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OUR MORE-THAN-TWENTY-YEAR PATENT TERM

Mark A. Lemley[†] *& Jason Reinecke*[††]

ABSTRACT

We study all of the nearly 4.5 million patents, filed on or after May 29, 2000, that were issued by the United States Patent and Trademark Office since 2005. We find that most patents (63.6%) get at least some "patent term adjustment" (PTA)—an additional patent term to compensate for delays in patent prosecution. The patents that 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. Some get as much as ten years of extra term.

Despite its imperfections, the PTA system works pretty well at achieving the goal of compensating patentees for patent prosecution delay. But we would be better off with a world in which delay wasn't nearly as common as it is, because adding a year at the end of a patent's life is not the same as having an extra year at the beginning. And the PTA system ends up disproportionately being used by patent trolls in litigation, a result that seems socially unproductive. We offer some suggestions for how to reduce delay and describe the more efficient PTA that could potentially result.

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We know there are a lot of acronyms in the paper, and they all have Ps in them. Sorry about that.

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TABLE OF CONTENTS

I. INTRODUCTION

Since 1995, patents in the United States expire twenty years from the day they were filed.[1] Except when they don't. Beginning in 2000, Congress provided certain "exceptions" to the twenty-year patent term, extending the life of patents to compensate for excessive delays in patent prosecution, for successful appeals, or certain other proceedings.[2] This is called patent term adjustment (PTA). These exceptions have swallowed the rule. In this Article, we study all of the nearly 4.5 million patents, filed on or after May 29, 2000

1. 35 U.S.C. § 154(a)(2). The law changed in 1995 from the former rule, under which patents expired 17 years after they were issued.

2. *See* American Inventors Protection Act, Pub. L. No. 106-13 (1999); 35 U.S.C. § 154(b).

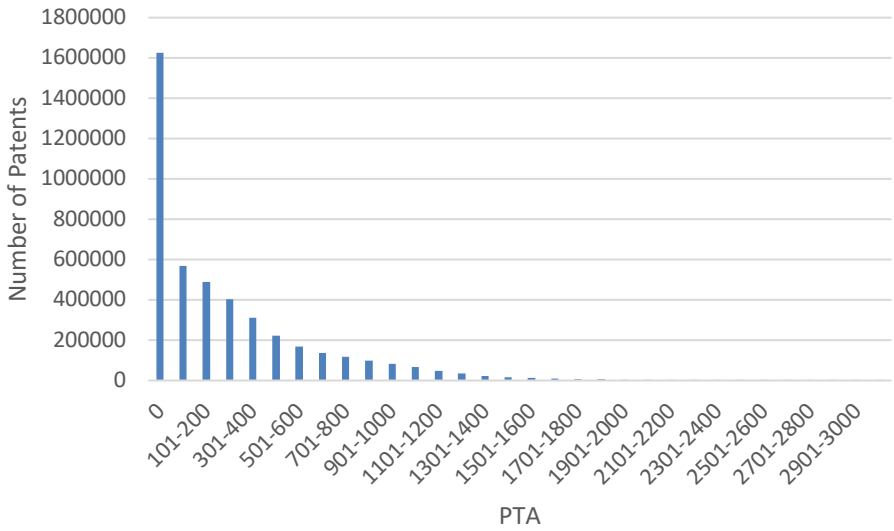
(the date the relevant statutory provisions took effect[3]), that were issued by the United States Patent and Trademark Office (USPTO) since 2005. We find that most patents (63.6%) get at least some PTA. The patents that do get PTA get more than a year on average (411 days, a median of 290 days), and 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. Table 1 below provides a summary of PTA statistics for all patents (including those that receive no extension), and Figure 1 below provides an illustration of the number of patents by the amount of PTA. As Figure 1 shows, as the amount of PTA increases, the number of patents with such PTA decreases.

Table 1: PTA for All Patents

	PTA (days)
Mean	261.7
Median	108
Standard Deviation	370
Min	0
25th Percentile	0
75th Percentile	384
95th Percentile	1030
99th Percentile	1568
Max	8398[4]

3. *See* American Inventors Protection Act, Pub. L. 106-13, § 4405 (1999).
4. This delay calculation appears to be an error. *See infra* note 54.

Figure 1: Number of Patents by Amount of PTA



Further exploration reveals interesting facts about the PTA patents. Contrary to our expectations, it is not life sciences patents that take the most advantage of extended patent terms, but software patents. We find that patents with PTA are overall less likely to be litigated than their non-PTA counterparts. But non-practicing entities (NPEs) are more likely to employ patents with extended terms. And the patents most likely to be litigated are those with either no PTA or substantial amounts of PTA.

Our results have important implications for understanding the patent system in general and patent litigation in particular. Despite the potential for abuse of the PTA system, we don't see clear evidence of patentees unfairly taking extra patent term. Most of the PTA results from the fact that, for large parts of this century, the USPTO has been slow to issue patents. And, as we discuss below, the current PTA rules allow for double-counting of PTA under some circumstances.

Because patents last longest in the very industries where technology moves the fastest, those patents can hold up innovation when they are enforced, particularly when plaintiffs enforce them at the end of their elongated patent term. Brian Love has shown that NPEs, for instance, tend to enforce very old software patents, and that that is bad as a matter of patent policy;[5] the disproportionate use of PTA in software makes that problem worse. And

5. *See generally* Brian J. Love, *An Empirical Study of Patent Litigation Timing: Could a Patent Term Reduction Decimate Trolls Without Harming Innovators?*, 161 U. PA. L. REV. 1309 (2013).

indeed, we find that NPEs, particularly the subset in the business of buying patents to assert them, make more use of term-extended patents than other plaintiffs. Below we suggest several possible changes to address these problematic observations.

We also analyze the other major form of term elongation: patent term extension (PTE).[6] This is a process specific to pharmaceutical patents that compensates for delays in receiving FDA approval. In short, we find that PTE is very rare. Only 331 patents that issued in the 2000s have received PTE. But those patents that have PTE have lots of it—the mean and median PTE are nearly 1000 days. And these patents are extremely important. We find that more than 30% of them have been litigated at least once, which is approximately fifteen to twenty times as likely as the typical patent. Moreover, assertions of such patents are overwhelmingly made by product companies, not NPEs.

In Part II, we explain the changes to the patent term at the end of the last century and the various forms of PTA Congress created. In Part III, we present our basic results on the prevalence of PTA and how it differs by industry, litigant status, and owner. In Part IV, we explore some of the potential policy implications of our results.

II. PATENT TERM

A. PATENT TERM ADJUSTMENT

In 1994, Congress enacted the Uruguay Rounds Agreement Act (URAA), which fundamentally changed the patent term in the United States.[7] Prior to that time, a patent expired seventeen years after the date it was *issued*.[8] Under the URAA, subject to some exceptions, a patent expired twenty years from the date the earliest nonprovisional U.S. patent application was *filed*.[9]

This change was primarily prompted by two developments. In 1994, member nations of the World Trade Organization entered into the Agreement

6. This type of delay is also often referred to as patent term restoration.

7. Uruguay Round Agreements Act, 103 Pub. L. No. 465, 108 Stat. 4809 (1994).

8. 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.").

9. Uruguay Round Agreements Act, 103 Pub. L. No. 465, 108 Stat. 4809 (1994); 35 U.S.C. § 154(a)(2). As a practical matter, the patent term usually ends 21 years from the earliest relevant filing, because most applications begin with a U.S. provisional application and/or a patent application in another country, after which the applicant has one year to file a nonprovisional U.S. application.

on Trade-Related Aspects of Intellectual Property Rights (TRIPS), which required patents to extend at least twenty years from the date of filing.[10] Additionally, because American patent term was calculated based on the date of issuance, applicants could delay a patent's issuance without any term penalty. This term-calculation scheme allowed applicants to shift the patent's term and, consequently, sometimes allowed patent owners to take a mature industry by surprise and force it to license the "new" technology.[11] There were multiple high-profile cases of patentees, who kept their applications pending in the office for more than forty years before popping up to sue companies that had employed the technology for decades.[12] Keying patent term to filing date weakens or eliminates the incentives to engage in such submarine patenting, because an applicant's prosecution delay generally results in a corresponding reduction in total patent term.[13] As a result, it encouraged patentees to prosecute their patents more quickly.

One concern with linking patent term to the filing date was that extensive delays during prosecution by the USPTO could significantly reduce the patent term from the previous seventeen-year term.[14] In response to this concern, in 1999, Congress enacted the American Inventor's Protection Act, which

10. Agreement on Trade-Related Aspects of Intellectual Property Rights, Apr. 15, 1994, Marrakesh Agreement Establishing the World Trade Organization, Annex 1C, 1869 U.N.T.S. 299, 33 I.L.M. 81, art. 33.

11. Such patents are often referred to as "submarine patents." *See, e.g.*, Lemley, *supra* note 8, at 377–80; Donald S. Chisum, *The Harmonization of International Patent Law: Introduction*, 26 J. MARSHALL L. REV. 437, 445 (1993); Fritz Machlup, *An Economic Review of the Patent System*, Study No. 15, Subcomm. Pat., Trademark, & Copyright, Jud. Comm., 85th Cong., 2d Sess. 10, 10 (1958).

12. *See, e.g.*, Hyatt v. USPTO, 904 F.3d 1361 (Fed. Cir. 2018); Symbol Tech., Inc. v. Lemelson, 277 F.3d 1361, 1363 (Fed. Cir. 2002); Mark A. Lemley & Kimberly A. Moore, *Ending Abuse of Patent Continuations*, 84 B.U. L. REV. 63, 79–80 (2003). This is still going on. *See, e.g.*, Hyatt v. Hirshfeld, 998 F.3d 1347, 1351–52 (Fed. Cir. 2021); Personalized Media Commc'ns, LLC v. Apple Inc., 57 F.4th 1346, 1351 (Fed. Cir. 2023).

13. Lemley, *supra* note 8, at 379.

14. *See, e.g.*, Robert A. Matthews, *Extensions for PTO Delays*, 1 ANNOTATED PAT. DIG. § 9:24; H.R. Rep. No. 106-287, 1999 WL 569140, at *32; Dana Rohrabacher & Paul Crilly, *The Case for a Strong Patent System*, 8 HARV. J.L. & TECH. 263, 265 (1995).

At the time, one of us (Lemley) predicted to the contrary that the change would generate longer effective patent terms by speeding up prosecution. *See generally*, Lemley, *supra* note 8.

Optimal patent timing is also bound up with the decision of when in a research process to file the patent application. *See generally* Christopher A. Cotropia, *The Folly of Early Filing in Patent Law*, 61 HASTINGS L.J. 65 (2009); Mark A. Lemley, *Ready for Patenting*, 96 B.U. L. REV. 1171 (2016).

provided for PTA for certain prosecution delays caused by the USPTO.[15] Specifically, as currently codified, 35 U.S.C. § 154 accommodates three types of delay, which are respectively referred to as "A delay" (under 35 U.S.C. § 154(b)(1)*(A)*), "B delay" (under § 154(b)(1)*(B)*), and "C delay" (under § 154(b)(1)*(C)*).

Type A delay generally guarantees prompt responses from the USPTO during prosecution.[16] In particular, the statute provides one day of extra patent term for each day that a patent's issuance is delayed by the USPTO's failure to comply with various deadlines. This includes no more than fourteen months from filing to the first Office action and four months for subsequent Office actions and certain additional actions.[17]

B delay generally provides PTA to make up for any USPTO-caused application pendency greater than three years.[18] In particular, the statute generally provides one day of term adjustment for each day that a patent's issuance is delayed by the USPTO beyond three years from filing.[19]

C delay compensates for delays due to derivation proceedings, secrecy orders, and appellate review if "the patent was 'issued under a decision in the review' reversing an adverse determination of patentability."[20]

PTA generally equals the sum of A, B, and C delay, with three noteworthy subtractions. First, where two or more periods of delay "overlap, the period of any adjustment . . . shall not exceed the actual number of days the issuance of the patent was delayed."[21] While this important limitation helps prevent double counting, its effectiveness was somewhat curbed in *Wyeth v. Kappos*.[22] There, the USPTO argued that A delays may sometimes "cause" B delays, leading to double-counting.[23] The Federal Circuit ruled against the USPTO, reasoning

15. *See* American Inventors Protection Act, Pub. L. No. 106-13 (1999). For a discussion of all term-tailoring mechanisms, see generally Sarah R. Wasserman Rajec, *Patent Term Tailoring* (work-in-progress) (manuscript on file with authors).

16. *See* 35 U.S.C. § 154(b)(1)(A).

17. *Id.*

18. *See* 35 U.S.C. § 154(b)(1)(B).

19. *Id.* This excludes time consumed by continued examination, secrecy orders, appellate review, or delays requested by the applicant.

20. *See* 35 U.S.C. § 154(b)(1)(C); *see also* SawStop Holding LLC v. Vidal, 48 F.4th 1355, 1356 (Fed. Cir. 2022) (holding that an appeal must directly result in the issuance of a patent; it is not enough that the patentee prevails on appeal on a particular ground but then faces a different rejection.).

21. 35 U.S.C. § 154(b)(2)(A).

22. 591 F.3d 1364 (Fed. Cir. 2010).

23. *Id.* at 1370 (explaining that if "A delays during the first three years of prosecution ultimately lead to B delays after the three-year mark from filing," "it would be double counting if A and B delays were both used to adjust because A delays 'cause' B delays.").

that the term "overlap" in the statute means that the delay must "occur at the same time."[24] As we discussed in Part IV.B.4, *Wyeth* improperly permits patentees to benefit from double counting. Specifically, for any patent that takes longer than three years to issue, USPTO delay in the first three years can lead to two days of PTA (one day of A delay and one day of B delay) even though it led to only one actual day of delay of patent term. The reason, as the USPTO explained, is because the one day of A delay also causes a day of B delay.

Second, the period of adjustment is also reduced by the amount "of time during which the applicant failed to engage in reasonable efforts to conclude prosecution of the application."[25] The goal of this reduction is to prevent submarine patentees from delaying prosecution of their own patents, knowing they will get the term back as B delay. But the reduction is only partial. The reduction will not apply during any period "during which there were no efforts in which the applicant could have engaged to conclude prosecution of the patent."[26] So if a patentee adds additional layers to the process, extending prosecution time, some but not all of that time may be returned in the form of an additional patent term. As discussed in more detail below, there are safeguards designed to avoid rewarding patentees for endless refiling.

Third, when a patentee files a terminal disclaimer—a statement by an applicant that disclaims part of the end of a patent's term—the patent ends on the last day not disclaimed regardless of PTA.[27] A patentee typically does this to overcome an argument that a patent is invalid because it is too similar to another of the patentee's patents.[28]

To take a concrete example, imagine the USPTO takes two years to issue a first Office action. The patentee takes six months to respond, filing a 3-month extension of time to do so. The USPTO takes six months to issue a "final rejection." Three months later the USPTO holds an interview, after which the examiner allows the claim, and the patent issues three months after that. The total time in the USPTO was forty-two months. The A delay is twelve

24. *Id.* at 1369.

25. 35 U.S.C. § 154(b)(2)(C).

26. Supernus Pharms., Inc. v. Iancu, 913 F.3d 1351, 1359 (Fed. Cir. 2019).

27. *See* 35 U.S.C. § 253.

28. This is referred to as obviousness-type-double patenting (ODP). For a discussion of ODP and its interaction with PTA, see, e.g., Robert A. Matthews, *General Prohibition Against Double Patenting*, 1 ANNOTATED PATENT DIGEST § 19:1; *see also In re* Cellect, LLC, 81 F.4th 1216, 1226 (Fed. Cir. 2023) ("[W]hile the expiration date used for an ODP analysis where a patent has received PTE is the expiration date before the PTE has been added, the expiration date used for an ODP analysis where a patent has received PTA is the expiration date after the PTA has been added.").

months—the difference between the fourteen-month target for the first Office action and the twenty-four months the USPTO actually took, plus the difference between the four-month target for responses and the six months it actually took. The B delay is six months—the difference between the forty-two months the prosecution takes and the thirty-six months the statute guarantees. The deduction is three months, because the patentee contributed to the delay by taking an extension and spending six instead of three months to respond to the Office action. So, the total PTA is sixteen months, and the total patent term is seventeen years and ten months. The patentee benefits from six months of double-counting; the patentee received six months of B delay, and there would have been no B delay if it weren't for the A delay.

In many instances, calculating PTA involves analyzing volumes of correspondence between the applicant and the USPTO. The USPTO currently utilizes a computer program to make PTA calculations.[29]

Although PTA may seem perfectly compensatory—qualifying delay attributable to the USPTO is accompanied by an equal increase in patent term—in reality it is much more complicated. For example, double-counting means that patentees can in fact benefit from delay. In addition, a lost day of patent term on the front end of a patent typically would not be worth the same as an added day of patent term on the back end. One reason is due to the time value of money: all else equal, a firm would rather be given the ability to make money today than a day far in the future.[30] That suggests PTA can be less valuable than a quick issuance. Another reason is that the value of inventions and patents generally depend on time. For example, pharmaceutical and biotechnology patents frequently cover inventions that remain relevant near the end of the patent term, and due to regulatory delays, the patents may even be most valuable at the end of their term. Conversely, software patents are more likely to cover inventions that quickly become technologically obsolete due to the constantly changing nature of the software industry.[31] So the value

29. *See* M.P.E.P. § 2734; *Explanation of Patent Term Adjustment Calculation*, USPTO, https://www.uspto.gov/patents/apply/checking-application-status/pair-announcements/explanation-patent-term (last visited Dec. 1, 2023). This computer is not perfect. *See infra* note 54.

30. *See, e.g.*, RONALD W. MELICHER & EDGAR A. NORTON, *Time Value of Money*, INTRODUCTION TO CORPORATE FINANCE (2013).

31. *See, e.g.*, Love, *supra* note 5, at 1342; Norhène Chabchoub & Jorge Niosi, *Explaining the Propensity to Patent Computer Software*, 25 TECHNOVATION 971, 975 (2005); Ronald J. Mann, *Do Patents Facilitate Financing in the Software Industry?*, 83 TEX. L. REV. 961, 979 (2005); Kimberly A. Moore, *Worthless Patents*, 20 BERKELEY TECH. L.J. 1521, 1543 (2005); Èloïse Gratton, *Should Patent Protection be Considered for Computer Software-Related Innovations?*, 7 COMP. L. REV. & TECH. J. 223, 231 (2003); Lemley, *supra* note 8, at 377 n.32; Eric Goldman, *Fixing Software Patents* 2 (Santa Clara Univ. School of Law Legal Studies, Working Paper No. 01-13, 2013), http://

of PTA may be either greater or less than the value of early issuance depending on the circumstances. Finally, some patent enforcement strategies deliberately target defendants at the end of patent life, when the industry is more mature and potential damages are greater.[32] For those plaintiffs, PTA may be more valuable than the lost early term.

B. PATENT TERM EXTENSION

PTE is available under the Drug Price Competition and Patent Term Restoration Act of 1984.[33] PTE is designed to counteract, for certain classes of products, loss of patent term due to a different type of agency delay: time taken to obtain FDA approval to market products.[34] PTE is capped at five years,[35] and the total patent life cannot be extended to exceed 14 years from the product approval date.[36]

PTE is reduced in two noteworthy ways. First, the extension is reduced by any time attributable to applicant delay.[37] Second, only half the time a product spends in testing counts for PTE.

Only one patent can be extended for any given regulatory review period for the same product (even if the relevant product is covered by multiple patents),[38] and a patent can only be extended once (even if the patent covers multiple FDA-approved products).[39] Furthermore, the PTE extension rights are "limited to any use approved for the product."[40]

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ssrn.com/abstract=2199180; Alan D. Lourie, *Patent Term Restoration: History, Summary, and Appraisal*, 40 FOOD & DRUG COSMETIC L.J. 351, 352 (1985).

32. Love, *supra* note 5, at 1334.

33. *See* 35 U.S.C. § 156.

34. *See* 35 U.S.C. § 156. This is important; empirical evidence suggests that pharmaceutical companies are more likely to abandon projects that have less market exclusivity. *See* Fabian Gaessler & Stefan Wagner, *Patents, Data Exclusivity, and the Development of New Drugs* (Working Paper, 2019). But patents are not the only or even the most important form of exclusivity for pharmaceuticals; data exclusivity periods may provide more robust protection. *See generally* John R. Thomas, *The End of "Patent Medicines"? Thoughts on the Rise of Regulatory Exclusivities*, 70 FOOD & DRUG L.J. 39 (2015).

35. 35 U.S.C. § 156(g)(6)(A).

36. 35 U.S.C. § 156I(3). The extension is added to the "expiration date of the patent, which shall include any patent term adjustment granted under section 154(b)." 35 U.S.C. § 156(a).

37. 35 U.S.C. § 156(c)(1).

38. 35 U.S.C. § 156(c)(4).

39. 35 U.S.C. § 156(a)(2).

40. 35 U.S.C. § 156(b)(1).

C. MAINTENANCE FEES

A patent will expire before the end of its term, unless the patentee renews their patent rights by making "maintenance" fee payments.[41] These payments are due 3.5, 7.5, and 11.5 years after the date of issue.[42] Only around forty to fifty percent of patents stay in force until the end of the full term.[43]

III. RESULTS

A. DATASET

The dataset we created to analyze PTA includes information for all patents filed on or after May 29, 2000 (the date the relevant statutory provisions took effect[44]) that issued between January 1, 2005 and June 21, 2022.[45] For each patent, we gathered basic information and PTA information from the Patent Examination Research Dataset ("PatEx") provided by the Office of the Chief Economist of the USPTO.[46] To obtain additional relevant information, we linked the patents to information contained in the Stanford NPE Litigation Database[47] and Lex Machina's Patent Portfolio Evaluator.[48]

41. 35 U.S.C. § 41(b).

42. *Id.*

43. Dennis Crouch, *Maintenance Fees 2015*, PATENTLYO (July 21, 2015), https://patentlyo.com/patent/2015/07/maintenance-fees-2015.html.

44. *See* American Inventors Protection Act, Pub. L. 106–113, § 4405 (1999).

45. Upon analyzing, we noticed that the dataset appears to be missing a very small number of patents, but the number missing is negligible (approximately 5,000 missing patents in a dataset of 4,468,930). It is also likely that many, if not most, of those patents were filed prior to May 29, 2000, meaning that they would not be governed by the relevant provisions anyway.

46. *Patent Examination Research Dataset (PatEx)*, USPTO, https://www.uspto.gov/ip-policy/economic-research/research-datasets/patent-examination-research-dataset-public-pair (last visited Apr. 20, 2023). In addition to the helpful explanatory material provided on the USPTO's website, the USPTO has provided a working paper describing the dataset. Stuart Graham, Alan Marco & Richard Miller, *The USPTO Patent Examination Research Dataset: A Window on the Patent Information* (USPTO Economic Working Paper No. 2015-4).

47. *Welcome to the Stanford NPE Litigation Database*, STAN. L. SCH. NPE LITIG. DATABASE, https://npe.law.stanford.edu/ (last visited Apr. 20, 2023). The team at Stanford Law School prepared an article discussing the dataset. Shawn P. Miller, Ashwin Aravind, Bethany Bengfort, Clarisse De La Cerda, Matteo Dragoni, Kevin Gibson, Amit Itai, Charles Johnson, Deepa Kannappan, Emily Kehoe, Hyosang Kim, Katherine Mladinich, Roberto Pinho, John Polansky & Brian Weissenberg, *Who's Suing Us? Decoding Patent Plaintiffs Since 2000 with the Stanford NPE Litigation Dataset*, 21 STAN. TECH. L. REV. 235 (2018).

48. LEX MACHINA, https://law.lexmachina.com/ (last visited Apr. 20, 2023). Thanks to Lex Machina for providing one of us (Jason Reinecke) with access for public interest purposes.

Based on this data, we produce several descriptive statistics,[49] chronicling the actual terms patents receive for the first time. We relate that data to a variety of variables, including the industry and technology of the patent, whether the patent was litigated and, if it was, the nature of the plaintiff.

We also ran a series of regressions to formally evaluate the statistical significance of our core results. The discussion that follows is consistent with the results provided by the regressions.[50]

B. BASIC PTA RESULTS

Overall, 63.7% of the nearly 4.5 million patents we studied have at least some PTA.[51] Figure 2 provides the percentage of patents with PTA by issue year. As shown in Figure 2, the percentage of patents with PTA exceeds 50% each year and climbs as high as 81% in 2010.[52] Thus, the shorthand that patents last twenty years from filing is false; the twenty-year term is the exception, not the rule.

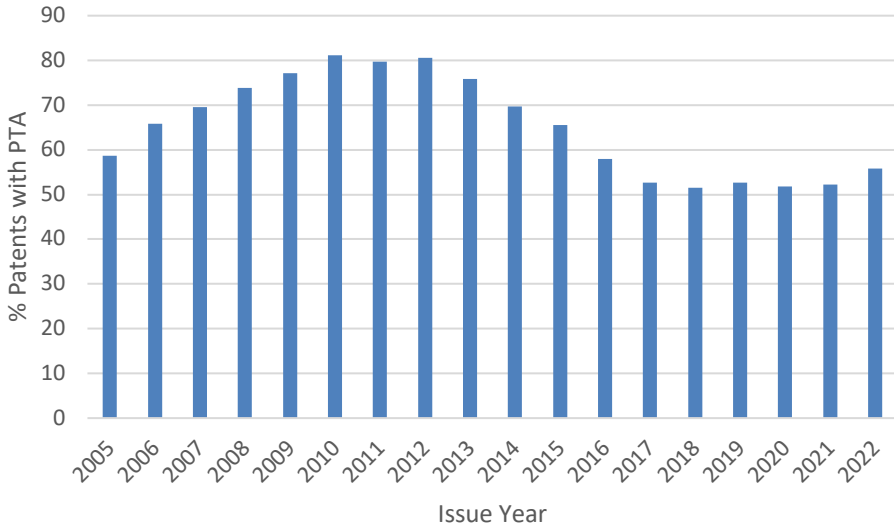
49. We report the results when looking at all the patents in the dataset because we are primarily concerned with describing the PTA that patents receive. We also separately analyzed only patents with no terminal disclaimers, only original patent application filings (by removing continuations, divisionals, and continuations-in-part), and only such patents with no terminal disclaimers. To identify terminally disclaimed patents, we utilized the dataset provided by one of us and Lisa Ouellette in a forthcoming article. *See* Mark A. Lemley & Lisa Larrimore Ouellette, *Fixing Double Patenting*, https://papers.ssrn.com/sol3/papers.cfm?abstract_id=4888563 (Working Paper, 2024). In general, such patents were even more likely to have PTA. We report the results for such patents when doing so provides additional insight.

50. Our full regression results are available in an online appendix.

51. For comparison, 71.8% of original patents have no PTA, and 69.3% of original patents with no terminal disclaimer have PTA.

52. The slight uptick in PTA around 2021 and 2022 appears to be because the USPTO has been slower to issue an initial office action rejection. Dennis Crouch, *Prosecution Delays and Patent Term Adjustment on the Rise Again*, PATENTLYO (Nov. 13, 2022), https://patentlyo.com/patent/2022/11/prosecution-delays-adjustment.html.

Figure 2: Percent of Patents with PTA by Issue Year



It would be one thing if most patents received only negligible amounts of PTA. But that's not the case. The mean PTA across all patents is 262 days (411 when looking only at patents with PTA) and median PTA is 108 days (290 when looking only at patents with PTA).[53] The fact that the mean is larger than the median indicates that a comparatively greater fraction of patents have large amounts of PTA.

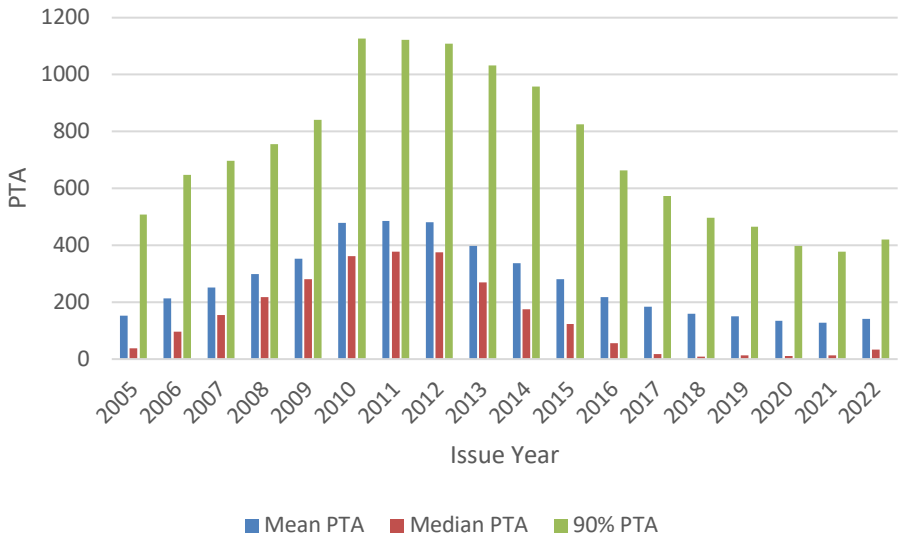
Twenty-six percent of patents have at least one year of PTA, just over five percent of patents have more than 1000 days of PTA, and one percent of patents have at least 4.25 years of PTA. One patent received *twenty-three years* of additional patent term.[54] Figure 3 below provides the mean, median, and 90th percentile PTA for patents by issue year. As with the percentage of

53. When looking only at original patents without terminal disclaimers, the values are somewhat larger: 302 days, 421 days, 168 days, and 301 days respectively.

54. It appears the USPTO miscalculated the PTA for this patent. Specifically, the calculated applicant delay was *negative* 6525 days, which must be incorrect. In total, we identified 156 instances of negative applicant delay. These are not the only errors the USPTO's automatic PTA calculation system makes. *See generally* Dinis Cheian, *I See Dead Patents: How Bugs in the Patent System Keep Expired Patents Alive*, 33 FORDHAM INTELL. PROP. MEDIA & ENT. L.J. 1 (2022); *USPTO Has Opportunities to Improve Its Internal Controls and Oversight Related to PTA and PTE Calculations*, Final Rpt. No. OIG-21-030-1 (July 6, 2021) (assessing the USPTO's PTA calculation procedures); S. Sean Tu, Dinis Cheian, Sarah Gabrielle, Benjamin N. Rome & Aaron S. Kesselheim, *The Cost of Drug Patent Expiration Date Errors* (unpublished manuscript).

patents with PTA, there is year-to-year variation, and the largest values again show up between 2010 and 2012.

Figure 3: PTA by Issue Year



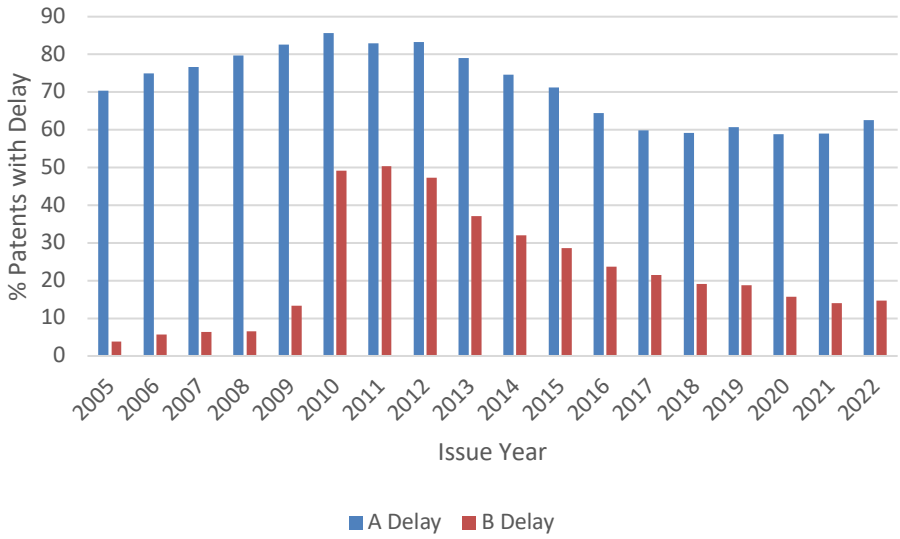
Mean and median patent terms from issuance to expiration are 17.17 years and 17.8 years, respectively. These values did not materially change regardless of whether we looked only at patents without any PTA, patents with at least some PTA, and patents with at least one year of PTA. These results suggest that generally PTA ensures that patentees do not receive less than the pre-GATT 17-year term. But although the length of the term may be preserved, as explained previously, delay and resulting PTA produces a patent term that is shifted in time, resulting in less term on the front end and additional term on the back end.

C. A, B, AND C DELAY

Next, we look at what type of PTA drives these results. In short, A delay (which generally guarantees prompt responses from the USPTO during prosecution) is the primary source of PTA, though B delay (which generally guarantees that patentees will not be harmed by an application pendency greater than three years) plays a significant role as well. C delay (which compensates for delays due to derivation proceedings, secrecy orders, and appellate review if the patent issues) plays little role.

Overall, 69.8%[55] of patents, and 99.7% of patents with PTA, have A delay; 24.0% of patents, and 36.4% of patents with PTA, have B delay; and 1.0% of patents, and 1.6% of patents with PTA, have C delay. Of patents with PTA and B delay, 99.5% also have A delay. Relatedly, of all patents with B delay, only 1% have no A delay. These facts provide some reason to believe that A delay often causes B delay, particularly because nearly all A delay occurs before the three-year clock starts ticking.[56] Figure 4 below displays the percentage of patents with A and B delay by issue year. The results once again generally follow the same trend, except the jump in B delay between 2009 and 2010 is particularly stark. Notably, the percentage of patents with A delay exceeds 50% every year.

Figure 4: Percent of Patents with A and B Delay by Issue Year



Mean and median A delay are 234 days and 141 days, respectively (360 days and 301 days if only patents with PTA are considered). Mean and median B delay are 67 days and 0 days, respectively (104 days and 0 days if only patents with PTA are considered). Ten percent of patents have at least 620 days of A delay (733 days if only patents with PTA are considered), and the same fraction of patents have at least 255 days of B delay (373 days if only patents with B delay are considered). One percent of patents have at least 3.2 years of A delay,

55. This value is somewhat larger (77.3%) when looking only at original patents.
56. *See infra* note 99 and accompanying text.

and the same fraction of patents have at least 2.3 years of B delay. Figures 5 and 6 respectively provide mean, median, and 90th percentile A and B delay by issue year. These figures show a similar trend to Figures 2–4.

Figure 5: A Delay by Issue Year

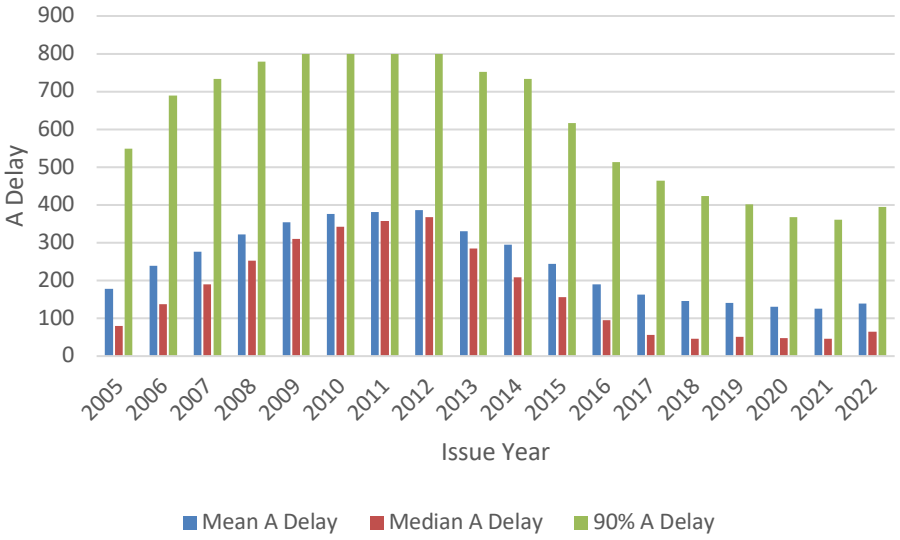
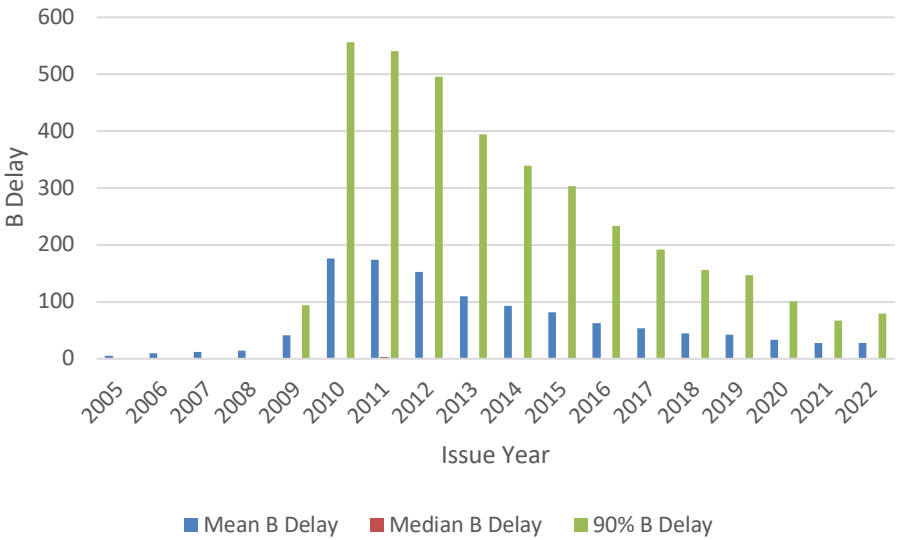


Figure 6: B Delay by Issue Year



D. RESULTS BY TECHNOLOGY

In this subsection, we assess PTA by technology. In short, we find significant variation across different technologies. Even though software and business method patents tend to be simpler on average than drug and chemical patents and have less complex prosecution histories,[57] the former tend to have the most PTA (along with computer, communications, and medical patents) and the latter the least PTA. That is particularly surprising because of the received wisdom that patents are important earlier in their lives in fast-moving industries like software, and more important at the end of their lives in FDA-regulated industries like pharmaceuticals.[58]

We divide the patents into the six technological categories identified by Hall, Jaffe, and Trajtenberg: computers and communications; drugs and medical; electrical and electronics; chemical; mechanical; and others.[59] We also assess the following three categories of patents that have been used in other studies: drugs, business methods, and software.[60]

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57. *See generally* John R. Allison, Mark A. Lemley, Kimberly A. Moore & Derek Trunkey, *Valuable Patents*, 92 GEO. L.J. 435 (2004); John R. Allison, Mark A. Lemley & David L. Schwartz, *Our Divided Patent System*, 82 U. CHI. L. REV. 1073 (2015); Bill Richardson, *Meeting Challenges in Pharmaceutical Patent Cases and Other Types of IP Litigation*, ASPATOR, 2011 WL 2532982, at *1 (2011); *see also* Michael Shur-Ofry, *Access-to-Error*, 34 CARDOZO ARTS & ENT. L.J. 357, 383 (2016) (noting the differences between industries).

58. FDA approval for a drug is an extremely time intensive process. *See, e.g.*, Gail A. Van Norman, *Drugs, Devices, and the FDA: Part 1 An Overview of Approval Processes for Drugs*, 1 JACC: BASIC TO TRANSLATIONAL SCIENCE 170, 171 (2016) (indicating that the FDA approval process for a drug takes 12 years, on average); Ross Tonkens, *An Overview of the Drug Development Process*, 31 PHYSICIAN EXECUTIVE 48 (2005) (indicating that it takes, on average, 2 to 12 years to bring a new drug to the market); Martin S. Lipsky & Lisa K. Sharp, *From Idea to Market: The Drug Approval Process*, 14 J. AM. BD. FAMILY PRACTICE 362, 364 (2001) (indicating that the drug development and approval process takes an average of 8 to 12 years); Eric V. Patridge, Peter C. Gareiss, Michael S. Kinch & Denton W. Hoyer, *An Analysis of Original Research Contributions Toward FDA-Approved Drugs*, 20 DRUG DISCOVERY TODAY 1182, 1185 (2015) (finding the gap between discovery and approval to be 12 years for industry and 24 years for academia). This lengthy process reduces the effective life of a patent, making the last part of the patent term the valuable part in industries that require FDA approval.

59. *See* Bronwyn H. Hall, Adam B. Jaffe & Manuel Trajtenberg, *The NBER Patent Citations Data File: Lessons, Insights and Methodological Tools* 3 (Working Paper No. 8498, 2001). We use these categories as updated by Lucy Xiaolu Wang. Lucy Xiaolu Wang, *Patent Classification Systems and Technological Categorization: An Overview and Data Update* (Working Paper, 2020).

60. *See, e.g.*, Brian J. Love, Shawn P. Miller & Shawn Ambwani, *Determinants of Patent Quality: Evidence from Inter Partes Review Proceedings*, 90 U. COLUM. L. REV. 67, 115–16 ns. 205–07 (2019); James Bessen, *A Generation of Software Patents*, 18 B.U. J. SCI. & TECH. 241, 253 (2012).

Figure 7 displays the percentage of patents with PTA for each of the nine categories. As shown in the figure, business method, software, medical, computer, and communications patents are most likely to have PTA—approximately 70% of such patents have PTA—and mechanical, chemical, other, electrical, and drug patents are the least likely to have PTA (63.8%, 62.8%, 62.4%, 58.1%, and 45.7%, respectively).[61]

Figure 7: Percent of Patents with PTA by Technology

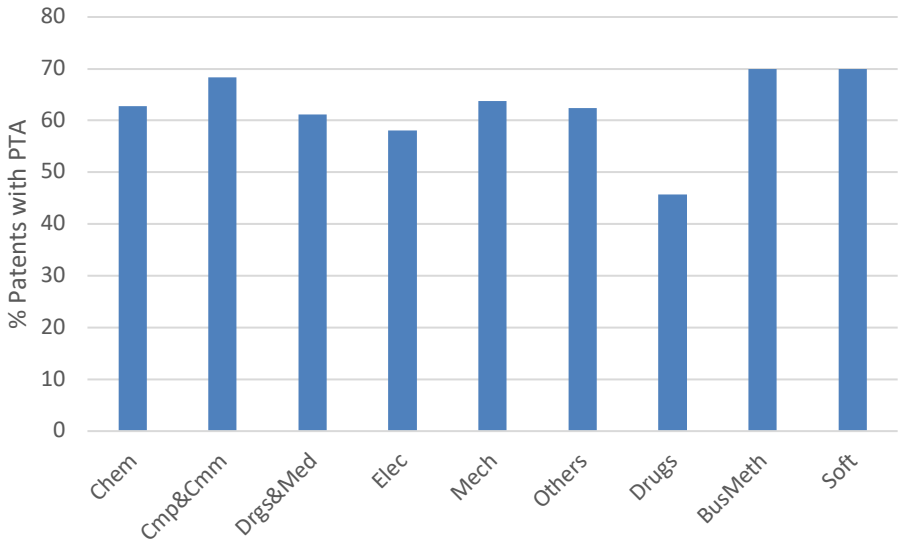


Figure 8 shows the mean, median, and 90th percentile PTA by technology category. And here, the same types of patents that are most likely to have PTA are the ones that have the most PTA, and the differences are particularly extreme when looking at the PTA for the top ten percent of patents. Figure 9 shows the same information, but only for the subset of patents with PTA. Even then, business method, software, computer, and communications patents tend to have more PTA than chemical and drug patents—except for the upper ten percent of drug patents, which have PTA similar to software, computer, and communications patents.[62]

61. We find similar relative trends even when looking only at patents without terminal disclaimers and/or original patents.

62. We find similar relative trends even when looking only at patents without terminal disclaimers and/or original patents.

Figure 8: PTA by Technology

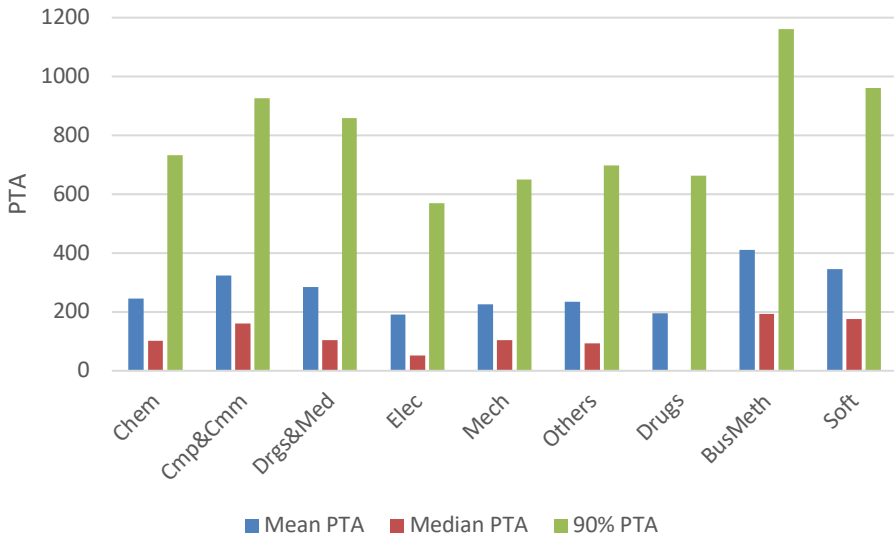
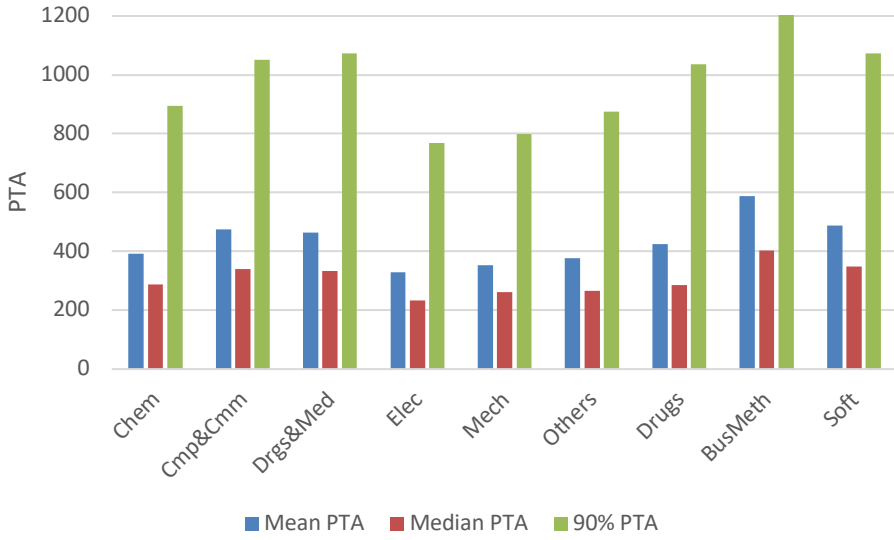


Figure 9: PTA by Technology (Only Patents With PTA)



Mean patent term from issuance to expiration does not significantly change depending on the technology, although mean patent term is somewhat less for drug and drug and medical patents (~15.9 years and ~16.7 years,

respectively). This may indicate an increased amount of applicant delay for those patents during prosecution.[63]

We also looked at the prevalence and amount of A, B, C, and applicant delay by industry. The results generally mirror the overall results by industry with two caveats: (1) drugs, medical, and business method patents have the most B delay, on average;[64] and (2) mean applicant delay (which reduces PTA) is by far the largest for drug patents.[65] It seems technology-specific backlog delay in the USPTO drives these industry-specific results. Software and computer art technology centers have a bigger backlog, so such patents receive more A delay. Drug and medical patents have longer and more complex prosecutions, so they have more B delay. Business methods are the outlier; they seem to have the largest A *and* B delay. This may be because business method patents face a tougher prosecution road,[66] which may delay the process for all applications in the group.

