. 5, 2024).

217. H.R. REP. NO. 113-657, at 7 (2014).

218. H.R. REP. NO. 114-529, at 4 (2016).

219. H.R. REP. NO. 114-529, at 6 (2016); S. REP. NO. 114-220, at 15 (2016).

220. H.R. REP. NO. 114-529, at 6 (2016); S. REP. NO. 114-220, at 14 (2016).

property.²²¹ Perhaps the most illuminating parts of her statement were the examples she provided on the dangers of trade secret theft from her home state of Minnesota:²²² Cargill, a victim of trade secret theft, had secrets stolen by a former employee who gave them to a Chinese university.²²³ By contrast, Valspar was not a victim of trade secret theft because the thief was caught before he could steal its trade secrets, but an employee had attempted to misappropriate \$20 million worth of trade secrets in exchange for a high-ranking job at a Chinese company.²²⁴ Senator Christopher Coons, another original cosponsor of the DTSA, shared a similar story about a rogue DuPont employee who leaked trade secrets to a Korean manufacturing rival, costing DuPont roughly \$1 billion.²²⁵ Senator Orrin Hatch, the DTSA's primary sponsor, spoke at length on the policy concerns motivating the passage of the DTSA and introduced a series of op-eds from American business leaders into the congressional record.²²⁶ One such piece, published in the *Washington Times* by David Hirschmann, president and CEO of the Center for Capital Markets and Competitiveness at the U.S. Chamber of Commerce, explains that once thieves are "in possession of the trade secret, criminals . . . will typically flee the country to peddle these precious corporate assets to the highest bidder," making it "critical that the right tools are in place to ensure that American ideas and jobs are not stolen and sold overseas."²²⁷

House floor statements expressed similar ideas. Representative Robert Goodlatte emphasized that "creating a Federal civil remedy for trade secrets misappropriation . . . will help American innovators protect their intellectual property from criminal theft by foreign agents."²²⁸ Representative Jerrold Nadler, the lead Democratic cosponsor of the bill, also spoke favorably about the DTSA's ability to respond to digital threats and address the shortcomings of state law, noting that state law was not "efficient or effective for incidents that cross State and, sometimes, international borders."²²⁹ He further explained that "today, trade secrets can be loaded onto a thumb drive and mailed out of State or even sent electronically anywhere across the globe in an instant. . . . The need for a Federal solution is, therefore, clear."²³⁰

221. 114 CONG. REC. S1626 (2016) (statement of Sen. Amy Klobuchar).

222. *Id.*

223. *Id.*

224. *Id.*

225. 114 CONG. REC. S1630 (2016) (statement of Sen. Christopher Coons).

226. 114 CONG. REC. S1628 (2016) (statement of Sen. Orrin Hatch).

227. 114 CONG. REC. S1629 (2016) (statement of Sen. Orrin Hatch).

228. 114 CONG. REC. H2030 (2016) (statement of Rep. Robert Goodlatte).

229. 114 CONG. REC. H2033 (2016) (statement of Rep. Jerrold Nadler).

230. *Id.*

Statements from both legislators and business leaders during congressional hearings reveal the same concerns about the threat of foreign actors exploiting stolen U.S. trade secrets. In his introductory statement in the hearing *Trade Secrets: Promoting and Protecting American Innovation, Competitiveness and Market Access in Foreign Markets*, Representative Nadler expressed concern that state law remedies for misappropriation were insufficient because “[f]ormer employees and industrial spies are likely to carry or transfer secret information across State borders or overseas.”²³¹ Richard Hertling, speaking on behalf of the Protect Trade Secrets Coalition, stressed that “foreign governments and firms were competing unfairly with U.S. competitors by stealing their trade secrets. Domestic firms were seeing their crown jewels stolen and taken overseas The remedy for this form of theft, however, remained entirely in the hands of State law.”²³² Thaddeus Burns, Senior Counsel for Intellectual Property and Trade at General Electric, speaking on behalf of the Intellectual Property Owners Association (IPOA), supported a federal civil remedy because “State courts are not well suited to respond to the nature of trade secret theft today, which is increasingly likely to involve the movement of trade secrets across State and even international lines.”²³³ IPOA emphasized that “the increased digitization of critical data and increased global trade have made it easier than ever before to misappropriate vast quantities of data and transport it across state and international boundaries.”²³⁴

In a Senate Judiciary Committee hearing on the DTSA, witnesses spoke not just about the threat of international trade secret theft, but also about how exactly the DTSA might or might not be able to address that threat.²³⁵ Senator David Perdue specifically asked the witnesses how the DTSA could effectively address the extraterritorial threat of cyber espionage.²³⁶ James Pooley, former Deputy Director General of the World Intellectual Property Organization, emphasized that federal courts are better equipped than state courts to handle international trade secret disputes:

231. *Hearing Before the House Judiciary Committee*, *supra* note 11, at 6.

232. *Id.* at 8.

233. *Id.* at 33.

234. *Id.* at 38.

235. *See generally Protecting Trade Secrets: the Impact of Trade Secret Theft on American Competitiveness and Potential Solutions to Remedy this Harm: Hearing on S.1890 Before the S. Comm. on the Judiciary*, 114th Cong. (2015), <https://www.judiciary.senate.gov/committee-activity/hearings/protecting-trade-secrets-the-impact-of-trade-secret-theft-on-american-competitiveness-and-potential-solutions-to-remedy-this-harm> (last visited May 4, 2025) [hereinafter *Hearing Before the Senate Judiciary Committee*].

236. *Id.* at 1:41:05.

[Extraterritoriality] is one of the major reasons why we need to have federal courts looking at these issues. Much more of the theft that happens these days, whether it's cybersecurity, cyberespionage, or whether it's done by actors locally who then might leave, the fact is there's an international component to it. State court judges, in my experience over the years, have a hard time dealing with this. Federal judges deal with international issues, the jurisdiction of courts here for the consequences of acts done in another place, they've seen that many times. They understand what comity is and isn't. And so we can get much more predictable and effective relief in federal court.²³⁷

While not a legislator, Mr. Pooley was still intimately familiar with the DTSA, as he had helped draft the bill and had been credited as “instrumental” to its passage by a sponsoring senator.²³⁸ He viewed the DTSA's primary advantage over state law in international trade secret disputes as its access to federal courts, rather than any substantive provision of the bill itself.²³⁹ Professor Sharon Sandeen, an internationally recognized trade secret scholar, testified against the DTSA's passage. When asked the same question as Mr. Pooley, she expressed much less optimism about the bill's efficacy.²⁴⁰ While Professor Sandeen was “very concerned” about international cyber-espionage, she “d[idn't] think [the] bill address[ed]” it.²⁴¹

Had legislators and commentators believed § 1837 to confer the broad extraterritorial protection affirmed in *Hytera II*, they would likely have sung the DTSA's praises in redressing extraterritorial trade secret theft. Instead, the legislative history emphasizes that the DTSA protects companies against thieves that flee the country with stolen information. Taken together, these statements indicate that Congress intended to remedy only extraterritorial harms stemming from the domestic acquisition of trade secrets.

2. *The Primary Goal of Congress Was Not to Create a Remedy for Extraterritorial Harms*

While plenty of statements in the DTSA's legislative history suggest that Congress intended some extraterritorial application, numerous others show that Congress was primarily concerned with providing effective remedies for domestic trade secret misappropriation and remained cognizant of the territorial limitations of its own legislative power. Section IV.B.2.a demonstrates that the DTSA's legislative history focuses primarily on domestic

237. *Id.* at 1:45:43.

238. JAMES POOLEY, <https://pooley.com/> [<https://perma.cc/D4UD-T5JA>] (last visited Dec. 20, 2024).

239. *See Hearing Before the Senate Judiciary Committee, supra* note 235, at 1:45:43.

240. *See id.* at 1:45:03.

241. *Id.* at 1:45:03.

applications. Section IV.B.2.b reveals legislators' reluctance to enact a trade secret law with sweeping extraterritoriality provisions. Section IV.B.2.c highlights Congress's hope that nations would use the DTSA as a model for their own trade secret protections to demonstrate it did not intend the DTSA to supplant other nations' own trade secret law.

a) A Primary Goal of the DTSA Was to Improve Wholly Domestic Remedies

Section IV.B.2.a.i. demonstrates that the primary motivator of the DTSA was improving the effectiveness of remedies across state lines. Section IV.B.2.a.ii emphasizes that the DTSA meets the stated policy goal that trade secrets should enjoy similar levels of protection as other federal IP rights.

i) The DTSA Overcomes State Trade Secret Law's Ineffectiveness in Addressing Wholly Domestic Trade Secret Misappropriation

The House Judiciary Committee report on the DTSA mentions the risk of a thief "boarding a plane and taking the secret beyond the reach of American law."²⁴² It mentions this risk, however, in the context of courts acting across state lines to prevent the thief from fleeing in the first place, rather than allowing the victim of such theft to recover damages for the thief's actions after fleeing.²⁴³ Both the House and Senate Judiciary Committee reports highlight that federal courts offer a more effective venue for victims seeking to "move quickly to Federal court, with certainty . . . to stop trade secrets from winding up being disseminated."²⁴⁴

Senator Orrin Hatch best explained this focus on domestic remedies in his statements on the Senate floor. He placed far greater emphasis on the need for a uniform federal remedy than on concerns about protection from foreign trade secret thieves. The "mixed bag of differing legal regimes" under state law forced plaintiffs to "wade through a quagmire of procedural hurdles in order to recover their losses Under a uniform Federal standard, the process would be far more efficient."²⁴⁵ In Senator Hatch's view, state law was "woefully insufficient" to protect trade secret owners from "interstate trade secret theft."²⁴⁶ A "uniform national law," however, and the powers of federal

242. H.R. REP. NO. 114-529, at 4 (2016).

243. *Id.*

244. *Id.* at 6; S. REP. NO. 114-220, at 15 (2016).

245. 114 CONG. REC. S1627 (2016) (statement of Sen. Orrin Hatch).

246. *Id.*

courts to act across state lines, would overcome the deficiencies that state trade secret laws could not.²⁴⁷

ii) Congress Intended the DTSA to Provide Protection in Line with Other Federal Intellectual Property Laws

The DTSA's legislative history shows Congress intended to give trade secrets similar legal protection as other federal IP rights, but not significantly more. The House Judiciary Committee's report on the 2014 Trade Secrets Protection Act—the precursor to the DTSA—stated that the bill's purpose was to allow “trade secret owners to protect their innovations by seeking redress in Federal court, just as owners of other forms of intellectual property, including copyrights, patents, and trademarks.”²⁴⁸ The Judiciary Committee's report on the DTSA in 2016 used exactly the same language.²⁴⁹ The Senate Judiciary Committee's report on the DTSA stated a similar purpose: because trade secrets were “[u]nlike other types of intellectual property,” being governed by state law, the DTSA would “allow trade secret owners to . . . seek[] redress in Federal court, bringing their rights into alignment with those long enjoyed by owners of other forms of intellectual property, including copyrights, patents, and trademarks.”²⁵⁰ Senator Hatch emphasized the need for parity across IP regimes, pointing out that trade secrets were “the only form of U.S. intellectual property where the owner d[id] not have access to a Federal civil remedy.”²⁵¹

The legislative history suggests that Congress intended the DTSA to bring trade secret protection up to the same federal protection standard enjoyed by other intellectual property regimes. This stated goal supports interpreting the DTSA's extraterritoriality provision similarly to those of other intellectual property regimes. On appeal, Hytera argued that “[i]t would be anomalous for private trade secret claims to reach extraterritorially when other intellectual-property rights generally do not.”²⁵² While the Seventh Circuit correctly noted that “the issue for [the courts] is statutory interpretation, not the public policy choices,”²⁵³ an assessment of just how “anomalous” the argued extraterritorial policy is could guide statutory interpretation through the lens of legislative intent.

247. *Id.*

248. H.R. REP. NO. 113-657, at 5 (2014).

249. H.R. REP. NO. 114-529, at 2 (2016).

250. S. REP. NO. 114-220, at 2–3 (2016).

251. 114 CONG. REC. S1627 (2016) (statement of Sen. Orrin Hatch).

252. Brief for Defendant-Appellant, *supra* note 112, at 55.

253. *Hytera II*, 108 F.4th at 486.

Congress was explicit that the DTSA should fit with other federal intellectual property statutes. Copyright and patent law require domestic conduct to directly cause extraterritorial harm before awarding damages,²⁵⁴ while trademark law requires a significant domestic connection through its “use in commerce” test before imposing extraterritorial liability.²⁵⁵ Sweeping extraterritorial liability under the DTSA would place trade secret protection in a class of its own—contrary to Congress’s intended congruence with other IP regimes. While courts should not twist the text of a statute to produce policy outcomes with which they agree, an examination of the DTSA’s legislative history suggests that the Seventh Circuit’s reading of the text in *Hytera II* contravenes Congress’s own stated policy goals. This historical context weighs against the soundness of the Seventh Circuit’s interpretation.

b) Legislative Discussions Reveal Hesitance About the
Extraterritorial Application of American Trade Secret Law

The DTSA’s legislative history reveals that Congress understood the territorial limitations of its own power and did not intend to draft a law that would regulate foreign trade secret disputes. While these statements are mostly found in congressional hearings—rather than more authoritative committee reports and floor statements—this is perhaps because legislators thought a sweeping extraterritorial application was so far out of the question that it did not merit serious discussion.

In the 2014 congressional hearing *Trade Secrets: Promoting and Protecting American Innovation, Competitiveness and Market Access in Foreign Markets*, David Simon, Senior Vice President for Intellectual Property at Salesforce, was asked directly about the appropriate extraterritorial scope of the statute. He cautioned against overbroad extraterritorial application, saying he did not think it would be good to go to the “extreme [of having] U.S. courts trying to tell Swiss watchmakers what they can do in Switzerland.”²⁵⁶

Around the same time DTSA legislation was pending, Congress rejected a different trade secrets bill that contained much more explicit extraterritorial provisions than the DTSA. Senator Jeffrey Flake of Florida introduced S.1770—the “Future of American Innovation and Research Act of 2013,” or the “FAIR Act.”²⁵⁷ This bill contained language invoking extraterritorial application if a trade secret misappropriation “cause[d] or is reasonably anticipated to cause an injury [] within the territorial jurisdiction of the United

254. See *supra* Sections II.B.2.a, b.

255. See *supra* Section II.B.2.c.

256. *Hearing Before the House Judiciary Committee, supra* note 11, at 58.

257. S. 1770, 113th Cong. (2013).

States.”²⁵⁸ Even under this bill’s broader standard, extraterritorial liability was tied to a domestic effects test, requiring the plaintiff to have sufficient connection to the United States.²⁵⁹ Rejecting this bill suggests Congress may have been wary about enacting a trade secret law with too much extraterritorial reach. By contrast, the Seventh Circuit’s reading of the DTSA in *Hytera II* imposes a looser standard, potentially allowing worldwide liability for actions as minor as a single email or phone call to the United States.

Congress understood the territorial limits of its legislative powers and chose to enact the DTSA in its present form, imposing liability for extraterritorial trade secret misappropriation only if the trade secret was acquired domestically.

c) The DTSA Was Meant to Model for Trade Secret Protection for Other Nations, Not to Supersede Their Laws

Legislators and business and IP professionals also spoke at length in congressional hearings about the importance of having strong, uniform trade secret protections in the United States—both as a bargaining tool for trade negotiations and as a model for other countries to improve their own trade secret protections.²⁶⁰ Representative Howard Coble, Chairman of the House Subcommittee on Courts, Intellectual Property, and the Internet, praised the DTSA for “arm[ing] our trade negotiators with a model they could point other countries to and encourage them to follow.”²⁶¹ Even before the DTSA’s passage, the U.S.-Colombia Trade Promotion Agreement, which took effect in 2012, contained explicit trade secret protections.²⁶² However, David Simon highlighted the weakness of negotiating without a uniform federal law to reference, explaining that U.S. trade negotiators “can only seek the lowest common denominator of those state and federal laws.”²⁶³

258. *Id.* § 3(c).

259. *See id.*

260. *See, e.g., Hearing Before the House Judiciary Committee, supra* note 11, at 26–27 (“The lack of consistent protection means that the USTR is restricted in bilateral and multilateral negotiations from trying to improve foreign trade secret protection.”); *id.* at 34 (“If the United States leads by example, however, we have an excellent opportunity to raise and harmonize the global framework for trade secret protection.”); *id.* at 42 (“To date, the United States has not consistently received cooperation from international jurisdictions in protecting trade secrets in part because it does not have its own federal civil statute to reference in encouraging the adoption and enforcement of similar legislation by its treaty partners.”).

261. *Id.* at 9.

262. *See* M. ANGELES VILLAREAL, CONG. RSCH. SERV., RL34470, THE U.S. COLOMBIA FREE TRADE AGREEMENT: BACKGROUND AND ISSUES 5 (2014).

263. *Hearing Before the House Judiciary Committee, supra* note 11, at 26.

Congress's intent to use the DTSA as a tool in trade negotiations explains why § 5 of Public Law 114–153 references extraterritorial conduct—even though Congress did not intend to create a remedy for such conduct.²⁶⁴ By declaring its sense that “trade secret theft occurs in the United States and around the world,”²⁶⁵ and that “trade secret theft, wherever it occurs, harms the companies that own the trade secrets and the employees of the companies,”²⁶⁶ Congress created a stronger, and more sound position in negotiations to encourage U.S. trading partners to improve their own trade secret protections. The Attorney General's reporting requirements further emphasize this purpose. These reports must discuss “[s]pecific progress made under trade agreements and treaties, including any new remedies enacted by foreign countries, to protect against theft of trade secrets of United States companies outside of the United States.”²⁶⁷ They must also address “[i]nstances of the Federal Government working with foreign countries to investigate, arrest, and prosecute entities and individuals involved in the theft of trade secrets outside of the United States.”²⁶⁸ These sections of Public Law 114–153 demonstrate Congress's hope that other nations would use the DTSA as a model to improve their own trade secret laws and cooperate with U.S. authorities to stop trade secret theft. If the DTSA had the broad extraterritorial reach permitted by *Hytera II*, it would obviate the need for other countries to improve their own laws and frustrate Congress's intent to enact the DTSA as a gold standard for trade secret protection.

d) Even If Congress Did Not Intend the DTSA to Apply Extraterritorially, Its Text Requires Extraterritorial Application

Contrary to this Note, some argue that Congress did not intend for the DTSA to have any extraterritorial application at all. In the words of one commentator, the “foreign impact of the bills was documented by its supporters to be more indirect.”²⁶⁹ The legislative history is replete with statements that a federal remedy would allow trade secret owners to act fast—

264. *See supra* Section IV.B.2.

265. Defend Trade Secrets Act of 2016, Pub. L. No. 114-153, § 5(1).

266. *Id.* § 5(2).

267. *Id.* § 4(b)(7).

268. *Id.* § 4(b)(6).

269. John Cannan, *A (Mostly) Legislative History of the Defend Trade Secrets Act of 2016*, <https://www.aallnet.org/wp-content/uploads/2018/01/Vol-109-No-3-A-Mostly-Legislative-History-of-the-Defend-Trade-Secrets-Act-of-2016.pdf> [https://perma.cc/2K2M-Q3QZ] (last visited Dec. 20, 2024).

before the thief is able to leave the country, rendering extraterritorial protection unnecessary.²⁷⁰

Congress may have intended to address the problem of international trade secret theft by implementing seizure remedies that could prevent the trade secret information from ever leaving the country's borders rather than by allowing recovery for damages in foreign countries.²⁷¹ Indeed, the committee reports from the Senate and House of Representatives devote much more analysis to the civil seizure provisions than any others and do not even include the words "extraterritorial" or "extraterritoriality" anywhere.²⁷² Without a committee report explicitly stating that Congress intended the DTSA to provide trade secret owners an extraterritorial remedy, the legislative history may be best understood as Congress's intent to enact strong domestic remedies that other countries could use as a model to improve their own laws. This argument ultimately fails because "we have not traveled, in our search for the meaning of the lawmakers, beyond the borders of the statute."²⁷³ The text of § 1837 explicitly gives extraterritorial effect to all of Chapter 90, including the DTSA, when it states, "[t]his chapter also applies to conduct occurring outside the United States."²⁷⁴

Courts should not conclude Congress mistakenly gave the DTSA extraterritorial effect by failing to amend § 1837 simply because the legislative history does not expressly support the extraterritorial reach authorized by the text. As Justice Scalia observed, "[p]urpose sheds light only on deciding which of various *textually permissible meanings* should be adopted."²⁷⁵ To the extent courts find it compelling that Congress did not extensively discuss the DTSA's extraterritorial bounds, they should use this silence as a guide for properly cabining its extraterritorial application to meritorious cases—not as a reason to disregard the textual grant of extraterritoriality.

270. See *supra* Section IV.C.2.a.i.

271. See H.R. REP. NO. 113-657, at 7 (2014) ("[K]eep a trade secret thief from boarding a plane and taking the secret beyond the reach of American law."); 18 U.S.C. § 1836(b)(2).

272. See H.R. REP. NO. 113-657, at 10–12 (2014) (writing approximately one and a half pages analyzing civil seizure and less than one page analyzing new remedies); H.R. REP. NO. 114-529, at 9–13 (2016) (writing approximately two and a half pages analyzing civil seizure and slightly more than one page analyzing new remedies); S. REP. NO. 114-220, at 5–9 (2016) (writing approximately two and a half pages analyzing civil seizure and approximately one and a half pages analyzing new remedies).

273. *United States v. Great N. Ry.*, 287 U.S. 144, 154 (1932).

274. 18 U.S.C. § 1837.

275. SCALIA & GARNER, *supra* note 84 (emphasis in original).

V. CONCLUSION

The Seventh Circuit's reading of the DTSA's extraterritoriality grant in *Hytera II* is overbroad, conflicting with both the statutory text and Congress's expressed intent. A more reasonable reading would limit "offense" to the acquisition of trade secrets, rather than extending it to all misappropriation. This narrower approach properly gives the two different terms "offense" and "misappropriation" two different meanings. Limiting extraterritoriality in this manner is also faithful to Congress's expressed intent in enacting the DTSA—focusing more on interstate than international misappropriation and encouraging other countries to improve their own trade secret protections rather than trying to impose American law worldwide. The Supreme Court denied review of the Seventh Circuit's holding, leaving other circuit courts the option to adopt a different application of extraterritoriality under the DTSA.

Allowing trade secret owners to recover foreign damages resulting from domestic trade secret theft is a sound policy that aligns with the DTSA's Congressional intent. Owners of other IP rights can recover foreign damages if they can show that domestic misconduct caused harm abroad. Congress intended for the DTSA to afford trade secret owners similar protection. Applying the DTSA to allow recovery of extraterritorial damages flowing from domestic trade secret theft is the soundest construction of the statute, compensating trade secret owners for domestic trade secret theft without imposing American law on disputes more appropriately resolved by foreign courts.

SYNTEL V. TRIZETTO: BALANCING COMPENSATION AND DETERRENCE IN TRADE SECRET REMEDIES

Duane H. Yoo[†]

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I. INTRODUCTION

On May 25, 2023, the Second Circuit decided *Syntel Sterling Best Shores Mauritius Ltd. v. The TriZetto Grp., Inc.*, vacating an approximately \$285 million

unjust enrichment award, which the district court had awarded to TriZetto, the prevailing plaintiff, under the federal Defend Trade Secrets Act.¹ The *Syntel* opinion has introduced a significant disagreement between circuit courts as to when and whether unjust enrichment damages may be awarded for costs that a defendant unjustly avoided through its trade secret misappropriation.² The Second Circuit held that TriZetto was not entitled to such an award because TriZetto's potential future harms had already been prevented by an injunction prohibiting Syntel's future use of the trade secret. According to the court, awarding an unjust enrichment award for Syntel's avoided costs would overcompensate TriZetto and effectively amount to "punitive damages under the guise of compensatory damages." The Second Circuit also openly disagreed with other circuit courts that had previously upheld similar unjust enrichment awards for avoided costs.

The Second Circuit raises a strong, fundamental point that compensatory awards should not overcompensate. However, because avoided-cost unjust enrichment awards are often of great monetary value, *Syntel's* curtailment of them may potentially diminish the deterrent effects of trade secret law and also encourage forum-shopping. Awarding attorney's fees, punitive damages, or reasonable royalty damages more often in trade secret misappropriation cases could help address these problems. These remedies could help ensure that would-be misappropriators face adequate monetary deterrents against trade secret misappropriation while also ensuring that aggrieved trade secret owners remain financially able and motivated to bring suit to enforce their rights, even in the absence of avoided-cost unjust enrichment awards.

II. LEGAL BACKGROUND

This Part will discuss the legal definition of a "trade secret," the scope of its legal protection under U.S. law, the policy purposes of conferring such legal protection, and the legal remedies available for aggrieved trade secret owners.

1. 68 F.4th 792, 797 (2d Cir. 2023), *cert. denied*, 144 S. Ct. 352 (2023). Although Syntel first filed suit against TriZetto, it was the latter which counterclaimed for trade secret misappropriation under the Defend Trade Secrets Act. For purposes of that trade secret misappropriation claim—and this Note—Syntel is the defendant and TriZetto the plaintiff.

2. See Edward D. Lanquist & Nicole Berkowitz Riccio, *Top Developments in Trade Secret Law*, BAKER DONELSON (Aug. 22, 2024), <https://www.bakerdonelson.com/top-developments-in-trade-secret-law> [https://perma.cc/2PPD-4V4R].

A. WHAT IS A TRADE SECRET?

The idea that information should be protected against “theft” has been around in some form since as early as the Roman empire.³ Today, the term “trade secret” encompasses such protected, economically valuable information that is not generally known to the public and is subject to reasonable precautions by its owner to preserve its secrecy.⁴

Virtually any information of economic value can be a trade secret if it meets the three requirements for trade secret protection: (1) secrecy; (2) independent economic value derived from its secrecy; and (3) the owner has taken reasonable efforts to maintain secrecy.⁵ Although many trade secrets consist of scientific and technical information, a wide range of confidential business information (such as marketing or sales data) can also be protected as trade secrets if it meets these requirements.⁶

B. TRADE SECRET PROTECTION IN THE UNITED STATES

This Section will discuss how trade secret law has evolved in the United States and the scope of American trade secret law as it exists today.

1. *From Common Law Origins to Federal Statutory Protection*

Trade secret law first spread to the United States in the mid-nineteenth century from English common law practice.⁷ American trade secret law evolved thereafter through the common law process, and by 1939, protection of trade secrets fell under tort law, collected in the Restatement of Torts.⁸ In 1979, the National Commission on Uniform State Laws introduced the Uniform Trade Secrets Act (UTSA), a model law separate from traditional tort

3. PETER S. MENELL, ROBERT P. MERGES, MARK A. LEMLEY & SHYAMKRISHNA BALGANESH, *INTELLECTUAL PROPERTY IN THE NEW TECHNOLOGICAL AGE*: 2023 44 (2023) (The Roman courts created a cause of action called “*actio servi corrupti*”—literally, an action for corrupting a slave. This action was used to protect slave owners from third parties who would “corrupt” slaves (by bribery or intimidation) into disclosing their masters’ confidential business information. The law made such third parties liable to the slave owner for twice the damages he suffered as a result of the disclosure.)

4. *Id.* at 45; *see generally* 18 U.S.C. § 1839(3); UNIF. TRADE SECRETS ACT § 1.4.

5. ELIZABETH A. ROWE & SHARON K. SANDEEN, *TRADE SECRET LAW: CASES AND MATERIALS* 51 (3d ed. 2021).

6. ROWE & SANDEEN, *supra* note 5, at 51.

7. MENELL ET AL., *supra* note 3, at 45.

8. *See id.*

principles.⁹ The UTSA was eventually adopted by every state except New York.¹⁰

Trade secret protection in the United States thus remained primarily a matter of state law¹¹ until 2016, when Congress enacted the Defend Trade Secrets Act (DTSA) and created a federal civil cause of action for trade secret misappropriation.¹² Modeled after the UTSA, the DTSA contains key provisions that are similar or identical to the UTSA.¹³ However, Congress did not preempt existing state trade secret laws.¹⁴ As a result, both state and federal law serve as sources of American trade secret law today, with previous judicial interpretations of the former influencing the latter.¹⁵ Despite this dual framework, the DTSA continues to grow in significance—around 80 percent of trade secret cases filed in federal courts in 2022 included a DTSA claim.¹⁶

2. *The Scope of American Trade Secret Protection*

The DTSA defines a trade secret as:

[A]ll forms of . . . information . . . whether tangible or intangible, and whether or how stored . . . if—(A) the owner thereof has taken reasonable measures to keep such information secret; and (B) the information derives independent economic value . . . *from not being*

9. *See id.*; *see also* UNIF. TRADE SECRETS ACT (1985).

10. MENELL ET AL., *supra* note 3, at 45. Meanwhile, New York continued to protect trade secrets by relying on the Restatement of Torts. *See Trade Secrets Law in New York*, DIGIT. MEDIA L. PROJECT (Sep. 9, 2024), <https://www.dmlp.org/legal-guide/new-york/trade-secrets-law-new-york> [<https://perma.cc/5N8T-FZ35>].

11. A notable exception was the federal Economic Espionage Act of 1996, which criminalized certain forms of industrial espionage and trade secret theft; however, the Act did not provide a federal civil remedy for trade secret misappropriation. *See* Pub. L. No. 104-294, 110 Stat. 3488 (1996).

12. *See* Pub. L. No. 114-153, § 2; Elizabeth A. Rowe, *Unpacking Trade Secret Damages*, 55 HOUS. L. REV. 155, 156 (2017).

13. *Id.* at 160; *compare, e.g.*, 18 U.S.C. § 1839(5), *with* UNIF. TRADE SECRETS ACT § 1.2 (both defining the term “misappropriation” using nearly identical language and statutory structure). Importantly, however, the DTSA added an important limitation on trade secret protection: an express immunity from suit—under federal *and state* law—for whistleblowers who disclose suspected illegal activity to the government and their attorney confidentially. *See* 18 U.S.C. § 1833(b); *see also* MENELL ET AL., *supra* note 3, at 52.

14. 18 U.S.C. § 1838.

15. Rowe, *supra* note 12, at 160.

16. Ching-Lee Fukuda, Aimee Fagan & Irene Yang, *The Rise of the Era of Trade Secret Litigation*, LITIG. DAILY (Jan. 4, 2024), <https://www.bloomberglaw.com/document/XEPV7KHC000000?jsearch=hdk45ffdkf#jcite>; *see also* Gaston Kroub, *3 Takeaways from the 2023 Lex Machina Trade Secret Litigation Report*, ABOVE THE LAW (July 18, 2023), <https://abovethelaw.com/2023/07/3-takeaways-from-the-2023-lex-machina-trade-secret-litigation-report/> [<https://perma.cc/BQW2-ZX9E>] (“80% of 2022’s trade secret filings included a DTSA claim . . .”).

generally known to, and not being readily ascertainable through proper means by, another person who can obtain economic value from the disclosure or use of the information.¹⁷

The definition in the UTSA is substantially similar.¹⁸ Importantly, the definition of “trade secret” requires that the information be “not generally known”: the information cannot be a trade secret if it is generally known, and it will cease to be a trade secret if it becomes generally known at some point in the future.¹⁹ On the other hand, so long as such information remains not generally known, it can retain its legal protection as a trade secret indefinitely.²⁰ In other words, a trade secret can potentially retain legal protection forever, but public disclosure of the trade secret destroys the “secret” and therefore ends its legal protection.²¹ Mishandling of the trade secret by anyone—including a thief—can inflict the loss of a valuable trade secret upon the secret’s owner.

The DTSA and state law UTSA’s protect against “misappropriation” of trade secret information, which includes not only outright theft, but also improper acquisition or disclosure by a person who knows or should know that the trade secret was acquired by “improper means.”²² These improper means include theft, bribery, misrepresentation, breach of a duty (or inducement of such a breach) to maintain secrecy, and espionage through electronic or other means.²³ A wide variety of circumstances can constitute misappropriation,²⁴ including: (1) employees improperly taking their employer’s trade secrets;²⁵ (2) business partners misusing their partnership’s trade secrets;²⁶ and (3) intrusion by unrelated third parties.²⁷ On the other hand, the definition of trade secret misappropriation affirmatively excludes lawful

17. 18 U.S.C. § 1839(3) (emphasis added).

18. See UNIF. TRADE SECRETS ACT § 1.4.

19. See MENELL ET AL., *supra* note 3, at 76.

20. A famous example is the recipe for the popular Coca-Cola soda drink, which has remained a trade secret for over 135 years. See *Why Didn't Coca-Cola Patent Their Secret Recipe?*, PAUL & PAUL (June 30, 2023), <https://www.paulandpaul.com/why-didnt-coca-cola-patent-their-secret-recipe/> [<https://perma.cc/6EFH-G6SY>].

21. See MENELL ET AL., *supra* note 3, at 76.

22. See *generally* 18 U.S.C. § 1839(5); UNIF. TRADE SECRETS ACT § 1.1–2.

23. See 18 U.S.C. § 1839(6)(A).

24. See MENELL ET AL., *supra* note 3, at 147.

25. See, e.g., *Rohm & Haas Co. v. Adco Chem. Co.*, 689 F.2d 424, 427–28 (3d Cir. 1982).

26. See, e.g., *ScentSational Techs., LLC v. PepsiCo, Inc.*, 2017 WL 4403308, at *2–7 (S.D.N.Y. 2017).

27. See, e.g., *Information About the Department of Justice’s China Initiative and a Compilation of China-Related Prosecutions Since 2018*, U.S. DEP’T JUST. (Nov. 19, 2021) (discussing several instances of trade secret theft carried out via computer hacking).

means of acquisition, such as reverse engineering.²⁸ Trade secret law does not protect trade secret owners against third parties who have independently developed the same or similar matter.²⁹ In other words, a trade secret owner cannot use its rights to prevent genuine independent development by others.

C. THE POLICY GOALS OF TRADE SECRET LAW

Trade secret law has three primary policy goals: (1) preserving commercial ethics; (2) encouraging invention and innovation; and (3) facilitating the sharing of information.³⁰ Preservation of commercial ethics was *the* main policy goal of trade secret law in its early years.³¹ In more modern times, as intellectual property became increasingly valuable and trade secrets began to be seen as a form of intellectual property, encouraging invention and innovation was emphasized, reasoning that the availability of legal protections would provide an incentive to innovate in the first instance—similar to patent law.³² Protecting trade secrets also facilitates the sharing of information. Without legal recourse against trade secret misappropriation, innovators would likely expend increased resources towards otherwise unproductive security precautions or be less willing to license others to use the trade secret, to the detriment of society as a whole.³³ As society and the economy become increasingly dependent on technology and informational assets, scholars have predicted that these policy concerns will accelerate the growth of trade secret law.³⁴

28. See 18 U.S.C. § 1839(6)(B).

29. ROGER M. MILGRIM & ERIC E. BENSON, MILGRIM ON TRADE SECRETS § 2.01 (2024) (Trade secret owners cannot use their rights “to prevent genuine independent development by others.”); see also ROWE & SANDEEN, *supra* note 5, at 256 (Activities that are deemed proper means to acquire trade secrets include: independent invention, reverse engineering, discovery under a license from the owner of the trade secret, observation of the item in public use or on public display, and obtaining the trade secret from published literature).

30. ROWE & SANDEEN, *supra* note 5, at 39; see also *Kewanee Oil Co. v. Bicron Corp.*, 416 U.S. 470, 481–89 (1974).

31. ROWE & SANDEEN, *supra* note 5, at 39; see also *E. I. duPont deNemours & Co. v. Christopher*, 431 F.2d 1012, 1016 (5th Cir. 1970) (“[O]ur devotion to free wheeling industrial competition must not force us into accepting the law of the jungle as the standard of morality expected in our commercial relations.”).

32. ROWE & SANDEEN, *supra* note 5, at 39; see also *Kewanee Oil*, 416 U.S. at 484 (“Certainly the patent policy of encouraging invention is not disturbed by the existence of another form of incentive to invention.”).

33. ROWE & SANDEEN, *supra* note 5, at 39; see also *Kewanee Oil*, 416 U.S. at 485–87.

34. See generally David S. Almeling, *Seven Reasons Why Trade Secrets Are Increasingly Important*, 27 BERKELEY TECH. L.J. 1091 (2012).

Meanwhile, other scholars have pointed out that the overprotection of trade secrets can also be harmful by hindering competition and potentially limiting innovation rather than fostering it.³⁵ Overly broad trade secret protection may prevent others from applying protected information in novel applications, even those that are completely dissimilar from the trade secret owner's uses and applications.³⁶

D. REMEDIES FOR TRADE SECRET MISAPPROPRIATION

The owner of a misappropriated trade secret can be entitled to several forms of civil remedies. A court may grant: (1) compensatory damages (actual losses or unjust enrichment caused by the misappropriation; or, alternatively, a reasonable royalty for the misappropriator's unauthorized disclosure or use of the trade secret); (2) punitive damages, for "willful and malicious" misappropriation; (3) reasonable attorney's fees, including for "willful and malicious" misappropriation; and (4) injunctive relief to prevent any future misappropriation.³⁷ Avoided-cost unjust enrichment awards, at issue in the *Syntel* case, belong in the first category (compensatory damages).

1. *Compensatory Damages*

Plaintiffs who successfully prove that their trade secrets were wrongly used or disclosed (as opposed to merely improperly acquired) can seek monetary relief from the defendant.³⁸ The UTSA and DTSA give plaintiffs some flexibility in how to establish harm, including by establishing (a) the plaintiff's loss and/or the defendant's unjust enrichment; or alternatively (b) a reasonable royalty measure of damages.³⁹

a) Plaintiff's Actual Loss

Plaintiffs are entitled to recover any actual losses they suffered as a result of the infringement.⁴⁰ These losses may include lost sales to a competitor, price

35. See, e.g., Camilla A. Hrdy & Christopher B. Seaman, *Beyond Trade Secrecy: Confidentiality Agreements That Act Like Noncompetes*, 133 YALE L.J. 669 (2024); Charles Tait Graves & James A. DiBoise, *Do Strict Trade Secret and Non-Competition Laws Obstruct Innovation?*, 1 ENTREPRENEURIAL BUS. L.J. 323 (2007).

36. See Camilla A. Hrdy, *Should Dissimilar Uses of Trade Secrets Be Actionable?*, 167 U. PA. L. REV. ONLINE 78, 80–81 (2019) (posing a hypothetical scenario where a misappropriated trade secret for manufacturing industrial diamonds is adapted for baking chocolate chip cookies—and questioning whether a misappropriation that is so significantly different from the trade secret owner's use should be actionable).

37. See 18 U.S.C. § 1836(b)(3); UNIF. TRADE SECRETS ACT §§ 2–4; see also ROWE & SANDEEN, *supra* note 5, at 488–91; MENELL ET AL., *supra* note 3, at 147–58.

38. 18 U.S.C. § 1836(b)(3)(B); ROWE & SANDEEN, *supra* note 5, at 489.

39. 18 U.S.C. § 1836(b)(3)(B); ROWE & SANDEEN, *supra* note 5, at 489–90.

40. MENELL ET AL., *supra* note 3, at 155; 18 U.S.C. § 1836(b)(3)(B)(i)(I).

erosion via the plaintiff being forced to lower its own prices to compete with the defendant, and out-of-pocket expenses the plaintiff incurred in dealing with the misappropriation (but not including litigation costs).⁴¹ If the trade secret has been destroyed, these damages can also include compensation for the plaintiff's loss of the value of the trade secret itself.⁴² Estimating such a loss requires determining the fair market value of the destroyed trade secret. This valuation can often be quite difficult to do in practice because entities seldom put trade secrets up for auction.⁴³ Plaintiffs bear the burden of proving their losses; it is not enough to speculate that the plaintiff would have succeeded in a new market but for the misappropriator's competition.⁴⁴

b) Defendant's Unjust Enrichment

In addition to actual losses, plaintiffs can also obtain disgorgement of the defendant's unjust enrichment from the misappropriation to the extent it is not already counted in the plaintiff's actual losses.⁴⁵ Unlike the plaintiff's actual losses, unjust enrichment is focused on the defendant's ill-gotten profits, disgorging liable defendants of any such profits that remain after the plaintiff's losses have been accounted for.⁴⁶

Unjust enrichment can also be awarded for costs that the defendant avoided by misappropriating the plaintiff's trade secret. Such an avoidance of costs constitutes an unjustly conferred benefit because "[a] saved expenditure . . . is no less beneficial to the recipient than a direct transfer."⁴⁷ An example is the research and development ("R&D") costs that a defendant avoided by

41. MENELL ET AL., *supra* note 3, at 155; 18 U.S.C. § 1836(b)(3)(B)(i)(I); *see, e.g.*, Roton Barrier, Inc. v. Stanley Works, 79 F.3d 1112, 1120 (Fed. Cir. 1996) (upholding a damages award for price erosion); *see also* Rowe, *supra* note 12, at 162.

42. MENELL ET AL., *supra* note 3, at 155.

43. *See* 18 U.S.C. § 1831 Element Three—*The Information Was a Trade Secret* in Criminal Resource Manual 1127, U.S. DEP'T JUST., <https://www.justice.gov/archives/jm/criminal-resource-manual-1127-18-usc-1831-element-three-information-was-trade-secret> [<https://perma.cc/H5PL-KLZP>] (last visited Dec. 20, 2024) (describing situations where the monetary value of a trade secret cannot be easily established).

44. MENELL ET AL., *supra* note 3, at 155; *see, e.g.*, LinkCo, Inc. v. Fujitsu Ltd., 232 F. Supp. 2d 182, 186 (S.D.N.Y. 2002) (noting that the plaintiff had gone out of business at around the same time as the alleged misappropriation, and the district court declined to award lost profits because that would require that the fact-finder speculate as to the revenue the plaintiff would have made if it had remained in business).

45. MENELL ET AL., *supra* note 3, at 155; 18 U.S.C. § 1836(b)(3)(B)(i)(II).

46. *See* MILGRIM & BENSON, *supra* note 29, at § 1.01 ("As long as there is no double counting, [the UTSA] adopts the principle of the recent cases allowing recovery of both a complainant's actual losses and a misappropriator's unjust benefit that are caused by misappropriation.").

47. RESTATEMENT (THIRD) OF RESTITUTION & UNJUST ENRICHMENT § 1 cmt. d.

misappropriating the plaintiff's trade secret. Prior to the Second Circuit's *Syntel* opinion, circuit courts had routinely allowed unjust enrichment awards for avoided costs in trade secret cases. Although there are many circuit court cases to date that have involved unjust enrichment awards for avoided costs in trade secret cases, for simplicity, this Note will focus on two particular cases that the Second Circuit expressly disagreed with in its *Syntel* opinion: the Seventh Circuit's *Epic Systems v. Tata Consultancy Services Ltd.*, and the Third Circuit's *PPG Industries v. Jiangsu Tie Mao Glass Co.*⁴⁸ Although these circuit courts did not expressly hold that avoided-cost unjust enrichment awards are available *whenever* there is trade secret misappropriation, they generally upheld such awards, so long as the allegations of the defendant's avoided costs satisfied all other legal and evidentiary requirements under general principles of unjust enrichment doctrine.⁴⁹ In other words, these circuits treated the avoided costs as they would any other benefit unjustly conferred upon the defendant.

c) Reasonable Royalty

The UTSA and DTSA provide for reasonable royalties as an alternative to actual loss and unjust enrichment: "In lieu of damages measured by any other methods, the damages caused by misappropriation may be measured by imposition of liability for a reasonable royalty for a misappropriator's unauthorized disclosure or use of a trade secret."⁵⁰ This measure of damages aims to award the trade secret owner a hypothetically agreed value of the trade secret that "the parties would have agreed to as a fair licensing price at the time that the misappropriation occurred."⁵¹

Despite the UTSA and DTSA provisions for reasonable royalty awards, they are rarely imposed in trade secret cases.⁵² In fact, the Senate Judiciary Committee Report on the DTSA indicates that the Senate disfavored reasonable royalty awards relative to lost profits and unjust enrichment awards:

48. See *infra* Section III.A (discussing *Epic Sys. Corp. v. Tata Consultancy Servs. Ltd.*, 980 F.3d 1117 (7th Cir. 2020); *PPG Indus. Inc. v. Jiangsu Tie Mao Glass Co.*, 47 F.4th 156 (3d Cir. 2022)).

49. See *Epic Sys.*, 980 F.3d at 1129–30; *PPG Indus.*, 47 F.4th at 163.

50. UNIF. TRADE SECRETS ACT § 3; see also 18 U.S.C. § 1836(b)(3)(B)(ii) (containing substantially similar language).

51. *LinkCo, Inc. v. Fujitsu Ltd.*, 232 F. Supp. 2d 182, 186 (S.D.N.Y. 2002) (internal citation omitted).

52. Between 2018 and 2022, reasonable royalties were awarded in just four trade secret cases, compared to actual damages being awarded in 55 cases, punitive and willfulness damages in 28 cases, and attorney's fees in 209 cases. LEX MACHINA, TRADE SECRET LITIGATION REPORT 2023, at 21 (July 2023); see also *AirFacts, Inc. v. Amezaga*, 30 F.4th 359, 367 (4th Cir. 2022) (describing case law addressing reasonable royalty awards in trade secret cases as "sparse").

“It is not the Committee’s intent to encourage the use of reasonable royalties to resolve trade secret misappropriation. Rather, the Committee prefers other remedies that, first, halt the misappropriator’s use and dissemination of the misappropriated trade secret and, second, make available appropriate damages.”⁵³ The Report also recorded in a footnote: “The Committee notes that courts interpreting the UTSA’s analogous provision have held that the award of reasonable royalties is a remedy of last resort.”⁵⁴

Upon closer examination of the Senate Judiciary Report, however, it seems that there may have been some confusion between (1) reasonable royalty damages (for *past* uses of a misappropriated trade secret) and (2) injunctions ordering a defendant to pay an *ongoing* royalty for *future* use of such a trade secret (which are awarded when totally barring future use would be inappropriate due to “exceptional circumstances”).⁵⁵ This is evident from a mismatch between the subject matter discussed in the body of the Report and the subject matter of the sources that the Report cites: although the body discusses reasonable royalty damages, the citations unambiguously discuss ongoing royalty injunctions.⁵⁶ It seems possible that the Senate actually intended to express its wariness towards ongoing royalty injunctions, rather than towards reasonable royalty damages awards.⁵⁷ Nevertheless, reasonable royalty damages are currently rarely awarded in trade secret cases.⁵⁸

2. Punitive Damages

The UTSA and DTSA provide that punitive damages (not to exceed twice the award of compensatory damages) may be awarded in cases of “willful and

53. S. REP. NO. 114-220, at 9 (2016).

54. *Id.* at 9 n. 17 (citing *Progressive Prods., Inc. v. Swartz*, 258 P.3d 969 (Kan. 2011) and UNIF. TRADE SECRETS ACT § 2 cmt.).

55. This remedy is discussed further *infra* Section II.D.4.

56. Although the Report’s body is discussing “reasonable royalties to resolve trade secret misappropriation,” it cites the *Progressive Products* opinion and the comment to § 2 of the UTSA, both of which clearly discuss ongoing royalty injunctions. *Compare* S. REP. No. 114-220, at 9, *with Progressive Prods.*, 258 P.3d at 978–80, *and* UNIF. TRADE SECRETS ACT § 2 cmt.

57. Although a detailed discussion of other intellectual property regimes is beyond the scope of this Note, it is notable that reasonable royalty damages awards are used far more routinely in other regimes, such as patent law. *See* 35 U.S.C. § 284 (prescribing reasonable royalty damages awards as a minimum remedy). Patent law features well-developed methodologies for determining these awards. *See generally Georgia-Pacific Corp. v. U.S. Plywood Corp.*, 318 F. Supp. 1116, 1120 (S.D.N.Y. 1970) (setting forth the *Georgia-Pacific* factors, which are used for determining reasonable royalty damages in the patent law context); *see also* Dan Werner & Joe Milbury, *Patent Damages Trends: Statistical Approaches to Apportionment*, in 16 *LANDSLIDE MAG.* (Apr. 1, 2024) (describing various calculation methodologies).

58. *See* TRADE SECRET LITIGATION REPORT 2023, *supra* note 52, at 21; *AirFacts*, 30 F.4th at 367.

malicious” misappropriation.⁵⁹ Generally, “willful and malicious” behavior is distinct from that which is required to prove trade secret misappropriation.⁶⁰ However, neither the UTSA nor the DTSA expressly define “willfulness” and “malice,”⁶¹ and this ambiguity has led to some variation in how courts handle the issue.

Some courts have held that “willful and malicious” misappropriation means “acting consciously in disregard of another person’s rights or acting with reckless indifference to the consequences, with the defendant aware, from his knowledge of existing circumstance and conditions, that his conduct probably would cause injury to another.”⁶² Based on this definition, these courts have found “willful and malicious” misappropriation when, for instance, a defendant “concealed her competing business from Plaintiff and misappropriated trade secrets in furtherance of that business.”⁶³ Such courts have also found “willful and malicious” misappropriation when a defendant “knew or had reason to know that by misappropriating the plaintiff’s . . . trade secret information, they were acquiring such information through improper means . . . [and] could not have believed that he was entitled to take the [trade secret], nor to use it, on behalf of a competing business.”⁶⁴ In other words, these courts—whether by judges conducting bench trials or juries following their jury instructions⁶⁵—are likely to find “willful and malicious” misappropriation when a defendant engages in trade secret misappropriation, with knowledge that the action is unlawful and violates the plaintiff’s rights, in a duplicitous and calculating manner.

Meanwhile, other courts have set a higher bar for a finding of “willful and malicious” misappropriation. According to at least one court, a showing of “malice” in the context of the DTSA requires “ill will, malevolence, grudge,

59. The maximum permissible amount of punitive damages therefore mathematically depends upon the amount of compensatory damages. *See* UNIF. TRADE SECRETS ACT §§ 3; 18 U.S.C. § 1836(b)(3)(C); Rowe, *supra* note 12, at 164.

60. Rowe, *supra* note 12, at 164.

61. *Smart Team Glob. LLC v. HumbleTech LLC*, No. 19-CV-4873 (AJN)(BCM), 2022 WL 847301, at *10 (S.D.N.Y. Feb. 18, 2022); *see also* *Chadha v. Chadha*, 2020 WL 5228812, at *4 (E.D.N.Y. Sep. 2, 2020) (remarking that “legal precedent regarding the definitions of ‘willful’ and ‘malicious’ in the context of DTSA is scarce”).