We also separately calculated mean PTA for each examiner art unit and then calculated the standard deviation of those values to obtain an estimate of the variability in PTA by art unit. We find substantial variation in mean PTA by art unit. For example, the standard deviation of the mean PTA values for each of the art units is 161 days, and the standard deviation for the 95th percentiles is 343 days. These results indicate that some art units are responsible for significantly more PTA than others.

Furthermore, we divided the patents into those that had and had not expired for nonpayment of maintenance fees. We assessed both the percentage of patents with PTA and the mean, median, and 75th percentile PTA for both groups of patents, controlling for issue year and technology. The differences were extremely small—the percentages of patents with PTA generally varied by less than three percent, and the amounts of PTA were typically within 50

63. Notably, however, the effective lives of drug and medical patents are often extended by the process of "evergreening"—obtaining multiple patents on variants of the same drug. *See* Robin Feldman, *Patent Term Extensions and the Last Man Standing*, 42 YALE L. & POL'Y REV. 1 (2023) (showing that the effective patent life for most drugs exceeds both PTA and PTE).

64. The mean for drugs and medical was 165 days, and the mean for business method was 181 days. The others (other than drugs, which was similar to drugs and medical) were between 70 and 126 days.

65. The mean for drugs was 115 days. The mean for the other categories (other than drugs and medical) were between 34 and 78 days (the mean for medical alone was 82 days).

66. *See Allowance Rate by USPC Class*, USPTO, https://developer.uspto.gov/visualization/allowance-rate-uspc-class (last visited July 31, 2023).

days of each other.[67] Moreover, there was no consistent trend that cut across issue year and technology.

E. PTA AND LITIGATED PATENTS

In this subsection, we focus on the PTA characteristics of litigated patents.[68] Litigated patents are less likely to have PTA. While 63.7% of patents have PTA, only 52.7% of litigated patents do. A smaller percentage of litigated patents have PTA even after controlling for technology.[69] After controlling for issue year, litigated patents are still less likely to have PTA, though the differences are rather small in the earliest years of the dataset and much larger in the later years.

This difference may be because, in many industries, the most valuable patents are prosecuted quickly so they can be asserted.[70] It could also be based on the interplay between delay and patent value. Figure 10 below depicts the percentage of patents with a given amount of PTA that are litigated as a function of the patent's PTA.[71] The patents most likely to be litigated are those with PTA at the poles—that is, patents with either no PTA or substantial amounts of PTA. This result is understandable. Patents without PTA are least likely to miss out on early patent term when patents tend to be most valuable. And because some patents are quite valuable later in life, some patents with lots of PTA are particularly valuable and worth asserting at the end of their life.

After controlling for issue year, we see this same general trend for the earlier issue years in the study. For the patents with later issue years, we do not

67. This result was nonetheless statistically significant ($p<0{,}001$), likely because of the enormous size of our database.

68. Although PTA accrues only when an "original" (i.e., not reissue) patent is delayed by a failure of the USPTO, *see* 35 U.S.C. § 154(b), reissue patents can still benefit from PTA because they issue for any "unexpired part of the term of the original patent." 35 U.S.C. § 251. In this section, we link reissues to their original patents and treat the reissues as having the same amount of PTA as the original. We also conducted the analysis ignoring reissues altogether, and the results are similar.

69. Unless stated otherwise, when we refer to controlling for something, we mean that we break the data down into parts based on that thing and analyze those parts separately.

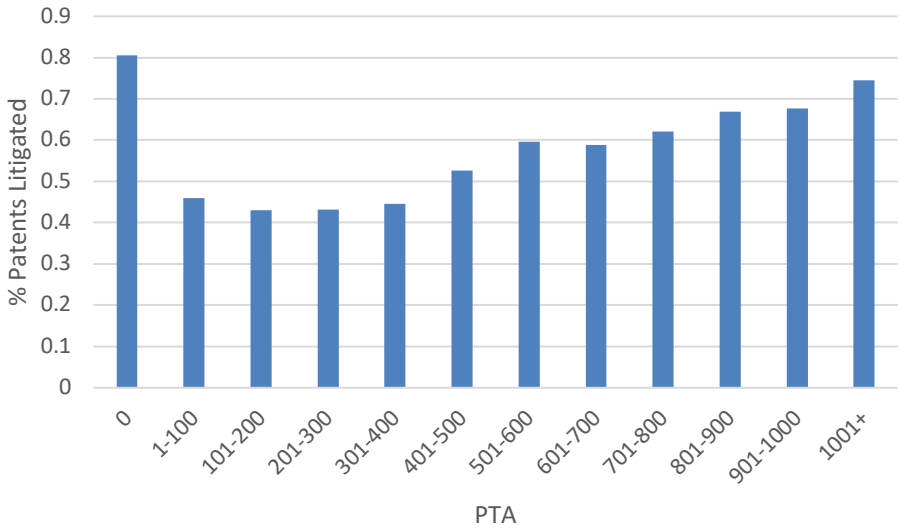
70. The USPTO has a special Track One status to allow applicants to pay for faster prosecution, *see USPTO's Prioritized Patent Examination Program*, USPTO, https://www.uspto.gov/patents/initiatives/usptos-prioritized-patent-examination-program (last visited Mar. 16, 2024), as well as a Petition to Make Special that allows for accelerated prosecution if the patentee has already identified a potential infringer. Manual of Pat. Examining Proc. § 708.02, https://mpep.uspto.gov/RDMS/MPEP/E8r8#/E8r8/d0e76445.html.

71. For example, 0.806% of patents with no PTA are litigated, whereas only 0.459% of patents with 1–100 days of PTA are litigated.

see a spike in the number of assertions of patents with significant PTA, presumably because those patents have not yet reached the later years of their term when they will be most valuable.

Deliberate delay does not appear to explain the litigation frequency of patents with significant PTA. It is A delay, not B delay, that is responsible for the vast majority of PTA. And we find that applicant delay occurs in the same percentage of patents with PTA as in patents without PTA. The mean and median applicant delays are also similar between the two. Furthermore, companies with PTA are no more likely to maintain their patents, which we would expect to see if companies were deliberately delaying issuance of their most valuable patents. So, it does not seem that delay in litigated patents is the result of applicant behavior.

Figure 10: Percent of Patents Litigated by PTA



While PTA can be meaningful in any patent case—additional patent term will frequently mean a longer-running royalty—we find additional evidence that PTA has a meaningful impact on patent assertion behavior.

Specifically, we compare assertion timing between patents with and without PTA after controlling for exogenous effects on the likelihood of delay over time.[72]

72. What we want to assess is whether the presence or absence of delay during prosecution and/or the resulting PTA causes a difference in assertion behavior. One difficulty

We find that litigation of PTA patents is somewhat more focused on late-term assertions than litigation of non-PTA patents. Figure 11 below provides assertion information for patents with PTA (red) and patents without PTA (blue) based on the years from expiration. We studied only patents without terminal disclaimers. The y-axis provides the number of assertions of PTA/non-PTA patents at the indicated number of years from expiration divided by the total number of PTA/non-PTA assertions possible at the time. The results show that PTA patents are generally more likely to be asserted near the end of their term and generally a bit less likely to be asserted early in the patent term.[73] We see the same general trend when we break down the data by technology. Except for chemical, drug, and medical patents, peak assertions are a few years earlier, and in most cases, patents without PTA tend to be slightly more likely to be asserted.

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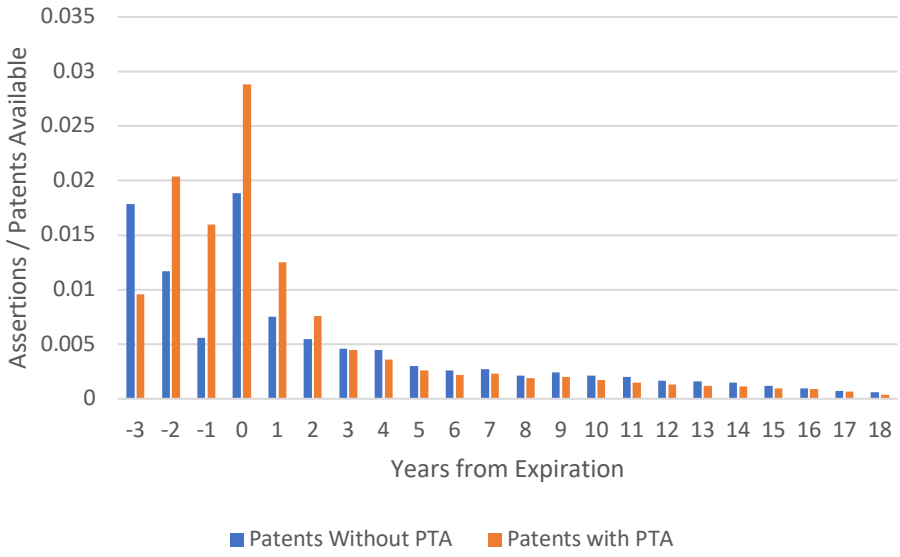
with such a comparison is that the distribution of expiration dates between PTA and non-PTA patents might differ, and it could be that distribution that causes an apparent difference in assertion timing. For example, suppose prosecution delays occurred almost exclusively during the last two years of the studied time period (note that this is obviously not the case in reality but rather provides a useful hypothetical). In that scenario, if we simply compared assertion behavior of PTA and non-PTA patents, we would find that non-PTA patent assertions are more likely to be near expiration than PTA patent assertions. But the reason would not be because of the prosecution delay or the added term but rather because patents with PTA are, on average, much younger and that many patents with PTA had not even matured to the point of being able to be asserted close to expiration.

To account for this issue, we calculate (separately for PTA and non-PTA patents) the number of assertions as a function of years from expiration and divide those values by the number of patents that could have been asserted that many years from expiration. For instance, suppose there were 100 assertions of PTA patents ten years from expiration and 50 assertions of PTA patents one year from expiration. Suppose also that 1000 PTA patents could have been asserted ten years from expiration but only 500 PTA patents could have been asserted one year from expiration (the others had expiration dates more than one year after the last studied day in the dataset). In this scenario, just looking at assertions would lead one to believe that near-expiration assertions are rarer than mid-life assertions, but after controlling for the number of patents that could have been asserted, mid- and late-term assertions seem approximately equally likely.

73. Because we studied patents that were filed on or after May 29, 2000, and that issued after 2005, many of the patents in our dataset are still in force and have not yet reached the later years of their term. Nevertheless, the dataset still included numerous patents without terminal disclaimers that nearly reached expiration. For example, nearly 150,000 such patents with PTA and nearly 300,000 such patents without PTA could have been asserted three years from expiration. And just over 50,000 such patents with PTA and nearly 90,000 such patents without PTA could have been asserted. It would be interesting to conduct the analysis again once more patents in the dataset have expired. The total number of asserted patents at -3 years from expiration is rather small for patents with PTA, which might explain the flip in the trend for that value.

Figure 11: Probability of Patent Assertion by Years from Expiration



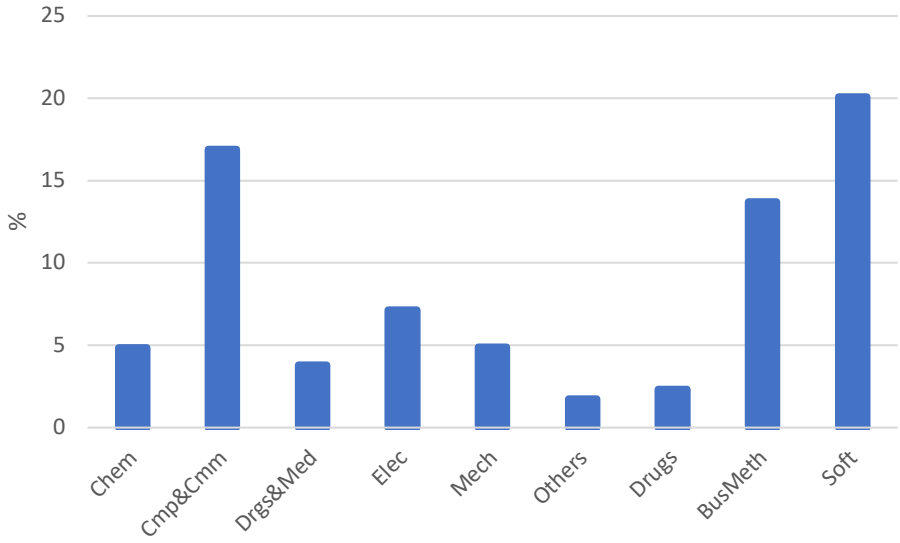
While we cannot draw causal conclusions from these associations, our findings are consistent with our theory noted above: patents with PTA miss out on some valuable early terms—making them less likely to be asserted early on. And PTA patents may be more likely to be asserted later, because a subset of patents particularly benefit from late-term extensions, whether that is because the technology is more useful at that late stage or because patent owners attempt to utilize late patent term to force a mature industry to license.

Figure 12 shows, by technology, the percentage of assertions of patents with PTA and no terminal disclaimer that fall within three years of expiration.[74] As shown in the figure, software, computer, communications, and business method patents are by far the most likely to be asserted within this time period. This result is surprising, considering such patents are widely believed to be most technologically relevant early in their lifespan.[75]

74. We find the same trend even after controlling for the fact that the distribution of expiration dates might differ for different technologies, an issue we discuss below. The total number of assertions for each category on the x-axis are as follows, respectively: 1178, 17595, 3858, 3287, 2286, 3298, 2352, 2363, and 9931.

75. *See supra* note 31 and accompanying text. Interestingly, another study showed that, in response to the changes in patent term following trips, market participants rushed to file certain software patent applications, suggesting that market actors care about patent term in the software space. *See* Neel U. Sukhatme & Judd N.L. Cramer, *Who Cares about Patents? Cross-Industry Differences in the Marginal Value of Patent Term*, 21 AM. L. & ECON. REV. 1, 5 (2019).

Figure 12: Percent of Patent Assertions Within Three Years of Expiration (Only Patents With PTA)



Next, we turn to the relationship between PTA and asserter type. For the rest of this section, when we refer to Patent Assertion Entities (PAEs), we mean those NPEs that acquire patents, and do not include individual patent owners, universities, or other NPEs asserting patents they themselves developed.[76] And when we refer to practicing entities (PEs), we mean product-producing companies and their subsidiaries.[77] We exclude litigation exclusively from patentees who do not fit in either category.[78]

Patents asserted by PAEs are more likely to have PTA than patents asserted by PEs (62.5% versus 51.1%). They also have more PTA. Looking only at patents that have PTA, patents asserted by PAEs tend to have more PTA (mean 593 days versus 466 days, median 508 days versus 340 days, 75th percentile 846 days versus 681 days), though the difference is fairly modest. We also compared these metrics when using each patent assertion as a unique

76. These entities are identified as Asserter Category 1 in the Stanford NPE Litigation Dataset.

77. These entities are identified as Asserter Categories 8 and 12 in the Stanford NPE Litigation Dataset.

78. The dataset includes more than 40,000 assertions by PEs and more than 20000 assertions by PAEs. The next closest asserter-type had fewer than 3500 assertions, and many had fewer than 1000.

data point (as opposed to each patent, so that patents are weighted by how frequently they are asserted) and reach similar findings.[79]

Many of these differences are explained by the differences in the technologies that patents asserted by PAEs and PEs tend to cover. In particular, after controlling for technology, the differences in the percentages of PAE- and PE-asserted patents with PTA goes away when the unit of measure is a patent. When weighted by the number of patent assertions, the differences largely remain,[80] suggesting that PAEs are more likely to assert patents with PTA more frequently. The differences in mean PTA largely go away regardless of weighting once we take technology into account, though PAE asserted patents still tend to have slightly more PTA than PE asserted patents.[81]

Although, after controlling for technology, PAE asserted patents are not all that different from PE asserted patents in terms of PTA, PAE assertion timing is different even after controlling for technology. For example, looking only at patents with PTA and no terminal disclaimer, 16.6% of PAE software patent assertions occurred within three years of expiration, while only 8.8% of PE assertions did.[82]

Of all such software patents PAEs asserted, 12.8% of them were asserted at least once in this timeframe. The same is true for only 3.5% of PE patents.[83] Comparing this to the numbers in the prior paragraph, it is evident that late assertions by PEs are concentrated in a small number of patents asserted multiple times (3.5% of PE patents make up 8.8% of PE assertions). The difference is much smaller for PAEs. The reason for this disconnect is unclear. For example, late-term PAE assertions may be more likely to focus only on the small percentage of patents that remain technologically relevant, while PAEs may be more likely to press even weak infringement claims near the end of a patent's term in an attempt to reap as much benefit as possible.

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79. For instance, the percentages of patents with PTA are similar, though slightly more disparate (65.6% versus 47.9%). The descriptive statistics concerning the amount of PTA are similar (mean 624 days versus 484 days, median 576 days versus 354 days, and 75th percentile 886 days versus 697 days).

80. The difference is 8 percentage points (73.0% versus 65.0%) for software patents and 6.9 percentage points for computer and communications patents (68.3% versus 61.4%).

81. Without weighting for number of assertions and looking only at patents with PTA, the means are 640 days versus 590 days for computers and communications, and 670 days versus 632 days for software. After weighting, the means are 645 days versus 602 days for computers and communications, and 677 days versus 645 days for software.

82. The percentages are similar for computer and communications patents (17.1% versus 6.9%).

83. The difference in the results is similar when looking at computer and communications patents (14.6% versus 3.3%).

Finally, we look at litigation outcomes between patents with and without PTA. We utilize Lex Machina's Patent Portfolio Evaluator, which provides information as to the number of validity and invalidity rulings issued by a district court concerning a patent.[84] For the rest of this section, the percentages refer to the percentages of patents with at least one invalidity or validity ruling. We find evidence that patents with PTA are slightly less likely to be held valid, on average, than patents without PTA. For example, 59.6% of patents without PTA have been the subject of only validity rulings, while the same is true for only 51.9% of patents with PTA. Patents with PTA are also more likely to be the subject of only invalidity rulings (42.2% versus 35.7%).[85]

We find similar, though generally smaller, differences when controlling for both assertion entity and technology. In particular, PE-asserted software patents with PTA are slightly less likely to be the subject of only validity rulings than such patents without PTA (32.6% versus 36.6%), though the percentages of patents subject to only invalidity rulings is approximately the same. PAE software patents with PTA are far more likely to be the subject of only invalidity rulings (76.9% versus 61.8%) and far less likely to be the subject of only validity rulings (16.7% versus 30.9%), though the total number of observations for patents without PTA (55) is relatively small.[86] When looking at computer and communications patents, the differences are still present but far smaller.[87]

As a robustness check, we also compared our dataset to Jonathan Ashtor's model that allows us to estimate similarity between patents.[88] Similarity between patents might be evidence of the weakness of the patents, since it suggests that the later patent does not differ significantly from the prior art.

84. The Evaluator includes rulings on motions, including rulings at the pleadings and at summary judgment. A patent can have more than one invalidity ruling where an initial invalidity decision invalidated only some claims of the patent.

85. The results for patents with PTA and B delay are extremely similar to the results for patents with PTA generally.

86. The values for patents with PTA and B delay are again similar to those for patents with PTA. Specifically, for PEs, 30.8% of such patents were subject to only validity rulings and 63.8% to only invalidity rulings. For PAEs, 15% of such patents were subject to only validity rulings and 82.5% to only invalidity rulings, though again the total number of such patents is small (40).

87. The difference between only validity and only invalidity rulings for PE patents is approximately 2%, and the differences for PAE patents is 6% and 4%, respectively.

88. *See generally* Jonathan H. Ashtor, *Investigating Cohort Similarity as an Ex Ante Alternative to Patent Forward Citations*, 16 J. EMPIRICAL LEG. STUD. 848 (2019). We are grateful to Jonathan Ashtor for sharing his dataset with us.

We find that patents with PTA are marginally more similar to their cohort than patents without PTA, but the difference is quite small.[89]

In short, the analysis of case outcomes suggests that among patents that were litigated to at least one merits decision, the weakest asserted patents are the ones that benefit most from PTA. But this observation appears to stem largely from the fact that software and computer patents—which tend to fare worse in court than other types of patents—tend to have the most PTA, as opposed to from some causal connection between patent strength and the patent's inherent ability to accumulate PTA.

F. PTE RESULTS

In this section we report our results relating to PTE, which were calculated based on the data we obtained from the USPTO website.[90]

In total, 949 patents have received PTE—a far cry from the millions of patents that have PTA. Patents that have PTE, however, have a lot of it: the mean PTE is 1048 days, the median PTE is 986 days, and 14.5% of the patents received the maximum 5-year extension. PTA and PTE are potentially cumulative,[91] and some patents have benefited from both.

For the rest of the analysis, we look only at the 331 patents that issued on or after 2000 because that's the first year of litigation coverage in the Stanford NPE Litigation Dataset. For such patents, the mean and median PTEs are similar (993 days and 966 days, respectively), and 10.3% of patents received the maximum 5-year extension.

The percentage of patents that have been litigated at least once is 31.1% (103 of 331), which is significantly larger than the percentage of patents that are litigated more generally, which is approximately 2% or less.[92] While the

89. Across all patents the mean cohort similarity is 2.34, with a higher number indicating more similarity. For PTA patents the mean is 2.35, and for patents without PTA the mean is 2.29. Because the standard deviation for the whole is 0.97, this difference is quite small.

90. *See Applications for Patent Term Extension and Patent Terms Extended Under 35 U.S.C. § 156*, USPTO, https://www.uspto.gov/patents/laws/patent-term-extension/patent-terms-extended-under-35-usc-156 (last visited June 2, 2023). For additional analysis concerning PTE, see generally Victor L. Van de Wiele, Aaron S. Kesselheim, Sarosh Nagar & S. Sean Tu, *The Prevalence of Drug Patent Term Extensions in the United States, 2000–2018*, 41 NATURE BIOTECHNOLOGY 903 (2023); Erika Lietzan & Kirstina M.L. Acri née Lybecker, *Distorted Drug Patents*, 95 WASH. L. REV. 1317 (2020).

91. *See* 35 U.S.C. § 156(a); John R. Thomas, *Towards FDA-USPTO Cooperation* (working paper 2024).

92. Mark A. Lemley, *Rational Ignorance at the Patent Office*, 95 NW. U. L. REV. 1495, 1507 (2001) (estimating 1.5%); Jean O. Lanjouw & Mark Schankermann, *Characteristics of Patent Litigation: A Window on Competition*, 32 RAND J. ECON. 129, 134–35 (2001); Christopher Beuchamp, *The First Patent Litigation Explosion*, 125 YALE L.J. 848, 882 (2016); David Pridham,

magnitude of the difference is quite striking, the direction of the difference is not. It is widely believed that life sciences, and particularly pharmaceutical, patents are most valuable,[93] and patents with PTE are on a subset of pharmaceutical inventions that have gone through the FDA regulatory approval process.[94] Comparing these percentages is also complicated by the fact that most litigation concerning FDA-approved drugs arises out of the Hatch-Waxman Act, which provides special rules that likely change the incentives to litigate.

The litigated and non-litigated patents with PTE have similar amounts of PTE. The mean and median number of assertions of litigated patents with PTE is 6 and 3, respectively.

Also contrary to patent assertions more generally, but not surprising given the FDA approval process, the vast majority of assertions were made by product companies. Specifically, all but three assertions were made by product companies (either alone or along with other entities), and the remaining three assertions were by an individual-inventor-started-companies. Of all the assertions, 85.3% were made solely by product companies or product companies and their subs. Only 4.7% of assertions were made by PAEs, and even those assertions were only made in cases where a product company was also a plaintiff.

While PTE is important because it will often delay generic entry, we briefly discuss litigation timing of PTE patents. Figure 13 below depicts the number of PTE patent assertions based on the number of years of remaining patent term. Most patents are asserted around the middle of their term, but there are still a meaningful number of assertions near the end of their term. We found

The Patent Litigation Lie, FORBES (Apr. 13, 2017), https://www.forbes.com/sites/davidpridham/2017/04/13/the-patent-litigation-lie/?sh=26a9df987ea9 (reporting Lex Machina data as showing a 1.9% litigation rate over the previous decade).

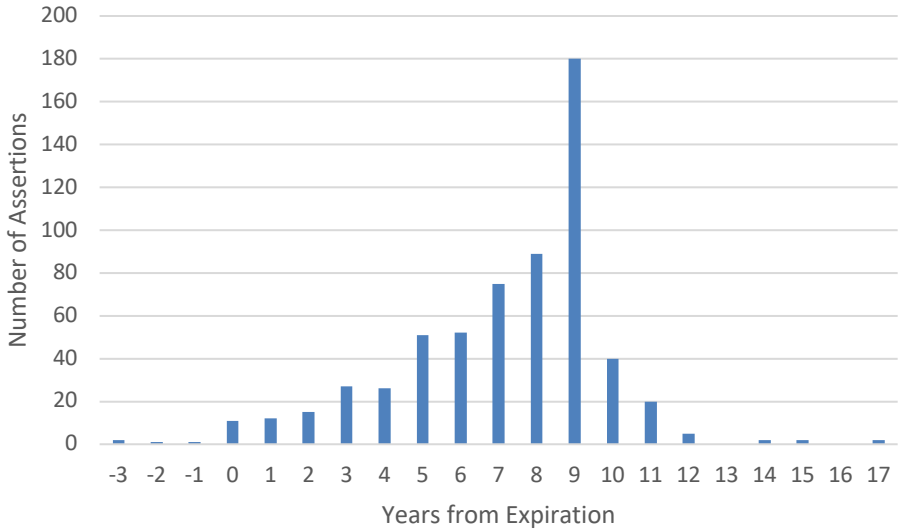
93. One study found that nearly half of the 170 top-selling drugs benefited from PTE, with the median extension being 2.75 years. *See* R.F. Beall, J.J Darrow & Aaron S. Kesselheim, *Patent Term Restoration for Top-Selling Drugs in the United States*, 24 DRUG DISCOVERY TODAY 29 (2019).

94. *See, e.g.*, WILLIAM M. LANDES & RICHARD A. POSNER, THE ECONOMIC STRUCTURE OF INTELLECTUAL PROPERTY LAW 316 (2003) ("[T]he strongest case for patents in something like their present form is said to be found in a subset of the drug industry."); JAMES BESSEN & MICHAEL J. MEURER, PATENT FAILURE (2008); Amy Kapczynski, Samantha Chaifetz, Zachery Katz & Yochai Benkler, *Addressing Global Health Inequities: An Open Licensing Approach for University Innovations*, 20 BERKELEY TECH. L.J. 1031, 1045 (2005) ("Many who accept these premises [that strong patents reduce innovation and welfare] nonetheless consider the pharmaceutical sector an exception."); Lisa Larrimore Ouellette, *How Many Patents Does it Take to Make a Drug – Follow-On Pharmaceutical Patents and University Licensing*, 17 MICH. TELE. & TECH. L. REV. 299, 302–04 (2010).

this somewhat surprising, because it suggests that many patents that received PTE would have been valuable even without it.[95]

We thought the results may be an artifact of the fact that we limited our analysis to patents that issued in 2000 or later, meaning that many patents in the dataset have not yet reached the end of their term. But while controlling for the distribution of expiration dates showed that late-term assertions are somewhat more common than Figure 13 would suggest; assertions are still by far most commonly raised between seven and nine years from expiration. The assertion timing results are also complicated by the fact that FDA-approved products are provided a period of regulatory exclusivity, and litigation does not typically ensue until these periods are nearly expired.

Figure 13: Assertions of PTE Patents Based on Years from Expiration



IV. IMPLICATIONS

A. THE PREVALENCE OF PTA IS PROBLEMATIC

Our data demonstrates that the exceptions to the twenty-year patent term have swallowed the rule. Most patents have at least some PTA, and many patents have significant amounts of PTA. And this PTA is relevant. Although patents without PTA are most likely to be litigated, patents with PTA are increasingly likely to be litigated as the amount of PTA increases. Relatedly,

95. One complication is evergreening, which means that even the end of PTE does not necessarily mean the end of regulatory exclusivity. Feldman, *supra* note 63, at 1.

patents with PTA are generally somewhat less likely to be litigated shortly after issuance and more likely to be litigated near expiration, possibly because such patents miss out on valuable early term on the front end and because some patents are quite valuable to the holder at the end of their term.

Surprisingly, business method, software, computer, and communications patents are among the most likely to have significant PTA. Prosecution delay for such patents is especially problematic because both effects of such delay—delayed issuance and extended term—raise concerns. Starting with delayed issuance, because these patents are most likely to be technologically relevant early in their lifespan,[96] prosecution delays reduce or eliminate the probability of obtaining such a patent while it still has value.[97] Such delays consequently reduce or eliminate the innovation incentive a patent is intended to provide.[98] And as we see, patents with PTA are generally somewhat less likely to be litigated on the front end.

Extended term can also be problematic in this context. For the reasons discussed previously, the extended term is unlikely to adequately compensate ordinary innovators for lost patent term up front.[99] At the same time, the extended term expands the opportunity for patent owners to assert technologically irrelevant patents to hold up innovation when they are enforced. And that is particularly problematic when the patents are bought late in life by PAEs who seek to assert them against a mature industry. Increased opportunity for gamesmanship with PTA patents could be why we see such patents asserted more frequently near expiration. In short, prosecution delay, and thus PTA, is most common in fields where the delay is most likely to reduce innovation incentives, and where the remedy is both least likely to compensate true innovators and most likely to increase opportunity for undesirable gamesmanship.

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96. *See supra* note 31.

97. Although patentees can obtain "provisional rights" damages between the date the patent application publishes and the date of issuance under some circumstances, those circumstances are rare: the accused infringer must have had "actual notice of the published patent application," and "the invention as claimed int eh patent is substantially identical to the invention as claimed in the published patent application." 35 U.S.C. § 154(d). Due to these strict requirements, even seeking such damages is extremely rare.

98. *See* Douglas Gary Lichtman, *The Economics of Innovation: Protecting Unpatentable Goods*, 81 MINN. L. REV. 693, 701–02 (1997); Rebecca S. Eisenberg, *Patents and the Progress of Science: Exclusive Rights and Experimental Use*, 56 U. CHI. L. REV. 1017, 1024–25 (1989); Edmund W. Kitch, *The Nature and Function of the Patent System*, 20 J.L. & ECON. 265, 276–77 (1977); Kenneth J. Arrow, *Economic Welfare and the Allocation of Resources for Invention*, THE RATE AND DIRECTION OF INVENTIVE ACTIVITY: ECONOMIC AND SOCIAL FACTORS 609, 615 (1962).

99. *See supra* notes 30–31 and accompanying text.

Indeed, we find that PTA is most likely to be exploited by opportunistic actors in these fields. PAE-owned patents with PTA have the greatest concentration of assertions near the end of their patent life that are most likely to benefit from PTA. PAEs who purchase patents from others to assert them make greater use of term-extended patents than other plaintiffs, and we find evidence that PAEs seem particularly likely to assert such patents after they are technologically obsolete.

The prevalence of PTA isn't ideal. It is not great for ordinary patentees, who get on the back end something that is oftentimes less valuable than what they lose on the front end from delay. It is also not ideal for the public, because inventions enter the public domain later than they otherwise would. The prevalence of PTA increases opportunities for gamesmanship, both in litigation and in patent prosecution.[100] Furthermore, this trend is particularly problematic because it strengthens the hand of the least socially useful patents—those purchased and asserted by PAEs at the end of the patent term in the software industry—well after the technology tends to be obsolete.

B. POTENTIAL SOLUTIONS

What we should do about the PTA problem depends on whether the source of delay is (a) prosecution gamesmanship by applicants, (b) the fault of the USPTO, or (c) problematic PTA rules. Our evidence suggests—to our surprise—that the latter two likely play the greatest role.

1. Is Gaming the Problem?

It seems unlikely that applicants have significant opportunity to game prosecution to obtain significant delay. As an initial matter, some applicant delay is subtracted from the total PTA calculation, which means that applicants would be able to game prosecution only by creating delay that gets credited against the USPTO. That is certainly possible in part, because filing certain additional documents (such as appeals) triggers additional USPTO responses, and once the three years have passed, the delay can be compensated as B delay

100. For one interesting example, see *In re* Xencor Corp., Inc., No. 23-2048 (Fed. Cir. Jan. 23, 2024). There, the patent applicant appealed an adverse PTAB decision to the Federal Circuit. The USPTO essentially confessed error, saying that the court should dismiss the appeal so the USPTO could reconsider the Board's decision. Despite the fact that the applicant seemed likely to win without having to argue its appeal, it opposed remanding the case. Why? Because it stood to lose 653 days of C delay if it did not obtain a reversal on appeal as opposed to an ultimate agreement to patentability. Dennis Crouch, *USPTO Again Asks for Remand in Xencor to Reconsider its Decisions*, PATENTLYO (Dec. 7, 2023), https://patentlyo.com/patent/2023/12/xencor-reconsider-decisions.html.

or C delay. Further, as we have seen, there is some amount of double-counting, so patentees interested in gaming the delay system can get extra benefits.

But if deliberate efforts at term extension were a significant problem, we would expect to see much more double-counting delay than we do. We would also expect to see manipulation that led to C delay—triggering appeals for certain claims, for instance. But C delay turns out to be a very small part of aggregate delay, suggesting that this behavior is relatively uncommon.[101] We would also expect patentees to be more likely to maintain their patents with PTA. But that is not the case. And we would expect that the parties engaging in gaming would turn out to be the ones asserting those patents at the end of the patents' lives. In fact, however, a large fraction of those assertions is by PAEs who buy the patents much later. They could not have been involved in the delay, and the chain of inferences that suggests patentees might deliberately delay prosecution in hopes of later selling to a PAE seems long and quite improbable.

Type A delay is the greatest source of PTA. We think it would be difficult for patent applicants to manufacture such delay. Type A delay relates to ensuring prompt responses from the USPTO during prosecution. It would generally be difficult for applicants to cause the USPTO to provide a delayed response. By far the biggest source of A delay is the USPTO's general inability to provide a first action within 14 months of the filing of a patent application.[102] It seems most likely that the USPTO's inability to meet this deadline is due to the brevity of this deadline and the volume of patent applications filed each year, not because certain applicants are drafting applications to delay USPTO response times.

Because we found that certain examiner art units are far greater sources of PTA than others,[103] it is theoretically possible that applicants could attempt to shoehorn their application into an art unit expected to provide significant PTA. While the prevalence of such a practice is worthy of future study, and although targeting favorable art units seems to happen at least to place patent applications in art units with high allowance rates,[104] we believe it is unlikely

101. *See supra* Part II.C.

102. *Patent Term Adjustment Data March 2023*, USPTO, https://www.uspto.gov/dashboard/patents/patent-term-adjustment-new.html (last visited May 10, 2023).

103. *See supra* Part II.D.

104. *See, e.g.*, John R. Allison & Starling D. Hunter, *On the Feasibility of Improving Patent Quality One Technology at a Time: The Case of Business Methods*, 21 BERKELEY TECH. L.J. 729, 738, 760–62, 786 (2006); *How Classification Works at the USPTO: Targeted Drafting to Influence Prosecution Outcomes*, LEXISNEXIS (June 16, 2020), https://www.lexisnexisip.com/resources/how-classification-works-at-the-uspto/; Terri Shieh-Newton & Mark D. Hammond, *Examining Art Units to Avoid Subject Matter Eligibility Challenges for Bioinformatics and AI-Related Patents*, MINTZ

that patent applicants are targeting backlogged art units in any significant respect.

Another significant source of PTA is B delay. Again, we think it is unlikely that applicants are manufacturing significant levels of B delay. As an initial matter, it appears that many instances of B delay are caused by A delay, and as we just discussed, we think it is unlikely that applicants are manufacturing significant A delay.

While the instances of B delay that are not caused by A delay seem to be at greater risk of gamesmanship, because applicants may attempt to draw out prosecution beyond three years to receive additional patent terms on the back end, current calculation practices minimize or eliminate such opportunities. In *Intra-Cellular Therapies, Inc. v. Iancu*, the Federal Circuit concluded that an applicant's response to a final Office action did not avoid a reduction for applicant-caused delay unless it was an appeal or an RCE, even if the response amounted to a bona fide attempt to address all outstanding issues.[105] And the PTA statute "prevents extension of PTA through B Delay accrual for time consumed by an RCE."[106]

Additionally, an applicant cannot file numerous child applications in hopes of accumulating additional delay: "a patent term adjustment in a parent patent does not apply to any child patent."[107] In view of these rules, it seems difficult to game prosecution to accrue substantial B delay simply by filing continuations or extra documents before the examiner in normal prosecution.[108]

(Nov. 18, 2021), https://www.mintz.com/insights-center/viewpoints/2231/2021-11-18-examining-art-units-avoid-subject-matter-eligibility; Gaurav Gupta, *Overcoming Abstract Idea Rejection with Targeted Patent Application Drafting*, SAGACIOUS IP, https://sagaciousresearch.com/blog/overcoming-abstract-idea-rejection-with-targeted-patent-application-drafting/ (last visited May 10, 2023); *Art Unit Predictor*, PATENTBOTS, https://www.patentbots.com/about-art-unit-predictor (last visited May 10, 2023); Gene Quinn, *Avoid the Patent Pit of Despair: Drafting Claims Away from TC 3600*, IPWATCHDOG (June 25, 2020), https://ipwatchdog.com/2020/06/25/avoid-patent-pit-despair-drafting-claims-away-tc-3600/id=122838.

105. Intra-Cellular Therapies, Inc. v. Iancu, 938 F.3d 1371, 1375, 1379–80 (Fed. Cir. 2019).

106. *Id.* at 1382.

107. Robert A. Matthews, *Extensions for USPTO Delays—Tacking a Patent Term Adjustment From One Patent to Another Patent*, 1 ANNOTATED PATENT DIGEST § 9:24.50; *see also*, *e.g.*, Mohsenzadeh v. Lee, 790 F.3d 1377 (Fed. Cir. 2015).

108. Nor can patent applicants game prosecution by filing continuation applications. *See, e.g.*, Matthews § 9:24:50 (explaining that PTA applies only to the patent for which the adjustment was issued).

2. Speeding the Prosecution Process

Because PTA seems largely due to delays caused by the USPTO, the best way to address PTA would be to examine patents faster. The changes in PTA from year to year largely stem from the USPTO catching up on its backlog over time, at least before Covid.[109] One way to do that is to increase the USPTO's examination resources (e.g., to increase the number of patent examiners),[110] or at least to prioritize resources in art units where PTA is most problematic. The USPTO could prioritize business method, software, computer, and communications patents because, as explained above, for these technologies PTA has a higher probability of promoting undesirable gamesmanship, a higher probability of reducing innovation incentives, and a lower probability of rewarding true innovation. Alternatively, it could prioritize certain applications that seem particularly important, like those likely to be listed in the FDA's Orange Book.[111] Doing so would cause pharmaceutical patents to expire earlier, reducing drug prices at the end of the patent term when the PTE patent is the one delaying generic entry. Whether that is a good thing depends on whether you think the existing system (including evergreening and multiple patents) provides too much protection to pharmaceutical companies or not enough.[112] Notably, the USPTO could do

109. *See supra* Part II.B.

110. There is a significant literature on when and whether it is efficient to devote more resources to patent examination. *Compare* Lemley, *supra* note 92, *with* Michael D. Frakes & Melissa F. Wasserman, *Irrational Ignorance at the Patent Office*, 72 VAND. L. REV. 975 (2019), *and* S. Sean Tu & Mark A. Lemley, *What Litigators Can Teach the Patent Office About Pharmaceutical Patents*, 99 WASH U. L. REV. 1673 (2022).

111. The Orange Book refers to the document that lists drugs that the FDA has approved, as well as applicable patents associated with each product. Lemley & Tu demonstrate that pharmaceutical patent applicants know in advance which of their patents are likely destined to be listed in the Orange Book. Tu & Lemley, *supra* note 109, at 1677. And Orange Book patents are far more important than the average patent. *See generally* Michael D. Frakes & Melissa F. Wasserman, *Investing in Ex Ante Regulation: Evidence from Pharmaceutical Patent Examination* 4–7 (Nat'l Bureau of Econ. Rsch., Working Paper No. 27579, 2020). For a discussion of how to predict which patents will be listed in the Orange Book, see Tu & Lemley, *supra* note 9; Colleen V. Chien, Nicholas Halkowski & Jeffrey M. Kuhn, *Distinguishing and Predicting Drug Patents*, 41 NATURE BIOTECHNOLOGY 317 (2023).

112. This is a complex empirical question we do not purport to resolve here. *See, e.g.*, Lisa Larrimore Ouellette, *Patent Experimentalism*, 101 VA. L. REV. 65, 75–87 (2015); Eric Budish, Benjamin N. Roin & Heidi Williams, *Do Firms Underinvest in Long-Term Research? Evidence from Cancer Clinical Trials*, 105 AM. ECON. REV. 2044 (2015); Eric Budish, Benjamin N. Roin, & Heidi Williams, *Do Fixed Patent Terms Distort Innovation?* (Chicago Booth, Working Paper No. 13-79, 2013); Robin Feldman, *'One-and-Done' for New Drugs Could Cut Patent Thickets and Boost Generic Competition*, STAT (Feb. 11, 2019), https://www.statnews.com/2019/02/11/drug-patent-protection-one-done/. Another option is that the system sometimes provides too

these things without any need for action by Congress, merely by reallocating resources.

The USPTO appears to have already begun making headway with respect to reducing PTA for software and computer patents. Specifically, we broke the data into patents issuing between 2005–2014 and patents issuing on or after 2015. We then looked at mean, median, and 75th percentile PTA. After doing so, we see an even starker difference for computer and software patents between 2005 and 2014 and very little difference between technology categories after 2014 (except drug and electrical patents still have less PTA, and software patents still tend to have a bit more PTA). The fact that the PTA differences converge in the later-studied years seems sensible considering that the overall prevalence of PTA was significantly smaller in that timeframe. In addition, we see that the USPTO increased its throughput of software patents more than other types of patents in the later time period, suggesting that the USPTO increased its examination resources for software patents.

Even though the prevalence of PTA in software patents has reduced in recent years and become closer to the amount observed in many other technology categories, we think more can be done. As explained previously, software patents seem particularly prejudiced by late grants and are most prone to be abused late-term, and thus there is a strong argument that software patents should have the least amount of PTA.

Even if the USPTO wasn't willing or able to devote more resources to accelerating patent prosecution, the USPTO could potentially change internal practices in ways that moved patents through the office more quickly. For example, it could promote interviews earlier in the process, in hopes of coming to agreement without going through multiple rounds of rejections.[113] It could change the way examiners are rewarded, to end the cycle of encouraging two office actions including a "final" rejection—a classic misnomer—in almost all cases.[114] It could shorten or eliminate the ability applicants have to extend virtually all deadlines.[115] And it could direct examiners to prioritize responses that are nearing the four-month threshold and patent applications that are

much protection and other times provides not enough, which would mean that PTA is a mixed bag.

113. *Full First Action Interview Pilot Program*, USPTO, https://www.uspto.gov/patents/initiatives/first-action-interview/full-first-action-interview-pilot-program (last visited Aug. 2, 2023).

114. Mark A. Lemley & Bhaven Sampat, 2010 STAN. TECH. L. REV. 1, 9 (2010).

115. The statute provides for a three-month response window, 35 U.S.C. § 154(b), but applicants can pay a fee to extend that time for another three months. *See How Does a Patent Extension of Time Work?*, PATENTTRADEMARKBLOG, https://www.patenttrademarkblog.com/patent-extension-of-time/ (last visited Mar. 16, 2024).

approaching the three-year threshold, reducing the incidence of both A and B delay. To be clear, we should approach these changes with care. Some, like early interviews, may have the effect of speeding the process by reducing the rigor of patent examination.[116] And that is probably undesirable. We are probably better off speeding patent examination, at least in what seem likely to be important patents.

3. Reducing Incentives for Filing Software Patent Applications

Even if increasing the USPTO's examination resources is infeasible, another potential solution is to reduce the workload—that is, reduce the number of business method, software, computer, and communications patent applications that are filed. While a cost-benefit analysis concerning the appropriate amount of patent protection afforded to software patents is beyond the scope of this article,[117] we simply note here that changes to the level of patent protection afforded to software patents could have a large impact on the number of software patent applications the USPTO must examine.[118]

4. Reforming PTA

Certain PTA rule changes might also be helpful. Most notably, we propose disposing of the rule set forth in *Wyeth*, because it permits patentees to receive PTA for A delay *and* B delay even when the A delay was the "but for" cause of the B delay.[119] The rule thus effectively permits double-counting of delay. A hypothetical discussed in *Wyeth* illustrates the point.[120] Suppose Applicant 1 and Applicant 2 each receive a (different) patent three years and thirty days after filing their applications, but Applicant 1 (and not Applicant 2) incurred 30 days of A delay before the 3-year mark. Here, Applicant 1 receives a sixty-day adjustment while Applicant 2 receives a thirty-day adjustment, even though both patents issued the same amount of time from filing, and even

116. Examiner interviews offer applicants an opportunity to dispute the merits of any rejection with the examiner. At the same time, the interviews are not recorded and usually complete with a limited record. Interviews often lead to the allowance of a patent but for unclear reasons. *See, e.g.*, Tu & Lemley, *supra* note 109, at n.88; *see generally* S. Sean Tu, *Patent Examination and Examiner Interviews*, 49 FLA. ST. U. L. REV. ONLINE 1, 12–13 (2021).

117. For an overview of the scholarly debate and potential fixes to software patents, see generally Mark A. Lemley, *Software Patents and the Return of Functional Claiming*, 2013 WIS. L. REV. 905.

118. Some have suggested that *Alice* created such a change, but in fact the number of software patents quickly rebounded to pre-*Alice* levels, *see* Nikola L. Datzov, *The Role of Patent (In)eligibility in Artificial Intelligence Innovation*, 92 UMKC L. REV. 1 (2023), in part because the USPTO adopted rules that granted patents *Alice* would not in fact uphold.

119. Wyeth v. Kappos, 591 F.3d at 1369–70.

120. *Id.* at 1370.

though Applicant 1 incurred B delay only because of the A delay. That is, after compensating Applicant 1 for the thirty days of A delay, Applicant 1 is placed in a position equivalent to where the patent would have properly issued three years after filing. Thus, Applicant 1 is fully compensated after receiving thirty days of PTA, not sixty.

The court in *Wyeth* countered with a hypothetical that, in its view, demonstrated that the "but for" approach also produces anomalous results. Specifically, suppose Applicant 1 incurs 400 days of A delay before the three-year mark and receives a patent exactly three years from filing. Suppose also that Applicant 2 also incurs 400 days of A delay before the three-year mark but additionally incurs one year of B delay (thus issuing one year after Applicant 1's patent). In such a scenario, both applicants would receive 400 days of PTA under the "but for" rule, which the court thought was imbalanced because Applicant 1's term would be a full year greater than Applicant 2's effective term (due to Application 2 issuing a year later) even though both parties incurred the same A delay.[121]

The court's hypothetical is not persuasive. It merely demonstrates that patent applications that spend additional time in prosecution generally have shorter effective terms. In other words, there is no imbalance here: Application 2 simply took longer to get through prosecution. Importantly, in this hypothetical, Application 2's B delay is due to otherwise timely prosecution—i.e., prosecution that would have been fully within the rules had there been no A delay. In such circumstances, it is understandable that applications 1 and 2 ultimately have different effective terms.[122]

To estimate the impact of *Wyeth*, we calculate that 22.9% of patents with PTA have A and B delay that both exceed the overlap delay (meaning the patent definitely benefits from at least some A delay and at least some B delay).[123] The number is slightly lower when looking at only litigated patents (19.4%) or drugs and medical patents (20.9%), and slightly higher when looking only at software patents (26.3%). Changing this rule alone could impact approximately a third of patents with PTA.