62. *Smart Team Glob.*, 2022 WL 847301, at *10.

63. *Hair Club for Men, LLC v. Ehson*, No. 1:16-cv-236, 2017 WL 1250998, at *3 (E.D. Va. Apr. 3, 2017).

64. *Smart Team Glob.*, 2022 WL 847301, at *10.

65. However, empirical analyses have demonstrated that juries are overall more likely to award punitive damages than judges. *See generally* Joni Hersch & W. Kip Viscusi, *Punitive Damages: How Judges and Juries Perform*, 33 J. LEGAL STUD. (Jan. 2004).

spite, wicked intention or a conscious disregard for the rights of another.”⁶⁶ These courts have been wary of awarding exemplary damages unless the evidence clearly shows that the defendant was motivated by such malice—and not merely by competition.⁶⁷ These courts have emphasized that competition by its very nature is “ruthless, unprincipled, uncharitable, unforgiving—and a boon to society.”⁶⁸ In other words, these courts seem unlikely to find “willful and malicious” misappropriation unless the defendant was specifically motivated by a desire to harm the plaintiff through its misappropriation.

Overall, punitive damages tend to be very rarely awarded in trade secret cases: an empirical study of 150 trade secret misappropriation cases from 2000 to 2014 revealed that punitive damages comprised about 2.15 percent of all damages cumulatively awarded in those cases.⁶⁹

3. *Reasonable Attorney’s Fees*

In the United States, the “American Rule” provides that prevailing litigants are ordinarily not entitled to collect attorney’s fees from the losing party.⁷⁰ But some exceptions exist. Courts possess the inherent power to impose attorney’s fees to punish litigants for certain forms of gross misconduct, such as willful disobedience of a court order, or when the losing party has acted in bad faith, vexatiously, wantonly, or for oppressive reasons.⁷¹ Outside such situations where a court may impose attorney’s fees under its own inherent power, the default “American Rule” can also be overcome when a controlling statutory or contractual provision provides otherwise.⁷² The UTSA (when legislatively adopted) and DTSA are two such statutory provisions.

The UTSA and DTSA provide for attorney’s fees awards when: (1) the trade secret was willfully and maliciously misappropriated; (2) a trade secret misappropriation claim is made in bad faith; or (3) a motion to terminate an injunction is made or opposed in bad faith.⁷³ The standard for “willful and malicious” misappropriation for the purpose of attorney’s fees is the same as that for punitive damages,⁷⁴ and a court which applies a more demanding

66. *MicroStrategy Inc. v. Bus. Objects, S.A.*, 331 F. Supp. 2d 396, 430 (E.D. Va. 2004); *see also Roton Barrier, Inc. v. Stanley Works*, 79 F.3d 1112, 1120–21 (Fed. Cir. 1996).

67. *See id.* (overturning the district court’s punitive damages award because there was insufficient evidence that defendant was motivated by “malice”).

68. *Id.* at 1120.

69. *See Rowe*, *supra* note 12, at 169–76.

70. *Alyeska Pipeline Serv. Co. v. Wilderness Soc’y*, 421 U.S. 240, 247 (1975).

71. *Id.* at 257–59.

72. *Id.* at 254–55.

73. *See UNIF. TRADE SECRETS ACT* § 4; 18 U.S.C. § 1836(b)(3)(D).

74. *See Smart Team Glob.*, 2022 WL 847301, at *10; *see also Roton Barrier*, 79 F.3d at 1120–

standard for “willful and malicious” misappropriation (for example, requiring an actual intent to inflict harm) is less likely to award attorney’s fees to a prevailing trade secret owner.⁷⁵ Meanwhile, claims of trade secret misappropriation brought in bad faith can also invite attorney’s fees awards,⁷⁶ thereby deterring plaintiffs who might abuse trade secret law.

Litigation costs are often formidable in trade secret cases. In 2022, the median litigation costs of trade secret misappropriation cases proceeding through trial (and appeal, if applicable) were between \$750,000 and \$2.75 million, depending on the amount in controversy.⁷⁷ These are average figures, and so individual cases can greatly exceed them. For example, in the *Syntel* case itself, the district court on remand ultimately awarded over \$14.5 million in attorney’s fees.⁷⁸ However, like punitive damages, attorney’s fees are rarely awarded: an empirical study of 150 trade secret misappropriation cases from 2000 to 2014 showed that attorney’s fees awards comprised about 8 percent of all damages cumulatively awarded in those cases.⁷⁹

4. *Injunctive Relief*

A court may issue preliminary or permanent injunctions against trade secret defendants, prohibiting them from further misappropriating trade secrets that they improperly acquired.⁸⁰ Courts apply the basic principles of injunctive relief to trade secret litigation under the UTSA and DTSA.⁸¹ Injunctions are commonly granted in trade secret cases, although their scope and duration are often tailored for the specific situation, given the widely

75. *See, e.g., Roton Barrier*, 79 F.3d at 1121.

76. *See, e.g., Gemini Aluminum Corp. v. Cal. Custom Shapes, Inc.*, 95 Cal. App. 4th 1249, 1261–64 (2002).

77. AIPLA, REPORT OF THE ECONOMIC SURVEY 2023, at 66 (Oct. 2023).

78. *Syntel Sterling Best Shores Mauritius Ltd. v. The TriZetto Grp., Inc.*, No. 15-cv-211 (LGS), 2024 WL 1116090, at *4 (S.D.N.Y. Mar. 13, 2024) (post-appeal proceedings before the district court).

79. *See Rowe*, *supra* note 12, at 169–76.

80. *See* 18 U.S.C. § 1836(3)(A); UNIF. TRADE SECRETS ACT § 2.

81. *See* ROWE & SANDEEN, *supra* note 5, at 489. A plaintiff seeking a preliminary injunction must establish: (1) that they are likely to succeed on the merits; (2) that they are likely to suffer irreparable harm in the absence of preliminary relief; (3) that the balance of equities tips in their favor; and (4) that an injunction is in the public interest. *See Winter v. Nat’l Res. Def. Council, Inc.*, 555 U.S. 7, 20 (2008); *see also eBay Inc. v. MercExchange, L.L.C.*, 547 U.S. 388, 391 (2006) (A plaintiff seeking a permanent injunction must demonstrate: (1) that it has suffered an irreparable injury; (2) that remedies available at law, such as monetary damages, are inadequate to compensate for that injury; (3) that, considering the balance of hardships between the plaintiff and defendant, a remedy in equity is warranted; and (4) that the public interest would not be disserved by a permanent injunction).

varying circumstances surrounding trade secret misappropriation.⁸² Injunctions can be prohibitory, such as an order forbidding the defendant from further possessing, using or disclosing the trade secret. A court may also use prohibitory injunctions to prohibit the defendant from producing products that would embody the trade secret.⁸³ Injunctions can also be mandatory, such as an order compelling the defendant to provide ongoing updates to the court or the trade secret's owner to demonstrate compliance,⁸⁴ assign any rights to inventions derived from the misappropriated trade secret,⁸⁵ or even force a prematurely-filing plaintiff to publicly apologize for its unsubstantiated claims.⁸⁶ Under "exceptional circumstances," courts may substitute a prohibitory injunction with a mandatory injunction requiring the defendant to pay an ongoing royalty for any future use of the trade secret.⁸⁷

Depending on the circumstances, courts may issue a preliminary injunction before a full adjudication on the merits, or they may wait until after trial to issue a permanent injunction.

a) Preliminary Injunctive Relief

A court can issue a preliminary injunction or temporary restraining order (TRO) against a defendant, if needed, before the defendant's actual or

82. See MENELL ET AL., *supra* note 3, at 147–48.

83. See MILGRIM & BENSON, *supra* note 29, at § 15.02 ("If . . . the [trade] secret is inextricably connected with defendant's manufacture of the product the court may enjoin defendant from making the product itself."); see, e.g., Gen. Elec. Co. v. Sung, 843 F. Supp. 776, 779–80 (D. Mass. 1994) (The district court enjoined the defendant from manufacturing an entire class of products because they were "inextricably connected" to the misappropriated trade secret, and the defendant could not be relied upon to "unlearn" the trade secret even if it were to be enjoined from using it).

84. See, e.g., Judgment in a Civil Case at 4–5, Epic Sys. Corp. v. Tata Consultancy Servs. Ltd., No. 3:14-cv-748-wmc (W.D. Wis. Oct. 3, 2017), ECF No. 978 [hereinafter *Epic Systems Injunction*].

85. See, e.g., Colgate-Palmolive Co. v. Carter Prods., Inc., 230 F.2d 855, 865 (4th Cir. 1956), *cert. denied*, 352 U.S. 843 (1956).

86. See, e.g., DARIN W. SNYDER & DAVID S. ALMELING, TRADE SECRET LAW AND CORPORATE STRATEGY § 7.01 (2018 ed.) (A trade secret plaintiff was forced to issue an embarrassing public apology after it prematurely filed suit for trade secret misappropriation without sufficient investigation and thereafter failed to substantiate its claims.).

87. See UNIF. TRADE SECRETS ACT § 2 cmt. ("Exceptional circumstances include the existence of an overriding public interest which requires the denial of a prohibitory injunction against future damaging use and a person's reasonable reliance upon acquisition of a misappropriated trade secret in good faith"); see also *Progressive Prods.*, 258 P.3d at 978 (upholding appellate court's reversal of ongoing royalty injunction because the trial court did not sufficiently indicate in its order how it found "exceptional circumstances" to exist).

threatened misappropriation has been fully established at trial.⁸⁸ Motions for preliminary injunctions are often filed at the same time as the plaintiff's complaint. The defendant is given an opportunity to respond to the motion. If issued, preliminary injunctions typically last until a decision on the merits.⁸⁹ Meanwhile, plaintiffs seek TROs in emergency situations when quick relief is needed to prevent imminent harm, such as when the plaintiff fears the public disclosure (and destruction) of its trade secrets.⁹⁰ Sometimes, depending upon the applicable rules of court, motions for a TRO are brought *ex parte* without notice to the defendant.⁹¹ However, if issued, TROs last for only a short period of time—usually no more than a week or two—until a hearing on a motion for preliminary injunction can be held.⁹²

In addition to TROs and preliminary injunctions, the DTSA introduced a new type of preliminary relief called an *ex parte* civil seizure order, which, if granted, requires federal law enforcement to seize the property specified in the order.⁹³ The requirements for issuing this order are stricter than those for a TRO: a court may only grant it under “extraordinary circumstances,” and only if the court determines from specific facts that the standard forms of preliminary relief would be inadequate “because the party to which the order would be issued would evade, avoid, or otherwise not comply with such an order.”⁹⁴ Courts have granted such seizure orders when plaintiffs alleged facts demonstrating that the defendant not only wrongfully obtained the trade secrets, but also that the defendant could easily evade an order to surrender the trade secrets (e.g., by copying the information onto another device without the knowledge of the court) and that the defendant's prior duplicitous actions demonstrated a willingness to evade or ignore the law.⁹⁵

88. See 18 U.S.C. § 1836(3)(A)(i) (A court may “grant an injunction to prevent any *actual or threatened* misappropriation”(emphasis added)); *Waymo v. Uber Techs.*, No. C-17-00939-WHA, 2017 WL 2123560, at *6–14 (N.D. Cal. 2017). However, as a condition of being granted such preliminary injunctive relief, the plaintiff is usually required to post a bond that will compensate the defendant in the event that preliminary relief was improvidently granted. ROWE & SANDEEN, *supra* note 5, at 489; see FED. R. CIV. P. 65(c); see, e.g., *Waymo*, 2017 WL 2123560, at *14 (requiring plaintiff to post a bond of \$5 million as a condition for the preliminary injunction becoming operative).

89. See ROWE & SANDEEN, *supra* note 5, at 492.

90. *Id.*

91. See FED. R. CIV. P. 65(b)(1).

92. ROWE & SANDEEN, *supra* note 5, at 492; see FED. R. CIV. P. 65(b)(2).

93. ROWE & SANDEEN, *supra* note 5, at 492; see 18 U.S.C. § 1836(b)(2).

94. See 18 U.S.C. § 1836(b)(2)(A).

95. See, e.g., *Blue Star Land Servs. v. Coleman*, No. CIV-17-931-C, 2017 WL 11309528 (W.D. Okla. 2017).

b) Permanent Injunctive Relief

A court can issue a permanent injunction at the conclusion of litigation, to restrain the defendant from further using the plaintiff's trade secret in the future.⁹⁶ Such an injunction can also require that the defendant take affirmative steps to protect the trade secret.⁹⁷ Despite the nomenclature, a “permanent” injunction is not necessarily permanent in duration—it can be dissolved after it is issued,⁹⁸ and a court may also set an expiration date at the time of its issuance.⁹⁹ In practice, courts do occasionally set expiration dates for permanent injunctions at the time of their issuance.¹⁰⁰ On other occasions, courts issue permanent injunctions without a specific time limit, especially in cases where the plaintiff's trade secret continues to exist (i.e., it has not been destroyed by public disclosure) at the time the injunction is granted—this makes sense because there is no telling how long the trade secrets will last.¹⁰¹

Injunctions can be issued in many forms: preliminary or permanent; with or without an expiration date; prohibitory or mandatory; and with a variety of substantive orders tailored specifically for the facts of a given case. This flexibility allows courts to adapt relief to the widely varying circumstances of trade secret misappropriation.¹⁰² However, injunctive relief alone cannot form a comprehensive remedy to all instances of trade secret misappropriation such as when the defendant has already disclosed or used the misappropriated trade secret, resulting in wrongful loss to the owner or unjust enrichment to the misappropriator.

96. See 18 U.S.C. § 1836(b)(3)(A); UNIF. TRADE SECRETS ACT § 2.

97. See 18 U.S.C. § 1836(b)(3)(A); UNIF. TRADE SECRETS ACT § 2.

98. See FED. R. CIV. P. 60(b)(5) (allowing a court to grant relief from a prior order if its continued application is “no longer equitable.”); see also *MicroStrategy, Inc. v. Bus. Objects, S.A.*, 369 F. Supp. 2d 725, 732 (E.D. Va. 2005) (In order to grant a Rule 60(b)(5) motion to modify a prior order, the court must find “a significant change either in factual conditions or in law.”); *Rufo v. Inmates of Suffolk Cnty. Jail*, 502 U.S. 367, 384 (1992) (“A party seeking modification of a consent decree may meet its initial burden by showing either a significant change either in factual conditions or in law.”).

99. See 18 U.S.C. § 1836(b)(3)(A)(i) (the court may grant an injunction on such terms as the court deems reasonable).

100. See, e.g., *Gen. Elec. Co. v. Sung*, 843 F. Supp. 776, 782 (D. Mass. 1994) (The district court set the period of its permanent injunction to seven years from the effective date of its order).

101. *ROWE & SANDEEN*, *supra* note 5, at 535; see, e.g., *PPG Indus., Inc. v. Jiangsu Tie Mao Glass Co.*, No. 2:15-cv-00965, 2020 WL 1526940, at *23 (W.D. Pa. 2020); see also *Why Didn't Coca-Cola Patent Their Secret Recipe?*, *supra* note 20 (showing that the Coca-Cola recipe has been a trade secret for over 135 years—and counting).

102. See *MENELL ET AL.*, *supra* note 3, at 147–48.

III. SYNTEL V. TRIZETTO: THE SPLIT BETWEEN THE SECOND CIRCUIT AND ITS SISTER CIRCUITS

On May 25, 2023, the Second Circuit decided *Syntel v. TriZetto*, vacating an approximately \$285 million unjust enrichment award for avoided costs under the DTSA.¹⁰³ Although other circuits had previously upheld similar avoided-cost unjust enrichment awards, the Second Circuit disagreed, holding that the plaintiff was not entitled to such an award under the circumstances.

A. SUMMARY OF PREVIOUS CASES WHICH SYNTEL CRITICIZES

This Section describes two previous cases from other circuits that the Second Circuit in *Syntel* specifically referenced and openly disagreed with: the Seventh Circuit's *Epic Systems v. Tata Consultancy Services Ltd.* and the Third Circuit's *PPG Industries v. Jiangsu Tie Mao Glass Co.* Each of these opinions upheld a district court's award of both (1) an injunction prohibiting the defendant from further using the misappropriated trade secret and (2) an avoided-cost unjust enrichment award for the costs that the defendant saved by misappropriating that trade secret.

1. *Epic Systems v. Tata Consultancy Services Ltd.* (7th Cir. 2020)

In *Epic Systems*, the defendant, an Indian company, gained unauthorized access to the plaintiff's confidential information and then used that information to compile a document called the "comparative analysis," which it used to determine whether it could develop and sell its own competing product in the United States.¹⁰⁴ The plaintiff filed suit for trade secret misappropriation under the Wisconsin UTSA.¹⁰⁵ The plaintiff presented evidence that the defendant had used its "comparative analysis" document to: attempt to sell its competing product to one of the plaintiff's largest customers, attempt to enter the U.S. market and compete directly with the plaintiff, and address key gaps in the defendant's own product, potentially improving it.¹⁰⁶ The "avoided cost" in this case was the monetary investment the defendant would have had to make to independently develop the "comparative analysis"

103. *Syntel*, 68 F.4th at 814.

104. *See Epic Sys. Corp v. Tata Consultancy Servs., Ltd.*, 980 F.3d 1117, 1124–26 (7th Cir. 2020).

105. *See id.* at 1138.

106. *See id.* at 1131.

document on its own.¹⁰⁷ There was no indication that the plaintiff's trade secret itself had been devalued or destroyed by the misappropriation.¹⁰⁸

The district court issued a permanent injunction, prohibiting the defendant from using, possessing, or retaining any of the plaintiff's trade secrets or confidential information "anywhere in the world" for four years.¹⁰⁹ The district court also awarded, *inter alia*, unjust enrichment damages for avoided costs in the amount of \$140 million.¹¹⁰

The Seventh Circuit upheld the district court's remedies because although "there is no single way to measure the benefit [unjustly] conferred on a defendant" and such analysis is "context dependent," one way a plaintiff may prove the value of an unjustly conferred benefit is by equating that benefit to an improper and significant "head start" in their operations.¹¹¹ The Seventh Circuit concluded that because a jury could find, based on the evidence, that the defendant used its "comparative analysis" document for various purposes, the jury could also find that this use of that "comparative analysis" document was a "head start," which was approximately valued at \$140 million, based on witness and expert testimony.¹¹²

2. PPG Industries v. Jiangsu Tie Mao Glass Co. (3d Cir. 2022)

In *PPG Industries*, the defendant, a Chinese company, solicited a former employee of the plaintiff to steal technical information for plaintiff's new product.¹¹³ Using this stolen information, the defendant began making plans to produce a similar competing product, and it also reached out to one of plaintiff's subcontractors and asked it to manufacture "the same molds" that it had previously produced for the plaintiff.¹¹⁴ The subcontractor, however, did not fulfill the order; instead, it alerted the plaintiff, which then filed suit for trade secret misappropriation under the Pennsylvania UTSA.¹¹⁵ There was no indication that the value of the trade secret itself had been harmed by the defendant's misappropriation.¹¹⁶

107. *See id.* at 1130.

108. *See id.* at 1117; *see generally* Opinion and Order, *Epic Sys. Corp. v. Tata Consultancy Servs. Ltd.*, 3:14-cv-748-wmc (W.D. Wis. Sep. 29, 2017); Opinion and Order, *Epic Syst. Corp. v. Tata Consultancy Servs. Ltd.*, 3:14-cv-748-wmc (W.D. Wis. Mar. 22, 2019).

109. *Epic Systems Injunction*, *supra* note 84, at 2–3; *see also Epic Systems*, 980 F.3d at 1127.

110. *Epic Systems*, 980 F.3d at 1127.

111. *See id.* at 1130.

112. *See id.* at 1131–32.

113. *See PPG Indus. Inc. v. Jiangsu Tie Mao Glass Co.*, 47 F.4th 156, 158–59 (3d Cir. 2022).

114. *See id.*

115. *See id.* at 159.

116. *See generally id.*

The plaintiff prevailed via default judgment, and the district court awarded approximately \$8.8 million in compensatory damages.¹¹⁷ The “avoided cost” in this case was the research and development costs which the defendant would have incurred to independently develop the stolen technical information.¹¹⁸ The district court also issued a permanent injunction of indefinite duration, prohibiting the defendant from conducting any business within the United States that involved the use, disclosure, or reference to the stolen trade secrets.¹¹⁹

The Third Circuit upheld the district court’s remedies: “The [unjust enrichment] damages award was for the development costs [defendant] avoided when, for example, it solicited molds from [plaintiff’s] subcontractor and began designing a production facility in China. Those were *past* uses of the misappropriated trade secrets for which [plaintiff] was entitled to damages.”¹²⁰ The court also rejected the defendant’s contention that the permanent injunction constituted double-recovery because it “was issued . . . long after [defendant’s] earlier and unlawful use of [plaintiff’s] trade secrets,” and therefore, the injunction and the unjust enrichment award “covered entirely separate periods of past and potential *future* use of misappropriated trade secrets.”¹²¹

B. THE SECOND CIRCUIT’S *SYNTEL V. TRIZETTO* OPINION

In its *Syntel* opinion, the Second Circuit openly disagreed with *Epic Systems* and *PPG Industries*.¹²² The Second Circuit held that plaintiff TriZetto was not entitled to an avoided-cost unjust enrichment award because its past and future harms had already been redressed via other remedies.¹²³ Thus, awarding an unjust enrichment remedy for defendant Syntel’s avoided costs would overcompensate TriZetto and effectively amount to “punitive damages under the guise of compensatory damages.”¹²⁴ However, the Second Circuit tempered the reach and impact of its holding by qualifying its disagreement with the other circuits and limiting its holding “to the specific facts of this case.”¹²⁵ The Second Circuit did not repudiate *all* avoided-cost unjust

117. *See id.* at 159–60.

118. *See id.* at 162–63.

119. *See* Order at 2, *PPG Indus., Inc. v. Jiangsu Tie Mao Glass Co., Ltd. et al*, 2:15-cv-00965, at *2 (W.D. Pa. Mar. 31, 2020), ECF No. 158 [hereinafter *PPG Industries Injunction*].

120. *PPG Industries*, 47 F.4th at 163 (emphasis added).

121. *Id.* at 163–64 (emphasis added).

122. *See Syntel*, 68 F.4th at 812–13.

123. *Id.* at 813.

124. *Id.*

125. *Id.* at 814.

enrichment awards as a remedy for trade secret misappropriation, leaving open the possibility that such awards could still be available based on the specific facts of the case.¹²⁶

1. *History of Syntel v. TriZetto*

Syntel v. TriZetto originated from a business partnership that turned sour.¹²⁷ TriZetto is a developer of software used by healthcare insurance companies, and one of its software products, Facets®, is a platform which “automates and manages common healthcare administrative tasks such as claim processing, claim adjudication, and billing.”¹²⁸ Syntel had been one of TriZetto’s subcontractors.¹²⁹ As part of their contractual relationship under a Master Services Agreement (MSA), TriZetto had shared its trade secrets with Syntel as a trusted business partner.¹³⁰ However, trouble arose when TriZetto was acquired by Syntel’s competitor.¹³¹ Syntel terminated the MSA (as was its right), but continued to use TriZetto’s confidential trade secrets to compete directly with TriZetto post-termination—despite TriZetto’s raising concerns as to such use.¹³²

In 2015, Syntel first sued TriZetto in the Southern District of New York, alleging breach of contract and various business torts stemming from the termination of the MSA.¹³³ TriZetto counterclaimed, alleging, *inter alia*, that Syntel had misappropriated its trade secrets in violation of the DTSA.¹³⁴ During discovery, Syntel destroyed documents and computers; as a result, the district court ordered a neutral forensic examination of Syntel’s electronic devices and files, which revealed that Syntel had been actively creating a repository of TriZetto’s trade secrets for use in future projects.¹³⁵ Although Syntel argued that the MSA authorized it to continue using the trade secrets post-termination,¹³⁶ the jury ultimately found Syntel liable for trade secret misappropriation under the DTSA.¹³⁷

With respect to damages, TriZetto’s expert witness testified that Syntel had avoided expending approximately \$285 million in R&D costs through its

126. *See id.* at 810–12.

127. *See id.* at 797.

128. *See id.* at 796.

129. *Id.* at 797.

130. *Id.*

131. *Id.*

132. *Id.*

133. *See id.*

134. *See id.*

135. *Id.*

136. *Id.* at 798.

137. *Id.* at 799.

misappropriation, and the jury ultimately awarded the same amount in an unjust enrichment award for Syntel's avoided costs.¹³⁸

2. *The Second Circuit Breaks with Other Circuits Regarding Unjust Enrichment Awards for Avoided Costs*

The Second Circuit held that TriZetto was not entitled to the \$285 million avoided-cost unjust enrichment award, primarily because the district court had already issued a permanent injunction which barred Syntel from further using the trade secrets. Because the injunction barred future use, it ended Syntel's ability to profit from any avoided costs.¹³⁹ Since the injunction would prevent any future harms to TriZetto, and the value of TriZetto's trade secret had not been damaged, the Second Circuit concluded that an avoided-cost unjust enrichment award—in the lofty amount of \$285 million, no less—would be more punitive than compensatory.¹⁴⁰

The Second Circuit also specifically referenced—and openly disagreed with—the Seventh Circuit's *Epic Systems* and the Third Circuit's *PPG Industries* opinions with regard to their respective treatment of avoided-cost unjust enrichment awards.¹⁴¹ In each of those cases, the respective circuit court had upheld such awards despite the existence of injunctions prohibiting the defendant from using or possessing the misappropriated trade secrets.¹⁴² To the extent that no further unaddressed harms to the trade secret owner was necessary for such an award, the Second Circuit wrote, “such a view unhinges avoided costs from the DTSA's compensatory moorings and overlooks the remedial benefits, as here, of a timely injunction that prevents the dissemination and use of a trade secret.”¹⁴³

3. *The Second Circuit Tempered the Reach and Impact of Its Syntel Opinion*

Although the Second Circuit in *Syntel* clearly expressed its disagreement with the reasoning of the other circuit court opinions, it also expressly qualified that disagreement. The court narrowed its disapproval to “to the extent no corresponding harm to the trade secret owner would be necessary,” and “insofar as it can be seen to endorse a view that avoided costs are available as compensatory damages under the DTSA whenever there is misappropriation of any trade secret relating to an owner's product.”¹⁴⁴

138. *Id.* at 798–99.

139. *Id.* at 811.

140. *Id.* at 814.

141. *See id.* at 812, 813 n. 42.

142. *See id.*

143. *Id.* at 813.

144. *See id.* (first two emphases added, third emphasis in original).

Additionally, the Second Circuit held that unjust enrichment damages for avoided costs were unavailable “under the specific facts of this case.”¹⁴⁵ The *Syntel* court, therefore, did not repudiate *all* avoided-cost unjust enrichment awards altogether in trade secret misappropriation cases.¹⁴⁶ Instead, the court left open the possibility of allowing avoided-cost unjust enrichment awards based on factual considerations such as “the extent to which the defendant has used the secret in developing its own competing product, the extent to which the defendant’s misappropriation has destroyed the secret’s value for its original owner, or the extent to which the defendant can be stopped from profiting further from its misappropriation into the future.”¹⁴⁷ Thus, while the *Syntel* opinion firmly rejected an avoided-cost unjust enrichment award under its own specific facts, it left open the question of precisely when such damages are or are not available in trade secret misappropriation cases.

IV. ARGUMENT

The *Syntel* opinion is correct in principle that unjust enrichment is a compensatory remedy and that it should not result in a windfall for trade secret owners. On the other hand, by addressing an overcompensation concern, the Second Circuit may have inadvertently created a different problem: underdeterrence against trade secret misappropriation.¹⁴⁸ By ruling out avoided-cost unjust enrichment awards in certain situations, the decision reduces the financial risk for trade secret misappropriators within such situations. At the same time, it reduces the financial motivations of aggrieved trade secret owners to file suit and brave the often-formidable costs of trade secret litigation to enforce their rights. Both will tend to diminish the deterrent effects of trade secret law. Furthermore, even though *Syntel* does not necessarily create a sharply-defined circuit split, the legal disagreement between the Second Circuit and its sisters is likely to encourage forum-shopping. Avoided-cost unjust enrichment awards often reach very large amounts, and plaintiffs who anticipate relying heavily on this theory of damages will now face powerful monetary incentives to file outside the Second Circuit.

145. *See id.* at 814.

146. *See id.* at 810–11 (the Second Circuit acknowledged that restitution “can require a defendant to return the costs it saved through the misappropriation”).

147. *See id.* at 812.

148. Although punitive damages are still available, its permissible amount is mathematically dependent upon the amount of compensatory damages, and *Syntel*’s reduction of compensatory remedies will therefore also reduce the maximum punitive damages that a court may award. *See* UNIF. TRADE SECRETS ACT § 3; 18 U.S.C. § 1836(b)(3)(C).

One potential evolution of trade secret remedies to help restore the deterrence in *Syntel's* wake is to broaden the availability of attorney's fees, punitive damages, or reasonable royalty awards in trade secret misappropriation cases.

A. SYNTEL IS CORRECT IN PRINCIPLE THAT UNJUST ENRICHMENT IS A COMPENSATORY REMEDY AND THAT IT SHOULD NOT OVERCOMPENSATE THE TRADE SECRET OWNER

The Second Circuit makes a compelling point in *Syntel*: unjust enrichment is a form of compensatory damages, and it should not be used to grant awards that would exceed its compensatory purpose.¹⁴⁹

The Second Circuit is right that awarding unjust enrichment damages for a defendant's avoided costs would exceed compensatory purposes if: (1) the plaintiff's past losses and the defendant's additional past profits (if any) resulting from the misappropriation can be remedied through lost profits and disgorgement of any remaining unjust gains; (2) the misappropriation has not diminished or destroyed the value of the trade secret; and (3) an injunction can be expected to fully restrain the defendant from using the trade secret further.¹⁵⁰ Under such circumstances, the plaintiff has been compensated for its past harms—by the defendant repaying it for direct monetary losses and surrendering any additional profits it made by the misappropriation. The plaintiff has also been assured against future harms from the defendant via an injunction. If past harms have been accounted for and future harms have been prevented, then the plaintiff has been fully compensated. Any additional remedy—such as an unjust enrichment award for avoided costs—would exceed compensatory purposes. Although it is possible that punitive damages or attorney's fees are also warranted, if so, any further monetary remedies should be couched in those forms of recovery.¹⁵¹

Meanwhile, as the *Syntel* court itself acknowledged, avoided-cost unjust enrichment awards may still be justified in certain situations.¹⁵² An important factual consideration is whether the defendant can actually be stopped from

149. See *Syntel*, 68 F.4th at 811.

150. See *id.* (“Beyond its lost profits . . . TriZetto suffered no compensable harm support an unjust enrichment award of avoided costs. The district court’s permanent injunction ended Syntel’s use of TriZetto’s trade secrets, and, therefore, its ability to profit from any avoided costs. Further, Syntel’s misappropriation did not diminish . . . the secrets’ continued commercial value to TriZetto.”).

151. See *id.* at 811 n. 36.

152. *Id.* at 812 (“To be sure, future cases may present a range of factual scenarios concerning a defendant who has . . . nevertheless, been enriched by avoided costs . . . at the expense of the trade secret holder.”).

using the trade secret in the future—a factor that directly influences the efficacy of an injunction.¹⁵³ For example, if the defendant is a foreign-based entity that has already transferred copies of the misappropriated trade secret to its offices overseas, there may be legitimate doubts about whether an injunction by a U.S. court could effectively stop the defendant from continuing to use (and profit from) the trade secret. Although U.S. courts could enter injunctions that apply to the defendant’s global conduct,¹⁵⁴ the defendant’s possession of the trade secret in physical locations outside U.S. jurisdiction may limit enforcement allowing the defendant to continue profiting from the misappropriated trade secret in the future. In such cases where the defendant effectively remains able to continue profiting from the trade secret, the costs that the defendant avoided through its misappropriation *would* constitute an unjust benefit. A court should be able to award unjust enrichment damages for avoided costs in such cases.¹⁵⁵

Although *Syntel* is correct in principle that avoided-cost unjust enrichment awards should not overcompensate trade secret owners, its limitation of a very potent form of damages can weaken the deterrence against would-be trade secret misappropriators.

153. *Id.* (Whether a defendant has been enriched by avoided costs at the expense of the trade secret holder “might depend on . . . the extent to which the defendant can be stopped from profiting further from its misappropriation into the future.”); *see also* Victoria A. Cundiff, *A Closer Look at Trade Secret Damages*, N.Y.C. BAR ASS’N 12 (Dec. 11, 2023) (“What if there is reason to doubt the efficacy of an injunction?”).

154. *See, e.g.*, Permanent Injunction Order at 7, *Syntel Sterling Best Shores Mauritius Ltd., and Syntel, Inc. v. TriZetto Grp., Inc.*, No. 1:15-CV-00211-LGS-SDA (S.D.N.Y. May 18, 2021), ECF No. 993 [hereinafter *Syntel District Court Permanent Injunction Order*] (The district court enjoined Syntel from possessing, using, or disclosing TriZetto’s trade secrets “anywhere in the world.”).

155. If copies of the trade secret have already been transmitted outside U.S. jurisdiction, not even an ex parte civil seizure order could be relied upon to prevent further use of the trade secret by the defendant. Just as the law authorizes ex parte civil seizure orders when lawbreakers are suspected to be not amenable to the enforcement of the court’s orders, *supra*, Section II.D.4, if a misappropriator has already finished arranging its affairs so as to be not amenable to the court’s orders, it would make sense for the law to do something about that—such as by requiring the misappropriator to pay the fair value of an unjust benefit that it can no longer truly return (or be truly relied upon to honestly return). The Second Circuit seems to have rightly recognized this possibility. *See Syntel*, 68 F.4th at 812 (Whether a defendant has been enriched by avoided costs at the expense of the trade secret holder “might depend on . . . the extent to which the defendant can be stopped from profiting further from its misappropriation into the future.”).

B. THE *SYNTEL* DOCTRINE CAN UNDER-DETER TRADE SECRET MISAPPROPRIATION

Syntel could systematically under-deter trade secret misappropriation by significantly limiting the misappropriator's exposure to monetary damages. Furthermore, because the availability of avoided-cost unjust enrichment awards under *Syntel* depends largely upon the misappropriator's behavior, *Syntel* may open new avenues for would-be trade secret misappropriators to strategically tailor their misappropriation in a manner that avoids liability for avoided-cost unjust enrichment damages.

1. *Syntel Can Rule Out a Potent Component of Trade Secret Compensatory Damages, Diminishing the Deterrent Effects of Trade Secret Law*

A would-be trade secret misappropriator may be tempted by the potentially lucrative gains that it might reap from misappropriating valuable trade secrets. As seen in *Syntel* and *Epic Systems*, trade secret misappropriators can avoid possibly hundreds of millions of dollars in development costs—\$285 million and \$140 million, respectively.¹⁵⁶ Although the \$285 million unjust enrichment award in *Syntel* was ultimately overturned, that amount represents what *Syntel* stood to gain had it gotten away with its trade secret misappropriation. In other words, it represents a \$285 million temptation to misappropriate trade secrets. Misappropriators lucky enough to get away with their misdeeds thus stand to benefit handsomely, which may motivate some to take their chances. Furthermore, misappropriators can then use their ill-gotten trade secrets to enhance their market competitiveness—for example, by incorporating stolen trade secrets into their products and reaping greater profits when those products perform better on the market. To date, the threat of formidable avoided-cost unjust enrichment damages has helped counterbalance these dramatic potential upsides of trade secret misappropriation. *Syntel* takes these damages off the table in certain situations which may greatly weaken deterrence against trade secret misappropriation.

Under *Syntel*, a trade secret misappropriator would likely not be liable for avoided-cost unjust enrichment damages if: (1) the plaintiff's past losses and any additional past profits by the defendant can be remedied with lost profits and disgorgement of remaining unjust gains; (2) the misappropriation did not diminish or destroy the value of the trade secret; and (3) an injunction would fully prevent the defendant from using the trade secret in the future.¹⁵⁷ Under

156. More precisely, the respective district courts found that the defendants before them had avoided incurring these amounts by misappropriating trade secrets. See *Syntel*, 68 F.4th at 798–99; *Epic Sys. Corp. v. Tata Consultancy Servs. Ltd.*, 980 F.3d 1117, 1123 (7th Cir. 2020).

157. See *supra* Section IV.A; *Syntel*, 68 F.4th at 811.

such circumstances, a misappropriator would risk little more than the return of what it should never have taken in the first place. Even if a misappropriator is detected, sued, and found liable for trade secret misappropriation, its financial liability may well be limited to any lost profits inflicted upon the plaintiff and any of the defendant's remaining profits,¹⁵⁸ plus its own litigation costs. The former will often be a mere return of what the defendant wrongfully gained from the misappropriation in the first place—and it may even be zero if the defendant had not yet fully commercialized the misappropriated trade secret by the time it was caught.¹⁵⁹ This could leave the misappropriator's own litigation costs as the only major expense that it stands to lose, relative to its financial position pre-misappropriation—and a misappropriator can likely exert some control over even this expense (for example, by settling early in the case). Conversely, an aggrieved trade secret owner stands to be awarded significantly less in compensatory relief, making it less financially worthwhile to file suit—which further reduces the risk for misappropriators.

While it may be true that awarding unjust enrichment damages for avoided costs *whenever* there is misappropriation of any trade secret could depart from the compensatory underpinnings of unjust enrichment damages (as the *Syntel* court feared),¹⁶⁰ it also seems questionable to have a system where adjudged misappropriators are not much worse off after losing in court than they would have been if they had never stolen the trade secret in the first place. If a would-be trade secret misappropriator anticipates that the worst-case scenario is simply giving back what was stolen (if caught), that will significantly hobble the deterrent effects of trade secret law.¹⁶¹

158. See 18 U.S.C. § 1836(b)(3)(B)(i).

159. See Petition for Writ of Certiorari at 32–33, *Syntel*, 144 S. Ct. 352 (2023) (“Defendants caught before they can turn a meaningful profit or otherwise harm the value of the trade secret will escape both actual-loss and unjust enrichment liability altogether . . .”).

160. *Syntel*, 68 F.4th at 813.

161. Would-be infringers under other intellectual property regimes often face significant compensatory damages, even if the plaintiff alleges no lost profits or unjust gains to be disgorged. For instance, would-be patent infringers often face at least reasonable royalty damages. See 35 U.S.C. § 284 (providing for compensatory damages “in no event less than a reasonable royalty”); would-be copyright infringers often face at least statutory damages and attorney's fees. See 17 U.S.C. §§ 504–05 (providing for up to \$150,000 in statutory damages, plus attorney's fees at a court's discretion against any defendant other than the United States); see also Michael Jacobs & Karl Johnston, *Attorney's Fees in Copyright Cases*, MORRISON & FOERSTER (Feb. 2022) (explaining how copyright law provides a favorable standard for awarding attorney's fees and citing relevant caselaw). By comparison, trade secret law does not provide for an equivalent minimum of compensatory damages. See *supra* Section II.D.1.

2. *Would-Be Trade Secret Misappropriators Can Take Advantage of Syntel by Strategically Tailoring Their Misappropriation*

A would-be trade secret misappropriator might do more than passively anticipate a *Syntel*-like set of circumstances—it could even actively attempt to create them by strategically tailoring its misappropriation. For instance, a misappropriator could steal another person’s trade secret, but while doing so, take deliberate care to not harm the value of the trade secret (e.g., by not further disclosing it) and ensure that there is no credible reason to doubt the efficacy of an injunction (e.g., by not transmitting any copies of the trade secret out of U.S. jurisdiction). If the misappropriator succeeds in doing this, it will have essentially re-created a *Syntel*-like situation under which a court would be unlikely to impose a costly avoided-cost unjust enrichment remedy, greatly reducing its exposure to compensatory remedies. The misappropriator could then rest assured that, even if its misdeeds are discovered, its financial exposure is likely limited to little more than giving back what it stole.

A particularly strategic misappropriator could take the above scenario a step further by exploiting the statute of limitations under trade secret law. Under the DTSA, the statute of limitations for trade secret misappropriation is three years from when the misappropriation is discovered or should have been discovered with the exercise of reasonable diligence.¹⁶² A trade secret misappropriator could go as far as to intentionally alert the trade secret owner to the misappropriation to start the clock on the statute of limitations. While the statute of limitations ticks away, the aggrieved trade secret owner would have reduced financial incentive to sue because the potent avoided-cost unjust enrichment remedy would remain off the table under *Syntel*.¹⁶³ Meanwhile, if the trade secret owner does not file suit within the statute of limitations period, its misappropriation claim will be barred—once this has happened, the misappropriator could begin commercializing the stolen trade secret with impunity from suit from the trade secret owner. If misappropriators can do this, the risk-reward calculus for unscrupulous entities may weigh in favor of misappropriation.

162. See 18 U.S.C. § 1836(d); UNIF. TRADE SECRETS ACT § 6. State law UTSA enactments are typically substantially similar. See, e.g., CAL. CIV. CODE § 3426.6 (substantially similar under California law); TEX. CIV. PRAC. & REM. CODE ANN. § 16.010 (substantially similar under Texas law). But see 765 ILL. COMP. STAT. ANN. 1065/7 (five-year statute of limitations period under Illinois law).

163. See *Syntel*, 68 F.4th at 814. The misappropriator could further reduce its own financial risk (and the plaintiff’s motivation to sue) by not commercializing the trade secret while the statute of limitations period runs, thus inflicting zero lost profits and gaining zero unjust profits during that time.

Syntel allows these scenarios because it under some circumstances would preclude avoided-cost unjust enrichment awards, which an aggrieved trade secret owner otherwise could pursue. Although these scenarios currently are merely theoretical possibilities in the initial years after *Syntel* was decided, they nevertheless represent possible gaps in the deterrent effects of trade secret law.

C. *SYNTEL* MAY PRODUCE DIFFERENT RESULTS ON THE SAME FACTS
AND ENCOURAGE FORUM-SHOPPING

The Second Circuit's reasoning in *Syntel* differs significantly from other circuits regarding avoided-cost unjust enrichment damages in trade secret misappropriation cases. Although the "circuit split" that *Syntel* creates is not as defined and clean-cut as other circuit splits in the past (which may have contributed to the U.S. Supreme Court denying certiorari), this disagreement between the Second Circuit and its sister circuits may nevertheless lead to significantly different remedy outcomes in cases with *Syntel*-like facts. This, in turn, will likely encourage forum-shopping in future trade secret misappropriation cases.

1. *Although the Split Between the Second Circuit and Its Sisters is Quite Mesy, Syntel is Ultimately Likely to Produce Different Results on the Same Facts*

Syntel did not present a well-defined and clean-cut circuit split. On one hand, key differences between the facts of *Syntel* and other circuits' decisions plus the Second Circuit's qualified statements in *Syntel* blur the legal disagreement between the Second Circuit and its sisters. On the other hand, and notwithstanding the blurred contours of the legal disagreement, the Second Circuit clearly disagreed with the results reached by the other circuits, and it placed critical importance upon the compensatory underpinnings of unjust enrichment damages, a consideration that its sister circuits have not clearly expressed. Ultimately, it is likely that *Syntel* will produce different remedy results than the other circuits on similar facts. In other words, although the precise legal disagreement between the Second Circuit and its sister circuits is murky, the Second Circuit's intense focus on keeping compensatory damages within their compensatory underpinnings likely means that *Syntel* will ultimately produce different remedy results.

a) *Syntel* Does Not Present a Well-Defined and Clean-Cut Circuit Split

Although the Second Circuit openly disagreed with previous opinions of other circuit courts¹⁶⁴ relating to avoided-cost unjust enrichment damages, a closer analysis of the *Syntel* opinion and the cases it criticizes reveals factual variations and qualified statements that render the legal disagreement less clear-cut.

i) Factual Differences Between *Syntel* and the Cases It Criticizes

Despite the Second Circuit's criticisms of the Seventh Circuit's *Epic Systems* and the Third Circuit's *PPG Industries* opinions regarding their treatment of unjust enrichment damages for avoided costs, there are key factual differences between these three cases that complicate the legal disagreement between the circuits. These factual differences are particularly important because they implicate a factor which the *Syntel* court itself acknowledged as being material to whether a defendant has been unjustly enriched by avoided costs: the extent to which the defendant can be stopped from profiting further from its misappropriation into the future.¹⁶⁵ Because these factual differences directly affect whether avoided-cost unjust enrichment is warranted, they obscure whether the awards in *Epic Systems* or *PPG Industries* would necessarily change under *Syntel*'s legal reasoning, blurring the legal disagreement between the circuit courts.

Syntel factually differs from *Epic Systems* and *PPG Industries* in several ways, as summarized in Table 1, below.

164. The Second Circuit specifically called out the Seventh and Third Circuits. *See Syntel*, 68 F.4th at 812, 813 n. 42 (openly disagreeing with the Seventh Circuit's opinion in *Epic Systems*, and the Third Circuit's opinion in *PPG Industries*).

165. *See id.* at 812.

Table 1: Comparison Between *Syntel*, *Epic Systems*, and *PPG Industries*

	<i>Syntel</i>	<i>Epic Systems</i>	<i>PPG Industries</i>
Defendant	Domestic company	Foreign company	Foreign company
Governing Law	DTSA and New York law	UTSA (Wisconsin)	UTSA (Pennsylvania)
Value of TS Damaged?	No	No indication	No indication
Injunction Scope	Worldwide	Worldwide	Within the U.S.
Injunction Duration	Indefinite	4 Years	Indefinite
Avoided Cost UE Award Upheld?	No	Yes	Yes
Circuit Court Reasoning	The district court injunction ended Syntel's use of the misappropriated trade secret and its ability to profit from any avoided costs in the future.	Defendant gained a "significant head start" by its misappropriation; UEAC has been awarded for such "head starts" in the past.	The UEAC award covered past uses of the misappropriated trade secret; the injunction, issued long after the misappropriation, covered potential future uses of that trade secret.

These factual differences may materially affect whether and to what extent each defendant can be stopped from profiting further from its misappropriation.¹⁶⁶ In *Syntel*, the district court issued an injunction of indefinite duration and worldwide scope.¹⁶⁷ Absent some specific reason to doubt the efficacy of that injunction (which does not appear to have been argued), the district court's injunction "ended Syntel's use of TriZetto's trade secrets, and, therefore, its ability to profit from any avoided costs."¹⁶⁸ By contrast, in *Epic Systems*, the district court issued an injunction lasting only four years in duration;¹⁶⁹ after that period, the defendant could potentially resume profiting from its misappropriation to some degree. In *PPG Industries*, the district court restricted its injunction to defendant's activities within the United

166. *See id.*

167. *See Syntel District Court Permanent Injunction Order, supra* note 154, at 7.

168. *See Syntel*, 68 F.4th at 811.

169. *See Epic Systems Injunction, supra* note 84, at 2.

States.¹⁷⁰ Thus, that defendant might be able to continue profiting from its misappropriation to some degree by engaging in the prohibited activities outside the United States. Because the defendants in both *Epic Systems* and *PPG Industries* might have been able to continue profiting from their misappropriation, they were arguably enriched by their avoided costs under *Syntel*'s reasoning.¹⁷¹ This factor obscures whether the unjust enrichment awards in *Epic Systems* or *PPG Industries* would necessarily be different under *Syntel*,¹⁷² muddying the legal disagreement between the circuit courts.¹⁷³

ii) Limited Holding and Qualified Statements in *Syntel* and the Absence of Squarely Opposing Statements by Other Circuits

The *Syntel* court limited its holding and qualified its disagreement with the other circuit courts.¹⁷⁴ This reduces the clarity of the present circuit split, compared to other typical circuit splits.

a. Limited Holding in *Syntel*

The *Syntel* court held that avoided-cost unjust enrichment damages were not available “under the specific facts” presented.¹⁷⁵ However, it also left open the possibility of allowing future avoided-cost unjust enrichment damages

170. See *PPG Industries Injunction*, *supra* note 119, at 2.

171. See *Syntel*, 68 F.4th at 812 (“[F]uture cases may present a range of factual scenarios concerning a defendant who has realized only modest profits from its misappropriation of trade secrets but has, nevertheless, been enriched by avoided costs in a large amount at the expense of the secret holder. This might depend on . . . the extent to which the defendant can be stopped from profiting further from its misappropriation into the future.”).

172. This refers to whether the unjust enrichment doctrine embraced by *Syntel* would necessarily demand reversal of the avoided-cost unjust enrichment awards under the facts and procedural posture of *Epic Systems* or *PPG Industries*. On the other hand, that the *Syntel* opinion specifically criticizes the *Epic Systems* and *PPG Industries* opinions on the unjust enrichment issue suggests that the Second Circuit would likely have decided the issue differently had those cases been heard in the Second Circuit. See *infra* Section IV.C.1.b.

173. In addition to the factual differences, there are other noteworthy legal and procedural differences between *Syntel*, and *Epic Systems* and *PPG Industries*. The trade secret misappropriation claim in *Syntel* was based on the federal DTSA and New York State law, although the damages award primarily relied on the DTSA. See *Syntel*, 68 F.4th at 797, 806–14. Meanwhile, the trade secret misappropriation claims in *Epic Systems* and *PPG Industries* were brought under Wisconsin and Pennsylvania State law, respectively. See *Epic Sys. Corp. v. Tata Consultancy Servs. Ltd.*, 980 F.3d 1117, 1138 (7th Cir. 2020); *PPG Indus. Inc. v. Jiangsu Tie Mao Glass Co.*, 47 F.4th 156, 159 (3d Cir. 2022). Although the effects of procedural posture and the nuances between the DTSA and UTSA are beyond the scope of this Note, they are briefly mentioned here for completeness’ sake because they introduce additional layers of complexity between the cases.

174. See *Syntel*, 68 F.4th at 812–14.

175. See *id.* at 814; see also *supra* Section III.B.3.

based on factual considerations such as “the extent to which the defendant has used the secret in developing its own competing product, the extent to which the defendant’s misappropriation has destroyed the secret’s value for its original owner, or the extent to which the defendant can be stopped from profiting further from its misappropriation into the future.”¹⁷⁶ Thus, while *Syntel* reached a clear outcome under its own specific facts, it left open the question of precisely when unjust enrichment damages for avoided costs are or are not available in trade secret misappropriation cases. This detracts from there being a clear-cut circuit split between the Second Circuit and its sisters.

b. Qualified Statements in *Syntel* and the Absence of Squarely Opposing Statements by Other Circuits

Although the Second Circuit in *Syntel* very clearly expressed that it disagreed with the reasoning of *Epic Systems* and *PPG Industries*, it also confined that disagreement to an interpretation of those opinions which would treat trade secret misappropriation as itself a sufficient condition for awarding avoided-cost unjust enrichment damages.¹⁷⁷

This qualification makes sense because the other circuit court opinions do not positively hold that trade secret misappropriation is by itself a sufficient condition for avoided-cost unjust enrichment awards. Rather, these opinions appear to have upheld them simply because the plaintiff’s allegations of the defendant’s avoided costs satisfied all other legal and evidentiary requirements under general principles of unjust enrichment doctrine.¹⁷⁸

c. Contrast with Other Circuit Splits

The circuit split stemming from *Syntel* sharply contrasts with other circuit splits that have been much more defined and clear-cut. For example, the U.S. Supreme Court recently granted certiorari in *Horn v. Medical Marijuana, Inc.*, addressing a split regarding civil liability under the Racketeer Influenced and Corrupt Organizations (RICO) Act.¹⁷⁹ The legal question was whether economic harm resulting from personal injuries are injuries to “business or property by reason of” the defendant’s acts for purposes of civil RICO.¹⁸⁰ The

176. See *Syntel*, 68 F.4th at 812; see also *supra* Section III.B.3.

177. See *Syntel*, 68 F.4th at 813 (“We disagree with the court’s reasoning insofar as it can be seen to endorse a view that avoided costs are available as compensatory damages under the DTSA whenever there is misappropriation of any trade secret relating to an owner’s product.” (emphasis in original)); see also *supra* Section III.B.3.

178. See *supra* Section III.A.

179. 80 F.4th 130 (2d Cir. 2023), cert. granted sub nom., *Medical Marijuana, Inc. v. Horn*, 144 S. Ct. 1454 (U.S. Apr. 29, 2024).

180. *Id.* at 135.

Second Circuit held in *Horn* that the civil-action provision of RICO does not bar a suit for damages simply because those damages flow from a personal injury.¹⁸¹ This directly conflicted with the Sixth Circuit's decision in *Jackson v. Sedgwick Claims Management Services, Inc.*, which squarely held that "both personal injuries and pecuniary losses flowing from those personal injuries *fail to confer relief* under" civil RICO.¹⁸² Neither *Horn* nor *Jackson* limited their holdings to their facts, and they produced two clearly opposing rules of law. By contrast, the limited holding and qualified statements in *Syntel*, and the absence of squarely opposing statements by other circuits, result in a circuit split that is less clearly defined and clear-cut.

- b) Nevertheless, *Syntel* Represents a Significant Difference in Reasoning Between Circuit Courts, Which May Ultimately Produce Different Remedy Outcomes on the Same Facts
 - i) *Syntel* Represents a Significant Difference in Reasoning Between Circuit Courts

The present disagreement between the Second Circuit and its sisters is nevertheless significant because *Syntel* approaches unjust enrichment awards from a fundamentally different perspective: it takes as a foundational principle that unjust enrichment awards must be compensatory and, thus, zealously guards against overcompensation.¹⁸³ Meanwhile, the other circuit courts generally have not placed such importance on guarding against overcompensation.¹⁸⁴ Combined with the Second Circuit's open criticism of the results reached by (and not just the reasoning of) its sister circuits, it is likely that the *Syntel* doctrine will ultimately produce different remedy outcomes in trade secret misappropriation cases within the Second Circuit as compared to other circuits.

The Second Circuit places clear and critical importance on the compensatory moorings of unjust enrichment in the *Syntel* opinion. Specifically, it emphasizes that unjust enrichment awards under the DTSA are meant to compensate trade secret owners whose injuries are not adequately

181. *Id.* at 142.

182. *Jackson v. Sedgwick Claims Mgmt. Servs., Inc.*, 731 F.3d 556, 565–66 (6th Cir. 2013) (en banc) (emphasis added).

183. *See Syntel*, 68 F.4th at 813.

184. *See generally*, *Epic Sys. Corp. v. Tata Consultancy Servs., Ltd.*, 980 F.3d 1117, 1128–33 (7th Cir. 2020); *PPG Indus. Inc. v. Jiangsu Tie Mao Glass Co.*, 47 F.4th 156, 161–64 (3d Cir. 2022).

addressed by lost profits.¹⁸⁵ It states that the DTSA’s unjust enrichment provision must be read in conjunction with the Act’s compensatory damages scheme so that unjust enrichment awards include only “*compensable harm[s]*” beyond [plaintiff’s] lost profits or profit opportunities.”¹⁸⁶ Lastly, *Syntel* holds that TriZetto suffered no *compensable* harm warranting an unjust enrichment award for avoided costs because “[t]he district court’s permanent injunction ended Syntel’s use of TriZetto’s trade secrets, and, therefore, its ability to profit from any avoided costs.”¹⁸⁷ The Second Circuit therefore reversed an approximately \$285 million unjust enrichment award.¹⁸⁸

Meanwhile, the other circuits have not been as explicitly committed toward keeping unjust enrichment damages strictly compensatory. For example, in the section of the *Epic Systems* opinion discussing the unjust enrichment award, the Seventh Circuit focused mostly on whether unjust enrichment for avoided costs is supported by precedent (the Seventh Circuit found that it did)¹⁸⁹ and whether a reasonable jury had a sufficient evidentiary basis to award the \$140 million avoided-cost unjust enrichment award (the Seventh Circuit found that it did).¹⁹⁰ The opinion did not expressly consider whether that \$140 million award was properly limited to a compensatory function.¹⁹¹

Similarly, in *PPG Industries*, the Third Circuit focused on whether unjust enrichment for avoided costs was an allowable remedy (the Third Circuit found that it was),¹⁹² and whether the defendant had benefitted by avoiding

185. See *Syntel*, 68 F.4th at 811 (“Section 1836(b)(3)(B)(i)(II) awards compensatory damages to aggrieved trade secret holders whose injuries are not adequately addressed by lost profits.”).

186. *Id.* (emphasis in original).

187. *Id.* (emphasis added).

188. See *id.* at 814.

189. See generally *Epic Systems*, 980 F.3d at 1128–30.

190. See generally *id.* at 1131–33.

191. One reason why the Seventh Circuit did not expressly consider whether the avoided-cost unjust enrichment award overcompensated the plaintiff may have been that the defendant did not extensively argue it on appeal. The defendant in *Epic Systems* seems to have primarily argued on appeal that the “comparative analysis” document could not constitute a “head start.” See generally Opening Brief for Tata Consultancy Servs. Ltd. at 44–60, *Epic Sys. Corp. v. Tata Consultancy Servs. Ltd.*, 980 F.3d 1117 (7th Cir. 2020) (*TCS Opening Appellate Brief*). Meanwhile, the defendant does not appear to have extensively argued on appeal that the \$140 million avoided-cost unjust enrichment award constituted double recovery when combined with the permanent injunction—in fact, the defendant’s opening appellate brief addresses the permanent injunction’s effects just once, buried in the middle of a footnote. See *TCS Opening Appellate Brief* at 50–51, 51 n. 7. The defendant’s reply brief does not address the injunction at all. See generally Combined Response & Reply Brief for Tata Consultancy Servs. Ltd., *Epic Sys. Corp. v. Tata Consultancy Servs. Ltd.*, 980 F.3d 1117 (7th Cir. 2020).

192. See *PPG Indus. Inc. v. Jiangsu Tie Mao Glass Co.*, 47 F.4th 156, 161–62 (3d Cir. 2022).

costs by its misappropriation (the Third Circuit found that it had, because the misappropriation allowed the defendant to “skip the R&D process completely and begin preparing for production without developing anything like the [stolen technology] on its own”).¹⁹³ The Third Circuit also considered whether the district court had properly determined the avoided costs. The Third Circuit found that it had, because the district court “did not look to [plaintiff’s] R&D costs to reimburse” the plaintiff; rather, the district court “looked to those costs as indicative of the costs” that the defendant avoided by misappropriating the fruits of the plaintiff’s work.¹⁹⁴ Although the opinion briefly addressed the defendant’s argument that awarding the unjust enrichment damages for avoided costs on top of issuing a permanent injunction amounted to a “double recovery,” the Third Circuit disagreed and formalistically characterized the unjust enrichment award as compensating for the defendant’s past uses of the trade secret and the injunction as covering potential future use of the trade secret.¹⁹⁵ Beyond that brief discussion, the Third Circuit did not expressly consider whether the district court’s \$8.8 million compensatory award was properly limited to a compensatory function.

ii) The Disagreement Between the Second Circuit and Its Sisters May Produce Differing Remedy Outcomes

If *Epic Systems*, *PPG Industries*, or a similar case were to be heard before the Second Circuit, it seems likely that the Second Circuit would ultimately reverse (or at least reduce) the avoided-cost unjust enrichment awards—despite its qualified statements and limited holding in *Syntel* itself.

First, the Second Circuit’s express criticism of the results in *Epic Systems* and *PPG Industries* on the unjust enrichment point¹⁹⁶ suggests that the Second Circuit would not have upheld the avoided-cost unjust enrichment awards in those cases and would reverse such awards under similar facts. In addition, although *Epic Systems* and *PPG Industries* differed from *Syntel* in some key factual respects (and therefore, the unjust enrichment doctrine embraced by *Syntel* might not necessarily demand reversal of such unjust enrichment awards),¹⁹⁷ the

193. See *id.* at 162.

194. See *id.* at 162–63.

195. See *id.* at 163–64.

196. See *Syntel*, 68 F.4th at 812–13, 813 n. 42.

197. See *supra* Section IV.C.1.a.ii. The district court in *Epic Systems* issued a permanent injunction of limited duration, while the district court in *PPG Industries* geographically limited the scope of the its permanent injunction to within the United States; both of these limitations tend to leave open whether the respective defendants might be able to continue profiting from its misappropriation into the future to some degree—a factor which the *Syntel* court itself acknowledged as a potentially important factor in whether an avoided-cost unjust enrichment award is proper.

Second Circuit would still likely reverse or reduce the unjust enrichment awards. The Second Circuit's intense focus on ensuring that compensatory awards stay within the bounds of their compensatory purposes would likely lead it to a similar conclusion as in *Syntel*.

In *Syntel*, the Second Circuit placed great importance on whether Syntel's misappropriation injured TriZetto beyond its lost profits.¹⁹⁸ The court determined that this depended largely upon whether the district court had issued an injunction preventing Syntel from further using the misappropriated trade secret.¹⁹⁹ Because the district court had issued such an injunction, Syntel was unable to profit from any avoided costs, and so the Second Circuit concluded that the avoided-cost unjust enrichment award was over-compensatory.²⁰⁰

If the Second Circuit were to apply the same compensatory focus to the facts of *Epic Systems*, it would likely view the avoided-cost unjust enrichment award in that case as over-compensatory and, therefore, reverse or reduce that award. In *Epic Systems*, the district court had issued a four-year injunction barring the defendant from using the misappropriated trade secrets. The jury also awarded approximately \$140 million in avoided-cost unjust enrichment.²⁰¹ The Second Circuit would likely focus on the fact that the injunction precluded the defendant's ability to profit from its "head start" (at least for four years, while the injunction is effective). Given this injunction, an avoided-cost unjust enrichment award would exceed compensatory purposes according to the Second Circuit. The Second Circuit is also likely to view the avoided-cost unjust enrichment award in *PPG Industries* as over-compensatory. In *PPG Industries*, the district court had issued both a permanent injunction barring the defendant's future use of the misappropriated trade secrets and also an avoided-cost unjust enrichment award of approximately \$8.8 million.²⁰² The Second Circuit would likely focus on the fact that even though the defendant may have been able to skip the R&D process using the stolen trade secret, the district court's injunction restricted the defendant's ability to profit from it in the future (within the United States, at least).²⁰³ Given this injunction, the

198. See *Syntel*, 68 F.4th at 810; see also *supra* Section IV.C.1.b.i.

199. See *Syntel*, 68 F.4th at 810–11; see also *supra* Section IV.C.1.b.i.

200. See *Syntel*, 68 F.4th at 811; see also *supra* Section IV.C.1.b.i.

201. See *Epic Sys. Corp. v. Tata Consultancy Servs. Ltd.*, 980 F.3d 1117, 1127 (7th Cir. 2020); *Epic Systems Injunction*, *supra* note 84, at 2.

202. See *PPG Indus. Inc. v. Jiangsu Tie Mao Glass Co.*, 47 F.4th 156, 160 (3d Cir. 2022); see also *supra* Section IV.C.1.b.i.

203. The district court's injunction was geographically limited to within the United States. See *PPG Industries Injunction*, *supra* note 119, at 2.

Second Circuit would likely find this avoided-cost unjust enrichment award to be over-compensatory.

2. *This Disagreement Between Circuits May Produce Very Different Remedy Outcomes and is Likely to Encourage Forum-Shopping*

Appellate forum shopping is the practice of selecting an appellate court with a favorable interpretation of the law and strategically placing the case in that jurisdiction.²⁰⁴ This practice is common in appellate litigation.²⁰⁵

The magnitude of avoided-costs unjust enrichment awards in trade secret misappropriation cases often reaches well into the millions of dollars. In *Syntel*, the award was worth approximately \$285 million.²⁰⁶ In *Epic Systems*, the award was worth approximately \$140 million.²⁰⁷ In *PPG Industries*, the award was worth approximately \$8.8 million.²⁰⁸ With awards of such magnitude on the line, trade secret plaintiffs who expect to find themselves in a position similar to TriZetto's in *Syntel* (plaintiffs who seek a prohibitory injunction but do not expect to argue for significant actual losses or disgorgement remedies) may now feel significant financial incentives to file suit outside the Second Circuit. Conversely, accused trade secret misappropriators, hoping to avoid such costly remedies, will likely be very motivated to change venue to a court within the Second Circuit.

D. POSSIBLE EVOLUTION OF TRADE SECRET REMEDIES FOR *SYNTEL*-LIKE TRADE SECRET CASES: IMPOSE ATTORNEY'S FEES, PUNITIVE DAMAGES, OR REASONABLE ROYALTY DAMAGES MORE OFTEN

In *Syntel*, the Second Circuit cast a skeptical eye towards avoided-cost unjust enrichment awards in situations where it would exceed compensatory purposes. Such situations occur when: (1) an injunction can be expected to foreclose the defendant from using the misappropriated trade secret in the future; and (2) the value of the trade secret has not been harmed.²⁰⁹ *Syntel* is correct in principle that unjust enrichment, as a form of compensatory damages, should not overcompensate or produce windfalls.²¹⁰ However, *Syntel's* purely compensatory approach towards unjust enrichment damages may reduce deterrence against trade secret misappropriation by restricting

204. Edward M. Mullins & Rima Y. Mullins, *You Better Shop Around: Appellate Forum Shopping*, 25 LITIGATION 32 (Summer 1999).

205. *See id.*

206. *See Syntel*, 68 F.4th at 799.

207. *See Epic Systems*, 980 F.3d at 1127–28.

208. *See PPG Industries*, 47 F.4th at 160.

209. *See Syntel*, 68 F.4th at 811.

210. *See supra* Section IV.A.

avoided-cost unjust enrichment awards (which are often substantial in monetary value).²¹¹ This loss of deterrent effect may be particularly pronounced when a would-be misappropriator can anticipate (or even create) *Syntel*-like facts, under which it would likely be financially liable for little more than its own litigation costs.²¹²

Awarding attorney's fees, punitive damages, or reasonable royalty damages more easily in trade secret cases would be a potentially effective method to restore the deterrent effect of trade secret law diminished by *Syntel*.

1. *Attorney's Fees Awards*

Awarding attorney's fees more frequently in these cases (at least, in those trade secret misappropriation cases with *Syntel*-like facts) could help restore trade secret law's deterrent effect by increasing the financial consequences for trade secret misappropriators and by restoring aggrieved trade secret owners' monetary incentives to bring suit even without the possibility of lucrative unjust enrichment awards.

The magnitude of attorney's fees can be significant in trade secret cases. In 2022, the median litigation costs of trade secret misappropriation cases proceeding through trial (and appeal, if applicable) were between \$750,000 and \$2.75 million, depending on the amount of money at risk in the litigation.²¹³ Individual cases can greatly exceed these averages—as the court in *Syntel* awarded \$14.5 million post-appeal.²¹⁴

The federal DTSA and State law UTSA's allow courts to award reasonable attorney's fees if the trade secret was “willfully and maliciously” misappropriated.²¹⁵ The requirements for establishing “willful and malicious” misappropriation can be challenging, and courts rarely award attorney's fees.²¹⁶ This rarity is especially true for courts that apply more demanding standards for “willful and malicious” misappropriation—these courts have denied attorney's fees awards when they found that a misappropriator's egregious misconduct was only motivated by competition (rather than an actual intent to

211. *See supra* Section IV.B.

212. *See supra* Section IV.B.

213. AIPLA, REPORT OF THE ECONOMIC SURVEY 2023, at 66 (Oct. 2023); *see also supra* Section II.D.3.

214. *Syntel Sterling Best Shores Mauritius Ltd. v. TriZetto Grp., Inc.*, No. 15-cv-211 (LGS), 2024 WL 1116090, at *4 (S.D.N.Y. Mar. 13, 2024) (post-appeal proceedings before the district court).

215. *See* 18 U.S.C. § 1836(b)(3)(D); UNIF. TRADE SECRETS ACT § 4; *see also supra* Section II.D.3.

216. *See supra* Section II.D.3; Rowe, *supra* note 12, at 169–76 (an empirical study of 150 trade secret misappropriation cases from 2000 to 2014 revealed that attorney's fees awards only comprised about 8 percent of all damages awarded in those 150 trade secret cases).

inflict harm).²¹⁷ Changing this practice may have some possible advantages and disadvantages.

a) Modes of Implementation

Whether courts may award attorney's fees (or punitive damages) for trade secret misappropriation under federal or state law depends on whether the misappropriation was "willful and malicious."²¹⁸ Currently, when interpreting the DTSA, courts "typically look to the state UTSA . . . inasmuch as the two are substantively identical."²¹⁹ Thus, whether a defendant's conduct qualifies as "willful and malicious" under either the DTSA or state law UTSA typically depends upon how the law of the applicable state defines that term. There are two ways to allow courts to award attorney's fees more often in trade secret cases: (a) judicially adopt a more flexible interpretation of "willful and malicious" misappropriation; or (b) statutorily adopt such an interpretation.

i) Judicially Adopt a Flexible Interpretation of "Willful and Malicious" Misappropriation

Different jurisdictions have applied different standards for "willful and malicious" conduct. Some states have adopted a more flexible standard, defining the term as "acting consciously in disregard of another person's rights or acting with reckless indifference to the consequences, with the defendant aware, from his knowledge of existing circumstances and conditions, that his conduct probably would cause injury to another."²²⁰ In other words, this definition allows courts to impose attorney's fees if the misappropriator knew that its actions would likely harm the trade secret owner and proceeded with its misappropriation anyway.

Meanwhile, other states have adopted a more restrictive standard for "willful and malicious," requiring an actual intent to harm or injure.²²¹ This definition allows courts to impose attorney's fees only if they find that the

217. See, e.g., *Roton Barrier, Inc. v. Stanley Works*, 79 F.3d 1112, 1120–21 (Fed. Cir. 1996) (despite agreeing that the defendant acted intentionally and with blatant duplicity, the appellate court ruled that the trial court's punitive damages and attorney's fees awards were an abuse of discretion because the defendant's actions were nevertheless motivated by competition and not an intent to harm).

218. See 18 U.S.C. § 1836(b)(3); UNIF. TRADE SECRETS ACT §§ 3, 4.

219. *Smart Team Glob.*, 2022 WL 847301, at *10.

220. See *Hair Club for Men, LLC v. Ehson*, No. 1:16-cv-236, 2017 WL 1250998, at *3 (E.D. Va. Apr. 3, 2017) (internal citations omitted) (applying Virginia law); *Smart Team Glob.*, 2022 WL 847301, at *10 (applying Virginia law).

221. See, e.g., *MicroStrategy Inc. v. Bus. Objects, S.A.*, 331 F. Supp. 2d 396, 430 (E.D. Va. 2004).

misappropriator engaged in its misappropriation with the specific intent and motivation to harm the trade secret owner.

If more jurisdictions adopt the more flexible interpretation of “willful and malicious,” courts in those jurisdictions would have greater discretion to award attorney’s fees whenever they find that the defendant misappropriated the trade secret intentionally and with knowledge that it would harm the trade secret owner.

ii) Statutorily Adopt a Flexible Interpretation of “Willful and Malicious” Misappropriation

A more uniform and straightforward mode of implementing the same effect would be for Congress to statutorily adopt a more flexible definition of “willful and malicious” for purposes of the DTSA. This would forego the need for different states to individually adopt the flexible definition on an ad hoc basis. However, achieving this change would require congressional legislation, which can be difficult to accomplish.

b) Potential Advantages

The potential advantages of awarding attorney’s fees more often in trade secret cases are that: (1) it would be consistent with compensatory purposes; and (2) it would be consistent with deterrence purposes.

i) Consistent with Compensatory Purposes

Awarding attorney’s fees is highly consistent with the goal of compensating the aggrieved trade secret owner. At a broad level, attorney’s fees awards merely compensate the trade secret owner for litigation costs that it would not have had to spend if the defendant had not misappropriated its trade secret in the first place.²²²

Furthermore, attorney’s fees seldom (if ever) result in windfalls for prevailing trade secret plaintiffs because these awards merely reimburse the prevailing party for the costs it incurred during litigation (and only *reasonable* litigation costs, at that).

222. Although this would be an exception to the standard “American Rule” in which each litigant pays for its own costs, it would not be a unique exception. For instance, copyright law allows courts very wide discretion to award attorney’s fees to the prevailing party. *See* 17 U.S.C. § 505; *see also* Jacobs & Johnston, *supra* note 161 (explaining how copyright law provides a favorable standard for awarding attorney’s fees and citing relevant caselaw). The above proposed solution for trade secret law would be a more limited exception to the “American Rule” in that it would still require that the misappropriator act with knowledge and reckless indifference to the harms it might inflict upon the trade secret owner.

ii) Consistent with Deterrence Purposes

Awarding attorney's fees more easily is consistent with deterrence purposes, by increasing trade secret misappropriators' financial exposure. Under *Syntel*, a misappropriator in a similar situation enjoys reduced exposure to monetary consequences because *Syntel* precludes the potential for formidable avoided-cost unjust enrichment awards under such facts.²²³ In such situations, a misappropriator might face little more than its own litigation costs, plus actual damages—which may be negligible if the misappropriator has not yet commercialized the stolen secret.²²⁴ Attorney's fees awards can help raise the stakes for misappropriators by putting trade secret owners' litigation costs—which average between \$750,000 and \$2.75 million²²⁵—in play against them. Even though these numbers are smaller than some notable avoided-cost unjust enrichment awards (e.g., \$140 million in *Epic Systems*), they would still improve the deterrent effects of trade secret remedies under *Syntel*.

Awarding attorney's fees more frequently will also restore aggrieved trade secret owners' monetary incentives to bring suit. When deciding whether to sue misappropriators, aggrieved trade secret owners naturally consider their financial situation, the likely costs of litigation, and the potential payoff if they prevail. *Syntel's* elimination of potentially lucrative avoided-cost unjust enrichment awards is likely to affect this calculus, making litigation less financially feasible—particularly for small businesses and resource-constrained plaintiffs. Attorney's fees awards can encourage trade secret owners to bring suit to enforce their rights, increasing the legal hazards for misappropriators and thus enhancing deterrence.

c) Potential Disadvantages

i) Overuse of Attorney's Fees Awards Might Over-Encourage Trade Secret Plaintiffs

A potential disadvantage of expanding attorney's fees awards in trade secret cases is that it might cultivate a cottage industry of plaintiff's attorneys who prod trade secret owners to bring misappropriation suits—even those of marginal merit. Scholars have previously raised similar concerns regarding over-eager trade secret litigation.²²⁶

223. See *supra* Section IV.B; see also Petition for Writ of Certiorari, *supra* note 159, at 32–33.

224. See *supra* Section IV.B; see also Petition for Writ of Certiorari, *supra* note 159, at 32–33.

225. AIPLA, REPORT OF THE ECONOMIC SURVEY 2023, at 66.

226. See, e.g., Camilla A. Hrdy, *The Value in Secrecy*, 91 FORDHAM L. REV. 557, 586 (2022).

However, statutory provisions already discourage such over-litigious behavior: plaintiffs themselves are also exposed to attorney's fees awards if they bring trade secret claims in bad faith.²²⁷ This is no empty threat: courts have previously imposed attorney's fees against plaintiffs who brought objectively weak misappropriation claims and refused to drop them after being informed of their dubious merit.²²⁸ Courts have also used non-monetary remedies to disincentivize meritless or overeager trade secret claims: public shaming. Plaintiffs who bring severely meritless trade secret misappropriation suits have sometimes been forced to issue public apologies for doing so.²²⁹ These safeguards deter trade secret owners against filing dubious trade secret misappropriation claims.

ii) Deterrent Value of Attorney's Fees Awards Does Not Scale Up Proportionately as Trade Secret Value Increases

Unlike avoided-cost unjust enrichment awards, whose value naturally reflects the trade secret's value to the misappropriator, attorney's fees awards do not necessarily scale proportionately with the monetary value of the trade secret at issue. Although average litigation costs tend to increase as the monetary stakes increase,²³⁰ there is no guarantee that litigating a more valuable underlying trade secret will translate into *proportionally* higher attorney's fees. It may be possible for a trade secret to be so valuable that even the threat of an attorney's fees award of millions of dollars fails to deter a shady competitor from taking its chances with trade secret misappropriation.

It may be true that attorney's fees is not a perfect solution that can provide the perfect amount of deterrence in all cases. However, with median award sizes between \$750,000 and \$2.75 million, they are likely to at least help make up for the deterrence lost by *Syntel's* curtailing avoided-cost unjust enrichment awards. Punitive damages could also help supplement deterrence, in some cases.²³¹

227. See 18 U.S.C. § 1836(b)(3)(D); UNIF. TRADE SECRETS ACT § 4.

228. See, e.g., *Gemini Aluminum Corp. v. Cal. Custom Shapes, Inc.*, 95 Cal. App. 4th 1249, 1261–64 (2002).

229. In one notable example, Informix, a tech firm, prematurely filed a trade secret misappropriation claim which turned out to be meritless, and it was forced to drop the suit; as part of the settlement, Informix was forced to issue an embarrassing public apology to Oracle, the defendant. See SNYDER & ALMELING, *supra* note 86, at § 7.01.

230. See AIPLA, REPORT OF THE ECONOMIC SURVEY 2023, at 66 (Oct. 2023) (illustrating how the average litigation cost of trade secret cases tends to increase as the monetary value at stake increases).

231. See *infra* Section IV.D.2.

2. Punitive Damages Awards

Under the federal DTSA and state law UTSA, punitive damages require “willful and malicious” misappropriation, similar to attorney’s fees awards.²³² Courts may award punitive damages of up to twice the amount of compensatory damages, in the event of “willful and malicious” misappropriation.²³³ Judicially or statutorily adopting more flexible standards for “willful and malicious” misappropriation—such as “reckless indifference”²³⁴—can allow courts to award punitive damages more often, in a manner similar to attorney’s fees awards.²³⁵

a) Potential Advantage: Consistent with Deterrence Purposes

The primary function of punitive damages in civil suits is generally to punish a defendant for egregious conduct and deter similar behavior in the future, rather than to compensate a plaintiff.²³⁶ Using punitive damages to restore the deterrence diminished by *Syntel* would therefore accord with the broader purpose of punitive damages in civil litigation.

b) Potential Disadvantages

i) Punitive Damages Are Mathematically Capped as a Function of Compensatory Damages

In accordance with the federal DTSA and state law UTSA, punitive damages awards may not exceed twice the amount of compensatory damages.²³⁷ The amount of punitive damages a court may impose is therefore limited if the amount of compensatory damages at issue is very small to begin with. Therefore, if compensatory damages are dramatically curtailed—for example, because a jurisdiction following *Syntel* takes avoided-cost unjust enrichment awards off the table under similar facts—punitive damages might be limited in their ability to provide additional deterrence.

232. See 18 U.S.C. § 1836(b)(3)(C); UNIF. TRADE SECRETS ACT § 3(b).

233. See 18 U.S.C. § 1836(b)(3)(C); UNIF. TRADE SECRETS ACT § 3(b).

234. See *Hair Club for Men, LLC v. Ehson*, No. 1:16-cv-236, 2017 WL 1250998, at *3 (E.D. Va. Apr. 3, 2017) (“acting consciously in disregard of another person’s rights or acting with reckless indifference to the consequences, with the defendant aware, from his knowledge of existing circumstances and conditions, that his conduct probably would cause injury to another”) (internal citation omitted); see also *supra* Section IV.D.1.a.

235. See *supra* Section IV.D.1.a.

236. See, e.g., MANUAL OF MODEL CIVIL JURY INSTRUCTIONS § 5.5 (NINTH CIR. JURY INSTRUCTIONS COMM.) (updated Sep. 2024).

237. See 18 U.S.C. § 1836(b)(3)(C); UNIF. TRADE SECRETS ACT § 3(b).

ii) Overusing Punitive Damages May Have Chilling Effects on Competition

Conversely, for any given increase in compensatory damages, the maximum allowable punitive damages will grow by twice that amount.²³⁸ Punitive damages in trade secret misappropriation cases could therefore grow to very large amounts.²³⁹ Some courts have previously cautioned against overzealous use of punitive remedies, emphasizing that competition by its very nature is “ruthless, unprincipled, uncharitable, unforgiving—and a boon to society.”²⁴⁰ If punitive damages are overused, they may have a chilling effect on competition and needlessly impede technological progress.

3. Reasonable Royalty Damages

Reasonable royalty damages are another form of recovery that courts could use to restore the deterrent effects of trade secret law diminished by *Syntel*. Currently, reasonable royalty damages are rarely awarded in trade secret cases.²⁴¹ Expanding their use to reinforce deterrence offers at least three potential advantages. First, courts already have flexible statutory authority to award them. Second, courts have previously awarded reasonable royalty damages in cases sharing some similarities with *Syntel*. And third, courts can draw upon well-established caselaw awarding reasonable royalty damages in other intellectual property regimes—especially patent law. On the other hand, the biggest disadvantage of expanding reasonable royalty damages in trade secret cases is likely the complexity typically involved in calculating the appropriate royalty amount.

a) Potential Advantages

i) Flexible Statutory Authority Already Exists

The DTSA and most state law UTSAAs already allow courts to award reasonable royalty damages as an alternative to actual loss and unjust enrichment damages.²⁴² These statutes do not impose any specific prerequisite

238. See 18 U.S.C. § 1836(b)(3)(C).

239. To illustrate, in the *Epic Systems* case, the jury awarded approximately \$140 million in compensatory damages. Under the DTSA, a court or jury finding “willful and malicious” misappropriation could thus award up to an additional \$280 million in punitive damages.

240. *Roton Barrier, Inc. v. Stanley Works*, 79 F.3d 1112, 1120 (Fed. Cir. 1996).

241. See *supra* Section II.D.1.c; *AirFacts, Inc. v. Amezaga*, 30 F.4th 359, 367 (4th Cir. 2022) (describing caselaw addressing reasonable royalty awards in trade secret cases as “sparse”).

242. See 18 U.S.C. § 1836(b)(3)(B)(ii); UNIF. TRADE SECRETS ACT § 3(a).

conditions to awarding these damages.²⁴³ The lack of statutory hurdles may be one of the greatest advantages of turning to reasonable royalty damages in *Syntel*-like trade secret misappropriation cases.²⁴⁴ Courts seeking to expand the use of reasonable royalty damages could likely do so without grappling with statutory prerequisite requirements (as they might, for instance, if they instead seek to award punitive damages or attorney's fees²⁴⁵).

ii) Pertinent Persuasive Authority Exists

Although the caselaw on reasonable royalty damages in trade secret cases may be “sparse,” it is not nonexistent. Courts have previously awarded reasonable royalty damages in cases with some similarities to *Syntel*. For example, in *LinkCo, Inc. v. Fujitsu Ltd.*, the Southern District of New York applied a reasonable royalty measure of damages when neither lost profits nor disgorgement of unjust gains were adequate remedies for the defendant's trade secret misappropriation.²⁴⁶ In *LinkCo*, the plaintiff's actual losses were difficult to establish because the company had ceased operations very close to the time of the alleged misappropriation; meanwhile, the defendant had made no profits from use of the misappropriated trade secret.²⁴⁷ Nevertheless, the district court found, “the lack of actual profits does not insulate the defendants from being obliged to pay for what they have wrongfully obtained.”²⁴⁸ The district court even remarked: “a reasonable royalty is the best measure of damages in a case where the alleged thief made no profits.”²⁴⁹

Courts applying *Syntel* could rely upon a similar rationale to award reasonable royalty damages when neither lost profits nor disgorgement would provide an aggrieved trade secret owner with adequate remedy.

243. However, the statutes do stipulate that reasonable royalty damages may only be imposed in lieu of other compensatory damages. *See* 18 U.S.C. § 1836(b)(3)(B)(ii); UNIF. TRADE SECRETS ACT § 3(a).

244. There is some evidence in the Senate Judiciary Report for the DTSA that the Senate did not intend to encourage the use of reasonable royalties in trade secret cases. *See* S. REP. No. 114-220, at 9. However, other evidence suggests that the Senate was actually referring to ongoing royalty injunctions for future use of a trade secret (rather than reasonable royalty damages for the past use of a trade secret). *See supra* Section II.D.1.c; S. REP. No. 114-220, at 9 n. 17 (citing sources which address ongoing royalty injunctions).

245. *See supra* Section IV.D.1.a.i.

246. *See LinkCo, Inc. v. Fujitsu Ltd.*, 232 F. Supp. 2d 182 (S.D.N.Y. 2002).

247. *See id.* at 186.

248. *Id.* (internal citations omitted).

249. *Id.* at 186–87.

iii) Guidance Exists from Other Intellectual Property Regimes

Courts awarding reasonable royalty damages in trade secret cases could also draw upon guidance from other intellectual property regimes—especially patent law.²⁵⁰ Under patent law, reasonable royalty damages are awarded much more frequently.²⁵¹ Courts could draw upon the existing patent caselaw to guide their calculations in trade secret misappropriation cases.²⁵²

b) Potential Disadvantages

Calculating reasonable royalty damages can be a complex and lengthy process. To illustrate, courts often consider fifteen separate factors (called the *Georgia-Pacific* factors) to determine the appropriate reasonable royalty damages in patent infringement cases.²⁵³ Accounting for each of these factors is often time-consuming because the factors often involve fine nuances (such as what sort of evidence may be considered), and litigation over what constitutes appropriate evidence often boils down to expensive battles between expert witnesses.²⁵⁴

The complexity and expense of determining reasonable royalty damages contrasts against the relative simplicity of calculating attorney's fees or punitive damages. Even though existing trade secret statutes allow courts to opt for reasonable royalty damages with relative ease (without having to wrangle with statutory prerequisites like "willful and malicious misappropriation"), the drawn-out complexities of subsequently calculating these royalty damages might present courts with significant difficulties. If the overall goal is to restore the deterrence lost under *Syntel*, it might ultimately be easier for courts to instead work with attorney's fees and punitive damage awards, even if it means they must wrangle with statutory prerequisites.

250. Patent law statutorily requires that courts use reasonable royalty as a minimum measure of damages. *See* 35 U.S.C. § 284.

251. *See* Andrew H. DeVoogd & James J. Thomson, *Expert Patent Damages Opinions Hit the Spotlight as Federal Circuit Scuttles Two Patent Infringement Verdicts Worth \$1.2 Billion in One Day*, MINTZ (Mar. 9, 2022), <https://www.mintz.com/insights-center/viewpoints/2231/2022-03-09-expert-patent-damages-opinions-hit-spotlight-federal> [<https://perma.cc/L235-TFAJ>] (explaining that patentees pursue reasonable royalties from accused infringers more commonly than they pursue lost profits from them).

252. In fact, that is exactly what the district court did in *LinkCo*. *See* 232 F. Supp. 2d at 186.

253. *See Georgia-Pacific Corp. v. U.S. Plywood Corp.*, 318 F. Supp. 1116, 1120 (S.D.N.Y. 1970).

254. *See, e.g., Lucent Techs., Inc. v. Gateway, Inc.*, 580 F.3d 1301, 1324–39 (Fed. Cir. 2009).

V. CONCLUSION

The Second Circuit's *Syntel* opinion has introduced a circuit split as to when and whether avoided-cost unjust enrichment awards are available in trade secret misappropriation cases. The Second Circuit presents a compelling argument that unjust enrichment is meant to be compensatory in nature and that avoided-cost unjust enrichment awards should only be granted when they would serve compensatory purposes. However, because avoided-cost unjust enrichment awards are often substantial, *Syntel* may potentially diminish the deterrent effects of trade secret law and encourage forum-shopping by trade secret litigants. Awarding attorney's fees, punitive damages, or reasonable royalty damages more often in trade secret cases could be effective ways to counteract this diminished deterrence and dampen the forum-shopping incentives. This approach will help ensure that would-be misappropriators face adequate monetary deterrents against trade secret misappropriation while also ensuring that aggrieved trade secret owners remain financially able and motivated to bring suit to enforce their rights, even without avoided-cost unjust enrichment awards.

DEVELOPING ANTI-KICKBACK COMPLIANCE GUIDANCE AT THE INTERSECTION OF “SPONSORED” AND “GENETIC TESTING” PROGRAMS

Yasameen Joulaee[†]

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I. INTRODUCTION

A patient experiencing symptoms of an undiagnosed health condition naturally seeks a diagnosis, regardless of its potential severity. Imagine that the patient has an opportunity to take an entirely free genetic test—in exchange for a blood or saliva sample—and to receive a diagnosis for their symptoms. A sponsoring company covers the cost of the test and coordinates the logistics with the physician and a third-party testing laboratory. Here, the test diagnoses potential genetic disorders. The patient might learn that they have a hereditary genetic mutation with a 10 percent chance of developing a disease. Alternatively, the patient might learn that they have a genetic disease, but there is an available medication that could reduce some of their symptoms. The patient might be comforted by receiving a diagnosis, devastated by the implications for their health, or relieved to have a treatment option.

If the patient receives a treatable diagnosis, the Office of Inspector General (OIG) concerns itself with how the patient can be offered medication treatment and by whom. The offer becomes especially suspect when companies sponsor genetic tests identifying the same conditions that they manufacture medications to treat. If the patient is insured through a federal healthcare program like Medicare or Medicaid, the government could be billed for the medication and subsequent care costs.

Economic and financial incentives underlying healthcare programs create vulnerabilities to overutilization costs and disrupt free market competition.¹ Congress enacted the Anti-Kickback Statute (AKS) in 1972 as a response to increasing fraud claims and growing Medicare and Medicaid costs.² Here, the AKS may flag the payment sponsoring genetic tests of fraudulent claims or Medicare and Medicaid costs. Any gamesmanship to induce the patient or the ordering physician into purchasing the medication conveniently manufactured by the sponsor would violate the AKS. The OIG applies the AKS broadly to any form of remuneration, or “anything of value.”³ While remuneration can take many forms, including cash, free rent, hotel stays, or meals, federal healthcare programs are predominantly antagonistic toward payments for referrals.⁴

1. See Richard P. Kusserow, *The Medicare & Medicaid Anti-Kickback Statute and the Safe Harbor Regulations—What's Next?*, 2 HEALTH MATRIX: J.L. & MED. 49, 52 (1992) (evaluating the economic incentives of referrals in the 1987 Social Security Act anti-kickback provisions).

2. Chinelo Diké-Minor, *The Untold Story of the United States' Anti-Kickback Laws*, 20 RUTGERS J.L. & PUB. POL'Y 103, 109–10 (2023).

3. *Fraud & Abuse Laws*, U.S. DEP'T OF HEALTH & HUM. SERVS., OFF. OF INSPECTOR GEN., <https://oig.hhs.gov/compliance/physician-education/fraud-abuse-laws/>.

4. *Id.*

The AKS seeks to protect patients from prescriptions improperly induced by sponsors or medication manufacturers. Still, the AKS does not cover every potential concern in offering a sponsored genetic test. First, the AKS does not evaluate the actual test results and the substantive impact that those results could have on a patient’s health. The patient is likely not concerned with the behind-the-scenes operation of the sponsored program. Instead, the patient is concerned with the validity of the test results and the availability of treatment options—regardless of who manufactures it. Second, the OIG lacks a mechanism for considering the positive impact that sponsored genetic testing programs offer the healthcare industry. The patient can confirm a hereditary condition or develop a heightened awareness of early-onset symptoms. The physician can diagnose the disorder or establish a monitoring plan for an at-risk patient.

The genetic test and subsequent sponsored program are regulated the entire time it is available on the market. The Food and Drug Administration (FDA) analyzes the safety and efficacy of products throughout their lifecycle, including genetic tests.⁵ The FDA provides the initial approval that the test is permissible for patient use. The OIG then enforces the AKS after the provider bills treatment costs arising from the sponsored test results to a federal healthcare program. Thus, the FDA regulates the genetic test, while the OIG regulates the sponsored program. Federal regulatory agencies simultaneously oversee sponsored genetic testing programs through distinct practices. Pharmaceutical manufacturers establishing a program must aggregate each agency’s guidance and piecemeal its policies with no guarantee of compliance. Thus, federal regulatory agencies must jointly devise a comprehensive guidance document for sponsored genetic testing programs to wholly evaluate both the financial and practical implications.

This Note takes a holistic view of the sponsored genetic testing landscape and bridges the isolated components of “sponsored” and “genetic testing” under one comprehensive compliance framework. This Note seeks to avoid employing the AKS as a fallback to impose sanctions on gamesmanship behavior. Rather, this Note identifies the FDA and the OIG as the appropriate regulatory conciliators and suggests evidentiary factors to strengthen regulatory compliance guidance. Part II describes the FDA and the OIG agencies and their existing mechanisms that guide industry compliance. Part III summarizes two relevant, contrasting outcomes—the OIG Advisory Opinions (“AO 22-06” and “AO 24-12”) and the *Ultragenyx* Settlement

5. *Quality and Compliance (Medical Devices)*, FDA, <https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/quality-and-compliance-medical-devices> (last updated Jan. 31, 2024).

Agreement—then discusses the regulatory rationale for reaching those outcomes. Part IV proposes a collaborative regulatory framework tailored to pharmaceutical manufacturers establishing sponsored genetic testing programs and explores the practical and policy implications of applying such a framework. Part V concludes.

II. SPONSORED GENETIC TESTING IN REGULATORY CONTEXTS

Sponsored genetic testing programs are subject to regulatory compliance. The United States Department of Health and Human Services (HHS) is the supervisory regulatory agency that oversees both the FDA and the OIG. The FDA and OIG each have distinct roles in regulating sponsored genetic testing programs, as evidenced by their objectives, enforcement initiatives, and guidance documents. Section II.A reviews the HHS's organizational structure. Section II.B summarizes the FDA's objectives and its regulation of medical devices, including genetic tests. Section II.C outlines the OIG's objectives, AKS enforcement, and compliance guidance for pharmaceutical manufacturers.

A. ORGANIZATIONAL STRUCTURE: THE HHS OVERSEES THE FDA AND THE OIG

The HHS is the overarching agency that supervises initiatives protecting the health and well-being of Americans.⁶ The Secretary is the highest authority role within the HHS.⁷ Under the Secretary, the organization bifurcates into two main groups: the Office of the Secretary and the Operating Divisions.⁸

The Office of the Secretary oversees HHS programs, including the OIG.⁹ The thirteen Operating Divisions administer a variety of health and human services and research initiatives, including the FDA.¹⁰

B. FOOD AND DRUG ADMINISTRATION (FDA)

The FDA is the primary agency responsible for ensuring the safety and effectiveness of food and drugs, though genetic tests are included within the

6. *HHS Organizational Charts Office of Secretary and Divisions*, U.S. DEP'T OF HEALTH & HUM. SERVS., <https://www.hhs.gov/about/agencies/orgchart/index.html> (last reviewed Sep. 19, 2024).

7. *Id.*; *HHS Agencies & Offices*, U.S. DEP'T OF HEALTH & HUM. SERVS., <https://www.hhs.gov/about/agencies/hhs-agencies-and-offices/index.html>.

8. *HHS Organizational Charts Office of Secretary and Divisions*, U.S. DEP'T OF HEALTH & HUM. SERVS., *supra* note 6.

9. *HHS Agencies & Offices*, U.S. DEP'T OF HEALTH & HUM. SERVS., *supra* note 7.

10. *Id.*

FDA's oversight as medical devices.¹¹ This Section explores how the FDA regulates genetic tests through its premarket approval pathways and provides an overview of the agency's collaborative regulatory initiatives.

1. *Agency Objectives*

The FDA is the nation's oldest consumer protection agency.¹² In 1906, the Pure Food and Drugs Act established the FDA to oversee food and drugs.¹³ In 1976, Congress established comprehensive medical device regulation through the Medical Device Amendments to the Federal Food, Drug, and Cosmetic Act.¹⁴ The Act delineated a three-class risk-based classification system, safety and effectiveness performance standards, and regulatory pathways for new medical devices.¹⁵ Through its regulatory oversight, the FDA seeks to promote the development and manufacture of high-quality medical devices.¹⁶

2. *Medical Device Regulation*

The FDA's classification system for medical devices clearly outlines the standards and pathways for premarket approval.¹⁷ However, genetic tests do not neatly fit into any single class; instead, the FDA has variably regulated genetic tests as different classes, created special guidance for certain tests, and, in some cases, exempted genetic tests from pre-approval altogether.

a) A Three-Class, Risk-Based Classification System

The 1976 Medical Device Amendments comprise the same three-class classification system in effect today.¹⁸ Classes I through III are ranked in order of increasing risk and regulatory oversight.¹⁹

11. *Direct-to-Consumer Tests*, FDA, <https://www.fda.gov/medical-devices/in-vitro-diagnostics/direct-consumer-tests> (last updated Dec. 20, 2019).

12. *A History of Medical Device Regulation & Oversight in the United States*, FDA, <https://www.fda.gov/medical-devices/overview-device-regulation/history-medical-device-regulation-oversight-united-states> (last updated Aug. 21, 2023).

13. *Id.*

14. *Id.*

15. Medical Device Amendments of 1976, Pub. L. No. 94-295, § 513(a)(1)(A)–(C), 90 Stat. 539, 540–41.

16. *Quality and Compliance (Medical Devices)*, FDA, *supra* note 5.

17. *How to Study and Market Your Device*, FDA, <https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/how-study-and-market-your-device> (last updated Oct. 12, 2023).

18. *A History of Medical Device Regulation & Oversight in the United States*, FDA, *supra* note 12.

19. AMANDA K. SARATA, CONG. RSCH. SERV., R47374, FDA REGULATION OF MEDICAL DEVICES 3 (2023); *Overview of Device Regulation*, FDA, <https://www.fda.gov/medical->

Across all three classes, every medical device is subject to compliance with general controls to uphold a standard of safety and effectiveness.²⁰ Some Class I and most Class II devices require a 510(k) premarket notification.²¹ A 510(k) is a premarket submission to the FDA that demonstrates a device is safe and effective by being “substantially equivalent,” or having the same design and purpose as another already approved (predicate) device.²² If the FDA determines that substantial equivalence is met, the device is cleared for marketing under the same class and regulatory controls as the predicate device.²³

The De Novo classification request is an alternate pathway to seek regulatory approval for medical devices when there are no legally marketed predicate devices.²⁴ The FDA determines De Novo eligibility by first verifying that there are no predicates, comparing the device to legally marketed devices.²⁵ Next, the FDA performs a substantive review.²⁶ If the FDA grants a De Novo request, the device will be assigned a new classification regulation for the new device type.²⁷ The De Novo pathway allows devices without predicates to enter the market as Class I or Class II devices, which are subject to fewer requirements than presumptively assigned, strictly regulated Class III devices.²⁸ Additionally, devices awarded De Novo classifications can serve as predicates for new devices of the same type in future premarket notifications.²⁹

b) Genetic Tests as Medical Devices

Genetic tests pose a unique challenge to FDA regulation based on their intermediate status as products that can be simultaneously offered as services. For example, genetic tests can be regulated as “in vitro diagnostic” (IVD)

devices/device-advice-comprehensive-regulatory-assistance/overview-device-regulation#:~:text=Quality%20System%20Regulation%20(QS%20regulation,compliance%20with%20the%20QS%20requirements; see also 21 U.S.C. § 360(c)(a)(1)(A)–(C).

20. SARATA, *supra* note 19, at 6.

21. *How to Study and Market Your Device*, FDA, *supra* note 17.

22. *Premarket Notification 510(k)*, FDA, <https://www.fda.gov/medical-devices/premarket-submissions-selecting-and-preparing-correct-submission/premarket-notification-510k> (last updated Aug. 22, 2024); Federal Food, Drug, and Cosmetic Act, 21 U.S.C. § 513(a)(4).

23. SARATA, *supra* note 19, at 9.

24. *De Novo Classification Request*, FDA, <https://www.fda.gov/medical-devices/premarket-submissions-selecting-and-preparing-correct-submission/de-novo-classification-request> (last updated Oct. 4, 2022).

25. *Id.*

26. *Id.*

27. *Id.*

28. SARATA, *supra* note 19, at 4–5.

29. *Id.* at 5.

products by individually considering the reagents used to make diagnoses.³⁰ Reagents (and their risks) vary from Class I to Class III devices, and the FDA may regulate reagents as “restricted devices,” placing specific restrictions on their sale, distribution, and use.³¹ Reagents are necessary to perform a genetic test, subsequently impacting genetic test regulation and marketing.