121. *Id.*

122. To be clear, the reason we take issue with the court's hypothetical is because the A delay caused the year of B delay. But suppose instead that application 2's additional year of prosecution included two months of A delay by the USPTO. Under our proposal, those two months would still be credited for the patentee—the cause of that delay is the USPTO's failure to meet a response deadline, not the initial period of A delay.

123. Because nearly all A delay occurs before the three-year clock starts ticking, this calculation provides a rough estimate for the percentage of patents benefitting from *Wyeth*. *See supra* note 99 and accompanying text.

To get a rough upper bound as to how much patents benefit from double-counting under *Wyeth*, for the relevant patents, we estimated double-counted delay as the lesser of A and B delay subtracted by the overlap delay. We also set a max double-counted delay to twenty-two months (the difference between three years and the fourteen months the USPTO is allotted to provide its first response). We calculate a mean double-counted delay of 218 days, a median of 189 days, a 75th percentile of 313 days, and a 95th percentile of 542 days. Although these calculations only provide an estimate, it thus appears that many patents receive significantly extended terms in view of *Wyeth*.

Measures to eliminate double-counting could go even further. One idea would be to get rid of A delay completely; B delay already accounts for undue delay by the USPTO, and an applicant can always move things along by filing an appeal. Because it is based on a set prosecution goal, B delay tries to ensure a minimum term (with important limitations we discussed above to prevent submarine patenting), which seems a laudable goal. A delay seems more based on fairness resulting from the prosecution process, but most significant delays in the prosecution process will be compensated for by B delay.

Short of eliminating A delay altogether, we think it makes sense to eliminate all double-counting of A and B delay. The purpose of term adjustment is to ensure that USPTO behavior and the vagaries of the prosecution process don't unfairly reduce patent terms. But that isn't a reason we should artificially increase patent term by counting the same delay twice. This change should only have modest effects in most cases.

By contrast, we would not eliminate the ability to cumulate PTE and PTA, except when the day involved is the same actual calendar day. Only in that scenario does the patentee earn two days of extension for only one true day of delay.[124] Unlike PTA, PTE is designed to compensate for lost term during the FDA regulatory review process. And while we might worry in theory about pharmaceutical patent owners deliberately racking up PTA to add on to the end of their term when their patents are most valuable, our data suggest that doesn't seem to be very common, and the law has safeguards to prevent most sorts of deliberate delay.

Since the requirement that the first response occur within fourteen months seems a bit arbitrary, another option would be to increase the time allotted for that deadline. If the increase was significant enough, the result would be to

124. *See, e.g.*, John R. Thomas, *Listening Session on Joint USPTO-FDA Collaboration Initiatives Additional Written Remarks of Professor John R. Thomas*, at 15 (Jan. 19, 2023). That scenario is extremely unlikely to occur, because PTA is calculated during prosecution and PTE is applied at the end of a patent term. It may happen only in unusual cases involving continuations or divisional applications.

effectively eliminate A delay except for the most egregious of cases. Another potential advantage would be that the deadline for the first action would better align with current realistic expectations from the USPTO.[125]

V. CONCLUSION

While we normally refer to patent term as running twenty years from the filing date, that's not true for most patents today. In practice, we have a patent term that runs somewhere between twenty and thirty years but averages something close to twenty-one years. PTA ensures that patentees don't lose term because of delays at the USPTO. But it isn't full compensation; an extra year at the end of a patent's life is not as good as an extra year at the beginning for most patent owners. And the PTA system ends up disproportionately being used by PAEs in litigation, a result that seems socially unproductive.

Despite its imperfections and notwithstanding some suggestions we have for reform, the PTA system works pretty well at achieving the goal of compensating patentees for patent prosecution delay. But we would be better off with a world in which delay wasn't nearly as common as it is.

125. If what we care about most is late-term patent abuse, we could increase the frequency or value of the maintenance fee payments so that more patents expire due to nonpayment of maintenance fees before reaching their final years. *See, e.g.*, Love, *supra* note 5, at 1356–59. Furthermore, we do not advocate for increasing patentees' ability to seek provisional rights because the strict limitations on those rights are important for reducing opportunity for gamesmanship and for ensuring at least some degree of notice. *See supra* note 99.

INTENTIONALITY IN TRADE SECRET LAW

Charles Tait Graves[†]

ABSTRACT

Trade secret law places more scrutiny on a party's intent—what it was thinking, what it considered, or what it should have considered—than other categories of intellectual property law. At inflection points across a range of possible disputes, the law inquires into the mindset of one party or the other. Embedded in the federal and state statutes is a legislative intent that absent wrongful intent—or at least constructive knowledge—there can be no misappropriation.

This focus on a party's state of mind comes as no surprise. Because trade secret rights are not registered with any government agency, there is no formal means by which they can be identified in advance. One encounters a trade secret in the wild, so to speak, and one may not always recognize it as such. There are no monopolies in trade secrets, and thus one may receive the same information from more than one source, rendering recognition of trade secret rights more difficult. For sound reasons, then, trade secret misappropriation is not a strict liability wrong.

Despite this statutory mandate, there has been little discussion of intentionality when it comes to questions of secondary liability. By secondary liability, we mean cases where a plaintiff seeks liability against one defendant for the act of another. This Article centers on such questions, because that is where the requirement that trade secret misappropriation be intentional most needs attention. There are three areas in particular where the law should better recognize intent-based defenses to secondary liability.

This Article offers three propositions. First, we will explore important language in the federal Defend Trade Secrets Act and the Uniform Trade Secrets Act which blocks liability in some instances where a defendant has received a trade secret from a third party by "accident or mistake." This clause presents a statutory safe harbor, in certain instances, for using a trade secret without intent. Courts should rescue this clause from seeming oblivion and apply it where one defendant has innocently received a trade secret from a third party and used it without notice.

Second, we will explore vicarious liability in trade secret law, where an employer-defendant is held to account for the actions of an employee within the scope of his or her employment even though company management was unaware of, and may well oppose, such conduct. Courts have adopted vicarious liability under the trade secret statutes. But they have largely overlooked common law exceptions that could apply in many cases, especially where a new employer should not be accountable for a new hire's off-premises activity.

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Third, this Article will analyze the statutory concept of willful and malicious misappropriation, where a defendant may face enhanced damages. Though courts apply relatively consistent standards to define this heightened level of wrongful intent, they have not distinguished between the differing levels of intent of an employer-defendant and an employee-defendant. There is a difference between top-down coordinated wrongdoing by company management and lower-level employees making ad-hoc decisions on their own. Highlighting different levels of intent in such cases could avoid the exaggerated damages claims so often seen in trade secret litigation.

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I. INTRODUCTION

Questions of a party's intent or state of mind are pervasive in trade secret law. The controlling statutes call for an examination of the defendant's state of mind—and, less often, the plaintiff's state of mind—at a variety of points spanning the lifecycle of a lawsuit. When one reviews the text of the federal Defend Trade Secrets Act (DTSA) and the state-law Uniform Trade Secrets Act (UTSA), the number of points across these statutes where a party's state of mind matters to the outcome is striking.[1]

But courts too often gloss over circumstances where a defendant's actual or constructive knowledge is less clear, especially when it comes to secondary liability—meaning, where a trade secret plaintiff seeks liability, or enhanced damages, against one defendant for the conduct of another.[2]

Focusing on intent in trade secret cases matters. Doing so has important consequences for reining in overbroad or exaggerated lawsuits. To that end,

1. Our focus here is civil disputes. Questions of intent in criminal trade secret cases are different, because in that context attempted misappropriation itself is a crime. *E.g.*, 18 U.S.C. § 1831(a)(4) (federal economic espionage statute; one who "attempts to commit any offense" described therein has engaged in a criminal act).

2. "Secondary liability" can mean different things in different legal contexts. To frame the concept for purposes of trade secret law, we could coin some bespoke term, to emphasize what is unique about the disputes at issue here. But that would needlessly complicate things. As this author has noted elsewhere, words such as "property" and "standing" have meanings peculiar to trade secret law. When analyzing trade secret law, we should always define such terms immanently, as it were, and not import meanings found in patent law or other areas of law.

this Article examines three intent-based inflection points where greater judicial attention could have a significant impact on how trade secret cases are adjudicated. Each is a question of secondary liability. In these instances, courts have not done enough to separately analyze the intent of each defendant. Doing so in these three scenarios could reduce the cost and complexity of trade secret cases, which are notoriously expensive and time-consuming, and help illustrate when small infractions by employees on the move are used to inflate cases against competitors which hire them.

Increased attention to questions of secondary liability is one way to impose limits on a structural problem in trade secret law: the ease of filing suit against multiple defendants and imposing asymmetrical costs on a rival, independent of the merits. Trade secret law is an area where one can file a lawsuit against a competitor based on relatively minor conduct by someone other than the primary defendant.

A ubiquitous example is lawsuits filed against a new employer where a departing employee downloaded files from the prior employer before joining the new one. That act, carried out while the employee was still employed by the plaintiff, can be a "hook"—so to speak—to bring costly and wide-ranging claims against the hiring company, even if it was unaware of the download, and even if the downloaded files carried little value or were never used. In such cases, we should not assume that the new employer could be secondarily liable for such activity, or subject to enhanced damages, even if the employee in transit could be.

Separating the intent of the individual defendant from the intent of the new employer in such disputes is a powerful means of reducing the temperature. If courts understand that a new employer or other corporate defendant is not always in the know, and that its intentionality must be separately assessed in order to impose separate liability, or to consider enhanced damages, greater attention to questions of intent can reduce lawsuits filed or maintained for anticompetitive purposes.

Our study of intentionality in trade secret law has four Parts. First, in order to frame three propositions regarding secondary trade secret liability, we will map the standards for assessing a defendant's intent as to "misappropriation" under the DTSA and the UTSA. That proves to be a complicated question, as trade secret law measures actual and constructive notice in a variety of contexts. We will explore the question of constructive knowledge in difficult instances, such as when a party receives a threat letter from a potential plaintiff. And we will probe whether or not imputed knowledge—a doctrine under which companies can be deemed to know what their executives know—can

substitute for actual and constructive knowledge where the executive remembers trade secrets from a prior job.

Then, with precise definitions of intentionality in trade secret law in hand, we turn to three underdeveloped areas of trade secret law where courts should pay greater attention to assessing intent when a plaintiff pursues secondary liability.

We begin with the "accident or mistake" language found in the DTSA and the UTSA. This is defensive language designed to reduce—or eliminate—one form of secondary liability for misappropriation. It provides a safe harbor from liability for misappropriation in situations where a defendant innocently received the plaintiff's trade secret from some other person or entity, and then undertakes some act in reliance on it, before learning that the information is the plaintiff's trade secret. Take, for example, a company which buys or licenses technology from a third party in an ordinary commercial transaction, believing that the seller or licensor has full rights to what it transfers. If the company then uses that information in reliance on its innocent acquisition, and only later learns of a trade secret problem, this statutory safe harbor could prevent (or at least limit) a finding of "misappropriation."

This powerful clause in the DTSA and the UTSA has been overlooked by litigants and courts. Vanishingly few cases address it. This statutory safe harbor should be rescued from oblivion and restored it to its rightful place in the calculus of what acts constitute trade secret misappropriation. The "accident or mistake" clause should provide protection for unintentional—that is, accidental or mistaken—receipt of a trade secret from a third party such as a commercial licensor or seller where the defendant has materially changed its position such that it would be inequitable to impose liability for using the information, including at least some degree of future use. Doing so would solve lingering uncertainty in the case law regarding downstream liability for innocent receipt of someone else's trade secret.

Second, we will examine a company's vicarious liability for acts of trade secret misappropriation by its employees. Most courts agree that the common law doctrine of vicarious liability applies to the DTSA and the UTSA. But very few courts address exceptions to vicarious liability: situations where the employer is not liable for an employee's acts outside the course and scope of employment. This is surprising because so many trade secret lawsuits turn on accusations that an employee downloaded files from the former employer when leaving the company, albeit without evidence that the files were used or transferred to the new employer. Because such cases can lead to anticompetitive attacks on smaller rivals, often simply to punish them for

hiring from the plaintiff, courts should be more attentive to limits to vicarious liability.

Third, we turn to enhanced damages for what the DTSA and the UTSA call "willful and malicious misappropriation." Here, a defendant found liable for misappropriation may face up to treble damages if a court or jury finds this heightened level of wrongful intent. But the term begs the question: whose intent? Company executives? Or ad-hoc conduct of lower-level employees, where management may have been unaware of their acts? What if there are different intentions by different employees? And what if the employer has provided at least some degree of training or policies to employees in order to reduce the possibility of trade secret problems? Courts should pay more attention to the distinction between malice by a company and malice by an employee, and not conflate the two.

These three proposals regarding secondary trade secret liability fill a gap in the trade secret literature. The scholarly commentary is thin when it comes to intentionality in trade secret cases. Few articles directly address any facet of intentionality.[3] Some important articles indirectly raise questions of intent

3. *See generally* Michael L. Rustad, *The Negligent Enablement of Trade Secret Misappropriation*, 22 SANTA CLARA HIGH TECH. L.J. 455, 458, 518–521 (2005) (proposing, in the wake of the U.S. Supreme Court's decision in *Metro-Goldwyn-Meyer Studios, Inc. v. Grokster, Ltd.*, 125 S. Ct. 2764, 2775 (2005), to allow an intentional inducement theory of copyright infringement liability against a peer-to-peer sharing tool, that trade secret law "be amended to give the corporate victims of espionage standing to file a statutory tort action against the primary wrongdoers as well as the software provider whose defective software frequently paves the way for economic or industrial espionage"; positing without empirical data that "[s]oftware vendors that market products with known vulnerabilities and online intermediaries who do not implement adequate security foreseeably enable cybercriminals to intercept data and misappropriate trade secrets"; commentor did not provide any data showing any such thing, adequately define a class of software vendors to which this would apply, or explain why someone using software to accomplish a misappropriation is any different than someone using a telephone or fax machine to that end). *Cf.* Robert G. Bone, *Secondary Liability for Trade Secret Misappropriation: A Comment*, 22 SANTA CLARA HIGH TECH. L.J. 529, 530, 535–41 (2005) (persuasive rebuttal to Rustad's proposal noting, among other things, that the notion of a software maker's "defect" that renders "secrets vulnerable to misappropriation" is a different context than Grokster-like tools that allow multiple acts of infringement by different people under no common control, but instead typically involve related groups of employees and a new employer, and that imposing potential liability on software makers on a theory that some third party would exploit the software for misappropriation could "chill software innovation); *see also* Elizabeth A. Rowe, *Contributory Negligence, Technology, and Trade Secrets*, 17 GEO. MASON L. REV. 1, 26–33 (2009) (proposing that the reasonable security measures element a plaintiff must satisfy be construed in light of how the plaintiff acted with respect to technical security risks, akin to the contributory negligence defense seen in common law tort claims); Lynda J. Oswald, *The Role of "Commercial Morality" in Trade Secret Doctrine*, 96 NOTRE DAME L. REV. 125, 166 (2020) (although not directly about intentionality, solidly critiquing some courts' recourse

when exploring particular aspects of trade secret law.[4] A new commentary by Tim Murphy focuses on the distinction between trade secrets that a former employee intentionally remembers from a prior job and information for which the employee does not recall the source.[5] Highlighting the DTSA and UTSA knowledge requirement, he proposes that courts be lenient with respect to the latter.[6]

Still, no article in the literature fully analyzes how the trade secret statutes define actual and constructive intent by a defendant and illuminates contexts where secondary liability matters to an outcome. This is surprising, because the trade secret statutes embed questions of intent to a much greater extent than do the Patent Act, the Copyright Act, and the Lanham Act—areas of intellectual property where innocent infringement can lead to direct liability.[7]

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to notions of "commercial morality" to judge a defendant's conduct under an ethical concept that "lack[s] a solid theoretical foundation.").

4. *See* Deepa Varadarajan, *Trade Secret Precautions, Possession, and Notice*, 68 HASTINGS L.J. 357, 384–86 (2017) (in-depth exploration of the reasonable security measures element of a trade secret claim; explaining that such measures play a "notice" function, thus highlighting the intent of the party seeking to use such information; "[i]f observers cannot discern the boundaries of patented inventions, copyrighted works, and trade secret protected information, then they may be overly cautious in their inventive and creative endeavors for fear of inviting litigation."); Camilla A. Hrdy & Mark A. Lemley, *Abandoning Trade Secrets*, 73 STAN. L. REV. 1, 48, 56 (2021) (exploration of how companies might be deemed to have abandoned trade secrets with a proposal that former employees be permitted to use such abandoned information, thus raising the question how an intent to abandon might be recognized by a would-be user; potential factors include declining to enter a market).

5. *See* Timothy Murphy, *Can't Get it Out of My Head: Trade Secrets Liability for Remembered Information*, 2023 WISC. L. REV. 1929, 1931 (2023).

6. *See id.* at 1934, 1962–66 ("As proposed here, courts should address remembered information as part of the misappropriation analysis, after the existence of a trade secret has been established. And thus, the issue of remembered information is closely tied to the defendant's conduct, rather than whether a trade secret exists."; outlining "a taxonomy of remembered information" to distinguish the degree to which an employee recalls the source of information in his or her memory).

7. *E.g.*, 35 U.S.C. § 271(a) (Patent Act: "whoever without authority makes, uses, offers to sell, or sells any patented invention, within the United States . . . . infringes the patent."); Playboy Ent., Inc. v. Frena, 839 F. Supp. 1552, 1559 (M.D. Fla. 1993) ("Intent to infringe is not needed to find copyright infringement. Intent or knowledge is not an element of infringement, and thus even an innocent infringer is liable for infringement; rather, innocence is significant to a trial court when it fixes statutory damages, which is a remedy equitable in nature."). The Patent Act does incorporate questions of constructive and actual notice regarding pre-lawsuit damages, centering on the issue of patent marking. *See* 35 U.S.C. § 287(a) ("In the event of failure so to mark, no damages shall be recovered by the patentee in any action for infringement, except on proof that the infringer was notified of the infringement and continued to infringe thereafter, in which event damages may be recovered only for infringement occurring after such notice. Filing of an action for infringement shall constitute such notice."). The Copyright Act has a comparable term. *See* 17 U.S.C. § 401(d) ("If a notice

Patent law has seen a lively debate over the extent to which the patent regime is one of "strict liability."[8] Likewise, commentators on copyright law have argued over whether copyright presents a strict liability standard or—especially as to the fair use defense—an intent-based standard.[9] Trademark law in particular has seen great attention to questions of secondary liability, perhaps due to the difficulties in suing counterfeiters.[10]

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of copyright in the form and position specified by this section appears on the published copy or copies to which a defendant in a copyright infringement suit had access, then no weight shall be given to such a defendant's interposition of a defense based on innocent infringement in mitigation of actual or statutory damages, except as provided in the last sentence of section 504(c)(2)."). *Cf.* 17 U.S.C. § 504(c)(2) (noting that innocent infringement can lead to a reduction of statutory damages, and that a fair use defense can also mitigate damages). For its part, the Lanham Act contemplates direct liability for trademark infringement without any showing of intent, though it also includes a unique safe harbor for "innocent" violators who merely printed the infringing mark limiting the reach of injunctive relief. *See* 15 U.S.C. § 1114(1), (2).

8. *E.g.*, Lynda J. Oswald, *The 'Strict Liability' of Direct Patent Infringement*, 19 VAND. J. ENT. & TECH. L. 993, 997 (2020) (arguing that using such terminology improperly turns attention away from the text of the patent act and improperly allows for consideration of "social policy concerns" for liability); Patrick R. Goold, *Patent Accidents: Questioning Strict Liability in Patent Law*, 95 IND. L.J. 1075, 1079 (2020) (advocating a negligence-based standard for patent law, where accidental patent infringement might be excused if the defendant exercised "all reasonable care to prevent any accidental patent infringement"); Saurabh Vishnubhakat, *An Intentional Tort Theory of Patents*, 68 FLA. L. REV. 571, 576 (2017) (noting that a "strict liability" regime leads to problems such as "indiscriminately impos[ing] liability on actions that are purely inadvertent or even unforeseeable"); Roger D. Blair & Thomas F. Cotter, *Strict Liability and its Alternatives in Patent Law*, 17 BERKELEY TECH. L.J. 799, 807 (2002) (noting, among other things, that "strict liability" is a misnomer in situations such as those where a patent owner does not mark the product and "damages only accrue from the date of actual notice").

9. *See e.g.*, Patrick R. Goold, *Moral Reflections on Strict Liability in Copyright*, 44 COLUM. J.L. & ARTS 123, 125–27 (2021) (noting that the "strict liability" standard in copyright is "entirely judge-made," and considering "the moral side of accidental infringement" to propose reforms such as facilitating "the introduction of a negligence liability rule into copyright"); Apostolos G. Chronopoulos, *Strict Liability and Negligence in Copyright Law: Fair Use as Regulation of Activity Levels*, 97 NEB. L. REV. 384, 387–89, 466 (2018) (asserting that copyright law "constitutes a mixed system" of both strict liability and negligence standards, with the fair use doctrine centering the latter); Patrick R. Goold, *Is Copyright Infringement a Strict Liability Tort?*, 30 BERKELEY TECH. L.J. 305, 310 (2015) (arguing that copyright law "is in fact a fault-based tort" because mere infringement is insufficient and "it must be shown that the defendant's copying was wrongful"); Steven Hetcher, *The Immorality of Strict Liability in Copyright*, 17 MARQUETTE INT. PROP. L. REV. 1, 2 (2013) (arguing that copyright is a "fault standard," not a strict liability standard, "as a result of the emergence of the fair use doctrine"); R. Anthony Reese, *Innocent Infringement in U.S. Copyright Law: A History*, 30 COLUM. J.L & ARTS 133 (2014) (providing a detailed examination of how early protections for innocent infringers shrank in recent decades).

10. *See generally* David S. Welkowitz, *Fault Lines in Trademark Default Judgments*, 22 GEORGIA J. INTELL. PROP. LAW. 101 (2014); Irene Calboli, Jane Ginsburg, Amy Cotton, Bob Weigel & Bruce Rich, *Proposed Secondary Liability Regimes for Trademark Infringement Online:*

To be sure, it is not clear that much can be transposed from debates in other fields of intellectual property law to trade secret law. The trade secret statutes contain unique language concerning intent. Moreover, trade secret cases often turn on contexts such as employee mobility that raise policy concerns not seen in other IP disciplines. We should debate questions of intentionality in trade secret law from scratch, as it were, to create best practices particular to this area of law.

In summary, questions of secondary liability in trade secret cases have seen little attention from courts and commentators despite their seeming utility in reducing unnecessary or exaggerated trade secret disputes. It is surprising that courts and defense attorneys have not often explored these possibilities. Ignoring that each plaintiff must establish intent as to each separate defendant allows plaintiffs to blend defendants together without satisfying their burden of proof as to each. By drawing an intent-based dividing line between different actors in trade secret cases, courts can reduce lawsuits filed, or over-litigated, for improper purposes.

II. MAPPING INTENTIONALITY ACROSS THE DTSA AND UTSA

A. THE STATE OF MIND NECESSARY TO ENGAGE IN MISAPPROPRIATION

The trade secret statutes do not contemplate strict liability for misappropriation. Nor is there liability for negligence. To the contrary, the DTSA and the UTSA structure their definitions of "misappropriation" with language that turns on the defendant's intent—that is, actual or constructive knowledge that one has acquired, used, or disclosed a trade secret without authorization.

For that reason, courts have stated that "[m]isappropriation of trade secrets is an intentional tort."[11] As the California Court of Appeal held in a

Commentary, 37 COLUM. J.L. & ARTS 621 (2014); John T. Cross, *Contributory Infringement and Related Theories of Secondary Liability for Trademark Infringement*, 80 IOWA L. REV. 100 (1994).

11. *See* PMC, Inc. v. Kadisha, 78 Cal. App. 4th 1368, 1382 (2000). Many other courts have used similar language, including Successware, Inc. v. Servicetitan, Inc., No. CV 20-5179 DSF (PVCx), 2020 U.S. Dist. LEXIS 262181, at *23–24 (C.D. Cal. Sept. 10, 2020) (quoting *PMC* on motion to dismiss); Eddie Kane Steel Prods., Inc. v. Alabama Plate Cutting Co., Inc., Civil Action No. 18-15167 (MAS) (LHG), 2019 U.S. Dist. LEXIS 121758, at *17 (D.N.J. July 19, 2019) (noting, on motion to dismiss and transfer, that "misappropriation of trade secrets is an intentional tort."); Eagle Oil & Gas Co. v. Shale Exploration, LLC, 549 S.W.3d 256, 283 (Tex. Ct. App. 2018) (stating that "misappropriation of trade secrets is an intentional tort" in ruling on exemplary damages); Mar Oil Co. v. Korpan, No. 3:11CV1261, 2015 U.S. Dist. LEXIS 131755, at *7 (N.D. Ohio Sept. 29. 2015) (in affirming finding of joint and several

2000 decision, "[u]se of a trade secret without knowledge it was acquired by improper means does not subject a person to liability unless the person receives notice that its use of the information is wrongful."[12] This vocabulary, centering on "tort" concepts, reminds us of trade secret law's origins in common law, before enactment of today's statutory regimes.

Although the statutes are not models of clarity, the DTSA and the UTSA define the act of "misappropriation" in four, somewhat overlapping ways—each one requiring actual or constructive knowledge that one's conduct flows from improper means or violation of a confidentiality duty.[13] First, one can wrongfully acquire a trade secret, or acquire it knowing that one's source previously had acquired it by improper means, with actual or constructive knowledge of that wrongfulness: "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."[14]

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liability, noting that "liability for trade secret misappropriation, an intentional tort, is joint and several"); Be In, Inc. v. Google Inc., No. 12-CV-03373-LHK, 2013 U.S. Dist. LEXIS 147047, at *9 (N.D. Cal. Oct. 9, 2013) (stating intentional tort language on motion to dismiss); Bovie Med. Corp. v. Livneh, No. 8:10-cv-1527-T-24EAJ, 2010 U.S. Dist. LEXIS 134490, at *18 (M.D. Fla. Dec. 20, 2010) ("Misappropriation of trade secrets in an intentional tort in the state of Florida."); Hagen v. Burmeister & Assoc., 633 N.W.2d 497, 503 (Minn. 2001) (noting that "misappropriation of trade secrets is an intentional tort" in case centering on vicarious liability); Miller v. Abrams Inc., 156 F.3d 598, 603 (5th Cir. 1998) ("[M]isappropriation of proprietary information and misuse of trade secrets are generally considered to be intentional torts."; remanding for determination of malice in case by former employer against bankrupt debtor); Micro Data Base Sys, Inc. v. Dharma Sys., Inc., 148 F.3d 649, 654 (7th Cir. 1998) (stating same in choice of law dispute); *cf.* Shell v. Henderson, No. 09-cv-00309-MSK-KMT, 2013 U.S. Dist. LEXIS 129006, *7 (D. Col. July 24, 2013) (noting, on motion for fees after successful motion to dismiss on jurisdictional grounds, that "[m]isappropriation of trade secrets is a tort, but not always an intentional tort"; noting that misappropriation can be based on constructive knowledge and apparently assuming that does not constitute intentional conduct).

12. *See PMC*, 78 Cal. App. 4th at 1383 (reversing trial court's summary judgment ruling and finding a triable issue of fact as to whether investors "in anticipation of enormous corporate and personal profit, knowingly invested at a bargain price in a corporation whose sole business assets consisted of stolen confidential information and processes, and subsequently controlled the entity which was engaging in unlawful conduct").

13. We will use California's UTSA as an exemplar here. *See* CAL. CIV. CODE §§ 3426.1(a)–(b); 18 U.S.C. § 1839(5).

14. *See* CAL. CIV. CODE § 3426.1(b)(1) (emphasis added); 18 U.S.C. § 1839(5)(A). "Improper means" is defined as intentional wrongdoing to obtain someone's trade secret: it "includes theft, bribery, misrepresentation, breach or inducement of a breach of a duty to maintain secrecy, or espionage." CAL. CIV. CODE § 3426.1(a); 18 U.S.C. § 1839(6). In somewhat repetitive language, an adjacent subsection provides for liability for "[d]isclosure or use . . . by a person who . . . [a]t the time of disclosure or use, knew or had reason to know that his or her knowledge of the trade secret was: (i) Derived from or through a person who

Second, one can use or disclose a trade secret after wrongfully acquiring it, effectively engaging in a second (or third) type of misappropriation following the first: "Disclosure or use . . . by a person who . . . *Used improper means to acquire knowledge* of the trade secret."[15]

Third, one can use or disclose a trade secret wrongfully, even if one's original acquisition of the trade secret was lawful: "Disclosure or use . . . by a person who . . . At the time of disclosure or use, *knew or had reason to know* that his or her knowledge of the trade secret was: [. . .] (ii) Acquired under circumstances giving rise to a duty to maintain its secrecy or limit its use."[16]

The fourth type of misappropriation stands apart from the others: the "accident or mistake" clause. It provides for liability where there is "[d]isclosure or use . . . by a person who . . . Before a material change of his or her position, *knew or had reason to know* that it was a trade secret and that knowledge of it had been acquired by accident or mistake."[17] In this instance, one can misappropriate a trade secret by straying outside the boundaries of a statutory safe harbor that protects use or disclosure of another party's trade secret. Specifically, the DTSA and the UTSA allow for a safe zone whereby if one acquires a trade secret by accident or mistake and uses it without realizing (or constructively realizing) the truth, such use is not "misappropriation." That said, once one has such a realization, the immunity might end at some point, depending on the degree of one's use of the trade secret to that point.

Notably, all four forms of statutory "misappropriation" require that the defendant either know the trade secret, or acquire the trade secret. The latter possibility presumably envisions a situation where a party has obtained information but has not studied its contents. Thus, a defendant which has not learned or acquired the alleged trade secret cannot be liable under the text of the DTSA and the UTSA. For example, in a 2010 California case, a company which had licensed a software product from a licensor that had misappropriated software source code used to make the product was not liable because it had neither learned nor acquired that source code.[18] It had merely obtained a software product made from the trade secret, not the trade secret

had utilized improper means to acquire it; [. . .] or (iii) Derived from or through a person who owed a duty to the person seeking relief to maintain its secrecy or limit its use." *See* CAL. CIV. CODE § 3426.1(b)(2)(B); 18 U.S.C. § 1839(5)(B)(ii).

15. *See* CAL. CIV. CODE § 3426.1(b)(2)(A) (emphasis added); 18 U.S.C. § 1839(5)(B)(i).

16. *See* CAL. CIV. CODE § 3426.1(b)(2)(B) (emphasis added); 18 U.S.C. § 1839(5)(B)(ii)(II).

17. *See* CAL. CIV. CODE § 3426.1(b)(2)(C); 18 U.S.C. § 1839(5)(B)(iii).

18. *See* Silvaco Data Systems v. Intel Corp., 184 Cal. App. 4th 210, 222–23 (2010) overruled in part on unrelated ground, Kwikset v. Superior Court, 51 Cal. 4th 310, 337 (2011).

itself.[19] This type of downstream liability is not something the trade secret statutes contemplate. The absence of such liability for mere use of a product created from the licensor's misuse of trade secrets, while not the subject of the present study, reinforces the intent-based nature of the statutory term "misappropriation."[20]

B. ACTUAL KNOWLEDGE VERSUS CONSTRUCTIVE KNOWLEDGE

Layered into the four types of statutory misappropriation is a distinction between actual knowledge that one has acquired a trade secret, or wrongfully used or disclosed it, and constructive knowledge. The phrase "had reason to know" (or, in the DTSA, "has reason to know") refers to the latter.

Presumably because a defendant's actual knowledge of wrongful conduct is often straightforward, there are not many cases addressing this type of intentional wrongdoing in detail. As one example, a 2020 case from the Southern District of New York found that where a departing employee copied the employer's trade secrets into a "personal directory" at work before leaving, and studied that information, this "satisfie[d] the knowledge requirement," as he knew that he was acquiring the employer's secrets by improper means, violating the terms of his employment agreement.[21] And in a 1997 case from the Central District of California, the court denied a defense motion for summary judgment which sought to contest the actual knowledge requirement.[22] In a case where the plaintiff alleged that the defendants had obtained and used customer-related information customarily treated as confidential, the court spent more effort than is typical in describing testimony from multiple employees of a corporate defendant showing their knowledge that the company had obtained information it knew came from the plaintiff in a context suggesting intent.[23]

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19. *See id.*; *see also* Architectural Models, Inc. v. Neklason, 264 F. Supp. 312, 317, 322 (N.D. Cal. 1967) (trade secret claim failed where plaintiff could not establish that defendants had been exposed to a drawing that was claimed as the trade secret).

20. A different question would arise if a downstream consumer unknowingly licensed or purchased a product that did contain, or reveal knowledge of, a trade secret the manufacturer wrongfully took from the original owner. In that case, the consumer would indeed have acquired the trade secret, albeit without intent to do so. *See infra* Part III.D. As discussed in Section III.D below, this seems to be a paradigmatic instance where the "accident or mistake" safe harbor of the DTSA and UTSA should govern.

21. *See* KCG Holdings, Inc. v. Khandekar, No. 17-CV-3533 (AJN), 2020 U.S. Dist. LEXIS 44298, at *33 (S.D.N.Y. Mar 12, 2020).

22. *See* Ernest Paper Prod., Inc. v. Mobil Chem. Co., CV 95-7918 LGB (AJAX), 1997 U.S. Dist. LEXIS 21817, at *23-25 (C.D. Cal. Sept. 17, 1997).

23. *See id.*; *see also* Successware, Inc. v. Servicetitan, No. CV 20-5179 DSF (PVCx), Inc., 2020 U.S. Dist. LEXIS 262181, at *23-24 (C.D. Cal. Sept. 10, 2020) (denying motion to dismiss

Of greater interest are cases wrestling with the degree of intentionality that constitutes a defendant's constructive knowledge. This second category of knowledge sufficient to trigger liability for misappropriation is less clear—as the DTSA and UTSA put it, liability applies only when a defendant had "reason to know" that what it received, used, or disclosed was someone else's trade secret.

We should unpack this dense concept. In order for constructive knowledge to exist, a defendant must know two things. First, the defendant must glean to at least some degree that the information at issue is a trade secret, which may not be clear. And it must also discern that the information belongs to someone else—which also may not be clear.[24] This can present a difficult conundrum. For example, imagine that a person learns information on the job that is similar to information that she saw in a university laboratory during graduate school. If she believes she can use the information lawfully, but a judge or jury disagrees, was she truly on notice? The trade secret statutes do not account for this type of mistake in one's judgment.

To take a second example, companies frequently have attorneys send letters to former employees and business rivals warning of confidentiality obligations or potential trade secret misuse. But not every letter-sender may have researched whether the information claimed as a trade secret really is so—in fact, in at least some cases, the sender will be wrong. This author has seen letters claim trade secrets in information that the claimant itself had published on its website.

In such instances, is a defendant on constructive notice simply because someone has declared that information—or some undefined swath of information—includes trade secrets? Having notice of a potential trade secret, or a threat of trade secret litigation, is not the same thing as having reason to know that some specific thing truly qualifies as a trade secret. The same

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where plaintiff alleged that when one defendant acquired a second defendant which possessed the plaintiff's trade secrets, the acquiring company began using a customer list to contact customers; finding that "information and belief" allegations that the acquiring company knew the customer list belonged to the plaintiff were sufficient due to the "value and rarity" of the list "considering the nature of the industry and target customer").

24. At least one court has rejected the notion that a defendant must know whose trade secret is at issue, as opposed to more generally knowing (or having reason to know) that it is someone else's trade secret. *See* Columbus Steel Castings Co. v. King Tool Co., No. 08AP-385, 2008 Ohio App. LEXIS 5262, at *20 (Ohio Ct. App. Dec. 4, 2008) (reversing summary judgment for defendant on trade secret claim where plaintiff alleged that defendant had obtained its trade secrets by working with a second defendant; rejecting defendant's argument that "it was necessary" that it know that the alleged trade secret at issue was the plaintiff's trade secret, as opposed to a trade secret of the second defendant; the court noted that the UTSA has no such requirement).

questions might be asked when a plaintiff sues over "inevitable disclosure"—that is, speculation that a newly-hired employee might someday misuse a trade secret, without evidence of actual misappropriation or a threat to misappropriate. In a lawsuit expressly grounded on speculation, who exactly is on notice of what?

The trade secret statutes do not provide definitional guidance for what "reason to know" means. While case law is sparse, the definition appears tethered to the common law concept of constructive knowledge. By way of example, California defines constructive notice by statute. It means "actual notice of circumstances sufficient to put a prudent [person] upon inquiry as to a particular fact[.]"[25] That definition focuses on what is enough to cause someone to start asking questions—not complete knowledge that some course of conduct is unlawful.

1. Cases Finding Constructive Knowledge

A 1990 California case, decided on facts pre-dating the UTSA, exemplifies what constructive notice means in the trade secret context. In *Ralph Andrews Productions, Inc. v. Paramount Pictures Corp.*, an employee of a television production company offered the defendant an idea for a television show.[26] He claimed that the idea was his own. The defendant knew that the employee worked for the production company. The defendant "was[also] explicitly given information which indicated another entity may have had rights to the concept."[27] This was sufficiently concerning to cause the defendant to ask the employee for a responsive written statement, but the defendant proceeded to enter the deal even though the employee never provided the statement. On a motion for summary judgment, the court found a triable issue of fact on the question of constructive notice.[28]

The ruling makes sense. The buyer had notice that something was amiss. Also, under the state's invention assignment statute, California employers own intellectual property rights in employee ideas that relate to the business.[29] Thus,

25. *See* CAL. CIV. CODE § 19.

26. Ralph Andrews Prods., Inc. v. Paramount Pictures Corp., 222 Cal. App. 3d 676 (1990).

27. *Id.* at 685.

28. *Id.* at 682, 685 (constructive notice occurs where someone "is aware of facts which would make a reasonably prudent person suspicious") (quoting Hobart v. Hobart Estate Co., 26 Cal. 2d 412, 438 (1945)).

29. *See* CAL. LAB. CODE §§ 2870–72. For an early case under the California UTSA examining the "had reason to know" element, see Speech Tech. Assoc. v. Adaptive Comm. Sys., Inc., No. C-88-2392-VRW, 1994 U.S. Dist. LEXIS 11660, at *26 (N.D. Cal. Aug. 16, 1994) (a defendant obtained technology under an oral agreement to redesign it, but sold the redesigned product without paying royalties).

because the defendant knew the employee was working for a television production company, it had reason to suspect that he did not own the idea.

A more recent constructive knowledge case is also straightforward. In a 2018 Ninth Circuit decision arising from a case in Arizona, the appellate court reversed a summary judgment in favor of a defendant which had purchased the plaintiff's database of consumer records.The trial court had held that the defendant did not have reason to know that the data records "were either secret or stolen."[30] Because the defendant had paid "less than 1% of the market rate for a one-time license to obtain actual ownership of data," obtained ownership though a method "unusual in the industry," and had "prior experience that should have put [it] on notice of an improper acquisition," the Ninth Circuit found the defendant possessed "constructive knowledge" that it had acquired a trade secret.[31]

Similar issues of constructive notice were apparent in a 2016 case where a trial court denied a motion to dismiss. In *Joshua David Mellberg, LLC v. Will*, a magistrate noted that the plaintiff alleged that even though a corporate defendant did not employ all individual defendants accused of downloading and using trade secrets, the plaintiff sufficiently alleged that the corporate defendant knew or should have known that it acquired and used the plaintiff's trade secrets through its contacts with them, which demonstrated their plans to mirror the plaintiff's sales program, the similarity of websites they launched to the plaintiff's websites, and presentations that were nearly identical to those of the plaintiff.[32]

A 2017 case from Connecticut is also notable because the court offered a specific definition of constructive knowledge under trade secret law. But the decision nonetheless raises nettlesome questions. *In Dur-A-Flex, Inc. v. Dy*, a trial court ruled on a defense motion for summary judgment where a corporate defendant previously had used floor coating materials from the plaintiff, but subsequently switched to buying from a new business founded by a chemist who had recently left the plaintiff.[33] Notably, the corporate defendant tested the chemist's version during the brief period after he resigned from the

30. Experian Info. Sols., Inc. v. Nationwide Mktg. Serv., 893 F.3d 1176, 1181 (9th Cir. 2018) (applying the Arizona UTSA).

31. *Id.* at 1189 (citing Syntex Opthalmics, Inc. v. Novicky, No. 80 C 6257, 1982 U.S. Dist. LEXIS 14175, at *2 (N.D. Ill. May 6, 1982) (finding that a $20,000 payment for technology that cost a million dollars to develop was evidence of the defendant's constructive knowledge it had acquired another's trade secret)).

32. *See* No. CV-14-02025-TUC-CKJ (CRP), 2016 U.S. Dist. LEXIS 32412, at *37–46 (D. Ariz. Jan. 22, 2016).

33. *See* No. X04HHDCV146049281S, 2017 Conn. Super. LEXIS 4241, at *9–10 (Super. Ct. Aug. 14, 2017).

defendant, "but before he formally ended his employment."[34] The court rejected the defendant's argument that actual notice is necessary for UTSA liability, and defined constructive knowledge in the trade secret context as follows:

> A defendant may have reason to know that information held by a third person is the trade secret of another when, based on the information in the defendant's possession, a reasonable person would have been put on notice, and an inquiry pursued with reasonable diligence would have disclosed that the information provided to the defendant was actually wrongfully obtained from another.[35]

The trial court found that the corporate defendant "should have suspected" that the departing employee's "newly-formulated floor product" "was likely to be based in some measure upon [the individual's] experience gained in the research and development of floor products as [plaintiff's] chemist, given that they "conducted tests[.]"[36]

Despite the ill-timed review of the chemist's new product, this lower court ruling is ambiguous. Must everyone who conducts business with a former employee conduct an inquiry into potential trade secret misappropriation? What if the basics of the formula contains common ingredients? What if many market competitors offer similar products? Having "experience" and creating a competing product surely should not be sufficient—again putting aside the timing issue in this particular case, which resembles the fact pattern in *Ralph Andrews*[37]—to raise a question of constructive knowledge. Said differently, while the case holding makes sense because the chemist had apparently begun work on a competing product before leaving his job, an ordinary situation of competition by a former employee surely cannot serve as constructive notice of wrongdoing.[38]

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34. *Id.* at *3.

35. *Id.* at *9.

36. *Id.* at *10.

37. *See Ralph Andrews Prods.*, *supra* note 26.

38. Because employees are permitted to transfer their general skills, knowledge, and experience from job to job, *see* Camilla A. Hrdy, *The General Knowledge, Skill, and Experience Paradox*, 60 B.C. L. REV. 2409 (2019), the exercise of such rights cannot in isolation be a trigger for constructive knowledge of misappropriation. Likewise, companies can hardly glean what may or not be a trade secret in the employment contract of an employee they hire from another company. As Camilla Hrdy and Chris Seaman have shown in a comprehensive study of such contract language, the confidentiality terms of employment agreements are generally vague about what is protectable and overbroad, encompassing unprotectable information as well. *See* Camilla A. Hrdy & Christopher B. Seaman, *Confidentiality Agreements that Act Like Noncompetes*, 133 YALE L.J. 669 (2023).

A 2014 case from Illinois was perhaps more attuned to such doubts. In *First Financial Bank, N.A. v. Bauknecht*, the court denied a defense motion for summary judgment where an employee who changed jobs was accused of using memorized customer information that his former employer claimed to be a trade secret.[39] As to the new employer, the court ruled that there was a triable issue of fact as to constructive knowledge because the new employer discussed the employee moving over customers from the plaintiff, and because it understood that customer information is "ordinarily confidential within the industry."[40] But the court also cautioned that a jury might not find constructive knowledge; because if the information turned out not to be secret, the employee would have been free to call customers. The new employer thus would have "acted upon the assumption that [new employee] was complying with the law."[41] This ruling at least recognizes the quandary in finding constructive knowledge where the very same facts could signal perfectly legal conduct.

In other cases, the constructive knowledge concept is sometimes used as something of a gap-filler where evidence of intent is lacking. For example, a 2001 case from the Middle District of Pennsylvania, the court found that a defendant should have known that a contractor who had worked for the plaintiff and was hired for the sole purpose of assisting with a bid used the plaintiff's bid-related trade secrets. It reasoned that the defendant made no inquiry of the contractor and thus "may not hide improper acquisition of trade secrets behind a veil of willful ignorance."[42] Other courts have implied a duty of confidentiality in circumstances where there was an expectation of such a duty. These decisions seem to fall within the concept of constructive knowledge rather than actual knowledge.[43]

39. *See* First Fin. Bank, N.A. v. Bauknecht, 71 F. Supp. 3d 819, 846–47 (N.D. Ill. 2014).

40. *See id.* at 846.

41. *See id.* at 847.

42. *See* First Health Group Corp. v. Nat'l Prescription Adm'rs, Inc., 155 F. Supp. 2d 194, 227–28 (M.D. Penn. 2001) ("NPA should have known, because of its knowledge of the industry and previous PACE bids, that Norton's contributions to its bid proposal included First Health's trade secrets.").

43. *See* Mineral Deposits Ltd. v. Zigan, 773 P.2d 606,608 (Col. Ct. App. 1989) (device lent to defendant for limited purpose; both defendants liable for using beyond that purpose through an "implied duty"); *see also* Griff Machine Prod. Co. v. Griptron Sys., Inc., Civil Action No. C84-434, 1985 U.S. Dist. LEXIS 18462, at *22 (N.D. Ohio June 27, 1985) (implying NDA for information obtained during "subcontract and sales negotiations" where defendants "should have known" of secrecy); Wilkes v. Pioneer Am. Ins. Co., 383 F. Supp. 1135, 1142 (D.S.C. 1974) (implying NDA where defendant had obtained secret from plaintiff under conditions giving rise to expectation of confidentiality).

Courts also employ the concept when a new employer disclaims any knowledge that its new hire misappropriated the plaintiff's trade secrets. These courts look at facts suggesting that the new employer should have connected the dots between the employee's work product and his or her former job.[44]

Many cases addressing questions of constructive knowledge are older, dating from before the UTSA was enacted. In one, a defendant used a plaintiff's allegedly secret mold obtained under a confidentiality agreement to produce products for a second defendant. The court held that a trade secret claim was stated against the second defendant because, citing the Restatement formulation of trade secret law, a defendant who knows of a breach of confidentiality by another is liable, and a defendant who receives notice of a breach of confidentiality is liable from that point onwards "provided that he has not in good faith paid value for the secret."[45] In another, there was a question whether a defendant had a duty of inquiry notice about the provenance of a design it had obtained from a contractor. The court found a triable issue of fact under the Restatement approach, noting that the defendant had "a long history of attempting to gain intelligence about [plaintiff's] electro-mechanical feeders by surreptitious means."[46] Under these cases, the general rule appeared to be that if the facts amount to inquiry notice that a party is using someone else's trade secret, that party has a duty to investigate further.

2. Cases Declining to Find Constructive Knowledge

Cases finding insufficient facts for constructive knowledge appear to be few and far between. A 2012 case from the Northern District of California, for example, found that the plaintiff failed to allege that licensee/purchaser

44. *See* Comput. Assoc. Int'l, Inc. v. Altai, Inc., 982 F.2d 693, 719 (2d Cir. 1992) (remanding on constructive notice issue where defendant disclaimed knowledge of its employee's theft of trade secrets); Rohm and Haas Co. v. Adco Chem. Co., 689 F.2d 424, 431 (3d Cir. 1982) (where defendant knew that plaintiff had only method for certain process, and new employee immediately delivered process for making one of plaintiff's products, defendant had at least a duty of inquiry).

45. *See* Colony Corp. v. Crown Glass Corp., 430 N.E.2d 225, 228 (Ill. App. Ct. 1981).