The FDA has also issued multiple orders and industry guidance documents advising on medical device classifications for specific genetic test systems. However, the variable guidance, compounded with the 510(k) and De Novo pathways, makes anticipating the appropriate submission pathway a challenging and unpredictable feat for manufacturers. For example, in November 2017, the FDA issued an order exempting autosomal recessive carrier screening gene mutation detection systems from the 510(k) requirement if a misdiagnosis would not be associated with high morbidity or mortality.³² Conversely, the FDA issued separate Class II Special Controls Guidance for breast cancer prognosis test systems and cardiac allograft gene expression profiling test systems.³³ Special controls guidance documents are developed to address the specific health risks associated with a test system.³⁴ Both guidance documents channel the genetic test systems through the 510(k) submission process, contradicting the 510(k) exemption ordered for the autosomal recessive carrier screening system.³⁵ Lastly, in September 2023, the FDA granted De Novo authorization for an IVD test that detects genetic variants associated with an elevated risk of developing certain cancers.³⁶ These examples illustrate how the premarket submission pathway is highly particular

30. Gail H. Javitt, *In Search of a Coherent Framework: Options for FDA Oversight of Genetic Tests*, 62 FOOD & DRUG L.J. 617, 619–20 (2007).

31. *Id.* at 620–21.

32. FDA Medical Devices, 82 Fed. Reg. 51567, 51569 (Nov. 7, 2017) (to be codified 21 C.F.R. pt. 866); *see also Class I and Class II Device Exemptions*, FDA, <https://www.fda.gov/medical-devices/classify-your-medical-device/class-i-and-class-ii-device-exemptions> (last updated Feb. 23, 2022) (on file with author).

33. FDA, CTR. FOR DEVICES & RADIOLOGICAL HEALTH (CDRH), GENE EXPRESSION PROFILING TEST SYSTEM FOR BREAST CANCER PROGNOSIS-CLASS II SPECIAL CONTROLS GUIDANCE FOR INDUSTRY AND FDA STAFF (2007); FDA, CDRH, CARDIAC ALLOGRAFT GENE EXPRESSION PROFILING TEST SYSTEMS-CLASS II SPECIAL CONTROLS GUIDANCE FOR INDUSTRY AND FDA STAFF (2009).

34. FDA, CDRH, CARDIAC ALLOGRAFT GENE EXPRESSION, *supra* note 33.

35. *Id.*; FDA, CDRH, GENE EXPRESSION PROFILING TEST SYSTEM FOR BREAST CANCER PROGNOSIS, *supra* note 33.

36. Press Release, FDA, FDA Grants First Marketing Authorization for a DNA Test to Assess Predisposition for Dozens of Cancer Types (Sep. 29, 2023), <https://www.fda.gov/news-events/press-announcements/fda-grants-first-marketing-authorization-dna-test-assess-predisposition-dozens-cancer-types>.

to the type of genetic test, arriving at different classification levels subject to different regulatory requirements.

In May 2024, the FDA issued a final rule amending the Federal Food, Drug, and Cosmetic Act to recognize IVDs as devices explicitly.³⁷ The rule focuses on the safety and effectiveness of laboratory developed tests (LDTs), a type of IVD designed, manufactured, and produced within a single laboratory for clinical use.³⁸ Large laboratories widely use LDTs in high volumes and frequently rely on them for critical healthcare decisions.³⁹ Before the rule, companies could market genetic tests as LDTs without FDA review.⁴⁰ Now, the FDA estimates that approximately 95 percent of IVDs will be Class I and II devices under the final rule.⁴¹ This shift reflects the FDA's recognition that genetic test regulations require closer regulatory attention and statutory reform. Nonetheless, the FDA continues to regulate genetic tests diversely, where even classification as an LDT can profoundly impact the premarket requirements.

3. *Specialized Task Force Programs*

The FDA has several initiatives that should be leveraged to reform its varied approach to genetic test regulation. The FDA should use collaborative communities to stay informed about industry-wide sponsored genetic testing concerns and advance its robust fraud program to detect suspect sponsored programs.

a) Collaborative Community Initiative

The FDA's Center for Devices and Radiological Health (CDRH) established the "Collaborative Community" as a forum for public and private sector members to solve medical device challenges and achieve shared goals.⁴²

37. FDA In Vitro Diagnostic Medical Devices, 89 Fed. Reg. 37286 (May 6, 2024) (to be codified at 21 C.F.R. pt. 809).

38. *Laboratory Developed Tests*, FDA, <https://www.fda.gov/medical-devices/in-vitro-diagnostics/laboratory-developed-tests> (last updated Oct. 30, 2024).

39. *Id.*

40. *Genetic Non-Invasive Prenatal Screening Tests May Have False Results: FDA Safety Communication*, FDA, <https://www.fda.gov/medical-devices/safety-communications/genetic-non-invasive-prenatal-screening-tests-may-have-false-results-fda-safety-communication> (last updated Apr. 19, 2022) (on file with the Berkeley Tech. L.J.); see also *FDA Issues Warning About Risks of Noninvasive Prenatal Screening*, HEALIO (Apr. 20, 2022), <https://www.healio.com/news/primary-care/20220420/fda-issues-warning-about-risks-of-noninvasive-prenatal-screening>.

41. Brittany Schuck, Deputy Off. Dir., *FDA's Total Product Lifecycle Approach to IVDs Webinar*, FDA (Oct. 24, 2024), <https://www.fda.gov/media/183011/download?attachment>.

42. *Collaborative Communities: Addressing Health Care Challenges Together*, FDA, <https://www.fda.gov/about-fda/cdrh-strategic-priorities-and-updates/collaborative-communities-addressing-health-care-challenges-together> (last updated Sep. 20, 2024).

Each collaborative community concentrates on a specific topic, such as standardizing laboratory practices in pharmacogenomics.⁴³ The CDRH is not the manager or controller of collaborative communities; rather, the CDRH can be a participating member that fosters community and encourages broad and fair representation.⁴⁴ Other members may include patients, academics, healthcare professionals, federal and state agencies, international regulatory bodies, and industry.⁴⁵ Members have a collective interest in working together when “challenges are ill-defined or there is no consensus on the definition of the challenges.”⁴⁶ Complex or prior failed efforts to address challenges, interrelated partners, and optimization interests are all driving factors that benefit from a collaborative community.⁴⁷

The Collaborative Community initiative has several successful programs where an external stakeholder manages the community, and the FDA participates as a member. The National Evaluation System for health Technology (NEST) leverages real-world experience and advanced analytics data to map medical device total product life cycles, informing both pre- and post-market regulatory decisions.⁴⁸ NEST aims to improve the quality of evidence that healthcare providers and patients use to make treatment decisions and foster medical device innovation while assuring safety.⁴⁹ The NEST Coordinating Center (NESTcc) collaborative community was created to reduce the time and cost of data collection while increasing the value and reach of evidentiary findings.⁵⁰ Members promote standards, monitor progress, and govern the NEST ecosystem.⁵¹ The NESTcc collaborative community is a textbook example that invites stakeholders to optimize how medical devices are employed across healthcare.

43. *Id.*

44. *Id.*; FDA, CDRH, 2018-2020 STRATEGIC PRIORITIES at 17 (Jan. 2018), <https://www.fda.gov/media/110478/download?attachment>.

45. *Collaborative Communities: Addressing Health Care Challenges Together*, FDA, *supra* note 42.

46. *Id.*

47. *Id.*

48. *National Evaluation System for Health Technology (NEST)*, FDA, CDRH, <https://www.fda.gov/about-fda/cdrh-reports/national-evaluation-system-health-technology-nest> (last updated Oct. 29, 2019).

49. *Id.*

50. *FDA in Brief: FDA Announces Participation in First Two ‘Collaborative Communities’ Working to Develop Solutions to Medical Device Innovation Challenges*, FDA, <https://www.fda.gov/news-events/fda-brief/fda-brief-fda-announces-participation-first-two-collaborative-communities-working-develop-solutions> (last updated Mar. 3, 2021).

51. *Id.*

Similarly, the “Case for Quality” collaborative community seeks to promote a competitive marketplace that values high-quality medical devices.⁵² The initiative was formed after the FDA identified common manufacturing risks that impacted product quality but vastly improved compliance and reduced complaints and corrective actions once managed.⁵³ The Case for Quality objectives include identifying manufacturers that consistently produce high-quality medical devices in compliance with FDA regulations.⁵⁴ Successful manufacturing practices are identified and shared to support other manufacturers in improving their product quality.⁵⁵ Thus, manufacturers identified by the Case for Quality initiative serve as benchmarks for compliance, quality, and innovation in medical devices, streamlining FDA premarket submissions and marketization.

b) Pharmaceutical Fraud Program (PFP)

The FDA established the Pharmaceutical Fraud Program (PFP) in 2010 to detect, prosecute, and prevent pharmaceutical, biologic, and medical device fraud.⁵⁶ As part of the FDA, the PFP supports the Office of Criminal Investigations (OCI) and the Office of General Counsel Food and Drug Division (OGC-FDD) in investigating criminal violations of federal healthcare and anti-fraud statutes.⁵⁷ The PFP gathers information from both FDA and non-FDA resources concerning fraudulent marketing schemes, application and clinical trial fraud, and blatant manufacturing violations.⁵⁸ The program’s primary goal is to detect and prosecute fraudulent conduct early, enabling the FDA to impede potential public harm from medical products that reach the market without following the appropriate FDA approval processes.⁵⁹ By restricting noncompliant medical products from reaching the market and consumers, the PFP saves healthcare programs from unnecessary

52. *Case for Quality*, FDA, <https://www.fda.gov/medical-devices/quality-and-compliance-medical-devices/case-quality> (last updated July 29, 2020); FDA CTR. DEVICES & RADIOLOGICAL HEALTH, 2018-2020 STRATEGIC PRIORITIES, *supra* note 44, at 18.

53. *Case for Quality*, FDA, *supra* note 52.

54. *Id.*

55. *Id.*

56. KATHLEEN M. BOOZANG, CHARLES A. SULLIVAN & KATE GREENWOOD, THE FALSE CLAIMS ACT AND THE POLICING OF PROMOTIONAL CLAIMS ABOUT DRUGS: A CALL FOR INCREASED TRANSPARENCY 25 (2015); U.S. DEP’T OF HEALTH & HUM. SERVS., OFF. OF INSPECTOR GEN., ANNUAL REPORT OF THE DEPARTMENTS OF HEALTH AND HUMAN SERVICES AND JUSTICE: HEALTH CARE FRAUD AND ABUSE CONTROL PROGRAM FY 2022, at 101 [hereinafter HHS OIG 2022 ANNUAL REPORT].

57. HHS OIG 2022 ANNUAL REPORT, *supra* note 56.

58. *Id.*

59. *Id.*

expenditures.⁶⁰ The PFP seamlessly aligns with AKS motivations but takes a preemptive, regulatory approach.

In 2023, the PFP opened eleven criminal investigations, with three targeting fraudulent marketing practices.⁶¹ The investigations concerned violations with severe public health consequences, including potential kickbacks by pharmaceutical sales representatives on the intended use of a drug.⁶² However, complex fraud investigations require extensive document review and can span five years or more from initiation to conclusion.⁶³ Despite this, PFP investigations have nonetheless resulted in several successful prosecutions.⁶⁴

C. OFFICE OF INSPECTOR GENERAL (OIG)

The OIG operates to detect and halt fraud and abuse in federal healthcare programs, as demonstrated by a lengthy history of congressional legislation. This Section will review the OIG’s mechanisms to regulate sponsored genetic testing programs, focusing on the AKS and the 2003 Compliance Program Guidance for Pharmaceutical Manufacturers as its chief regulatory documents.

1. *Agency Objectives*

The OIG was established in 1976 and has long served as the nation’s principal agent in combating waste, fraud, and abuse while improving the efficiency of Medicare, Medicaid, and other HHS programs.⁶⁵ However, the OIG’s work also spans from advanced data analytics to cybersecurity matters.⁶⁶ In fiscal year 2023, the OIG allocated 23 percent of its efforts to Public Health, Science, and Regulatory Agency oversight, including the FDA.⁶⁷ The OIG focused the remaining 77 percent on Medicare and Medicaid oversight, which

60. *Id.*

61. U.S. DEP’T OF HEALTH & HUM. SERVS., OFF. OF INSPECTOR GEN., ANNUAL REPORT OF THE DEPARTMENTS OF HEALTH AND HUMAN SERVICES AND JUSTICE, HEALTH CARE FRAUD AND ABUSE CONTROL PROGRAM FY 2023, at 94–95 [hereinafter HHS OIG 2023 ANNUAL REPORT].

62. *Id.* at 95.

63. *Id.*

64. *Id.*

65. *About OIG*, U.S. DEP’T OF HEALTH & HUM. SERVS., OFF. OF INSPECTOR GEN., [https://oig.hhs.gov/about-oig/#:~:text=Who%20We%20Are,Human%20Services%20\(HHS\)%20programs](https://oig.hhs.gov/about-oig/#:~:text=Who%20We%20Are,Human%20Services%20(HHS)%20programs). (The OIG performs “independent criminal and civil investigations, audits, evaluations, administrative enforcement actions, data analytics, and other activities to fulfill its mission.”).

66. U.S. DEP’T OF HEALTH & HUM. SERVS., OFF. OF INSPECTOR GEN., FACT SHEET, <https://oig.hhs.gov/documents/root/1140/About-OIG-Fact-Sheet.pdf>.

67. *Id.*

includes kickback enforcement in federal healthcare programs.⁶⁸ This imbalance demonstrates the OIG's focus on enforcement actions and recovery of misspent funds, which squarely aligns with the AKS objectives.

The OIG and the Department of Justice (DOJ) are primarily responsible for enforcing the AKS.⁶⁹ Kickbacks include any remuneration to induce or reward referrals of items or services payable by a federal healthcare program.⁷⁰ Under the AKS, individuals who offer or pay prohibited remuneration, and, on the other end, individuals who solicit or receive the prohibited remuneration are liable for kickbacks.⁷¹

The OIG aims to resolve uncertainties and interpret AKS requirements by issuing publicly accessible Advisory Opinions.⁷² Advisory Opinions explore what constitutes remuneration under the AKS, determine whether an arrangement satisfies the AKS criteria for activities that do not result in prohibited remuneration, and assess whether an activity poses grounds for AKS sanctions.⁷³ Any requesting party can submit an advisory opinion request to the OIG via email and expect a response within ten business days.⁷⁴ While Advisory Opinions are only binding between the OIG and the requesting party for that particular agreement, they are indisputably a vital resource consistently consulted by health law practitioners.⁷⁵ Notice and Comment Rulemaking and Special Advisory Bulletins are other OIG-authored forms of interpretive guidance.⁷⁶ Case law provides a judicial review of the AKS; however, whistleblowers commonly file qui tam suits under the False Claims Act, where courts have been hesitant to find kickbacks from Medicare and Medicaid claims alone.⁷⁷

68. *Id.*

69. ADA JANOCINSKA & GEOFFREY KAISER, *THE FEDERAL ANTI-KICKBACK STATUTE AND SAFE HARBORS 2* (2d ed. 2024).

70. *Drug Spending*, U.S. DEP'T OF HEALTH & HUM. SERVS., OFF. OF INSPECTOR GEN., <https://oig.hhs.gov/reports-and-publications/featured-topics/drug-spending/guidance.asp> (last updated Aug. 9, 2024).

71. HHS OIG Special Fraud Alert: Speaker Programs, 87 Fed. Reg. 51683 (Nov. 16, 2020).

72. JANOCINSKA & KAISER, *supra* note 69, at 4.

73. *Id.*

74. *Advisory Opinion Process*, U.S. DEP'T OF HEALTH & HUM. SERVS., OFF. OF INSPECTOR GEN., <https://oig.hhs.gov/compliance/advisory-opinions/process/>.

75. JANOCINSKA & KAISER, *supra* note 69, at 5.

76. *Id.*

77. *Id.*; Adam W. Overstreet & Matthew J. Kroplin, *The Causation Trend in Anti-Kickback False Claim Cases: Courts' Rejection of Relators' Taint Theory Should Cause Them Concern at the Summary Judgement Stage of Qui Tam Litigation*, 31 HEALTH L. 1, 1–5 (Oct. 2018).

2. *Anti-Kickback Statute (AKS): 42 U.S.C. § 1320a-7b(b)*

Congress established the Anti-Kickback Statute (AKS) in 1972 to combat fraud and abuse in healthcare costs.⁷⁸ Congress recognized that violations “adversely impact[ed] all Americans” by “cheat[ing] taxpayers,” “divert[ing] from those most in need, the nation’s elderly and poor,” and “erod[ing] the financial stability” of state and local governments.⁷⁹ Nonetheless, by 1977, Congress discovered tremendous evidence of Medicare and Medicaid provider fraud and abuse, estimating over \$1 billion in violations annually.⁸⁰ Thus, the Anti-Fraud and Abuse Amendments heightened AKS violations to a felony punishable by up to five years imprisonment and a maximum fine of \$25,000.⁸¹ Additionally, the AKS expanded to prohibit “any remuneration (including any kickback, bribe, or rebate) directly or indirectly, overtly or covertly, in cash or in kind.”⁸² In 1980, Congress narrowed the AKS to apply solely when the violation was done “knowingly and willfully.”⁸³

In *United States v. Greber*, the Third Circuit unpacked the term “remuneration,” ruling that payment for services that were actually performed still counts as an AKS violation if it was in furtherance of business.⁸⁴ The *Greber* holding is discrete in its language, yet paramount in consequences: inducement of future referrals does not have to be the basis for payment—as long as it is *one* purpose of the arrangement, it is a violation.⁸⁵

The OIG enacted AKS safe harbors in 1991, carving out ten “innocuous arrangements” that should not be prosecuted.⁸⁶ Additional safe harbors have been created and revised over the last thirty-three years to date.⁸⁷ Still, the true “safety” of these safe harbors is unclear, such as whether meeting all of the conditions of a safe harbor provision guarantees absolute protection from prosecution.⁸⁸ For example, the OIG stated in the preamble to the 1991 enactment that if a person fully complies with a safe harbor provision, they

78. Diké-Minor, *supra* note 2.

79. H.R. REP. NO. 95-393, at 44 (1977); 1977 U.S.C.C.A.N. 3039, 3047.

80. 123 CONG. REC. S16011 (1977).

81. Medicare-Medicaid Anti-Fraud and Abuse Amendments, Pub. L. No. 95-142, § 4, 91 Stat. 1175, 1179–83 (1977).

82. *Id.* (emphasis added).

83. Omnibus Reconciliation Act of 1980, Pub. L. No. 96-499, 94 Stat. 2599 (1980).

84. 760 F.2d 68, 69 (3d Cir. 1985).

85. Diké-Minor, *supra* note 2, at 113.

86. Final Rule: OIG Anti-Kickback Provisions, 56 Fed. Reg. 35952, 35957 (July 29, 1991).

87. *Safe Harbor Regulations*, U.S. DEP’T OF HEALTH & HUM. SERVS., OFF. OF INSPECTOR GEN., <https://oig.hhs.gov/compliance/safe-harbor-regulations/>.

88. Donald H. Romano, *How Safe Are the Safe Harbors: An In-Depth Look at Statutory and Regulatory Exceptions to the Anti-Kickback Statute*, 30 HEALTH L. 1 (Dec. 2017).

will not be prosecuted for the arrangement.⁸⁹ Likewise, each safe harbor provision states that “‘remuneration’ does not include” a certain arrangement, meaning if the safe harbor is met, there is no remuneration and therefore no AKS violation.⁹⁰ The “discounts” safe harbor excludes items or services paid for wholly or partially under federal healthcare programs from qualifying as remuneration.⁹¹ Two courts have nonetheless said in dicta that a lack of intent is required to satisfy safe harbor provisions—meeting the provisions alone is not enough.⁹² These decisions have blurred the objective criteria of safe harbor provisions by incorporating subjective intent considerations.⁹³ Safe harbors present challenges for program sponsors, who not only have to strictly adhere to the contours of a safe harbor provision but also anticipate variable judicial interpretation.

3. *Compliance Program Guidance for Pharmaceutical Manufacturers*

In 2003, the OIG issued compliance guidance for pharmaceutical manufacturers, outlining the fundamental elements to achieve an effective compliance program.⁹⁴ The guidance identifies “kickbacks and other illegal remuneration” as a specific risk area for pharmaceutical manufacturers to address during legal review and in the development of policies and procedures.⁹⁵

The guidance instructs pharmaceutical manufacturers to identify liability risks under the AKS by framing a two-part test to identify arrangements with a significant potential for abuse: (1) identify any remunerative relationship between the manufacturer and those individuals or entities in a position to directly or indirectly generate federal healthcare business for the manufacturer, then (2) determine whether any one purpose of remuneration would induce a referral or recommendation for services at least partially payable by a federal healthcare program.⁹⁶ Even if a manufacturer satisfies this test, the guidance encourages further consideration of practices that courts have recognized as high-risk for prosecution.⁹⁷ Problematic practices include interfering with

89. *Id.* at 3; *see also* 56 Fed. Reg. at 35954.

90. 42 C.F.R. § 1001.952(a)–(jj).

91. 42 C.F.R. § 1001.952(h)(5)(ii).

92. *See* United States v. Shaw, 106 F. Supp. 2d 103 (D. Mass. 2000); United States *ex rel.* Westmoreland v. Amgen, Inc., 812 F. Supp. 2d 39 (D. Mass. 2011); *see also* Romano, *supra* note 88, at 3–4.

93. *See* Romano, *supra* note 88, at 3–4.

94. OIG Compliance Program Guidance for Pharmaceutical Manufacturers, 68 Fed. Reg. 23731 (May 5, 2003).

95. *Id.* at 23733.

96. *Id.* at 23734.

97. *Id.*

clinical decision-making, increasing costs to federal healthcare programs, increasing inappropriate or overutilization risks, and raising patient safety or quality of care concerns.⁹⁸

The guidance advises manufacturers to review their arrangements in the totality of all facts and circumstances, even if they do not fit squarely within an AKS safe harbor.⁹⁹ Key considerations include the nature of the relationship between the parties (e.g., the manufacturer and the physician), how the remuneration is determined, the value of the remuneration and its potential impact on federal healthcare programs, and potential conflicts of interest.¹⁰⁰ While these considerations are adopted from the PhRMA Code on Interactions with Healthcare Professionals, compliance does not guarantee protection from AKS liability.¹⁰¹ Nonetheless, the guidance still recognizes methods to substantially reduce fraud and abuse risks and demonstrate a good-faith effort to comply with federal healthcare laws.¹⁰²

In April 2023, the OIG announced plans to publish updated industry segment-specific compliance program guidance documents.¹⁰³ In September 2024, the OIG that specified it anticipates publishing a pharmaceutical manufacturer-specific document with the release date to be determined, though guidance documents for other industries are planned through 2025.¹⁰⁴ In the interim, the compliance guidance from 2003 and recent cases are the best indicators of where the OIG stands on sponsored genetic testing programs.

III. OPPOSITE OUTCOMES IN SPONSORED GENETIC TESTING PROGRAMS

Two principal cases illustrate contrasting regulatory compliance holdings for sponsored genetic testing programs, where agencies determined if the disputed programs violated the AKS. Section III.A summarizes two OIG Advisory Opinions (AO 22-06 and AO 24-12). Section III.B outlines the *United States v. Ultragenyx* Settlement Agreement. Lastly, Section III.C reviews an outstanding DOJ investigation against BioMarin Pharmaceuticals, assesses

98. *Id.*

99. *Id.* at 23737.

100. *Id.*

101. *Id.*

102. *Id.*

103. *Compliance Guide*, U.S. DEP'T OF HEALTH & HUM. SERVS., OFF. OF INSPECTOR GEN., <https://oig.hhs.gov/compliance/compliance-guidance/> (last updated Sep. 18, 2024).

104. *Id.*

regulatory implications following *Loper Bright*, and reflects on current industry concerns regarding sponsored genetic testing program regulations.

A. FAVORABLE OUTCOMES: OIG ADVISORY OPINIONS

The OIG has issued three Advisory Opinions addressing sponsored genetic testing programs.¹⁰⁵ Each Opinion illustrates a Requestor's program that was not sanctioned under the AKS. While the Requestors adequately mitigated fraud and abuse risks to avoid sanctions, the Opinions reflect how advisory opinions can be narrow in scope and lack reliability to draw broader compliance principles.

1. *OIG Advisory Opinion 22-06 (AO 22-06)*

The OIG wrote its first advisory opinion on sponsored genetic testing programs in AO 22-06. The OIG distinguished the program based on the genetic test's limited results and the Requestor's shielded marketing practices, finding that these safeguards were sufficient to avoid sanctions under the AKS.

a) Factual Background

The Requestor, a biopharmaceutical company, manufactures two FDA-approved medications that treat a disease deriving from a genetic disorder.¹⁰⁶ The disorder can present in different forms that are distinguishable by the bodily systems affected and the symptoms presented.¹⁰⁷ Here, the form of the disorder (the "disease") primarily impacts the heart and can lead to heart failure and death.¹⁰⁸ The disease can be inherited ("hereditary" form) or occur spontaneously ("spontaneous" form).¹⁰⁹ The Requestor manufactures two FDA-approved medications that each treat both forms of the disease by reducing cardiovascular-related hospitalizations and mortalities.¹¹⁰ The Requestor's sole interest in manufacturing, marketing, or financing items or services that treat the disease centers on the medications.¹¹¹

105. The OIG continues to publish Advisory Opinions that align with the same analyses and outcomes discussed *infra* Section III.A. See U.S. DEP'T OF HEALTH & HUM. SERVS., OFF. OF INSPECTOR GEN., OIG ADVISORY OPINION NO. 25-07 (2025), <https://oig.hhs.gov/documents/advisory-opinions/10472/AO-25-07.pdf>. For the scope of this Note, only Advisory Opinions 22-06 and 24-12 are discussed.

106. U.S. DEP'T OF HEALTH & HUM. SERVS., OFF. OF INSPECTOR GEN., OIG ADVISORY OPINION NO. 22-06, at 2 (2022) [hereinafter AO 22-06], <https://oig.hhs.gov/documents/advisory-opinions/1028/AO-22-06.pdf>.

107. *Id.*

108. *Id.*

109. *Id.* Note that the spontaneously developed form name is redacted in the AO, hence "spontaneous" is proposed as an abbreviated name.

110. *Id.*

111. *Id.*

i) The Genetic Test

The genetic test offered through the Requestor's sponsored program is insufficient on its own to diagnose the disease.¹¹² The genetic test must be ordered in parallel with other diagnostic tests to determine if the disease is present and to rule out other possible conditions.¹¹³ Only after conducting these parallel tests can the genetic test results be used to identify the form of the disease present.¹¹⁴

The genetic test provides valuable results for three types of patients. First, previously diagnosed patients can learn if they have the hereditary or spontaneous form of the disorder, where the hereditary form may have a quicker expected disease progression.¹¹⁵ Second, undiagnosed symptomatic patients can learn which form they have if the parallel test confirms a diagnosis.¹¹⁶ Third, patients related to someone with the hereditary form can be made aware of whether they carry a gene mutation associated with the disease and seek monitoring by a cardiologist, potentially shortening the time from symptom onset to diagnosis.¹¹⁷

Healthcare providers thus employ the genetic testing program to supplement their evaluation, but the genetic test results alone are not a conclusive basis for prescribing the Requestor's medications.¹¹⁸ The Requestor's medications are solely for patients with a confirmed diagnosis; the medications have not been approved for the prevention of the disease or treatment of undiagnosed patients.¹¹⁹ To put this limitation in context, for a specific mutation that causes a majority of the hereditary form cases, only 10 to 20 percent of patients with that mutation will develop the disease.¹²⁰ Thus, many patients who test positive for a gene mutation may never develop the disease.¹²¹ Even if a medication is ultimately required, the physician's prescription is not influenced by the genetic test results since both medications treat both forms of the disease.¹²²

112. *Id.*

113. *Id.*

114. *Id.* at 2–3.

115. *Id.*

116. *Id.* at 3.

117. *Id.*

118. *Id.*

119. *Id.*

120. *Id.*

121. *Id.*

122. *Id.*

ii) The Sponsored Program

The Requestor's genetic testing program operates through an arrangement with a contracted third-party laboratory and a contracted third-party genetic counseling service.¹²³ The laboratory is responsible for developing and producing a customized specimen collection kit and conducting genetic tests for the program.¹²⁴ If a physician refers the patient to the optional counseling service, the laboratory provides patient information to the counseling vendor.¹²⁵ The Requestor never receives any individually identifiable patient health information.¹²⁶ Instead, the Requestor only receives aggregate monthly reports from the laboratory to track participation, again with de-identified information that complies with 42 C.F.R. § 164.514(b)(2) privacy standards.¹²⁷ The Requestor does not receive sufficient information to identify physicians who order tests through the program unless the physicians voluntarily disclose this information.¹²⁸

iii) Requestor's Marketing

The Requestor restricts its sales force from accessing any data received from the laboratory or counseling vendors and does not use this data in its sales or marketing activities.¹²⁹ Instead, the Requestor identifies cardiologists who are likely to diagnose and treat patients with the disease.¹³⁰ The Requestor's sales representatives do not consider a physician's use of the program or their history of prescribing the Requestor's medication when distributing specimen collection kits.¹³¹ Likewise, sales representatives have a limited number of specimen collection kits that can be distributed to any individual physician.¹³²

Patients may learn about the sponsored genetic testing program through the Requestor's patient support program, which provides information after a patient has been prescribed one of the Requestor's medications.¹³³ Patients may also learn about the program through patient advocacy groups.¹³⁴ The

123. *Id.* at 4–5.

124. *Id.* at 4.

125. *Id.* at 5.

126. *Id.*

127. *Id.*

128. *Id.*

129. *Id.*

130. *Id.* at 6.

131. *Id.*

132. *Id.*

133. *Id.*

134. *Id.*

laboratory and counseling vendors are prohibited from promoting the Requestor's program or medications to patients and providers.¹³⁵

b) OIG Opinion and Holding

In April 2022, the OIG issued AO 22-06, finding that the Requestor's sponsored genetic testing program implicated the AKS because it provided remuneration to both patients and their physicians, who may prescribe or induce patients to purchase the Requestor's medications.¹³⁶ However, for patients, the program provides free genetic testing and counseling services that are "inherently valuable."¹³⁷ For physicians, the program enables offering a service at no cost to them or their patients, albeit creating an opportunity to bill for additional services or expand their care in unrelated capacities.¹³⁸ Despite these concerns, the OIG held that the program posed a "sufficiently low risk of fraud and abuse" under the AKS for three primary reasons:

1. The program is unlikely to lead to overutilization or inappropriate utilization.¹³⁹ The genetic test alone is not enough to diagnose the disease and only indicates if one of the gene mutations is present.¹⁴⁰ Without a confirmed diagnosis, the Requestor's medications will not be prescribed, and the Requestor has no other financial interest in the disease beyond its two medications.¹⁴¹ Here, the nexus between the remuneration offered and the ordering of products is attenuated.
2. The program is unlikely to skew clinical decision-making or raise patient safety or quality of care concerns.¹⁴² First, physicians are not incentivized to recommend or prescribe the Requestor's products.¹⁴³ Second, patients can benefit from earlier detection, shortening the time between the onset of symptoms and a diagnosis and enabling treatment during the early stages of the disease.¹⁴⁴
3. The program has safeguards to prevent its use as a marketing or sales tool.¹⁴⁵ The Requestor cannot identify individual patients or physicians from the data shared by the vendors.¹⁴⁶ The sales force cannot access

135. *Id.*

136. *Id.* at 7.

137. *Id.*

138. *Id.*

139. *Id.*

140. *Id.*

141. *Id.* at 7–8.

142. *Id.* at 8.

143. *Id.*

144. *Id.* at 8–9.

145. *Id.* at 9.

146. *Id.*

any data and does not distribute materials in a personalized manner.¹⁴⁷ The laboratory vendor cannot promote the program to patients or providers. The counseling vendor cannot discuss treatment options or promote the Requestor's medications to patients.¹⁴⁸

The OIG, through its analysis, held that although the sponsored genetic testing program technically generates prohibited remuneration under the AKS, it would not impose sanctions on the Requestor.¹⁴⁹

2. *OIG Advisory Opinion 24-12 (AO 24-12)*

The OIG wrote its second opinion on sponsored genetic testing programs in AO 24-12, two and a half years after AO 22-06. The OIG distinguished AO 24-12 based on the rarity of the genetic condition and the specificity of both the genetic test and the Requestor's medication.

a) Factual Background

The Requestor manufactures one FDA-approved medication that treats an ultra-rare genetic condition (the "condition").¹⁵⁰ Here, the condition leads to recurrent kidney stones and chronic kidney disease that can progress to end-stage renal disease.¹⁵¹ The condition has three known subtypes, each caused by one type of genetic mutation.¹⁵² The Requestor manufactures one FDA-approved medication that only treats Subtype 1, the most severe and common subtype, affecting approximately 80 percent of patients with the condition.¹⁵³

i) The Genetic Test

The Requestor's sponsored program offers three types of genetic tests, each with varied levels of specificity.¹⁵⁴ The first genetic test is a forty-five-gene panel that tests for multiple genetic disorders associated with kidney stone diseases.¹⁵⁵ The panel largely tests for rare or ultra-rare diseases to rule out potential causes of symptoms rather than to diagnose a specific genetic condition.¹⁵⁶ The second genetic test is condition-specific, testing only for the

147. *Id.*

148. *Id.*

149. *Id.* at 10.

150. U.S. DEP'T OF HEALTH & HUM. SERVS., OFF. OF INSPECTOR GEN., OIG ADVISORY OPINION NO. 24-12, at 2 (2024) [hereinafter AO 24-12], <https://oig.hhs.gov/documents/advisory-opinions/10117/AO-24-12.pdf>.

151. *Id.*

152. *Id.*

153. *Id.* at 2–3.

154. *Id.* at 3.

155. *Id.*

156. *Id.*

three subtypes of the genetic mutation.¹⁵⁷ The condition-specific test is appropriate for patients with a family history or as a follow-up to preliminary tests that strongly indicate the condition.¹⁵⁸ The third genetic test is familial variant testing, narrowly testing for a specific variant or mutation seen in a direct relative.¹⁵⁹ All three genetic tests are commercially available by laboratories outside of the sponsored genetic testing program.¹⁶⁰

The Requestor distinguished how the genetic test compares to other clinical methods used to diagnose the condition. The genetic mutation that causes the condition results in an overproduction and accumulation of oxalate; however, oxalate accumulation can occur in organs other than the kidneys.¹⁶¹ Thus, the symptoms of recurrent kidney stone disease are non-specific and overlap with other diagnoses.¹⁶² Additionally, the traditional method of testing requires urine collection over a twenty-four-hour period, possibly twice—an inconvenient, costly, and difficult collection method with poor compliance and accuracy.¹⁶³ Genetic testing similarly faces limited insurance coverage.¹⁶⁴ The Requestor reflects on these challenges to explain how the condition’s diagnosis is often delayed.¹⁶⁵

A genetic test is not required to prescribe the Requestor’s medication to patients.¹⁶⁶ However, the Requestor’s medication is only approved to treat Subtype 1 of the condition, and not all patients diagnosed with Subtype 1 are prescribed the medication.¹⁶⁷ Instead, the patient’s healthcare provider must determine if the medication is appropriate by considering factors, such as the patient’s average oxalate levels, lifestyle and dietary changes, and other competing products and medications.¹⁶⁸

ii) The Sponsored Program

The Requestor instituted its program intending to use genetic testing as a diagnostic resource to identify, diagnose, and treat inherited diseases, and “particularly, to support disease awareness around hereditary conditions that

157. *Id.*

158. *Id.*

159. *Id.*

160. *Id.*

161. *Id.* at 2.

162. *Id.*

163. *Id.*

164. *Id.* at 3.

165. *Id.* at 2.

166. *Id.* at 3.

167. *Id.*

168. *Id.*

may cause kidney stones.”¹⁶⁹ The Requestor entered an arrangement with a contracted laboratory, where the laboratory or a subsidiary furnishes the genetic testing and counseling services.¹⁷⁰ The healthcare provider can order one of the three genetic tests for an eligible patient.¹⁷¹ The provider can additionally order a sponsored assay test if the initial test results are inconclusive.¹⁷² The Requestor does not receive any identifiable patent data that would allow the determination of a specific patient’s genetic test or results.¹⁷³ Likewise, the Requestor does not receive information to identify the ordering healthcare providers or their institutions.¹⁷⁴ Two designated individuals—a program lead and a data lead—receive de-identified aggregate data to monitor program efficiency and ensure that the program’s contractual and operational obligations are met.¹⁷⁵ Neither individual has any performance objectives or compensation incentives linked to the Requestor’s products, including the medication.¹⁷⁶

iii) Requestor’s Marketing

The Requestor offers two websites that provide general disease awareness information about the condition.¹⁷⁷ The first website is mainly directed toward the public (including patients), offering guidance on managing the condition and providing connections to supportive organizations.¹⁷⁸ The public-oriented website includes information about the sponsored genetic testing program but is not branded with the Requestor’s medication or specific therapeutic options.¹⁷⁹ The second website is tailored to healthcare professionals, educating them about the condition and genetic testing as a diagnostic tool.¹⁸⁰ The provider-oriented website similarly does not include medication branding or specific therapeutic information.¹⁸¹ However, the Requestor is identified as the website sponsor “for transparency.”¹⁸² Thus, the Requestor’s websites aim to educate about the condition and inform the public and healthcare providers

169. *Id.* at 4.

170. *Id.*

171. *Id.* at 5.

172. *Id.*

173. *Id.* at 6.

174. *Id.*

175. *Id.* at 7.

176. *Id.*

177. *Id.* at 4.

178. *Id.*

179. *Id.*

180. *Id.*

181. *Id.*

182. *Id.* at 4 n.5.

about the sponsored genetic testing program—all without advertising the Requestor’s medication.

b) OIG Opinion and Holding

The OIG issued AO 24-12 in December 2024, affirming its earlier decision in AO 22-06: the OIG may issue a favorable advisory opinion if a program presents a sufficiently low risk of fraud and abuse.¹⁸³ The OIG’s rationale in AO 24-12 aligns with the same three rationales in AO 22-06 while supplementing specific facts about the Requestor’s sponsored program:

1. The program’s safeguards reduce the risk of overutilization or inappropriate utilization.¹⁸⁴ The eligibility criteria are “specific and narrow,” limited to patients with impaired renal function or a family history of the condition.¹⁸⁵ Similarly, the condition is ultra-rare, where the tests are narrowly tailored to rule out rare kidney stone diseases rather than diagnose the condition in most cases.¹⁸⁶
2. The program is unlikely to skew clinical decision-making or raise concerns about patient safety or quality of care.¹⁸⁷ The sponsored tests are already commercially available outside of the program.¹⁸⁸ The Requestor does not incentivize healthcare providers to prescribe its medication, which is only prescribed to treat some—but not all—Subtype 1 patients.¹⁸⁹ Similarly, the Requestor cannot target marketing efforts because it does not receive identifiable patient or provider information.¹⁹⁰
3. The remuneration provided by the Requestor to the laboratory and subsidiary presents a low risk of fraud and abuse, despite the potential for direct or indirect referrals for the Requestor’s medication.¹⁹¹ The Requestor pays fixed fees for the contracted services and only receives de-identified information.¹⁹² The laboratory and subsidiary only discuss genetic tests and hereditary diseases, not treatment options.¹⁹³

183. *Id.* at 8.

184. *Id.* at 9.

185. *Id.*

186. *Id.*

187. *Id.*

188. *Id.*

189. *Id.*

190. *Id.*

191. *Id.*

192. *Id.*

193. *Id.*

Although the sponsored genetic program resulted in potential remuneration, the OIG determined it would not impose administrative sanctions on the Requestor for AKS violations.¹⁹⁴

3. *Implications*

AO 22-06 and AO 24-12 provide guideposts for favorable safeguards and signal a green light for the Requestors to proceed with their sponsored genetic testing programs. Even so, the OIG issues its rulings within strict confines, clarifying that each advisory opinion applies only to the specific Requestor and cannot be relied upon by any other person.¹⁹⁵ Likewise, the opinions are limited to the Requestor's genetic testing program and cannot be applied to any other program.¹⁹⁶ The opinions warn that any differentiation in the facts or a clearer nexus between remuneration and purchases of the Requestor's products would likely result in a different outcome.¹⁹⁷ Lastly, the advisory opinions only apply to the statutory provisions cited in the analysis—the OIG declines to comment on any other regulation or law that could apply to the program.¹⁹⁸

On balance, AO 24-12 simultaneously narrows and widens the scope of prior AO 22-06. The Requestor in AO 24-12 sponsored a genetic test that diagnoses the genetic disorder without parallel testing, thus narrowing the OIG's inquiry to one test with independent diagnostic abilities. However, the genetic condition in AO 24-12 is ultra-rare and manifests in three subtypes, where the Requestor's medication treats just one subtype.¹⁹⁹ Additionally, the Requestor's medication is not the only available treatment, and healthcare providers must consider other therapeutic options before prescribing it.²⁰⁰ These elements broaden the analysis, introducing fact-specific considerations that depend on both the genetic test and the condition.

Similarly, it is unclear if AO 24-12 supersedes or coexists with AO 22-06. While the factual differences between the two opinions allow them to coexist, recency could push deference toward AO 24-12. At a minimum, AO 24-12 provides new food for thought on compliance safeguards. For example, AO 22-06 established data protection from marketing use as an implicit compliance requirement. Under AO 24-12, public-facing websites—branded with the Requestor's name for transparency—could become a recommended

194. *Id.* at 10.

195. AO 22-06, *supra* note 106, at 10.

196. *Id.*

197. *Id.* at 8.

198. *Id.* at 10.

199. AO 24-12, *supra* note 150.

200. *Id.* at 3.

feature for sponsored genetic testing programs. Although the OIG's narrowly disclosed opinions stress that they are bespoke to the Requestor's specific program, they nonetheless create pressure for sponsors to adopt similar safeguards.

While pharmaceutical manufacturers can deduce a few clear compliance guidelines from the advisory opinions, they must frame this deduction on two levels: (1) a fine-tuned inquiry on program-specific safeguards, and (2) a wide-cast inquiry on other applicable regulations. Manufacturers must proceed with great caution, understanding that any slight variation could flag their program for remuneration sanctions, not only from the OIG but from any other regulatory bodies as well.

B. AN UNFAVORABLE OUTCOME: *ULTRAGENYX*

The *Ultragenyx* settlement outlines a sponsored genetic testing program that violated the AKS and faced \$6 million in sanctions. After paying for genetic test results from a contracted laboratory, the Ultragenyx sales group followed up by marketing directly to ordering physicians. Ultragenyx faced harsh criticism for its conduct, serving as a grave warning to other manufacturer-sponsors.

1. *Factual Background*

Ultragenyx is a pharmaceutical manufacturer that develops therapies and treatments for rare diseases.²⁰¹ For example, Ultragenyx developed and sells Crysvida, a drug that treats X-linked hypophosphatemia (XLH).²⁰² XLH is a rare, inherited disorder that can lead to soft, weak bones and features such as bowed or bent legs, short stature, and dental abscesses.²⁰³ XLH is characterized by low phosphate levels in the blood, which can be difficult to diagnose or susceptible to confusion with other disorders that have similar symptoms.²⁰⁴

a) The Genetic Test

A genetic test is often required to make a definitive diagnosis of XLH.²⁰⁵ Ultragenyx was aware that, in some instances, physicians required a positive genetic test result to diagnose XLH and prescribe Crysvida to a patient.²⁰⁶

201. Settlement Agreement at 1, *United States ex rel. Ruggiero v. Ultragenyx Pharm. Inc.*, No. 1:21-cv-11176-ADB, at 1 (D. Mass. Dec. 19, 2023) [hereinafter *Ultragenyx Settlement Agreement*], https://www.justice.gov/d9/2023-12/usa_v._ultragenyx_-_settlement_agreement.pdf.

202. *Id.*

203. *Id.*

204. *Id.*

205. *Id.*

206. *Id.* at 2.

Ultragenyx was equally aware that insurers—including Medicare and Medicaid—sometimes require a positive genetic test result for the XLH mutation to reimburse prescriptions of Crysivita.²⁰⁷ In these cases, the lack of a genetic test was the primary obstacle preventing a Crysivita prescription.

b) The Sponsored Program

Ultragenyx established an agreement with a third-party laboratory to conduct the necessary genetic testing to diagnose XLH and provide the results to the ordering physician.²⁰⁸ Separately, Ultragenyx paid the laboratory to provide the test results back to Ultragenyx.²⁰⁹ The test results sent to Ultragenyx did not include patient names but did include the ordering physician’s name, along with a de-identified patient ID number, the test order date, and the test result itself (collectively referred to as the “results report”).²¹⁰

c) Ultragenyx’s Marketing

Ultragenyx shared the laboratory results report with its commercial team, which used the results to identify potential Crysivita patients and their physicians and pursue them with follow-up marketing initiatives.²¹¹ The sales force also followed up with physicians on the test results.²¹² This internal practice of receiving and distributing test results to the sales force and instructing Crysivita sales calls to physicians who ordered a test or had patients with positive test results continued until Ultragenyx became aware of AO 22-06 in April 2022.²¹³

2. *Settlement Agreement Between the DOJ on Behalf of the OIG and Ultragenyx*

In December 2023, the DOJ, acting on behalf of the OIG, Ultragenyx, and the Relator, reached a \$6 million settlement agreement.²¹⁴ Ultragenyx admitted, acknowledged, and accepted responsibility for its conduct from February 1, 2019 through May 30, 2022.²¹⁵ Ultragenyx’s conduct resulted in the submission of false claims to Medicare and Medicaid by paying remuneration to patients and the laboratory vendor, thereby violating the AKS.²¹⁶ For patients,

207. *Id.*

208. *Id.*

209. *Id.* at 2–3.

210. *Id.* at 3.

211. *Id.* at 2–3.

212. *Id.* at 3.

213. *Id.*

214. *Id.* at 1, 3–4.

215. *Id.* at 2–3.

216. *Id.* at 3.

Ultragenyx covered the cost of genetic testing, which could induce the purchase of Crysvida and result in reimbursement under Medicare or Medicaid.²¹⁷ For the laboratory vendor, Ultragenyx induced the laboratory to separately provide the results report to Ultragenyx, consequently enabling Ultragenyx's sales force to target physicians to prescribe Crysvida reimbursable through Medicare and Medicaid.²¹⁸ These two operations were designed to encourage Crysvida prescriptions and violated the AKS by improperly influencing federal healthcare program billing.

3. *Implications*

The settlement agreement is brief and direct. In just four pages, the settlement agreement summarizes Ultragenyx's medication, sponsored genetic testing program, conduct, and liability.²¹⁹ Ultragenyx admitted and accepted responsibility for AKS violations and paid millions in fines to end the dispute.²²⁰ Still, the full extent of conduct alleged against Ultragenyx is not clear.

From a high-level perspective, Ultragenyx's payment to receive a results report and its sales force's use of the report for targeted follow-ups were irrefutable AKS violations. From a closer view, however, there are potential margins for permissible conduct that are not fully teased out. For example, if Ultragenyx received a results report without the ordering physician's name, the scale might have tipped toward usage for tracking purposes only, thereby reducing sales and marketing concerns.

Likewise, the settlement agreement does not explain the timeline of Ultragenyx's conduct. While Ultragenyx admits it ceased providing results reports to its sales force after learning of AO 22-06 in April 2022, the alleged conduct continued through May 30, 2022.²²¹ Likewise, the agreement does not outline Ultragenyx's internal plan to restructure its results reports dissemination and reinstruct sales force personnel to stop outreach to physicians. The settlement agreement does away with Ultragenyx's violations and implicitly assumes the company has taken the proper steps to reconcile its internal practices and procedures. However, these ambiguities and slight distinctions become readily apparent when planning future conduct around the settlement agreement holdings.

217. *Id.*

218. *Id.*

219. *See id.* at 1–4.

220. *Id.* at 2.

221. *Id.* at 3.

Lastly, the DOJ represented the United States as a party in the litigation and acted on behalf of the OIG.²²² Following the settlement, the Attorney's Office issued a press release to "[l]et this case be a warning to others," stating that "anyone engaging in similar conduct [would] face similar consequences."²²³ The press release targets pharmaceutical manufacturers that "insert themselves" into the physician-patient relationship by potentially undercutting the objectivity of treatment decisions.²²⁴ The DOJ made clear that Ultragenyx "will not be allowed to exploit patient data to target patients for treatments in order to boost their bottom line at the expense of taxpayer-funded health care programs."²²⁵ These harsh, accusatory statements certainly send warnings to pharmaceutical manufacturers to avoid any intervening in clinical decision-making. Yet, for manufacturers trying to avoid intervention while promoting a compliant sponsored genetic testing program, the question still stands: which behaviors are fraudulent or abusive?

C. AN UNCERTAIN FUTURE: SHIFTING REGULATORY REVIEW

In February 2024, the DOJ subpoenaed BioMarin Pharmaceuticals regarding its sponsored genetic testing program for two medications. BioMarin Pharmaceuticals agreed to fully comply with the investigation but also expressed concerns about an industry-wide sentiment: the simultaneous breadth and narrowness of regulation makes compliance an ambiguous concept.

1. *An Outstanding DOJ Subpoena of BioMarin Pharmaceuticals*

BioMarin Pharmaceuticals is a biotechnology company that develops genetic therapies for conditions with significant unmet medical needs.²²⁶ In February 2024, BioMarin Pharmaceuticals announced that it was subpoenaed by the DOJ to produce documents regarding its sponsored testing programs for two FDA-approved medications, Vimizim and Naglazyme.²²⁷

222. *Id.* at 1. Note that the OIG is an independent entity within the Department of Justice. *Office of the Inspector General*, U.S. DEP'T OF JUST., <https://www.justice.gov/doj/office-inspector-general>.

223. Press Release, U.S. Dep't of Just., Pharmaceutical Company Ultragenyx Agrees to Pay \$6 Million for Allegedly Paying Kickbacks to Induce Claims for its Drug Crysvita (Dec. 21, 2023) (internal quotations omitted) [hereinafter Ultragenyx Press Release], <https://www.justice.gov/usao-ma/pr/pharmaceutical-company-ultragenyx-agrees-pay-6-million-allegedly-paying-kickbacks-induce>.

224. *Id.*

225. *Id.*

226. *About Us*, BIOMARIN, <https://www.biomin.com/company/>.