46. *See* FMC Corp. v. Spurlin, 596 F. Supp. 609, 616 (W.D. Penn. 1984). For other older cases, see Curtiss-Wright Corp. v. Edel-Brown Tool & Die Co., Inc., 407 N.E.2d 319, 324 (Mass. Ct. App. 1980) (affirming jury verdict against defendant which obtained drawings from the Navy, which had a contract with the plaintiff, where the plaintiff had notified the defendant of its rights); Metallurgical Indus., Inc. v. Fourtek, Inc., 790 F.2d 1195, 1204 (5th Cir. 1986) (finding a triable issue of act on a question whether a defendant had failed to investigate a possible misappropriation where it had purchased a third party entity, and was aware that the entity had been sued by the plaintiff for misappropriation; although the purchased entity told the defendant that the allegations were meritless, the court found that a reasonable jury would find that [defendant] should have inquired" because he "knew of possible problems but did nothing but rely on [third party's] dismissals").

knew or had reason to know that information it acquired from co-defendant included the plaintiff's trade secrets.[47]

In perhaps the most notable case, a 2007 decision from the Central District of California granted summary judgment on a trade secret claim and rejected the plaintiff's argument that the defendant was on constructive notice of an alleged misappropriation.[48] In that case, the court rejected a constructive knowledge argument even though the plaintiff alleged that the corporate defendant had acquired the information from an individual seller in order to frustrate password protection to the plaintiff's software and had been dishonest about curtailing its use of the plaintiff's software.[49] The court noted that the plaintiff's allegations were distinct from facts from which one could infer that the corporate defendant knew that the individual seller "was under a duty to maintain the confidentiality" of the information sold.[50]

Similarly, a 1998 Indiana case refused to imply an obligation of confidentiality or find the "had reason to know" requirement satisfied where a manufacturer disclosed drawings to a competitor, but did not mention the confidentiality of, mark the drawing as confidential, and where evidence of industry custom regarding confidential treatment of such information was inconclusive.[51]

3. The Problem of Notice Letters and Constructive Knowledge

As noted above, threat letters and so-called reminder letters are common in trade secret law; this author has seen hundreds over the decades. In many instances, a former employer simply sends a polite reminder about confidentiality to a former employee or his or her new employer. In others, the former employer complains of downloading or other file exfiltration and

47. *See* Mediostream, Inc. v. Microsoft Corp., 869 F. Supp. 2d 1095, 1114 (N.D. Cal. 2012).

48. *See* Unicom Sys., Inc. v. Farmers Group, Inc., No. CV 04-4604-GHK (AJWx), 2007 U.S. Dist. LEXIS 110825, at *49–50 (C.D. Cal. June 12, 2007).

49. *See id.*

50. *See id.*

51. *See* Flotec, Inc. v. S. Rsch., Inc., 16 F. Supp. 2d 992, 1006–07 (S.D. Ind. 1998) (finding no implied NDA where manufacturer disclosed drawings to competitor but never mentioned confidentiality, drawings were not marked, and evidence of industry customer not conclusive; should have known prong not satisfied). For similar rulings, see also Tenax Corp. v. Tensar Corp., No. H-89-424, 1990 U.S. Dist. LEXIS 10671, at *15 (D. Md. May 31, 1990) (no implied agreement where alleged disclosure took place in a context of free flow of information, and where plaintiff waited more than 10 years to assert a confidential relationship; thus, no finding that defendant "should have known"); U.S. Plywood Corp. v. Gen. Plywood Corp., 370 F.2d 500, 508 (6th Cir. 1966) (finding that plaintiff who disclosed alleged secret to prospective licensees had extinguished any secrecy).

seeks remediation short of litigation. Yet others threaten litigation directly. All of this begs the question whether a defendant could be on constructive notice due to receipt of such a letter, especially given the variety of forms they take.

Case law is sparse. On a motion to dismiss in 2016, two corporate officers argued that the plaintiff did not state a claim against them for misappropriation, in addition to arguing that they could not be liable for acts of employees.[52] The court denied the motion after examining the DTSA's "reason to know" language.[53] It noted that the plaintiff had alleged that it sent the company a "cease and desist" letter, asking it to explain how it obtained certain customer contact information.[54] The plaintiff also alleged that it sent a second letter a week later, but that the defendants "denied possession of this information and, apparently, took no steps to prevent" the corporate defendant "from using this information." The court found that this sufficed to state a claim under a constructive knowledge theory.[55]

Two early cases from California also offer examples. A 1977 ruling found a director liable for an employee's misappropriation where he was aware of a letter accusing the employee of misappropriation and then, after the lawsuit was filed, undertook development of the technology at issue. The case states that an employer can be liable "provided that he utilizes the information with notice of the secret nature thereof and with notice that the employee has disclosed it in breach of his duty to the former employer."[56] This conclusion seems dubious: receiving a threatening letter plus continuing to do business cannot be enough for employer liability. People send threatening letters all the time, and not all such letters reflect a well-researched accusation. Similarly, a 1966 case found two directors liable for misappropriation because "they were notified . . . that the corporation of which they were directors was making unauthorized use of trade secrets improperly transmitted to it by . . . [others],

52. *See* Solarcity v. Pure Solar Co., No. CV 16-01814-BRO (DTBx), 2016 U.S. Dist. LEXIS 199522, at *12–14 (C.D. Cal. Dec. 27, 2016).

53. *See id.*

54. *See id.* For a case featuring a letter but a defendant further afield from the action, see Smart Mort. Ctrs., Inc. v. Noe, No. 21-cv-3606, 2022 U.S. Dist. LEXIS 49580, at *21–22 (N.D. Ill. Mar. 21, 2022) (granting motion to dismiss as to corporate defendant where motion focused on "the state of mind required for DTSA trade secret misappropriation"; as to a downstream corporate defendant which worked with a primary defendant, the plaintiff alleged that someone associated with the primary defendant was an "undisclosed principal" of the downstream corporate defendant and alleged that he had received a legal letter notifying him of trade secret allegations; court found that plaintiff failed to plead that the downstream corporate defendant had acquired the alleged trade secrets as of the date of the letter, and thus dismissed the claim).

55. *See id.*

56. *See* Cybertek Comput. Prods., Inc. v. Whitfield, 203 U.S.P.Q. 1020, 1025 (1977).

their fellow directors. They and the corporation nonetheless continued to use these manufacturing processes. Thus they, too, are liable."[57] This case is questionable for the same reason.

C. IMPUTED KNOWLEDGE IS NOT A SUBSTITUTE FOR ACTUAL OR CONSTRUCTIVE KNOWLEDGE

Because trade secret liability can turn on constructive knowledge—what one had reason to know—this raises the intriguing question of whether a business could be liable through the imputed knowledge of an executive who learned trade secrets at a former employer. The answer should be "no," as otherwise the meaning of "misappropriation" would be stretched outside the DTSA/UTSA statutory boundaries into strict liability.

Imputed knowledge is a common law doctrine providing that, at least in the case of high-ranking employees, the company is deemed to know what that employee knows. The doctrine is a legal fiction; a person with imputed knowledge is deemed to have gained that knowledge by operation of law. For example, California law—which is governed by a statutory definition of imputed knowledge—classifies it as a form of constructive notice: "[i]mputed knowledge is constructive, not actual knowledge."[58]

It is easy to see how a former employer might have an appetite for this theory in bringing a trade secret lawsuit. A plaintiff might argue that a competing business which hired one of its executives has imputedly learned its trade secrets, simply by hiring her. The former employer might accordingly argue that merely to hire the individual amounts to an unlawful acquisition of trade secrets. Or, such a plaintiff might even use the argument to bolster an argument for an "inevitable disclosure" injunction, which posits that a court should fire an employee from a new job on the premise that the employee will at some future point engage in a trade secret misappropriation that has not yet occurred.

All such theories should fail. To start, imputed knowledge clashes with the text of the UTSA, which provides—as described above—that constructive knowledge be premised on a finding that the defendant "had reason to know" that one was acquiring someone else's trade secret without authorization to do so. Strictly speaking, imputed knowledge does not meet that test, even if it is

57. *See* Components for Rsch., Inc. v. Isolation Prod., Inc., 241 Cal. App. 2d 726, 729–30 (Cal. Ct. App. 1966) (citing RESTATEMENT OF TORTS § 758[b]).

58. *See* Cal. Ins. Guar. Assn. v. Workers' Comp. Appeals Bd., 163 Cal. App. 4th 853, 863 (2008) (discussing Cal. Civ. Code § 2332). "And it has been held . . . that section 2332 of the Civil Code [defining when principal is "deemed to have notice" of agent's notice] should not be applied to meet the requirement of actual knowledge." Rosenthal v. Garner, 142 Cal. App. 3d 891, 895 (1983) (citing Ismay v. Tyler, 169 Cal. App. 2d Supp. 883, 885 (1959)).

described by some courts as a species of constructive knowledge. Rather than calling for a "had reason to know" inquiry, it could impose a finding of knowledge simply because someone remembers a trade secret, but never shares it with her new employer.

But even if a trade secret plaintiff could otherwise leverage imputed knowledge under the "had reason to know" language of the DTSA and the UTSA in order to buttress a claim of unlawful acquisition, the argument should still fall short. This is so because the common law has long recognized an important exception to the imputed knowledge: a principal is not deemed to know what which an agent is duty-bound not to disclose.

Although the cases are scattered across many decades, they are uniform in holding that where an agent has a duty to a third party to hold information in confidence, such information will not, as a matter of law, be imputed to the principal.[59] Some 150 years ago, the United States Supreme Court faced an argument that an agent had fraudulently acquired property, but the principal was unaware of the fraud and asserted that it was an innocent purchaser.[60] While applying the general rule of imputed knowledge against the principal, the court was careful to describe an exception. As the court explained, where "it is not the agent's duty to communicate such knowledge, when it would be unlawful for him to do so, as, for example, when it has been acquired confidentially as an attorney for a former client in a prior transaction," the general rule does not apply.[61] Cases since then, in a variety of circumstances, have examined and sometimes applied the exception the Supreme Court described.[62]

Given the temptation to short-cut the rules for finding intent in trade secret cases, it is unsurprising that trade secret plaintiffs have sought to impose

59. *See* cases cited *infra* notes 59, 61.

60. *See* The Distilled Spirits, 78 U.S. 356, 367 (1871).

61. *See id.* ("When it is not the agent's duty to communicate such knowledge, when it would be unlawful for him to do so . . . the reason of the rule ceases; and in such a case an agent would not be expected to do that which would involve the betrayal of professional confidence, and his principal ought not to be bound by his agent's secret and confidential information.").

62. For various examples, see generally In re Marriage of Cloney, 91 Cal. App. 4th 429, 441 (2001) (finding information non-confidential as predicate to imputing it to principal); Reinninger v. Prestige Fabricators, Inc., 136 N.C. App. 255, 261 (1999) (refusing to impute third party confidential information to principal); Davenport v. Correct Mfg. Corp., 24 Ohio St. 3d 131, 134 (1986) ("knowledge would not be imputed to the principal if the agent acquired it while acting in a position of confidentiality"); Imperial Fin. Corp. v. Fin. Factors, Ltd., 53 Haw. 203, 207 (Haw. 1971) ("An exception to the general rule imputing knowledge from the agent to the principal is most frequently applied when . . . the agent acquires confidential information, creating a duty not to disclose such information to his principal.").

liability through imputed knowledge. For example, the Ninth Circuit reversed a jury finding of misappropriation in a 1976 case where the corporate defendant's employee had received the plaintiff's allegedly confidential idea for the design of a backpack.[63] Although the defendant had hoped to pursue a defense of "subsequent independent invention" for the backpack design the plaintiff sued over, the court instructed the jury that "[i]t is not a defense to the corporation that [the employee] did not inform other officers" regarding his knowledge of the plaintiff's idea.[64]

This jury instruction imputed liability to the corporation by eviscerating its fact-based defense that others at the company who had not learned of the plaintiff's idea had independently designed the challenged backpack concept. The Ninth Circuit reversed, noting that despite the general rule of imputed knowledge under California law, "[i]n light of the emphasis in trade-secret law on unfair use, it is generally not appropriate to direct a jury to impute an agent's knowledge of a secret to the principal. Such an instruction would permit recovery even when the trade secret was not actually communicated to or used by the principal. The plaintiff is not entitled to a windfall when in fact there has been no invasion of those interests which trade-secret law seeks to product."[65]

A 2016 case in Arizona rejected a trade secret plaintiff's argument for a finding of imputed liability. In *Joshua David Mellberg, LLC v. Will*, a magistrate judge faced a fact pattern where an employee had downloaded files from a prior employer.[66] The judge refused to impute knowledge of those files to the company, because the imputed knowledge doctrine generally does not apply regarding an agent's knowledge of "a secret to the principal" that has not been "actually communicated or used by the principal."[67]

The result would differ, however, where the agent/employee is not someone who merely remembers a trade secret from a former job, but learns a trade secret from a third party in the course of employment with the corporate defendant. In such straightforward scenarios—that is, outside the employee-mobility context—courts may indeed find imputed knowledge.[68]

63. *See* Droeger v. Welsh Sporting Goods Corp., 541 F.2d 790, 792–93 (9th Cir. 1976).

64. *Id.*

65. *Id.*

66. Joshua David Mellberg, Ltd. Liab. Co. v. Will, No. CV-14-02025-TUC-CKJ (CRP), 2016 U.S. Dist. LEXIS 32412, at *42 n.2 (D. Ariz. Jan. 22, 2016).

67. *See id.* (citing *Droeger*, 541 F.2d at 792–93).

68. *See* Myerburg v. Medtronic, Inc., No. 03-20616-CIV-COOKE/MCALILEY, 2004 U.S. Dist. LEXIS 31385, at *30–31 (S.D. Fla. Sept. 29, 2004) (where plaintiff alleged that defendant's agents met with him and heard his ideas, court agreed that agents' knowledge was imputed to the defendant, but that finding did not matter "since Plaintiff did not have a trade

III. THE OVERLOOKED SAFE HARBOR FOR TRADE SECRET MISTAKES AND ACCIDENTS

We turn now from an examination of how trade secret law defines intentionality to questions of intent in three instances of secondary liability. Each is a situation where a plaintiff seeks to hold a company defendant liable (or seeks to enhance its liability) as a follow-on claim of misappropriation—that is, for the acts of employees or business partners. Each is a situation where the courts have not yet adequately defined exceptions to liability in these secondary contexts. Our first question focuses on DTSA and the UTSA statutory language which can foreclose, or limit, liability in certain cases of "accident or mistake."

A. THE DTSA/UTSA "ACCIDENT OR MISTAKE" SAFE HARBOR CLAUSE

As described, each act of "misappropriation" in the UTSA and DTSA requires actual or constructive knowledge. This begs the question whether there could be liability where a party innocently obtains another's trade secret without even constructive knowledge, and uses it under the belief that it has a right to do so.

The answer under the DTSA and the UTSA is "no," at least where the use of the trade secret (or the preparation to use it) before receiving notice is "material." Both statutes provide what we will term a safe harbor for defendants who use a trade secret without the required level of intent that doing so violates another party's rights. The statutes expressly permit accidental or mistaken acquisition of a trade secret, and use of it. Specifically, the UTSA defines its third and final form of "misappropriation" to exclude such mistaken or accidental use:

> b) "Misappropriation" means:
>
> (1) 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
>
> (2) Disclosure or use of a trade secret of another without express or implied consent by a person who:

secret" in the idea he shared); *see also* Darton Env't, Inc. v. Fjuvo Collections, LLC, 332 F. Supp. 3d 1022, 1038 (W.D. Va. 2018) (denying motion to dismiss where two individual defendants had viewed plaintiff's allegedly secret technology and each was accused of misusing it with two spin-off companies that each was involved with; court noted that "[a]t this stage, those two [corporate defendants] can be imputed the knowledge of their principals").

> (A) Used improper means to acquire knowledge of the trade secret; or
>
> (B) At the time of disclosure or use, knew or had reason to know that his or her knowledge of the trade secret was:
>
> (i) Derived from or through a person who had utilized improper means to acquire it;
>
> (ii) Acquired under circumstances giving rise to a duty to maintain its secrecy or limit its use; or
>
> (iii) Derived from or through a person who owed a duty to the person seeking relief to maintain its secrecy or limit its use; or
>
> (C) Before a material change of his or her position, knew or had reason to know that it was a trade secret and that knowledge of it had been acquired by accident or mistake.[69]

The DTSA contains nearly identical language.[70] This "accident or mistake" concept has an antecedent. Specifically, the 1939 Restatement of Torts—which provided the structure for the states' adjudication of trade secret disputes before the UTSA's gradual enactment—contained a largely similar clause. It stated that:

> One who learns another's trade secret from a third person without notice that it is secret and that the third person's disclosure is a breach of duty to the other, or who learns the secret through a mistake without notice of the secrecy and the mistake
>
> (a) is not liable to the other for a disclosure or use of the secret prior to receipt of such notice, and
>
> (b) is liable to the other for a disclosure or use of the secret after the receipt of such notice, unless prior thereto he has in good faith paid

69. For two UTSA examples, see CAL. CIV. CODE § 3426.1(b) and WASH. REV. CODE 19.108.010(2)(b)(iii) (Washington); *see also* UNIFORM TRADE SECRETS ACT WITH 1985 AMENDMENTS § 1(2), https://www.uniformlaws.org/viewdocument/final-act-128. As discussed further below, a number of states' UTSA enactments cross-reference this clause in the remedies sections of the statute with additional language that speaks to what remedies are (or are not) available when the safe harbor clause applies. Moreover, as the UTSA enactments vary somewhat from state to state, not every jurisdiction is uniform. New Jersey, for example, appears to provide a safe harbor for material reliance without notice that is broader than just accidents and mistakes; its version of the clause reads "before a material change of position, knew or had reason to know that it was a trade secret and that knowledge of it had been acquired through improper means." N.J. REV. STAT. 56:15-2. Oregon, by contrast, omitted that clause entirely, while keeping the safe harbor limitations discussed below in its remedial sections. *See* OR. REV. STAT §§ 646.461(2)(d); 646.463(2); 646.465(1).

70. *See* 18 U.S.C. § 1839(5)(b)(iii) (definitions of "misappropriation").

> value for the secret or has so changed his position that to subject him to liability would be inequitable.[71]

One notable difference between the Restatement's formulation and that of the UTSA and DTSA is whether there is protection for one "who has in good faith paid value for the secret" after acquiring it, but before receiving notice that it does not have a right to use the trade secret. Under the Restatement version, an innocent buyer faces no liability. As the Commentary to § 758 put it, "[o]ne who actually pays value in good faith for a trade secret prior to receipt of notice as stated in this Section is relieved of the duty to which receipt of notice would otherwise give.[72]

In other words, the Restatement made a sharp distinction between one who innocently purchased a trade secret and one who innocently received it for free. In the latter case, the Restatement did not provide complete immunity, and courts instead were to weigh the facts and balance interests: "But not every change of position prevents the recipient of a trade secret from being subjected to the duty not to disclose or use the trade secret after purchase. The issue is whether the imposition of a duty would be inequitable under the circumstances."[73]

The UTSA and DTSA present a more nuanced answer. They dropped the absolute protection for innocent purchasers, as no such language appears in either statute.[74]

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71. *See* RESTATEMENT OF TORTS § 758 (1939). Another restatement expressed a similar principle. The Restatement of Agency noted that a party which obtains "confidential information" from an agent but does not have "notice of its confidential nature, although paying no value, is not subject to liability for revealing the secret to others; if before notice he has paid value for the information, he is not subject to liability to the principle for its subsequent use." *See* RESTATEMENT OF AGENCY (SECOND) § 312, cmt. c (1958); *see also* Note, *Protection and Use of Trade Secrets*, 64 HARV. L. REV. 976, 981 (1951) ("If through mistake or betrayal, disclosure is received innocently without paying value, liability should start only as of the time notice is received." (citing the Restatement)).

72. *See* RESTATEMENT OF TORTS § 758 cmt. e. (1939) ("[I]t is deemed fairer and more consistent with the general principles underlying the protection of the interests in trade secrets to permit him to enjoy the expectancies of the investment."). Notably, this language focuses on buyers, and not licensees, though there is no way to know if that was an intentional choice.

73. *See id.*

74. *See* UNIFORM TRADE SECRETS ACT WITH 1985 AMENDMENTS § 2 cmt., https://www.uniformlaws.org/viewdocument/final-act-128 ("With respect to innocent acquirers of misappropriated trade secrets, Section 2(b) is consistent with the principle of 4 Restatement Torts (First) § 758(b) (1939), but rejects the Restatement's literal conferral of absolute immunity upon all third parties who have paid value in good faith for a trade secret misappropriated by another. The position taken by the Uniform Act is supported by Forest Laboratories, Inc. v. Pillsbury Co., 452 F.2d 621 (CA7, 1971) in which a defendant's purchase of assets of a corporation to which a trade secret had been disclosed in confidence was not

At the same time, the UTSA and the DTSA preserved a before-and-after distinction for the period before one receives notice and the period after one receives notice seen in the Restatement, which used the phrases "prior to receipt" and "after the receipt."[75] The Restatement made clear that an innocent acquiror's activity before receiving notice would not subject it to liability.[76] For the period after receipt of notice, however, the innocent acquiror "is liable for a disclosure or use of the secret after notice," unless "his position has changed prior to receipt of notice," which "may relieve him from the effects which notice would otherwise have[.]"[77] The UTSA and the DTSA employ language that is less clear, but which recognizes the same constructs regarding the timing of receiving notice and the possibility that the innocent acquirer has undertaken a material change of position before receiving such notice.[78]

B. INTERPRETING THE STATUTORY SAFE HARBOR FOR ACCIDENTS AND MISTAKES

This language offers one way to avoid, or to limit, secondary liability for trade secret misappropriation. But the "accident or mistake" language in the UTSA and DTSA requires some unpacking. The statutes do not define what acquisition by accident or mistake means, but the necessary implication is some form of receipt of the trade secret without actual or constructive knowledge of the information's status. The statutes also do not define a "material" change of position, but again the necessary implication is some use of the trade secret where the bell would be difficult to unring.

1. The UTSA's Official Commentary

The UTSA's commentary on the "accident or mistake" clause is a model of poor writing; it does not explain what is most important about that clause. The comments tell us that the safe harbor clause is distinct from a situation where a party loses trade secret rights altogether by failing to use proper

considered to confer immunity upon the defendant."); *see also* James Pooley, TRADE SECRETS § 2.03[3] at n.26 ("The Uniform Act "rejects the [First] Restatement's literal conferral of absolute immunity upon all third parties who have paid value in good faith for a trade secret misappropriated by another."). The other well-known trade secret treatise does not discuss this UTSA and DTSA language. As it was first written decades ago and so often is frankly outdated, it briefly notes the older Restatement formulation without much illumination. *See* MILGRIM ON TRADE SECRETS § 7.02[2][d].

75. *See* RESTATEMENT OF TORTS § 758 (1939).

76. *See id.*, cmt. c ("One is not liable for a disclosure or use prior to receipt of notice, under the rule state in Clause (a), whether he has paid value for the secret or received it free.").

77. *See id.*, cmt. d.

78. *See* UNIFORM TRADE SECRETS ACT WITH 1985 AMENDMENTS § 1(2)(ii)I ("Before a material change of his or her position, knew or had reason to know that it was a trade secret and that knowledge of it had been acquired by accident or mistake.").

security measures: "[t]he type of accident or mistake that can result in a misappropriation under Section 1(2)(ii)(C) involves conduct by a person seeking relief that does not constitute a failure of efforts that are reasonable under the circumstances to maintain its secrecy under Section 1(4)(ii)." This seems to say that a plaintiff's sloppiness in guarding its trade secrets may lead to an accident or mistake on the part of another actor that does *not* result in "misappropriation" where the safe harbor might apply.[79] That would make sense, as plaintiff's failure to use reasonable security measures simply negates trade secrecy, before a court would even reach the question whether there was misappropriation. Even so, this comment is notably unilluminating, and not merely because it is expressed in the negative.[80] It does not explain why the UTSA drafters felt it necessary to contrast the requirement that a trade secret holder employ reasonable security measures with this exception to the definition of "misappropriation." It does not provide concrete examples to illustrate the point it struggles to make. It fails to tell us what kinds of "accidents or mistakes" the UTSA encompasses or what constitutes a "material" change in position. And it fails to specify the conditions under which a defendant which has materially changed its position may continue to use the trade secret after receiving notice: indefinitely, for some reasonable period of time, or not at all.

2. The UTSA Drafting History

By contrast, we find some clues as to the meaning of the "accident or mistake" clause in the 1970s committee proceedings that led to the UTSA. As early as 1972, for example, the drafters of what was tentatively called the "Uniform Trade Secrets Protection Act" expressed the safe harbor principle ultimately seen in the act:

> The tentative proposal of the Special Committee is to limit the remedies available against a person who as acquired knowledge of a misappropriated trade secret in good faith, provided that person has materially and prejudicially changed his position prior to notice of misappropriation. On the other hand, if that person has not detrimentally relied on his innocently acquired knowledge, we would

79. *See* UNIFORM TRADE SECRETS ACT WITH 1985 AMENDMENTS § 1 cmt, https://www.uniformlaws.org/viewdocument/final-act-128. By contrast, the DTSA commentary does not offer insights regarding the accident-or-mistake term. *See* Report 114-220, Senate Committee on the Judiciary, Defend Trade Secrets Act of 2016, at 3 (Mar. 7, 2016) (noting that the DTSA's definition of misappropriation is modeled on the Uniform Trade Secrets Act).

80. *See id.*

> subject him, following notice, to the same remedies as a bad faith misappropriation[.][81]

The committee further noted that "in other words, he can continue to use it himself, notwithstanding the notice," where he had "materially and prejudicially changed his position prior to notice of misappropriation," but might be enjoined from "further disclosure to third parties."[82]

By 1978, the definition of "misappropriation" had a carve-out for acquisition by mistake without notice, but there was not yet language governing whether one would avoid liability for changing one's position before receiving notice:

> (1) "Misappropriation" means:
>
> [. . .] (ii) Disclosure to others or use of a trade secret of another without the latter's express or implied consent where a person:
>
> [. . .] (B) At the time of disclosure or use, knew or had reason to know that:
>
> [. . .] (III) Knowledge of the trade secret was acquired by mistake.[83]

Discussions at the time showed confusion over this language, and whether it was meant to refer to the trade secret holder's failure to use reasonable security measures to protect it—a requirement that a valid trade secret exists in the first place. One committee member asked "Whose mistake are we talking about here? If it's the mistake of the employer, certainly there should be no penalty in this going into the public domain."[84] Another committee member asked a question along the same lines: "with reference to knowledge of a trade secret that's acquired by mistake, I would be pleased to have a little more indication of what you mean by 'mistake.':

> Supposing the person who develops the trade secret—and let's say he's the holder, or the owner, if you believe there's property involved here—and he just goes and leaves written version of it around, and somebody picks it up, is that the kind of mistake that you are talking about?

81. Proceedings in Committee of the Whole, Uniform Trade Secrets Protection Act, Aug. 10, 1972, at 19.

82. *Id.* at 20.

83. *See* Proceedings in Committee of the Whole, Uniform Trade Secrets Protection Act, Aug. 3, 1978, at 11.

84. *Id.* at 13–14.

> If it is the situation where he has sold the secret to somebody else, who is using it under some kind of arrangement, and that person is negligent?"[85]

In response, another committee member sought to clarify that the clause was intended to be distinct from the separate requirement that a valid trade secret be the subject of reasonable security measures:

> I think we were thinking of the Restatement concept. Their illustrations typically involved misdelivered memos and letters. If a person is negligent in maintaining secrecy, under the definition of a 'trade secret'—if they are negligent enough, that can forfeit them protection. So if the negligence goes to the reasonableness of the efforts to maintain secrecy, you can lose protection. But if you just misdeliver something that you are trying to keep confidential, you can impose liability.[86]

The most important debate took place in the 1979 committee proceedings. By that time, the key phrase had been revised to read "at the time of the acquisition of the trade secret, knew or had reason to know, that it was a trade secret and that knowledge of it had been acquired by accident or mistake."[87] There was, as yet, still no language protecting the party which changed its position before receiving notice that the information it had acquired by accident or mistake was someone else's trade secret.

As with the 1978 proceedings, there was a question about what the clause meant, and an explanation that it was not the same as the requirement that the trade secret holder use reasonable security measures or lose its rights.[88] One committee member, however, noted that the concept of a mistake could apply to a downstream acquiror:

> In this section [. . .] it is possible for someone to have acquired the information not directly from the person who had first acquired it by accident or mistake. There could be a channel through which this information could go. Or, alternatively, at the time the information was acquired by the person who was about to use it, they may not have been aware that their source had obtained it by accident or mistake.
>
> Am I correct that if they are innocent of knowledge of it at the time of acquisition, but later learned that their source was tainted, in the

85. *Id.* at 23.

86. *Id.*

87. Proceedings of the Committee of the Whole—Uniform Trade Secrets Act, Aug. 6, 1979 at 3–4.

88. *See id.* at 8–9, 13–14.

> sense of having acquired it by accident or mistake, but not by improper means, they are free to use the information without violation of the trade secret?"[89]

The response sought to clarify whether or not one has notice as the key issue in determining whether one acquiring the secret by accident or mistake would be deemed to have engaged in "misappropriation."[90] Another commentor sought to differentiate "negligent conduct" by the trade secret holder, and receipt by accident or mistake.[91] And, finally, a commentor noted the risk that a party acquires a trade secret by accident or mistake without notice, and acts in good faith by using it:

> You have a situation where there is a disclosure. A person starts to use this, and develops an alternate system. A person tools up prior to finding out that it is a trade secret. At what point are you going to protect the person who in good faith acted on this information, but has not yet put it on the market? At what point does 'use' cut it to protect this individual?"[92]

This question seems to have led the committee to draft the final language seen in the UTSA, with the concept that there is a safe harbor if one acquires a trade secret by accident or mistake, and before receiving notice, undertakes "a material change of his position."[93] That said, there appears never to have been a clear statement speaking to all possibilities. As a committee member noted when explaining this language, "[a]nd the result of that is that if you acquire, knowing that you have acquired, by accident or mistake, then you are a misappropriator. If you acquire not knowing that, but know it before you disclose or use it, you are a misappropriator. But if you acquire and disclose or use before you know that it was by accident or mistake, you are not a misappropriator."[94] However, this explanation does not define what happens in the case of a "material change of position," especially after one subsequently receives notice that the information is a trade secret.

3. The Restatement's Unsatisfactory Examples

These comments suggest that the UTSA drafters slowly worked toward a position that would protect defendants in cases of secondary liability, where the party has received the trade secret mistakenly and has already begun some

89. *Id.* at 14–15.
90. *See id.* at 15–17, 23–25, 27–28.
91. *See id.* at 19–20.
92. *Id.* at 38.
93. *See id.* at 116–117.
94. *Id.* at 117.

significant use of it without actual or constructive knowledge that the information belongs to someone else. However, neither these comments, nor the official comments to the final UTSA, offer much in the way of concrete examples.

By contrast, the 1939 Restatement did provide examples where an innocent acquiror could have avoided liability—though some seem whimsical through today's eyes, and none are particularly useful for contemporary analysis. For example, it imagined a scenario where two potential buyers were trying to buy a trade secret, and the owner accidentally sent a letter revealing the secret to one of them with no strings attached.[95]

But some of its other scenarios of accident or mistake would be equally plausible today, especially where the innocent acquiror has materially changed its position by using the trade secret before receiving notice. In such circumstances, the Restatement invited readers to consider the equities where a party innocently obtained a trade secret, and before receiving contrary notice it (1) "makes a substantial investment in plant and machinery for the use of the secret"; (2) "liquidates another business in order to establish a new business on the basis of the secret"; or (3) "makes substantial expenditures in surveys and research preparatory to establishing the business in an effort to improve the secret process."[96] The Restatement noted, as a counterweight, that a party who "merely makes up his mind to do something in the future or carries on negotiations with others [. . .] is not undergoing a change of position sufficient to relieve him from liability[.]"[97]

4. Interpreting the Accident and Mistake Language for Real-World Scenarios

The DTSA/UTSA safe harbor, to be sure, is qualified: it does not apply if the defendant receives some form or notice or information that the plaintiff has rights in the trade secret, after accidental or mistaken acquisition, but before first doing anything with the trade secret. On the other hand, the language appears to state that if the defendant has materially changed its position when it lacked such notice, "misappropriation" does not exist. Presumably, in at least some circumstances, the defendant can continue the unintentional use it has made of the trade secret even after receiving notice.

But again, the statutes do not define what kind of notice would be sufficient to preclude the safe harbor. If a plaintiff sends a cease-and-desist letter, but the defendant reasonably disputes the claim, is that sufficient? The UTSA commentary—again with poor phrasing that seems contradictory—

95. *See* RESTATEMENT OF TORTS § 758, cmt. c., illus. 3 (1939).
96. *See id.*, cmt. e.
97. *See id.*

suggests both that notice "makes" one "a misappropriator" while simultaneously stating that a court can decline to enjoin that party after balancing the interests:

> The prejudice to a good faith third party justification for withholding prohibitory injunctive relief can arise upon a trade secret owner's notification to a good faith third party that the third party has knowledge of a trade secret as a result of misappropriation by another. This notice suffices to make the third party a misappropriator thereafter under Section 1(2)(ii)(B)(I). In weighing an aggrieved person's interests and the interests of a third party who has relied in good faith upon his or her ability to utilize information, a court may conclude that restraining future use of the information by the third party is unwarranted.[98]

This tells the reader little about what type of notice would suffice to make one a "misappropriator," much less what kind of notice would weigh more strongly than others in determining whether the innocent acquiror may continue to use the trade secret at issue. It also does not explain the statute's "material change of position" language and how it might alter the conclusions expressed in the comment. Indeed, the statement "[t]his notice suffices to make the third party a misappropriator thereafter" does not explain whether that would be true for the defendant which has so changed its position in reliance on the information it innocently acquired.

More important than notice, then, what kinds of change of position are "material," and which are immaterial? One can imagine a scenario where a defendant has only just begun using a trade secret in product development without wrongful intent—and another situation where the defendant has already launched a product into the market using someone else's trade secret, and plans to continue to do so based on the business unit it has built for that purpose. Would both defendants receive safe-harbor protections, or only the latter? Either way, is such protection finite, or permanent—and would future use be subject to any payment by the defendant?[99]

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98. *See* UNIFORM TRADE SECRETS ACT WITH 1985 AMENDMENTS § 2 cmt., https://www.uniformlaws.org/viewdocument/final-act-128.

99. It may be tempting to look at definitions of materiality, or reliance, in other areas of law for guidance. But these terms are used so often, and in so many different contexts, that it feels arbitrary to choose one or another to plug in for an analogy. For example, public companies have to decide what lawsuits and other legal events are material enough to include in SEC filings, reliance is a key aspect of fraud lawsuits, while § 2-209 of the Uniform Commercial Code speaks of weighing the effect of a "material change of position" on a waiver between contracting parties. U.C.C. § 2-209. Rather than attempting to cherry-pick words from some other, unrelated context to offer in some metaphorical sense, we should consider

Said differently, is the safe harbor an immunity lasting indefinitely, or a temporary protection that lasts solely until the defendant receives notice that the information is a trade secret? Either way, does the answer differ in different circumstances? The well-known Pooley treatise asserts that the language means the latter, and that receipt of notice even where one has used the trade secret as "a particular step in a complex manufacturing process" could "immediately" turn a party into a "misappropriator" "upon receiving notice of the facts."[100] It similarly states that "when the recipient is put on notice, then he is prospectively liable for misappropriation."[101]

But that position overstates the language in the UTSA and its official commentary. Certainly, the UTSA and the DTSA tell us that a defendant who receives notice after an accidental or mistaken receipt, but before use, is a misappropriator with respect to such use. But for those defendants who have materially changed their position in the meantime, a reading of the entire text suggests that there is a meaningful degree of allowance for the reliance the defendant made upon its good-faith belief that the information was available for its use—an allowance which should continue into the future to at least some degree. To that extent, use following a material change of position is not "misappropriation" or at least is not subject to the range of remedies available for ordinary misappropriation. The statutes suggest that this outcome is not a remote possibility, but instead an intended outcome.

If it were otherwise—that is, if one's liability automatically kicked in upon notice, despite materially changing one's position before receiving such notice, the material-change-of-position language in the DTSA and the UTSA would serve no purpose. The statute would instead refer to receiving notice, full stop, as the point at which "misappropriation" begins. It would not need to contemplate whether or not the defendant had materially changed its position before notice. Something close to strict liability for "misappropriation" would instantly arise once a defendant, who innocently acquired a trade secret and

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circumstances common to trade secret disputes to determine how these statutory terms are best construed.

100. *See* James Pooley, TRADE SECRETS § 2.03[3] at n.25 (2021) ("In effect this means that an acquiror that had materially changed its position (for example, by including a particular step in a complex manufacturing process) in good faith would not be a "misappropriator," but could become one immediately upon receiving notice of the facts. As the comment to § 2 points out, however, a court would take into account the circumstances and refuse to grant an injunction, and instead impose a reasonable royalty as consideration for continued use by the misappropriator."). Of note, I was an editor on the Pooley treatise from 2006–2009 but did not write this portion of the text.

101. *See id.* § 6.04[1] ("Appropriation Without Knowledge of Secrecy"); *see also id.* § 6.04[2] ("The recipient is not subject to liability for use or disclosure unless and until he or she becomes aware that the disclosure was an accident.").

innocently changed its position by using the trade secret, received notice of the trade secret. Under that reading, the material-change-of-position language would indeed be superfluous: a party without notice would not be liable, whether or not it changed its position before notice, and a party with notice would be liable for any use afterwards, whether or not it changed its position before notice.

The phrase "material change of position" speaks to a different vision. It contemplates some meaningful course of action by the defendant before receiving notice of the trade secret where consequences flowing from that action will continue past the point of notice, rather than a harsh outcome where one who innocently and materially changes its position in reliance on a belief that the information can permissibly be used must pay damages for any continuing use after notice. While a defendant's new and distinct use or disclosure—one not linked to the material change of position—should be a different story, continuing conduct in line with that change of position would receive safe-harbor protection, to at least some significant degree.

Adding to these interpretive difficulties, some (but not all) states enacted a version of the UTSA that sheds some light on these questions. It contains modified language in the statutory section defining whether and when injunctive relief and monetary relief are possible in cases where the safe harbor clause protects a defendant. Specifically, in the version of the statute finalized in 1985, the remedial sections state that damages are not available when there has been "a material and prejudicial change of position prior to acquiring knowledge or reason to know of misappropriation," but that in "exceptional circumstances" such as these, "an injunction may condition the defendant's potential future use upon payment of a reasonable royalty" while a non-use injunction is "inequitable."[102] In short: the 1985 version of the UTSA permits (but does not require) a court to order a royalty for future use of the trade secret, but damages for past use and a non-use injunction are not allowed when the safe harbor applies. But again, the official commentary does not explain

102. *See* UNIFORM TRADE SECRETS ACT WITH 1985 AMENDMENTS §§ 2–3, https://www.uniformlaws.org/viewdocument/final-act-128 (see underlined text for changes to this version on these points regarding remedies). Vermont, Massachusetts, and South Dakota are examples of states which enacted this language. *E.g.*, VT. STAT. §§ 4602(b) ("exceptional circumstances" where an injunction can "condition future use" upon payment of a royalty "include a material and prejudicial change of position prior to acquiring knowledge or reason to know of misappropriation that renders a prohibitive injunction inequitable."); 4603(a)(1) ("Except to the extent that a material and prejudicial change of position prior to acquiring knowledge or reason to know of misappropriation renders a monetary recovery inequitable, a complainant is entitled to recover damages for misappropriation."); MASS. GEN. LAWS ch. 93 §§ 42A(b), 42B (same); S.D. CODIFIED. LAWS. §§ 37-29-2, 37-29-3 (same).

when such a royalty should be ordered, or why, versus when it should not be.[103] And the DTSA, as well as some versions of the UTSA including in technology-heavy jurisdictions such as California and Washington, contain no such language.[104]

It is easy to imagine practical, real-world contexts where full safe harbor protection would make sense. A defendant in the midst of selling a product that contains an innocently-acquired trade secret can hardly hit pause immediately without harm to its business, and delays in redevelopment. The same is true of the hypothetical discussed above in the Pooley treatise, where an innocent acquiror includes a trade secret in a "complex manufacturing process" before receiving notice. Almost any use of a trade secret where the information is embedded into or made part of some larger product, process, or technology would be "material" simply because starting over and removing the information would create meaningful risk, uncertainty, and disruption to an innocent actor. The text of the DTSA and the different versions of UTSA seem to envision that there would be no "misappropriation" in such circumstances, or at least that the sole remedial option of a royalty order could be "inappropriate."[105]

Certainly the UTSA and the DTSA do not adopt a bona fide purchaser theory where anyone who first obtains a trade secret is free to use it, even if notice comes before such use. The UTSA commentary expressly rejects that possibility, noting that the statute "rejects the Restatement's literal conferral of

103. *See* UNIFORM TRADE SECRETS ACT WITH 1985 AMENDMENTS §§ 2–3, *supra* note 102.

104. *See generally* 18 U.S.C. § 1836(b)(3); CAL. CIV. CODE §§ 3426.2–3426.3; WASH. §§ 19.108.020.030.

105. The Pooley treatise points to the language in the 1985 UTSA commentary stating that, after receiving notice, a party could be liable for misappropriation but merely would have to pay a royalty instead of being enjoined. *See* James Pooley, TRADE SECRETS § 2.03[3] at n.25. The commentary, however, is nuanced. It makes clear that in some cases, at least, a royalty also might be as "inappropriate" as an injunction in such circumstances: "When Section 2(b) applies, a court has discretion to substitute an injunction conditioning future use upon payment of a reasonable royalty for an injunction prohibiting future use. Like all injunctive relief for misappropriation, a royalty order injunction is appropriate only if a misappropriator has obtained a competitive advantage through misappropriation and only for the duration of that competitive advantage. In some situations, typically those involving good faith acquirers of trade secrets misappropriated by others, a court may conclude that the same considerations that render a prohibitory injunction against future use inappropriate also render a royalty order injunction inappropriate." *See* UNIFORM TRADE SECRETS ACT WITH 1985 AMENDMENTS §§ 2-3, https://www.uniformlaws.org/viewdocument/final-act-128. To be sure, the language is ambiguous. It is unclear whether it is speaking about a situation where party which has innocently acquired a trade secret has received notice before use, after immaterial use, or after a truly material change in condition. Indeed, the problem with the UTSA commentary as a whole is that it does not define or explain the consequences that flow from a defendant's material change of position before receiving notice that the information is a trade secret.

absolute immunity upon all third parties who have paid value in good faith for a trade secret misappropriated by another."[106] The result is a more nuanced safe harbor, where the innocent acquiror who commits to using the trade secret into the future, before receiving notice, is granted latitude for at least some measure of continuing use, in recognition of the difficult position it is in.

C. CASE LAW ON THE SAFE HARBOR REMAINS SCARCE

Case law is exceedingly sparse as to any of these questions.[107] It is almost as if litigants shy away from litigating the mistake-or-accident clause of the DTSA and UTSA. Perhaps the unwieldy thicket of statutory text and UTSA comments scare courts and parties away.

In *Myers v. Williams*, the defendant, a convicted inmate, had argued that his criminal conduct resulted from using a treatment for a sleeping disorder.[108] He submitted a Freedom of Information Act request for information disclosed to regulators about the treatment, and the FDA mistakenly sent him a "document containing the chemical formula for the manufacture" of the treatment.[109] A few months later, the FDA informed the manufacturer, which then requested

106. *See* UNIFORM TRADE SECRETS ACT WITH 1985 AMENDMENTS § 2 cmt., https://www.uniformlaws.org/viewdocument/final-act-128 ("With respect to innocent acquirers of misappropriated trade secrets, Section 2(b) is consistent with the principle of 4 Restatement Torts (First) § 758(b) (1939), but rejects the Restatement's literal conferral of absolute immunity upon all third parties who have paid value in good faith for a trade secret misappropriated by another. The position taken by the Uniform Act is supported by Forest Laboratories, Inc. v. Pillsbury Co., 452 F.2d 621 (CA7, 1971) in which a defendant's purchase of assets of a corporation to which a trade secret had been disclosed in confidence was not considered to confer immunity upon the defendant."); *see also* James Pooley, TRADE SECRETS § 2.03[3] ("The sixth type of misappropriation arises from accidental or mistaken disclosure. Liability for damages for disclosure or use is imposed if, before a material change of position, the defendant knew or should have known that the information was a trade secret and that it had been acquired by accident or mistake. Although Section 1 of the Act does not specifically address the issues, the official comments in Section 2 of the Act state that providing notice to a previously innocent acquiror 'suffices to make the third party a misappropriator thereafter.' This is a departure from the common law as defined in the *Restatement of Torts*, which excused a good faith user from any liability.").

107. Indeed, commentary by academics or practitioners on the "accident or mistake clause," or any kind of treatment in the case law, is almost non-existent, even though some versions of the UTSA have been in force for more than 40 years. An occasional case will mention the clause as dicta, or in a passing reference, but not in the context of an innocent acquiror. *E.g.*, Compulife Software, Inc. v. Newman, 959 F.3d 1288, 1313 (11th Cir. 2020) (noting, when remanding a case where two of the defendants obtained knowledge of a database, that the trial court could have decided that if their receipt was an accident or mistake, they were on notice and use thus would have been misappropriation).

108. Myers v. Williams, 819 F. Supp. 919, 920–21 (D. Or. 1993)

109. *Id.*

that the inmate destroy all copies.[110] The defendant refused, and "instead attempted to sell" the formula to other pharmaceutical companies.[111]

On this extremely unusual set of circumstances, the court granted a preliminary injunction under the Oregon UTSA, and found that the statute's accident-or-mistake clause did not apply.[112] The court reasoned that the defendant was aware he had received the trade secret formula by mistake, and that there was "no evidence that [he] had undergone a material change in position since acquiring" it, and instead "persisted" in threats to disclose it to others.[113]

In a more apposite fact pattern, the Eastern District of New York faced a 1981 case where a game manufacturer received a game idea via a solicitation from a trusted source.[114] Unbeknownst to the defendant, the game idea originated with the plaintiff and had wrongfully been taken.[115] Although the defendant primarily won judgment as a matter of law because it established that it had independently developed its own game, it also won under § 758 of the Restatement (the predecessor to today's DTSA/UTSA safe harbor clause). Specifically, the court found that even if the defendant had received notice that the game idea was the plaintiff's trade secret and even if it had used the idea, it had changed its position by spending on "tooling and other production components, for advertising, and possibly some inventory."[116] Thus, under § 758 it could not be liable because liability would subject it to loss "for action taken when there was no such duty."[117] This appears to be the only fully-developed case to apply the safe harbor principle for a use of trade secrets before receiving notice.

A 1971 case, also under the Restatement, was later cited by the Uniform Act's drafters.[118] In *Forest Labs, Inc. v. Pillsbury Co.*, the defendant had purchased assets from a third party which had been subject to a confidentiality agreement

110. *Id.*
111. *Id.*
112. *Id.*
113. *See id.* at 921.
114. *See* Vantage Point, Inc. v. Parker Bros., Inc., 529 F. Supp. 1204, 1214–15 (E.D.N.Y. 1981).
115. *See id.* at 1208.
116. *Id.* at 1215.
117. *Id.* at 1216.
118. UNIFORM TRADE SECRETS ACT WITH 1985 AMENDMENTS § 2 cmt., https://www.uniformlaws.org/viewdocument/final-act-128 ("The position taken by the Uniform Act is supported by Forest Laboratories, Inc. v. Pillsbury Co., 452 F.2d 621 (CA7, 1971) in which a defendant's purchase of assets of a corporation to which a trade secret had been disclosed in confidence was not considered to confer immunity upon the defendant.").

with the plaintiff.[119] The plaintiff alleged that the third party had divulged its trade secret to the defendant in a manufacturing process, via the asset purchase.[120] However, the asset purchase did not transfer the third party's liabilities to the purchaser, because the defendant was not a successor to the third party.[121]

This begged the question whether the defendant, as an innocent acquiror, could be liable under Wisconsin's pre-UTSA, Restatement-based trade secret common law. The Seventh Circuit thus analyzed § 758.[122] Although the defendant had paid for the assets its purchased, the court evaded the good-faith-purchaser exception in § 758 by finding that there was no evidence that the defendant "paid value for [plaintiff's] trade secret" as opposed to a more general asset purchase, and on that basis found that it "remained liable to [plaintiff] for using the trade secret after receipt of notice."[123] The court was not called upon to consider whether the defendant had materially changed position before receiving notice of the trade secret. The decision is unsatisfactory, and feels forced, because the court introduced a self-created notion—separating the purchase of assets including the trade secret from a purported separate value of the trade secret—to impose liability. That outcome is not consonant with the DTSA and UTSA statutory text and thus should have little purchase today.

In a case with some similarities but key differences, a court in 1980 declined to apply the Restatement's § 758 safe harbor where a firm providing account management services for a defendant obtained copies of backup tapes containing the plaintiff's trade secrets in a complicated fact pattern where it at first did not know that its receipt was improper.[124] However, it did not pay any value for those tapes and thus could not rely on § 758 of the Restatement to avoid liability.[125]

Finally, while the Alabama Supreme Court once held that a defendant could be liable under that state's Trade Secrets Act for continuing to use a trade secret after receiving notice, the statute in question notably differs from the UTSA and the DTSA by not including an exception for those who have

119. *See* Forest Labs., Inc. v. Pillsbury Co., 452 F.2d 621, 624–25 (7th Cir. 1971).
120. *Id.*
121. *Id.* at 625–26.
122. *See id.* at 626–627.
123. *Id.* at 627.
124. *See* Comput. Print Sys., Inc. v. Lewis, 422 A.2d 148 (Pa. Super. Ct. 1980).
125. *See id.* at 151, 155–56.

materially changed position before receiving such notice.[126] It thus sheds no light on interpretive questions in other jurisdictions.

D. REVIVING THE SAFE HARBOR AS A DEFENSE TO MISAPPROPRIATION CLAIMS

Because the case law regarding the "accident or mistake" clause is almost nonexistent, it is not clear exactly what one must do to sufficiently change position before receiving notice in order to avoid liability. Notwithstanding the dearth of cases construing it, the plain purpose of the DTSA/UTSA safe harbor is to protect defendants—whether completely or to some meaningful degree—who innocently receive trade secrets, get entangled through material reliance by using the trade secret before receiving notice, and then face litigation.

Indeed, there are countless everyday contexts where the DTSA/UTSA safe harbor clause could protect an innocent defendant which has used a trade secret by accident or mistake. Consider that in many business-to-business transactions, the seller or licensor provides representations and warranties—and even a promise of indemnification—that it is providing information or technology it has a right to provide. Absent some indicia that something is amiss, an ordinary buyer or licensee is entitled to rely on such representations, and in fact must do so in order to engage in such transactions. To that end, indemnity clauses protecting the buyer are not constructive notice as they are common and agnostic to the circumstances. That a good attorney negotiates for such a clause is not constructive notice that anything is amiss.

It is easy to imagine parties such as a licensee of source code, a licensee of a semiconductor design, a party which outsources chemistry work to a contracted entity for a life sciences pharmaceutical development project using what they receive—indeed, materially relying on an innocently-received trade secret by embedding or commingling it—as just one part of a larger development or design. In such cases, it is also easy to imagine that it would be difficult, disruptive, and expensive to unring the bell and remove such information and replace it. Thus, if such a party were to receive notice (whether convincing or not) that a plaintiff claimed trade secret rights in what the third party provided, the DTSA/UTSA safe harbor clause should be raised as not only a defense to misappropriation, but as a basis to continue such use.[127]

126. *See* IMED Corp. v. Sys. Eng'g Assoc., 602 So.2d 344 (1992) (construing Alabama's trade secret statute (ALA. CODE. § 8-27-3)).

127. This is not to suggest that applications of "accident or mistake" should be limited to such business transactions, only that this seems the most likely instance when litigants and courts should be attuned to the statutory safe harbor.

IV. VICARIOUS LIABILITY AS A SUBSTITUTE FOR INTENT—AND ITS EXCEPTIONS

We turn now to the question of vicarious liability, where a trade secret plaintiff seeks to hold a new employer liable for the acts of an employee who has switched jobs. A question of intentionality looms large here, especially in lawsuits where a former employer alleges that a departing employee downloaded (or retained) files from the job and uses that accusation to engage in wide-ranging and costly discovery into the hiring company's development efforts. As the deep pocket, the corporate defendant also potentially faces monetary remedies for the individual's download. But while some such downloading episodes are significant, many are trivial. Nonetheless, even the latter is a low barrier to entry, so to speak, where a former employer files suit against the new employer and impose millions in discovery costs on an opponent. So it is notable that defendants in such cases have not explored exceptions to vicarious liability more robustly, as a means to limit at least some such cases.

Because so many trade secret cases feature employees who have changed jobs, and because so few trade secret cases feature accusations that company management knowingly colluded with newly-hired employees, courts have often had to grapple with questions of a company's vicarious liability for the actions of employees. These problems of secondary liability arise when company management does not know or suspect what an employee has done, such that the ordinary rules of actual and constructive knowledge under the DTSA/UTSA—as discussed above—would not result in liability for the corporate defendant.

Because the UTSA does not mention vicarious liability, courts have had to decide if the doctrine applies in misappropriation cases. Notwithstanding one prominent exception, almost all courts have agreed that traditional common law rules that govern whether an employer is liable for the act of an employee apply in trade secret cases. That said, few have gone further, and asked when the doctrine does not apply to an employer which lacked intent to engage in wrongdoing. The question matters because separating employee liability from the liability of a new employer can be an important tool to thwart overreaching lawsuits filed by former employers.

A. THREE EARLY CASES ON VICARIOUS LIABILITY UNDER THE UTSA

Two early cases set the tone. Notably, and importantly for the proposals this Article will advance, both suggested that vicarious liability was not automatic, and that there are defenses an employer can raise against it. A 2001 decision in the Eastern District of Virginia was perhaps the most influential

case to grapple with the application of vicarious liability under the UTSA. *Newport News Industries v. Dynamic Testing, Inc.* held that the Virginia UTSA does not displace the common law of vicarious liability, but instead merely allows for a defense to vicarious liability when the employer has innocently made a material change of position before receiving notice of the misappropriation.[128]

In reaching its holding, the *Newport News* court reviewed the history of the UTSA and compared vicarious liability for other torts and statutory violations. It also examined the preemption clause of the Virginia statute, which states that it "displaces conflicting tort, restitutionary, and other law of this Commonwealth providing civil remedies for misappropriation of a trade secret."[129] The court reasoned that vicarious liability is not a conflicting cause of action or remedy that would be preempted by the UTSA, but instead "it is a legal precept that presupposes the existence of an underlying claim and assesses liability not because of the act giving rise to the claim but because of a certain status."[130]

The court also considered the possibility that an employer might escape liability where it did not reasonably have notice of an employee's act of misappropriation. It held open the possibility of a defense to liability on such ground, noting that "[c]ontrary to the Defendants' position, the exception for a material and prejudicial change in position before discovery of the misappropriation in both the injunction and damages sections [of the UTSA] does not preclude respondeat superior liability, but instead provides a *defense* to

128. *See* Newport News Indus. v. Dynamic Testing, Inc., 130 F. Supp. 2d 745, 754 (E.D. Va. 2001).

129. *Id.* at 751.

130. *Id.* The court added that one cannot bring an independent tort claim for vicarious liability, to distinguish it from the type of claims preempted by the UTSA, and noted that the Virginia UTSA does not expressly preclude vicarious liability. Subsequent Virginia UTSA cases have held that vicarious liability is available, albeit without such detailed statutory analysis. *See generally* Microstrategy, Inc. v. Business Objects, S.A., 331 F. Supp. 2d. 396, 418 (E.D. Va. 2004) ("The defendant contends that respondeat superior is inapplicable in this case because its employees signed an employment agreement forbidding them from obtaining or using confidential information from competitors. This argument is unavailing. One can act in the scope of one's employment even if the specific acts performed are explicitly forbidden by the employer, so long as the act was intended to further the employer's interests rather than being wholly motivated by personal interest. Moreover, the employer need not even be aware of its employee's activity."); Tao of Sys. Integration, Inc. v. Analytical Serv. & Materials, Inc., 299 F. Supp.565, 575 (E.D. Va. 2004) (stating rule and holding that claim was properly stated against employer); Physicians Interactive v. Lathian Sys., Inc., No. CA-03-1193-A, 2003 U.S. Dist. LEXIS 22868, at *28–29 (E.D. Va. Dec. 5, 2003) (granting request for preliminary injunction and holding that plaintiff had shown a likelihood that employee was acting in course and scope of his employment for apparent misappropriation, and thus vicarious liability argument likely to succeed).

vicarious liability for innocent employers."[131] With respect to such a defense, the court explained that "[o]ne can imagine that an employer could be liable for the wrongful acts of his employee, but could not qualify for the exception because it has not yet made a 'material' or 'prejudicial' change of position."[132]

Minnesota courts also faced the question of vicarious liability under the UTSA early on, and also focused on limits to liability under such a theory. In *Hagen v. Burmeister & Associates*, an insurance salesperson reached an apparent agreement with his former employer allowing him to solicit certain customers but not others. The new employer was aware of the agreement, but not the details, and it was aware that the salesperson began soliciting many customers of the former employer, which duly sued for claims including trade secret misappropriation.[133]

After a 1999 appellate decision ruled that vicarious liability is available in misappropriation cases—pointing to its availability for intentional torts more generally—the state supreme court accepted that premise for purposes of appeal.[134] The lower courts had struggled with the question of vicarious liability where the new employer believed that its newly-hired salesperson had an agreement with the former employer allowing some degree of customer solicitation.[135] The high court held that in the case at issue, the employer was not vicariously liable for the acts of its employees, where Minnesota's version of the theory requires that "the tort is related to the employee's duties" and is "foreseeable" in the sense that the act is the type of "well-known industry hazard" that should fairly be allocated to a company's costs of doing business.[136] That was so because, under the Minnesota law of vicarious liability, the plaintiff had failed to show that the act of misappropriation was foreseeable because it did not introduce any evidence to establish that "the risk of employees misappropriating trade secrets is a well-known hazard in the

131. *See Newport News*, 130 F. Supp. 2d at 752 (emphasis in original).

132. *Id.* at 754 n.4.

133. *See* Hagen v. Burmeister & Assoc., Inc., 633 N.W.2d 497, 500–02 (Minn. 2001).

134. *See id.* at 504; *see also* Hagen v. Burmeister & Assoc., Inc., C8-98-864, 1999 Minn. App. LEXIS 85 (Minn. Ct. App. Jan. 26, 1999) (intermediate appellate decision). The state supreme court noted that it accepted that vicarious liability is available under the Minnesota because the appellate court had so ruled, and because the corporate defendant did not specially appeal that ruling. *See Hagen*, 633 N.W.2d at 504; *see also* Tanya Dobash, *Trade Secret Theft & Employer Vicarious Liability in Hagen v. Burmeister & Assoc., Inc.*, 29 WM. MITCHELL L. REV. 375 (2002) (providing detailed case analysis).

135. *See* Hagen, 633 N.W.2d at 501–02 (explaining lower court history).

136. *Id.* at 505 (explaining state's "scope-of-employment" test, which also includes whether the "tort occurs within work-related limits of time and place").

insurance industry."[137] Like *Newport News*—the other early, foundational case on UTSA vicarious liability—*Hagen* pointed to the limits of vicarious liability, and a defense to it.

By contrast, there is only one major court ruling holding that the Uniform Trade Secrets Act does not provide for vicarious liability. In *Infinity Products v. Quandt*, an Indiana appellate court found that a departing employee took documents with him relating to customer contact information.[138] When the employee arrived at his new employer, he immediately began contacting those customers and using pricing information to negotiate sales. The trial court had found that there was insufficient evidence that the new employer was vicariously liable.[139] The appellate court looked to the rulings in Virginia and Minnesota discussed above finding that vicarious liability is available under the UTSA, held that it was likewise available under the Indiana version, and reversed the trial court.[140]

But the state supreme court decided otherwise. The Indiana high court held that the UTSA displaces the common law of vicarious liability because the statute's express terms (regarding actual or constructive knowledge in order to engage in misappropriation) require "scienter" by the employer.[141] The court also placed emphasis on the UTSA's preemption clause, which is typically used to eliminate overlapping tort causes of action, and held that it applied to vicarious liability as well.[142]

B. COURTS HAVE VIRTUALLY ALWAYS FOUND VICARIOUS LIABILITY AVAILABLE

Notwithstanding *Infinity Products*, seemingly every court since has taken the majority approach, leaving Indiana as an outlier. For example, in a 2017 case applying the Ohio UTSA, the District of Minnesota explained that "[n]early every UTSA jurisdiction has held that similar provisions suggest vicarious liability," and noted that the UTSA's preemption clause that displaces

137. *Id.* at 505 ("We will not assume, absent introduction of some evidence, that UTSA violations are a common hazard in the insurance industry.").

138. Infinity Prod., Inc. v. Quandt, 775 N.E.2d 1144, 1147–48 (Ind. Ct. App. 2002) (overruled by state supreme court decision discussed below).

139. *Id.* at 1152.

140. *See id.* at 1152–53.

141. Infinity Prods., Inc. v. Quandt, 810 N.E.2d 1028, 1034 (Ind. 2004).

142. *Id.*; There does not appear to have been much law on the issue in Indiana since. *E.g.*, Patriot Homes, Inc. v. Forest River Housing, Inc., No. 3:05-CV-471 AS , 2007 U.S. Dist. LEXIS 70697, at *11 (N.D. Ind. Sept. 20, 2007) (noting the *Quandt* standard and stating that, although vicarious liability is unavailable under the Indiana UTSA, the plaintiff can still seek to show that the new employer is directly liable; finding that because the new employer "turned a blind eye as to what was happening," a defense motion for summary judgment failed).

conflicting tort remedies does not apply to a remedy that is not a free-standing cause of action.[143] Similarly, a 2013 case in the Northern District of California rejected a defense argument that the doctrine did not apply. It held that "[t]he majority view, however, is that the UTSA does not preempt the *respondeat superior* doctrine," and that a defendant "cannot prevail at summary judgment merely by arguing that it was not aware of the acts of its employees[.]"[144] Many others have followed suit.[145]

The same is true for the only state without a trade secret statute, New York. A New York trial court denied a motion to set aside a jury verdict in a case where a former law firm associate, used impersonation to access confidential client information from his former firm..[146] As to vicarious liability, the court affirmed the jury's findings that the associate's conduct took place within the scope of employment and that the employer had ratified the conduct because the associate had brought in an extraordinary number of new clients, whose client intake forms a partner had signed.[147] It noted that a jury could correctly have found that the firm "should have conducted a more thorough inquiry as to where the clients were coming from."[148]

143. *See* Deluxe Fin. Serv., LLC v. Shaw, No. 16-3065 (JRT/HB), 2017 U.S. Dist. LEXIS 122795, at *10–12 (D. Minn. Aug. 3, 2017) ("Because OUTSA's statutory provisions align with the majority of UTSA jurisdictions, the Court believes the Ohio Supreme Court would follow the majority approach.").

144. Language Line Serv., Inc. v. Language Serv. Assoc., Inc., 944 F. Supp. 2d 775, 783 (N.D. Cal. 2013) (denying motion for summary judgment where defendant argued it could not be liable under the California UTSA for acts of employees).

145. *See e.g.*, Navigation Holdings, LLC. v. Molavi, No. 19-CV-02644-LHK, 2020 U.S. Dist. LEXIS 154268, at *10 (N.D. Cal. Aug. 25, 2020) (denying motion to dismiss where defendant alleged plaintiff failed to plead vicarious liability; citing cases for proposition that an employer can be vicariously liable for trade secret misappropriation committed within the scope of employment, and at least in part to benefit the employer, even if the employer has forbidden it); Brain Injury Ass'n of Cal. v. Yari, No. CV 19-5912-MWF (JCx), 2020 U.S. Dist. LEXIS 120201, at *17–18 (C.D. Cal. Apr. 30, 2020) (same); Solarcity Corp. v. Pure Solar Co., 2016 U.S. Dist. LEXIS 199522, at *14–15 (same); MTG Guarnieri Mfg., Inc. v. Clouatre, 2010 Okla. Civ. App. LEXIS 52, at *33–34 (Okla. Ct. App. June 17, 2010) (noting, in reversing summary judgment, that employer might be liable for misappropriation for acts of its employees under respondeat superior, defined as "willful torts of an employee acting within the scope of employment in furtherance of assigned duties"); Thola v. Henschell, 164 P.3d 524, 528–529 (Wash Ct. App. 2007) (holding that UTSA did not displace common law rules of vicarious liability).

146. Rosenberg, Minc & Armstrong v. Mallilo & Grossman, 8 Misc. 3d 394, 398, 399 (N.Y. Sup. Court Mar. 24, 2005). The plaintiff brought claims including "misappropriation" which appears to have been more or less equivalent to a trade secret misappropriation claim, as the court noted it was based on "confidential information.".

147. *Id.* at 400.

148. *Id.*

Because many companies use contractors—as distinct from full-time employees—questions also arise about vicarious liability for trade secret misappropriation by a contractor. The Missouri Supreme Court considered such a question in 2014.[149] In that case, someone signed an agreement as an "independent contractor" which also stated that the contractor had no right to bind the company by his actions.[150] He was accused of misappropriating the plaintiff's customer list and using it for the benefit of the defendant, but the defendant never accessed the list and had no way of knowing it had been pilfered.[151] Because the plaintiff had not alleged any kind of employer/employee or principal/agent relationship, the court affirmed a finding that there was no vicarious liability.[152]

That outcome begs the question of the result when the plaintiff is careful enough to allege an agency relationship against a company which hired a contractor accused of misappropriation. While trade secret case law appears sparse,[153] common law principles indicate that contractor liability may well be possible in a similar manner to vicarious liability, but it is less clear. Taking California as an example, principle/agent liability questions turn on factors such as the principal's selection of the contractor and the degree to which the contractor's work was observable and influenceable. At the same time, courts may consider whether the contractor's duty is of a type found to be nondelegable.[154] This type of test is hardly an automatic endorsement of liability for a contractor's actions but indicates that such liability is possible.

149. *See* Cent. Trust and Invest. Co. v. Signalpoint Asset Mgm't, LLC, 422 S.W.3d 312, 322 (Mo. 2014).

150. *Id.* at 323.

151. *Id.* at 322.

152. *See id.* at 323.

153. *See* Great Am. Opportunities, Inc. v. Cherrydale Fundraising, LLC, No. 3718-VCP, 2010 Del. Ch. LEXIS 15, at *81–85 (Del. Ch. Jan. 29, 2010) (unpublished) (in a case with claims including misappropriation of trade secrets, finding no vicarious liability as to one company for actions of another, where "scant" evidence did not establish either a "servant" relationship or sufficient evidence of control over an independent contractor).

154. *See* Barry v. Raskov, 232 Cal. App. 3d 447, 453 (1991) ("Today, however, the exceptions have so overwhelmed the "general rule" it is more accurate to say the employer of an independent contractor will generally be held liable for the contractor's torts and that nonliability is the exception."). *Barry* was not a trade secret case but noted that liability for the acts of an independent contractor is commonplace despite an earlier common law rule to the contrary. *See id.*; *see also* Vargas v. FMI, Inc., 233 Cal. App. 4th 638, 646–50 (2015) (discussing factors for agency liability with independent contractors).

C. States Use Different Tests to Apply Vicarious Liability in Trade Secret Cases

In deciding whether vicarious liability applies as a general rule—as opposed to whether it is theoretically available under the trade secret statutes—courts apply the existing common law test in each state.[155] Such tests can differ. Taking California as an example, that state provides that an employer is liable for torts committed by an employee who acts within the scope of their employment, regardless of whether the employee acted in excess of their authority, or contrary to instructions they received.[156] In turn, whether an act was committed within the scope of employment depends on (1) whether the act was required by, or incident to, the employee's duties; or (2) whether the act could reasonably be foreseen as an outgrowth of the employee's duties.[157] That test puts at least some weight on an employer's expectations.

Applying these principles, in *Cisco Systems, Inc. v. Chung*, the Northern District of California defined vicarious liability as a rule where employers are liable for torts of employees, committed within the scope of their employment, including intentional, unauthorized torts, as long as there is a causal nexus between the wrongful act and the employee's work, and the act was undertaken at least in part to benefit the employer.[158] The court also noted that an

155. One might wonder why we focus here on the UTSA, rather the federal DTSA. The DTSA does not speak to vicarious liability, and it does not preempt state law (which is why a plaintiff can bring both DTSA and UTSA claims together in the same lawsuit). *See* 18 U.S.C. § 1838 ("Except as provided in section 1833(b), this chapter shall not be construed to preempt or displace any other remedies, whether civil or criminal, provided by United States Federal, State, commonwealth, possession, or territory law for the misappropriation of a trade secret[.]"). Generally speaking, when federal statutes are silent as to vicarious liability, state law fills the gap. *See* Meyer v. Holley, 537 U.S. 280, 285 (2003) (analyzing the Fair Housing Act, which "says nothing about vicarious liability"; "[T]he Court has assumed that, when Congress creates a tort action, it legislates against a legal background of ordinary tort-related vicarious liability rules and consequently intends its legislation to incorporate those rules."). Thus, especially where a trade secret plaintiff can already bring a parallel UTSA cause of action, a DTSA claim would seemingly incorporate the same vicarious liability rules as the state law governing the UTSA claim.

156. *See* Witkin, SUMMARY OF CALIFORNIA LAW § 115 (collecting many cases); *see also* Judicial Council of California, CACI 3700, 3720 (jury instructions for "vicarious responsibility" and scope of employment).

157. *See id.*

158. 462 F. Supp. 3d 1024, 1056–57 (N.D. Cal. May 26, 2020) (on motion to dismiss, finding that plaintiff stated misappropriation claim under vicarious liability theory).

employer can be directly liable where it ratifies an employee's act even if the act was originally unauthorized.[159]

Similarly, in a case where the court issued a preliminary injunction over a customer list, it enjoined the new employer as well as individual employees based on a vicarious liability theory.[160] The court noted that "California and federal courts have allowed vicarious liability claims under the UTSA," and found evidence that the new employer was aware that the employees stated that they would bring business with them from the plaintiff.[161]

Other states' tests appear to place little if any weight on the employer's state of mind. For example, where employees of a corporate defendant obtained and used documents that clearly contained the plaintiff's confidentiality markings, a court found in a bench-tried case that the corporate defendant was vicariously liable under the Pennsylvania UTSA.[162] The court noted that "[t]he near unanimous consensus of federal and state courts holds that the Uniform Trade Secret Act . . . does contemplate vicarious liability when state law otherwise provides the cause of action."[163] It applied Pennsylvania's common law test—which asks whether the employee's wrongful act was similar in kind to the job the employee was hired for, whether it occurred substantially within the time and space boundaries of the employer, and was motivated at least in part to benefit the employer—and found all elements present.[164]

Under Georgia law, a 2011 case applied that state's test—"courts will hold an employer responsible for the conduct of its employee if the employee acted in the course of the employer's business and with a desire to benefit the employer"—in finding a likelihood of vicarious liability to support a preliminary injunction.[165] Three employees, whom the corporate defendant had hired, took files containing trade secrets and used them to solicit healthcare facilities their former employer worked with.[166] A new co-worker

159. *Id.* at 1057 (finding that plaintiff stated a claim under this theory because it alleged that defendant's executives did not reprimand the employee for making disclosures or caution him against doing so).

160. Extreme Reach, Inc. v. Spotgenie Part., LLC, No. CV 13-07563-DMG (JCGx), 2013 U.S. Dist. LEXIS 201300, at *20–21 (C.D. Cal. Nov. 22, 2013).

161. *Id.*

162. Advanced Fluid Sys., Inc. v. Huber, 295 F. Supp. 3d 467, 486 (M.D. Pa. 2018).

163. *Id.* at 472.

164. *Id.*

165. Amedisys Holding, LLC v. Interim Healthcare of Atlanta, Inc., 793 F. Supp. 2d 1302, 1314 (N.D. Ga. 2011) (noting that there would be no vicarious liability for a purely personal act by an employee).

166. *Id.* at 1309.

had asked "when we meet can u please brng ur cheat sheet lol u have from [former employer]."[167]

D. CONTEXTS WHERE VICARIOUS LIABILITY IS INAPPLICABLE

Although early, foundational cases regarding vicarious liability under the UTSA—*Newport News* and *Hagen*—pointed to situations where the doctrine would not apply, cases addressing exceptions to vicarious liability appear to be rare.

There should be many situations where vicarious liability does not apply.[168] Indeed, given the frequency of lawsuits filed against departing employees and new employers, it is surprising that litigants seem to have only rarely argued such points, and that courts have been inattentive to these issues. There may be practical explanations, of course: intellectual property practitioners may be less familiar with doctrines based in employment law, a distinct field. And at a more mundane level, law firm associates tasked with writing briefs are more likely to work from existing trade secret cases found in online databases, rather than crafting less-familiar arguments anew.

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167. *Id.* at 1314.

168. Although vicarious liability is recognized in other areas of intellectual property law, the fact patterns generally involve third parties the defendant is able to control, and thus offer trade secret law little by way of analogy. *See, e.g.*, Sentius Int'l, LLC v. Apple Inc., 2020 U.S. Dist. LEXIS 192203, *12-13 (N.D. Cal. Oct. 2015) (collecting authorities; noting that because "[p]atent infringement is a tort action . . . . [p]atent law thus presumptively incorporated vicarious liability principles," but noting that in both patent and copyright law, the doctrine is about control over the actions of third parties); Kilina Am., Inc. v. SA & PW, Inc., No. CV 19-03786-CJC (KSx), 2019 U.S. Dist. LEXIS 230737, at *5–6 (C.D. Cal. Aug. 27, 2019) (same; granting motion to dismiss on claim for vicarious copyright infringement where plaintiff did not sufficiently alleged that one business had control over another accused of infringing pattern designs); Luvdarts, LLC v. AT&T Mobility, LLC, 710 F.3d 1068, 1071–72 (9th Cir. 2013) (affirming motion to dismiss where plaintiff alleged that mobility messaging network was vicariously liable for messages sent on its networks that allegedly infringed copyrights; explaining that vicarious copyright liability requires both the right and ability to supervise the infringing activity and a direct financial stake in that activity); Louis Vuitton Malletier, S.A. v. Akanoc Sol. Inc. 591 F. Supp. 2d 1098, 1113 (N.D. Cal. 2008) (noting that vicarious trademark infringement requires that the defendant and the infringer have a partnership or apparent partnership with the ability to bind one another or exercise joint ownership over the infringing product; granting summary judgment where website provider had no such relationship with infringer); *cf.* Cambridge Univ. Press v. Becker, No. 1:0B-CV-1425-ODE, 2010 U.S. Dist. LEXIS 149486, at *43–44 (N.D. Ga. Sept. 30, 2010) (in a copyright case turning on whether employees acted within the scope of employment for purposes of vicarious liability, finding that university instructors who used copyrighted materials outside the boundaries of fair use were acting within the scope of employment unless they engaged in "egregious" violations of university's copyright policy).

One situation with potentially broad application is the fact pattern where a departing employee downloads files from the prior employer before leaving the company. That action—which takes place when the individual is still employed by the former employer, and before they commence work for the new employer—raises the question whether vicarious liability could apply to such acts by employees in transit between jobs, especially if nothing further happens to the downloaded files. If, for example, a departing employee shares company files containing trade secrets to a personal cloud storage account when leaving the company, but then never transfers the files to the new employer's storage networks, such actions would have taken place entirely outside, and antecedent to, the course and scope of work for a new employer.

An unpublished Washington case from 2014 suggests one approach. In *Kassa Insurance Services, Inc. v. Pugh*, an employee took a customer list containing trade secrets when leaving his prior job.[169] The court noted that "[u]nder the doctrine of respondeat superior, an employer or principal is vicariously responsible for the torts of an employee or agent who is acting on the employer's or principal's behalf." But it also noted that, in contrast, if the employee is pursuing a personal objective, the employer is not liable unless, under a theory of ratification, "the employer accepts the benefits of the acts with full knowledge of the facts."[170] The court affirmed a trial court finding that the employer was not vicariously liable, explaining that the employer had "no control over" the actions of the individual defendant "when he compiled the client list and e-mailed it to himself" before his new employment started, and because the plaintiff failed to establish that the employer knew the client list originated from the plaintiff.[171]

Similarly, a 2023 ruling on a motion to dismiss in the Northern District of California also points the way to robust attention to the limits of vicarious liability. In *Alert Enterprise, Inc. v. Rana*, the individual defendant allegedly downloaded 2600 files, moved additional files to a personal drive, and took steps to "destroy evidence of his actions."[172] The plaintiff sued the new employer as well, but did not include fact allegations that it received or used the asserted trade secrets the individual had taken.[173] Most important for present purposes, the court found that the plaintiff failed to plead a vicarious liability theory because it did not plausibly allege that the individual was acting

169. Nos. 31196-1-III, 31300-0-III, 2014 Wash. App. LEXIS 1036, at *39–40 (Apr. 29, 2014).

170. *Id.*

171. *Id.* at *40–42.

172. Alert Ent., Inc. v. Rana, No. 22-cv-06646-JSC, 2023 U.S. Dist. LEXIS 44590, at *2–3 (N.D. Cal. Mar. 16, 2023).

173. *Id.* at *6, *13.

as the employer's agent "when he took the trade secrets," or that the new employer ever ratified that act.[174]

It is surprising that rulings like that seen in *Kassa* and *Alert Enterprise* are not more common. If the new employer has never received downloaded files (and thus never acquired or learned any trade secrets within them), if they were downloaded before the employment relationship began, and if the new employer never ratified the downloading, then a trade secret plaintiff seemingly would have to clear significant hurdles to establish a misappropriation by the new employer. On one hand, an employer with some inkling that a new hire was using illicit information would be at least on constructive notice, likely leading to a finding of vicarious liability. On the other, a mere download by an employee leaving the plaintiff's employment seems hardly a basis for liability against the new employer.

Not all employee downloads are the same. That is, not every case where a former employee possesses files from the prior employer is one where the employee downloaded the material with intent to use it in the future. Given the multiplicity of accounts and devices employees use, it is unsurprising that employees often inadvertently retain emails, photos, files, and other documents in personal accounts or devices that were collected in the ordinary course of work, and then forgotten.[175]

In such cases, questions of vicarious liability may not arise at all because the individuals' passive, inadvertent possession is not grounds for trade secret liability against the employee—much less the new employer. For example, in a 2020 case involving Apple, the company hired an employee who "retained [the former employer's] technical information, accessed it while in Apple's employ, and gave misleading statements about how much of it they retained."[176] The court granted summary judgment to Apple on the trade secret claim, reasoning that "showing that employees had the information is not

174. *Id.* at *10–13. Another 2023 ruling addressed a trade secret claim against a distributor which was accused of working with a company founded by the plaintiff's former employees. The court dismissed the claim because the plaintiff alleged no facts that the distributor acquired the alleged trade secrets. More important, it added that the plaintiff "has cited no authority which would support that a distributor which sells a competitor's product, even taking as true that the competitor here engaged in misappropriation of trade secrets, can also be liable for misappropriating trade secrets."; *see* Sysco Machinery Corp v. DCS USA Corp., No. 5:23-CV-134-BO-RJ, 2023 U.S. Dist. LEXIS 204845, at *6–7 (E.D.N.C. Nov. 15, 2023) (citing cases referring to conspiracy claims and stating "the weight of the authority supports that there can be no conspiracy or secondary liability for DTSA claims").

175. My personal experience over the years with engineers, scientists, and salespersons suggests that such inadvertence is common.

176. *See* Hooked Media Grp., Inc. v. Apple Inc., 55 Cal. App. 5th 323, 332 (2020) (affirming summary judgment in favor of defendant).

sufficient to establish that Apple improperly acquired or used it," and that "by itself, a lack of candor regarding the amount of confidential information the employee kept [does not establish] use or acquisition by Apple."[177] The court emphasized that "mere possession of information is not enough to establish improper acquisition of a trade secret."[178] The decision was consistent with earlier California cases which had deigned to find individuals liable for such mere possession of a former employer's trade secrets.[179]

In sum, while the courts appear to have substantially adopted theories of secondary liability in situations where a company defendant's management is unaware of misappropriation by an employee, they have not scratched the surface of the limitations to vicarious liability in trade secret practice. Applying the limits to vicarious liability is one way to avoid or reduce the costly discovery and wild accusations against new employers that often result from individual acts of downloading that never make their way to the company. Courts and practitioners should pay closer attention to such limitations given commonplace accusations of downloading against departing employees.

V. CORPORATE DEFENDANTS AND WAYWARD EMPLOYEES: THE QUESTION OF INTENT FOR ENHANCED DAMAGES

Our third exploration of intentionality in trade secret law focuses on the question of secondary enhanced damages. The DTSA and the UTSA both provide that a defendant can be liable for up to treble damages—and in some jurisdictions, fees and costs as well—for engaging in "willful and malicious misappropriation." This too is a question of intent, or the defendant's state of mind. And, as with vicarious liability, interpretive questions arise when a trade secret plaintiff seeks exemplary damages against a corporate defendant for the acts of non-executive employee-defendants.

177. *See id.*

178. *See id.* at 333.

179. *See* FLIR Sys., Inc. v. Parrish, 174 Cal. App. 4th 1270, 1279 (2009) (cited by *Hooked Media*; stating rule regarding passive retention in case where former executive possessed a hard drive where he had attempted to download files from a company system in the course of working there, but download did not work and he had drilled holes in the drive to disable it); Gibson-Homans Co. v. Wall-Tite, Inc., 26 U.S.P.Q.2d 1867, 1871 (C.D. Cal. 1992) (finding that employee's mere possession of notebook containing former employer's trade secrets not a "threat" of misappropriation under California law); Golden State Linen Serv., Inc. v. Vidalin, 69 Cal. App. 3d. 1, 8 (1977) (noting that injunctions against a former employee who competes with his former employer can reach only the "use" of trade secret information, and "not to his mere possession or knowledge of it").

For example, a court might ask what the employer knew, and with what level of wrongful intent, versus whether the individual employee acted with malice. The company's knowledge and intent might differ from that of the employee. Such different intent could lead to a different outcome, especially where the employee acts without coordinated, top-down instruction. In addition, courts might consider training and policies the company had in place, relative to the size and maturity of the division or department at issue. Specifically, if a company has provided reasonable guidelines or training, in context, to avoid the misuse of trade secrets from former employers and business partners, and if an ordinary employee maliciously engages in misappropriation notwithstanding such reminders, this could be an additional factor discounting the possibility that such malice could be attributed to the corporate defendant.

A. "WILLFUL AND MALICIOUS MISAPPROPRIATION" UNDER THE TRADE SECRET STATUTES

Under the DTSA and most UTSA enactments, a plaintiff can win up to trebled damages if it establishes that the defendant acted with a higher level of wrongdoing: "willful and malicious misappropriation."[180] For example, California's UTSA states that "If willful and malicious misappropriation exists, the court may award exemplary damages in an amount not exceeding twice any award made under [the UTSA damages provisions.]"[181]

These formulations show that some heighted level of improper intent is required to obtain enhanced damages beyond simply engaging "misappropriation" by "improper means."[182] Some courts require that this additional showing satisfy a higher burden of proof, namely clear and convincing evidence.[183]

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180. *See* 18 U.S.C. § 1836(b)(3)(C); UNIFORM TRADE SECRETS ACT WITH 1985 AMENDMENTS at 10, https://www.uniformlaws.org/viewdocument/final-act-128.

181. *See* CAL. CIV. CODE § 3426.3. California's version of the UTSA also permits recovery of costs, not just fees. Not every UTSA version is identical. Vermont, for example, provides that "[i]f malicious misappropriation exists, the court may award punitive damages," which is seemingly not capped at treble damages. *See* Vt. St. Ch. 143 § 4603(b).

182. *See* PetroChoice Holdings, Inc. v. Orobono, No. 2:19-cv-06152-JMG, 2022 U.S. Dist. LEXIS 7380, at *13 (E.D. Pa. Jan. 14, 2022) (noting that simply because a party improperly engaged in misappropriation, that does not necessarily mean that it acted willful and maliciously).

183. *See, e.g.*, Advanced Fluid Sys., Inc. v. Huber, 295 F. Supp. 3d 467, 493 n.9 (M.D. Pa. 2018) (noting split in case law on this point and finding that it would not matter in that case because the evidence supported a finding of willful and malicious misappropriation "under either standard."); *see also* Mattel, Inc. v. MGA Ent't, Inc., 801 F. Supp. 2d 950, 952 (C.D. Cal. 2011) ("Though the existence of willful and malicious misappropriation is ordinarily

B. DEFINING "WILLFUL AND MALICIOUS MISAPPROPRIATION"

The meaning of "willful and malicious" acts can vary. Pennsylvania defines the term in its version of the UTSA: it means "intentional acts or gross neglect of duty as to evince a reckless indifference of the rights of others on the part of the wrongdoer, and an entire want of care so as to raise the presumption that the person at fault is conscious of the consequences of his carelessness."[184] That is an exception, however, as the DTSA and most states do not define the term within the statute or in legislative history.[185] Indeed, as the Fourth Circuit noted in 2021, it could find "not cases that define that term in the context of" the DTSA, while UTSA cases "offer competing definitions, each based on how 'malice' is defined in other contexts under the relevant state's laws."[186] The court affirmed a trial court jury instruction that the term, under the DTSA and Texas trade secret law, meant an intent to cause injury or harm. Based on the lack of consensus among courts construing the UTSA, it rejected the trade secret claimant's argument that the instruction should have required a lesser showing of a conscious disregard for the rights of another.[187]

Unlike Pennsylvania, UTSA jurisdictions generally do not define "willful and malicious misappropriation." As a result, and as the Fourth Circuit noted, a slew of recent cases around the country have imported state common law as a gap-filler to define the term. For example, in *Caudill Seed & Warehouse Co., Inc. v. Jarrow Formulas, Inc.*, the Sixth Circuit affirmed a jury finding of exemplary damages under the Kentucky UTSA.[188] In that case, the defendant's CEO knowingly asked a newly-hired research scientist from the plaintiff to send a zip file of confidential information, where the scientist told co-workers he had

considered a fact that a jury must find by clear and convincing evidence, the court calculates the amount of exemplary damages."); Yeti by Molly Ltd. v. Deckers Outdoor Corp., 259 F.3d 1101, 1111 (9th Cir. 2001) (finding error in jury damages version over standard; "Nothing in the MUTSA suggests that exemplary damages and attorneys' fees need to be proved by clear and convincing evidence."); Vacco Indus., Inc. v. Van Den Berg, 5 Cal. App. 4th 34, 54 (1992) (affirming fees award given "jury's determination, upon clear and convincing evidence, that defendants' acts of misappropriation were done with malice").

184. AgroFresh Inc. v. Essentive LLC, No. 16-662 (MN), 2020 U.S. Dist. LEXIS 222898, at *23 (D. Del. Nov. 30, 2020) (quoting 12 Pa. Con. Stat. Ann. § 5302).

185. *See* API Americas Inc. v. Miller, 380 F. Supp. 3d 1141, 1151 (D. Kan. 2019) (noting that the state legislature and the courts had not yet defined the term under the Kansas UTSA); Kassa Ins. Servs., Inc. v. Pugh, 2014 Wash. App. LEXIS 1036, at *14–15 ("Because neither 'willful' nor 'malicious' is defined by statute, we resort to dictionary definitions for clarification.").

186. *See* Steves and Sons, Inc. v. Jeld-Wen, Inc., 988 F.3d 690, 726 (4th Cir. 2021) (affirming trial court's challenged trade secret jury instructions).

187. *See id.* (also noting the appealing party's "perfunctory and undeveloped argument" on the point).

188. 53 F.4th 368 (6th Cir. 2022).

something that took six months of research—when he was only one month into his job—and where there was evidence that both planned to use deceit.[189] The court noted that "willful and malicious misappropriation" under the UTSA cannot mean simply intentional misappropriation, as the basic claim already requires intentional conduct. It thus affirmed a jury instruction referring to "behavior motivated by spite or ill will and a disregard for the rights of another with knowledge of probable injury."[190]

In a 2021 Ohio case granting a motion to dismiss claims for exemplary damages under the DTSA and Ohio UTSA, the court found that the plaintiff had failed to plead allegations to support a claim for "willful and malicious" misappropriation.[191] The plaintiff alleged that the defendant had engaged in misappropriation, but its conclusory recitation of the words "willful" and "malicious" was insufficient to plead sufficient facts to support that theory of recovery. The court held that under Ohio law, a sufficient pleading would require alleging a "state of mind under which a person intentionally does a wrongful act without a reasonable[,] lawful excuse and with the intent to inflict injury or under circumstances from which the law will infer an evil intent."[192] In the alternative, the court also noted that one might plead "conscious disregard for the rights of others," which is a "high bar" requiring " a mental state so callous in its disregard for the rights and safety of others that society deems it intolerable."[193]

Other cases have offered similar formulations. Under the Virginia UTSA, for example, willful and malicious 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 circumstances and conditions, that his conduct probably would cause injury to another."[194] A Washington court affirmed a finding of willful and malicious misappropriation where the defendant took a customer list. It used a legal dictionary to define willful as "voluntary" or "intentional," and malicious as

189. *Id.* at 376–77, 395.

190. *Id.* at 394–95.

191. Trent P. Fishers Ent., LLC v. SAS Automation, LLC, No. 3:20-cv-216, 2021 U.S. Dist. LEXIS 62914, at *17–19 (S.D. Ohio Mar. 31, 2021).

192. *Id.* at 16 (citing an Ohio case and BLACK'S LAW DICTIONARY).

193. *Id.* at 17. It should be noted that the case refers to "punitive" damages, which is not the same thing as "exemplary" damages, and thus its recitation of the legal standard may not be entirely correct.

194. *See* Smart Team Global, LLC v. Humbletech, LLC, No. 19-CV-4873 (AJN) (BCM), 2022 U.S. Dist. LEXIS 30281, at *28–29 (S.D.N.Y. Feb. 18, 2022) (applying the DTSA and the Virginia UTSA; ruling on a motion for default and noting that, because the DTSA does not define "willful and malicious," courts look to the relevant state UTSA for guidance).

"substantially certain to cause injury" and "without just cause or excuse."[195] It affirmed the trial court's finding of willful and malicious misappropriation in a case where a defendant took a secret customer list because the taking was voluntary, it was substantially certain that his acts would injure the plaintiff, and he had no just cause or excuse.[196]

Relying on common law definitions, an Ohio court defined the terms as "willful, i.e., done with actual or constructive knowledge of its probable consequences" and "malicious, i.e., done with an intent to cause injury."[197] The Ninth Circuit affirmed a case finding that under California law, "'malice' means conduct which is intended by the defendant to cause injury to the plaintiff or despicable conduct which is carried on by the defendant with a willful and conscious disregard of the rights and safety of others."[198] And a Florida case construing the DTSA and the state UTSA-found that "[i]n the civil context, statutes that require 'willful' behavior are generally interpreted to permit a finding of liability when the complained of behavior is 'knowing or reckless.'"[199]

Federal district courts have also considered "the duration of misappropriative conduct, the defendant's consciousness of resulting injury and any efforts to cover up malfeasance,"[200] "the need to deter similar misconduct in the future,"[201] "the amount of compensatory damages awarded," and "the wealth of the particular defendant[.]"[202] Cases frequently

195. Kassa Ins. Serv., Inc. v. Pugh, 2014 Wash. App. LEXIS 1036, at *14–15.

196. *Id.*

197. Trent P. Fisher Enterprises, LLC v. SAS Automation, LLC, No. 3:20-CV-216, 2021 U.S. Dist. LEXIS 62914, at *16–17 (S.D. Ohio Mar. 31, 2021) (citing 4 MILGRIM ON TRADE SECRETS § 15.02 (2020)).

198. Citcon USA, LLC v. RiverPay, Inc., No. 18-cv-2585-NC, 2020 U.S. Dist. LEXIS 163600, at *14 (N.D. Cal. Sept. 8, 2020) (citing California jury instruction CACI 4411), aff'd in relevant part, No. 20-16929, 2022 U.S. App. LEXIS 2717, at *5 (9th Cir. Jan. 31, 2022).

199. Behav. Analyst Certification Bd., Inc. v. Rodriguez, No. 1:21-cv-22834-SCOLA/GOODMAN , 2022 U.S. Dist. LEXIS 135221, at *30 (S.D. Fla. July 29, 2022), report and recommendation adopted as modified, No. 21-22834-Civ-Scola, 2022 U.S. Dist. LEXIS 174109, at *30–39 (S.D. Fla. Sept. 26, 2022).

200. *See* AgroFresh Inc. v. Essentiv LLC, 2020 U.S. Dist. LEXIS 222898, at *73 (quoting Advanced Fluid Sys., Inc. v. Huber, 295 F. Supp. 3d 467, 493 (M.D. Pa. 2018), aff'd 958 F.3d 168 (3rd Cir. 2020)).

201. *See* DiscoverOrg Data, LLC v. Bitnine Global, Inc., No. 19-CV-08098-LHK, 2020 U.S. Dist. LEXIS 210494, at *27–8 (N.D. Cal. Nov. 9, 2020).

202. *See Citcon USA*, 2020 U.S. Dist. LEXIS at *5; Proofpoint, Inc. v. Vade Secure, Inc., No. 19-cv-04238-MMC, 2021 U.S. Dist. LEXIS 223204, at *11 (N.D. Cal. Nov. 18, 2021) (similar factors as to amount of damages and wealth of defendant).

offer slightly different standards and wording. We thus lack a nationwide consensus.[203]

At the same time, courts find that merely acting for competitive business motives is insufficient for exemplary damages.[204] For example, in a Pennsylvania case, the plaintiff satisfied the "willful and malicious" standard as to one key defendant who "siphoned [plaintiff's] trade secrets to [corporate defendant] for almost an entire year," and "worked tirelessly to divert" contracts from his current employer to a competitor.[205] That defendant also altered "title blocks" on documents, showing his consciousness of wrongdoing, wrongfully downloaded files, and engaged in "wholesale destruction of evidence" after receiving a subpoena.[206] As the court put it, "[w]e struggle to conceive a pattern of conduct more emblematic of willfulness and malice."[207] However, the court declined to find enhanced damages against other defendants, because their acts were wrongful, but "their motives were purely competitive."[208]

Echoing that theme, some courts underscore that simply engaging in trade secret misappropriation is insufficient for enhanced damages. Under Texas law, for example, "the intent to commit the tort" of trade secret

203. Other such cases include Brightview Grp., LP v. Teeters, No. SAG-19-2774, 2021 U.S. Dist. LEXIS 64487, *69–70 (D. Md. Mar. 29, 2021) (where plaintiff sought recovery of attorneys' fees under the Maryland UTSA and the DTSA, the court denied a defense motion for summary judgment; the court followed the Maryland standard that "willful and malicious" means "'an act does for an improper motive and without legal justification' and 'to deliberately cause harm or injury'") (citation omitted); Ajaxo Inc. v. E*Trade Group, Inc., 135 Cal. App. 4th 21, 45 (2005) (affirming finding of "willful and malicious misappropriation" where trial court instructed jury that "willful" means "a purpose or willingness to commit the at or engage in the conduct in question, and the conduct was not reasonable under the circumstances then present and was not undertaken in good faith," and that "malice" means "conduct which is intended by the defendant to cause injury to the plaintiff or despicable conduct which is carried on by the defendant with a willful and conscious disregard for the rights of others when the defendant is aware [of] the probable consequences of its conduct and willfully and deliberately fails to avoid those consequences. Despicable conduct is conduct which is so vile and wretched that it would be looked down upon and despised by ordinary decent people.").