227. BioMarin Pharm. Inc., Annual Report 48 (Form 10-K) (Feb. 26, 2024).

In response, BioMarin produced the requested documents and announced full cooperation with the DOJ investigation.²²⁸ However, BioMarin also acknowledged that while it seeks to comply with the AKS, its sponsored testing programs may not meet all the criteria for safe harbor protection.²²⁹ BioMarin highlighted that practices intended to induce prescribing, purchases, or recommendations could be subject to scrutiny.²³⁰ In BioMarin’s words, “[t]here is no assurance that such sponsored testing programs . . . will not be found to violate such laws.”²³¹

The DOJ’s findings and next steps in the investigation are still outstanding while BioMarin’s sponsored testing programs and medications, each with over a decade of FDA approval, are examined.²³²

2. *Post-Loper Bright Risks to Regulatory Agency Authority and Rulemaking*

In June 2024, the Supreme Court overruled *Chevron* in *Loper Bright Enterprises v. Raimondo*, opening a new chapter for the judicial review of agency action.²³³ In the context of sponsored genetic testing, agencies face uncertainty in two key areas: authority and rulemaking. First, the FDA’s ability to interpret and subsequently regulate medical devices could face increased scrutiny—particularly as the FDA expands oversight to new medical device categories, including LDTs.²³⁴ Second, the FDA and the OIG’s rulemaking authority could similarly face more frequent challenges. For example, the OIG’s safe harbor provisions are extensions of the AKS that expand protection from prosecution to specifically enumerated arrangements.²³⁵ If a safe harbor provision narrows the requirements for protection, where compliance with the provision necessarily satisfies a broader statutory exemption, courts may still defer to the statutory exception rather than the agency’s interpretation.²³⁶ Looking forward, these open areas are susceptible to judicial review and signal the need to consider administrative fallbacks or alternate avenues to impose change. To preserve the FDA and the OIG’s ability to regulate and issue

228. *Id.*

229. *Id.*

230. *Id.*

231. *Id.*

232. *See* BioMarin Pharm. Inc., Quarterly Report 55 (Form 10-Q) (June 30, 2024).

233. *Loper Bright Enters. v. Raimondo*, 603 U.S. 369 (2024).

234. *See* FDA In Vitro Diagnostic Medical Devices, 89 Fed. Reg., *supra* note 37.

235. *See* U.S. DEP’T OF HEALTH & HUM. SERVS., OFF. OF INSPECTOR GEN., *supra* note 87.

236. *See id.*

guidance, congressional action will be imperative to delegate and affirm agency rulemaking authority.²³⁷

3. *Questions Posed for the Genetic Testing Industry, Particularly Regulatory Agencies*

The actively shifting role of regulatory agencies and courts in statutory interpretation and enforcement actions creates ambiguity for the future of sponsored genetic testing programs. BioMarin's briefing to the SEC highlights a key concern recognized by the industry:

Due to the *breadth* of the healthcare and privacy and data protection laws described above, the *narrowness* of available statutory and regulatory exceptions and safe harbors and the *increased focus* by law enforcement authorities in enforcing such laws, our business activities could be subject to challenge under one or more of such laws.²³⁸

This statement highlights a critical issue: statutory regulations specific to sponsored testing programs are few and far between, while government agencies aggressively ramp up enforcement efforts.²³⁹ Pharmaceutical manufacturers are caught in a crossfire, where the decision to offer a sponsored testing program that diagnoses patients with genetic disorders instead risks hefty monetary fines. Regulatory agencies must answer key questions for manufacturers to proceed with certainty. First, which agency should have the authority to draft and oversee compliance guidance for sponsored genetic testing programs? Second, which features of sponsored genetic testing programs should be included in compliance guidance?

IV. GAUGING AN APPROPRIATE THRESHOLD FOR REGULATORY OVERSIGHT AND GUIDANCE, AND FORGING A PATH FORWARD TO SPONSORED GENETIC TESTING COMPLIANCE

No single resource comprehensively outlines the compliance standards for sponsored genetic testing programs. Instead, sponsorship and genetic testing are separately overseen by two regulatory agencies: the OIG oversees sponsorship, while the FDA regulates genetic testing.

237. *Loper Bright*, 603 U.S. at 395.

238. Form 10-K, *supra* note 227, at 50 (emphasis added).

239. Enforcement priorities are also susceptible to change between administrations and political appointments, where the HHS Secretary is an elected official.

Sponsored genetic testing programs challenge a niche intersection between the premarket approval of genetic tests and the use of those tests in sponsored programs, where third-party vendors provide them at no cost to physicians or patients. This intersection prompts evaluation of the FDA's and the OIG's roles. Section IV.A calls for cross-agency collaboration between the FDA and OIG to synthesize their distinct roles and determine the appropriate considerations for a compliance guidance document. Section IV.B proposes a risk-based spectrum approach to assess and enforce compliance considerations in sponsored genetic testing programs.

A. REGULATORY AGENCIES MUST MODIFY EXISTING COLLABORATIONS TO JOINTLY DRAFT A COMPLIANCE GUIDANCE

The FDA and the OIG have distinct regulatory motivations in their independent enforcement actions that are not entirely captured by the AKS. However, existing FDA initiatives should be adapted to create guidance and enforcement mechanisms specific to sponsored genetic testing programs.

1. *The FDA and the OIG Have Distinct Approaches to Regulating Sponsored Genetic Testing Programs That Cannot Be Reconciled Through the AKS*

The FDA and the OIG have entirely separate motivations that inform their regulation of sponsored genetic testing programs. Even so, the OIG maintains auditing power over the FDA and can propose recommendations to the FDA. This existing dynamic is not conducive to AKS regulation, nor does the AKS have any provisions that align with sponsored genetic testing regulation.

a) *The FDA Oversees Genetic Test Safety and Reliability While the OIG Oversees Financial Kickbacks*

The OIG acts as an oversight committee for the FDA. While the OIG's role naturally implies that it works toward the same outcomes as the FDA, each agency has fundamentally different motives and leadership that shape the focus of its investigations, opinions, and individual regulatory goals.

The FDA ensures the safety, efficacy, and security of human and veterinary drugs, biological products, and medical devices.²⁴⁰ As of January 2024, the FDA oversees over 6,500 medical device products.²⁴¹ Medical devices are part of the FDA's medical device and radiological health programs, which had a \$746.2 million budget in FY 2023—yet only made up 11 percent of the FDA's

240. *What We Do*, FDA, <https://www.fda.gov/about-fda/what-we-do> (last updated Nov. 21, 2023).

241. FDA, *FDA AT A GLANCE* (2024), <https://www.fda.gov/media/175664/download>.

total budget for the year.²⁴² While the FDA does manage the substantive function and classification of medical devices, where genetic tests can be considered medical devices, the FDA's regulation of genetic tests is highly variable.²⁴³

The FDA's official recognition of LDTs as medical devices exemplifies its motivation to ensure the safety and effectiveness of tests increasingly used to make critical healthcare decisions.²⁴⁴ However, the FDA's efforts to finally regulate LDTs might be taking force too little, too late. Public health concerns have mounted over a decade as LDTs advanced to high-tech instrumentations used in large testing volumes, steadily impacting more and more patients.²⁴⁵ Evidence from scientific literature, class-action lawsuits, and the FDA's own experience demonstrated that some LDTs provided inaccurate test results or performed worse than FDA-authorized tests.²⁴⁶ Concurrently, LDTs were used to select cancer treatment, aid in COVID-19 diagnoses, manage rare diseases, and identify patients' risk of cancer.²⁴⁷ In response, FDA Commissioner Dr. Robert M. Califf announced that the new LDT rule "aims to provide crucial oversight . . . to help ensure that important health care decisions are made based on test results that patients and health care providers can trust."²⁴⁸ While the LDT rule is just one corner of the FDA's regulation of genetic tests, the FDA foundationally seeks for patients and physicians to "continue to have access to the tests they need while having greater confidence that the tests they rely on are accurate."²⁴⁹

Conversely, the OIG serves to improve compliance, implement enforcement actions, and recover misspent funds, subsequently prioritizing review for kickbacks.²⁵⁰ In fact, the OIG quantifies its annual performance through enumerated enforcement actions: criminal actions against individuals engaged in Medicare and Medicaid-related crimes, civil actions including false claims, unjust enrichment lawsuits, civil monetary penalty settlements, and

242. *Id.*

243. Javitt, *supra* note 30.

244. Press Release, FDA, FDA Takes Action Aimed at Helping to Ensure the Safety and Effectiveness of Laboratory Developed Tests (Apr. 29, 2024), <https://www.fda.gov/news-events/press-announcements/fda-takes-action-aimed-helping-ensure-safety-and-effectiveness-laboratory-developed-tests>.

245. *Id.*; see Angela M. Caliendo & Kimberly E. Hanson, *Point-Counterpoint: The FDA Has a Role in Regulation of Laboratory-Developed Tests*, 54 J. CLINICAL MICROBIOLOGY 829 (2016).

246. FDA Takes Action, FDA, *supra* note 244.

247. *Id.*

248. *Id.*

249. *Id.*

250. FACT SHEET, *supra* note 66.

exclusions from federal healthcare programs.²⁵¹ From its outset, the AKS was enacted in response to increasing claims of fraud and Medicare and Medicaid costs, establishing the basis for the OIG's cost-focused investigations.²⁵² For example, in the *Ultragenyx* press release, OIG Special Agent in Charge Roberto Coviello stated that “[t]he goals of [the OIG’s] continued enforcement in this area are to protect the integrity of taxpayer-funded health care programs such as Medicare and Medicaid.”²⁵³ Press releases on other genetic testing kickback schemes similarly promote that “[the OIG’s] commitment to safeguarding the integrity of the Medicare program remains unwavering.”²⁵⁴ While the OIG is steadfast in its focus on kickback arrangements as an “investigative priority,” it pays little regard to the implications of genetic tests themselves.²⁵⁵

Thus, the FDA is motivated by ensuring that only safe and reliable medical devices reach the market, while the OIG is motivated by discovering kickbacks to federal healthcare programs. Each agency focuses on different aspects of a sponsored genetic testing program: the test results report and the billing for those reports. Both agencies must weigh in on the proper conduct to fully address the compliance expectations for a pharmaceutical manufacturer or program sponsor.

b) The OIG Exercises Auditing Power Over the FDA but Encourages the FDA to Have Greater Involvement in Enforcement Actions

Each regulatory agency's enforcement actions demonstrate its distinct roles in overseeing sponsored genetic testing programs. The FDA is the primary gatekeeper for genetic tests to reach the marketplace. Once a test is in the marketplace, the FDA is responsible for continually overseeing its approvals and auditing as needed. At this stage, the OIG becomes a secondary gatekeeper by overseeing transactions between manufacturers, physicians, and patients, particularly targeting kickbacks to federal healthcare programs. The OIG can also exercise its power to audit the FDA's effectiveness in overseeing its approvals. Thus, the OIG not only guides the manufacturing industry but

251. HHS OIG 2022 ANNUAL REPORT, *supra* note 56, at 1.

252. Diké-Minor, *supra* note 2, at 109.

253. *Ultragenyx* Press Release, *supra* note 223.

254. Press Release, U.S. Dep't of Just., Lab Owner Sentenced for \$463M Genetic Testing Scheme (Aug. 18, 2023) (internal quotations omitted), <https://www.justice.gov/opa/pr/lab-owner-sentenced-463m-genetic-testing-scheme>; *see also* Press Release, U.S. Dep't of Just., Doctor and Wife Admit Genetic Testing Kickback and Bribery Scheme (Nov. 22, 2023), <https://www.justice.gov/usao-nj/pr/doctor-and-wife-admit-genetic-testing-kickback-and-bribery-scheme>.

255. *Ultragenyx* Press Release, *supra* note 223.

also holds other regulatory agencies accountable to its compliance standards and recommendations.

The OIG has previously criticized the FDA for lacking policies and procedures to respond to consumer complaints, including its failure to investigate a major infant formula supply recall.²⁵⁶ In June 2024, the OIG audited the FDA to determine if it had taken “prompt, appropriate, and effective action” in response to consumer and whistleblower complaints on powdered infant formula products.²⁵⁷ The OIG determined that the FDA lacked policies and procedures that appropriately received, escalated, and responded to whistleblower complaints.²⁵⁸ The OIG found that the FDA took over fifteen months to identify and forward one whistleblower complaint and over four months to escalate another complaint to senior leadership.²⁵⁹ Likewise, the FDA inaccurately entered data into its complaint system for thirty-seven out of sixty-three consumer complaints.²⁶⁰ From the thirty-seven complaints entered, thirty-two did not have planned follow-up assignments and six had inaccurate complaint results, such as death or life-threatening injury.²⁶¹ Lastly, the FDA lacked guidance on when and how to initiate a mission-critical inspection during public health emergencies.²⁶² Certainly, the health of over 3.5 million infants, many of whom rely on formula at some point, qualified as a public health emergency.²⁶³

The OIG subsequently proposed nine recommendations, including implementing policies and procedures to determine when and how to conduct

256. U.S. DEP’T OF HEALTH & HUM. SERVS., OFF. OF INSPECTOR GEN., NO. A-01-22-01502, THE FOOD AND DRUG ADMINISTRATION’S INSPECTION AND RECALL PROCESS SHOULD BE IMPROVED TO ENSURE THE SAFETY OF THE INFANT FORMULA SUPPLY 1 [hereinafter OIG AUDIT OF FDA INSPECTION AND RECALL REPORT], <https://oig.hhs.gov/documents/audit/9908/A-01-22-01502.pdf>; see also U.S. DEP’T OF HEALTH & HUM. SERVS., OFF. OF INSPECTOR GEN., THE FOOD AND DRUG ADMINISTRATION’S INSPECTION AND RECALL PROCESS SHOULD BE IMPROVED TO ENSURE THE SAFETY OF THE INFANT FORMULA SUPPLY (2024), <https://oig.hhs.gov/reports/all/2024/the-food-and-drug-administrations-inspection-and-recall-process-should-be-improved-to-ensure-the-safety-of-the-infant-formula-supply/>.

257. OIG AUDIT OF FDA INSPECTION AND RECALL REPORT, *supra* note 256, at 1.

258. *Id.* at 9.

259. *Id.* at 9–11.

260. *Id.* at 12.

261. *Id.*

262. *Id.* at 15.

263. *Id.* at 1. The United States House of Representatives Subcommittee on Oversight and Investigations met in May 2022 concerning “Formula Safety and Supply: Protecting the Health of America’s Babies.” *Protecting the Health of America’s Babies: Hearing Before the H. Subcomm. on Oversight and Investigations of the H. Comm. on Energy and Com.*, 117th Cong. (2022) <https://www.congress.gov/117/meeting/house/114821/documents/HHRG-117-IF02-Transcript-20220525.pdf>.

timely inspections and policies and procedures specific to the FDA's recall authority for infant formula.²⁶⁴ The FDA concurred with all nine recommendations, though none have been implemented.²⁶⁵ The infant formula recall provides a clear example of the OIG's authority over the FDA and the FDA's subsequent deference in complying with the OIG's demands.

Undoubtedly, the infant formula recall is not the same type of FDA investigation that would be engaged if complaints arose about the safety or efficacy of a genetic test. Nonetheless, the FDA regulates all subject matters with the overarching goal of protecting public health and safety. Likewise, the OIG can audit any of the FDA's oversight initiatives. If the FDA does not implement an OIG recommendation, it could be listed on a publicly accessible tracker that includes the issuance date, the proposed action, and the status.²⁶⁶ The infant formula recall is just one recent and relevant illustration of the OIG in action, auditing the FDA's efficacy in enforcing regulatory compliance.

Although the OIG's auditing power over the FDA creates somewhat of a supervisory dynamic, the FDA still independently regulates the compliance of genetic tests as medical devices. The OIG steps in when problems or concerns arise regarding the FDA executing its responsibilities. For example, the OIG's infant formula audit assessed the FDA's policies, procedures, and response time metrics.²⁶⁷ The analyses looked at the internal processes that facilitated the FDA's response, but not the substantive implications, such as the ramifications posed by contaminated infant formula.²⁶⁸ The OIG was concerned that the FDA lacked awareness of positive contamination results due to insufficient reporting requirements, but it did not further probe the direct health risk to susceptible infants.²⁶⁹ While both concerns are fundamental in ensuring a compliant infant formula supply, the OIG leans toward the procedural side of FDA operations. Thus, the working relationship between the FDA and the OIG, particularly the OIG's recommendations to the FDA, should be leveraged to address procedural and substantive concerns in sponsored genetic testing programs.

264. OIG AUDIT OF FDA INSPECTION AND RECALL REPORT, *supra* note 256, at 20–21.

265. *Id.* at 53–60; U.S. DEP'T OF HEALTH & HUM. SERVS., OFF. OF INSPECTOR GEN., THE FOOD AND DRUG ADMINISTRATION'S INSPECTION AND RECALL PROCESS SHOULD BE IMPROVED TO ENSURE THE SAFETY OF THE INFANT FORMULA SUPPLY (2024), <https://oig.hhs.gov/documents/audit/9908/A-01-22-01502.pdf>.

266. *See Recommendations Tracker*, U.S. DEP'T OF HEALTH & HUM. SERVS., OFF. OF INSPECTOR GEN., <https://oig.hhs.gov/reports/recommendations/tracker/?view-mode=top-unimp-recs&responsible-agency=all#results>.

267. OIG AUDIT OF FDA INSPECTION AND RECALL REPORT, *supra* note 256, at 8.

268. *See id.*

269. *Id.* at 19.

The OIG seemingly favors the FDA exercising increased authority in enforcement actions. In 2022, the OIG recommended that the FDA seek legislative authority to enforce FDA assessment plans and impose civil monetary penalties on companies that fail to comply with registration requirements.²⁷⁰ While the OIG has the leeway to propose idealistic recommendations, implementing them is a separate feat—which may explain why the recommendation has remained outstanding since 2012.²⁷¹ Granting the FDA increased authority to enforce a requirement that it already oversees is not outlandish. However, the FDA has long faced resource constraints, particularly in drug and device regulation.²⁷² In 2002, Congress rescinded and reallocated \$71 million in drug safety funding.²⁷³ Currently, the FDA's new LDT rule faces concerns about the FDA lacking the infrastructure to support the review process.²⁷⁴ While the FDA cannot comfortably take on additional authority with its current resources, it remains the agency that is exceedingly familiar with the dynamics of the medical device industry based on its leadership of the premarket approval process.²⁷⁵ Therefore, the FDA should not be entirely excluded from enforcement and remuneration concerns; rather, the FDA should instead be invited to assess the appropriate compliance regime. The FDA's ongoing efforts to formalize genetic testing regulation provide valuable insight into regulatory considerations for the review of sponsored genetic testing programs.²⁷⁶ Establishing a cross-agency initiative would facilitate the development of comprehensive compliance guidance for such programs.

270. U.S. DEP'T OF HEALTH & HUM. SERVS., OFF. OF INSPECTOR GEN., OIG'S TOP UNIMPLEMENTED RECOMMENDATIONS: SOLUTION TO REDUCE FRAUD, WASTE, AND ABUSE IN HHS PROGRAMS 41–42 (2022), <https://oig.hhs.gov/documents/top-unimp-recs/1206/OIG-TUR-2022-Complete%20Report.pdf>. Note that OIG recommended that the FDA seek the civil monetary penalty authority for food facilities. The FDA previously expressed support for the recommendation and its openness to pursuing the authority in the future. *See, e.g.*, U.S. DEP'T OF HEALTH & HUM. SERVS., OFF. OF INSPECTOR GEN., OEI-01-11-00211, DIETARY SUPPLEMENTS: COMPANIES MAY BE DIFFICULT TO LOCATE IN AN EMERGENCY 12 (2012), <https://oig.hhs.gov/oei/reports/oei-01-11-00211.pdf>.

271. U.S. DEP'T OF HEALTH & HUM. SERVS., OFF. OF INSPECTOR GEN., OIG'S TOP UNIMPLEMENTED RECOMMENDATIONS, *supra* note 270.

272. *See* INST. MED. F. ON DRUG DISCOVERY, DEV., & TRANSLATION, CHALLENGES FOR THE FDA: THE FUTURE OF DRUG SAFETY, WORKSHOP SUMMARY (2007).

273. *Id.*

274. Melissa B. Miller, Mary Lee Watts & Linoj Samuel, Commentary, *FDA's Proposed Rule for the Regulation of Laboratory-Developed Tests*, 62 J. CLINICAL MICROBIOLOGY (2024).

275. *See supra* Section II.B.2.

276. *See supra* Section II.B.2

c) AKS Safe Harbors are an Improper Statutory Mechanism to Implement Sponsored Genetic Test Guidance That Includes Safety and Reliability Concerns

Safe harbors provide a protective outlet for practices that might otherwise raise suspicion or pose risks of kickbacks but are not treated as offenses.²⁷⁷ However, obtaining safe harbor protection requires strict compliance with the conditions enumerated in the corresponding safe harbor provision.²⁷⁸ Currently, no existing safe harbor covers sponsored genetic testing programs directly. The closest potentially relevant safe harbor pertains to discounts, yet the provision precludes induced purchases reimbursed by federal healthcare programs from protection.²⁷⁹ The safe harbor for discounts specifically excludes from the definition of “discount”:

Supplying one good or service without charge or at a reduced charge to induce the purchase of a different good or service, unless the goods and services are reimbursed by the same Federal health care program using the same methodology and the reduced charge is fully disclosed to the Federal health care program and accurately reflected where appropriate, and as appropriate, to the reimbursement methodology.²⁸⁰

Thus, a free genetic test offered in exchange for a future prescription of the same pharmaceutical manufacturer’s treatment drug is excluded from the safe harbor provision for discounts. Likewise, AO 22-06, AO 24-12, and the *Ultragenyx* settlement did not consider any safe harbor exemptions in their analyses of each program.²⁸¹

A new safe harbor protection would provide the most immediate and readily enforceable solution, consistent with the OIG’s practice over the last thirty years. However, another safe harbor protection would simply revert to the OIG to draft additional features required for compliance. Additionally, relying on safe harbor protections creates a practice of excusing liability for kickbacks and fails to address the larger concern of lacking current guidance for pharmaceutical companies to devise compliant sponsored programs. Physicians and patients are still involved parties interested in receiving valid

277. *Safe Harbor Regulations*, U.S. DEP’T OF HEALTH & HUM. SERVS., OFF. OF INSPECTOR GEN., *supra* note 87.

278. OIG Compliance Program Guidance for Pharmaceutical Manufacturers, *supra* note 94, at 23734.

279. 42 C.F.R. § 1001.952(h).

280. 42 C.F.R. § 1001.952(h)(5)(ii).

281. AO 22-06, *supra* note 106; AO 24-12, *supra* note 150; Ultragenyx Settlement Agreement, *supra* note 201.

test results with lesser concern for marketing tactics or billing practices aimed at federal healthcare programs.

The unfitting OIG-authored safe harbors, coupled with the FDA's and OIG's conflicting motives and enforcement actions, underscores the pressing need for a clearly designated agency to author and lead compliance guidance.

2. *Current FDA-Initiated Cross-Agency Collaborations Should Be Adapted for Drafting Sponsored Genetic Testing Program Guidance*

The FDA has two existing initiatives that could be jointly revised to address regulatory concerns in sponsored genetic testing program contexts. First, the Collaborative Community Initiative should form a working group to gather industry feedback on sponsored genetic testing program concerns. Second, the Pharmaceutical Fraud Program should serve as a baseline for developing an enforcement program that investigates sponsored genetic testing programs.

a) *The FDA Collaborative Community Initiative Should Facilitate a Dialogue Between Pharmaceutical Manufacturers, Regulatory Agencies, and Healthcare Stakeholders*

The Collaborative Community Initiative unites public and private sector organizations and individuals to solve shared problems in a collegial setting.²⁸² Each entity faces individual challenges that underlie a greater vested interest in achieving the best patient outcomes through compliant means.²⁸³

Here, a collaborative community for sponsored genetic testing programs is needed. These programs are divided between multiple engaged stakeholders: the sponsorship-concerned OIG, the genetic testing-concerned FDA, physicians, patients, pharmaceutical manufacturers, and third-party vendors. Each stakeholder provides a unique perspective and expertise as each party is involved in some facet of a sponsored genetic testing program. A pharmaceutical manufacturer would chair the community, with the FDA and OIG as participants. Other pharmaceutical manufacturers, physicians, and patients would be invited to join. One collaborative community is appropriate to encompass all sponsored genetic testing programs since the stakeholders likely face the same regulations and obstacles. This advantageous and efficient forum would be an opportunity to discuss potential AKS violations without facing liability or the pressures of an audit. The community would be a practical platform for manufacturers and regulatory agencies to openly grapple with their concerns and cooperate to reach an amicable solution.

282. *Collaborative Communities: Addressing Health Care Challenges Together*, FDA, *supra* note 42.

283. *See id.*

To be effective, regulatory agencies must first welcome communication and establish an environment where participants feel safe and open to candidly express their views. Next, the agencies must identify the chief concerns of stakeholders and compare them to the existing regulations or statutes they enforce. By evaluating consistencies and discrepancies between stakeholder concerns and existing regulations, agencies are best placed to address these concerns. They may draft amendments to existing regulations or provide individual feedback to the stakeholders on how to proceed. The agencies may also identify a compliant program and share it as a baseline example for stakeholders, similar to the Case for Quality initiative. In other words, an AO 22-06-like document could be developed into a guidance resource that pharmaceutical manufacturers could faithfully rely upon when structuring sponsored genetic testing programs.

The Collaborative Community initiative is a starting point to invite feedback from the OIG, the FDA, and healthcare stakeholders to share insights, concerns, and lessons learned from prior AKS violations. The collective feedback should be synthesized to propose a new, comprehensive pharmaceutical manufacturer-specific compliance guidance document that incorporates successful Case for Quality-style examples.

b) The FDA Pharmaceutical Fraud Program (PFP) is a Pertinent Criminal Investigation Model That Can Be Adapted to Enforce Healthcare-Specific Violations

The Pharmaceutical Fraud Program (PFP) enables the FDA to prosecute fraudulent conduct and stop public harm caused by medical products that reach the marketplace without proper approval.²⁸⁴ The PFP partially functions as an enforcement mechanism for sponsored genetic testing compliance.²⁸⁵ Violations of the AKS are criminal conduct and therefore within the scope of the PFP.²⁸⁶ However, the variation in FDA regulation of genetic tests means that only some genetic tests would be recognized as “potentially dangerous medical products” or subject to PFP scrutiny.²⁸⁷ For instance, under the 510(k) and De Novo pathways and the new LDT rule, certain genetic tests that failed to acquire premarket notification or reached the market before the LDT rule are potentially dangerous. The uneven application of PFP poses administrative

284. BOOZANG ET AL., *supra* note 56, at 25; HHS OIG 2022 ANNUAL REPORT, *supra* note 56, at 101.

285. HHS OIG 2022 ANNUAL REPORT, *supra* note 56, at 101.

286. *See id.* (“The PFP is designed to detect, prosecute, and prevent pharmaceutical, biologic, and medical device fraud.”).

287. *See id.*

challenges regarding how routinely sponsored genetic testing programs would be investigated.

The PFP satisfies the need for a mechanism that evaluates a product from its earliest development stages while concurrently considering its involvement in fraudulent marketing schemes. However, the extremely high bar to qualify for the PFP and the lengthiness of its investigations are ill-fitted for the comparatively narrower scope of a sponsored genetic testing program. Instead, the FDA and OIG should jointly perform a more limited investigation, focusing on a single pharmaceutical manufacturer. At a minimum, the structural framework of the PFP can serve as a model for a healthcare-focused program targeting criminal violations.

After the Collaborative Community establishes a communication channel to collect feedback from the FDA, OIG, and stakeholders, the PFP offers the most closely aligned framework with the proposed goal of merging medical device oversight and marketing practice review under one agency. The dynamics of the PFP should be leveraged to outline an enforcement program that conducts investigations of sponsored genetic test programs in a feasible, administrable manner.

B. A RISK-BASED SPECTRUM APPROACH SHOULD ESTABLISH COMPLIANCE FACTORS FOR SPONSORED GENETIC TESTING PROGRAMS

The OIG Risk Spectrum is a powerful tool to evaluate fraudulent use of federal healthcare programs. Thus, the Risk Spectrum should be tailored to sponsored genetic testing programs by incorporating program-specific considerations into its existing set of factors. This revision would successfully formulate compliance guidance that does not generate policy concerns.

1. *The OIG Risk Spectrum Should be Adapted to Sponsored Genetic Testing Programs by Expanding Upon the Existing Factors with Fact-Specific Considerations*

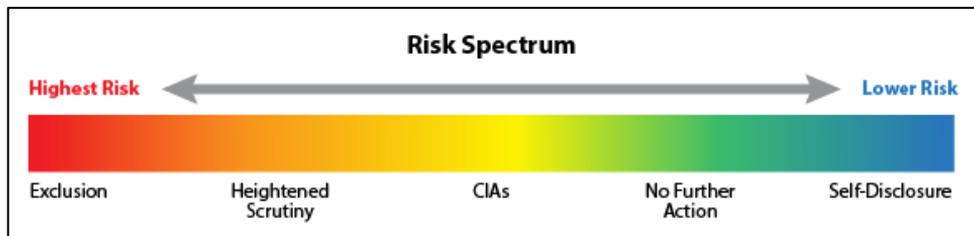
Once established, the joint FDA-OIG task force should first outline the features of a compliant sponsored genetic testing program by drawing on precedent guidance and cases, namely OIG Advisory Opinions and the *Ultragenyx* settlement.

- a) The OIG Risk Spectrum Performs a Weighted Assessment That Can Exclude AKS Violators from Participating in Federal Healthcare Programs

The OIG has already established a “Risk Spectrum” tool that provides approaches for resolving healthcare fraud cases under the False Claims Act.²⁸⁸ Under the AKS, the OIG can exclude entities engaged in fraud, kickbacks, and other prohibited conduct from participating in federal healthcare programs.²⁸⁹

Exclusion is an aggressive remedial action that precludes an entity from offering a product or service to anyone who could bill federal healthcare programs.²⁹⁰ In April 2016, the OIG issued criteria for applying its exclusion authority, which assumes a presumption in favor of exclusion that is rebuttable based on nonbinding factors.²⁹¹ While these criteria were established to protect federal healthcare programs, the OIG recognizes that, in practice, compliance must be corrected and strengthened to prevent future violations.²⁹² The OIG thus debuted a continuum to apply exclusion based on the assessment of future risk to federal healthcare programs:

Figure 1: OIG Risk Spectrum²⁹³



The OIG concluded that exclusion is not often necessary if the entity agrees to “integrity obligations.”²⁹⁴ Further, the OIG may require corporate integrity agreements in exchange for releasing the exclusion authority.²⁹⁵ Integrity obligations allow an entity to develop its compliance program while

288. *Fraud Risk and Heightened Scrutiny*, U.S. DEP’T OF HEALTH & HUM. SERVS., OFF. OF INSPECTOR GEN., <https://oig.hhs.gov/fraud/fraud-risk-spectrum/>.

289. Social Security Act § 1128(b)(7), 42 U.S.C. § 1320(a)–(b)(7).

290. *See* Social Security Act § 1128(b)(7).

291. U.S. DEP’T OF HEALTH & HUM. SERVS., OFF. OF INSPECTOR GEN., CRITERIA FOR IMPLEMENTING SECTION 1128(B)(7) EXCLUSION AUTHORITY 1 (2016), <https://oig.hhs.gov/exclusions/files/1128b7exclusion-criteria.pdf>.

292. *Id.* at 2.

293. *Fraud Risk and Heightened Scrutiny*, U.S. DEP’T OF HEALTH & HUM. SERVS., OFF. OF INSPECTOR GEN., *supra* note 288.

294. U.S. DEP’T OF HEALTH & HUM. SERVS., OFF. OF INSPECTOR GEN., *supra* note 291, at 2.

295. *Id.* at 1.

enabling the OIG to oversee and mitigate risks.²⁹⁶ In other cases, an entity may have a relatively low risk where exclusion or integrity obligations are unnecessary. However, the release of exclusion without integrity obligations is limited to scenarios where there is no egregious misconduct, low financial harm, or where the entity is a successor owner.²⁹⁷ Likewise, a good-faith self-disclosure of fraudulent conduct or an agreement to robust integrity obligations with a state or the DOJ can be sufficient remedies that do not require exclusion.²⁹⁸ The OIG's weighted assessment of integrity obligations and surrounding circumstances forms the foundation of the Risk Spectrum.

The entity's placement on the Risk Spectrum depends on a fact-specific inquiry of four factors, each categorized as higher risk, lower risk, or neutral risk.²⁹⁹ The factors are (1) nature and circumstances of conduct, (2) conduct during investigation, (3) significant ameliorative efforts, and (4) history of compliance.³⁰⁰ Each factor has a list of considerations that indicate the corresponding risk level, if applicable.³⁰¹

b) The OIG Risk Spectrum Factors Should Incorporate Sponsored Genetic Testing Program-Specific Considerations to Create a Pharmaceutical Manufacturer Risk Spectrum

The OIG's Risk Spectrum has served the OIG in investigating fraudulent violations and assigning exclusionary remedies since 2016.³⁰² However, the OIG Compliance Program Guidance for Pharmaceutical Manufacturers was issued in 2003.³⁰³ Thus, the Risk Spectrum should form the basis of new manufacturer-oriented guidance outlining compliance risks that can be mitigated at the outset of a sponsored genetic testing program. By directing a risk spectrum to manufacturers, the OIG can define concrete compliance objectives with minimal ambiguity. In turn, the OIG can cite these factors in its investigations as industry-wide benchmarks familiar to both the agency and manufacturers.

In drafting a new "Pharmaceutical Manufacturer Risk Spectrum," the probing questions in the 2003 Compliance Guidance should be integrated into the four OIG Risk Spectrum factors. The Pharmaceutical Manufacturer Risk

296. *Id.* at 2.

297. *Id.* at 2–3.

298. *Id.* at 3.

299. *Id.* at 3–4.

300. *Id.* at 4–7.

301. *Id.*

302. *Id.* at 1.

303. OIG Compliance Program Guidance for Pharmaceutical Manufacturers, 68 Fed. Reg., *supra* note 94.

Spectrum should supplement the risk spectrum factors with considerations specific to sponsored genetic testing programs. These program-specific considerations will frame a fact-specific inquiry for the OIG and manufacturers to use when determining the level of risk to healthcare programs. A particular focus on the “nature and circumstances of conduct” and “significant ameliorative efforts” factors is most appropriate.

- i) Nature and Circumstances of Conduct Should Consider the Severity of the Genetic Disorder, the Cost to Administer the Test, and Data Management

Adverse impact on individuals is one of the primary conduct considerations, particularly conduct with the potential to cause any adverse physical, mental, or financial impact to program beneficiaries, recipients, or other patients.³⁰⁴ However, the adverse impact consideration excludes a lack of patient harm from the risk assessment.³⁰⁵ For sponsored genetic testing programs, the potential for patient harm from a genetic test is negligible compared to the enduring harm of an undiagnosed genetic disorder. For example, if a genetic test screened for terminal disease with a highly abbreviated life expectancy, the adverse impact of barring a sponsored program would be gravely detrimental to patient outcomes. The severity of the genetic disorder coincides with the value of the genetic test, and the added value of a sponsored diagnosis places a low risk of abuse of federal healthcare programs.

Financial loss to federal healthcare programs is another critical conduct consideration, where a greater amount of actual or intended loss is associated with higher risk.³⁰⁶ For sponsored genetic testing programs, the administrative costs vary, depending on the target population of the genetic disorder. In AO 22-06, the permissible program did not standardize the distribution of test kits, and physicians could order additional kits from the testing vendor as needed.³⁰⁷ Physicians were therefore active parties in using additional test kits that could, in turn, bill federal healthcare programs. Correspondingly, the physician’s specialty influences the patient population served. For example, cardiology, immunology, and neurology are vastly different practice areas with vastly different genetic disorders. If the symptoms of a neurological disorder predominantly present in patients sixty-five years and older, physicians will

304. U.S. DEP’T OF HEALTH & HUM. SERVS., OFF. OF INSPECTOR GEN., *supra* note 291, at 4.

305. *Id.*

306. *Id.*

307. AO 22-06, *supra* note 106, at 6.

administer diagnostic genetic tests to Medicare-qualifying individuals, subsequently increasing the cost to federal healthcare programs. Thus, testing frequency is beyond the control of the manufacturer or program sponsor, and the underlying genetic disorder complicates quantifying actual or intended loss costs.

Financial implications can also be evaluated by the diagnostic capability of the genetic test and its impact on medication prescriptions. In AO 22-06, the Requestor's genetic test could not independently diagnose the disorder.³⁰⁸ In this regard, the genetic test was unnecessary if a different test could independently diagnose the disorder. However, the Requestor's genetic test added value by identifying which form of the genetic mutation was present.³⁰⁹ Identifying the specific genetic mutation form was inherently valuable for understanding symptoms, such as earlier disease progression in the hereditary form.³¹⁰ Again, however, the genetic test might not be necessary if the Requestor's treatment options do not differentiate between mutation forms. In AO 22-06, the Requestor manufactured two medications that treated both mutation forms.³¹¹ Here, if the goal was to prescribe the Requestor's medications, then the genetic test results served a marginal role in confirming which medication was appropriate. Instead, the mutation form results were more informative in anticipating disease progression and establishing a monitoring plan for asymptomatic patients with a genetic mutation. The OIG analogously determined that the risk of fraud and abuse was sufficiently low in AO 22-06.³¹² Improved patient information and testing as a diagnostic supplement are proposed Risk Spectrum factors that pose a low risk for federal healthcare kickbacks. While financial losses remain a key motivator for OIG enforcement under the AKS, they should carry less weight in sponsored genetic testing program contexts because the diagnostic value of the tests outweighs the risk of fraud and abuse.

Conduct that occurs as part of a pattern of wrongdoing and conduct that continues until or after the person learns of a government investigation are both high-risk considerations.³¹³ In *Ultragenyx*, the company's distribution of genetic test results reports to sales force personnel represented a pattern of wrongdoing that persisted until Ultragenyx learned of AO 22-06 and halted

308. *Id.* at 2.

309. *Id.* at 2–3.

310. *Id.*

311. *Id.* at 2.

312. *Id.* at 7.

313. U.S. DEP'T OF HEALTH & HUM. SERVS., OFF. OF INSPECTOR GEN., *supra* note 291, at 4.

the practice.³¹⁴ The *Ultragenyx* situation is uniquely situated between two conduct considerations. On one hand, Ultragenyx wrongfully acquired results reports through a separate payment to the third-party laboratory. Likewise, Ultragenyx is not shielded by any safe harbors: sharing information with sales personnel does not qualify for personal services or employment safe harbors because the remuneration is to the physicians prescribing Ultragenyx medications, not the sales personnel.³¹⁵ On the other hand, Ultragenyx complied with de-identification standards by acquiring results reports that removed patient names and corresponding health information.³¹⁶ There is no explicit requirement that physician names must also be removed. While Ultragenyx might have had “actual knowledge” that the results report information could be used to identify patients, they only contacted the physician regarding the test results.³¹⁷ Ultragenyx’s practices tread a fine line between leveraging patient data for marketing treatments and avoiding outrightly using patient names. The results reports were at the heart of the *Ultragenyx* case and certainly motivated the DOJ in its attack on Ultragenyx’s conduct. From an AKS standpoint, regardless of how Ultragenyx managed the results reports, the end goal of marketing Crysvida was achieved.

Ultragenyx did stop its activity as soon as it learned of AO 22-06.³¹⁸ While this act could be construed as an admission of fault, Ultragenyx simultaneously took accountability to remedy its data management practices. Ultragenyx’s underlying motivations are cloudy, but its external conduct, according to the OIG Risk Spectrum, carries less risk. Of course, this conduct did not stop the DOJ from reaching a \$6 million settlement with Ultragenyx.³¹⁹ Thus, conduct that continues following a federal investigation is a reduced concern compared to other conduct considerations. For sponsored genetic testing programs, *Ultragenyx* teaches a daunting lesson for marketing data management. Moving forward, pharmaceutical manufacturers are likely to keep results reports under lock and key. While patterned or continuous conduct merits scrutiny, it should take deference to adverse impact and financial motivation considerations.

314. Ultragenyx Settlement Agreement, *supra* note 201, at 3.

315. *Id.*

316. *Id.*; 42 C.F.R. § 164.514(b)(2).

317. Ultragenyx Settlement Agreement, *supra* note 201, at 3; 42 C.F.R. § 164.514(b)(2)(ii).

318. Ultragenyx Settlement Agreement, *supra* note 201, at 3.

319. *Id.* at 2–3.

ii) Significant Ameliorative Efforts Should Consider Alternate Treatment Availability and Supplementary Informational Materials

Significant changes within an entity are a primary consideration in evaluating ameliorative efforts.³²⁰ If the entity is a pharmaceutical manufacturer, then the *Ultragenyx* marketing data management concerns arise again. If a pharmaceutical manufacturer takes disciplinary action or devotes additional resources to remedy or enforce compliance, there is a lower risk to federal healthcare programs. These considerations align with the existing OIG Risk Spectrum.³²¹ If the entity includes the physician and patient, then the mechanisms of the sponsored genetic testing program warrant closer review.

The availability of alternate treatments increases the risk associated with sponsorship programs. If a program sponsor manufactures a treatment for the genetic disorder diagnosed in the sponsored genetic test, then an inevitable motivation to attain subsequent prescriptions exists. Alternate treatment options compete with the program sponsor or manufacturer, each seeking to acquire as many prescriptions as possible. Treatment options can range from drugs to regenerative therapies to surgeries—each option places a weighty decision on the patient and impacts the treatment plan. Some patients might be better suited to take medications, while others might undergo surgical procedures to treat their symptoms. Regardless, the treatment plan is an intimate, subjective decision between the patient and the physician. Regulatory parties should not interfere unless safety or efficacy concerns arise. Pharmaceutical manufacturers that support patients in achieving the best health outcomes and provide unbiased informational guides to educate patients on their options are the most favorably viewed. Thus, a manufacturer that devotes significant resources to compliance has made significant ameliorative changes.³²²

In AO 24-12, the Requestor required the provider to consider other competing products and medications before prescribing the Requestor's medication.³²³ The Requestor also maintained two educational websites—one for patients and one for providers—to further quell competitive conduct concerns.³²⁴ A double-blinded arrangement between the physician and program sponsor that provides a comprehensive account of treatment options,

320. U.S. DEP'T OF HEALTH & HUM. SERVS., OFF. OF INSPECTOR GEN., *supra* note 291, at 6–7.

321. *See id.*

322. *Id.*

323. AO 24-12, *supra* note 150, at 3.

324. *Id.*

including lists of manufacturers offering the same medication or different treatment options, would similarly neutralize the risk of fraud or abuse.

Conversely, if no alternatives are available, the physician would prescribe the sponsor's treatment to positive-testing patients, irrespective of whether the patient participated in the sponsored program. In such cases, the sponsored genetic testing program poses a nominal risk since market competition is not a motivating factor for the sponsor or manufacturer. Thus, while alternate treatment options carry high risk, offering patient and physician informational materials and lacking market competition present low risks to federal healthcare programs.

The expected value in patient care greatly outweighs the remuneration or kickback risks in many conduct and ameliorative effort considerations. Thus, the OIG Risk Spectrum criteria must be tailored to integrate sponsored program-specific information and substantive medical considerations. Genetic tests are a powerful tool that present unique regulatory concerns balanced against benefits to regulatory agencies, manufacturers, physicians, and patients. Their innovative potential should be harnessed into a methodical evaluation along a familiar risk-based spectrum.

2. *The Proposed Pharmaceutical Manufacturer Risk Spectrum Approach Achieves the Desired Compliance Guidance Form and Does Not Create Policy Concerns*

The proposed Pharmaceutical Manufacturer Risk Spectrum refines the existing OIG Risk Spectrum into a sponsored genetic testing program-specific approach while staying consistent with the AO 22-06, AO 24-12, and *Ultragenyx* holdings. In turn, this approach is inclusive of stakeholders in sponsored genetic testing programs and, more broadly, the healthcare industry.

a) *The Spectrum Approach Reaches the Same Outcomes in AO 22-06, AO 24-12, and Ultragenyx*

While the spectrum approach provides tailored guidance to pharmaceutical manufacturers and refines existing considerations for sponsored genetic test programs, its implementation poses administrative challenges. The spectrum approach is a qualitative balancing test. While the focus has been narrowed to a niche sector of the healthcare industry, the programs offered within this sector are still highly variable. Differences exist in genetic disorders, diagnostic capabilities of the tests, and available treatment options. Likewise, each disorder impacts diverse patient populations that may interface with the different offerings of federal healthcare programs. These substantive considerations vary case by case and are subject to the contours of a given

sponsored program. The spectrum approach establishes a middle ground between the two cases.

In AO 22-06, the OIG focused primarily on achieving a definitive diagnosis, prescribing treatment, and establishing safeguards against marketing use.³²⁵ Under the spectrum approach, the genetic test could not independently diagnose the disorder, but its diagnosis of the mutation form (hereditary or spontaneous) made the patient better placed to monitor disease progression.³²⁶ Likewise, the Requestor only used the results report to track participation and entirely avoided marketing.³²⁷ There was an adequately low risk across all factors to be considered compliant and not federal healthcare program abuse.

In AO 24-12, the OIG focused primarily on the rarity of the genetic disorder and the narrow applications of both the genetic test and medication.³²⁸ Under the spectrum approach, the provider exercised discretion in selecting from three genetic test options.³²⁹ The provider only prescribed the Requestor's medication after evaluating competitor treatments.³³⁰ The Requestor also provided informative websites where the online information and branding—despite listing the Requestor's name for transparency—dually strengthened the program's credibility.³³¹ Lastly, existing diagnostic options delayed results and lacked adequate insurance coverage.³³² The Requestor's consideration of alternatives and disclosure to the OIG created a low risk for fraud and abuse that would satisfy spectrum compliance.

In *Ultragenyx*, the OIG was most concerned with data management.³³³ Under the spectrum approach, the patient data complied with de-identification results.³³⁴ Similarly, *Ultragenyx* undertook remedial efforts to stop high-risk conduct upon learning of the AO 22-06 decision.³³⁵ However, its practice of targeting positive-testing patients through their ordering physicians demonstrated gamesmanship and interfered with physician-patient decision-making.³³⁶ A double-blinded program would have minimized the significant risk of abuse. The spectrum approach would have reached the same outcome

325. See generally AO 22-06, *supra* note 106.

326. *Id.* at 2.

327. *Id.* at 5.

328. See generally AO 24-12, *supra* note 150.

329. *Id.* at 5.

330. *Id.* at 3.

331. *Id.* at 4 n.5.

332. *Id.* at 2–3.

333. See generally *Ultragenyx Settlement Agreement*, *supra* note 201.

334. *Id.* at 3.

335. *Id.*

336. See *id.*

as in *Ultragenyx*, but with less hostility than the DOJ or with lower remuneration sanctions.

The spectrum approach is a promising avenue to reform sponsored genetic testing program investigations, but its adoption depends on administrative and substantive implementation by the OIG and FDA, respectively. In turn, regulatory reform would better equip pharmaceutical manufacturers to gauge and improve the compliance of their sponsored genetic testing programs.

b) The Spectrum Approach Accounts for Stakeholder Interests within the Larger Healthcare System

Healthcare is a team sport where the key players are patients, providers, and regulatory agencies. Pharmaceutical manufacturers and laboratories are sideline players who support these players when needed.

Patients want timely, accurate diagnoses and treatments to live healthy and fulfilled lives. Understanding that patient safety is the top priority, there are coinciding risks to data privacy.³³⁷ While HIPAA, additional statutes, and certain healthcare practices shield patients, the reality is that a competitive marketplace of vying manufacturers underlies every healthcare transaction.³³⁸ Even so, healthcare is an omnipresent, integral part of everyday life, from taking daily medications to being inundated by pharmaceutical advertisements. The spectrum approach recognizes data management as an independent consideration in its analysis and rewards efforts to safeguard risks to patients in favor of compliance.

Healthcare providers want to practice medicine while being fully informed of current treatment options and alternatives. However, the AKS applies to remuneration received by providers, too.³³⁹ Several other statutes, including the Stark Law, also enumerate expected conduct for physicians in medical decision-making.³⁴⁰ Thus, physicians can be held personally liable for prescribing test sponsor medications. While the proposed spectrum approach is geared toward pharmaceutical manufacturers, establishing compliance at the outset of a sponsored genetic testing program provides some security to participating physicians. The data management consideration within the

337. See generally CHRISTINA MUNNS & SUBHAJIT BASU, *PRIVACY AND HEALTHCARE DATA: 'CHOICE OF CONTROL' TO 'CHOICE' AND 'CONTROL'* (2017).

338. See 110 Stat. 1936; *Understanding Patient Safety Confidentiality*, U.S. DEP'T OF HEALTH & HUM. SERVS., <https://www.hhs.gov/hipaa/for-professionals/patient-safety/index.html> (last updated Oct. 22, 2024).

339. See U.S. DEP'T OF HEALTH & HUM. SERVS., OFF. OF INSPECTOR GEN., *supra* note 71.

340. See 42 U.S.C. § 1395nn.

spectrum approach explicitly warns manufacturers against potential marketing outreach or targeting of ordering physicians.

Protecting the private patient-physician relationship is the crux of quality care. Sponsored genetic testing programs should be structured in line with this foundational value. Sponsored programs can respect the patient-physician relationship by providing alternate options supra• and comprehensive education opportunities for physicians and patients alike to make fully informed treatment decisions. By leaving full decisional authority in the hands of the patient and their physician, the spectrum approach ensures that genetic testing is just one step in a patient's care journey, rather than a tool for steering prescriptions.

V. CONCLUSION

While the Advisory Opinions and *Ultragenyx* decisions represent two opposite poles of regulatory compliance, concentrating on the objectives of sponsored genetic testing programs reveals a niche intersection between FDA and OIG oversight. The FDA's primary focus on the safety and efficacy of medical devices is addressed through premarket notification. The OIG's primary focus on fraud or abuse of federal healthcare programs through remuneration is later enforced through the AKS. Sponsored genetic testing programs must carefully navigate the challenge of offering vetted genetic tests at no cost to patients or physicians without kickbacks that run afoul of federal healthcare laws. Pharmaceutical manufacturers must strike this balance by reflecting on AO 22-06 and AO 24-12, which guardedly permitted tests with narrow diagnostic abilities and strict data access restrictions, and *Ultragenyx*, which emphatically denounced the usage of test results for any marketing purposes.

Between these two extremes, the FDA has several community initiatives that welcome stakeholder collaboration, and the OIG has pharmaceutical manufacturer-specific guidance (most recently in 2003). By uniting the FDA and OIG as joint authorities over sponsored genetic testing programs, a risk-based spectrum approach can be formulated to weigh the substantive factors of both genetic tests and sponsored programs. Empowering pharmaceutical manufacturers to self-assess and advance compliance initiatives through a dedicated framework will reduce the sizeable fraud and abuse kickbacks affecting federal healthcare programs and the number of enforcement actions by regulatory agencies.

RING THE ALARM: AN ANALYSIS OF THE FTC’S HEALTH BREACH NOTIFICATION RULE

Alexis Tatum[†]

ABSTRACT

In 2024, the Federal Trade Commission updated and enforced the once-dormant Health Breach Notification Rule (HBNR) relating to privacy violations by health information technology disruptors that are not regulated under Health Insurance Portability and Accountability Act (HIPAA). The FTC’s modernized definitions of terms like “breach of security” and “health care provider” are significant and helpful changes to reflect the world consumers face, rather than limiting enforceable privacy protections to technology that existed over a decade ago. However, the agency’s inconsistent enforcement and subsequent changes to the Rule have opened the regulation to heightened procedural scrutiny. In an era of criticism of federal agency authority and increasing judicial restraints on federal agency actions, the FTC’s enforcement of the Health Breach Notification Rule demonstrates a potential path towards clear, effective, and meaningful privacy law enforcement that encourages businesses to protect the privacy of individual consumers.

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I. INTRODUCTION

These days, it is very convenient for consumers to manage, record, and understand their health conditions from their homes and personal devices. Consumers can track their heart rate, blood oxygen levels, and sleep by wearing a smartwatch. Consumers can choose from dozens of phone applications designed to track menstrual cycles, ovulation, and fertility with increasing levels of specificity. Virtually any American can bargain shop for prescription and over-the-counter medications such as diabetes test strips, nicotine patches, and birth control pills in exchange for an input of personal health information to companies like GoodRx.¹

1. *How Do I Find and Use Coupons for Over-The-Counter Medications and Medical Supplies?*, GOODRX, <https://support.goodrx.com/hc/en-us/articles/360000677866-How-do-I-find-and-use-coupons-for-over-the-counter-medications-and-medical-supplies> (last visited Feb. 12, 2025); *see also GoodRx Terms of Use*, GOODRX, <https://support.goodrx.com/hc/en-us/articles/115005225563-GoodRx-Terms-of-Use> (last accessed May 3, 2025). GoodRx offers prices and coupons for many popular over-the-counter medications, including Zyrtec, aspirin, vitamins, Claritin, and nicotine patches. The company also advertises discounted medical supplies and devices like test strips, needles, and meters. The information required for a GoodRx account to access these discounted items includes a user's date of birth, prescription information, home or billing addresses, and more.

Now more than ever, direct-to-consumer (D2C) products help inform consumers' personal health decisions without the safeguards of a doctor's office or a hospital, where the collection of consumer information is federally regulated by the U.S. Department of Health and Human Services (HHS).² Americans began using telehealth services for physical and mental health at unprecedented levels during the COVID-19 pandemic, and that telehealth use remained significantly higher than pre-COVID levels in 2024.³ The dominance of D2C healthcare has created new ways for consumers to track and manage their health themselves, including the ability to request consumer-initiated lab testing without the guidance or authorization of a doctor.⁴ D2C healthcare is also extremely profitable—in April 2020, D2C healthcare was already a \$700 billion industry.⁵ While D2C healthcare provides consumers with convenience and greater accessibility, the industry is largely unregulated by the federal government and businesses face requirements to adhere to typical standards of transparent communication and patient privacy. As a result, sensitive data, including social security numbers, biometric profiles, test results, and insurance information, is not protected by HHS regulations when shared with D2C healthcare companies.

HHS can only enforce the provisions of the Health Insurance Portability and Accountability Act (HIPAA) in traditional health care provider settings.⁶ Many people mistakenly assume that the HIPAA regulations apply to all people or entities that have access to an individual's health information, but HIPAA's regulations do not cover many D2C providers because they are not traditional health care providers, as defined by HIPAA.⁷ As consumers take

2. *Summary of the HIPAA Privacy Rule*, U.S. DEP'T OF HEALTH & HUM. SERVS., <https://www.hhs.gov/hipaa/for-professionals/privacy/laws-regulations/index.html> (last visited May 3, 2025).

3. Oleg Bestseny, Greg Gilbert, Alex Harris & Jennifer Rost, *Telehealth: A Quarter-Trillion-Dollar Post-Covid-19 Reality?*, MCKINSEY & CO. (July 9, 2021), <https://www.mckinsey.com/industries/healthcare/our-insights/telehealth-a-quarter-trillion-dollar-post-covid-19-reality>; see also Michael Kalinowski, *Telehealth Testing and Direct-to-Consumer Lab Testing Give Patients a Prominent Seat at the Healthcare Table*, LIGOLAB (Sept. 13, 2024), <https://www.ligolab.com/post/telehealth-and-direct-to-consumer-testing-give-patients-a-prominent-seat-at-the-healthcare-table>. Today, most states allow consumers to order some (or all) of their laboratory tests directly without the involvement of a physician. This is an example of how the telehealth industry has grown rapidly since the COVID-19 pandemic.

4. See Kalinowski, *supra* note 3.

5. Adam B. Cohen, Simon C. Matthews, E Ray Dorsey, David W. Bates & Kyan Safavi, *Direct-To-Consumer Digital Health*, THE LANCET (Apr. 2020), [https://www.thelancet.com/journals/landig/article/PIIS2589-7500\(20\)30057-1/fulltext](https://www.thelancet.com/journals/landig/article/PIIS2589-7500(20)30057-1/fulltext).

6. *Summary of the HIPAA Privacy Rule*, *supra* note 2.

7. See generally PAUL M. SCHWARTZ & DANIEL J. SOLOVE, *PRIVACY LAW FUNDAMENTALS* 79 (International Association of Privacy Professionals, Inc., 7th ed. 2024).

more control of their health choices, the information used to make those decisions is used for purposes far beyond their control. Until 2023, GoodRx allegedly shared consumer prescription information and other identifying information with third-party advertising platforms for purposes that were never shared with consumers.⁸ This kind of unauthorized disclosure of sensitive consumer information often leads to data breaches, exposures, and leaks that publicize and compromise important consumer information. In 2023, the Identity Theft Resource Center reported an unprecedented number of such incidents, amounting to more than three thousand different breaches.⁹ A majority of Americans on both ends of the political spectrum think there should be more government regulation of what companies can do with customers' personal information in light of steadily increasing privacy concerns over the past decade.¹⁰

In the case of the GoodRx breach, consumers' personal health privacy was violated by GoodRx's broken promises. The company told its users that it would "never" share personal information with advertisers or other third parties, then allegedly did just that for several years, unbeknownst to millions of GoodRx customers.¹¹ GoodRx users had no options for direct recourse because this sort of injury does not currently create a cause of action that can be redressed in court.¹² As demonstrated by the Supreme Court's decision in *TransUnion LLC v. Ramirez*,¹³ a company's violation of its privacy policies is not enough of an injury to provide a consumer with standing to sue, absent a showing of further harm such as the theft of credit information.¹³

8. *See generally* Complaint Against GoodRx for Permanent Injunction, Civil Penalties, and Other Relief, United States v. GoodRx Holdings, Inc., No. 23-cv-460 (N.D. Cal. Feb. 1, 2023).

9. *2023 Data Center Report, IDENTITY THEFT CTR.* (2024), https://www.idtheftcenter.org/wp-content/uploads/2024/01/ITRC_2023-Annual-Data-Breach-Report.pdf (last visited Dec 20, 2024).

10. *See* Michelle Faverio, *Key Findings About Americans and Data Privacy*, PEW RSCH. CTR. (Oct. 18, 2023), <https://www.pewresearch.org/short-reads/2023/10/18/key-findings-about-americans-and-data-privacy/> ("Some 78% of Democrats and 68% of Republicans think there should be more government regulation of what companies can do with customers' personal information.").

11. GoodRx Complaint, *supra* note 8, at ¶ 3.

12. *See, e.g.,* Dyer v. Nw. Airlines Corps., 334 F. Supp. 2d 1196, 1200 (D.N.D. 2004) (holding that plaintiffs could not maintain suit against Northwest Airlines for breach of its privacy statement because it was not a contract). Similarly, the GoodRx Terms of Service do not constitute a contract for which individual plaintiffs could raise a breach of contract claim against GoodRx.

13. Schwartz, *supra* note 7, at 418. ("Health information is considered by many to be among the most private information . . . Pursuant to its authority under the Health Insurance Portability and Accountability Act (HIPAA), enacted in 1996, the Department of Health and

In 2023, the Federal Trade Commission (FTC) took the unusual step of filing an enforcement action against GoodRx for its data practices, citing the Health Breach Notification Rule (HBNR), which the agency had not invoked in over a decade.¹⁴ For the first time, the FTC stepped in to address the reckless exposure of consumer data and breach of their private health data by enforcing a once-abandoned federal rule targeting the failure to protect sensitive consumer data as an illegal “unfair or deceptive trade practice.”¹⁵ Despite widely documented concerns about digital privacy, especially in the health care context, Congress has rarely produced legislation that acknowledges and protects against these privacy violations.¹⁶ The HBNR is the result of only a small set of privacy laws ever passed by Congress.

The FTC’s investigation and enforcement resulted in GoodRx hiring a vice president of Data Privacy, creating written standards of data maintenance and security, and ceasing its disclosures to third parties.¹⁷ Since this first action, the FTC has committed to enforcing the HBNR against vendors of personal health records “with vigor.”¹⁸ In 2024, the Commission finalized updates to “modernize” the Rule in support of this mission to protect sensitive health data for consumers, who often lack any meaningful opportunity to limit the use of their personal information when they solicit goods or services related to their health.¹⁹

The FTC’s decision to enforce the once inoperative HBNR and later update the Rule to clearly demonstrate its scope and compliance requirements is exactly the type of flexible action the Commission should take to avoid agency rules becoming ignored, inconsistently enforced, or outdated. While critics suggest that the FTC’s updates to the Rule are an unauthorized

Human Services promulgated regulations under HIPAA. The ensuing framework . . . provides a minimum level of protection for all states.”).

14. Lesley Fair, *First FTC Health Breach Notification Rule Case Addresses GoodRx’s Not-So-Good Privacy Practices*, Federal Trade Commission, <https://www.ftc.gov/business-guidance/blog/2023/02/first-ftc-health-breach-notification-rule-case-addresses-goodrxs-not-so-good-privacy-practices> (last visited Mar. 17, 2025).

15. GoodRx Complaint, *supra* note 8, at ¶ 9.

16. *See generally* U.S. Privacy Laws, ELEC. PRIV. INFO. CTR., <https://epic.org/issues/privacy-laws/united-states/> (last visited Feb. 12, 2025) (The most recent privacy-related statutes passed by Congress were passed in the 1990s and do not address digital consumer privacy).

17. GoodRx Complaint, *supra* note 8, at ¶ 59.

18. Fed. Trade Comm’n, Remarks by Chair Lina M. Khan on the Health Breach Notification Rule Policy Statement Commission File No. P205405 (Sep. 15, 2021), https://www.ftc.gov/system/files/documents/public_statements/1596360/remarks_of_chair_lina_m_khan_regarding_health_breach_notification_rule_policy_statement.pdf.

19. Health Breach Notification Rule, 89 Fed. Reg. 47028 (May 30, 2024) (16 C.F.R. § 318).

expansion of agency power, the Commission's actions are well within their statutory authority and necessary to address the myriad of unauthorized invasions of health privacy that American consumers face today. Congress outlined a specific privacy concern when it contemplated that D2C health information technology not covered by HIPAA would eventually play a larger role in the lives of Americans and that it would need effective regulation to avoid disastrous erasure of health information privacy. To address this concern, Congress authorized the Commission to create a Rule responsive to those concerns.²⁰ In an era of attacks on federal agency power, the FTC should balance the aggressive approach to protecting consumers from fraught health privacy concerns with maintaining its legitimacy as an institution. When the FTC enforces the HBNR, it should take special care to respect due process and work with Congress to provide recommendations, insights, and progress reports to encourage Congress to pass more notice-and-comment privacy rulemaking statutes. Congress should produce more legislation authorizing privacy rules like the Health Breach Notification Rule to (1) provide agencies the necessary flexibility to address privacy violations when new, disruptive D2C businesses that escape regulation arise, (2) allow agencies a clearer and faster process to respond to privacy harms caused by businesses to consumers, and (3) re-emphasize the legitimacy of the FTC and other agencies tasked with protecting consumers' privacy interests.

The ability to review and update privacy rules promulgated by the FTC is one of the few options the federal government has to ensure that the law catches up with technological disruptors that often enter the market and spend years avoiding preexisting regulations that should apply to them. For example, the FTC's modernized definition of terms like "breach of security" is a significant and helpful change to reflect the world consumers face presently, not the world as it was in 2009, because the new definition reflects how privacy experts describe breaches today.²¹ The HBNR should be strongly enforced,

20. American Recovery and Reinvestment Act (ARRA), Pub. L. No. 111-5, § 13410 (2009).

21. *See, e.g.*, WOODROW HARTZOG & DANIEL SOLOVE, BREACHED!: WHY DATA SECURITY LAW FAILS AND HOW TO IMPROVE IT 5 (Oxford University Press 2022) ("Data breaches, by which we mean the unauthorized exposure, disclosure, or loss of personal information, are not only more numerous; they are more damaging."); *see also* National Institute for Standards and Technology Computer Security Resource Center, <https://csrc.nist.gov/glossary/term/breach> (last visited Feb. 12, 2025) (defining breach as "[t]he loss of control, compromise, unauthorized disclosure, unauthorized acquisition, or any similar occurrence where: a person other than an authorized user accesses or potentially accesses personally identifiable information; or an authorized user accesses personally identifiable information for another than authorized purpose.").

and its enforcement should be recognized as an example of impactful privacy law that acknowledges and protects consumer interests.

This Note explores the FTC's HBNR as a meaningful and effective method of regulating an increasingly pervasive data economy in the health information technology sector. Part II discusses the Rule in the context of the FTC's other congressionally mandated data privacy rules and the Commission's policy focus on protecting consumer privacy under the direction of Chair Lina Khan from 2021 to January 2025. Part III examines the odd and arguably controversial enforcement and promulgation history of the Rule from its inception in 2009 to its 2024 revision and related enforcement actions. Finally, Part IV will suggest improvements to the largely positive impact of the Rule on federal data protection, demonstrated by heightened privacy protections, notice, and opportunities for consent that resulted from the FTC's enforcement of the Health Breach Notification Rule.²² These improvements protect consumers seeking to maintain their privacy while taking a more convenient, informed part in their health choices by using D2C health services and products.

II. BACKGROUND

Over the course of the agency's history, the FTC has become the premier agency for regulating information privacy. Section II.A outlines where the FTC gets general authority to enforce information privacy laws and policies and explains the history and function of the HBNR. Sections II.B and II.C discuss the significance of breach notification rules as a method of privacy protection and the role of the HBNR in the FTC's broader information privacy protection regime, most of which consists of breach notification rules.

A. GENERAL FTC AUTHORITY TO REGULATE INFORMATION PRIVACY

The FTC has the authority to promulgate rules under two statutes: the Federal Trade Commission (FTC) Act and the Administrative Procedure Act (APA).²³ The FTC Act provides the agency with broad authority but requires complex processes to promulgate substantive rules protecting consumers. Alternatively, the APA provides a series of straightforward rulemaking processes, including the notice-and-comment rulemaking procedure.²⁴

22. See, e.g., *GoodRx Complaint*, *supra* note 8; at ¶ 115; see also *Complaint against EasyHealthcare, Inc. for Permanent Injunction, Civil Penalty Judgment, and Other Relief*, *United States v. EasyHealthcare, Inc.*, No. 1:23-cv-3107 (N.D. Ill. May 17, 2023).

23. Federal Trade Commission Act, 15 U.S.C. §§ 41–58 (1914); Administrative Procedure Act (APA), 5 U.S.C. §§ 551–559 (1946).

24. 5 U.S.C. § 553 (1976).

1. *The FTC's Authority Under the Federal Trade Commission Act*

The Federal Trade Commission was established in 1914 to police the problem of “bigness” through regulating monopolies and large businesses that achieved their “bigness” from unfair and deceptive trade practices.²⁵ The agency’s statutory authority to achieve this mission is largely encompassed in the FTC Act, which prohibits unfair and deceptive trade practices, and the Clayton Act, which prohibits unlawful corporate mergers and acquisitions, among other anticompetitive business arrangements.²⁶ The Commission’s ability to protect consumer interests specifically originated in the Wheeler-Lea Act of 1938, in which Congress amended § 5 of the FTC Act to include “unfair and deceptive acts or practices in or affecting commerce” and “unfair methods of competition” as illegal activity that the Commission could specifically define and proscribe rules to regulate.²⁷ This development drastically expanded the scope of FTC power from an agency primarily focused on issues of unfair competition between businesses to an agency tasked with investigating and enforcing fair business practices for consumers and competitors alike.²⁸ Over time, the FTC focused on invasive advertising practices and business communications to consumers as an area ripe with unfair and deceptive trade practices.²⁹ Because today’s businesses use consumers’ personal data to advertise, and advertising is a category of business practices that the FTC has historically regulated, data privacy falls into the FTC’s purview.³⁰

The FTC utilizes § 5 of the FTC Act in part by promulgating and enforcing rules, which Congress authorized in § 6 and § 18 of the FTC Act.³¹ Section six provides the Commission with authority to “make rules and regulations for the purpose of carrying out the provisions of this subchapter” and is cited by the FTC for its authority to regulate competition law.³² Section six rulemaking authority is limited to procedural rules enforcing specific provisions within the FTC Act.³³

The FTC’s exclusive authority for issuing substantive rules with respect to unfair or deceptive trade practices is found in § 18 of the FTC Act, also

25. See generally Marc Winerman, *The Origins of the FTC: Concentration, Cooperation, Control, and Competition*, 71 ANTITRUST L.J. 1 (2003).

26. See FTC Act, *supra* note 23; see also Clayton Antitrust Act, 15 U.S.C. §§ 12–27 (1914).

27. See FTC Act § 45(a) (also referred to as) Wheeler-Lea Act, Pub. L. 75-447.

28. CHRISTOPHER HOOFNAGLE, *FEDERAL TRADE COMMISSION PRIVACY LAW & POLICY* 36–39 (Cambridge University Press, 2016).

29. *Id.*

30. See *id.* at 58–59.

31. 15 U.S.C. § 46(g); 15 U.S.C. § 57(a).

32. 15 U.S.C. § 46.

33. *Id.*

referred to as the Magnuson-Moss rulemaking authority.³⁴ Here, Congress specifically provided the Commission with broad authority to promulgate substantive rules to protect consumers from unfair and deceptive trade practices. When Congress amended the FTC Act in 1975 to include § 18, the legislative body recognized that, to be effective, the FTC needed flexibility to respond to the inevitability of new problems that would otherwise escape regulation, demonstrating Congress’s intent to protect consumers from activity escaping regulation.³⁵

Section eighteen empowers the Commission to “promulgate trade regulation rules, which define with specificity acts or practices that are unfair or deceptive acts or practices in or affecting commerce.”³⁶ The statute allows the FTC to establish trade regulations that “may include requirements prescribed for the purpose of preventing such acts or practices.”³⁷ Notably, § 18 allows the FTC to enforce substantive rules with civil penalties and injunctions under § 5 of the FTC Act.³⁸ The ability to promulgate rules under § 18 that effectuate Congress’s ban on unfair or deceptive business practices theoretically allows the FTC to produce structural effects on the market to better reflect a balance between business’s ability to reach consumers and each consumer’s right to not be deceived or treated unfairly in the name of targeted advertising.

With great enforcement power, however, comes great procedural requirements.³⁹ In Title II of § 18, Congress detailed a unique agency rulemaking procedure complete with advance notices and public hearing requirements. The FTC’s § 18 rulemaking authority is unique because it has more stipulations than what is required of agency rules by the APA and is a much lengthier rulemaking process that historically takes several years to complete.⁴⁰ Section eighteen authority has gone unused by the FTC for

34. 15 USC § 57(a); *see also* HOOFNAGLE, *supra* note 28, at 55. (“Title II [of the Magnuson-Moss Warranty Act] codified a framework for the Agency to draft “interpretive rules and general statements of policy” defining specific practices as unfair or deceptive.”).

35. *See* HOOFNAGLE, *supra* at 28, at 55.

36. 15 U.S.C. § 57(a); *see also* 16 C.F.R. § 1.8 (interpreting the nature, authority, and use of trade regulations by the FTC under 15 U.S.C. 57(a)).

37. 15 U.S.C. § 57(a).

38. *Id.*; *see also* HOOFNAGLE, *supra* note 28, at 101. Existing trade regulations are codified in the Code of Federal Regulations and have the binding authority of civil law once promulgated.

39. *FTC Privacy Rulemaking: The Steps to Get There*, IAPP, https://iapp.org/media/pdf/resource_center/ftc_privacy_rulemaking_infographic.pdf (last visited May 3, 2025).

40. *See* 5 U.S.C. § 553; *see also* 15 U.S.C. § 57. While the APA only requires agencies to initiate a rule, provide a Notice of Proposed Rulemaking (NPR) and a public comment period before finalizing a regulatory rule, § 18 requires additional steps, including publishing an

decades, largely because of how long it would take the FTC to finalize a rule. As a result, the FTC has never promulgated a privacy rule even though the agency technically has the authority to do so under § 18.⁴¹ In August 2022, the FTC began the process of adopting a wholly new trade regulation rule, the Commercial Surveillance and Data Protection rule under § 18.⁴² If successful, it would be the first time the FTC has promulgated a § 18 Rule in modern day.⁴³

2. *FTC's Authority Under the Administrative Procedure Act*

Like every other federal agency, the FTC can create substantive rules that have the effect of law under § 553 of the Administrative Procedure Act.⁴⁴ While the statute outlines multiple ways to formulate, propose, and finalize a rule, the most commonly employed method of promulgating an agency rule is the notice-and-comment rulemaking process.⁴⁵ The FTC follows the notice-and-comment rulemaking procedures by issuing a notice of proposed rulemaking, providing opportunity for public comment, then developing and publishing a final rule.⁴⁶ Congress typically instructs the agency to use the notice-and-comment rulemaking process when it grants an agency authority to enforce a particular statute.⁴⁷ The FTC promulgated the HBNR through the notice-and-comment rulemaking process in accordance with a statutory mandate from Congress, as well as several other privacy rules.⁴⁸

Advanced Notice of Proposed Rulemaking (ANPR) in the Federal Register, providing advanced notice to Congress, and informal hearings before a new FTC rule can be developed and published.

41. See CHRIS D. LINEBAUGH, CONG. RSCH. SERV., LSB1083, *FTC CONSIDERS ADOPTING COMMERCIAL SURVEILLANCE AND DATA SECURITY RULES (2022)* (“The [Commercial Surveillance and Data Security Rules] ANPRM is also noteworthy because it would be the first time in decades that the FTC has adopted a wholly new “Trade Regulation Rule” (TRR) (i.e., a rule adopted under Section 18 of the FTC Act).”).

42. See *id.*

43. *Id.*; see also Kurt Walters, *Reassessing the Mythology of Magnuson-Moss: A Call to Revive Section 18 Rulemaking at the FTC*, 16 HARV. L. & POL'Y REV. 519, 531–32 (2022) (Following intense backlash and critiques of the FTC's rules promulgated under § 18, Congress passed legislation that restricted the FTC's ability to utilize the substantive rulemaking process. Consequently, the FTC has not successfully promulgated a rule under § 18 since the 1980's).

44. 5 U.S.C. § 553.

45. See TODD GARVEY, CONG. RSCH. SERV., R41546, *A BRIEF OVERVIEW OF RULEMAKING AND JUDICIAL REVIEW*, 2–5 (2017).

46. *Notice-and-Comment Rulemaking*, Admin. Conf. of the U.S., Information Interchange Bulletin No. 014 (2021).

47. See, e.g., Children's Online Privacy Protection Act of 1998 (COPPA), 16 C.F.R. § 312. (15 U.S.C. § 6505) authorizing the FTC to promulgate the COPPA Rule.

48. See Pub. L. 111-5, *supra* note 20.

B. WHY BREACH NOTIFICATION RULES?

Most of the few statutory privacy regulations passed by Congress, including the HBNR, are breach notification rules.⁴⁹ Data or security breach notification laws require entities that possess sensitive individual user data, normally for business purposes, to notify individuals and other parties when an unauthorized access or use of their personal data occurs.⁵⁰ These rules, frequently used on both the state and federal level, allow individuals an opportunity to mitigate risks associated with the breach of their privacy and to incentivize businesses to strengthen their data security practices before a breach of security occurs.⁵¹ Because data breach laws are drafted and enforced in a variety of ways, their efficacy varies. Generally, breach notification laws decrease the number of injuries that result from breaches, such as identity theft.⁵² Although there is currently no comprehensive federal breach notification statute, all fifty states have some sort of breach notification statute for businesses that vary in scope and remedies, in addition to sector-specific federal rules such as the Gramm-Leach-Bliley Act (GLBA), which regulates the financial services industry.⁵³

These breach notification requirements are a response to real concerns held by consumers today. The International Association of Privacy Professionals surveyed 4,750 individuals across nineteen countries and found that nearly seventy percent of consumers globally are either somewhat or very concerned about their privacy online.⁵⁴ In 2019, Pew Research Center reported that roughly six out of ten Americans believe it is not possible to go through daily life without having their data collected, and seventy-nine percent of Americans said they are not too or not at all confident that companies will admit mistakes and take responsibility if they misuse or compromise personal

49. *See, e.g.*, COPPA Rule, 16 C.F.R. § 312; *see also* GLBA Standards for Safeguarding Customer Information Rule (GLBA Safeguards Rule), 16 C.F.R. § 314. Each of these rules are breach notification methods of consumer privacy protection: HIPAA Security Rule, 45 CFR Part 160 and Subparts A and C of Part 164. The HBNR and HIPAA rules are the only federal breach notification rules related to health.

50. *Id.*

51. *See generally* GINA STEVENS, CONG. RSCH. SERV., RL34120, FEDERAL INFORMATION SECURITY AND DATA BREACH NOTIFICATION LAWS (2010).

52. *See generally* Aniket Kesari, *Do Data Breach Notification Laws Work?*, 26 N.Y.U. J. LEGIS. & PUB. POL'Y 173–237 (2023).

53. *Security Breach Notification Laws: 50-State Survey*, JUSTIA (Jan. 15, 2025), <https://www.justia.com/consumer/identity-theft/security-breach-notification-laws-50-state-survey/>; *see also* 16 C.F.R. § 314, *supra* note 49.

54. Müge Fazlıoğlu, *LAPP Privacy and Consumer Trust Report*, IAPP (Mar. 2023), <https://iapp.org/resources/article/privacy-and-consumer-trust-summary>.

information.⁵⁵ While breach notification rules do not entirely erase the possibility of breaches of consumer privacy, they at least require consumers to receive information about these breaches and further encourage preventative measures that deter violations of consumer trust.

C. COMPARING THE HBNR TO OTHER FEDERAL BREACH RULES

While there is no federal breach notification statute, the HBNR is one of a few breach notification rules employed by U.S. federal agencies to protect sensitive information, all of which focus primarily on information related to health, finance, and children's privacy.⁵⁶ Each Rule was developed to enforce statutory mandates from Congress to protect consumers' sensitive data in the normal course of business.⁵⁷ Federal agencies were authorized to create each statutory breach notification rule in HIPAA, the HITECH Act as part of the Recovery and Reinvestment Act, the Gramm-Leach-Bliley Act (GLBA), and the Children's Online Privacy Protection Rule (COPPA).⁵⁸ Four of the six statutory breach notification rules are enforced by the Federal Trade Commission.⁵⁹ The FTC Health Breach Notification Rule is the first in a series of updates to existing statutorily authorized privacy rules first promulgated in the late 1990s.⁶⁰ In November 2023, the FTC announced final updates to the GLBA Safeguards Rule, which require financial institutions to provide additional consumer notices in the event of a breach.⁶¹ Similarly, in December 2023, the FTC proposed amendments to the COPPA Rule to "respond to changes in technology and online practices, and where appropriate, to clarify and streamline the Rule."⁶²

55. Brooke Auxier, Lee Rainie, Monica Anderson, Andrew Perrin, Madhu Kumar & Erica Turner, *Americans and Privacy: Concerned, Confused and Feeling Lack of Control Over Their Personal Information*, PEW RSCH. CTR. (Nov. 15, 2019), <https://www.pewresearch.org/internet/2019/11/15/americans-and-privacy-concerned-confused-and-feeling-lack-of-control-over-their-personal-information>.

56. *See, e.g.*, the Gramm-Leach-Bliley Act (GLBA) Safeguards Rule promulgated and enforced in part by the FTC, *supra* note 49.

57. *Id.*

58. *See* Health Insurance Portability and Accountability Act of 1996 (HIPAA), 42 U.S.C. § 1320d-9; *see also* Pub. L. 111-5, *supra* note 20; Gramm-Leach-Bliley Act (GLBA), Pub. L. 106-102, 113 Stat. 1338; Children's Online Privacy Protection Act of 1998 (COPPA) (15 U.S.C. 6505).

59. *See* STEVENS, *supra* note 51, at 10–12. The FTC's authority to enforce these rules has made the FTC the primary administrative agency responsible for most federal consumer privacy protection.

60. *See, e.g.*, the COPPA Rule, *supra* note 49.

61. *Id.*

62. *See supra* note 49.

III. THE FTC'S HEALTH BREACH NOTIFICATION RULE

The FTC's HBNR has an atypical enforcement history that has caused confusion and concern about the scope of the Rule. Section III.A outlines the statutory origins and original promulgation of the HBNR. Section III.B explains the FTC's inconsistent enforcement of the HBNR, including the FTC's first two HBNR enforcement actions against GoodRx and Easy Healthcare.

A. STATUTORY ORIGINS AND ENFORCEMENT HISTORY

The FTC's Health Breach Notification Rule is an extension of privacy protections established by HIPAA.⁶³ Passed in 1996, HIPAA establishes guidelines by which personally identifiable health information should be protected from unconsented disclosure by traditional health care providers such as clinics, hospitals, nursing homes, doctors' offices, health care insurance providers, billing services, and employer-sponsored health plans.⁶⁴ The statute provides the Department of Health and Human Services the authority to enforce privacy rules against traditional healthcare providers with civil and criminal penalties.⁶⁵ The HIPAA privacy rules do not apply to nontraditional D2C health service providers, such as the data collected by an Apple Watch, an app that tracks menstrual cycles, or a consumer's prescription history from a telemedicine platform.⁶⁶ While an obstetrician's office is required to ensure effective protection of personal health information related to a patient's fertility, D2C providers had no such requirement to ensure secure information collection and storage practices. Thus, the FTC HBNR was authorized by the HITECH Act to complement the existing privacy and security rules in HIPAA, promulgated and enforced by HHS.⁶⁷ Congress recognized that

63. See generally Health Breach Notification Rule, 89 Fed. Reg. 47028 (May 30, 2024) (16 C.F.R. § 318).

64. See 42 U.S.C. § 1320d-9 (1996).

65. 42 U.S.C. § 1320(j) (1996).

66. See HIPAA Summary, *supra* note 2 (“The [HIPAA] Privacy Rule . . . appl[ies] to health plans, health care clearinghouses, and to any health care provider who transmits health information in electronic form in connection with transactions for which the Secretary of HHS has adopted standards under HIPAA (the “covered entities”). These are all “traditional” healthcare providers that the public expects to be covered by HIPAA.

67. See Pub. L. 111-5, § 13410, *supra* note 20; see also CLINTON T. BRASS, CAROL HARDY VINCENT, PAMELA J. JACKSON, JENNIFER E. LAKE & KAREN SPAR, CONG. RSCH. SERV., R40537, AMERICAN RECOVERY AND REINVESTMENT ACT OF 2009 (P.L. 111-5): SUMMARY AND LEGISLATIVE HISTORY (2009) (“the HITECH Act includes a series of privacy and security provisions that amend and expand the current federal standards under the Health Insurance Portability and Accountability Act (HIPAA). Among other things, it establishes a breach notification requirement for health information that is not encrypted. . .”).

people would be skeptical of the digitalization of their records because of the presumed increased risk of security breaches by hackers or poor management practices.⁶⁸ As a result, Congress held several hearings on a health information and privacy statute, which ultimately culminated in the HITECH Act, implemented as Title XIII of the 2009 Recovery Act.⁶⁹ Each of these rules contains a breach notification as a method of protecting privacy.⁷⁰ This Section outlines the significance of breach notifications, the FTC's "modernized" HBNR, and how the Rule is enforced.

1. 2009 Promulgation

In 2009, Congress passed the American Reinvestment and Recovery Act ("Recovery Act") to reinvigorate the national economy following the 2008 financial crisis.⁷¹ As part of Congress's years-long effort to update health systems and adopt health information technology that reduces the difficulties faced by patients and their physicians accessing paper health records, Congress passed the Health Information Technology for Economic and Clinical Health ("HITECH Act").⁷² The HITECH Act was enacted as Title XIII of the Recovery Act.⁷³ The statute expanded the scope of the HIPAA Privacy and Security Rules and authorized the promulgation of the FTC Health Breach Notification Rule.⁷⁴ Notably, several members of Congress and panelists before them expressed doubts about the HIPAA rules being effective in protecting patient privacy due to their lack of enforcement.⁷⁵ In particular, members of Congress noted that since the promulgation of the HIPAA Privacy Rule, the HHS Office of Civil Rights (OCR) received over thirty thousand complaints of alleged violations of the Rule,⁷⁶ but no penalties were issued on any of those complaints.⁷⁷ As Congresswoman Hilda Solis commented, "[t]he OCR, as you know, is already overburdened by existing

68. See generally John H. Cochran, *Investing in Health IT: A Stimulus for a Healthier America*, 13 PERMANENTE J. 65–70 (2009).

69. See, e.g., *Fourth in a Series on Health Care Information Technology: Hearing Before the Subcomm. on Health of the H. Comm. on Ways and Means*, 109th Cong. (April 6, 2006).

70. See generally Stevens, *supra* note 51, at 10–12.

71. ARRA, *supra* note 20; see also BRASS ET AL., *supra* note 67.

72. *Id.*

73. ARRA, *supra* note 20.

74. BRASS ET AL., *supra* note 20.

75. See Devin McGraw, *Discussion Draft of Health Information Technology and Privacy Legislation Before the H. Comm. on Energy and Com.*, CTR. FOR DEMOCRACY & TECH. (June 4, 2008); see also statement by House Representative Henry Waxman: ("... the Administration has not imposed a single civil fine under the Federal Medical Privacy Rule, despite over 30,000 complaints of violations since the rule has been in effect.")

76. McGraw, *supra* note 75.

77. *Id.*

privacy complaints, and consequently complaints related to discrimination, language access, and racial and ethnic health disparities are not being adequately addressed in my opinion.⁷⁷⁸ In light of the poor enforcement of the HIPAA rules and the acknowledgment of new potential D2C health services, Congress authorized the FTC to create the Health Breach Notification Rule with an eye towards improved enforcement.

Rather than amend the HIPAA statute to broaden the scope to whom the statute would apply, Congress authorized the FTC to promulgate a new rule to maintain relative flexibility in the health technology space.⁷⁹ This approach allowed Congress to address the growing concern about vendors of personal health records that may not provide a health service, such as vendors that provide online repositories of sensitive health data for personal use by the consumer.⁸⁰ Subtitle D of the HITECH Act addresses the privacy and security concerns associated with the electronic transmission of sensitive, identifiable personal health information, updates the existing HIPAA rules, and enables the promulgation of the HBNR.⁸¹ Since 2009, the FTC and HHS have continued to collaborate to promote uniformity in health and health technology privacy rules by announcing guidance together.⁸²

While the FTC's HBNR and the HIPAA breach rules may seem redundant on their face, Congress specified that the FTC's ability to enforce regulations of health data was necessary due to a growing gap in HIPAA's coverage of certain emerging health technologies, especially services and products that use health information but do not involve doctors, hospitals, or health insurance.⁸³ Congress was aware of this discrepancy and the OCR's limited ability to effectively enforce existing rules when it updated the HIPAA Privacy and Security rules and authorized the FTC to promulgate another health privacy rule in the HITECH Act. During a Senate floor hearing on the Recovery Act, Senator Whitehouse defended the inclusion of the HITECH Act and its privacy provisions:

78. *Id.*

79. Health Breach Notification Rule, 89 Fed. Reg. 47028, 47029 (May 30, 2024) (16 C.F.R. § 318).

80. *FTC Issues Final Breach Notification Rule for Electronic Health Information*, FED. TRADE COMM'N (Aug. 17, 2009), <https://www.ftc.gov/news-events/news/press-releases/2009/08/ftc-issues-final-breach-notification-rule-electronic-health-information>.

81. Health Breach Notification Rule, 89 Fed. Reg. 47028, 47029.

82. *See, e.g., FTC and HHS Warn Hospital Systems and Telehealth Providers about Privacy and Security Risks from Online Tracking Technologies*, FED. TRADE COMM'N (July 20, 2023), <https://www.ftc.gov/news-events/news/press-releases/2023/07/ftc-hhs-warn-hospital-systems-telehealth-providers-about-privacy-security-risks-online-tracking>.

83. *See generally* Discussion Draft of Health Information Technology and Privacy Legislation Before the H. Comm. on Energy and Com., *supra* note 76.

[W]e all know that health information technology is ultimately about patients. Patients must trust and participate in the health information technology revolution if it is going to reach its full potential. Therefore, the Recovery bill includes a number of vital privacy protections to ensure the security and the confidentiality of electronic patient records. These protections include changes in notification policy if there is an unauthorized acquisition or disclosure of health information. It includes the establishment of privacy officers in HHS regional offices, new restrictions on the sale of health information, improved enforcement of violations to privacy law and other strong provisions. I am well aware that privacy is a controversial and highly charged area of debate. I think it is important we all view the privacy provisions in this bill as the beginning and not the end of our national discussion about health care privacy. These provisions will require oversight and, perhaps over time, adjustment. I look forward to this ongoing challenge and remain committed to being engaged in it. But for now, this is a good, strong privacy package. It has, I think, solid agreement in this building.⁸⁴

Congress viewed the HBNR as necessary because it recognized both the need for digital health recordkeeping and the growing existence of direct-to-consumer health information technology. The provisions of the HITECH Act were meant to advance the use of such technology, but not at the expense of consumers' privacy.⁸⁵

On August 24, 2009, the Federal Trade Commission issued the Final HBNR to officially implement the provisions in the HITECH Act, as instructed by Congress. The Rule applies to vendors of personal health records and related third parties that are not covered by HIPAA, which provides a similar Rule applicable to certain "covered entities" and "business associates" traditionally recognized or associated with healthcare providers.⁸⁶ The FTC provided very few examples of vendors of personal health records when it announced the Final Rule, but noted that devices like blood pressure cuffs or pedometers, whose readings consumers can upload into their personal health records, are examples.⁸⁷ The HBNR outlines steps that vendors of unsecured "personal health record" (PHR) identifiable health information are required to take in light of a "breach of security" as defined by the statute.⁸⁸ The main

84. 155 CONG. REC. S1474–S1614. S1510–12 (2009) (statement of Sen. Sheldon Whitehouse).

85. *Id.*

86. HIPAA Security Rule, 45 C.F.R. § 164.304 (2003); 45 C.F.R. § 164.308 (2003); 45 C.F.R. § 164.310 (2003).

87. *See FTC Issues Final Breach Notification Rule*, *supra* note 80.

88. 16 C.F.R. § 318.2 (2024).

steps in the statute include notifying each affected individual, the Federal Trade Commission, and in some cases, the media.⁸⁹ As noted in § 13407(g)(2) of the HITECH Act, the HBNR is meant to be temporary until Congress enacts new legislation “establishing requirements for notification in the case of a breach of security.”⁹⁰ Any violation of the Rule may be treated by the FTC as an unfair or deceptive trade practice subject to civil penalties as outlined by § 5 of the FTC Act.⁹¹ Following the enactment of this legislation, the health care industry began implementing the use of health information technology and digital health records.⁹²

In addition to authorizing the HBNR, the Recovery Act instructed the FTC and the HHS to produce a study on potential privacy, security, and breach notification requirements.⁹³ But the agencies never produced the study, and the Rule was not enforced once in the first eleven years following its promulgation.⁹⁴ The lack of enforcement over the decade does not appear to be intentional; a review of the agency’s annual report shows that the FTC was focused on pharmaceutical mergers, price inflation generally, the real estate market, and a multitude of other pertinent topics at the time.⁹⁵ Direct-to-consumer health apps and related devices were hardly in existence and did not raise significant HBNR enforcement concerns in 2009, but they quickly gained expansive commercial popularity over the following decade. For example, one of the most popular D2C healthcare products among US consumers is fitness trackers. The first major digital activity tracker with a connected app, the Fitbit Tracker, was released in 2009, followed by the Apple Watch in 2015.⁹⁶ Since 2010, Fitbit has sold over 143 million devices worldwide and counted around 128 million registered users in 2023, while an estimated thirty-eight

89. 16 C.F.R. § 318.5 (2024).

90. See Pub. L. 111—5, *supra* note 20, § 13407(g)(2). (“If Congress enacts new legislation establishing requirements for notification in the case of a breach of security, that apply to entities that are not covered entities or business associates, the provisions of this section shall not apply to breaches of security discovered on or after the effective date of regulations implementing such legislation.”).

91. 15 U.S.C. § 45(a).

92. See *From Paper to Digital: The History of Healthcare Communication*, KNO2, (Aug. 15, 2024), <https://kno2.com/from-paper-to-digital-the-history-of-healthcare-communication/> (“The HITECH Act of 2009 provided significant financial incentives for the adoption of [electronic health records] . . . Interoperability was a key component of [the incentive] criteria, driving further advancements in data exchange capabilities.”).

93. See ARRA, *supra* note 20, at 42 U.S.C. § 17953.

94. See Fair, *supra* note 14.

95. FTC Annual Report, 2009, https://www.ftc.gov/sites/default/files/documents/reports_annual/annual-report-2009/2009ftcrptsv_0.pdf.

96. Peter Rubin, *How Fitbit Started the Wearables Craze That Got Us All Moving*, WIRED (Sep. 15, 2018), <https://www.wired.com/story/how-fitbit-got-us-all-moving/>.

million people owned an Apple Watch by 2023.⁹⁷ Despite this rapid expansion of health technology, the FTC did not enforce the HBNR against these devices until several years later.

B. 2020–2024 ENFORCEMENT AND UPDATES

Following a routine decennial review of the Rule in 2020,⁹⁸ the FTC issued a Policy Statement announcing the agency’s intent to enforce the dormant Rule and putting businesses on notice to comply with the Rule.⁹⁹ The Statement clarified that the Rule was originally created to ensure that businesses or entities that are not covered by HIPAA because they are not “health plans,” “healthcare providers,” “healthcare clearinghouses,” or specific “business associates” of “covered entities” nevertheless “face accountability when consumers’ sensitive health information is compromised.”¹⁰⁰ The Statement did not explain why the Rule was not enforced in the first ten years of its existence, but noted that “the explosion in health apps and connected devices makes its requirements concerning them more important than ever.”¹⁰¹ With this Statement, the Commission stated for the first time that developers of health applications and connected devices are covered by the Rule. The Statement did not yet suggest that the Commission intended to change the language of the Rule. The Policy Statement was only intended to “clarify the scope of the Rule, and place entities on notice of their ongoing obligation to come clean about breaches.”¹⁰² The Commission also cited business guidance and an interactive tool that had been previously used to put nontraditional vendors of “personal health records” on notice of their responsibility in light of a “breach of security.”¹⁰³

The Statement was approved by a 3-2 vote, across party lines—the two Republican Commissioners both dissented from the Statement, citing procedural concerns with what they viewed as an unauthorized expansion of

97. Statista Research Department, Fitbit-Statistics & Facts, STATISTA (Oct. 16, 2024), <https://www.statista.com/topics/2595/fitbit/#topicOverview>; See also David Curry, *Apple Statistics (2025)*, BUS. OF APPS, <https://www.businessofapps.com/data/apple-statistics/> (last visited May 3, 2025).

98. See Retrospective Review of FTC Rules and Guides, FED. TRADE COMM’N, <https://www.ftc.gov/enforcement/rulemaking/retrospective-review-ftc-rules-guides> (finding that since 1992, the FTC has conducted a review of existing Rules every 10 years).

99. *Statement of the Commission on Breaches by Health Apps and Other Connected Devices*, FED. TRADE COMM’N (Sep. 15, 2021).

100. *Id.*

101. *Id.*

102. *Statement of the Commission on Breaches by Health Apps and Other Connected Devices*, *supra* note 99.

103. *Id.*

FTC authority.¹⁰⁴ Because Congress did not explicitly intend for the Health Breach Notification Rule to cover technology like fitness trackers and health apps, the Republican Commissioners argued that the agency was expanding the scope of the Rule beyond the HITECH Act to include these health-related products.¹⁰⁵ However, if the FTC left the HBNR unenforced, the Rule would remain frozen in time and become a superfluous copy of the HIPAA rules. The FTC's enforcement of the HBNR properly captures the sorts of technologies that Congress had the foresight to imagine, even if it could not name them specifically in 2009. Digital records inevitably lead to new methods of accessing and organizing information, and it was reasonable to expect that consumers would be able to directly access this health information. The FTC's enforcement action against GoodRx demonstrates an application of the Rule that reflects Congress's intent in passing the HITECH Act.

1. *GoodRx Enforcement Action*

Two years after the Policy Statement, the Commission decided to enforce the 2009 Rule for the first time against GoodRx, a consumer-focused digital healthcare platform.¹⁰⁶ In the original February 1, 2023 complaint, submitted to a federal district court on the same day as the subsequent stipulated order, the Department of Justice brought the lawsuit “upon notification and on behalf of the [FTC]” for violations of § 5 of the FTC Act and the HBNR.¹⁰⁷

The FTC alleged that GoodRx violated the statute and the Rule by engaging in deceptive and unfair trade practices and noted that GoodRx had 55.4 million users.¹⁰⁸ GoodRx's deceptive and unfair trade practices included actions such as violating its own privacy policy's promise that it would not share sensitive user information and sharing user data without notice or consent to advertising targeting platforms.¹⁰⁹ The sensitive health information at issue included GoodRx users' prescription medications and personal health conditions.¹¹⁰ Notably, though it was not mentioned in the complaint or accompanying press release, this information would include birth control

104. See Dissenting Statement of Commissioner Christine S. Wilson Regarding the Policy Statement on Breaches by Health Apps and Other Connected Devices, FED. TRADE COMM'N MATTER NO. P205405 (Sep. 15, 2021).

105. *Id.*

106. See generally Goodrx Complaint, *supra* note 8.

107. 15 U.S.C. § 45(a)(1); see C.F.R. § 318; GoodRx Complaint, *supra* note 8, at 1.

108. See generally GoodRx complaint, *supra* note 8.

109. *Id.* at ¶ 38.

110. *Id.* at ¶ 8.

prescriptions and abortion pills.¹¹¹ Additionally, the Commission alleged that GoodRx’s inaction, including a failure to implement sufficient policies or procedures to prevent the improper disclosure of sensitive health information and a failure to notify users of breaches, constituted unfair and deceptive practices.¹¹²

The FTC was first notified of GoodRx’s data privacy practices by a *Consumer Reports* article in early 2020.¹¹³ Within a month of the *Consumer Report* article, GoodRx created a new position, Vice President of Data Privacy, to oversee and coordinate the company’s data privacy efforts and to limit data sharing.¹¹⁴ The company also created an internal, written policy governing third-party data sharing.¹¹⁵ Despite these changes, the FTC continued to investigate GoodRx to ensure its compliance with the Rule and eventually brought an enforcement action because the company continued to share personal health information with Facebook and other third-party platforms, in violation of the HBNR, until at least November 2020.¹¹⁶ While the company quickly announced that *Consumer Reports*’ “feedback” led them to update their policies in February 2020, the FTC found that GoodRx continued to violate the Rule by transmitting personal health information to Facebook pixel, a coding feature that allows Facebook to measure, optimize and build targeted ad campaigns, as late as November 2020.¹¹⁷

The FTC and GoodRx quickly reached a settlement agreement,¹¹⁸ and a stipulated order granting the FTC’s requested relief was issued by the United States District Court for the Northern District of California.¹¹⁹ The settlement agreement included a \$1.5 million civil penalty for GoodRx and a stipulated

111. Sarah Gupta, *5 Steps to Getting Birth Control Without Seeing a Doctor*, GOODRX (Mar. 1, 2024), <https://www.goodrx.com/conditions/birth-control/heres-how-to-get-birth-control-without-a-doctors-prescription>.

112. Stipulated Order for Permanent Injunction, Civil Penalty Judgment, and Other Relief, *United States v. GoodRx Holdings, LLC*, No. 3:23-cv-460, (N.D. Cal. Feb. 1, 2023).

113. Thomas Germain, *GoodRx Saves Money on Meds—It also Shares Data with Google, Facebook, and Others*, CONSUMER REPORTS (Mar. 6, 2020), <https://www.consumerreports.org/health/health-privacy/goodrx-saves-money-on-medsit-also-shares-data-with-google-facebook-and-others-a6177047589/>.

114. GoodRx Complaint, *supra* note 8.

115. *Id.* at ¶ 57.

116. *Id.* at ¶ 63.

117. *Id.* at ¶¶ 56–5, 63.

118. See HOOFNAGLE, *supra* note 28, at 111–12. Most FTC enforcement actions end in settlements. While this series of FTC actions is atypical, this settlement agreement is not.

119. Germain, *supra* note 113.

order that imposed “a flat-out prohibition on GoodRx sharing user health data with applicable third parties for advertising purposes.”¹²⁰

GoodRx released its own press release, stressing that the company did not admit any wrongdoing and generally disagreed with the FTC’s “novel” enforcement of the HBNR.¹²¹ GoodRx also stated that “the requirements detailed in the settlement will have no material impact on our business or on our current or future operations,” but the FTC’s continued investigation resulted in direct and immediate changes to how GoodRx handles personal health information.¹²² Though the Consumer Report article played a significant part in highlighting GoodRx’s privacy practices, the FTC’s enforcement of the Health Breach Notification Rule effectively forced the company to honor its promise to consumers.