204. *See* Arnold's Office Furniture, LLC v. Borden, No. 5:20-cv-05470-JMG, 2022 U.S. Dist. LEXIS 150824, at *4–7 (E.D. Pa. Aug. 23, 2022) (reciting standard and declining to award additional damages where defendant was motivated by greed but factors were not clearly met); *Proofpoint*, 2021 U.S. Dist. LEXIS 223024, at *10–11 (same; there was no finding of actual loss and the jury's unjust enrichment award was unclear).

205. *Huber*, 295 F. Supp. 3d at 493.

206. *Id.*

207. *Id.* at 494.

208. *Id.*

misappropriation "alone cannot justify an award of exemplary damages."[209] Rather, the defendant's conduct "must have been outrageous, malicious, or otherwise reprehensible."[210] Thus, even a defendant's act of concealing who was acquiring certain mineral leases in the course of misappropriation did not suffice for exemplary damages, because this was insufficient to show malice, and there was no evidence that the defendants caused the plaintiff "an injury independent of and qualitatively different than the misappropriation itself."[211]

Similarly, in a 2020 District of Delaware case, a jury found willful and malicious misappropriation despite a fair amount of evidence showing that the defendant depended on the representations of a third party who brought the technology to the company. In *AgroFresh Inc. v. Essentiv LLC*, an individual who was well-known as an inventor in the relevant field offered technology to the defendant in an agreement where he made customary representations that he was the "sole owner" of the technology and had the right to disclose it.[212] The defendant sought assurances that the inventor could convey the technology "free and clear" of encumbrances."[213] At the same time, the defendant was aware that the inventor had previously worked with another company in the same field but did not make efforts to learn its intellectual property assignment terms. Perhaps most significantly, the defendant also concealed its relationship with the inventor.[214] Admitting these mixed facts, the court affirmed the jury's verdict. However, it declined to award enhanced UTSA damages, because these facts did not show any effort to engage in continuing misconduct, as the defendant had changed course when it learned the facts.[215]

C. SEPARATING EMPLOYEE MALICE FROM MANAGEMENT INTENT

There is a remarkable absence of analysis in the case law to distinguish the malicious intent of a corporate defendant from the intent of the wayward

209. *See* Eagle Oil & Gas Co. v. Shale Expl., LLC, 549 S.W.3d 256, 283 (Tex. Ct. App. 2018).

210. *See id.* (noting that exemplary damages are available only in the most exceptional instances).

211. The court applied a clear and convincing evidence standard in its finding. *See id.* at 285 ("[Defendant's] intentional misappropriation of [plaintiff's] trade secrets is not legally sufficient evidence of malice. If it were, exemplary damages would be recoverable as a matter of course in every misappropriation case, rather than the exceptional case involving egregious misconduct and injury."; "Because the record lacks clear and convincing evidence of an intent on [defendant's] part to inflict substantial injury, independent and qualitatively different than the compensable harms associated with misappropriation of [plaintiff's] trade secrets, we hold that the evidence is legally insufficient to support the jury's finding of malice.").

212. *AgroFresh*, 2020 U.S. Dist. LEXIS 222898, at *23–24.

213. *See id.*

214. *See id.* at *25.

215. *See id.* at *72–83.

employee who engaged in misappropriation. Where malice (however defined) must be shown, the differences in a corporate defendant's intent and the intent of an employee may be significant. As in our discussion of vicarious liability, this difference would be apparent in cases where a new hire downloads files from the prior employer and the new employer is unaware of that conduct. It would be difficult to attribute malice to the new employer where it is difficult to attribute vicarious liability in the first place.

But even in a case where vicarious liability for employee conduct is tenable, imposing exemplary damages for malicious intent is distinct from liability for ordinary remedies. It requires a judgment that the employer-defendant itself harbored an enhanced level of wrongful intent. Thus, courts should distinguish uncoordinated or ad-hoc behavior by employees from top-down directives from company management in assessing these questions. As with paying closer attention to questions of vicarious liability, these distinctions may reduce the exaggerated damages claims that so often plague trade secret lawsuits.

In some instances, courts applying caution might still separate corporate defendants which provide some degree of training or policies to employees on trade secret issues from employee-defendants who ignore such guidance. There is a material difference between a company defendant that trains employees not to use potential trade secrets from former employers and an employee-defendant who chooses to violate such training through ad-hoc decisions. There are caveats. The majority of companies likely do not provide such training, and the mere absence of training should not be construed as evidence in favor of a finding of malice, especially without empirical metrics comparing training at similarly-situated companies.[216] Moreover, the size and maturity of a business (or the department or division at issue) will surely play into the analysis, as less mature companies are even less likely to provide such training or policies. And many of those who do provide training on information-handling may focus more on protecting the company's own information than the information of others. All that said, the intentionality of an employee who violates express training is not the same as the intentionality of the company which provides such training, to whatever degree.

216. I have been unable to find statistics on companies providing trade secret training. In this author's experience, a sizable majority of small and mid-sized technology companies do not. Large company training tends to focus on protection of the company's own information and not practical instruction to avoid trade secret problems with other employers. For these reasons, it would not be wise for courts to assess "willful and malicious misappropriation" based on the presence or absence of such training, in a corporate environment where such training is not customary. The question is rather the need to separate the intentionality of companies that opt to provide such training from employee-defendants who violate it.

With the rise in trade secret litigation in recent years, at least some companies provide workforce training sessions on how to avoid trade secret risks. This author has given many such training sessions over the past two decades, often spurred by letters sent by former employers to newly-hired company employees; though few companies seem to have such training or policies in place. And in 2021, as part of its ongoing series of commentaries on trade secret law, the Sedona Conference promulgated guidelines on such training.[217] Those guidelines recommend training new hires, noting that employees "need to understand that they have an obligation to protect the third party's trade secret information from misappropriation."[218] They explain that "training on preventing use of former-employer information when an employee is wondering whether he or she is able to use an item of information can include practical guidance on searching the public domain," as well as telling others "that they might be inappropriately sharing information that might appear to be the trade secrets of others."[219]

To be sure, a startup or mid-sized company rarely would have the administrative staff or the resources for employee training, especially on a relatively esoteric issue like trade secret risk. Different departments or divisions within a company might treat the issue differently, based on their sophistication and history. Using such training to assess whether a company's level of intent differs from that of a wayward employee who behaved with malice might thus differ on a sliding scale based on the size and longevity of the company, and its maturity in the circumstances. But even with such variability, it is somewhat surprising that the case law on exemplary damages has not inquired into the distinction between corporate intent and the actions of wayward employee-defendants who disobey training and instructions. In such cases, can a corporate defendant who had provided any degree of policies or training be found to have engaged in "willful and malicious misappropriation," no matter how egregious the behavior of a lower-level employee-defendant who the direct target of the accusations is?

In such cases, courts should make a principled distinction between the willfulness and malice of one, but not the other. By the same token, if a company were to implement a workforce IP training program, and if it were later sued for trade secret misappropriation for the acts of a non-executive

217. *See* The Sedona Conference, *Commentary on Protecting Trade Secrets Throughout the Employment Life Cycle*, 23 SEDONA CONF. J. 807 (2022), https://thesedonaconference.org/node/10020. I provided comments on an early draft but was not otherwise involved in this publication.

218. *See id.* at 872–73.

219. *See id.* at 874.

level employee, the company might use the program as evidence in support of an argument against exemplary damages, making a distinction between itself and a wayward employee-defendant who, for example, maliciously downloaded information from his or her prior employer and used it at the new job.

VI. CONCLUSION

Trade secret law puts more emphasis on questions of the defendant's intent than other areas of intellectual property law. This Article offers three normative proposals to illuminate the importance of intentionality in the context of secondary liability.

First, courts should rescue the "accident or mistake" safe harbor in the trade secret statutes from inattention and use it when one defendant buys or licenses information from a third party in an ordinary commercial transaction that turns out to contain another's trade secret, and innocently uses the information. Second, courts should pay more attention to exceptions to vicarious liability, especially when a former employer sues a rival based on a departing employee's download of files before leaving the plaintiff's employ. Third, when assessing questions of enhanced damages for willful and malicious misappropriation, courts should pay more attention to the distinction between the intent of a company-defendant and the actions of a wayward employee.

THE RIGHT OF PUBLICITY CAN SAVE ACTORS FROM DEEPFAKE ARMAGEDDON

Alice Preminger[†] *& Matthew B. Kugler*[††]

ABSTRACT

The entertainment industry is being rocked by the potential of deepfakes. A deepfake of a performer can appear to be the performer in a way that no CGI or makeup-enhanced stunt double possibly could, potentially serving as direct competition for them or deceiving audiences. It is now possible to have dead actors star in new productions, to revise casting choices months after filming, and to simulate extras electronically. The law has not caught up with this technological revolution. This Article traces the ways in which right of publicity law struggles to control this new form of identity exploitation. Specifically, it examines how traditional protections for expressive uses—key for allowing the depiction of real-world figures in biopics and historical dramas—are too broad when applied to digital replicas like deepfakes. This Article proposes changes to how right of publicity law treats expressive uses and also considers the problems raised by current right of publicity licenses and the overbroad terms they regularly contain. In the past, the problems created by these broad licensing terms were limited by technology—one could only do so much with the film available. But now new canons of interpretation are needed to prevent the contracts being used to justify uses beyond what the contracting parties could have imagined.

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I. INTRODUCTION

Imagine you have just finished shooting a 10-episode season of a TV show for a leading streaming service. The media is abuzz with anticipation. Two weeks before the show's scheduled release, you find out that your lead actor has engaged in odious behavior. Every major news outlet is reporting on it, and influencers are calling for a boycott. The streaming service is threatening to drop the project, which would result in a staggering financial loss. To salvage the show, your only option is to recast the disgraced lead, spending millions to reshoot scenes.[1] Or at least that had been the case. But now there is a new solution in the form of deepfakes, also referred to as synthetic media. Deepfakes are a form of video editing technology that allows you to replace one person's appearance and voice with another's. Use of deepfakes would allow you to digitally recreate the entire season without reshooting a single scene. But what kind of permission do you need to do that? And what kind

1. For an example of this, see Kevin Spacey's removal from *All the Money in the World*. *See* Mark Brown, *Kevin Spacey Cut Out of Film and Replaced by Christopher Plummer*, GUARDIAN (Nov. 9, 2017), https://www.theguardian.com/culture/2017/nov/09/kevin-spacey-cut-out-of-film-and-replaced-by-christopher-plummer.

should you need? Should deepfakes be viewed differently than standard video editing?[2]

The Screen Actors Guild certainly thinks so. In July 2023, its members abandoned their sets, joining their compatriots in the Writers Guild of America in what threatened to be one of the most significant media-industry strikes in recent history.[3] The reason? A scenario much like the one just described, in which actors once tapped for starring leads could be relegated to mere extras, having lost their roles to their own digital doubles.[4] The demand? More rigorous protections against the threats posed by artificial intelligence.[5]

Deepfake regulation is an incredibly broad and diverse topic, with implications ranging into issues of harassment, intimidation, and sexual privacy.[6] Deepfakes can be used in overtly nefarious ways, including portraying celebrities engaging in taboo sexual acts, fabricating declarations of war or surrender by political leaders, or even feigning scientific breakthroughs or personal accomplishments.[7] Previous work has considered how deepfakes have been used both as tools for personal degradation as well as threats to democracy.[8]

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2. *See, e.g.*, Zack Sharf, *Keanu Reeves Says Deepfakes Are 'Scary,' Confirms His Film Contracts Ban Digital Edits to His Acting: 'They Added a Tear to My Face! Huh?'*, VARIETY (Feb. 15, 2013), https://variety.com/2023/film/news/keanu-reeves-slams-deepfakes-film-contract-prevents-digital-edits-1235523698/.

3. Lisa Richwine, *Hollywood Studios Race to Avoid Actors' Strike at Midnight*, REUTERS (July 12, 2023), https://www.reuters.com/world/us/hollywood-studios-racing-avoid-actors-strike-midnight-2023-07-12/; Lois Beckett & Kari Paul, *"Bargaining For Our Very Existence": Why The Battle Over AI Is Being Fought In Hollywood*, GUARDIAN (July 22, 2023), https://www.theguardian.com/technology/2023/jul/22/sag-aftra-wga-strike-artificial-intelligence.

4. *See* Beckett & Paul, *supra* note 3.

5. *See* Chris Isidore, *Actors Are Poised to Go On Strike Against Studios and Streaming Services*, CNN (July 12, 2023), https://www.cnn.com/2023/07/12/business/sag-aftra-actors-strike-deadline.

6. *See generally* Matthew B. Kugler & Carly Pace, *Deepfake Privacy: Attitudes and Regulation*, 116 NW. U. L. REV. 611 (2021).

7. *See id.*; Bobby Allyn, *Deepfake Video of Zelenskyy Could Be 'Tip of the Iceberg' in Info War, Experts Warn*, NPR (Mar. 16, 2022), https://www.npr.org/2022/03/16/1087062648/deepfake-video-zelenskyy-experts-war-manipulation-ukraine-russia; Yashraj Sharma, *Deepfake Democracy: Behind the AI Trickery Shaping India's 2024 Election*, ALI JAZEERA (Feb. 20, 2024), https://www.aljazeera.com/news/2024/2/20/deepfake-democracy-behind-the-ai-trickery-shaping-indias-2024-elections (describing the ways in which deepfakes are being used deceptively in Indian elections).

8. *See* Kugler & Pace, *supra* note 6; Danielle Citron & Bobby Chesney, *Deep Fakes: A Looming Challenge for Privacy, Democracy, and National Security*, 107 CAL. L. REV. 1753, 1766–1785 (2019).

But recent uses of generative artificial intelligence have prompted renewed interest in the use of deepfakes for traditional entertainment and advertising purposes. These are the deepfakes that keep Hollywood up at night. They feature celebrities engaging not in sexual acts, but instead using products they have never tried or in roles they have never played.[9] Rather than portraying a politician declaring war, they might instead depict a prominent leader giving a commencement speech. They might be commissioned by fandoms to portray alternative endings for television series whose actual finales left something to be desired, or by a major film studio to replace a disgraced lead actor on the fly. These deepfakes do not have the visceral harms of democracy destruction or sexual exploitation, but they have the potential to massively transform a major industry. Despite this, these types of videos have received very little discussion within the legal community. This is a glaring gap in legal scholarship, as deepfake creation and use are poised to become increasingly common in the entertainment industry—something the Screen Actors Guild already correctly perceives.

Indeed, there are few tools as enticing as deepfakes in terms of their potential for content generation, and production companies have already recognized their utility.[10] Deepfakes are stunningly versatile. Just a few of their proposed uses include serving as a replacement for the clunky and unconvincing practice of "dubbing" foreign-language films,[11] reconstructing youthful versions of actors to "play" younger versions of themselves, and resurrecting venerated deceased talents.[12] Further, they allow for easier film editing, eliminate the need for costly re-shoots, and alleviate the pragmatic and logistical challenges of coordinating filming sessions among busy, highly sought-after actors.[13] Actors too may enjoy the increased flexibility that

9. *See* Beckett & Paul, *supra* note 3; Lisa Richwine, *Digital Doubles, Fake Trailers: AI Worries Hollywood Actors Before Labor Talks*, REUTERS (June 1, 2023), https://www.reuters.com/world/us/digital-doubles-fake-trailers-ai-worries-hollywood-actors-before-labor-talks-2023-06-01/.

10. Cooper Hood, *How Deepfake Technology Can Change The Movie Industry*, SCREENRANT (Aug. 2021), https://screenrant.com/movies-deepfake-technology-change-hollywood-how/.

11. Vejay Lalla, Adine Mitrani & Zach Harned, *Artificial Intelligence: Deepfakes in the Entertainment Industry*, WORLD INTELLECTUAL PROPERTY ORGANIZATION (June 2022), https://www.wipo.int/wipo_magazine/en/2022/02/article_0003.html.

12. Hood, *supra* note 10.

13. *Id.*

deepfakes afford them, as they are able to participate in greater numbers of projects[14] and have new outlets for engagement with their fan bases.[15]

Far from being melodramatic, entertainers' speculation that companies may seek to contract with actors, musicians, and other talents for deepfake "rights" rather than for performances is all too real.[16] Such a prospect would likely be highly attractive to production companies, and indeed, some celebrities have already contracted to have their likeness reconstructed in lieu of an in-body performance.[17] Bruce Willis, for one, granted such a license to the media company Deepcake, which created his digital twin in an advertisement for a Russian telecommunications company.[18]

The resulting deepfake was an enormous success, and Willis himself praised the creation, admiring "the precision with which my character turned out."[19] He waxed lyrically about how his "digital twin" afforded him "a great opportunity to go back in time," perhaps referring to his recent aphasia diagnosis, which had caused his capacity for speaking to deteriorate and necessitated his retirement from acting.[20] And Willis is not the only one who has noticed that deepfakes have the power to compensate for deficits in performers' own capacities. Deepfakes have been used to restore performers' vocal abilities, as in the case of actor Val Kilmer, who sought the services of an artificial intelligence (AI) firm after losing his voice in a battle with throat cancer.[21] A team of the firm's audio-engineers created a voice clone for the actor, allowing him to take on speaking roles once again, and resume his career.[22]

Of course, screen performers are becoming all too aware of the dark side of such compelling AI-driven performances. While deepfakes may be used by

14. *See* Zack Sharf, *Deepfake Studio Used 34,000 Bruce Willis Images to Create the Actor's 'Digital Twin,' But It Doesn't Own the Rights to His Image,* VARIETY (Oct. 3, 2022), https://variety.com/2022/film/news/bruce-willis-sells-rights-deepfake-digital-twin-1235388442/ (quoting Bruce Willis, who lauded the "modern technology" of deepfakes for allowing him to participate in projects from afar).

15. Lalla, Mitrani & Harned, *supra* note 11 (commenting that deepfakes can be used by influencers to produce individualized messages for fans).

16. *See, e.g.*, Will Bedingfield, *The Bruce Willis Deepfake Is Everyone's Problem*, WIRED (Oct. 17, 2022), https://www.wired.com/story/bruce-willis-deepfake-rights-law/.

17. Sharf, *supra* note 14.

18. *Id.*

19. *Id.*

20. *See id.*; *A Statement from the Willis Family*, ASS'N FOR FRONTOTEMPORAL DEGENERATION (Feb. 16, 2023), https://www.theaftd.org/mnlstatement23/.

21. Dalvin Brown, *AI Gave Val Kilmer His Voice Back. But Critics Worry The Technology Could Be Misused*, WASH. POST (Aug. 18, 2021), https://www.washingtonpost.com/technology/2021/08/18/val-kilmer-ai-voice-cloning/.

22. *Id.*

actors to enhance their abilities, both in terms of artistic talent and availability for projects, they may also be used by production companies to bypass the inconvenience of dealing with human performers at all. Because an actor's "digital twin" is far more versatile than the living actor themselves, deepfakes may be used to do what living actors can or will not do—be it stunts, sex scenes, or low budget performances. Because deepfakes may be construed as "[one] person's face swapped into someone else's performance," a studio could cast celebrities based solely on their aesthetics and social appeal without regard to their talent, relying on artificial intelligence to account for any artistic deficits.[23]

In effect, this is the next evolution of having an actor in a sensor-suit perform the motions of an artificially generated dragon.[24] A performance exists, the sounds and motions of that performance are analyzed by a computer, and a new set of sounds and motions is overlaid on top. Except now: (1) the original actor does not need to wear a sensor suit since any high-definition footage will do, and (2) the created image or footage can be realistic enough to depict a human rather than limited to something as forgivingly artistic as a fantastical dragon.[25] So one could have a cheap extra perform a role, and then replace their image and voice with those of someone who is more expensive, dead, or otherwise unlikely to physically appear in the production. A production company only needs high resolution images and audio of a depicted individual, and these items are often publicly available for anyone remotely prominent. Companies like Disney have already capitalized on deepfake use to avoid paying for costly talent.[26] Rather than having to hire talented—and expensive—performers for each role, companies may instead employ only a handful of seasoned actors and use deepfake technology for the rest.[27]

23. Karen Hao, *Inside the Strange New World of Being a Deepfake Actor*, MIT TECH. REV. (Oct. 9, 2020), https://www.technologyreview.com/2020/10/09/1009850/ai-deepfake-acting/ (describing how deepfakes allow one performer to effectively puppet another's face and body).

24. *See* Cameron Frew, *Incredible Behind The Scenes Footage Shows Benedict Cumberbatch Acting Role of Smaugh Without CGI*, LADBIBLE, https://www.ladbible.com/entertainment/incredible-footage-shows-benedict-cumberbatch-as-smaug-without-cgi-20220402 (last updated Apr. 5, 2022).

25. A human face that looks slightly off may be instantly detected, whereas nonhuman or nonface images are not so quickly judged. *See, e.g.*, Gillian Rhodes, *Face Recognition*, OXFORD HANDBOOK OF COGNITIVE PSYCH. 46, 50 (Daniel Reisberg ed., 2013).

26. Robert Marks, *Can Deepfakes Substitute for Actors?*, MIND MATTERS (Jan. 26, 2021), https://mindmatters.ai/2021/01/can-deepfakes-substitute-for-actors/.

27. *Id.*

With the increasing ease of deepfake creation, which requires fewer resources and can be more broadly disseminated than earlier forms of appropriation of likeness, there is an increasing need to standardize how deepfakes are addressed within different contexts. In the entertainment production context, the central legal regime comes from right of publicity law, which has long allowed people to control the use of the name or likeness in the commercial arena.

The right of publicity faces two challenges in the deepfake context. First, when is a person's permission required to depict a person in a deepfake? Traditional "commercial" uses of likeness, such as uses in advertising or commercial products generally require a person's permission.[28] Such uses constitute exploitations of an individual's identity for the purposes of commercial gain, as the identity of an individual is used purely to generate interest in, and attract consumers to, an underlying product.[29]

But use of a person's likeness in an "expressive" product raises harder questions in the right of publicity context. Courts recognize sharp limitations on people's ability to control uses of their likeness when an individual's identity is incorporated into a work that is artistic or seeks to convey a particular idea.[30] Unlike commercial uses, which nearly always give rise to a finding of liability, expressive uses may enjoy First Amendment protection.[31] This protection for expressive uses creates a problem in the entertainment context because the vast majority of works at issue—movies, television shows, internet videos—are expressive in nature. Further, some right of publicity statutes, like those of Illinois, explicitly exempt impersonation in a film or tv show from their scope.[32]

Law has historically permitted unlicensed depictions of people by actors and impersonators and scholars have often called for even greater protection for such uses.[33] In our view, however, deepfakes are different than many of the depictions giving rise to that body of case law. There is a difference

28. *See* Toffoloni v. LFP Publishing Group, LLC, 572 F.3d 1201, 1208, 1212 (11th Cir. 2009) (finding that a magazine's publication of nude photographs constituted a commercial use of likeness given the tenuous relationship between the content of the magazine article, and the nature of the photographs).

29. *See* Comedy III, Prods., Inc. v. Gary Saderup, Inc., 21 P.3d 797, 808 (Cal. 2001) (delineating the transformative use test and explaining that a permissible use of another's identity must do more than use the depicted person's likeness to draw attention to the product).

30. *Id.* at 799.

31. *See*, *e.g.*, Jennifer Rothman, THE RIGHT OF PUBLICITY 138–153 (2018).

32. *See* 765 ILL. COMP. STAT. 1075/35 (b)(1). *But see supra* note 310 and accompanying text on the recent amendment.

33. *See* Rothman, *supra* note 31 at 154–59.

between featuring a still image or clumsy avatar of a celebrity in a videogame and using their deepfakes in a movie or social media video. The dignitary and economic consequences of treating the deepfake as a protected use are far greater, yet the law has thus far not had an opportunity to recognize that.

This brings us to the second major issue presented by deepfakes: licensing. In addition to requiring permission for many expressive uses of deepfakes, we also believe that the kind of permission required should be more explicit than is required in other contexts, where an individual grants permission to use their likeness. And unlike those other contexts, such heightened standards should apply in the case of both expressive and commercial deepfakes. Appropriations of identity, or "uses of likeness" within right of publicity parlance, have long been recognized as taking many forms, ranging from literal photographs to more abstract evocations of identity. Actors know this, and they use it to their advantage, licensing their face, voice and other indicia of identity to film studios and advertising firms. But despite the myriad manners in which one's likeness can be appropriated, the law treats them all the same for purposes of liability for infringement upon an individual's right of publicity. Thus far, this practice has not been a problem, as one can only get so far in reconstructing someone's identity using static photographs, video footage, or voice recordings. As the acting community correctly perceives, however, these constraints no longer exist when AI enters the scene. For example, studios have allegedly proposed that they be allowed to scan the faces of "extras" in exchange for one day's wage, and then use them perpetually in different productions.[34]

Here, we argue that the creation of deepfakes ought to constitute a distinct type of "use of likeness" within the right of publicity context. Deepfakes can create greater commercial and reputational injury than traditional types of appropriations of likeness in two ways. First, they may serve as substitutions for the individuals in question in a commercial context. A deepfake can use a person's likeness to sell any kind of good or service or perform in any kind of scene. Why hire an extra repeatedly if you can own their likeness perpetually? Second, given deepfake's realism, they may threaten to undermine an individual's agency by functionally "hijacking" their record of behavior. Taylor Swift may be able to go on record regarding her negative perception of violence and automatic weapons, but a deepfake can still show her hawking AR-15s. A sufficiently powerful deepfake may cause reputational damage that even the most sophisticated public relations team cannot undo. And while a

34. Andrew Webster, *Actors Say Hollywood Studios Want Their AI Replicas — For Free, Forever*, VERGE (July 13, 2023), https://www.theverge.com/2023/7/13/23794224/sag-aftra-actors-strike-ai-image-rights.

successful lawsuit may provide monetary compensation and injunctive remedies, fan bases cannot magically "unsee" disturbing behavior.

These concerns give rise to two major proposals, namely, requiring specific rather than general licenses for commercial deepfakes, and requiring permission for some expressive uses. First, commercial uses of deepfakes should require a specific, rather than general, license. Many right of publicity licenses—even those written by major universities—are written extremely broadly.[35] At the time they were written, however, the contracting parties could not have imagined the current—or future!—types of possible uses. Repurposing someone's likeness in a deepfake is more akin to sublicensing it, which is already subject to a specificity requirement.[36] Rather than treating a deepfake as part of a general use of likeness, deepfake reconstruction ought to be a separately negotiated element of entertainment contracts. This approach will require contracting parties to contemplate the creation of deepfakes ex ante, ensuring parties do not inadvertently grant permission to create a deepfake while granting other permissions under the right of publicity. Imposing this restriction in the deepfake context would protect actors and performers who have previously signed broad releases without careful consideration of this new world.

Second, the expressive use defense—which avoids the need for any license at all—ought to be construed narrowly in the context of deepfakes. Some court decisions in this area have alluded to treating certain kinds of expressive uses as per se protected based on their plot or communicative elements.[37] Were this approach expanded into the world of deepfakes, it would permit nearly all television and movie uses. Instead, the better approach is a revised transformative use test, which appropriately accounts for the twin problems of reputation destruction and economic replacement.

This Article begins in Part II with an examination of the current state of right of publicity law, including the broad way it defines use of likeness. In this

35. *See, e.g.*, *Consent, License And Release Agreement*, PENNSTATE (2023) https://bpb-us-e1.wpmucdn.com/sites.psu.edu/dist/c/155813/files/2023/07/Consent-License-and-Release-Agreement.pdf (granting "irrevocable, world-wide, royalty-free right and license to Penn State and Penn State Representatives to use, exploit, adapt, [and] modify" media of the undersigned, and authorizing to the use of "name, image, likeness and voice in the Media for all Materials or any other purposes deemed appropriate by Penn State"); *see also infra* Part IV.A.1 (reviewing more of these licenses and the problems in them).

36. *See* Shamsky v. Garan, 167 Misc. 2d 149, 160 (N.Y. Sup. Ct. 1995) (finding that the grant of authorization to Major League Baseball team regarding the use of players' photos did not extend to team's sub-licensing of the images to a third-party commercial clothing company).

37. Champion v. Take Two Interactive Software, 64 Misc. 3d 530, 535 (N.Y. Sup. Ct. 2019).

review, we will first show that use of deepfakes easily counts as a use of likeness and then that deepfakes should be considered as a special use of likeness. Part III will then consider whether a given use of a deepfake falls within the scope of the right of publicity or whether it is instead a protected expressive use. Part IV will conclude with a proposal for enhanced protection for those depicted in deepfakes. It addresses both the issue of overbroad right of publicity licenses as well as overbroad protection of expressive works. Some of this proposal can be implemented by courts, changing their interpretations of contract provisions and their construal of the First Amendment's requirements, and some requires actions by state legislatures, reforming overly broad carveouts for certain kinds of artistic works.

II. FOUNDATIONS OF THE RIGHT OF PUBLICITY

The right of publicity is a synthesis of multiple approaches to protecting an individual's identity from exploitation. Initially, appropriation and exploitation of identity were viewed as a species of privacy rights, derived from "the right to be let alone."[38] Courts later embraced Prosser's four-tort framework,[39] conceptualizing the right of publicity as protecting against appropriation of an individual's name or likeness for the defendant's advantage in commercial contexts.[40] This articulation of a privacy-based interest in preventing nonconsensual commercial appropriation served as the foundation of common law publicity actions.[41] This section reviews the core elements of a right of publicity claim and its theoretical underpinnings. It then uses these foundations to serve as a basis for considering how deepfakes are regulated under the right of publicity, arguing that they should be treated as a special use of likeness.

A. PRIVACY VERSUS PROPERTY

The amorphous cause of action surrounding publicity rights was first dubbed the "right of publicity" in the decidedly economic context of a contract

38. J. THOMAS McCarthy, THE RIGHTS OF PUBLICITY AND PRIVACY 1:19 (2d ed. 2023); Kirby v. Sega of Am., Inc., 144 Cal. App. 4th 47, 55 (2nd Cir. 2006).

39. *See, e.g.*, Motschenbacher, v. R.J. Reynolds Tobacco Co., 498 F.2d 821, 824 (9th Cir. 1974); Gionfriddo v. Major League Baseball, 94 Cal. App. 4th 400, 408 (2001).

40. Prosser conceptualized the right to privacy as protecting against a suite of four types of personal invasions: intrusion upon an individual's seclusion, solitude, or private affairs; public disclosure of private facts; publicity placing an individual in a false light within the public eye; and appropriation, for the defendant's advantage, of an individual's name or likeness. *See* William L. Prosser, *Privacy*, 48 CAL. L. REV. 383, 389 (1960).

41. *Id.*

dispute.[42] The court in *Haelan Labs v. Tops Chewing Gum* considered the exploitation of an individual's identity in the context of property law, finding that the right to use photographs could be exclusively granted via contract.[43] The court attributed to such photographs a "pecuniary worth" that ought to be legally enforceable.[44] Such a property interest was construed by the *Motschenbacher* court as a legally cognizable "species of trade name" in which an individual had an exploitable commercial interest.[45]

In contrast to this economic framing, courts sometimes ground the right of publicity in terms of a person's interest in controlling their own identity.[46] Underlying this privacy-based rationale are concerns regarding the "natural rights" to human identity and allowing individuals to exert their own personal agency by retaining control over their representation in the public sphere.[47] This interpretation makes the right of publicity a "right of self-definition," as it prohibits unauthorized uses of an individual's identity that might "interfere with the meaning and values the public associates with that person."[48]

More frequently, however, courts and scholars have conceived of the right of publicity as a vehicle for protecting an individual's opportunities to profit from the commercial value of their identity.[49] This economic approach construes the commercial value derived from one's identity as a type of "property," accompanied by corresponding exclusionary rights.[50] Under this theory, personal identity is a scarce resource, and recognition of identity as a property right is justified by the economic interest in ensuring "the best and most efficient" way of allocating resources.[51] Absent the promise of an "exclusive grant" in a commercially exploitable identity, "many prominent persons…. would feel sorely deprived,"[52] and perhaps less inclined to participate in public life in a manner that would cause them to attain social prominence.[53]

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42. Haelan Labs v. Tops Chewing Gum, 202 F.2d 866, 868 (2d Cir. 1953); Daniel Gervais & Martin Holmes, *Fame, Property & Identity: The Purpose and Scope of the Right of Publicity*, 25 FORDHAM INTELL. PROP. MEDIA & ENT. L.J. 181, 188 (2014).

43. *Id.*

44. *Id.*

45. *See Motschenbacher*, 498 F.2d at 825.

46. *Id.* at 825.

47. McCarthy, *supra* note 38 § 2:2.

48. *Id.* at § 2:9.

49. *Gionfriddo*, 94 Cal. App. 4th at 408; *see, e.g.*, Richard Posner, *The Right of Privacy*, 12 GA. L. REV. 393, 411–414 (1978).

50. McCarthy, *supra* note 38 § 2:7; *see also Haelan Labs*, 202 F.2d at 868.

51. McCarthy, *supra* note 38 § 2:7.

52. *Haelan Labs*, *supra* note 50.

53. *See* McCarthy, *supra* note 38 § 2:6.

Courts sometimes synthesize the two approaches by characterizing the right of publicity as a species of privacy right, that turns on whether there are "commercially exploitable opportunities embodied in [one's] likeness."[54] Under this formulation, economic losses accompanying commercial exploitation of one's identity are required to make a right of publicity claim actionable (the commercially exploitable side),[55] but dignitary concerns may be recognized in awards of damages (the privacy side).[56] So a right of publicity claim can only succeed where there's an injury to property, but damages can account for harms associated with "humiliation, embarrassment, or outrage."[57]

B. ELEMENTS OF RIGHT OF PUBLICITY CLAIMS

Right of publicity is a creature of state law, since each jurisdiction has a slightly different regime.[58] A handful of states, including most notably New York and California, have enacted statutes codifying the right of publicity, while others rely on common law.[59] Despite this rag-tag approach, right of publicity actions tend to share common elements. Central to the cause of action are the nonconsensual use of the plaintiff's identity, commercial exploitation, and resulting injury.[60] But states vary when they set the precise contours of the right. States also differ in their requirements for who can

54. Lugosi v. Universal Pictures, 603 P.2d 425, 431 (Cal. 1979).

55. *Motschenbacher*, 498 F.2d at 824–825.

56. Waits v. Frito-Lay Inc., 978 F.2d 1093, 1103–04 (9th Cir. 1992).

57. *Motschenbacher*, 498 F.2d at 824–825; *Waits*, 978 F.2d at 1104.

58. International Trademark Association, *Right of Publicity State Law Survey* (2019), https://www.inta.org/wp-content/uploads/public-files/advocacy/committee-reports/INTA_2019_rop_survey.pdf.

59. Mark Roesler & Garrett Hutchinson, *What's in a Name, Likeness and Image? The Case for a Federal Right of Publicity Law*, ABA (2020), https://www.americanbar.org/groups/intellectual_property_law/publications/landslide/2020-21/september-october/what-s-in-a-name-likeness-image-case-for-federal-right-of-publicity-law/.

60. Thomas Phillip Boggess, *Cause of Action for an Infringement of the Right of Publicity* § 5, 31 COA 2d 121 (2006).

invoke the right,[61] whether they recognize post-mortem publicity rights,[62] as well as exceptions and affirmative defenses.[63]

California and New York offer useful models for understanding the right of publicity. California recognizes the right of publicity under both common law and state statute: sections 3344 and 3344.1 of the California Civil Code govern right of publicity among living and deceased persons, respectively.[64] To succeed in a common law cause of action in California, a plaintiff must prove: (1) the defendant's use of the plaintiff's identity; (2) the appropriation of plaintiff's name or likeness to defendant's advantage, commercially or otherwise; (3) lack of consent; and (4) resulting injury.[65] Statutory causes of action require the additional elements of "knowing use" of the plaintiff's identity[66] in "direct connection" with a "commercial purpose."[67]

New York, alternatively, allows only statutory right of publicity claims through sections 50 and 51 of New York Civil Rights Law.[68] Section 50 renders it a misdemeanor to use "the name, portrait or picture of any living person without having first obtained the written consent of such a person" for either

61. International Trademark Association, *Right of Publicity State Law Survey* (2019), https://www.inta.org/wp-content/uploads/public-files/advocacy/committee-reports/INTA_2019_rop_survey.pdf (stating Arizona and Louisiana only recognize right of publicity claims for soldiers); *cf.* N.Y. CIV. RIGHTS L. § 50-f (McKinney 2022) (recognizing a post-mortem right of publicity for a "deceased performer" defined as a "deceased natural person domiciled in this state at the time of death who, for gain or livelihood, was regularly engaged in acting, singing, dancing, or playing a musical instrument;" and "deceased personality" who is "any deceased natural person domiciled in this state at the time of death whose name, voice, signature, photograph, or likeness has commercial value at the time of his or her death").

62. Herman Miller, Inc. v. Palazzetti Imps. & Exps., Inc., 270 F.3d 298, 326 (6th Cir. 2001) (reviewing cases and states).

63. New York State recognizes exceptions if the work is a play, book, magazine, newspaper, or other literary work; musical work or composition; work of art or other visual work; work of political, public interest, educational or newsworthy value, including comment, criticism, parody or satire; audio or audiovisual work, radio or television program, if it is fictional or nonfictional entertainment; or an advertisement or commercial announcement for any of the foregoing works. N.Y. CIV. RIGHTS § 50-f(2)(d)(ii). California recognizes as uses that are protected by the First Amendment as affirmative defenses, most notably the "transformative use test." Keller v. Elec. Arts Inc., 724 F.3d 1268, 1273 (9th Cir. 2013).

64. *Right of Publicity: Overview*, WESTLAW PRAC. L. INTELL. PROP. AND TECH.

65. White v. Samsung Electronics America, Inc., 971 F.2d 1395, 1397 (9th Cir. 1992).

66. Defined as an individual's "name, voice, signature, photograph or likeness." CAL. CIV. CODE § 3344(a).

67. CAL. CIV. CODE § 3344; *Abdul-Jabbar v. G.M. Motors*, 85 F.3d 407, 414 (9th Cir. 1996); CAL. CIV. CODE § 3344(a) ("commercial purposes" include: use "on or in products, merchandise, or goods, or for purposes of advertising or selling, or soliciting purchases of, products, merchandise, goods or services").

68. *Right of Publicity: Overview*, *supra* note 64.

"advertising purposes or for the purposes of trade," by "any person, firm or corporation,"[69] while section 51 creates an analogous private right of action.[70]

New York's statutory right of publicity claims under sections 50 and 51 are broad, extending to both celebrities and non-celebrities alike.[71] The statute does include exceptions, however, including those for literary works, television and audio works, parody, and satire.[72] The recently passed section 50-f is more limited. The statutory provision covers only "deceased performers" and "deceased personalities" who were domiciled in the state at the time of their death and "regularly engaged in acting, singing, dancing, or playing a musical instrument" (deceased performers) or "whose name, voice, signature, photograph, or likeness has commercial value at the time of his or her death" (deceased personalities).[73] The statute is replete with exceptions, including those where the use is connected with a "literary work; musical work or composition; work of art or other visual work; work of political, public interest, educational or newsworthy value… audio or audiovisual work, radio or television program."[74] It also includes works of "parody, satire, commentary or criticism,… political or newsworthy value, or similar works,…a representation of a deceased performer as [themselves]… except in live performances, de minimis or incidental [use]," as well as "in connection with any news, public affairs or sports program or account or political campaign."[75]

Despite the differences between New York and California in theory, there are substantial commonalities in effect. Across jurisdictions, the "name or likeness requirement" has been interpreted broadly to include "any type of "indicia of identity" so long as it is distinctive, including voice and personal style.[76] The likeness need not be a literal depiction of an individual so long as the depiction renders the individual recognizable.[77] The definitions of "commercial advantage" and "advertising purposes or for the purpose of trade" have also both been broadly construed, with courts defining these types of appropriation as any use intended to gain an audience's attention.[78] Yet

69. N.Y. CIV. RIGHTS L. § 50 (McKinney 2023).

70. N.Y. CIV. RIGHTS L. § 51 (McKinney 2023).

71. *See* Stephano v. News Grp. Publ'ns, 64 N.Y.2d 174, 182 (1984) ("Section 51 of the Civil Rights Law has been applied in cases, such as the *Roberson* case, where the picture of a person who has apparently never sought publicity has been used without his or her consent for trade or advertising purposes.").

72. N.Y. CIV. RIGHTS L. § 50-f(2)(d)(ii) (McKinney 2023).

73. N.Y. CIV. RIGHTS L. § 50-f (McKinney 2023).

74. N.Y. CIV. CODE §§ 50-f(2)(d)(i)–(iii) (McKinney 2023).

75. *Id.*

76. *Waits*, 978 F.2d at 1102; *White*, 971 F.2d at 1399, *Abdul-Jabbar*, 85 F.3d at 415–416.

77. *See White*, 971 F.2d at 1399; *Abdul-Jabbar*, 85 F.3d at 415–416.

78. *Abdul-Jabbar*, 85 F.3d at 415–416.

differences do emerge once cases move away from direct advertising to consider more expressive uses. To avoid running afoul of the First Amendment, many states create either an exception or an affirmative defense regarding uses that are in the public interest or otherwise expressive works.[79] But the details of these exceptions vary markedly across jurisdictions.[80]

C. DEEPFAKES AS A SPECIAL TYPE OF USE OF LIKENESS

Deepfakes are a type of "digital replica" which may be defined as a "virtual replica of a living or non-living physical entity."[81] These include the types of media referenced by statutes such as that of New York, which pertains to a "computer-generated, electronic performance in which the person did not actually perform that is so realistic that a reasonable observer would believe it is a performance by the individual."[82] Deepfakes are created by AI tools which work by "finding and learning similarities" between images of a given individual's face, or audio clips of an individual's voice.[83] These "learned traits" are "reduced to their shared common features" and then superimposed on a second "body," which can then be made to do and say anything.[84]

1. Deepfakes as a Use of Likeness

Courts typically take a broad view of what should count as a use of likeness for right of publicity purposes, finding a use of likeness when a celebrity's highly distinctive traits are emulated.[85] Unless confined by a statutory definition,[86] courts generally construe likeness liberally and hold that "the right of publicity does not require that appropriations of identity be accomplished

79. *Right of Publicity: Overview*, *supra* note 64.

80. See *infra* Part III.C.

81. David Mailhot, *Digital Twins: How the Digital Replica Concept is Used by Robotic Systems*, MOBILITY ENG'G (June 1, 2020), https://www.mobilityengineeringtech.com/component/content/article/37096-digital-twins.

82. N.Y. CIV. CODE § 50-f(2)(b) (Consol. 2023).

83. *Deconstructing Deepfakes—How Do They Work and What Are the Risks?*, U.S. GOV'T ACCOUNTABILITY OFFICE (Oct. 20, 2020), https://www.gao.gov/blog/deconstructing-deepfakes-how-do-they-work-and-what-are-risks; Ethan Baker, *Deepfake Voice—Everything You Should Know in 2023*, VERITONE VOICE (Jan. 24, 2023), https://www.veritonevoice.com/blog/everything-you-need-to-know-about-deepfake-voice/.

84. *Id.*

85. *See, e.g.*, *White*, 971 F.2d at 1399 (holding that the defendant re-constructed a likeness of White by adorning a robot with White's signature hairstyle, dresses and jewelry); *see also* Midler v. Ford Motor Co., 849 F.2d 460 (9th Cir. 1989); *Waits*, 978 F.2d at 1093.

86. *White*, 971 F.2d at 1397 (finding that the use of a "robot with mechanical features" did not fall within the statutory definition of "likeness" under California right of publicity statute § 3344).

through particular means to be actionable."[87] For example, the use of a racecar driver-plaintiff's signature vehicle was sufficient for a finding of appropriation of identity, notwithstanding the fact that the driver's face was not actually visible, and his name was never used.[88]

Whether an impersonation, reconstruction, or other non-literal use of likeness constitutes appropriation of identity depends on the extent to which a commercially valuable "sign or symbol" associated with a celebrity distinctively evokes their identity, such that a user can exploit such a personal trait for personal financial gain.[89] In the seminal *Midler v. Ford* case, for example, the court found liability where an advertiser commissioned a "sound-alike" to replicate Bette Midler's distinctive voice for a car commercial.[90] After Midler declined to lend her voice to the car commercial, an actress was hired and given the instruction to "sound as much as possible like the [Midler] record.[91] The result was an impersonation so compelling that even Midler's "close personal friends" believed she had performed in the commercial.[92] Upon conferring liability, the court reasoned that the defendant's use of such an iconic feature inextricably linked to Midler's identity in the interest of evoking a "warm connection" with an advertised product functionally "pirated" her identity for commercial gain.[93]

Other non-literal representations and reconstructions of likeness have been held to a similarly forgiving standard.[94] This can be seen in the case of Samsung's infamous "Wheel of Fortune" VCR ad, featuring a blonde-wigged robot clad in a long gown and jewelry standing beside a Wheel of Fortune game-board.[95] The Ninth Circuit held that this was not a literal use of likeness, as required by California's statutory right of publicity,[96] but that the holistic representation of Vanna White's person—including the robot's highly evocative hairstyle and dress, and the presence of the iconic Wheel of Fortune Game Board—was a use of likeness under California common law, as, despite

87. *Id.* at 1398.
88. *Motschenbacher*, 498 F.2d at 821.
89. *Midler*, 849 F.2d at 463.
90. *Id.*
91. *Id.* at 461–62.
92. *Id.*
93. *Id.* at 463.
94. *White*, 971 F.2d at 1399 (explaining that actionability seems to be determined in large part by the circumstance of the use—both in terms of the composite picture conveyed by the representation); Faulkner v. Hasbro, 2016 WL 3965200 at *4 (D. N.J., July 21, 2016).
95. *White*, 971 F.2d at 1396–97.
96. *Id.* at 1397.

being a non-literal representation, a viewer would have no question about who was being depicted.[97]

Finally, likenesses constructed by computer generated imaging, more commonly referred to as "CGI," have come within the purview of right of publicity law. Courts continuously hold that CGI portrayals in video games count as uses of likeness when video game companies create "digital avatars" "that resemble their real-life counterparts."[98] Infringement liability is especially likely to be found where the digital avatars exist in similar contexts as their celebrity counterparts, and engage in analogous activities and pursuits.[99] Such protection extends beyond representations of the celebrities themselves, and also applies to the use of character "skins" which are "cosmetic add-ons that customize the look of game characters."[100] Such "skins" may change the "look" of a video game character such that they resemble a particular celebrity, even if the character is not originally designed to be a representation of the celebrity. In the context of sports video games, courts have found that "skins" that replicate an actual athlete's skin and hair colors, musculature, posture, "play style," and athletic accessories are all sufficiently evocative of the athlete themselves to constitute an impermissible appropriation of likeness.[101]

Ultimately, the crux of whether a representation is sufficient to confer liability seems to turn on identifiability, and whether that identifiable trait or feature is being "pirated" for commercial gain.[102] As a result, there may be somewhat of a sliding scale regarding the precision of the non-literal likeness or impersonation, and the fame of the individual whose identity is being appropriated. The more famous a person is, the more readily elements of their identity will be recognized, resulting in a greater likelihood of finding liability for even non-literal appropriations of likenesses.[103] Conveniently, the AI tools used to create deepfakes work by "learning" and then reconstructing these very same defining features of individuals, including, for example, the smooth

97. *Id.* at 1396–98.