Additionally, GoodRx took issue with the FTC complaint’s focus on the company’s use of advertising tracking pixels, which are commonly used by many websites.¹²³ This, however, does not change the fact that the advertising tracking technology offers no meaningful opportunity for user consent and uses personal, identifiable information of consumers for purposes well beyond the services GoodRx offers.¹²⁴ The company also failed to notify consumers that their information could or would be used for anything other than finding affordable medical offerings.¹²⁵ This unauthorized disclosure of information, according to the FTC’s interpretation of the 2009 Health Breach Notification Rule, is a violation of the Rule and an unfair or deceptive trade practice.¹²⁶

2. *Easy Healthcare (Premom App) Enforcement Action*

On May 17, 2023, the FTC announced that it had settled its second enforcement action of the Health Breach Notification Rule against Easy Healthcare, the company behind an ovulation tracking and fertility health app,

120. *Id.*; see also Fair, *supra* note 14.

121. *GoodRx Response to FTC Settlement*, GOODRX, (Feb. 1, 2023), <https://www.goodrx.com/corporate/business/goodrx-response-to-ftc>.

122. *Id.*

123. *Id.*

124. See Rita Ganz, *Understanding GDPR Compliance of Tracking Pixel Declarations Using Privacy Filter Lists*, SWISS FED. INST. OF TECH. (ETH) ZURICH (Feb. 18, 2022); see also FTC Office of Technology, *Lurking Beneath the Surface: Hidden Impacts of Pixel Tracking*, FED. TRADE COMM’N (Mar. 16, 2023), <https://www.ftc.gov/policy/advocacy-research/tech-at-ftc/2023/03/lurking-beneath-surface-hidden-impacts-pixel-tracking>.

125. Goodrx Complaint, *supra* note 8, at ¶ 7.

126. See generally GoodRx Complaint, *supra* note 8.

Premom.¹²⁷ The FTC's initial complaint largely mirrored the February complaint against GoodRx, stressing that the company had violated its own privacy policy by sharing users' personal health data with third parties for advertising without user notice and consent and failed to implement written policies to address breach concerns created by the third-party usage.¹²⁸ In particular, Easy Healthcare allegedly failed to encrypt data that it shared with third parties or notify consumers of the unauthorized disclosures.¹²⁹ In the settlement, Easy Healthcare agreed to a \$100,000 civil penalty and agreed to certain compliance reporting practices and requirements.¹³⁰ Easy Healthcare's Response to the FTC settlement was not specific and did not directly address the allegations in the complaint or stipulated order.¹³¹

3. *Comparing the FTC's First Two HBNR Enforcement Actions*

The FTC's first HBNR enforcement actions against GoodRx and Easy Healthcare highlight interesting developments in the FTC's approach to enforcing information privacy protections under the direction of former Chair Lina Khan. First, both enforcement actions address poor data security practices, such as the failure to notify users that third parties have access to their data, as unauthorized disclosures constituting "breaches of security" under the definitions provided in the HITECH Act and the agency's 2009 Rule.¹³² This is an atypical conception of a security breach in a data privacy context because, historically, the term typically applies to cybersecurity hacks by an outside third party, rather than the intentional disclosure of sensitive information by the company authorized to collect the information for a consumer service.¹³³ This approach to data privacy violations centers the consumer, by identifying the business collecting consumer information as the

127. *See generally* Stipulated Order for Permanent Injunction, Civil Penalty Judgment, and Other Relief, *United States v. Easy Healthcare Corporation*, No. 1:23-cv-3107 (N.D. Ill. June 22, 2023).

128. Complaint for Permanent Injunction, Civil Penalty Judgment, and Other Relief, *United States v. Easy Healthcare Corporation*, No. 1:23-cv-3107 (N.D. Ill. May 17, 2023).

129. *Id.* ¶ 32.

130. *See* Easy Healthcare Complaint, *supra* note 128.

131. *Easy Healthcare's Response to the FTC Settlement*, PREMOM (May 17, 2023), <https://premom.com/ftc-response/>.

132. Pub. L. 111-5, *supra* note 20.

133. *See Security Breach Definition*, CAMBRIDGE DICTIONARY (2024), <https://dictionary.cambridge.org/us/dictionary/english/security-breach> (defining a security breach as "a failure in a system that is intended to protect a person, building, organization, or country against threats such as crimes or attacks." This definition assumes an outside party always causes the breach).

perpetrator of the violation when they disclose sensitive information without authorization from consumers.

Second, both actions were enforced against companies handling sensitive health data related to reproductive health, fertility, and abortion access. These actions were enforced within a year of the Supreme Court's decision in *Dobbs v. Jackson Women's Health Organization*, which overturned *Roe v. Wade* and eliminated the constitutional right to abortion.¹³⁴ Given this timing, the FTC's enforcement actions can reasonably be seen as responsive to the *Dobbs* decision and subsequent state actions taken to criminalize abortion.¹³⁵ At least thirteen states have outlawed abortion entirely, and another twelve states have enacted laws or policies that restrict or prohibit access to abortion care.¹³⁶ The FTC's enforcement actions under the Health Breach Notification Rule limit the likelihood of data leaks from private businesses publicizing whether someone sought or obtained an abortion. Such information, once obtained by states that criminalized abortion after *Dobbs*, could be used to prosecute people for health choices that they reasonably expected to remain private. The HBNR privacy protection is legally sound beyond the abortion context, but the decision to enforce the protection for the first time against purveyors of sensitive reproductive health information is an unusual development for the FTC, which has historically been considered apolitical.¹³⁷ In October 2024, the House Committee on Oversight and Accountability published a staff report alleging that FTC Chair Lina Khan "has consistently betrayed the obligation of the Commission to be an independent, bipartisan agency" through a slew of Democratic policies.¹³⁸ Remarkably, the report did not mention the FTC's "political" enforcement of a facially neutral rule on a hot-button issue as an example of Chair Khan's break from the FTC's "mandate of nonpartisanship, impartiality, and independence."¹³⁹

Finally, both actions preceded any updates to the Health Breach Notification Rule, which were introduced and finalized a year after these settlements. The fact that each enforcement action and settlement occurred before the HBNR was modified is significant because the settlements indicate

134. *See generally* *Dobbs v. Jackson Women's Health Org.*, 597 U.S. 215 (2022).

135. *After Roe Fell: Abortion laws by State*, CTR. FOR REPROD. RTS. (2024) <https://reproductiverights.org/maps/abortion-laws-by-state/>.

136. *Id.*

137. *See* HOOFNAGLE, *supra* note 28, at 9–11.

138. *Oversight Committee Releases Staff Report Finding FTC Chair Khan Abused Authority to Advance the Biden-Harris Administration's Agenda*, U.S. HOUSE COMM. ON OVERSIGHT & ACCOUNTABILITY 4 (Oct. 31, 2024), <https://oversight.house.gov/wp-content/uploads/2024/10/HCOA-Majority-Staff-Report-FTC-Investigation.pdf>.

139. *Id.* at 16.

that the Rule was sufficiently enforceable before the FTC updated the Rule in 2024. The Commission referenced insights from the two businesses when it decided to update the Rule. The updates clarify the scope and associated definitions of the Rule to provide covered businesses and entities with clear, direct notice. The update to the Rule was reasonable because businesses, law firms, privacy experts, and consumer protection organizations remained uncertain about the applicability of the HBNR following the FTC's 2021 Policy Statement announcing the intention to enforce the Rule.¹⁴⁰

4. 2024 Updates to the Health Breach Notification Rule

Following the FTC's first-ever HBNR enforcement action in 2023, the updated Health Breach Notification Rule was finalized in May 2024 ("Final Rule").¹⁴¹ The notice-and-comment period of updating the HBNR also provided affected businesses with an opportunity to comment on and raise their concerns about the FTC's future enforcement of the rule. Among other things, the updates (i) clarified what it means for a vendor of PHR to draw PHR identifiable health information from multiple sources, (ii) revised the definition of breach of security to clarify that a breach of security includes data security breaches and unauthorized disclosures, and (iii) extended the Rule's timing requirement for notifying the FTC of a breach of security.¹⁴² These amendments addressed concerns raised in more than one hundred comments submitted during the Rule's notice-and-comment period before the Final Rule was announced.¹⁴³ The changes also add clarifying language to help businesses know whether they are expected to comply with the Rule, and specific

140. Mariah Bellamoroso, *FTC Signals Move Towards Tighter Data Privacy for Healthcare Apps*, HARV. J. L. & TECH. (Nov. 6, 2021), <https://jolt.law.harvard.edu/digest/ftc-signals-move-towards-tighter-data-privacy-for-healthcare-apps>.

141. 16 C.F.R. § 318, *supra* note 19.

142. *See* Health Breach Notification Rule, 89 Fed. Reg. 47028, 47029 (May 30, 2024) (16 C.F.R. § 318). The full suite of amendments to the 2024 HBNR (1) clarify the Rule's scope, including its coverage of developers of many health applications ("apps"); (2) clarify what it means for a vendor of personal health records to draw personal health record (PHR) identifiable health information from multiple sources; (3) revise the definition of breach of security to clarify that a breach of security includes data security breaches and unauthorized disclosures; (4) revise the definition of PHR related entity; (5) modernize the method of notice; (6) expand the content of the notice; (7) extend the Rule's timing requirement for notifying the FTC of a breach of security; and (8) improve the Rule's readability by clarifying cross-references and adding statutory citations, consolidating notice and timing requirements, articulating the penalties for non-compliance, and incorporating a small number of non-substantive changes.

143. *Id.*

requirements for how to do so.¹⁴⁴ In particular, the FTC clarified that only PHR-related entities are subject to the HBNR, and they include entities offering products and services through any online service, including mobile applications, if they access or send unsecured PHR identifiable health information.¹⁴⁵ Third parties that may access unsecured PHR in their course of business are not PHR-related entities simply because they have access to sensitive information.

IV. ANALYSIS

This Part explains the FTC's subsequent updates to the HBNR following its first two enforcement actions and highlights the significance of the HBNR as an effective privacy provision. Section IV.A outlines the primary criticisms of changes to the HBNR, including the updated definitions of "breach" and "health care providers." Sections IV.B and IV.C consider the critiques of updated definitions in the 2024 HBNR and highlight the significance of the HBNR's enforcement amidst the proliferation of D2C health care options. Section IV.D examines the potential impact of a recent Supreme Court holding that curtails some federal agency enforcement capabilities. Finally, Section IV.E suggests improvements for further enforcement of the HBNR and takeaways from the HBNR that can create an effective and more cohesive federal privacy framework.

A. CRITICISMS OF THE 2024 HEALTH BREACH NOTIFICATION RULE

After the Final Rule was promulgated, Republican Commissioners Melissa Holyoak and Andrew Ferguson published another dissent regarding the new HBNR, citing concerns about the substance, scope, and the FTC's authority to enforce the Rule.¹⁴⁶ In particular, they raised concerns that the Rule exceeds the commission's statutory authority by broadening the definitions Congress provided in the HITECH Act.¹⁴⁷ This criticism fails to recognize the congressional acknowledgment in 2009 that new technologies would continue to emerge and escape privacy regulation, and that the FTC was entrusted with the responsibility to promulgate a Rule that avoids that outcome. The updated definitions do not create punitive measures against covered health care

144. *See* Health Breach Notification Rule, 89 Fed. Reg. 47028, 47044 (May 30, 2024) (16 C.F.R. §. 318).

145. *Id.*

146. Fed. Trade Comm'n, Statement of Commissioner Melissa Holyoak, Joined by Commissioner Andrew Ferguson on the Health Breach Notification Rule, File No. P205405 (Apr. 26, 2024), https://www.ftc.gov/system/files/ftc_gov/pdf/p205405_hbnr_mhstmt_0.pdf.

147. *Id.*

providers under the HBNR—they clarify which entities are expected to comply with the Rule now that so many exist and remain in high demand after the COVID-19 pandemic.¹⁴⁸

The dissent also noted that the Rule imposes affirmative obligations on companies to notify their service providers if they are covered by the Final Rule, regardless of whether they experienced an external breach.¹⁴⁹ This affirmative obligation is a minimal addition to other disclosures that businesses typically share with third parties; it only requires that third parties are put on notice that at least some of the data to be shared across companies includes sensitive PHR information.¹⁵⁰ Furthermore, the Rule only requires further action in the event of intentional, unauthorized disclosures of user information to capture more than external cyber hacks to reflect an updated understanding of breaches as they relate to individual users, rather than defining breach only from the perspective of the business housing the private information.¹⁵¹ Data privacy experts today define a breach generally as “the unauthorized exposure, disclosure, or loss of personal information.”¹⁵² This updated definition reflects changes in the data privacy industry and accurately reflects the sort of privacy risks that consumers face today. In addition to criminal intrusions onto company data, a company entrusted with sensitive consumer health information can violate consumer privacy expectations by sharing that unencrypted information with a third-party advertiser or data broker.

Finally, the Commissioners argued that the Rule puts companies at risk of perpetual non-compliance and may undermine institutional integrity by artificially broadening its scope without clarity. In particular, they argue that unclear definitions of terms like “health care provider” cause confusion about who the Rule applies to.¹⁵³ Congress defined providers as “a provider of medical or other health services” and “any other person furnishing health care services or supplies,” which encompasses both HIPAA-covered entities and entities that would only be regulated by the HBNR.¹⁵⁴ The new HBNR specifies which entities are non-HIPAA covered “healthcare providers” in part by whether or not they house unsecured PHR identifiable health information,

148. *See generally* Bestsenny, *supra* note 3. Many Americans turned to telehealth providers for mental and physical health during the height of the COVID-19 pandemic, when most states had imposed stay-at-home orders and enforced quarantine requirements.

149. Holyoak, *supra* note 146.

150. Health Breach Notification Rule, 89 Fed. Reg. 47028, 47044 (May 30, 2024) (16 C.F.R. § 318).

151. *Id.*

152. *Id.*

153. Holyoak, *supra* note 146.

154. Pub. L. 111-5, *supra* note 20.

simplifying which businesses must comply with the HBNR.¹⁵⁵ Furthermore, these semantic concerns are a natural and well-anticipated part of regulating a rapidly changing industry. After all, Congress intended for consumers to learn of breaches of their unsecured PHR identifiable health information that fall outside HIPAA; the changes to the definitions in the HBNR help ensure consumers will receive the notification Congress intended.¹⁵⁶ To the extent that the FTC cannot provide a Rule that perfectly defines every possible violator, the agency can use other administrative tools, such as policy statements and notices, to further draw the line between a tangential health connection and a covered “health care provider” for purposes of the Rule and its enforcement.

B. SIGNIFICANCE OF THE 2024 HBNR “BREACH OF SECURITY”
DEFINITION

Perhaps the most significant change in the 2024 HBNR (“modernized Rule”) is that the HBNR makes an intentional, unauthorized disclosure by an entity a “breach of security” and a violation of the Rule.¹⁵⁷ For example, GoodRx and Easy Healthcare’s decisions to share information with third-party ad platforms without notice to consumers are violations of the HBNR.¹⁵⁸ Historically, experts in privacy law have defined “breaches of security” as issues raised when an entity experiences a hack or some other nefarious seizure of information by an unknown or unapproved third party.¹⁵⁹ Many privacy experts, researchers, policy advocates, and even state lawmakers recognize that a breach of information privacy, as it relates to an individual user, extends beyond this traditional model.¹⁶⁰ Even the HITECH Act defines the term “breach” generally as the “unauthorized acquisition, access, use, or *disclosure* of

155. 16 C.F.R. § 318.2.

156. Health Breach Notification Rule, 89 Fed. Reg. 47028, 47034 (May 30, 2024) (16 C.F.R. § 318).

157. 16 C.F.R. 318.2 (2024); *see also* Health Breach Notification Rule, 89 Fed. Reg. 47028, 47029 (May 30, 2024) (16 C.F.R. § 318) (“The Commission further clarified that health apps and other products experience a “breach of security” under the Rule when they disclose users’ sensitive health information without authorization; a breach is “not limited to cybersecurity intrusions or nefarious behavior.”).

158. *See supra* Part II.

159. *See* CAMBRIDGE DICTIONARY, *supra* note 134.

160. *See, e.g., Data Breaches*, NAT’L ASS’N OF ATT’YS GEN., <https://www.naag.org/issues/consumer-protection/consumer-protection-101/privacy/data-breaches/> (“A data breach can be defined as the unlawful and *unauthorized* acquisition of personal information that compromises the security, confidentiality, or integrity of personal information.” (emphasis added)).

protected health information which compromises the security or privacy of such information.”¹⁶¹

The new breach definition in the HBNR better fulfills the goals of breach notification rules; it is a stronger measure to curtail poor data practices that are not the result of traditional cybersecurity, like phishing or hacking. This definition also centers around the stakeholders who suffer the most harm when a breach occurs: the individual whose sensitive health information was disclosed for any number of uses without their permission. The FTC has fulfilled its congressional mandate in the HITECH Act by creating an enforceable sectoral privacy rule that addresses historical and contemporary understandings of security breaches. By promulgating and enforcing the HBNR with this breach definition, the FTC holds businesses accountable for their privacy practices that allow for breaches of consumer privacy to happen, including decisions to share identifiable information without the approval or knowledge of the consumer.

C. SIGNIFICANCE OF THE ENFORCEMENT ACTIONS

In addition to being one of only a few entities empowered to protect consumers’ data privacy, the FTC is one of the only sources of privacy jurisprudence at all, especially for federal privacy regulations.¹⁶² As discussed by U.S. privacy law scholars Daniel Solove and Woodrow Hartzog, “in practice, the FTC privacy jurisprudence has become the broadest and most influential regulating force on information privacy in the United States—more so than nearly any privacy statute or any common law tort.”¹⁶³ Most, if not all the aforementioned jurisprudence consists of settlement agreements rather than case law, leaving observers without a workable information privacy doctrine.¹⁶⁴ Solove and Hartzog argue that the FTC’s decades of settlement agreements for privacy violations should be treated as common law to highlight certain norms and standards that are considered baseline privacy protections.¹⁶⁵ While FTC settlement agreements are the primary source of standards and expectations of consumer privacy, these actions are often too case-specific to provide meaningful recommendations for future cases.¹⁶⁶

161. 42 U.S.C. § 17921(1)(A) (emphasis added).

162. See *supra* Section II.A.

163. Daniel J. Solove & Woodrow Hartzog, *The FTC and the New Common Law of Privacy*, 114 COLUM. L. REV. 583, 583 (2014).

164. *Id.*

165. *Id.* at 625.

166. See, e.g., Easy Healthcare Stipulated Order, *supra* note 22. The settlement does not require a federal court to reach a conclusion as to whether the company’s behavior is definitely

Regardless of whether the FTC's settlement agreements can or should be treated as common law, it remains clear that little precedent exists for federal privacy enforcement, and the FTC's more robust enforcement of the Health Breach Notification Rule can help further develop a significant body of privacy policies and law. However, robust enforcement is unlikely in the next four years due to a change in presidential administrations and FTC Chairs. In 2025, President Donald Trump appointed Andrew Ferguson to replace Lina Khan as Chair of the FTC.¹⁶⁷ Ferguson dissented from the FTC's updates to the HBNR, so it is unlikely that the FTC will continue to enforce the HBNR under Ferguson's leadership.¹⁶⁸

The FTC's failure to enforce the HBNR over the next four years would have a significant effect on consumers because the agency would effectively eliminate a rare federal protection and remedy from business practices that expose consumers to harm. In many cases, consumers have no choice but to rely on the FTC to enforce the HBNR because they otherwise lack the individual ability to redress digital privacy injuries.

In 2021, the Supreme Court "significantly undermined the effectiveness of many privacy laws" by nullifying certain private rights of action due to a lack of standing.¹⁶⁹ In *TransUnion LLC v. Ramirez*, the Court held that a subset of a class of plaintiffs lacked Article III standing to sue a credit reporting agency for violations of the Fair Credit Reporting Act because they failed to demonstrate that their privacy injuries were concrete.¹⁷⁰ Specifically, their asserted harm was not similar to any harm "traditionally recognized as providing a basis for a lawsuit in American courts" and lacked a close historical or common law analogue for the asserted injury.¹⁷¹ This ruling makes enforcing privacy rights increasingly difficult because "traditionally recognized" is a vague legal standard, and it most likely means that privacy lawsuits dealing with technology are much less likely to find standing in court since they do not have a long historical analogue that the Court is willing to recognize.¹⁷²

a violation of the HBNR as the FTC alleges. This, in effect, leaves the FTC's application of the HBNR uncontested as applied to these facts, without expanding upon the FTC's rationale.

167. *Andrew N. Ferguson Takes Over as FTC Chairman*, FED. TRADE COMM'N, (Jan. 22, 2025), <https://www.ftc.gov/news-events/news/press-releases/2025/01/andrew-n-ferguson-takes-over-ftc-chairman>.

168. *See supra* Section IV.A.

169. Daniel J. Solove & Danielle Keats Citron, *Standing and Privacy Harms: A Critique of TransUnion, LLC v. Ramirez*, 101 B.U.L. REV. ONLINE 62, 62 (2021); *see also* *TransUnion LLC v. Ramirez*, 594 U.S. 413 (2021). This holding limited many consumers' standing to sue for infringements of their privacy.

170. *TransUnion*, 594 U.S. 413 (2021).

171. *Id.*

172. *See* Solove, *supra* note 169.

After *TransUnion's* Court-induced limitation on the ability of consumers to bring private lawsuits to assert and enforce their data privacy rights, consumers must rely on rules enforced by federal agencies, primarily the FTC and HHS, to enforce their data privacy rights. At the same time, all federal agencies face concerns about the ability to impose their rules with the force of law, especially after *Chevron U.S.A., Inc. v. Natural Resources Defense Council, Inc.* was overturned in 2024, ending the discretion that federal agencies enjoyed when interpreting ambiguous statutes based on their particular expertise.¹⁷³ Section IV.D considers the impact of the *Loper Bright* decision on the FTC's interpretation of the HBNR. When actively enforced, the FTC Health Breach Notification Rule provides a path for consumer relief and prevention of privacy harms that they themselves cannot raise in a court of law.

Additionally, the Commission's ability to enforce the Health Breach Notification Rule allows for more immediate changes in company conduct and self-governance. Through civil penalties and court-approved injunctions on unfair and deceptive business practices, the FTC's enforcement of the HBNR brings about a direct change for consumers. The combination of investigations, penalties, notification requirements, and public settlements causes businesses facing enforcement actions to make responsive changes to comply with the law and avoid future liability. These immediate actions include hiring data privacy professionals, establishing an internal system to avoid unnecessary and unauthorized disclosures of information to third parties, and routine review of the company's privacy practices.¹⁷⁴ The HBNR's ability to cause immediate and direct change to business behaviors that improve the consumer experience aligns with the FTC's general mission to combat bigness and its negative effects on the public.

Finally, though the FTC always requires that no more than three members of the Commission belong to the same party, the Rule's enforcement history until 2024 highlights a different political divide arising in the typically apolitical agency.¹⁷⁵ There is an underlying politicism in the fact that the first two enforcement actions were against companies that were careless with access to and disclosure of personally identifiable reproductive health information. While many onlookers have noticed that the agency has been criticized as politically extreme under former Chair Lina Khan, few have highlighted the

173. *Loper Bright Enters v. Raimondo*, 603 U.S. 369 (2024).

174. *See, e.g., GoodRx Settlement*, *supra* note 113.

175. *See Winerman, supra* note 25, at 59; *see also* Will Weissert & Christopher Rugaber, *Trump Fires 2 Democrats on the Federal Trade Commission, Seeking More Control over Regulators*, ASSOCIATED PRESS (Mar. 18, 2025) (showing that in the first 100 days of the second Trump administration, the FTC has become even more politicized when President Trump fired Democratic commissioners Alvaro Bedoya and Rebecca Kelly Slaughter without cause).

significance of the FTC's HBNR enforcement as an example of the agency's political motives.¹⁷⁶ The FTC's protection of reproductive health privacy after the Supreme Court struck down the federal right to abortion further demonstrates the significance of the harms that consumers face when their digital privacy is compromised. Whereas privacy actions on behalf of individual consumers often lack a concrete harm that provides standing to bring a lawsuit, the political divide on reproductive health produces a significant risk of concrete harm when data is leaked that confirms, for example, that a resident of an anti-abortion state accessed the abortion pill through an online provider like GoodRx.¹⁷⁷ Given the likelihood that Ferguson's FTC will not enforce the HBNR with nearly as much rigor, if at all, it is not yet clear how this underlying politicization in the FTC will further change the agency's approach to privacy enforcement.

D. *LOPER BRIGHT CONCERNS*

Considering the Court's recent decision in *Loper Bright Enterprises v. Raimondo*, every federal agency, including the FTC, faces potential restrictions on its ability to promulgate and enforce rules if it relies too heavily on the agency's interpretation of an ambiguous statute ("*Chevron* deference").¹⁷⁸ While the FTC is sure to face continued legal objections to how it enforces certain rules, the Commission is well within its statutory duty to enforce the HBNR, even without *Chevron* deference, by interpreting the statute creating the HBNR. The statute authorizing the Rule is not ambiguous, but the updated Rule may be subject to review as to whether enforcement of the "modernized" language goes beyond the scope of authority that Congress intended. Newly installed Chair Ferguson agrees with this sentiment, as demonstrated by his dissent from the Final Rule, but this alone does not put the Rule at risk of elimination, especially because the FTC can simply choose not to enforce the HBNR without more instruction from Congress.

A comparison of the HBNR to the FTC's recent Noncompete Rule and its legal challenges provides an illustrative example of why the updated HBNR is likely not a breach of agency authority. On April 23, 2024, the FTC finalized the Noncompete Rule, which "adopts a comprehensive ban on new noncompetes with all workers," including senior executives.¹⁷⁹ The Rule was set to become effective in September 2024, but in August, a federal judge in

176. See, e.g., House Oversight and Accountability Committee Report, *supra* note 138.

177. See, e.g., Texas Heartbeat Act (Texas Health & Safety Code §§ 171.201–171.212) (authorizing private citizens to sue various stakeholders for violating or assisting in the violation of the state's restrictive anti-abortion laws).

178. GoodRx Settlement, *supra* note 113.

179. FTC Noncompete Rule, 16 C.F.R. §§ 910, 912.

the Northern District of Texas blocked the Rule with a nationwide injunction by siding with Ryan, LLC, a Dallas, Texas-based tax services provider and related co-Plaintiffs.¹⁸⁰ The FTC argued that the challenged Rule was within its authority to establish rules related to “unfair methods of competition” under § 6 and that noncompete agreements are unfair methods of competition under § 5 of the FTC Act.¹⁸¹ Furthermore, the FTC based the promulgation of the Rule on its findings and conclusions after years of investigation, public hearings, and review of academic studies.¹⁸² The district court rejected this argument and concluded that the FTC exceeded its statutory authority because the Commission’s ability to promulgate rules concerning unfair methods of competition does not explicitly include the authority to create *substantive* rules regarding unfair methods of competition.¹⁸³ As a result, the Noncompete Rule as a method of combating an unfair method of competition is not enforceable by the FTC because it is a substantive and not procedural rule, thus exceeding the FTC’s rulemaking authority in this area of law and policy.¹⁸⁴ The district court concluded that this result is further supported by the fact that § 6(g) rulemaking authority does not have a penalty provision, while § 18 does.¹⁸⁵

Conversely, the HBNR finds initial authority in § 18 of the FTC Act, which in turn authorizes civil penalties in § 5.¹⁸⁶ The rulemaking authority in § 18 applies to the creation of substantive rules dealing with unfair or deceptive practices—not unfair methods of competition.¹⁸⁷ Furthermore, Congress specifically instructed the Commission to create and enforce the Health Breach Notification Rule in the HITECH Act.¹⁸⁸ Congress expressly delegated the enforcement of the provisions in § 13407 to the Commission. Under these circumstances, the court would review a challenge to the Rule by recognizing the constitutional delegation and “ensuring the agency has engaged in reasoned decision-making.”¹⁸⁹ In the process of updating the HBNR, the Commission updated the Rule in an effort to honor Congress’s mandate by clarifying the

180. Ryan, LLC v. Fed. Trade Comm’n, 746 F. Supp. 3d 369, 370 (N.D. Tex. Aug. 20, 2024).

181. 15 U.S.C. § 57(a).

182. Ryan, LLC, 746 F. Supp. 3d at 377.

183. *Id.* at 384 (“By plain reading, Section 6(g) of the Act does not expressly grant the Commission authority to promulgate substantive rules regarding unfair methods of competition” because it only allows the FTC to “make rules and regulations for the purpose of carrying out the provisions of this subchapter. 15 USC § 46(g).”).

184. *Id.*

185. Ryan, LLC, 746 F. Supp. 3d at 385.

186. See *supra* Part II.

187. 15 U.S.C. § 57(a).

188. See *supra* Part II.

189. Loper Bright, 603 U.S. at 395.

Rule's scope and several definitions, and providing more time to comply with the notice requirement of the Rule following a breach.¹⁹⁰ Additionally, the House Judiciary Committee reviewed the FTC's proposed amendments to the HBNR in its FTC oversight meeting and expressed no concerns with the Rule before its finalization.¹⁹¹

Finally, there is an additional significant distinction between the FTC's Noncompete Rule and the HBNR. In its final dismissal of the Noncompete Rule, the district court stated that "the Rule imposes a one-size-fits-all approach with no end date, which fails to establish a 'rational connection between the facts found and the choice made.'"¹⁹² In contrast, the HBNR is directed to a specific audience of vendors of personal health records that are not covered by HIPAA, as Congress determined, and the Rule has a statutory research and guidance in the HITECH Act.¹⁹³ Because the FTC had express, statutory authority to promulgate and enforce the HBNR, it is much less likely to face the scrutiny that the Noncompete Rule did. Furthermore, the HBNR is unlikely to face scrutiny because it is unlikely to be significantly enforced in the foreseeable future.

E. SUGGESTED IMPROVEMENTS TO HBNR ENFORCEMENT GUIDANCE AND PRACTICES

The following improvements would help the FTC fend off challenges to its authority and related resistance to its HBNR enforcement actions, which are ultimately meant to promote compliance and reduce injuries to consumers caused by a business's unfair or deceptive trade practices. These suggested improvements include further defining nontraditional health care providers for the purposes of the HBNR and exploring less aggressive administrative remedies in edge cases.

1. *Distinguishing Between Traditional and Nontraditional Health Care Providers and Related Definitions to Provide Fair Notice*

Many of the definition changes in the modernized Rule to terms related to health were intended to capture non-HIPAA health care providers.¹⁹⁴ Similarly, the Commission noted that it intentionally retained or added catchall terms that do not expand the original Rule's breadth but instead address existing

190. See 16 C.F.R. § 318, *supra* note 13.

191. Rules of Practice for Adjudication Proceedings, Vol. 88, Fed. Reg. 18382 (2023) (12 C.F.R. § 1081).

192. *Ryan, LLC*, 746 F. Supp. 3d at 388.

193. Health Information Technology for Economic and Clinical Health (HITECH) Act, 42 U.S.C. § 300jj; ARRA, *supra* note 20, at § 13405.

194. 16 C.F.R. § 318.2.

health technology “to ensure the Rule’s language can accommodate future changes in technology.”¹⁹⁵ Many of these changes follow logically from the proliferation of mobile phone health apps, which did not exist in 2009 when the HBNR was promulgated but nonetheless were clearly intended by Congress to be covered by the Rule.¹⁹⁶ The Rule sets an ambiguous standard for edge cases that make the Rule susceptible to challenges to its enforcement. When it is unclear whether an entity is a vendor of personal health records and therefore subject to compliance with the HBNR, the threshold inquiry is whether “an app, website, or online service must provide an offering that relates more than tangentially to health.”¹⁹⁷

This standard could cause enforcement issues in the future because the malleable standard is not predictable or clear enough when it comes to online or digital services that are arguably related to health. For example, in the same year that the FTC issued two enforcement actions against GoodRx and Easy Healthcare, the FTC also secured a settlement against BetterHelp, an online mental health counseling service.¹⁹⁸ The FTC alleged that BetterHelp engaged in deceptive trade practices by promising users that their information, including their mental health status and data from intake questionnaires used to match users with therapists, would remain private but shared unauthorized, identifiable personal health records with third parties for targeted advertising purposes.¹⁹⁹ However, the Commission did not invoke the HBNR in its complaint challenging BetterHelp’s practices, though it seems that the deceptive behavior violated the 2009 Rule and the 2024 Rule by engaging in the same activities as other non-HIPAA covered health providers like GoodRx and Easy Healthcare. A month before the 2024 Final HBNR was announced, the FTC settled two more enforcement actions against an alcohol addiction treatment company, Monument, and a subscription-based telehealth platform, Cerebral.²⁰⁰ In both cases, the FTC made consistently similar claims of “breach of security” and issued injunctions that banned both businesses from disclosing consumers’ health information for targeted advertising purposes.²⁰¹

195. Health Breach Notification Rule, 89 Fed. Reg. 47028, 47035 (May 30, 2024) (16 C.F.R. § 318).

196. *Id.*

197. *Id.*

198. Complaint, In the Matter of BetterHelp, Docket No. C-4796 (July 14, 2023).

199. *Id.*

200. *See generally* Complaint for Permanent Injunction; Civil Penalty Judgment, and Other Relief, United States v. Monument, Inc., No. 1:24-cv-01034, (D.D.C. 2024); Complaint, United States v. Cerebral, Inc., No. 1:24-cv-21376-XXXX (S.D. Fla. Apr. 15, 2024).

201. *Id.*

The enforcement actions resulted in quickly updated privacy policies in both companies, but neither enforcement action invoked the HBNR. Such inconsistent enforcement of the HBNR opens the FTC's enforcement up to more criticism and minimizes the FTC's ability to enforce a necessary privacy provision. This inconsistent enforcement also wastes opportunities to clarify the scope of D2C healthcare providers covered by the HBNR by not explicitly noting that the Rule applies to these entities or explaining why it does not. It is unclear why the FTC, in its aggressive enforcement of consumer privacy against these three D2C health-related companies, did not seek enforcement actions under the new Health Breach Notification Rule with clarified definitions and an extended period to comply.²⁰² The FTC should take steps to clarify discrepancies and maintain consistent enforcement of the HBNR to effectively put the affected businesses on notice and to provide Congress with a clean record of enforcement actions that can help inform other privacy notification statutes.

2. *Administrative Hearings and Cure Notices as Measures to Respect Due Process*

When an agency enforces a regulation or a statute, it must adhere to a fair notice standard of “ascertainable certainty,” which has been endorsed by several circuits.²⁰³ The standard provides that fair notice exists if a regulated party reviewing an agency regulation or statement “would be able to identify, with ‘ascertainable certainty,’ the standards with which the agency expects parties to conform.”²⁰⁴ While the FTC provided both a Policy Statement²⁰⁵ before enforcing the HBNR and published a Notice of Proposed Rulemaking²⁰⁶ before the 2024 Rule was issued and enforced, the rulemaking and enforcement timeline still raises some concerns about notice, a fundamental requirement of due process.²⁰⁷ For example, in the HBNR's very short enforcement history, it has not been enforced consistently. When the FTC brought actions against D2C healthcare providers BetterHelp, Cerebral, and Monument for failure to protect consumers' health information, it did not

202. 16 C.F.R. § 318.4.

203. *See, e.g.,* Gen. Elec. Co. v. Env't Prot. Agency, 53 F.3d 1324, 1329 (D.C. Cir. 1995).

204. *Id.*

205. *See* 2021 Policy Statement, *supra* note 99.

206. FTC Health Breach Notification Rule Notice of Proposed Rulemaking, 16 C.F.R. § 318.

207. U.S. CONST. amend. V (“No person shall . . . be deprived of life, liberty, or property, without due process of law.”).

allege an HBNR violation.²⁰⁸ Each of these enforcement actions was settled just months before the updated Rule took effect on July 29, 2024. It is unclear why the agency enforced these actions while updates to the Rule were nearly finalized. The amended Rule clarifies existing definitions and updates the Rule in response to modern realities, such as the time it takes to investigate a breach of privacy by an unauthorized third party, like a cybersecurity hack, but the updated Rule does not expand the scope of enforcement beyond vendors of personal health records.²⁰⁹ Even though the Rule does not expand the scope of vendors handling personal health records and attempts to clarify its scope by providing entities with advance fair notice, the FTC's decision to continue enforcing the Rule while promulgating its updates raises a credible due process concern, especially for the businesses that settled with the FTC before it published its clearer, more explanatory version of the HBNR. Now that the FTC has finalized a clearer version of the old Rule, it should enforce the HBNR as consistently and transparently as possible to avoid future due process concerns. This caution is especially warranted considering recent Supreme Court decisions that chip away at the agency's enforcement capabilities and increasing public skepticism about the role and legitimacy of federal agencies.²¹⁰

To address these concerns, when the FTC enforces the HBNR or any other privacy rule, the Commission should consider a notice-and-cure approach, which provides opportunities to comply with the HBNR before an enforcement action. The FTC should also consider adjudicative agency hearings in cases where the applicability of the HBNR is not clear from a plain reading of the Rule or any of the FTC's public statements. These cases may arise when the FTC targets entities whose business activities include both covered and non-covered functions. The HBNR makes no mention of hybrid entities, but the Department of Health and Human Services recognizes hybrid entities in its enforcement of the HIPAA Privacy Rule.²¹¹ Under the HIPAA Privacy Rule, such an entity may elect to be designated as a hybrid entity and

208. Concurring Statement of Commissioner Christine S. Wilson Regarding BetterHelp, Fed. Trade Comm'n File No. 2023169. (Mar. 2, 2023), https://www.ftc.gov/system/files/ftc_gov/pdf/commissioner_wilson_concur_betterhelp_3.2.23.pdf.

209. Health Information Technology for Economic and Clinical Health (HITECH) Act, 42 U.S.C. § 300jj; ARRA, *supra* note 20, at § 13405.

210. *See generally, e.g., Loper Bright*, 603 U.S.; *AMG Cap. Mgmt., LLC v. Fed. Trade Comm'n*, 593 U.S. 67 (2021), Sec. & Exch. Comm'n v. *Jarkesy*, 603 U.S. 109 (2024).

211. *When Does a Covered Entity Have Discretion to Determine Whether a Research Component of the Entity is Part of Their Covered Functions, and Therefore, Subject to the HIPAA Privacy Rule?*, U.S. DEPT. OF HEALTH & HUM. SERVS., <https://www.hhs.gov/hipaa/for-professionals/faq/315/when-does-a-covered-entity-have-discretion-to-determine-covered-functions/index.html> (last visited May 3, 2025).

must define and designate its health care component(s).²¹² This distinction allows for clearer compliance expectations for the regulated entity and the agency by indicating which parts of the entity should reasonably be expected to comply with the HIPAA Privacy Rule before a breach ever occurs. Because the HBNR covers a more ambiguous category of vendors of consumer health data that falls outside HIPAA, many D2C businesses likely have hybrid or potentially hybrid models.

Notice-and-cure remedies typically apply to contracts, including contracts with the government. They alert businesses of the government's intent to end a contractual relationship due to the business's failure to comply with the conditions of the contract.²¹³ Government contracts are not the only place this strategy is employed. When the California Consumer Privacy Act (CCPA) was initially passed into law, the statute provided consumers with a right of action to sue businesses that failed to comply with the CCPA.²¹⁴ Prior to bringing suit, consumers were required to provide "a business 30 days' written notice identifying the specific provisions of this title the consumer alleges have been or are being violated."²¹⁵ Unlike the CCPA, the FTC's HBNR is focused only on breach notification requirements, but an informal notice-and-cure approach may still be helpful to inform businesses as to whether they are a covered health care provider under the HBNR and may be subject to an HBNR enforcement action. Rather than burden the consumer with the responsibility of providing notice to businesses that may be out of compliance with the FTC HBNR, the FTC should issue notices to businesses to allow them to comply before facing civil penalties and permanent injunctions.²¹⁶ In particular, the FTC could send notices to potential hybrid entities that might arguably be identified as a "health care provider" for purposes of the statute. These notices would provide clearer compliance expectations for all parties, reduce pushback on the agency's enforcement power without diluting the consistency and enforcement power of the HBNR, and maintain the FTC's legitimacy as a federal institution. Additionally, the FTC should always welcome guidance and compliance questions from businesses making a good faith effort to comply with the statute.

212. *Id.*

213. *See, e.g.*, Delinquency Notices, 48 C.F.R. § 49.607.

214. Cal. Civ. Code § 1798.150.

215. *Id.*

216. Note that this proposed "notice-and-cure" method of compliance is a different compliance measure than a notice of penalty offense, which is "a document listing certain types of conduct that the Commission has determined, in one or more administrative orders (other than a consent order), to be unfair or deceptive in violation of the FTC Act." *Notices of Penalty Offenses*, FED. TRADE COMM'N, <https://www.ftc.gov/enforcement/penalty-offenses>.

In addition to an informal notice-and-cure approach, the FTC can also make use of administrative agency hearings. Rather than immediately file complaints seeking penalties and injunctions in federal district court, as the FTC did in GoodRx, Easy Healthcare, BetterHelp, Monument, and Cerebral, the agency should file complaints with an administrative law judge (ALJ).²¹⁷ This method would allow for a more detailed fact-finding process and remedy due process concerns by having a full examination before imposing a penalty.²¹⁸ Even if the Commission finds that there was a violation of the HBNR, the harshest penalty that the Commission can impose in an administrative hearing is a cease-and-desist order; the agency cannot proscribe the harsher penalties often sought in federal district court.²¹⁹ The agency does, however, retain the ability to seek a civil suit in a district court if the entity fails to comply with the cease-and-desist order.²²⁰ The records from these proceedings can also provide further clarity to other businesses that are hesitant on sure how to obtain affirmative express consent from consumers when attempting to share their sensitive information or whether the business is a covered healthcare provider under the HBNR.

The FTC should provide clarity on the HBNR and its privacy enforcement by using the notice-and-cure approach and expanding the use of administrative hearings. These solutions would address due process concerns, provide material contributions to the development of federal breach notification and privacy rules, and encourage more businesses' cooperation, balanced by the possibility of further punitive measures in federal district court. These solutions are also better than maintaining stricter parameters within the HBNR, which would eliminate the necessary flexibility to adapt to changes in the direct-to-consumer healthcare industry. As applied to the HBNR, the legal maxim that hard cases make bad law rings true; the FTC should not restrict its enforcement capabilities under the HBNR because it cannot anticipate every kind of D2C healthcare provider that may face enforcement under the law. When these cases do arise, the FTC should apply less force to encourage learning and compliance, not punitive measures.

V. CONCLUSION

The Federal Trade Commission's revival and enforcement of the Health Breach Notification Rule shows promise for the future of data privacy protection, especially as it relates to sensitive health information. The original

217. See Rules of Practice for Adjudication Proceedings, *supra* note 191.

218. *Id.*

219. 15 U.S.C. § 45(b).

220. *Id.*

2009 Rule was created to complement the American public's increased reliance on digital services and personal records, which peaked during the 2019 COVID-19 pandemic. The updates to the HBNR acknowledge that reality. The FTC's updates to the HBNR reflect its purpose: to put covered entities on notice of their compliance requirements and confirm that they cannot enter the direct-to-consumer market without facing regulations that prioritize and protect consumer interests as it relates to their sensitive health information.

The HBNR's updates were within the FTC's statutory authority to make and were completed through a robust and democratic campaign of business guidance, congressional oversight, and more. While past Commissions have been reluctant to pursue consumer privacy regulations, the 2024 Commission demonstrated a commitment to producing meaningful and lasting change in consumer data privacy.

SURVEY OF ADDITIONAL IP AND TECHNOLOGY LAW DEVELOPMENTS

Berkeley Technology Law Journal[†]

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I. PATENT DEVELOPMENTS

A. *SNAPRAYS, LLC V. LIGHTING DEFENSE GROUP, LLC*

SnapRays v. Lighting Defense Group presents a novel way to find personal jurisdiction over a defendant outside of their home state by using Amazon.com’s procedure to remove patent-infringing product listings.¹ The Amazon Patent Evaluation Express (APEX) is a low-cost procedure “to efficiently resolve claims that third-party product listings infringe utility patents.”² To initiate an APEX proceeding, a patent owner submits an APEX agreement identifying a patent claim and up to twenty allegedly infringing listings to Amazon.³ When Amazon sends the APEX Agreement, it send it to all sellers who have three options to avoid automatic removal: (1) opt into the APEX program and its subsequent third-party evaluation, (2) resolve the claim directly with the patent owner, or (3) file a lawsuit for declaratory judgement of noninfringement.⁴ If the alleged infringer takes no action after three weeks, Amazon removes the accused listings.⁵

In *SnapRays*, the appellee, Lighting Defense Group (LDG), was a Delaware limited liability company with its principal place of business in Arizona.⁶ Appellant and patent owner, SnapPower (SP), is a Utah company with its principal place of business in Utah.⁷ Both LDG and SP sell products on Amazon.com.⁸

LDG submitted an APEX Agreement, which notified SP as a potential infringer.⁹ In response, SP filed a motion for declaratory judgement of

1. *See SnapRays v. Lighting Def. Grp.*, 100 F.4th 1371, 1378 (Fed. Cir. 2024).

2. *Id.* at 1373.

3. *Id.*

4. *Id.*

5. *Id.*

6. *Id.*

7. *Id.*

8. *Id.*

9. *Id.* at 1374.

noninfringement in Utah.¹⁰ LDG then filed a motion to dismiss for a lack of personal jurisdiction, which the district court granted, citing a lack of sufficient contacts in Utah.¹¹ The district court found that “SnapPower did not demonstrate LDG purposefully directed activities at SnapPower in Utah, or that the action arose out of or related to any LDG activities in Utah” and instead found that “LDG’s allegations of infringement were directed toward Amazon in Washington, where the APEX Agreement was sent.”¹² SP appealed.¹³

Personal jurisdiction has three factors: “(1) whether the defendant ‘purposefully directed’ its activities at residents of the forum; (2) whether the claim ‘arises out of or relates to’ the defendant’s activities with the forum; and (3) whether assertion of personal jurisdiction is ‘reasonable and fair.’”¹⁴ If (1) and (2) are met, jurisdiction is “presumptively reasonable” unless defendant presents a compelling case that makes it otherwise.¹⁵

Here, the Federal Circuit held that specific jurisdiction over LDG in Utah was proper.¹⁶ On factor (1), the court held that LDG, by intentionally submitting the APEX Agreement to Amazon, purposefully directed activities in Utah, knowing that Amazon would notify SP and potential inaction from SP would automatically affect activities in Utah by delisting SP’s products.¹⁷ Submitting the APEX Agreement was also sufficient to meet factor (2); this action “arose out of” LDG’s activities with the forum because the APEX Agreement was directed towards SP in Utah, aimed to affect “marketing, sales, and other activities.”¹⁸ On factor (3), the court held that LDG failed to present a compelling case as the floodgates concern was limited to only APEX and its subsequent allegedly infringing states.¹⁹ Taken together, the court found that LDG’s action satisfied the test for specific personal jurisdiction.²⁰

B. *REGENTS OF THE UNIVERSITY OF CALIFORNIA V. BROAD INSTITUTE*

In *Regents of the University of California v. Broad Institute*, researchers from the University of California and the Broad Institute each alleged that they were the

10. *Id.*

11. *Id.*

12. *Id.*

13. *Id.*

14. *Id.* (citing *Xilinx, Inc. v. Papst Licensing GmbH & Co. KG*, 848 F.3d 1346, 1353 (Fed. Cir. 2017) (internal citations omitted)).

15. *Id.* at 1375 (citing *Xilinx*, 848 F.3d at 1356 (internal citations omitted)).

16. *Id.* at 1378.

17. *Id.* at 1375.

18. *Id.* at 1377.

19. *Id.* at 1378.

20. *Id.*

first to invent a “CRISPR-Cas9 system that contains a ‘single-guide’ RNA that edits or cleaves DNA in eukaryotic cells.”²¹ CRISPR-Cas9, or more colloquially, CRISPR, is a novel method by which researchers can edit cellular DNA.²² Bioengineering labs around the world using CRISPR have had “a revolutionary impact on the life sciences” and have “contribut[ed] to new cancer therapies and may make the dream of curing inherited diseases come true.”²³ For their work on this technology, Jennifer A. Doudna from the University of California, Berkeley and Emmanuelle Charpentier from Max Planck Unit for the Science of Pathogens received the Nobel Prize in Chemistry.²⁴

As a result of both The Regents of the University of California (“Regents”) and Broad Institute (“Broad”) both claiming to be the inventor of CRISPR in various patent applications, the Patent Trial and Appeal Board (PTAB) instituted an interference—an administrative procedure in which the Patent Office determines “which party first invented the commonly claimed invention.”²⁵ In this context, invention is defined by conception or “the formation in the mind of the inventor, of a definite and permanent idea of the complete and operative invention, as it is hereafter to be applied in practice.”²⁶ In the interference proceeding, the PTAB determined that Regents had not proved that they had conceived of CRISPR before Broad because “Regents’ scientists did not know their CRISPR-Cas9 system would produce the effects on genes in a eukaryotic cell.”²⁷

Regents argued that the PTAB erred by “requiring Regents’ scientists to know that their invention would work.”²⁸ The Federal Circuit agreed, holding that “[a]t the conception stage, it is well-established that an inventor need not know that his invention will work for conception to be complete.”²⁹ In the PTAB proceeding, the PTAB relied on “Regents’ scientists’ statements expressing uncertainty about whether the experiments had succeeded” to conclude that the Regents had not conceived of the invention when they

21. *Regents of the Univ. of Cal. v. Broad Inst., Inc.*, 136 F.4th 1367, 1371 (Fed. Cir. 2025).

22. *See id.*

23. Press Release, *Nobel Prize Outreach 2025*, NOBEL PRIZE (Oct. 7, 2020), <https://www.nobelprize.org/prizes/chemistry/2020/press-release/>.

24. *Id.*

25. *Regents*, 136 F.4th at 1375; MPEP § 2301 (9th ed. Rev. 1, 2024).

26. *Regents*, 136 F.4th at 1378 (quoting *Burroughs Wellcome Co. v. Barr Lab’y, Inc.*, 40 F.3d 1223, 1228 (Fed. Cir. 1994)).