98. Hart v. Elec. Arts, Inc., 717 F.3d 141, 147 (3d Cir. 2013).

99. Robert Cumbow, *What They Do for a Living: The Right of Publicity in Video Games and Movies*, ABA (Sept. 2020), https://www.americanbar.org/groups/intellectual_property_law/publications/landslide/2020-21/september-october/right-of-publicity-video-games-movies/.

100. Dean Takahashi, *Newzoo: U.S. Gamers Are In Love With Skins And In-Game Cosmetics*, VENTUREBEAT (Dec. 18, 2020), https://venturebeat.com/games/newzoo-u-s-gamers-are-in-love-with-skins-and-in-game-cosmetics/.

101. Vikki Blake, *League Of Legends Developer Loses Lawsuit To Soccer Player*, IGN, https://www.ign.com/articles/2017/08/14/league-of-legends-developer-loses-lawsuit-to-soccer-player (last updated Aug. 16, 2021).

102. Cumbow, *supra* note 99.

103. *White*, 971 F.2d at 1399.

baritone timbre of Morgan Freeman's voice, Jim Carrey's exaggerated facial features, and Donald Trump's signature tangerine pallor.[104] By definition, deepfakes are no more than replications of those characteristic traits that make a person most recognizable—and most "like themselves."

2. Why Deepfakes are "Special"

In its current form, right of publicity law would almost certainly characterize the creation of a deepfake as an appropriation of likeness. What it would fail to do, however, is recognize that deepfakes are a distinctive form of "likeness," unlike any other the law has yet addressed. Deepfakes are fundamentally different from other forms of "likeness" in two ways. First, deepfakes can be made without consent and still serve as perfect commercial substitutes for the actual person, replacing their labor directly in commercial contexts. Second, deepfakes provide a unique vehicle for reputational damage, taking away a person's control of their image in a way that goes beyond what was previously possible.

Deepfakes have the power to supplant an individual. No existing type of use of likeness carries the same potential for allowing production companies to replace talent in such a comprehensive way. Traditional CGI is far more limited than deepfakes.[105] For one thing, CGI reconstructions of humans often result in artificial, synthetic-looking images.[106] Its renderings of faces and skin are particularly unconvincing, with viewers readily able to spot the differences between a CGI human and a live one.[107] Deepfakes do not suffer this deficit, and instead are lauded for their astoundingly life-like quality.[108] A second glaring shortcoming of CGI relative to deepfakes is that CGI only creates

104. *See* Diep Nep, *This Is Not Morgan Freeman – A Look Behind the Deepfake Singularity*, YOUTUBE (July 29, 2021), https://youtu.be/F4G6GNFz0O8; *The Shining Starring Jim Carry: Episode 1 – Concentration*, YOUTUBE (July 8, 2019), https://youtu.be/HG_NZpkttXE; *Donald Trump in Toddlers and Tiaras Deepfake,* YOUTUBE (June 16, 2019), https://youtu.be/i9KrJFLYxTI; Ian Sample, *What are Deepfakes and How Can You Spot Them*, GUARDIAN (June 13, 2020), https://www.theguardian.com/technology/2020/jan/13/what-are-deepfakes-and-how-can-you-spot-them.

105. *3 Differences Between CGI and Deepfake,* THISANSWER (Aug. 11, 2022), https://thisanswer.com/3-differences-between-cgi-and-deepfake/.

106. Martin Anderson, *Disentanglement is the Next Deepfake Revolution*, UNITE.AI, https://www.unite.ai/disentanglement-is-the-next-deepfake-revolution/ (last updated Dec. 9, 2022).

107. Natalie Wolchover, *Why CGI Humans are Creepy and what Scientists Are Doing About It*, LIVE SCI. (Oct. 18, 2011), https://www.livescience.com/16600-cgi-humans-creepy-scientists.html.

108. Peter Suciu, *Deepfake Star Wars Videos Portent Ways The Technology Could Be Employed For Good And Bad*, FORBES (Dec. 11, 2020), https://www.forbes.com/sites/petersuciu/2020/12/11/deepfake-star-wars-videos-portent-ways-the-technology-could-be-employed-for-good-and-bad/.

images; it does not generate audio.[109] Other forms of likeness appropriation, including manipulation of photographs or use of impersonators, are more limited still in their capacity to entirely replace their subjects. A deepfake of a performer can replace the performer in a way that no 1990s CGI or makeup-enhanced stunt double possibly could.

Given that actors can command tens of millions of dollars for a single film role,[110] and well over a million dollars per episode for television series,[111] the prospective economic loss to those actors is astounding. These types of losses are precisely the type of commercial harm contemplated by right of publicity law and are thus squarely within its purview.

Further, deepfake creation does not just threaten direct commercial interests. Deepfakes have the potential to fundamentally re-write a social narrative regarding a public (or private) figure's behavior, proclivities, and associations. Consider how this could play out in the context of a biopic. Some political figure, perhaps President Obama, would traditionally be depicted by an actor. Some archival footage from public archives that depicts real events would be interspersed between live-action scenes featuring the actor. But there would be clear separation between the fictionalized actor scenes and the real archival scenes. The audience would intuitively know whether they are looking at real or interpreted history. Not so with deepfakes. With deepfakes, the actor-recreated scenes could look just as authentic as the real archival footage.

Deepfake technology is also far more sophisticated and convincing than existing forms of manipulated media.[112] Unlike the teenagers who photoshop the heads of female celebrities onto the bodies of porn stars, the technology produces extraordinarily lifelike depictions, which may be difficult to distinguish from reality.[113] Deepfake content thus has a far greater capacity for

109. THISANSWER, *supra* note 105.

110. Travis Clark & Kirsten Acuna, *27 of the Highest-Paid Movie Roles of All-Time, Including Tom Cruise's Massive Pay Day for 'Top Gun: Maverick'*, BUS. INSIDER (Dec. 26, 2022), https://www.businessinsider.com/16-of-the-highest-paid-movie-roles-of-all-time-2018-5?op=1.

111. Jamie Burton, *14 TV Shoes Where the Cast Got More Than $ 1 Million Per Episode,* NEWSWEEK (Sept. 14, 2021), https://www.newsweek.com/14-tv-shows-cast-paid-more-1-million-per-episode-actor-salary-1628870.

112. Korey Clark, '*Deepfakes' Emerging Issue in State Legislatures*, STATE NET CAPITAL J. (June 4, 2021), https://www.lexisnexis.com/en-us/products/state-net/news/2021/06/04/Deepfakes-Emerging-Issue-in-State-Legislatures.page.

113. Rikki Schlott, *It's Not Just Taylor Swift 'Nudes': Millions of Teen Girls Victimized As Classmates Turn Them Into Deepfake Porn*, N.Y. POST (Feb. 2, 2024), https://nypost.com/2024/02/02/news/teen-girls-turned-into-deepfake-porn-like-taylor-swift/; Ian Sample, *What Are Deepfakes – And How Can You Spot Them?*, GUARDIAN (Jan. 13, 2020), https://www.theguardian.com/technology/2020/jan/13/what-are-deepfakes-and-how-can-you-spot-them.

deception, to the point where—as one software executive observed—it may become impossible "to distinguish fact from fiction," regarding portrayals of an individual.[114]

Given such realism, deepfakes can hijack an individual's entire persona and fundamentally alter how they are perceived. If those depictions show the individual engaging in behavior that is criminal, socially taboo, or, at a minimum, misaligned with that person's values, the individual's reputation may be permanently tarnished, as the public has no assurance other than the individual's word that the acts in question never happened.[115] Though Bette Midler and Vanna White may have resented their "appearances" in unauthorized commercials, these types of appropriations lack the gravity of the consequences that Alexandria Ocasio-Cortez could face as result of a pornographic deepfake "AOC Do Anything for Congressional Votes."[116]

III. COMMERCIAL AND EXPRESSIVE DEEPFAKES

Not every use of likeness is actionable under right of publicity law. Written into most right of publicity statutes is the qualifier that the use of a person's likeness is actionable only when used "in any manner, on or in products, merchandise, or goods or for purposes of advertising or selling, or soliciting purchases of, products, merchandise, goods, or services,"[117] or "for advertising purposes or for the purposes of trade."[118] Liability for use of likeness thus essentially comes down to two types of uses: "on or in a product," for example by "placing a celebrity's name on a 'special edition' of a [product]," or "in advertising or selling a product," such as by "using that name in a commercial to endorse the [product]."[119]

114. Aayushi Pratap, *Deepfake Epidemic Is Looming—And Adobe Is Preparing For The Worst*, FORBES (June 29, 2022), https://www.forbes.com/sites/aayushipratap/2022/06/29/deepfake-epidemic-is-looming-and-adobe-is-preparing-for-the-worst/?sh=5048d2445b81.

115. *See* Tom Chivers, *What Do We Do About Deepfake Videos*, GUARDIAN (June 23, 2019), https://www.theguardian.com/technology/2019/jun/23/what-do-we-do-about-deepfake-video-ai-facebook (commenting that some public figures have even proposed creating "authenticated alibis" by filming themselves at all times to be able to disprove any deepfakes that might later surface).

116. Abigail Loomis, *Deepfakes and American Law*, DAVIS POL. REV. (Apr. 20, 2022), https://www.davispoliticalreview.com/article/deepfakes-and-american-law.

117. CAL. CIV. CODE § 3344.

118. N.Y. CIV. RIGHTS § 50 (Consol. 2023).

119. Einstein v. Baby Einstein Co., LLC, 2009 WL 10670676 at *8 (citing *Comedy III* at 801).

This is an area where state laws meaningfully differ. Though the right of publicity does not cover noncommercial or personal uses in most states, California's common law right of publicity does extend to these uses. Under California law, a defendant may be found liable where the appropriation of name or likeness is "to the defendant's advantage, commercially or otherwise."[120] The language "or otherwise" creates what is seemingly the only avenue for a finding of infringement upon an individual's right of publicity in cases where money is not at least indirectly changing hands. For example, a California court found liability where a political campaign "ad" for then-Senator John McCain incorporated a song by well-known songwriter and ardent member of the Democratic party, Jackson Browne.[121] The court found the use was an "advantage" to McCain's candidacy, albeit a noncommercial one, as the use may have "benefitted" his campaign through "increased media attention."[122] Such a finding suggests that courts might extend this reasoning to include other uses where appropriation of likeness may result in increased publicity or visibility on social media, as well as possible reputational benefits.

This Part considers how the right of publicity will serve to regulate deepfakes in three separate contexts. The first context is direct commercial advertising: deepfakes used to sell products. These deepfakes raise highly traditional issues under the right of publicity and will very often require the consent of the person depicted.

The second kind of deepfakes are deepfakes that are produced in noncommercial settings, such as for distribution on social media, and when the deepfake itself is a product. Ultimately, whether the right of publicity will require the consent of the depicted individual here will turn on the commercial nature of the enterprise, and this will lead to some difficult line-drawing questions.

The third and final kind of deepfakes are ones created for commercial distribution as expressive products. While this category of deepfakes is central to our consideration of the use of deepfakes in entertainment, it unfortunately presents the least clear doctrinal answer. Whether these deepfakes require the consent of the person depicted will depend on whether they receive constitutional protection as expressive uses. We will argue that many of these commercially oriented expressive deepfakes should require the permission of the depicted individuals. This will lead into our discussion in Part IV on how

120. *White*, 971 F.2d at 1397.
121. Browne v. McCain, 611 F. Supp. 2d 1062 (2009).
122. *Id.* at 1070.

that permission should be obtained and how the law of expressive uses should be clarified to strengthen this conclusion.

A. USE OF DEEPFAKES TO SELL PRODUCTS

Though there are some edge cases, an appropriation of likeness for use in advertising is one of the most straightforward and common types of cases addressed by right of publicity law.[123] The general answer is simple: right of publicity law—under both statutory and common law—prohibits the unauthorized use of likeness "for advertising purposes."[124]

Courts characterize uses for advertising purposes as those bearing "not the slightest semblance of an expression of an idea, a thought, or an opinion,"[125] but instead "merely advertise another unrelated product."[126] Examples of such verboten "uses in advertising" have included the incorporation of Tom Waits' throaty rasp in a Doritos advertisement,[127] the depiction of a professional racecar driver's signature car in a cigarette commercial, [128] and the aforementioned prominent appearance of an evocative, wig-and-dress wearing robot flipping Wheel-of-Fortune tiles in a promotion for Samsung VCRs.[129] While courts tolerate using a celebrity or other famous figure's likeness in material that is "commercially sponsored" or "involves paid advertising"—for example, accompanying an article in a magazine—such uses must have a bona fide connection to the purpose of the use.[130]

Some uses of deepfakes can unambiguously be characterized as uses in advertising. The use of celebrity deepfakes in promotional materials has already proven attractive to businesses, as they provide a fast and relatively cheap way to generate the type of clout surrounding a product that's typically

123. *White*, 971 F.2d at 1401 n.3 (drawing a distinction between appropriation used in advertising, and appropriation in other contexts); Eric Johnson, *Disentangling the Right of Publicity*, 111 N.W. L. REV. 891, 923 (proposing that courts generally find liability for commercial exploitation of identity in the context of advertising).

124. N.Y. CIV. RIGHTS L. §§ 50, 51 (McKinney 2023).

125. *Toffoloni*, 572 F.3d at 1208.

126. Cardtoons, L.C. v. Major League Baseball Players Ass'n, 95 F.3d 959, 970 (10th Cir. 1996).

127. *Waits*, 978 F.2d at 1097.

128. *Motschenbacher*, 498 F.2d at 822.

129. *White*, 971 F.2d at 1396.

130. *See* Finger v. Omni, 77 N.Y.2d 126, 138 (1990) (describing the requirement of a nexus between the use of a photo and the content of a magazine article such that the photo is not merely an "advertisement in disguise"); Downing v. Abercrombie & Fitch, 265 F.3d 994, 1002 (9th Cir. 2001) (explaining that given the tenuous relationship between the use of a famous surfer's photograph and the content of a fluff piece, the photograph was "essentially window-dressing to advance the catalog's surf-theme, and thus functioned like an advertisement).

achieved only through celebrity endorsement.[131] For example, there is Elon Musk's role in the promotional video for the real estate investment group, reAlpha Tech Corp., which depicted him tied up in a chair pitching the company's mission of "democratizing real estate investing."[132] At first, the ad suggests Musk was kidnapped for the purposes of promoting the startup, but then quickly reveals itself to be a deepfake as the reconstructed Musk chides the company, "don't they know it would be easier to deepfake me?"[133] While Musk himself may literally not have been tied up and forced to do the commercial, his presence was nevertheless nonconsensual, as the iconoclastic billionaire never signed an endorsement agreement.[134]

Companies making this kind of use have acknowledged the risk of a right of publicity lawsuit, but they seem willing to embrace the possibility as a risk well-justified by the interest of generating publicity.[135] ReAlpha, for one, attempted to avoid liability by leaning heavily on the use of disclaimers that both disavowed any actual participation by Musk and emphasized the nature of the commercial as being satire, though ultimately conceded that the use might be actionable.[136] And indeed, the video is clearly exploiting Musk's identity to peddle an unrelated populistic real estate investment service, which is the essence of an actionable commercial use.[137]

B. USE OF DEEPFAKES IN PRODUCTS AND FOR NONCOMMERCIAL PURPOSES

Courts are somewhat less consistent when considering cases in which a person's likeness is used for something other than direct advertising. Though commercial uses of products that bear an appropriated likeness may be actionable, the mere fact that the use of the likeness is in the context of a commercial enterprise does not alone confer liability.[138] Still, how courts decide when involvement in a commercial enterprise confers liability varies tremendously.

131. *See* Patrick Coffee, "*Deepfakes" of Celebrities Have Begun Appearing in Ads, With or Without Their Permission*, WSJ (Oct. 25, 2022), https://www.wsj.com/articles/deepfakes-of-celebrities-have-begun-appearing-in-ads-with-or-without-their-permission-11666692003.

132. reAlpha, *Elon Musk Held Hostage in a Warehouse (Will He Comply?)*, YOUTUBE (Oct. 19, 2022), https://www.youtube.com/watch?v=UuszlOBKkrM.

133. *Id.*

134. Coffee, *supra* note 131.

135. *Id.*

136. *Id.*

137. *See id.; Comedy III*, 21 P.3d at 802.

138. *See Comedy III*, 21 P.3d.

Consider the question of the least commercial uses of deepfakes, such as the distribution of deepfakes on ad-revenue driven social media platforms. Most deepfakes are not produced by marketing firms to be used in advertising or by governments to undermine their adversaries but rather are generated by at-home users and posted to social media platforms.[139] For these recreational users, the value of deepfakes lies in their potential for personal amusement and entertainment or to drive traffic to their channels.[140]

Though social media sites like TikTok and YouTube are commercial enterprises that generate massive profit through advertising revenue,[141] their user-generated content is not rendered commercial merely by appearing there.[142] While courts have yet to explicitly address the issue in the context of the right of publicity, it is plausible that they might adopt approaches similar to those used in assessing whether social media posts constitute commercial speech under the Lanham Act. In that context, it appears that all Circuits require some type of reference to a commercial transaction within the posted content for the content to be deemed commercial.[143] For example, the Ninth Circuit deemed an artisan's Facebook photographs of whimsically designed brooms "unquestionably commercial speech."[144] This was not because they were posted on social media but instead because of the images' nature. The offending photographs all entailed "people trying to sell the brooms" and were captioned with messaging clearly intended to "influence consumers to buy their goods."[145]

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139. Mika Westerlund, *The Emergence of Deepfake Technology: A Review*, 9 TECH. INNOVATION MGMT. REV., 39, 40 (2019); Steven Zeitchik, *Ready or Not, Mass Video Deepfakes are Coming*, WASH. POST (Aug. 20, 2022), https://www.washingtonpost.com/technology/2022/08/30/deep-fake-video-on-agt/.

140. Zeitchik, *supra* note 139 (describing the proliferation of synthetic media and its capacity for viral viewership).

141. Business Model Toolkit, *TikTok*.

142. *See* Yurish v. Sinclair Broadcast Group Inc., 866 S.E.2d 156, 168 (W. Va. 2021) (declining to characterize an audio recording as commercial speech, notwithstanding the fact it was posted to social media).

143. *See* ADB Interest, LLC v. Wallace, 606 S.W.3d 413, 422–28 (2020) (holding that the defendant's social media post to be non-commercial in nature, despite the fact it was both about a product, and posted on defendant's business's Facebook page, as it failed a four-part test inquiring whether the statements were in the context of a sale, arising out of a commercial transaction, or if the intended audience of the content are actual or potential consumers); *Yurish*, 866 S.E.2d at 167 (reiterating the definition of commercial speech as that which does "no more than propose a commercial transaction"); Ariix, LLC v. NutriSearch Corporation, 985 F.3d 1107, 1115 (2021) (describing the Ninth Circuit's test for commercial speech, which requires that the speech at issue is intended "for the purpose of influencing consumers to buy defendant's goods or services").

144. H.I.S.C., Inc. v. Franmar International Importers, Ltd., 2022 WL 104730, at *5.

145. *Id.* at *5–6.

But most common deepfakes are not that. Consider the innumerable high-profile deepfakes of former President Donald Trump. The real estate mogul-turned-reality-television-star-turned-president has been depicted exchanging trash talk with President Joe Biden while playing the first-person shooter game *Overwatch*,[146] giving advice on money-laundering as crooked lawyer Saul Goodman in the acclaimed television series *Breaking Bad*,[147] and mocking the Belgian government for their continued membership in the Paris climate agreement.[148] None of these have direct connections to any commercial transaction. Though one could *make* such videos commercial—for instance, by selling them as products or coupling them with donation requests—they are not inherently so.

This is not to say there is no economic benefit to these "free" videos. Though Chris Ume initially created his TikTok series of Tom Cruise deepfake videos for personal amusement, his account quickly went viral and established a massive following.[149] The flurry of attention was arguably what caught the eyes of entrepreneurs and investors, who supplied Ume with the capital needed to create the generative AI company Metaphysic.[150] Further, one could plausibly argue that the notoriety he gained alone might be adequate for a finding of personal advantage under California common law. Given that "increased media attention" has already proven to be grounds for such a finding of personal benefit in the context of political campaigns, courts might apply the same logic where such attention may lead to other types of visibility and professional opportunities.[151]

In sum, noncommercially oriented deepfake videos are likely outside the scope of most right of publicity statutes in most states. But edge cases, where the deepfake videos directly lead to commercial advantage, and the vagaries of California common law, make this just unclear enough to cause issues.

Deepfake videos as products raise a different set of questions. Consumer products incorporating a person's likeness have long been held to be

146. Allegra Rosenberg, *AI-Generated Audio of Joe Biden and Donald Trump Trash Talking While Gaming is Taking Over TikTok*, BUS. INSIDER (Mar. 1, 2023), https://www.businessinsider.com/voice-ai-audio-joe-biden-donald-trump-tiktok-2023-3.

147. Victor Tangermann, *Someone Deepfaked Trump into Breaking Bad and It's Horrifying*, BYTE (Sept. 23, 2019), https://futurism.com/the-byte/deepfake-trump-breaking-bad.

148. Hans Von Der Burchard, *Belgian Socialist Party Circulates 'Deep Fake' Donald Trump Video*, POLITICO (May 21, 2018), https://www.politico.eu/article/spa-donald-trump-belgium-paris-climate-agreement-belgian-socialist-party-circulates-deep-fake-trump-video/.

149. Zeitchik, *supra* note 140.

150. *Id.;* Dean Takahashi, *Metaphysic, AI Startup Behind Tom Cruise Deepfakes, Raises $7.5M*, VENTUREBEAT (Jan. 25, 2022), https://venturebeat.com/games/metaphysic-ai-startup-behind-tom-cruise-deepfakes-raises-7-5m/.

151. Browne v. McCain, 611 F. Supp. 2d 1062, 1070 (2009).

actionable.[152] For example, in *Comedy III*, a court held that t-shirts depicting an original rendering of the Three Stooges violated the plaintiff's statutory and common law right of publicity under California law.[153] While the shirts were decidedly not advertising, they nevertheless entailed "use within a product " as the shirts were "tangible personal property" that were "made as products to be sold," and thus constituted the type of commercial use contemplated by California's right of publicity statute.[154] Similar commercial use has been found in *Uhlaender v. Henricksen*, in which a board game company incorporated retired professional baseball players' professional statistics into a "parlor game,"[155] as well as in *Carson v. Here's Johnny Portable Toilets*, in which Carson's signature introductory phrase "Here Comes Johnny" was adopted as the double-entendre name of a portable toilet company.[156] Unlike other advertising cases, in which an individual's identity is exploited for the purposes of selling an unrelated product, in *Uhlaender* and *Carson*, the exploitation was embedded in the product itself.[157]

Deepfakes could be used to incorporate celebrities into a variety of products. Content creators have already been tapped to produce celebrity deepfakes to be used for commercial purposes other than advertising.[158] For example, Slack Shack Films, the firm behind reAlpha's Musk commercial, is frequently asked to produce celebrity deepfakes to be used internally by businesses for "training, communications, parties or other purposes."[159] Slack Shack, which describes itself as "a group of creative storytellers" who "exercise our creativity on any platform that doesn't kick us off first" is blatantly a commercial service, marketing itself to those "on any budget."[160] In these cases, the deepfakes themselves are the commodity.

This type of deepfake use may be common in the future. Commentators have already speculated that deepfakes may prove popular as educational tools.[161] Indeed, teachers have already taken advantage of the opportunity to revive long-deceased historical figures to add a splash of "relevancy" to history

152. *Comedy III*, 21 P.3d at 802.
153. *Id.*
154. *Id.*
155. Uhlaender v. Henricksen, 316 F. Supp. 1277, 1278 (D. Minn. 1970).
156. Carson v. Here's Johnny Portable Toilets, Inc., 698 F.2d 831 (6th Cir. 1983).
157. *Comedy III*, 21 P.3d at 802.
158. *See* Coffee, *supra* note 131.
159. *Id.*
160. Slack Shack, Slackshack.tv.
161. Jessica Ice, *Defamatory Political Deepfakes and the First Amendment*, 70 CASE W. RES. L. REV. 417, 428 (2019).

lessons,[162] and it is easy to imagine educators sourcing deepfakes of more contemporary public figures in the interest of making otherwise dry course material more engaging. While educational uses qualify for the fair use exception in the copyright context, there does not appear to be an analogous carve-out in the right of publicity framework.[163] Consequently, a firm like Slack Shack may be confronted with liability for commissioning a celebrity deepfake, regardless of whether their client is Salesforce or the Chicago Public Schools.

With all this in mind, actually selling deepfakes is likely to cause issues under existing right of publicity law frameworks, both statutory and common law. Yet there is substantial overlap between the types of deepfakes that might be sold and those that verge most closely on First Amendment values. A deepfake of a political candidate embedded in a rival's campaign donation solicitation is likely commercial enough to qualify as a use in trade or advertising. But is it protectable, nonetheless?

C. EXPRESSIVE USES OF DEEPFAKES

If a deepfake that puts a well-known person in a new video is created, the video could escape liability because it is not a commercial use.[164] But what if the video is plainly commercial? Courts are in agreement that the right of publicity, though broad, is not absolute.[165] Given their prominence in society, "celebrities take on public meaning" such that the use of their identity or likeness may be unavoidable.[166] This recognition that appropriation of celebrity likeness can have a valuable role in fostering "an uninhibited marketplace of ideas" has given rise to broadly recognized public interest or expressive use exceptions to right of publicity claims.[167] Unfortunately, outcomes of right of publicity actions pertaining to unauthorized use of likeness in expressive works—including in fiction, film, television and other artistic works—are far more difficult to predict than those brought in the cases of advertising or consumer products, as such uses are subject to a byzantine set of exceptions

162. *See* Erik Ofgang, *How to Teach With Deep Fake Technology*, TECH & LEARNING (Nov. 21, 2022), https://www.techlearning.com/news/how-to-teach-with-deep-fake-technology.

163. *See* Boggess, *supra* note 60 at 31.

164. *See supra* Part III.B.

165. No Doubt v. Activision Publ'g, Inc., 192 Cal. App. 4th 1018, 1030 (2011).

166. *Id.*

167. *Id.*; Redish & Shust, *Right of Publicity and the First Amendment in the Modern Age of Commercial Speech*, 56 WM. & MARY L. REV. 1443, 1443 (2015). Additionally, claims brought in California courts may also be subject to an anti-SLAPP motion to strike. Such motions arise when a use of likeness is "in furtherance of a person's right of petition or free speech," and where the plaintiffs are "unlikely to prevail on their claim." CAL. CIV. PROC. § 425.16(a), (e).

and affirmative defenses designed to protect content creators' First Amendment rights.

To understand the complexity surrounding how right of publicity law would approach "expressive" deepfakes, one must first consider the existing schemes for assessing when an expressive use of likeness is actionable, and when it is shielded from liability by the First Amendment, including those under common law, and various state statutes.

1. Contemporary Approaches to Expressive and Protected Uses

Noted right of publicity scholar Jennifer Rothman titles her chapter on expressive uses as "The Black Hole of the First Amendment" and describes the doctrine as "the current mess."[168] She ultimately categorizes five different approaches for determining whether a particular use is protected by the First Amendment.[169] Two of these approaches, both used by the Ninth Circuit, are variants of a transformative use balancing test.[170] The other three—despite Rothman's heroic efforts—are not especially coherent, considering variously the "predominant purpose" of the work, the "relatedness" of the work to the person depicted, and an ad-hoc balancing of interests between the person depicted and the creator of the expressive work.[171]

Since the transformative use approach has generated the largest and most coherent body of case law, we will examine it in detail. This approach considers whether an unauthorized appropriation of likeness is sufficiently "transformative." [172] A court fundamentally asks, "whether a product containing a celebrity's likeness is so transformed that it has become primarily the defendant's own expression rather than the celebrity's likeness."[173] In short, is this art a picture of Barack Obama, or is it a work of the artist?

In the Ninth Circuit, this transformative use test is comprised of five inquiries.[174] First, whether "the celebrity likeness is one of the 'raw materials' from which an original work is synthesized."[175] If not, the rest of the test is not considered relevant. Second, whether the work "is primarily the defendant's own expression . . . [and also is expression of] something other than the

168. Rothman, *supra* note 31 at 138.
169. *Id.* at 145.
170. *See id.* at 146.
171. *See id.* at 145–48.
172. *See Comedy III*, 21 P.3d at 809.
173. *Id.* at 809.
174. Keller v. Elec. Arts Inc.,724 F.3d 1268, 1274 (9th Cir. 2013); *see* Hamilton v. Speight, 827 F. App'x 238, 240 (3d Cir. 2020) for application of transformative use test by the Third Circuit; *Comedy III*, 21 P.3d at 808.
175. *Comedy III*, 21 P.3d at 809.

likeness of the celebrity."[176] Third, "whether [quantitatively] the literal and imitative or creative elements predominate in the work."[177] Fourth, whether "the marketability and economic value of the challenged work derive primarily from the fame of the celebrity depicted."[178] Finally, the work is deemed less likely to be transformative if "an artist's skill and talent is manifestly subordinated to the overall goal of creating a conventional portrait of a celebrity so as to commercially exploit his or her fame."[179]

The outcome of the transformative use test seems to turn on different factors depending on the specific nature of the unauthorized use. In *Comedy III*, which pertained to the use of likeness on articles of clothing, the court reasoned that the t-shirts might qualify for protection under the First Amendment if the use of the likeness in the product transcended a "conventional depiction" of the Three Stooges that was being exploited for commercial gain.[180] Unfortunately for the defendant, the court found that "the marketability and economic value of [defendant's] work derives primarily from the fame of the celebrities depicted" rather than any unique expression of his own, and found in favor of the plaintiff's right of publicity claim.[181]

In the context of literature, courts appear to emphasize the extent to which the use of likeness was one of the "raw materials" from which the work was created. When the test was applied in the case of a comic book featuring characters bearing striking likeness to acclaimed musicians Johnny and Edgar Winter, for example, courts emphasized the extent to which the representations were enhanced by the author to create "fanciful, creative characters."[182] Though the depictions of the brothers were highly evocative, prominently featuring the "long white hair and albino features" that made the musicians so recognizable, they were in the context of "half-human, half-worm" creatures, rendering them non-literal depictions that were "distorted for purposes of lampoon, parody or caricature."[183] These differences, according to the court, rendered the use of the likenesses to be a "raw material" used in the composition of "a larger story, which itself is quite expressive" and

176. *Keller*, 724 F.3d at 1274.
177. *Id.*
178. *Id.*
179. *Id.* (citing *Comedy III*, 21 P.3d at 809).
180. *Comedy III*, 21 P.3d at 811.
181. *Id.*
182. Winter v. D.C. Comics, 134 Cal. Rptr. 2d 634, 642 (2003).
183. *Id.* at 638.

predominately the work of the author.[184] The court therefore afforded the comic books First Amendment protection and declined to extend liability.[185]

Conversely, the inquiry as applied to toys seems to rest primarily on the third inquiry, which is whether the toy would "threaten the market for celebrity memorabilia that the right of publicity is designed to protect."[186] This was seen in a case that confronted the question of whether a popular line of dolls bearing a striking resemblance to members of well-known female pop group OMG Girlz constituted expressive speech protectable under the First Amendment.[187] While the court acknowledged that the dolls had some transformative qualities, including "designs and looks that differ greatly" from the OMG members, it found that the dolls' "musical theme" mirrored the "public depictions" of the group. Such similarity led the court to "believe that the OMG Girlz market overlaps with the potential purchasers of the OMG Dolls," and caused concern that the dolls might supplant the market for sanctioned OMG Girlz products.[188] Perhaps, had the manufacturer chosen a different profession for the dolls, say, as athletes, visual artists, or doctors, the court may have found the toys sufficiently transformed from their real-life counterparts.

Contrasted with this transformative use approach, some other jurisdictions, including New York state courts, take a more "medium-centric" approach.[189] Potentially expressive uses are assessed based on whether they constitute trade or advertising, or instead may be construed as a form of art, news, or social commentary.[190] Unfortunately for litigants, this approach is much less developed than the transformative use test. Whereas the toy manufacturer in California could point to the altered physical characteristics of the toy relative to the person, or call attention to the fact that the doll exists within a different fictional world (e.g., a "musician" version of a political figure, etc.) and have their work deemed "expressive," a New York toy manufacturer would have to first convince the court that the dolls, despite being commercial products, are also artistic works to which right of publicity claims do not apply.[191] The manufacturer might, for example, call the toys "sculptures," in

184. *Id.* at 641.

185. *Id.* at 642.

186. MGA Entertainment, Case No. 2:20-cv-11548-J VS (AGRx), 2022 WL 4596697, at *16 (quoting *Comedy III*, 25 Cal. 4th at 405).

187. *Id.* at *15.

188. *Id.* at *16.

189. *See* Dryer v. National Football League, 55 F. Supp. 3d 1181, 1188 (D.Minn. 2014).

190. Champion v. Take Two Interactive Software, Inc., 64 Misc. 3d 530, 535 (Sup. Ct. 2019).

191. Burk v. Mars, Inc., 571 F. Supp. 2d 446, 451 (S.D.N.Y. 2008).

which case they may be entitled to sell copies.[192] Unfortunately for the toy manufacturer, courts scrutinize such purportedly artistic works closely, considering the "underlying nature of the work"[193] and whether it possesses certain key defining attributes of the artistic medium.[194] While courts have not clearly delineated the criteria for work to be properly characterized as "sculpture" in the same manner that they have alluded to the criteria required for a work to be "literary," even if the dolls did qualify as art, the mass distribution of dolls would exceed the sale of only a "limited number of copies," which courts condone.[195]

Complicating matters, that same toy manufacturer, regardless of the circuit, could prevail in a right of publicity suit by claiming the toy constituted social commentary or criticism. The beloved merchandise retailer Target found great success using this approach after being sued for producing and selling an informational plaque engraved with the image of civil rights icon Rosa Parks.[196] Despite the fact the plaques were mass-produced and sold at one of the nation's most prominent department stores, the courts excused the product on the grounds that the plaques "communicate[ed] information, express[ed] opinion[s], recite[ed] grievances, [and] protest[ed] claimed abuses," and was "necessary to chronicling and discussing the history of the Civil Rights Movement."[197]

In the context of literary works, these medium-centric jurisdiction courts have held that "works of fiction do not fall within the narrow scope of the statutory definitions of advertising or trade,"[198] regardless of their purpose, or the scale of their production and distribution.[199] Such fictional works have been held to include novels and films based on public figures, which depict fictionalized accounts of actual events,[200] as well as television shows with

192. *See* Simeonov v. Tiegs, 159 Misc. 2d 54, 58–59 (Civ. Ct. 1993).

193. *See* Hoepker v. Kruger, 200 F. Supp. 2d 340, 352 (S.D.N.Y. 2002).

194. *Champion*, 64 Misc. 3d at 535 (commenting that video game in question lacked certain defining literary features including narrative plot and character development).

195. *Hoepker*, 200 F. Supp. 2d at 349.

196. Rosa Parks Inst. for Self-Development v. Target Corp., 812 F.3d 824 (11th Cir. 2016).

197. *Id.* at 831–32.

198. Costanza v. Seinfeld, 279 A.D.2d 255, 255 (2001) (internal quotation marks omitted).

199. Hicks v. Casablanca Records, 464 F. Supp. 426, 432 (S.D.N.Y. 1978).

200. *Id.* at 433 (holding that, "the Court finds that the right of publicity does not attach here, where a fictionalized account of an event in the life of a public figure is depicted in a novel or movie, and in such novel or movie it is evident to the public that the events so depicted are fictitious.").

entirely fictional characters.[201] Courts have, however, suggested that the permissibility of fictionalized portrayals may be contingent upon the content creators' providing disclaimers regarding the content, such that it becomes clearly "evident to the public" that such elements are fictitious.[202]

2. Deepfakes in the Expressive Use Context

In many cases, deepfake videos may take the form of political speech or social commentary, thus qualifying as a form of speech protected under the First Amendment under any test.[203] Political figures have become popular targets of deepfakes, which range from whimsical TikTok reels of Biden, Trump, and Obama playing video games,[204] to more nefarious portrayals, such as the doctored clip of an ostensibly inebriated Nancy Pelosi, in which she appears to be slurring her words.[205] Deepfakes seem to provide potent forms of social commentary, given the wide publicity and media attention surrounding videos such as the fabricated CBS interview with Mark Zuckerberg. The counterfeited interview was clearly intended as a derisive commentary on the social media platform's disregard for, and malfeasance regarding, user privacy and autonomy, as the tech mogul alluded to having the power to control the future by manipulating "billions of people's stolen data."[206]

While some uses of politicians and other prominent figures within deepfake videos are clearly social commentary—such as the 2018 video depicting former President Obama calling then-President Trump a "dipshit" and warning the audience about the potential for deepfakes to interfere with democratic processes[207]—others are more ambiguous. Such uncertainty is

201. *Costanza*, 279 A.D.2d at 255 (finding no liability for Seinfeld creators, despite the fact the name of the fictional character "George Costanza" belonged to an actual man).

202. *Hicks*, 464 F. Supp. At 433.

203. Gloria Franke, *The Right Of Publicity Vs. The First Amendment: Will One Test Ever Capture The Starring Role?*, 79 S. CAL. L. REV. 945, 960–61 (2006).

204. Tmparagon, *Trump Plays Destiny with Biden and Obama*, TIKTOK (Feb. 19, 2023), https://www.tiktok.com/@tmparagon/video/7202039315461917994.

205. Simon Parkin, *The Rise of the Deepfake and the Threat to Democracy*, GUARDIAN (June 22, 2019), https://www.theguardian.com/technology/ng-interactive/2019/jun/22/the-rise-of-the-deepfake-and-the-threat-to-democracy.

206. Samantha Cole, *This Deepfake of Mark Zuckerberg Tests Facebook's Fake Video Policies*, VICE (June 11, 2019), https://www.vice.com/en/article/ywyxex/deepfake-of-mark-zuckerberg-facebook-fake-video-policy.

207. James Vincent, *Watch Jordan Peele Use AI to Make Barack Obama Deliver a PSA About Fake News*, VERGE (Apr. 17, 2018), https://www.theverge.com/tldr/2018/4/17/17247334/ai-fake-news-video-barack-obama-jordan-peele-buzzfeed.

especially acute in cases where the public figures in question wear multiple hats, such as in the case of celebrity politicians.

Though the majority of current expressive uses of deepfakes fit into this category of short-form comedy entertainment, the future could be far different. What about the hypothetical from our introduction, of a deepfaked TV star? TV shows and movies are expressive works, the same as literature. Scripted TV shows and movies have long incorporated some real-world footage of actual persons and events, but these uses have been constrained by the requirement that the footage actually exist. Deepfakes remove that restriction. Could someone deepfake a presidential address to announce a Martian invasion? Could they otherwise deepfake a noteworthy person into a movie as a cameo? Or replace an actor entirely? Could they create a deepfake of a person to star in a biopic of their own life?

The 2023 amendments to the Screen Actors Guild contract struggled with these questions. Under that contract, the use of "independently created digital replicas" requires explicit consent and compensation, except when either the person depicted is playing themselves or the use is "protected by the First Amendment (e.g., comment, criticism, scholarship, satire or parody, use in a docudrama, or historical or biographical work, to the extent protected by the First Amendment.)"[208] So the contract would prohibit a production from using a guild member to play a role without their consent, but it would allow the production to create a deepfake of people playing themselves. Does the right of publicity provide a remedy for someone not party to the contract or insufficiently protected by it? A recent spate of cases pertaining to use of likeness within video games may provide clues as to how courts would address the matter. Like deepfakes, video games involve the use of digital replicas that depict individuals doing things their real-life counterparts have not done. Unfortunately, use of likeness within video games is itself a murky class of right of publicity litigation that has only started developing over the past twenty years. In general, courts have found that unauthorized importation of athletes into sporting games is not a protected expressive use, but the law is less clear for other sorts of applications.[209]

208. SAG-AFTRA, *TV/Theatrical Contracts 2023: Summary of Tentative Agreement* 3, https://www.sagaftra.org/files/sa_documents/TV-Theatrical_23_Summary_Agreement_Final.pdf.

209. *See* Davis v. Elec. Arts, Inc., 775 F.3d 1171, 1181 (9th Cir. 2015); *see* Keller, 724 F.3d at 1270, 1276; *see* Dryer, 55 F. Supp. 3d. at 1204.

3. Deepfakes in Transformative-Use Jurisdictions

Generally speaking, jurisdictions using the transformative use test recognize video games as being inherently expressive works entitled to the full protections of the First Amendment pending their satisfaction of the transformative use test.[210] While not a traditional form of creative expression, video games, nevertheless, are classified among "books, plays and movies" based on their capacity to "communicate ideas and even social messages," and are thus assessed accordingly.[211]

So too with deepfakes. While a Trump vs. Obama *Fortnite* battle may not contain the most sophisticated "social message," it nevertheless communicates an idea: how would two of the most radically different former Presidents' personas manifest themselves in a virtual video game battle?[212] Like video games, then, "the pivotal issue is whether the work is transformative."[213]

Cases seem to turn on whether the celebrities are portrayed in the professional and physical contexts in which they are known in real life. While courts acknowledge that the capability to alter celebrity avatars may add new expression beyond "celebrity's literal likeness," such transmutability is viewed as a sideshow rather than main feature.[214] What courts consider more relevant is whether "the appeal of the game lies in the user's ability to play as or alongside" the celebrities depicted.[215] If playing as the celebrity is the primary draw of the game, "the graphics and other background content of the game" are akin to an artist's skill and talent which are "subordinated to the overall goal of creating a conventional portrait of a [celebrity] so as to commercially exploit [its] fame."[216] Such lines of reasoning can be distilled to two fundamental inquiries, which seem to be dispositive. First, are the characters in the game doing the "same activity for which they are known in real life?"[217] Second, is the context in which the activity in the game occurs the same setting as where the public would actually encounter the celebrity?[218] When the

210. Brown v. Entm't Merchs. Ass'n, 131 S. Ct. 2729, 2733 (2011).

211. *Id.*; *see also* Zacchini v. Scripps-Howard Broad. Co., 433 U.S. 562, 576 (1977). ("broadcast of petitioner's entire performance, unlike the unauthorized use of another's name for purposes of trade or the incidental use of a name or picture by the press, goes to the heart of petitioner's ability to earn a living as an entertainer").

212. Realbekfast09, *Trump and Obama 1v1 on Fortnite,* TIKTOK (Feb. 17, 2023), https://www.tiktok.com/@realbekfast09/video/7201351989286980907.

213. *Kirby*, 144 Cal. App. 4th at 60.

214. *No Doubt*, 192 Cal. App. 4th at 1034.

215. *Hart*, 717 F.3d at 168.

216. *No Doubt*, 192 Cal. App.4th at 1035.

217. *Keller*, 724 F.3d at 1276.

218. *Id.*

answers to these questions are both yes, any other creative elements of a game, no matter how fanciful, will not militate against a finding of non-transformativeness.[219]

Applying this reasoning to deepfakes, the greater the extent to which a celebrity or public figure is transposed into a different role, the more transformative the video. For example, the TikTok video series depicting Trump, Obama, and Biden in spirited *Fortnite* battles would likely qualify as transformative based on the courts' current approach.[220] First, none of the Presidents participating in the first-person-shooter game competitions appear to have an affinity for video games, nor do they participate in para-military tactical operations of the sort depicted in the games themselves. Trump is well-known to have evaded military service,[221] Obama has gone on record encouraging children to "put down the video games and do something with your life,"[222] and Biden has championed bills banning assault-style weapons of the sort prominently featured in the games.[223] Similarly, the context in which the activity occurs—the presidents competing amongst themselves after-hours and from their respective homes—is decidedly *not* where the public would encounter these prominent public figures. In fact, arguably, the entire appeal of the videos turns upon the juxtaposition of the gravitas of the U.S. Presidency, with the banal triviality of a gaming competition,[224] essentially putting the politicians in a role in which they've never been seen before.

Conversely, consider the Zuckerberg deepfake video, depicting the Facebook founder giving an interview and speaking about the potentially sinister uses of customer data. Unlike Obama, Trump and Biden, who have never been known to play Fortnite, Zuckerberg regularly conducts interviews

219. *No Doubt*, 192 Cal. App. 4th at 1034 (finding that a game was non-transformative despite allowing players to place celebrity avatars in unusual settings "surrounded by unique, creative elements, including in fanciful venues such as outer space").

220. Realbekfast09, *supra* note 212.

221. Mariana Alfaro, *Donald Trump Avoided the Military Draft Five Times but It Wasn't Uncommon for Young Men from Influential Families to Do So During the Vietnam War*, INSIDER (Dec. 26, 2018), https://www.businessinsider.com/donald-trump-avoided-the-military-draft-which-was-common-at-the-time-vietnam-war-2018-12?op=1.

222. Brian Crecente, *Video Games Owe a Lot to President Obama's Administration*, POLYGON (Jan. 20 2017), https://www.polygon.com/2017/1/20/14335040/barack-obama-gaming-president.

223. John Yoon, *Shootings Revive Push for an Assault Weapons Ban*, N.Y. TIMES (Jan. 2023), https://www.nytimes.com/2023/01/24/us/california-assault-weapon-ban.html.

224. Ana Diaz, *TikTok Videos are Using AI Tools to turn Biden, Trump and Obama into Discord Goblins*, POLYGON (Feb. 22, 2023), https://www.polygon.com/23610381/presidents-play-minecraft-ai-voice-meme-joe-biden-trump.

in which he speaks about the collection and use of customer data.[225] In fact, the deepfake was released on the heels of the 2018 scandal regarding Facebook's negligence surrounding the harvesting and exploitation of millions of users' data by a political consulting firm, an event which prompted Zuckerberg to give numerous highly publicized interviews about Facebook's data collection practices.[226] So both the content and context of the video—Zuckerberg apparently giving an interview on the hot-button issue of data protection to a news outlet—reflect Zuckerberg's real-life activities. As such, a California court might not characterize the video as transformative.

Moving into the world of longer-form entertainment, nonconsensual deepfakes would likely often violate the right of publicity. Deepfaking a presidential address to add an air of authenticity to an alien invasion movie is likely not transformative in the sense of the *Overwatch* videos; we expect presidents to give addresses. Nor is it social commentary. The movie makers would have a difficult time claiming that they intended to opine on Biden, Trump, or Obama's approach to extraterrestrial life.

Using deepfakes to put an actor into a work—or to add scenes with an actor—would likely also violate the right of publicity. As in *OMG Girlz* dolls case, the deepfake would introduce a directly competing product, infringing on what is traditionally licensed.

4. Deepfakes in Medium-Centric Jurisdictions

Medium-centric jurisdictions will face greater challenges here. Though New York recognizes that some video games may be within the ambit of the First Amendment protection, coverage is contingent upon the nature of the video game, as "not every video game constitutes fiction or satire."[227] This logic may be extended to deepfakes, which, like video games, may be required to have a "unique nature" and contain characteristics such as "a story, characters, dialogue and environment," to qualify as a work of art.[228] The problem here is that the elements that make video games fall out of protection

225. *See* Kevin Roose & Sheera Frenkell, *Mark Zuckerberg's Reckoning: 'This Is a Major Trust Issue'*, N.Y. TIMES (Mar. 21, 2018), https://www.nytimes.com/2018/03/21/technology/mark-zuckerberg-q-and-a.html; *see* Arjun Kharpal, *Facebook CEO Mark Zuckerberg's Key Comments On the Data Scandal*, CNBC (Mar. 22, 2018); *see* Ana Alexandre, *Mark Zuckerberg Considers Blockchain Authorization of Data in Recent Interview*, COINTELEGRAPH (Feb. 2019), https://cointelegraph.com/news/mark-zuckerberg-considers-blockchain-authorization-of-data-in-recent-interview.

226. Roose & Frenkel, *supra* note 225.

227. Champion, 64 Misc. 3d at 51.

228. *Id.* at 541.

in New York are precisely the same elements that make movie and television deepfakes especially dangerous.