27. *Id.*

28. *Id.*

29. *Id.* (quoting *Burroughs*, 40 F.3d at 1228 (internal citations omitted)).

claimed.³⁰ The Federal Circuit distinguished “factual uncertainty that bears on the problem of conception and general uncertainty surrounding experimental sciences” by stating that “[f]actual uncertainty is when the subsequent course of experimentation, especially experimental failures, reveals uncertainty that so undermines the specificity of the inventor’s idea that it is not yet a definite and permanent reflection of the complete invention as it will be used in practice.”³¹ The court found that the PTAB erred by “focusing on Regents’ scientists’ statements of uncertainty, without considering whether those statements led to modifications in their experiments that substantively changed their original idea, when determining whether they had a ‘definite and permanent idea.’”³²

The Federal Circuit found that the PTAB had not used the proper framework for determining conception, vacated the previous decision, and remanded for proper application of the legal framework.³³

II. COPYRIGHT DEVELOPMENTS

A. *WARNER CHAPPELL MUSIC, INC. V. NEALY*

In *Warner Chappell Music, Inc. v. Nealy*, the Supreme Court held that a plaintiff who files a timely copyright infringement claim is entitled to damages and not restricted by when the infringement occurred.³⁴ This decision overrules the previous interpretation of the Copyright Act, which had previously applied the three-year time limit for discovering the infringement to the time period a plaintiff could also collect damages.³⁵

In 1983, Sherman Nealy and Tony Butler formed a short-lived musical collaboration, Music Specialist, Inc., which created the copyrighted works at issue in this case.³⁶ After the collaboration dissolved, Butler licensed the work of Music Specialist, Inc. to Warner Chappell Music, Inc. without Nealy’s knowledge.³⁷ This license resulted in the songs being interpolated and used in many other songs, including one in the popular show “So You Think You Can Dance” (Flo Rida’s “In the Ayer”).³⁸

30. *Id.*

31. *Id.* at 1379 (quoting *Burroughs*, 40 F.3d at 1229 (internal citations omitted)).

32. *Id.* (quoting *Burroughs*, 40 F.3d at 1230).

33. *Id.* at 1382.

34. *Warner Chappell Music, Inc. v. Nealy*, 601 U.S. 366, 374 (2024).

35. *See* 17 U.S.C. § 507(b); *Petrella v. Metro-Goldwyn-Mayer, Inc.*, 572 U.S. 663, 685 (2014).

36. *Warner Chappell Music*, 601 U.S. at 368.

37. *Id.* at 368–69.

38. *Id.* at 369.

In 2018, after discovering Warner Chappell's use of the songs in 2016, Nealy sued Warner Chappell for copyright infringement dating back to 2008.³⁹ Warner argued that even though Nealy's claims were within the three-year discovery period, he could only recover damages from infringing activity that occurred within the last three years.⁴⁰ The District Court for the Southern District of Florida relied on a decision from the Second Circuit⁴¹ and agreed with Warner Chappell that Nealy could not recover money from infringing acts beyond the three years prior to filing the claim.⁴² The Court of Appeals for the Eleventh Circuit reversed, stating Nealy's claims were timely under the discovery rule and there is no time limitation for the recovery of damages.⁴³

Many circuits had used the previous Supreme Court decision, *Petrella v. Metro-Goldwyn-Mayer, Inc.*, to argue in favor of the three-year restriction on damages.⁴⁴ The language in that case, taken out of context, could support the time limit on relief, but the Court clarified that the limitations in *Petrella* on relief were discussed when the plaintiff did not file a timely claim.⁴⁵ In *Petrella*, the plaintiff had known of the defendant's infringement longer than three years and could only file for the infringements that occurred in the three years before her claim.⁴⁶ The Court determined that that is not the situation at issue in this case because the plaintiff filed within three years of discovering the infringement and therefore the claim was timely.⁴⁷

The Supreme Court ultimately concluded that there was no time limit on damages in the Copyright Act or its remedial sections.⁴⁸ Judge Gorsuch's dissenting opinion argued that because the infringement acts took place so long before Nealy's discovery that his claims were untimely, and therefore, he should not be able to recover damages.⁴⁹ The Court's five-three decision affirmed the Eleventh Circuit's opinion that Nealy should be able to recover all damages.⁵⁰

39. *Id.* at 369–70.

40. *Id.* at 370.

41. *See* *Sohm v. Scholastic Inc.*, 959 F.3d 39, 51–52 (2d Cir. 2020).

42. *Warner Chappell Music*, 601 U.S. at 370.

43. *Id.* at 374.

44. *See id.* at 373.

45. *Id.* at 372.

46. *Petrella*, 572 U.S. at 670.

47. *Warner Chappell Music*, 601 U.S. at 374.

48. *See id.*

49. *Id.* at 375 (Gorsuch, J., dissenting).

50. *Id.* at 366.

B. *APPLE INC. V. CORELLIUM, INC.*

Apple Inc. sued Corellium, Inc. in 2019, alleging copyright infringement in Corellium’s virtualization software, CORSEC, that could run iOS on non-Apple hardware.⁵¹ Apple brought three specific claims: (1) direct copyright infringement of iOS, (2) direct copyright infringement of Apple’s icons and wallpapers, and (3) contributory copyright infringement of the aforementioned icons and wallpapers.⁵² The district court granted summary judgment for Corellium on all three claims, finding that fair use protected Corellium’s use.⁵³ After the district court’s summary judgment for Corellium, Apple appealed to the Eleventh Circuit.⁵⁴

In 2023, the Eleventh Circuit affirmed the district court’s finding that Corellium’s use of iOS was protected by fair use but vacated and remanded counts two and three because the district court had not independently analyzed those claims.⁵⁵ Apple’s subsequent petition for rehearing was denied.⁵⁶

In its opinion, the Eleventh Circuit thoroughly analyzed the four statutory fair use factors. First, the court found that CORSEC was “moderately transformative” because it added features not available on iOS that serve security research purposes, including the ability to see and halt running processes, modify the kernel, and take live snapshots.⁵⁷ While acknowledging that Corellium’s use was commercial, the court noted that “many fair uses are commercial” and that “Corellium’s commercial use does little to change [the] analysis” within the first factor.⁵⁸

Second, the court recognized that while iOS’s nature embodies some creativity, it is a “primarily functional” software that falls “‘further . . . from the core of copyright’ than protected works like paintings, movies, and books.”⁵⁹ Third, the court found that Corellium’s copying was “reasonable in relation to the purpose of the copying” and “proportional and necessary to achieve Corellium’s transformative purpose.”⁶⁰ Fourth, the court found “no evidence that [CORSEC] had affected, let alone materially affected, Apple’s

51. *Apple Inc. v. Corellium, Inc.*, No. 21-1283, 2023 WL 3295671 (11th Cir. 2023).

52. *Id.* at *3.

53. *Id.* at *4.

54. *Id.*

55. *Id.* at *1.

56. *Id.*

57. *Id.* at *6.

58. *Id.* at *9.

59. *Id.* at *10 (quoting *Google LLC v. Oracle Am., Inc.*, 593 U.S. 1, 29 (2021)).

60. *Id.* at *13.

market or the market value for iOS.”⁶¹ The court specifically noted that CORSEC is “a poor substitute for iOS on a real iPhone.”⁶²

Corellium establishes an important precedent for security research and the fair use of software. The ruling recognizes that creating virtualization software enabling security researchers to study operating systems constitutes fair use, even when that use is commercial in nature.⁶³ This decision reinforces the notion that copyright law’s fair use doctrine provides important protections for security research that ultimately serves the public interest by improving the security and functionality of widely used software.⁶⁴ The Eleventh Circuit’s reasoning aligns with copyright’s constitutional purpose “to promote the progress of science and useful arts” by allowing transformative uses that advance scientific progress without superseding an original work’s market.⁶⁵

III. TRADE SECRET DEVELOPMENTS

A. PEGASYSTEMS INC. V. APPIAN CORP.

In *Pegasystems Inc. v. Appian Corp.*, the Virginia Court of Appeals reversed a jury verdict with a damage award exceeding \$2 billion, remanding the case for a new trial due to erroneous jury instructions and improper exclusion of evidence.⁶⁶ Appian and Pegasystems are competitors within the business process management (BPM) industry, offering platforms where third-party business customers can build complex software applications to automate their own business functions.⁶⁷ While Pegasystems focused primarily on serving larger companies by offering reliability and scalability, Appian’s platform emphasized a user-friendly experience through ease-of-use and simplicity.⁶⁸ Here, Appian alleged Pegasystems misappropriated trade secrets to imitate Appian’s user-friendly features.⁶⁹ Pegasystems did not have direct access to Appian’s platform because it was not made publicly available without license terms.⁷⁰ To bypass this control and maintain secrecy, Pegasystems’s head of intelligence, John Petronio, hired consultant Youyong Zou, who had access to Appian’s platform through his job and provided 200 hours of consultation,

61. *Id.* at *12.

62. *Id.*

63. *See id.* at *9–10.

64. *See id.* at *10.

65. U.S. CONST. art. I, § 8, cl. 8; *see Apple v. Corellium*, 2023 WL 3295671, at *12.

66. *Pegasystems Inc. v. Appian Corp.*, 81 Va. App. 433, 448, 508 (2024).

67. *Id.* at 449.

68. *Id.* at 449–50.

69. *Id.* at 450.

70. *Id.* at 450.

including nearly 100 videos demonstrating the platform's features and analyzing their strengths and weaknesses.⁷¹ In 2015, Petronio left Pegasystems and was later hired by Appian as a consultant, eventually revealing the illicit activities he undertook at Pegasystems, leading to the dispute at issue.⁷²

Appian sued under the Virginia Uniform Trade Secrets Act (VUTSA)⁷³ and the Virginia Computer Crimes Act,⁷⁴ claiming Pegasystems misappropriated trade secrets and confidential documentation.⁷⁵ Key points of dispute between the parties included whether the information constituted a trade secret, as determined by whether adequate secrecy was maintained; whether Pegasystems's improvements were the result of corporate espionage or independently developed; admissibility of evidence; and the method of determining damages.⁷⁶ At trial, the jury returned a verdict for Appian, finding Pegasystems and Zou misappropriated trade secrets in violation of VUTSA and awarded \$2,036,860,045 in damages—the largest damage award in Virginia's history—plus attorney fees, costs, and interest.⁷⁷ The trial court denied Pegasystems's motions to strike the evidence and set aside the verdict, as well as Pegasystems's request for a new trial subject to remittitur.⁷⁸ Pegasystems subsequently appealed.⁷⁹

1. *Motion to Strike and Set Aside the Verdict*

First, the Court of Appeals affirmed the trial court's denial of Pegasystems's motions to strike and set aside the verdict.⁸⁰ The court rejected Pegasystems's arguments that (1) “none of Appian's purported secrets were trade secrets as a matter of law because they exposed them without requiring confidentiality” and (2) “Appian did not identify key trade secrets with requisite particularity,” instead asserting these issues were “questions for the factfinder.”⁸¹ When addressing the first argument, the court emphasized that Virginia does not require “absolute secrecy,” but rather permits licensing and disclosures “made in confidence.”⁸² Furthermore, the court noted that there

71. *Id.* at 449–51.

72. *Id.* at 452.

73. VA. STAT. § 59.1-336–343.

74. VA. CODE § 18.2–152.1.

75. *Pegasystems*, 81 Va. App. at 452, 454–55.

76. *Id.* at 455–62.

77. *Id.* at 448, 463.

78. *Id.* at 463.

79. *Id.* at 463.

80. *Id.* at 476.

81. *Id.* at 464–65.

82. *Id.* at 466 (quoting *Dionne v. SE Foam Converting & Packaging, Inc.*, 240 Va. 297, 302 (1990)).

was “considerable evidence that [Appian] took careful steps to safeguard its secrets,” including the use of license agreements, restricted access to documentation, firewalls, multifactor authentication, encryption, user authentication, and password change requirements.⁸³ In response to the particularity argument, the court noted Appian’s expert witness provided testimony for almost three days, which resulted in over 800 transcript pages, providing sufficient detail about the trade secrets Pegasystems was accused of misappropriating.⁸⁴ Consequently, the court found the cause of action was sufficient to survive a motion for judgment as a matter of law, drawing all reasonable inferences in favor of Appian, the non-moving party, thus, the trial court did not err in its denial.⁸⁵

2. *Jury Instructions*

Second, the Court of Appeals rejected the trial court’s instructions to the jury regarding the burden of proving proximate causation, thus leading to a reversal and remand for a new trial.⁸⁶ The instruction in question shifted the burden of proof such that Appian was only required to prove misappropriation of a trade secret and Pegasystems’s total sales revenue rather than proving the misappropriation of trade secrets was the proximate, or “but-for,” cause of Pegasystems’s sales.⁸⁷ As a result of the erroneous jury instruction, the burden shifted to Pegasystems to prove what portion of the sales were not attributable to the allegedly misappropriated trade secrets.⁸⁸ In other words, Appian only had to establish Pegasystems was enriched rather than the higher burden of proving “unjust enrichment.”⁸⁹ The burden-shifting approach utilized by the trial court contravened both the statute and Virginia’s jurisprudence.⁹⁰ The court emphasized that even under the Restatement, only after the plaintiff has established sales causation does the burden shift to the defendant to raise other considerations, such as expenses to be deducted from revenues and the apportionment of sales resulting from misappropriated information relative to “just” profits.⁹¹

83. *Id.* at 469.

84. *Id.* at 475.

85. *Id.* at 466–67, 472, 476.

86. *Id.* at 476.

87. *Id.* at 477, 479.

88. *Id.* at 477.

89. *Id.* at 479.

90. *Id.* at 479–81; VA. CODE § 59.1-338(A); *see Hale v. Fawcett*, 214 Va. 583, 585–86 (1974).

91. *Pegasystems*, 81 Va. App. at 483–84.

3. *Exclusion of Evidence*

Finally, the Court of Appeals ruled that the trial court abused its discretion in excluding evidence relevant to damages and causation as well as Pegasystems's software evidence.⁹² The exclusion of evidence that would have aided Pegasystems in demonstrating that over 50% of its sales revenue was attributable to unrelated products was excluded by the trial court due to an incorrect interpretation of an interrogatory, in which the court conflated "products" and "versions" of the same product rather than distinguishing them.⁹³ As a result, Pegasystems was essentially prohibited from providing a breakdown of its revenue by product line.⁹⁴ This led to a much higher damage award than appropriate, particularly when combined with the erroneous burden-shifting instruction provided by the trial court.⁹⁵ During the trial, Pegasystems also sought to introduce a copy of the software at issue to demonstrate versions of the software to the jury.⁹⁶ The court denied this request, stating the laptop Pegasystems proposed to use was not the same laptop that had been provided to Appian during discovery.⁹⁷ In assessing whether the trial court abused its discretion, the Court of Appeals emphasized that Appian had been allowed to show the software on a different laptop, Pegasystems had exhibited the ability to authenticate the software, and Appian attacked Pegasystems during closing arguments for not presenting software evidence while arguing to the jury.⁹⁸ The Court of Appeals found no justification for the exclusion of the evidence in question, thus necessitating a new trial.⁹⁹

Although not at issue on appeal, the court also provided direction regarding the trial court's instruction to the jury that the number of people with access to Appian's platform was not relevant.¹⁰⁰ The court emphasized that while user numbers alone are not determinative, it is relevant, being emphasized in both prior jurisprudence and the Restatement of Torts.¹⁰¹ Consequently, the court directed that Appian's requested jury instruction

92. *Id.* at 491–92, 495.

93. *Id.* at 488–89.

94. *Id.* at 489.

95. *Id.* at 492.

96. *Id.* at 500.

97. *Id.* at 494–95.

98. *Id.* at 494–95, 501.

99. *Id.* at 491.

100. *Id.* at 501.

101. *Id.* at 504–05; *see* *SI Handling Sys., Inc. v. Heisley*, 753 F.2d 1244, 1256 (3d Cir. 1985); Restatement (First) of Torts § 757 cmt. b (1939).

regarding the irrelevance of evidence about the number of users should not be granted.¹⁰²

IV. PRIVACY AND CYBERLAW DEVELOPMENTS

A. *MURTHY V. MISSOURI*

In *Murthy v. Missouri*, the Supreme Court reversed a Fifth Circuit decision regarding First Amendment rights and the misinformation on social media, holding that “neither the individual nor the state plaintiffs have established standing to seek an injunction against any defendant.”¹⁰³

Social media platforms like Meta have long been targeting harmful speech and misinformation, and they continued during the COVID-19 pandemic and the 2020 Presidential Election.¹⁰⁴ The White House publicly asked the platforms to work to address COVID-19 misinformation and brought up the possibility of making legal reforms aimed at the platforms.¹⁰⁵ The CDC worked with these platforms by sending reports alerting them to misinformation and providing fact checks to the platforms on claims about the pandemic.¹⁰⁶ Similarly, the FBI and Cybersecurity and Infrastructure Security Agency (CISA) communicated with the platforms about misinformation relating to the 2020 election, warning of potential Russian interference.¹⁰⁷

The States of Missouri and Louisiana alleged that the platforms suppressed the speech of state entities, officials, and citizens.¹⁰⁸ The individual plaintiffs included doctors who questioned COVID-19 policies and received restrictions in 2020 on social media prior to the White House and CDC entering discussions with those platforms.¹⁰⁹ An individual, Jim Hoft, joined the suit because he claimed the CISA was tracking and restricting his content through X.¹¹⁰ However, X suspended his brother’s account, not his own.¹¹¹ Jill Heins hosted Heath Freedom groups on Facebook, which were demoted and deleted, allegedly in connection with the suggestions given to Meta by the White House.¹¹²

102. *Pegsystems*, 81 Va. App. at 507.

103. *Murthy v. Missouri*, 603 U.S. 43, 56 (2024).

104. *Id.* at 50–51.

105. *Id.* at 52.

106. *Id.* at 53.

107. *Id.*

108. *Id.*

109. *Id.* at 63.

110. *Id.* at 64.

111. *Id.*

112. *Id.* at 65.

When plaintiffs filed suit, the district court issued a preliminary injunction, holding that the government agencies likely “coerced” or “significantly encouraged” the platforms to make the moderation decisions that harmed the plaintiffs.¹¹³ The Fifth Circuit agreed, reviewing the defendants’ alleged coercive behavior and the district court’s standing analysis.¹¹⁴ The Fifth Circuit determined that all the government agencies at issue significantly encouraged or exercised “active, meaningful control” in the moderation, while only the White House officials, Surgeon General’s office, and FBI coerced by implying “some form of punishment” would follow noncompliance.¹¹⁵

On review, the Supreme Court rejected that any plaintiffs had established standing to seek an injunction against any defendant.¹¹⁶ The Court noted that Article III standing requires that a plaintiff show “that she has suffered, or will suffer, an injury that is “concrete, particularized, and actual or imminent; fairly traceable to the challenged action; and redressable by a favorable ruling.”¹¹⁷ The plaintiffs’ claims related to the censorship of their speech or, in the case of the states, their “right to listen” to their citizens.¹¹⁸ However, the plaintiffs were not seeking relief from the platforms that censored them—rather they were seeking an injunction against the government.¹¹⁹ The Court analyzed each plaintiff’s claims and found that none had standing because of a lack of “any concrete link between their injuries and the defendants’ conduct” and because the plaintiffs sought “only forward-looking relief” and provided only evidence of past injuries.¹²⁰ The Court reversed and remanded the decision.¹²¹

The dissent sees this case as a crucial free speech case being wrongly decided because the coercion from the government was sophisticated.¹²² The plaintiffs provided many instances where Meta was pressured by the Surgeon General’s Office and other government entities.¹²³ The communications from the government could be seen as containing “thinly veiled threats” to Meta if they were not compliant.¹²⁴ The dissent disagreed that no plaintiffs had

113. *Missouri v. Biden*, 680 F. Supp. 3d 630, 694, 729 (W.D. La. 2023).

114. *See generally* *Missouri v. Biden*, 83 F.4th 350 (5th Cir. 2023).

115. *Id.* at 377, 380, 388, 389, 391.

116. *Murthy*, 603 U.S. at 56.

117. *Id.* at 57 (quoting *Clapper v. Amnesty Int’l USA*, 568 U.S. 398, 409 (2013) (internal citations omitted)).

118. *Id.*

119. *Id.*

120. *Id.* at 58–59, 76.

121. *Id.* at 76.

122. *Id.* at 80 (Alito, J., dissenting).

123. *Id.* at 79–88 (Alito, J., dissenting).

124. *Id.* at 102–03 (Alito, J., dissenting) (citing *Bantam Books, Inc. v. Sullivan*, 372 U.S. 58, 68 (1963)).

standing, believing that Jill Hines did.¹²⁵ Hines demonstrated that the conduct of the officials in question was a factor leading to her censoring and the dissent saw this relationship as likely casual unlike the majority.¹²⁶ The dissent also believed that because Hines' censorship continued after suing, it passes the test of assuming future injury.¹²⁷

B. *NATIONAL RIFLE ASSOCIATION OF AMERICA V. VULLO*

The National Rifle Association (NRA) sued Maria Vullo, former superintendent of the New York Department of Financial Services (DFS), alleging that Vullo violated the First Amendment rights of NRA by coercing DFS-regulated parties to punish or suppress the NRA's gun-promotion advocacy.¹²⁸ Vullo then filed a motion to dismiss, which was denied.¹²⁹ The Court of Appeals for the Second Circuit then reversed and remanded.¹³⁰ NRA then appealed the Supreme Court, which granted Certiorari.¹³¹

The NRA, as a benefit of membership, offered insurance policies such as "Carry Guard," which insured gun owners against from intentional criminal acts.¹³² NRA promoted Carry Guard without the required insurance producer license.¹³³ Chubb Limited ("Chubb") and Lloyd's of London ("Lloyd's") underwrote this policy.¹³⁴ In the context of the Parkland shooting, DFS issued guidance letters to evaluate insurance companies' risks dealing with NRA, review any relationships with the NRA, and take prompt actions to manage these risks and promote public health and safety.¹³⁵ DFS then entered consent decrees and enforced insurance law violations against Chubb and Lloyd's, in which they admitted to violations of law, agreed to pay fines, and agreed not to provide any NRA-endorsed insurance programs.¹³⁶

The Supreme Court on appeal sought to answer whether the factual allegations of the NRA complaint, if true, constructed a plausible scenario that Vullo engaged in conduct that could be "reasonably understood to convey a

125. *Id.* at 98 (Alito, J., dissenting).

126. *Id.* (Alito, J., dissenting).

127. *Id.* at 92. (Alito, J., dissenting).

128. *Nat'l Rifle Ass'n of Am. v. Vullo*, 602 U.S. 175, 180–81 (2024).

129. *Id.* at 181.

130. *Id.* at 186.

131. *Id.*

132. *Id.* at 181.

133. *Id.* at 181–82.

134. *Id.* at 182.

135. *Id.* at 176, 182.

136. *Id.* at 176.

threat of adverse government action in order to punish or suppress the plaintiff's speech."¹³⁷

The alleged facts are as follows: Vullo conducted private meetings with DFS regulated entities, particularly with Lloyd's.¹³⁸ Vullo cited insurance-law violations of Lloyd's and said that if they were to cease in providing insurance to pro-gun groups such as the NRA, DFS would be "less interested in pursuing the infractions" and Vullo would focus her enforcement actions "solely" on the syndicates with ties to the NRA.¹³⁹ Lloyd's then instructed its syndicates to terminate existing agreements with the NRA and publicly announced its decision to cut ties with the NRA.¹⁴⁰

Here, the Court held that the alleged facts were sufficient to demonstrate Vullo's violation of the First Amendment rights of NRA.¹⁴¹ Under *Bantam Books*, a government official may not indirectly do what she could not directly do—using governmental powers to coerce insurance companies and effectively suppress NRA activity in this case.¹⁴² Three contextual factors constituted coercion: (1) Vullo's authority and power to enforce and regulate insurance companies in New York, (2) Vullo's alleged communications with DFS-regulated entities, and (3) the reaction of Lloyd's to cease underwriting firearm-related policies, scale back its NRA related business, and terminate all insurance policies related to the NRA.¹⁴³ Taken together, the Court held that Vullo's communications with Lloyd's can be "reasonably understood as . . . coercive."¹⁴⁴ The complaint, when "assessed as a whole" plausibly alleged that Vullo violated the First Amendment by threatening to use her power against those refusing to aid in her push to punish NRA's advocacy.¹⁴⁵ The Court vacated the Second Circuit's opinion and remanded for further proceedings.¹⁴⁶

C. GEOFENCE WARRANTS & REVERSE KEYWORD WARRANTS

The increasing use and people's diverging opinions about geofence warrants sparked a split between the Fourth and Fifth Circuits over their constitutionality under the Fourth Amendment. Geofence warrants compel information about anyone whose mobile device located them within a

137. *Id.* at 191.

138. *Id.* at 192.

139. *Id.*

140. *Id.* at 193.

141. *Id.* at 198.

142. *Id.* at 190 (citing *Bantam Books*, 372 U.S. at 67–69).

143. *Id.* at 189–91.

144. *Id.* at 193.

145. *Id.* at 194.

146. *Id.* at 199.

geographic area during a specific time.¹⁴⁷ Unlike traditional warrants, geofence warrants seek to identify suspects based on geographic and temporal circumstances, rather than requesting information about known suspects.¹⁴⁸

In *United States v. Chatrie*, the Fourth Circuit held that geofence warrants do not constitute a Fourth Amendment search under the third-party doctrine.¹⁴⁹ The Court reasoned that since users must opt-in to Location History collection,¹⁵⁰ maintain some control over the data,¹⁵¹ and voluntarily provide the data to Google,¹⁵² the defendant therefore lacked a reasonable expectation of privacy.¹⁵³

Conversely, in *United States v. Smith*, the Fifth Circuit ruled that geofence warrants are unconstitutional modern-day general warrants, but applied the good-faith exception to allow the warrant in this instance.¹⁵⁴ The court criticized geofence warrants as “general, exploratory rummaging” prohibited by the Fourth Amendment, because they target “anything or everyone in sight” and not a specific individual.¹⁵⁵ Moreover, the court found that the defendant had an expectation of privacy in just a few hours of location data, given the data’s intrusive nature and that cell phones which collect location data are essential in modern life.¹⁵⁶ The Court rejected the third-party doctrine because users are “hardly informed” about forfeiting their Fourth Amendment rights when opting-in to Location History, especially when encouraged to do so across multiple apps.¹⁵⁷

In November 2024, *Chatrie* was granted a rehearing,¹⁵⁸ potentially leading to a ruling more aligned with *Smith*. The new ruling may also consider Google’s policy change to store location data on users’ devices instead of Google data centers, making this data unavailable for Google to comply with geofence warrants.¹⁵⁹

147. *Reverse Search Warrants*, NAT’L ASS’N OF CRIM. DEF. LAWS., <https://www.nacdl.org/Landing/Reverse-Search-Warrants> (last visited Apr. 19, 2025).

148. *Id.*

149. *United States v. Chatrie*, 107 F.4th 319, 339 (4th Cir. 2024).

150. *Id.* at 322.

151. *Id.* at 323.

152. *Id.* at 322, 325–26.

153. *Id.* at 330.

154. *United States v. Smith*, 110 F.4th 817, 820, 840 (5th Cir. 2024).

155. *Id.* at 836–37.

156. *Id.* at 827, 832–33.

157. *Id.* at 823, 835–36.

158. *United States v. Chatrie*, No. 22-4489, 2024 WL 4648102 (4th Cir. Nov. 1, 2024).

159. Mario McGriff, *Updates to Location History and New Controls Coming Soon to Maps*, GOOGLE BLOG (Dec. 12, 2023), <https://blog.google/products/maps/updates-to-location-history-and-new-controls-coming-soon-to-maps/>.

Similarly, reverse keyword warrants raise constitutional questions regarding users' search histories. Like geofence warrants, reverse keyword warrants compel search histories from all users who searched specific terms within a defined timeframe, before suspects are identified.¹⁶⁰

Only the Colorado Supreme Court has ruled on reverse keyword warrants. In *People v. Seymour*, Colorado held that the defendant had a reasonable expectation of privacy in his searches, but found the warrant sufficiently particularized based on narrow search terms, time frame constraints, and initial anonymization of results.¹⁶¹ The Court also applied the good-faith exception given the search's unprecedented nature.¹⁶² The Court did not apply the third-party doctrine because the Colorado Constitution provides stronger privacy protections.¹⁶³ *Seymour* thus echoes aspects of both *Chatrue* and *Smith*. Like location data in *Chatrue*, the *Seymour* Court suggests that the third-party doctrine may apply to search history data since users voluntarily submit queries to third-party search engines.¹⁶⁴ Like *Smith*, *Seymour* found both an expectation of privacy in the data and applied the good-faith exception to a novel law enforcement practice.¹⁶⁵

Ultimately, considerable uncertainty remains for the constitutionality of both geofence and reverse keyword warrants, given the circuit split on geofence warrants, and that reverse keyword warrants have yet to be examined in federal court.

D. *MEDICAL IMAGING & TECHNOLOGY ALLIANCE V. LIBRARY OF CONGRESS*

The United States Court of Appeals for the District of Columbia Circuit vacated and remanded a motion to dismiss in the District Court for the District of Columbia.¹⁶⁶ The Court of Appeals considered the question: Are rules for copyright under the Digital Millennium Copyright Act (DMCA) reviewable under the Administrative Procedure Act (APA)?¹⁶⁷ The Court said yes.¹⁶⁸

The DMCA anti-circumvention laws protect digital media from infringement.¹⁶⁹ At the same time, these laws make non-infringing uses harder

160. *Reverse Search Warrants*, *supra* note 147.

161. *People v. Seymour*, 536 P.3d 1260, 1267, 1270 (Colo. 2023).

162. *Id.* at 1278–79.

163. *Id.* at 1272.

164. *Id.*

165. *Id.* at 1272.

166. *Med. Imaging & Tech. All. v. Libr. of Cong.*, 103 F.4th 830, 841 (D.C. Cir. 2024).

167. *Id.* at 833.

168. *Id.*

169. *Id.*

through the prevention of access.¹⁷⁰ The Library of Congress has a process for addressing copyright issues that involves submitting applications to the Register of the Copyright Office.¹⁷¹ The Register evaluates several factors, including the proposed use, its impact on fair use, and its effect on the market, before making a recommendation to the Librarian of the Library of Congress.¹⁷² The plaintiffs are trade associations representing medical device manufacturers for devices such as MRI machines and surgery-assisting robots.¹⁷³ These companies have previously pushed against access to their software by third parties.¹⁷⁴ Independent service operations petitioned the Copyright Office for an exemption to the DMCA's anti-circumvention provision, claiming it was fair use to access information on repairs because, without them, they couldn't do their necessary duties during the pandemic.¹⁷⁵ The Register recommended the Library grant this exemption because they were fair uses that the provision was negatively impacting, such as the diagnosis and maintenance of medical devices and systems.¹⁷⁶

The District Court held that APA claims were barred by the Library of Congress's sovereign immunity.¹⁷⁷ However, the Court determined DMCA rules, like any copyright rules, are subject to the APA.¹⁷⁸ The APA governs copyright decisions meaning the DMCA rules are subject to the APA and should be seen *in pari materia*, or "as if they were one law."¹⁷⁹ Because the APA applies, there is, therefore, no sovereign immunity barring the claims.¹⁸⁰ Courts have the power to provide judicial review on administrative actions.¹⁸¹ While Congress could withhold that review, that is not the case here because there is no indication Congress would want the Librarian and Register to not have their power checked by judicial review.¹⁸² While the defense argues that the Library of Congress is free from judicial review, Title 17 specifies that the APA applies to "all actions taken by the Register of Copyrights."¹⁸³ The defense's argument that the Register's analysis isn't final was seen as too extreme a statutory

170. *Id.* at 834.

171. *Id.*

172. *Id.*

173. *Id.*

174. *Id.* at 835.

175. *Id.*

176. *Id.*

177. *Id.* at 833.

178. *Id.*

179. *Id.* at 837; *United States v. Freeman*, 44 U.S. 556, 564 (1845).

180. *Med. Imaging*, 103 F.4th at 838.

181. *Id.* at 839.

182. *Id.*

183. *Id.*; 17 U.S.C. § 701(e).

interpretation because it could make all copyright regulations free from judicial review, as the Registers tend to just make recommendations.¹⁸⁴

The Court vacated the judgment and remanded the case “to consider the merits of the APA claims in the first instance.”¹⁸⁵

E. ILLINOIS BIOMETRIC INFORMATION PRIVACY ACT

In August 2024, Illinois Governor Pritzker signed amendments to sections 15(b) and 15(d) of the Illinois Biometric Information Privacy Act to prohibit companies from collecting a person’s biometric information multiple times in the same manner.¹⁸⁶ However, the Act also prohibits plaintiffs from receiving damages for each individual violation.¹⁸⁷ The amendments specifically came about from the dispute in *Cothron v. White Castle System, Inc.*, where the Illinois Supreme Court found that using the same collection method for biometric collection data, even multiple times, is considered multiple violations.¹⁸⁸

The question certified to the court in *Cothron* was whether section 15(b) and 15(d) claims accrue each time a private entity scans a person’s biometric identifier and each time a private entity transmits such a scan to a third party, respectively, or only upon the first scan and first transmission.¹⁸⁹ To answer this question, the court assumed that the defendant, White Castle System, had violated the rights of the plaintiff, a manager of a White Castle restaurant in Illinois, under the Illinois Biometric Information Privacy Act.¹⁹⁰ The alleged violation resulted from not explicitly obtaining the Plaintiff’s consent to a biometric-collection system.¹⁹¹ Specifically, White Castle required its employees to scan their fingerprints to access their pay stubs and computers, leading to the cause of action.¹⁹²

Cothron argued that the “plain meaning of the statutory language” demonstrated that claims under sections 15(b) and 15(d) accrue every time a private entity collects or disseminates biometrics without prior informed consent.¹⁹³ In particular, the plaintiff asserted that the use of the word “first”

184. *Med. Imaging*, 103 F.4th at 841.

185. *Id.* at 841–42.

186. Ian Fisher, Gillian Lindsay & Elizabeth Babbitt, *Illinois BIPA Reform Offers Welcome Relief to Businesses*, LAW360 (Aug. 12, 2024), <https://www.law360.com/articles/1868530/illinois-bipa-reform-offers-welcome-relief-to-businesses>.

187. *Id.*

188. *Cothron v. White Castle Sys., Inc.*, 2023 IL 128004, at 918, 920 (Ill. 2023).

189. *Id.* at 922.

190. *Id.* at 920.

191. *Id.*

192. *Id.*

193. *Id.* at 923.

in section 15(b) modifies the words “informs” and “receives.”¹⁹⁴ White Castle argued that the sections focused on the consent, which would only pertain to the “first instance” of disclosure or dissemination.¹⁹⁵

The Illinois Supreme Court sided with Cothron, holding that the plain language of sections 15(b) and 15(d) demonstrates that violations occur with every scan or transmission, instead of just at the first instance.¹⁹⁶ However, the court limited the damages plaintiffs can receive to the first violation to prevent “the financial destruction of a business.”¹⁹⁷

In the context of the holding of Cothron, the amendments to the Illinois Biometric Information Privacy Act recognize individual privacy protection but also incorporate protections for businesses. These amendments are important because Illinois is the first state to have a biometric data privacy law. Many other states have and will continue to look to Illinois as an example of how to implement privacy laws as new developments arise to better protect their constituents’ data while balancing the needs of corporations.

F. EUROPEAN UNION ARTIFICIAL INTELLIGENCE ACT

Some believe the EU’s regulation of artificial intelligence at the initial level in accordance with the *precautionary principle* will prevent further development of AI systems in the EU marketplace.¹⁹⁸ This blurb will discuss the relevant articles of the Act in the context of the ultimate spirit of the EU legislation.

1. *What AI Systems Are Prohibited?*

To show that it prioritizes the safety of its own citizens, the EU has banned some AI models.¹⁹⁹ Some of the banned AI practices include “deploying subliminal, manipulative, or deceptive techniques to distort behavior and impair informed decision-making, causing significant harm, . . . evaluating or classifying individuals/groups based on social behavior or personal traits, causing detrimental or unfavorable treatment of those people (“social

194. *Id.*

195. *Id.*

196. *Id.* at 926.

197. *Id.* at 929.

198. *The Precautionary Principle: Definitions, Applications and Governance*, EUR. PARLIAMENT THINK TANK (Sep. 12, 2015), [https://www.europarl.europa.eu/thinktank/en/document/EPRS_IDA\(2015\)573876](https://www.europarl.europa.eu/thinktank/en/document/EPRS_IDA(2015)573876).

199. *EU AI Act, Article 5: Prohibited AI Practices*, FUTURE OF LIFE INST. (Feb. 2, 2025), <https://artificialintelligenceact.eu/article/5/>.

scoring”), . . . and inferring emotions in workplaces or educational institutions, except for medical or safety reasons.”²⁰⁰

2. *Risk Categories*

The AI Act mentions three categories of risks associated with AI systems: (1) unacceptable,²⁰¹ (2) high,²⁰² (3) limited. AI systems that compromise basic rights or safety will be categorized as high risk and fall into one of two groups: “(1) AI systems that are used in products falling under the EU’s product safety legislation. This includes toys, aviation, cars, medical devices and lifts,”²⁰³ and “(2) AI systems falling into specific areas that will have to be registered in an EU database, such as law enforcement, and assistance in legal interpretation and application of the law.”²⁰⁴

To regulate high-risk AI systems, the AI Act determines standards such as establishing risk management systems,²⁰⁵ conducting data governance,²⁰⁶ record keeping,²⁰⁷ human oversight,²⁰⁸ and implementing cybersecurity measures throughout the lifecycle of the AI system.²⁰⁹

3. *Extraterritoriality and Enforcement*

Despite not being enshrined in a single article, General Protection Data Regulation-style extraterritoriality gives the AI Act worldwide impact.²¹⁰ The Act is essentially a global standard because non-EU suppliers are required to abide by the standard if their products are used inside the Union.²¹¹ Moreover,

200. *High-Level Summary of the AI Act*, FUTURE OF LIFE INST. (Feb. 27, 2024), <https://artificialintelligenceact.eu/high-level-summary/>.

201. Regulation (EU) 2024/1689, of the European Parliament and of the Council of 13 June 2024 on Laying Down Harmonised Rules on Artificial Intelligence and Amending Regulations (EC) No 300/2008, (EU) No 167/2013, (EU) No 168/2013, (EU) 2018/858, (EU) 2018/1139 and (EU) 2019/2144 and Directives 2014/90/EU, (EU) 2016/797 and (EU) 2020/1828 (Artificial Intelligence Act), 2024 O.J. (L) Preamble ¶¶ 26, 31, 46, 179 [hereinafter EU AI Act]. The examples of the unacceptable risk AI models are also mentioned as prohibited AI models.

202. EU AI Act, art. 6, 2024 O.J. (L) 53–54.

203. *EU AI Act: First Regulation on Artificial Intelligence*, EUR. PARLIAMENT: TOPICS (Feb. 19, 2025), <https://www.europarl.europa.eu/topics/en/article/20230601STO93804/eu-ai-act-first-regulation-on-artificial-intelligence#ai-act-different-rules-for-different-risk-levels-6>.

204. *Id.*

205. EU AI Act, art. 9, 2024 O.J. (L) 56–57.

206. EU AI Act, art. 10, 2024 O.J. (L) 57–58.

207. EU AI Act, art. 12, 2024 O.J. (L) 59.

208. EU AI Act, art. 14, 2024 O.J. (L) 60–61.

209. EU AI Act, art. 15, 2024 O.J. (L) 61.

210. EU AI Act, art. 2, 2024 O.J. (L) 45–46; *see* General Data Protection Regulation, INTERSOFT CONSULTING, <https://gdpr-info.eu/> (last visited May 14, 2025).

211. EU AI Act, art. 2, 2024 O.J. (L) 45–46.

the enforcement of the Act is based on a decentralized model: The EU AI Office²¹² handles cross-border cases, while notifying authorities²¹³ oversee compliance.²¹⁴

4. Sandboxes

The most innovative element of the Act, Article 57, creates pan-EU regulatory sandboxes that enable startups to trial AI systems with supervisory oversight.²¹⁵ In contrast to fintech sandboxes aimed at market entry, these prioritize ethical experimentation; participants are required to show compliance with basic rights, even though they are exempt from certain technical standards.

5. Noncompliance and Enforcement

Finally, the EU AI Act creates strict compliance standards and costly consequences for noncompliance.²¹⁶ Depending on the type of noncompliance or violation, penalties can range from EUR 7.5 million, or 1.5 percent of global annual sales, to EUR 35 million, or 7 percent of global annual turnover.²¹⁷

G. ARTIFICIAL INTELLIGENCE, INVENTORSHIP, AND AUTHORSHIP

Over the last year, both the U.S. Patent and Trade Office (USPTO) and U.S. Copyright Office (USCO) have issued memoranda regarding the use of artificial intelligence in patented and copyrighted works in response to the growing use of artificial intelligence.

1. USPTO Guidelines on AI Inventorship

On February 13, 2024, in response to the rise of artificial intelligence (AI) aided inventions, the USPTO published guidelines on AI-related inventorship.²¹⁸ Citing *Thaler v. Vidal*, where the court held that only a natural person can be an inventor, the USPTO reiterated that AI alone does not qualify as an inventor.²¹⁹ The guidelines addressed whether inventions developed with AI assistance are eligible for patent protection when listed as joint inventors.²²⁰

212. EU AI Act, art. 3, 2024 O.J. (L) 46–50.

213. *Id.*

214. EU AI Act, art. 55, 2024 O.J. (L) 86.

215. EU AI Act, art. 57, 2024 O.J. (L) 88–89.

216. EU AI Act, art. 99, 2024 O.J. (L) 115–16.

217. *Id.* ¶ 3.

218. 2024 Guidance Update on Patent Subject Matter Eligibility, Including on Artificial Intelligence, 89 Fed. Reg. 58128 (Jul. 17, 2024) [hereinafter USPTO AI Guidance].

219. *Id.*; see *Thaler v. Vidal*, 43 F.4th 1207, 1213 (Fed. Cir. 2022).

220. See generally USPTO AI Guidance.

The USPTO stated that if one or more natural—meaning human—persons “significantly contributed” to the invention, the invention can be patentable, even if AI was instrumental in the creation of such, with one caveat.²²¹ A human must have contributed significantly to every claim on the patent.²²²

The USPTO guidelines established several specific criteria: (1) Recognizing a problem and having a general goal or research plan is not sufficient conception; not a significant contribution.²²³ However, if prompting particularly for a specific solution for a specific problem, it may be considered more significant.²²⁴ (2) Appreciating an inventive property of an AI output is not as significant if it is apparent to a person having ordinary skill in the art (PHOSITA).²²⁵ However, if one applies the output to significantly contribute to an invention, it may be proper.²²⁶ (3) While merely overseeing the AI system is not an invention, if the AI system is built, designed, or trained in view of a specific problem and solution, it could be considered a significant contribution.²²⁷

2. USCO Guidelines on AI Authorship

Similarly to USPTO, the United States Copyright Office (USCO) issued guidance on AI-generated material reiterating the human authorship requirement.²²⁸ The USCO cites both *Thaler v. Perlmutter*, as well as the 1973 Compendium of Copyright Office Practices, both of which indicate that the term “author” excludes nonhumans.²²⁹ Consequently, a work produced solely by AI cannot be copyrighted.²³⁰

The USCO also states that if the work’s traditional elements were produced by machine, it lacks human authorship; if the machine determines how instructions are carried out, it would not be protected.²³¹ However, if a work has sufficient human authorship, only the human authored aspects,

221. *Id.*

222. *Id.*

223. *Id.*

224. *Id.*

225. *Id.*

226. *Id.*

227. *Id.*

228. Copyright Registration Guidance: Works Containing Material Generated by Artificial Intelligence, 88 Fed. Reg. 16190–94 (Mar. 16, 2023) (to be codified at 37 C.F.R. pt. 202).

229. *Id.* (citing *Thaler v. Perlmutter*, No. 1:22-cv-01564 (D.D.C.), currently *Thaler v. Perlmutter*, 130 F.4th 1039 (D.D.C. 2025)).

230. *Id.*

231. *Id.*

independent of the whole work, are protected and the AI-generated material itself is still unprotected.²³²

The USCO recommends that for submitting registration, indicate which parts of works are created by the author and which are generated by AI, without necessarily specifying the particular AI program used.²³³

3. *Conclusion*

Taken together, the general trend in AI and its usage-legality seems positive based on form; as long as there is some significant contribution or at least human authorship in the work's traditional elements, AI usage has potential pathways to be protected works of both inventors and artists in the near future.

4. *Doe v. Github*

Here, various software developers who submitted their code to GitHub publicly sued GitHub and OpenAI regarding the development of Codex and Copilot programs, alleging breaches of contract, fraud, torts, and statutory violations.²³⁴ Codex and Copilot programs were developed by OpenAI using machine learning from data scraped from various public sites, including GitHub, to come up with the best code solution to a prompted problem.²³⁵ However, when producing the solution, the resulting output misattributed copyrights, notices, and license terms, violating the open-source licenses of possibly millions of software developers who have published their code on GitHub.²³⁶

As for claims of privacy and property right violations, the court held that while the alleged harms were not particularized enough to the plaintiffs to award the plaintiffs' damages, they still have standing to pursue injunctive relief.²³⁷ For many allegations, the court granted leave to amend due to insufficient specific facts in the pleadings, while dismissing claims for civil conspiracy and declaratory relief as they were not independent causes of action.²³⁸

While inconclusive at this time, this case represents an important overarching problem in the development of AI: When data is trained upon licensed data, what is to be made of the licenses and their subsequent violations? How do we legally gather and train data?

232. *Id.*

233. *Id.*

234. *Doe 1 v. GitHub, Inc.*, 672 F. Supp. 3d 837, 847 (N.D. Cal. 2023).

235. *Id.* at 845.

236. *Id.* at 846.

237. *Id.* at 850.

238. *Id.* at 861–62.

V. ANTITRUST DEVELOPMENTS

A. *EPIC GAMES INC. V. APPLE, INC.*

The dispute in *Epic Games Inc. v. Apple, Inc.* focused on whether Apple's App Store policies violated federal antitrust laws under the Sherman Act and California's Unfair Competition Law.²³⁹ Epic Games brought legal action against Apple in 2020 after Apple removed Fortnite from the App Store as a response to Epic's attempt to bypass Apple's in-app purchase system and its 30 percent commission.²⁴⁰

Epic Games Inc. v. Apple, Inc. was initially heard in the District Court for the Northern District of California, which ruled in favor of Epic Games on one count, finding that Apple violated California's Unfair Competition Law, but ruled in favor of Apple on all other counts.²⁴¹ The Ninth Circuit affirmed the district court's conclusion that Apple's App Store anti-steering rules violated California's Unfair Competition Law and upheld the nationwide injunction against those rules.²⁴²

However, the district court rejected Epic's Sherman Act claim, acknowledging that although Apple has significant market power, it did not achieve or maintain it through anticompetitive conduct.²⁴³ The court acknowledged that Apple did not create a completely open ecosystem where developers and users could "transact freely without any mediation."²⁴⁴ However, the Ninth Circuit affirmed the district court's denial of antitrust liability alleging that Epic Games failed to establish a market definition of how Apple violated the Sherman Act.²⁴⁵

The Ninth Circuit also concluded that Epic Games failed to meet its burden under the "rule of reason" framework required in antitrust claims.²⁴⁶ The court found that although Apple's restrictions on app distribution and in-app purchases limited competition, Epic did not provide sufficient evidence that these limitations were unreasonable when weighed against Apple's justifications related to security, privacy, and payment processing.²⁴⁷ The Ninth

239. *Epic Games, Inc. v. Apple, Inc.*, 67 F.4th 946, 966 (9th Cir. 2023).

240. *Id.* at 966–67.

241. *Id.* at 966.

242. *Id.*

243. *Id.* at 972.

244. *Id.* at 967.

245. *Id.* at 970–71.

246. *Id.* at 966.

247. *Id.* at 996.

Circuit ultimately concluded by emphasizing that they are not able to resolve the relationship between online transaction platforms with market power.²⁴⁸

The Ninth Circuit's decision reinforced the narrow path for successful antitrust claims in digital platform markets, while still recognizing the importance of consumer choice and fair business practices under state law. Although Epic failed to dismantle Apple's App Store model entirely, questions about the scope of platform power, the role of privacy and security justifications, and how future cases might challenge similar ecosystems under both federal and state law remain.

B. *UNITED STATES V. GOOGLE, LLC*

The U.S. District Court for the District of Columbia held that Google LLC violated § 2 of the Sherman Act by illegally maintaining a monopoly over general search services and general search text ads.²⁴⁹

Section 2 of the Sherman Act makes it a crime for a person to “monopolize, or attempt to monopolize, or combine or conspire with any other person or persons, to monopolize any part of the trade or commerce among the several States, or with foreign nations.”²⁵⁰ Violation of § 2 can result in fines up to \$100 million for corporations or fines up to \$1 million or imprisonment not exceeding ten years for any other person.²⁵¹

In October 2020, the DOJ and attorneys general of eleven states sued Google for § 2 illegal monopolization violations of the Sherman Act.²⁵² The plaintiffs alleged that Google formed exclusive agreements in order to secure the default distribution of its search and advertising services to maintain monopolies in three online markets.²⁵³ In December 2020, thirty-eight other states sued Google for violations of the Clayton Act.²⁵⁴

Google took some anticompetitive steps, such as acquiring competitors, forcing adoption of Google's tools, distorting auction competition, and auction manipulation.²⁵⁵ Therefore, Judge Mehta found Google in violation of § 2 and stated the following relevant reasons for the judgment:

248. *Id.* at 1004.

249. *United States v. Google LLC*, 747 F. Supp. 3d 1, 187 (D.D.C. 2024).

250. 15 U.S.C. § 2 (2018).

251. *Id.*

252. *Google*, 747 F. Supp. 3d at 33.

253. *Id.*

254. *Id.*

255. Press Release, *Justice Department Sues Google for Monopolizing Digital Advertising Technologies*, U.S. DEP'T OF JUST. (Jan. 24, 2023), <https://www.justice.gov/archives/opa/pr/justice-department-sues-google-monopolizing-digital-advertising-technologies>.

- There are relevant product markets for general search services and general search text ads;
- Google has monopoly power in (a) general search services and (b) general search text ads markets; and
- Google's distribution agreements are exclusive and have anticompetitive effects.²⁵⁶

Google did not offer valid pro-competitive justifications for those agreements.²⁵⁷

256. *See generally Google*, 747 F. Supp. 3d.

257. *Id.* at 171.