In the context of video games, New York courts suggest that the existence of a "plot created by game designers" as well as the presence of pre-defined characters may bring a game within the realm of protected speech, whereas games where " the users create the plot, storyline and […] character" enjoy no such status.[229] For example, in *Take Two v. Champion*, decided under New York law, the video game at issue was the first-person player basketball game *NBA2K18*, in which users "play basketball as an avatar in a virtual world."[230] The game involved users controlling certain "playable […] characters" in multiple story modes, including a "MyCAREER" mode in which "the goal of the user is to take their self-created avatar through the process of becoming an National Basketball Association player."[231] Given this user-directed nature of the game's progression, the court dismissed the game's inherent protectability, stating that "a determination the NBA2K18 is protected fiction or satire as a matter of law is untenable."[232] Under New York law, certain games are not recognized as speech inherently by their nature, and thus any appropriated likenesses within them would not qualify for protection, regardless of how transformative they were. Conversely, once a video game is deemed as being within the realm of the Free Speech clause of the First Amendment, it would appear that any use of likeness becomes acceptable, no transformation required.[233]

As far as deepfakes are concerned, whether the deepfake constitutes art, and would thus be deemed protectable may turn on whether the video has whatever qualities or elements of an audiovisual work that the court characterizes as essential to the work's nature as a film. Just as the court refused to view NBA2K18 as art because its user-directed nature rendered it insufficiently plot-driven, so too might the court decline to recognize certain

229. *Id.* at 531.

230. *Id.* at 532.

231. *Id.* at 532–33.

232. *Id.* at 541.

233. Gravano v. Take-Two Interactive Software, Inc., 142 A.D.3d 776, 777, 37 N.Y.S.3d 20, 22 (2016) ("[P]laintiffs' claims should be dismissed because this video game does not fall under the statutory definitions of 'advertising' or 'trade'. . . . [Grand Theft Auto V's] unique story, characters, dialogue, and environment, combined with the player's ability to choose how to proceed in the game, render it a work of fiction and satire."); *see also* Burck, 571 F. Supp. 2d at 457 (noting that parody can be of a hybrid nature and include both artistic expression and commercial promotion); Simeonov, 159 Misc. 2d at 54 ("An artist may make a work of art that includes a recognizable likeness of a person without her or his written consent and sell at least a limited number of copies thereof without violating Civil Rights Law sections 50 and 51.").

deepfakes as "works of fiction," despite them being inventive. For example, consider the popular "Deepfake Roundtable," featuring the likes of Tom Cruise, George Lucas, and Ewan McGregor, who have convened to discuss the relative merits of different streaming platforms, the inspiration behind some of their most famous works, and their smartphone applications of choice.[234] While the video expertly captures the dynamic nature of a group conversation, it also reconstructs the chaos, non-sequiturs, and tangential ramblings that are intrinsic to such multi-party discussions. Just as the *Champion* court concluded that the lack of a pre-constructed game-play narrative was enough to remove the game from the purview of fiction,[235] a court might find the confab devoid of the type of plot arc expected of fictional cinematic works. Conversely, a deepfake like the Trump *Breaking Bad* clip, in which Trump's character advises his hapless drug dealer client to purchase a nail salon for use as a front in a money-laundering operation, has a more clearly delineated story, developed characters, and takes place in the distinct setting of a nail salon.[236]

Core entertainment uses, such as replacing actors in movies and creating fake scenes involving real people, are literary works in a way that video games are not. They have plots and character arcs. In a medium-centric jurisdiction, real people can quite possibly be deepfaked into movies and TV shows. There is limited guidance from New York courts on this question, with most relevant opinions coming from lower courts in that jurisdiction. The logic of the above cases indicates that such deepfaking should be permitted so long as the movies are works of art. We, therefore, may have an outcome-determinative split between jurisdictions. In the 9th Circuit, such uses are very likely not protected speech. In New York, they very well might be protected.

IV. PROPOSAL FOR NEW RIGHT OF PUBLICITY SCHEME AS APPLIED TO DEEPFAKES

Currently there is no systematic legal framework to address deepfakes or provide redress to individuals suffering reputational or commercial harms as a

234. Collider Video, *Deepfake Roundtable with George Lucas, Tom Cruise, Robert Downey Jr. and More,* COLLIDER (Nov. 14, 2019), https://collider.com/deepfake-roundtable-george-lucas-tom-cruise-robert-downey-jr/.

235. Champion v. Take Two, 64 Misc. 3d at 540–41.

236. *Better Call Trump: Money Laundering 101[Deepfake]*, YOUTUBE (Sept. 18, 2019), https://www.youtube.com/watch?v=Ho9h0ouemWQ.

result of their creation and dissemination.[237] Some states have recognized the unique character of deepfakes and incorporated special provisions surrounding their use into their right of publicity and privacy laws. In most cases, however, the laws are cabined to address the use of deepfakes in specific contexts. New York makes deepfake creation actionable in cases where the deepfake is either a "digital replica" of a "deceased personality"[238] or constitutes nonconsensual pornography.[239] Other states, including California and Texas, have introduced laws barring the creation or distribution of a deepfake with the intent to harm a political candidate within a limited period prior to an election.[240] In 2023, Illinois enacted a law that allows civil actions against distributors of unauthorized pornographic deepfakes.[241] It then enacted a pair of laws regulating commercial use of deepfakes in 2024.[242]

While right of publicity law has been invoked as one possible avenue for pursuing claims against deepfake creators,[243] there is substantial uncertainty on several key questions. Two demand attention. First, does a broad grant of publicity rights automatically include deepfakes? This is a question of special importance as many actors who are famous now—or will become famous in the next few decades—signed such releases prior to the advent of deepfakes. Second, how are we to draw the line demarcating expressive uses? Some use of public figures should be allowed, even in commercialized works. It would be truly strange to say that an actor could not play former President Obama in a movie about his own life. But does that also imply that it should be permissible to deepfake Obama for that purpose?

We propose addressing these concerns by characterizing deepfake creation as a special type of use of likeness. Specifically, we propose both requiring explicit and detailed consent to acquire license rights by contract and a more

237. Robert C. Post & Jennifer E. Rothman, *The First Amendment And The Right(s) Of Publicity*, 130 YALE L.J. 89, 127–28 (2020); Carolyn Pepper, Peter Raymond, Jonathan Andrews, & Talia Fiano, *Reputation Management and the Growing Threat of Deepfakes*, BLOOMBERG LAW (July 9, 2021), https://news.bloomberglaw.com/us-law-week/reputation-management-and-the-growing-threat-of-deepfakes.

238. Clark, *supra* note 112.

239. N.Y. CIV. CODE § 52-c(1)(a).

240. Clark, *supra* note 112.

241. ILL. PUB. ACT 103–0294, https://www.ilga.gov/legislation/publicacts/fulltext.asp?Name=103-0294. To be codified at 720 ILL. COMP. STAT. 5/11-23.5.

242. *See infra* note 290 on licensing; *see infra* note 310 on entertainment uses.

243. Pepper et. al., *supra* note 237.

limited scope of permissible expressive uses. By drawing a distinction between deepfakes and other uses of likeness, contracting parties will have to seek separate licenses to create a deepfake, allowing individuals to retain more control. And by holding expressive uses of deepfakes to a higher standard to receive First Amendment protection, deepfake creators would need to exercise greater care in their representations should they choose to create and publish deepfakes, thus militating against the most dangerous dignitary harms that deepfakes pose.

A. COMMERCIAL USES—A REVISED LICENSING SCHEME

To avoid running afoul of right of publicity laws, those hoping to use a celebrity's likeness in a commercial context typically seek a license from the individual depicted.[244] The scope of such licenses varies tremendously, and previously entertainers (and their lawyers) did not have significant occasion to consider whether deepfakes fall within the suite of rights such licenses may grant.

Right of publicity clauses embedded within a performance contract can be extraordinarily broad. Consider several university examples. Pennsylvania State University's license form for speakers and presenters affirmatively grants to the university "irrevocable, world-wide, royalty-free right and license" to "adapt, modify, reproduce, distribute, publicly perform, and display" "photographs, video, and/or audio."[245] Stanford's equivalent form grants simply "permission to use my name, likeness and biographic information and the Materials to use, promote or exploit the Recording or any derivative work of the Recording."[246] One of Yale's speaker release forms grants Yale the "right to copy, reproduce, photograph, distribute, transmit, broadcast, exhibit, transcribe, digitize, display, copyright, license, transfer, reproduce, translate, edit or otherwise use perpetually throughout the world in all media now existing and hereinafter developed all or a portion of the recording of such Performance and my name and biographical information, for educational,

244. *Publicity Rights: Artists vs. Celebrities*, LICENSE GLOBAL (2018), https://www.licenseglobal.com/reports/publicity-rights-artists-vs-celebrities.

245. *Consent, License And Release Agreement*, *supra* note 35.

246. *Release for Speakers/Presenters/Performers*, STANFORD UNIV., https://ucomm.stanford.edu/wp-content/uploads/sites/15/2021/10/speakerrelease_final.pdf.

promotional or other purposes that support Yale's mission." [247] It also expressly releases Yale "from any claims arising from the use of the Performance including any claims that Yale has defamed me, invaded my privacy, or infringed my moral rights, rights of publicity or copyright."[248] What is a deepfake, but a derivative or edited work? An adaptation? Courts have proven to honor such sweeping grants pertaining to the specific types of likeness covered, interpreting affirmative grants to use a party's likeness "without limitation" to indeed be limitless.[249]

Provisions pertaining to particular uses of likeness and assignment and sub-licensing of publicity rights can be equally extreme, with agreements requiring parties to authorize uses of likeness for "promotional, educational, informational, advertising or commercial materials and communications in any form now known or later developed" "in the Media for all Materials or any other purposes deemed appropriate." [250] Such language gives licensing agreements vast reach, frequently resulting in bewilderment on the part of the individual contracting, who may discover they have unwittingly granted consent to be depicted in a video game after signing what was ostensibly a sports contract.[251]

Yet granting the right to create and use a deepfake may have far greater implications than licensing the right to use other forms of likeness. To recognize it as such, courts ought to construe the grant of license to create a deepfake as separate from any other type of waiver. Much like the right to sub-license or assign a right of publicity, courts ought to construe entertainment contracts as prohibiting use of a form of likeness, absent a specific provision. Further, where the right is granted, the grant ought to presumptively extend to a single use, absent language specifically naming and describing a particular set of uses. Even "unlimited" grants ought to be subject to a limitation period,

247. *Speaker's Permissions Form*, YALE UNIV., https://celebratewomen.yale.edu/sites/default/files/files/Yale-Speakers-Permission-Form.pdf.

248. *Id.*

249. Neal v. Elec. Arts, Inc., 374 F. Supp. 2d at 577–79 (allowing use of college football player's likeness in a video game based on the player's contract with the sports league, assigning "to the NFLPA and its licensing affiliates, if any, the exclusive right to use and to grant to persons, firms or corporations (collectively 'licensees') the right to use his name, signature facsimile, voice, picture, photograph, likeness, and/or biographical information (collectively 'image') in group licensing programs").

250. *Consent, License And Release Agreement*, *supra* note 35.

251. Neal, 374 F. Supp. 2d 574.

such as the seven-year limitation that applies to personal service contracts in California's entertainment industry.[252]

Requiring such specificity would be consistent with the provisions of the 2023 Screen Actors Guild contract.[253] The contract requires fresh consent to reuse a person's likeness in a new motion picture unless "a reasonably specific description of the intended use is provided for each identified project" is included in the initial license.

Courts have already proven willing to stretch the doctrinal limits of right of publicity law in cases where appropriations of likeness pose an existential threat to one's livelihood. In the only right of publicity case to reach the Supreme Court, it held that such threats were special and worthy of additional protection.[254] It held that a news report of a human cannonball act that showed the entire short act could give rise to liability even though the report was both newsworthy and brief.[255] Given deepfakes' potential to significantly impinge upon opportunities for performers to generate income, these unique forms of likeness ought to be viewed with the same scrutiny, including in contexts where uses of likeness might otherwise be authorized, such as when the right to use of likeness is licensed in performance contracts and entertainment agreements.

1. Limitations of Existing Licensing Scheme

Publicity rights have been construed as being alienable since their inception, with individuals having the right and power to contract around the right to use their likeness.[256] Waivers of publicity rights already feature prominently in film and media contracts, and "use of likeness" is heavily

252. CAL. LAB. CODE § 2855(a).

253. *See* SAG-AFTRA, *supra* note 208 at 2.

254. *See* Zacchini v. Scripps-Howard Broad. Co., 433 U.S. 562, 575 (1977) (holding that the First Amendment did not block a right of publicity action brought by an entertainer performing a "human cannonball" since "[t]he broadcast of a film of petitioner's entire act poses a substantial threat to the economic value of that performance").

255. *See id.* at 574–75 (finding what might otherwise be a wholly protected "newsworthy" use—a television broadcast of man shooting himself from a cannon—to be an "unlawful appropriation" of the Plaintiff's identity, because, despite being a matter of legitimate public interest the media might otherwise be free to report on, the cannon-ball performance constituted plaintiff's "entire act," which, given its availability on television, the public would be less willing to pay to see the live, depriving the plaintiff of the "economic benefit of cultivating his own talent").

256. *See Haelan Labs*, 202 F.2d at 868.

negotiated.[257] Currently, as used in such agreements, performers would likely presume the term "likeness" to have its traditional meaning, entailing the use of photograph, video, voice, or, perhaps, an impersonation or non-literal recreation.[258] In the deepfake era, however, "use of likeness" may be interpreted to include an additional use that has not been contemplated by performers, namely, the freedom for rightsholders to create and use digital reconstructions of performers without additional consent.[259]

Because liability regarding infringement upon one's right of publicity is found only when rightsholders have exceeded the scope of their license to use a likeness,[260] parties receiving broad waivers regarding "use of likeness" have significant leeway regarding depictions of the contracting individual. For example, one court found that a football player's "NFL Player's Contract" granting the "exclusive right to use and to grant to persons, firms or corporations (collectively "licensees") the right to use his name, signature, facsimile, voice, picture, photograph, likeness and/or biographical information" was sufficient to defeat right of publicity claims arising from his subsequent depiction in a video game licensed by the NFL.[261] Such sweeping grants to use of likeness come standard in media contracts, meaning that companies—as well as any parties those companies contract with[262]—have vast ownership rights over performers' likenesses.[263]

257. *See* Lalla, Mitrani & Harned, *supra* note 11. Sample right of publicity clauses include sweeping language, granting producers the right to "unrestricted, worldwide, royalty-free right to use, reproduce, publish and otherwise distribute your name, photograph, video presence, personal story and/or likeness," and "use Narrator's name, likeness, and biographical information, within reasonable commercial standards and in good taste." Right of Publicity *Sample Clauses*, Law Insider.

258. *See* Lalla, Mitrani & Harned, *supra* note 11 (saying that "it is unlikely that talent releases or agreements generally contemplate the right to use likeness rights as a wrapper to generate a potentially infinite number of lifelike deepfakes.").

259. *See* Lalla, Mitrani & Harned, *supra* note 11.

260. Miller v. Glenn Miller Prods., 318 F. Supp. 2d 923, 939 (finding that defendant's sub-licensing the use of deceased musician's name exceeded the scope of their licensing agreement regarding permitted uses of likeness, and was thus infringement of right of publicity).

261. *Neal*, 374 F. Supp. 2d at 577–79.

262. Delaney v. Newsday, Inc., 1991 WL 95125 (1991), at *2 (concluding that when a release is sufficiently broad, it can apply to "any persons acting with the permission" of the licensee, or third party for whom a licensee "might be acting" indicating virtually limitless scope for purposes of use).

263. *See* Marks, *supra* note 26.

The monetary losses to performers as the result of such expansive ownership rights could be staggering. Assuming broad right of publicity grants have been given to studios by virtue of signing an entertainment contract, studios would "own" the performances of actors—and all of their derivatives. Entire films and television series could be updated as "reboots" without replacing cast members, or, alternatively, a single cast member could be swapped out and replaced, perhaps in light of a scandal or dispute that tainted a single actor.[264] This would not require the use of motion capture suits or similar bits of physical technology; software alone could make a stunt double pass for the real thing. Given the extraordinary salaries that actors are offered to reprise roles in reboots and spinoffs, the loss of such opportunities to deepfakes represents massive economic losses.[265] Thus far, however, the issue has only just now been recognized by the media industry and has yet to be systematically addressed by state legislatures.[266]

Consider again Bruce Willis' commercial.[267] Willis was savvy and created a narrow agreement, ensuring he granted the company the right to reconstruct his "digital twin" for the limited purpose of a single advertisement only.[268] But because there is currently no system in place to ensure footage, including any consensually created deepfakes, will not be abused or exploited, contracting parties are left "flailing about," trying to protect their economic and reputational interests.[269] Actors unions have already warned about the potential for "actors' bodies, voices, and personalities" to be "lifted from their screen work and manipulated into footage they do not approve of and don't get any compensation for."[270] Lawsuits have also been filed regarding the reputational damage wrought by deepfakes.[271]

264. *See* Hood, *supra* note 10.

265. *See* Jason Pham, *And Just Like That Cast Salary: The Highest-Paid Cast Member Isn't the Same as SATC*, STYLE CASTER (June 23, 2023), https://stylecaster.com/entertainment/tv-movies/1241011/and-just-like-that-salaries/.

266. *See* Marks, *supra* note 26. New York is a notable exception, and the only state whose right of publicity laws specifically addresses deepfakes outside the context of either nonconsensual pornography, or election-tampering.

267. Sharf, *supra* note 14.

268. *Id.*

269. Hao, *supra* note 23.

270. Marks, *supra* note 26.

271. *See* Pepper et. al., *supra* note 237.

Current trends surrounding contracting—both procedural and substantive—leave performers especially vulnerable to this type of exploitation. Contracting has become a precarious affair, as terms and provisions are increasingly less personalized,[272] and parties are increasingly less inclined to carefully read and asses them.[273] Contract scholars have pointed out that with the rise of the internet, contracting parties—particularly those with enhanced bargaining power—have increased access to cheap, boilerplate contracts that include disproportionately favorable provisions.[274] Indeed, free, open-source resources offer sample right of publicity clauses that can be easily incorporated into more comprehensive entertainment contracts.[275] These clauses are almost laughably broad, including language like right to use likeness "in all media, whether now known or hereafter devised" and "in all forms including, without limitation, digitized images or video, throughout the universe in perpetuity."[276] While such clauses appear hyperbolic, they in fact do appear in real consent agreements and liability waivers, such as the university ones cited above.[277] The ubiquity of such provisions creates a normative force regarding performers and entertainers' expectations when contracting, eroding entertainers' bargaining power, such that they grant far more valuable rights than what they are ostensibly contracting for.[278]

Courts have generally enforced broadly written right of publicity licenses, even ones granting assignability of the right, broad uses of the likeness itself, and waivers of dignitary rights associated with such uses.[279] This is particularly concerning in the deepfake era, as releases from ancillary claims that might otherwise be invoked to combat the creation and dissemination of particularly

272. *See* David Hoffman, *Defeating the Empire of Forms*, 109 VIR. L. REV. 1367, 1382 (2023) (discussing the increasing prevalence of boilerplate contracts pulled from open-source online resources).

273. *Id.* at 1379–86.

274. *Id.*

275. *See Right of Publicity Sample Clauses*, LAW INSIDER, https://www.lawinsider.com/clause/right-of-publicity.

276. *Id.*

277. *Consent, License And Release Agreement*, PENN STATE UNIV. (2023); *Speaker's Permissions Form*, YALE UNIV., https://celebratewomen.yale.edu/sites/default/files/files/Yale-Speakers-Permission-Form.pdf.

278. *See* Hoffman, *supra* note 272 at 16.

279. Krupnick v. NBC Universal, Inc., 2010 WL 9013658 (SC NYC 2010) at *4, 5. *Neal*, 374 F. Supp. 2d at 579.

offensive unauthorized deepfakes, including invasion of privacy or libel, have been honored by courts as sufficient to avoid liability.[280]

2. Proposal for Separate "Deepfake License"

While savvy performers may certainly address the production and use of deepfakes, and establish precise parameters regarding such uses,[281] greater protection is warranted to protect less sophisticated parties because of the power and versatility of deepfakes. Rather than assuming deepfakes are encompassed within a "use of likeness" clause unless otherwise stated or separately addressed, there ought to be a default assumption that the right to digitally reconstruct and use a performer's likeness is inherently outside the scope of "use of likeness" clauses, and instead requires a separately negotiated provision.

Under this scheme, deepfake rights may be granted only as a specific form of license, separately negotiated from the traditional suite of right of publicity rights. This license should speak specifically about "digital replicas," "deepfakes," or similar, and not stretch terms like "adaptation," "derivative work," or "image" to include these new types of uses. In the absence of such a license, nearly any creation or use of a deepfake in a commercial context may be considered a *per se* infringement of right of publicity. While studios may have many legitimate reasons to wish to create deepfakes, for example, in the interest of streamlining editing, or even reconstructing a younger version of the actor for a given role, contracting parties will be forced to negotiate the parameters of permitted deepfake uses.[282] This would be similar to the contractual riders created for actors and actresses who are asked to do nude scenes.[283]

Such a proposal is in keeping with courts' current approach regarding certain facets of right of publicity licensing. Where contracts are completely silent regarding the nature of the likeness that may be created and the scope of

280. *Krupnick* at *4, 5.

281. Lalla, Mitrani & Harned, *supra* note 11; SAG-AFTRA, *supra* note 208 at 2.

282. Lalla, Mitrani & Harned, *supra* note 11.

283. *See, e.g.*, Gordon Firemark, *Nudity Riders – What They Are, Why You Need Them*, FIREMARK (Nov. 2, 2015), https://firemark.com/2015/11/02/nudityrider/; Anthony Ferranti, *Everything You Ever Wanted to Know about Nudity Clauses but Were too Shy to Ask*, FILM INDEP. (Aug. 18, 2017), https://www.filmindependent.org/blog/everything-you-ever-wanted-to-know-about-nudity-clauses-but-were-too-shy-to-ask/.

its use, courts are reluctant to impute any specific authorization on the part of a plaintiff.[284] For example, courts draw a distinction between a plaintiff's grant of consent for the purposes of having likeness reproduced, and their authorization regarding the distribution or sale of such reproductions or representations. [285] Similarly, absent explicit provisions pertaining to a licensee's right to assign granted publicity rights, courts typically construe agreements as precluding such transfers and sublicenses.[286] Finally, courts are likewise wary of exclusive licenses, and require exclusivity grants to be express and unqualified before granting a licensee party standing to challenge a third-party's use of the contracting individual's likeness as infringing upon their contracted-for right of publicity.[287]

Conveniently, these heightened standards could be implemented through common law alone, as courts appear not to have had occasion to consider whether the creation or use of a deepfake was covered by a publicity rights waiver. While courts have concluded that use of likeness in video games—which involves an imitation of likeness using CGI technology—is included within broad grants of the right to use "likeness,"[288] the creation of an AI-generated deepfake is different in-kind.[289] So courts already have tools to construe right of publicity clauses in media, entertainment, sports, and other performance contracts to inherently exclude the right to create deepfakes, absent explicit waiver.

In addition to implementing this in the common law, statutes could achieve the same result. A simple addition to a right of publicity statute could add this term under transferability: "A written transfer of publicity rights—or a waiver of publicity claims—shall not be read to license the creation of

284. Brinkley v. Casablancas, 438 N.Y.S.2d 1004, 1008–09 (1981).

285. *Id.* at 1008–09 (drawing a distinction between a model's legitimate grant of approval regarding participation in a "poster project," and lack of consent regarding the ensuing distribution of the photos that resulted as the final product.).

286. *See*, *e.g.*, HBC Ventures, LLC v. Holt MD Consulting, Inc., 2011 WL 13233177, at *18 (finding against the right to grant a sublicense to use an author's likeness in the marketing and promotion of book, as "one must have express permission to sublicense intellectual property rights such as trademark and the right to publicity."); Shamsky v. Garan, Inc.,167 Misc. 2d 149 (N.Y. Sup. Ct. 1995) (finding that grant of authorization to major league baseball team regarding the use of players' photos did not extend to team's sub-licensing of the image to a commercial clothing company).

287. Fighters Inc. v. Elec. Arts Inc., 2009 WL 10699504 (C.D. Cal.), at *6.

288. *See supra* Part II.

289. *See supra* Part IV.

realistic digital replicas unless the transfer specifically mentions digital replicas, deepfakes, or similar term." Digital replica could be defined as "a computer-generated representation of speech or conduct that has been materially manipulated or altered to falsely appear to a reasonable person to be an authentic record of an act, a statement, or the conduct." This would include, for example, anything that appeared to be a live video of George Clooney doing something. It would not, however, include a digital George Clooney avatar playing professional football as part of a video game—that would not falsely appear to a reasonable person to be an authentic record. Further, it would not include a cartoon of George Clooney, a comic of George Clooney, or a doll of George Clooney. Those would all be handled as before.

Such a scheme may have exceptions, including in cases of "de minimis" uses. For example, a license that permits dubbing into a foreign language may also be fairly read to allow deepfakes to be used to match the performer's lips to the already-authorized new dialogue. But such editing should not be used to create entirely new dialogue or scenes without the consent of the depicted individual. And that consent may be freely granted in many cases regardless. Given the choice between allowing deepfake editing for a scene or reshooting it, the actor may be quite happy to forgo the extra hours in the makeup chair.

The state of Illinois enacted a law in the summer of 2024 that would do much of this reform work. It creates a new provision on "unenforceable agreements" that would hold contrary to public policy any contract provision that "allows for the creation and use of a digital replica of the individual's voice or likeness in place of work the individual would otherwise have performed in person" if the provision does not "include a reasonably specific description of the intended uses of the digital replica" unless the individual was represented by counsel or a union who negotiated the digital replica provision.[290]

B. EXPRESSIVE USES—HEIGHTENED STANDARDS FOR FIRST AMENDMENT PROTECTION

In cases where permission is required, the major question for the law is the scope of the license. But where is permission required? Can a studio deepfake a public figure into a cameo appearance even without permission? This returns us to the issue of expressive uses. Many of the kinds of deepfakes considered

290. Digital Voice and Likeness Protection Act Public Act 103-0830, ILL. GEN. ASSEMBLY, https://www.ilga.gov/legislation/publicacts/fulltext.asp?Name=103-0830&GA=103.

here—TV shows, movies, commissioned digital videos—are potentially expressive.

In jurisdictions applying the transformative use test, whether a would-be infringing use may receive this protection is conditioned upon whether the work adds "significant creative elements so as to be transformed into something more than a mere celebrity likeness or imitation."[291] Such a standard reflects a compromise between society's interest in freedom of expression and dissemination of information, and an individual's right to control the uses of their identity and benefit from the exploitation of their persona.[292] In jurisdictions that take a more medium-centric approach, uses in certain expressive works fall entirely outside of the types of uses in trade and advertising that are subject to liability.[293] Such an exemption is an attempt to strike a "careful balance of a person's right to privacy against the public's right to a free flow of ideas."[294]

Unfortunately, the current right of publicity framework is constructed in a manner that unintentionally incentivizes the production of deepfakes over other types of appropriations of likeness. The existing articulation of the transformative use test, which grants protection where "a celebrity's likeness is so transformed that it has become primarily the defendant's own expression," means that many deepfakes may clear the transformative use threshold.[295] Because deepfakes inherently transform the source material and lend themselves especially well to use in artistic expression, satire and social commentary, existing approaches actually award their creators *greater* protection than creators who employ other uses of likeness, despite their significantly greater capacity to harm the individuals they depict.

The outcome is even bleaker in jurisdictions such as New York, which instead rely on sweeping categorical exemptions from liability for infringement for appropriations of likeness in the context of art and satire.[296] Because New York courts have cleared nonconsensual uses of likeness in film and television as being non-implicative of "use for advertising and trade," a production

291. *Comedy III*, 21 P.3d at 799.
292. *No Doubt*, 192 Cal. App. 4th at 1029–31.
293. *Dryer*, 55 F. Supp. 3d at 1188.
294. *Foster*, 7 N.Y.S.3d at 104.
295. *Comedy III*, 21 P.3d at 809.
296. *Dryer*, 55 F. Supp. 3d at 1197–99; *Simeonov*, 159 Misc. 2d at 59–60.

company could very plausibly substitute a deepfake for a live actor with no liability.[297] Additionally, because uses in "satire and parody" are similarly exempted, an argument could be made in favor of the majority of deepfakes that their content is intended to lampoon, and thus may be characterized as protected social commentary.[298]

Such misalignment calls for a re-evaluation of how deepfakes are approached and underscores the need for developing a more rigorous approach for this special type of use of likeness. For transformative use jurisdictions, this may take the form of a revised transformative use test addressing whether the deepfake is so overwhelmingly transformative as to offset the risk that the deepfake may be construed as an actual representation of the individual or substantially undermine their economic interests. In medium-centric jurisdictions, it may look like passing laws similar to New York's posthumous right of publicity statute, prohibiting uses of digital replicas in contexts where the public is likely to be deceived. By establishing such a standard, the law can ameliorate the risk deepfakes pose to an individual's economic and reputational interests, while still preserving the public's right to engage with this form of creative expression.

1. Revising the Transformative Use Test

For transformative use jurisdictions, re-tooling the law's approach to deepfakes may be as simple as re-defining the standard by which transformativeness is assessed. In its current form, the transformative use test is primarily content-focused, emphasizing the degree to which the content was the creator's own expression versus a mere capitalization on the identity of another.[299] This may be a helpful inquiry in most contexts of appropriation of likeness, which entail exploiting "literal depiction or imitation of a celebrity for commercial gain . . . without adding significant expression" such that the works become "likely to interfere with the economic interest protected by the right of publicity."[300] Such an assumption is based on the premise that transformative elements widen the gap between how the depicted individual may present themselves and their representation in the challenged work,

297. Sondik v. Kimmel, 131 A.D.3d 1041, 1042 (N.Y. 2015).

298. *See* Sam Gregory & Katerina Cizek, *Just Joking, Deepfakes, Satire and the Politics of Synthetic Media*, MIT (2023).

299. Post & Rothman, *supra* note 237 at 129.

300. *Comedy III*, 21 P.3d at 808.

making that representation less threatening.[301] Unfortunately, in the case of deepfakes, these assumptions are simply not correct. For example, if deepfakes' greatest commercial threat to actors is their potential to eliminate the need for the actor themselves, ensuring that deepfakes add adequate "creative expression" around the depictions of the actor does nothing to mitigate this harm. In fact, adding "additional creative expression" to the depiction of an actor is inherent to the process of filmmaking. Facilitating the addition of such creative expression is precisely what the actor is being compensated for.

Rather than scrutinizing the added original expressive content, in cases involving deepfakes, it is more useful to examine how the work will be perceived by the viewer and its effect on the economic interests of the person depicted. The effect on the viewer portion of this inquiry would turn on whether the deepfake subject was depicted in a manner that would suggest to the viewer either that (1) the video is genuine, rather than generated, or (2) the video was authorized, rather than made without permission. The second portion of the inquiry would consider whether the use in question is one for which people would normally be paid.

Let us consider the viewer perception portion first. Imagine a TikTok creator famous for deepfakes produces a mashup of *Seinfeld* and *Pulp Fiction*, in which Jerry Seinfeld is recast in an iconic scene in which he unsuccessfully attempts to ward off the film's two hitmen protagonists, portrayed by John Travolta and Samuel L. Jackson.[302] The banal travails of the middle-aged Manhattanites in *Seinfeld* never entailed Jerry flailing a revolver,[303] and the comedian himself has expressed a personal distaste for violence and violent behavior,[304] making the representation immediately appear somewhat fake.

301. *Id.*

302. DesiFakes, *Jerry Seinfeld in Pulp Fiction [Deepfake]*, YOUTUBE (Feb. 6, 2022), https://www.youtube.com/watch?v=S1MBVXkQbWU.

303. While an episode of *Seinfeld* does address Jerry's apartment getting robbed, it does not involve any type of confrontation between Jerry and the invaders, who snuck in through an open door. *Seinfeld: The Robbery* (NBC television broadcast June 7, 1990).

304. Matt McGloin, *Jerry Seinfeld Thought Man Of Steel Had Too Much Violence,* COSMIC BOOK NEWS (Jan. 6, 2014), https://cosmicbook.news/jerry-seinfeld-thought-man-steel-had-too-much-violence.

But actors routinely engage with vastly divergent types of roles.[305] One would therefore need to look to the video's context. Seinfeld is an established character being injected into a single highly recognizable scene from *Pulp Fiction*, [306] which is well-known and widely regarded as a cinematic masterpiece.[307] And the video is being displayed on a channel where one would not expect authorized works. No reasonable person would assume that Seinfeld has agreed to such a role or to hold him reputationally responsible for it. The use would then seem substantially transformative.

Imagine instead that a movie studio wishes to create a novel action movie. As before, they decide to cast a deepfake of Jerry Seinfeld in a role. Here, we have a vastly different set of circumstances. Movie studios generally produce real and authorized content, and this work is not spoofing a well-known and well-established cultural icon with a single minor change; it is doing something entirely new. Normally this "entirely new" aspect would help the transformativeness of the work, but here it should not. We expect live actors to create entirely new content. The novelty of the work is precisely why we would think it was real or authorized. It would now be the kind of work that would be incorporated into the broader "Seinfeld" image.

These two examples underscore the economic interest point. In the case of the TikTok video, the economic effect on Jerry Seinfeld is likely zero. It is arguably even slightly positive, as it might raise his profile among TikTok users who are too young to readily recall his signature show's decade-long run. A Coasian bargain[308] between Seinfeld and the creator would result in either a nominal fee or no fee at all. In the case of the new action movie, however, things would be very different. Seinfeld is an award-winning performer with numerous TV and movie appearances. He is normally well-compensated for such work, and it would cause him serious economic damage to be so completely replaced, as in *Zacchini's* human cannonball.

305. *See* Johnny Brayson, *24 Actors & The 2 Most Extremely Different Roles They've Ever Played*, BUSTLE (Sept. 17, 2019), https://www.bustle.com/p/24-actors-the-2-most-extremely-different-roles-theyve-ever-played-18741414.

306. Ben Sherlock, *10 Best Pulp Fiction Scenes that Fans Still Think About Today*, SCREENRANT (May 8, 2021), https://screenrant.com/most-memorable-scenes-pulp-fiction/.

307. Tom Brook, *Pulp Fiction at 20: How a Phenomenon Was Born*, BBC CULTURE (May 13, 2014), https://www.bbc.com/culture/article/20140514-how-pulp-fiction-shook-up-film.

308. A bargain which assumes low to no transaction costs.

2. New Statutory Provisions

In addition to asking courts to adopt a different test in the First Amendment context, a statutory solution is also necessary in some states. Consider Illinois' Right of Publicity Act, which – up until 2024 – included an exception to liability for the "use of an individual's identity in an attempt to portray, describe, or impersonate that individual in a live performance, a single and original work of fine art, play, book, article, musical work, film, radio, television, or other audio, visual, or audio-visual work."[309] This provision goes beyond the First Amendment in that it appears to simply exempt such works from the right of publicity altogether.

In August of 2024, Illinois amended this exception to not apply to digital replicas. It defined digital replica as: "a newly created, electronic representation of the voice, image, or likeness of an actual individual created using a computer, algorithm, software, tool, artificial intelligence, or other technology that is fixed in a sound recording or audiovisual work in which that individual did not actually perform or appear, and which a reasonable person would believe is that particular individual's voice, image, or likeness being imitated."[310] Digital replicas can be used without permission under certain circumstances, for instance in a news, public affairs, or sports broadcast, in a political campaign, or for parody, satire, or commentary. But broad exemptions for educational and newsworthy uses, or uses in docudramas, are contingent on not giving a reasonable viewer or listener the false impression that the replica is the genuine article.[311]

Other states could adopt similar provisions. If they do not wish to follow the example of Illinois, they could either prohibit the use of digital replicas outright or otherwise subject their use to the same transformative use standard as transformative use jurisdictions: requiring that no reasonable person would believe it was an actual representation. Courts may then use similar inquiries as invoked by the transformative use test to establish whether the deepfake in question meets this standard.

Such a heightened standard is particularly warranted in the context of deepfakes that might be characterized as satire, commentary, or that may

309. 765 ILL. COMP. STAT. 1075/35(b)(1) (1999).
310. ILL. PUB. ACT 103-0836, to be codified at 765 ILCS 1075/5.
311. *Id.*

otherwise fall under the "public interest" umbrella.[312] Because deepfakes are so realistic, they have the potential to blur the line between satire and misinformation.[313] This creates an added need for people to be clear about what is and is not a deepfake. A depiction of former President Trump being brutalized by the police is only socially valuable political commentary if people know it is intended to be a dramatization rather than a depiction of actual events. Obscuring what is real and fake turns the definition of "newsworthiness" on its head, such that the content becomes a greater and greater threat to shared social reality the more ostensibly "newsworthy" its content.

Consider how this interacts with traditional cameo depictions of political figures. Imagine a film scene in which an actor is depicted meeting the president. The president is shown from the back, and he is plainly a thin black man with short hair. A voice is heard that sounds much like that of former President Obama. Or the wall of a post office is shown, and on that wall is the official portrait of then-President Obama. Both of these uses would conjure the image of the former president, but neither would imply to a reasonable viewer that he had been involved in the movie. A deepfake of Obama that shows his face, speaks with something indistinguishable from his voice, and can interact directly with the actors in the movie conveys a very different impression to the viewer. A reasonable viewer would think the former president had been involved, and that he was perhaps paid a fee. Were the movie something offensive, this false impression could easily damage his reputation. And, notably, this would be entirely permissible, even under the 2023 Screen Actors Guild contract.

3. Implications of a New Approach

Applying this heightened standard, either through the application of a specialized transformative use test or through new legislation, has several benefits. To start, it comports with social expectations and desires regarding the use of deepfakes. The overwhelming majority of individuals support the regulation of deepfakes,[314] and are opposed to even nonpornographic

312. N.Y. CIV. CODE § 50-f(2)(d)(i).

313. Hao, *supra* note 23.

314. Jeffrey Gottfried, *About Three-Quarters of Americans Favor Steps to Restrict Altered Videos and Images*, PEW RESEARCH CENTER (June 14, 2019), https://www.pewresearch.org/short-

deepfakes absent a disclaimer or other clear acknowledgement of their falsehood.[315] Subjecting expressive deepfakes to the heightened standard of no reasonable person believing their veracity may prove more useful than merely requiring such deepfakes to contain a disclaimer or "truth label" regarding their authenticity.[316] First, such disclaimers may be readily overlooked by viewers who have only limited "fast interactions" with content, and may not even notice the label denoting the content as false.[317] Second, given that deepfakes are highly susceptible to being shared and reposted on social media,[318] it is plausible that disclaimers might get lost as the deepfake migrates from one platform to another. Consider how movie and tv show clips are often taken out of context and reposted on TikTok, for instance. Finally, and perhaps most pressingly, many viewers engage with deepfake content because at some level they may want to believe it is genuine, and they thus may be prone to overlooking anything indicating otherwise, including disclaimers. Given such constraints, it is possible that the most effective way to disclaim a deepfake's portrayal would be to embed the disclosure within the deepfake itself, in the form of content that is so clearly distorted that even the most cursory viewer would realize it is not true.[319]

Applying this standard has the collateral benefit of conferring additional protection for private persons that become targets of a deepfake. While private persons are less likely to suffer the same staggering commercial losses as celebrities, the risk of irreparable personal harm in the form of reputational damage and enduring psychological distress is just as profound.[320] The "no reasonable person" standard provides extra protection for private persons because unlike celebrities, who are "known" for particular attributes, private individuals are not widely known for anything at all. Consequently no

reads/2019/06/14/about-three-quarters-of-americans-favor-steps-to-restrict-altered-videos-and-images/.

315. Kugler & Pace, *supra* note 6 at 660.

316. *See* David Elder, *Applicable First Amendment Standards, Privacy Torts* § 4:14 (2022).

317. *Id.*

318. *See* Nicole Brown Chau, "*Emotional Skepticism" Needed to Stop Spread of Deepfakes on Social Media, Expert Says*, CBS NEWS (Nov. 12, 2019), https://www.cbsnews.com/news/deepfakes-on-social-media-users-have-responsibility-not-to-spread-fake-content-expert-says/.

319. Elder, *supra* note 8.

320. *See* Nina Jankowicz, *The Threat From Deepfakes Isn't Hypothetical. Women Feel It Every Day*, WASH. POST (Mar. 25, 2021), https://www.washingtonpost.com/opinions/2021/03/25/threat-deepfakes-isnt-hypothetical-women-feel-it-every-day/.

"reasonable person" could say with any certainty whether a deepfake of a stranger accurately mimics their behavior. This is especially true in the context of the insidious pornographic class of deepfakes, as subjects are depicted engaging in intimate acts to which the public would never be privy. Such a heightened protection for private individuals is appropriate based on the traditional precepts of privacy law, which draw a distinction between private and public figures regarding reasonable expectations of privacy.[321]

Instituting this approach would also, of course, present certain challenges. First, implementing such a revised standard would have the effect of pushing deepfake uses that might otherwise be permissible into the realm of uses requiring a license. For example, certain deepfakes created for purposes of education might pose challenges, particularly where the subject of the deepfake is living, or has only recently died. While a deepfake of Albert Einstein teaching physics would not be problematic,[322] as no reasonable person would believe he has been resurrected, a deepfake of the President of the United States giving a civics lecture might be problematic, as presidents have been known to make classroom visits from time to time.[323]

Second, such a scheme would require certain jurisdictions, like New York, to pass additional legislation regulating deepfakes. Lawmakers are sometimes wary of deepfake regulation, which has been construed as limiting freedom of expression.[324] Recent legislation in Illinois that proposed granting civil recourse to victims of "digital forgeries" faced opposition, with objectors citing First Amendment concerns and fears that protection for works of parody and social commentary would be eroded.[325]

Finally, as of now, many deepfakes are beyond the reach of right of publicity laws in most jurisdictions, as the majority of deepfakes are posted and

321. Elder, *supra* note 316.

322. Ashish Jaiman, *Positive Use Cases of Synthetic Media (aka Deepfakes)*, TOWARDS DATA SCI. (Aug. 14, 2020), https://towardsdatascience.com/positive-use-cases-of-deepfakes-49f510056387.

323. Mike Allen, *Many Presidents Spoke in Schools*, POLITICO (Sept. 7, 2009), https://www.politico.com/story/2009/09/many-presidents-spoke-in-schools-026829.

324. Tiffany Hsu, *As Deepfakes Flourish, Countries Struggle with Response,* N.Y. TIMES (Jan. 22, 2023), https://www.nytimes.com/2023/01/22/business/media/deepfake-regulation-difficulty.html.

325. Patrick M. Keck, *Digital Forgeries Bills Advance out of House, Senate Committees*, STATE JOURNAL-REGISTER (Mar. 9, 2023), https://www.sj-r.com/story/news/politics/state/2023/03/09/bills-allowing-deepfake-victims-to-sue-pass-committee-votes/69968885007/.

shared on social media, rather than commissioned in a commercial sale.[326] While certain right of publicity frameworks such as California's common law cause of action may construe a content creator's reputational benefit as being a sufficient "personal advantage" for purposes of conferring liability, the overwhelming majority of jurisdictions would likely characterize viral social media posts as "noncommercial" and thus outside the scope of a right of publicity cause of action.[327] Addressing such uses would require the application of either defamation law, or criminal laws targeting nonconsensual pornography.

V. CONCLUSION

Right of publicity law has always been informed by the means of appropriation available to would-be infringers. In fact, it is itself a response to the threats posed by increasingly sophisticated modes of invoking another's likeness.[328] Among the theoretical underpinnings of the right of publicity, particularly in the Warren and Brandeis-era privacy-based context, was concern regarding the potential dignitary harms made possible by the burgeoning mass-media industry, and increasing ease by which one could capture an individual's likeness.[329] While Warren and Brandeis may have had concerns regarding the speed with which a snap of a photograph could capture a subject's image relative to sitting for a portrait,[330] the existence of deepfake technology means one's likeness can now be appropriated without the presence or knowledge of a subject at all.

The ability to create deepfakes represents the next quantum leap in the potential to easily appropriate another's likeness in a manner that profoundly undermines both the economic and reputational interests that right of publicity law seeks to protect. Deepfakes are uniquely threatening in the commercial context, as they are veritable substitutes for their subjects. In the reputational context, by nature of their uncanny resemblance to reality, deepfakes threaten to confuse even those closest to the depicted individual, and in doing so

326. For where deepfakes appear, see Jeffery T. Hancock & Jeremy N. Bailenson, *The Social Impact of Deepfakes*, 24 CYBERPSYCHOLOGY, BEHAVIOR AND SOCIAL NETWORKING 149 (2021).

327. *See supra* Part III.

328. Eric Johnson, *Disentangling the Right of Publicity*, NU. L. REV. 891–98 (2017).

329. *Id.* at 898–99.

330. *Id.*

undermine their subjects' capacity for self-definition and autonomy.[331] The new magnitude of personal damage deepfakes may wreak demands the law take a commensurately significant leap in approach.

Right of publicity law must be prepared to confront this peculiar form of likeness, and by doing so, venture toward its next frontier. Indeed, that seems to be the conclusion reached by the actors participating in the AFTRA strike. After a long 118-days, the actors finally won the hard-fought concession requiring studios first obtain actors' consent before using AI-generated images, and then compensate those actors at a rate commensurate with their living performance.[332] Though this contract helps with some of their concerns, it is only a start. The question of how to address recreational use of deepfakes, how to protect people outside of the guild system, and other circumstances in which there was never a contract to begin with remain open. Our proposals, both in common law and new legislation provide answers to these outstanding questions, by imposing more concrete limits on when deepfakes can be construed as transformative art versus when they begin to encroach upon an individual's right to privacy and self-determination.

331. Bernard Marr, *Deepfakes – The Good, The Bad, and The Ugly*, FORBES (Jan. 11, 2022), https://www.forbes.com/sites/bernardmarr/2022/01/11/deepfakes--the-good-the-bad-and-the-ugly.

332. Megan Cerullo, *The SAG-AFTRA Strike Is Over. Here Are 6 Things Actors Got In The New Contract*, CBS NEWS (Nov. 14, 2023).

DANCE OF THE BIOLOGICS

Robin Feldman[†] *& Gideon Schor*[††]

ABSTRACT

From COVID-19 vaccines to cancer treatments, biologic medicines are gaining importance in the U.S. health care system. Their high price tags, however, make these medications difficult for many Americans to afford. The Biosimilars Act, enacted in 2010, aimed to reduce costs and increase access to biologic medications by encouraging follow-on competition. The legislative effort followed in the footsteps of its predecessor, the Hatch-Waxman Act of 1984.

Although the Hatch-Waxman system succeeded in creating a landscape of more affordable and widely used generic drugs, the Biosimilars Act has failed to live up to its promise. Biologic drugs in the United States remain largely unaffordable, and no popular follow-on biologic market, akin to its non-biologic counterpart, has arisen.

Investigating the reasons behind these disappointing results requires an analysis of the inner workings of the Biosimilars Act, but such an analysis is difficult to find. In fact, the system set forth by the Biosimilars Act is so complex that scholarship has largely avoided explaining it. To fill this gap in the literature and examine why the results of the Act have been so underwhelming, this Article explains the following: how the Biosimilars Act works in theory, how the parties are gaming the system, and why neither the theory nor the practice functions effectively. Through strategic tactics, biologic and biosimilar companies alike are ignoring and sidestepping the system.

The causes can be traced to the structure of the Act, itself. Specifically, by giving too much control to the parties involved, the Act enables them to work against society's interests and the legislature's goals. Although these misaligned incentives led to disappointing outcomes, the Article suggests that realigning the system does not require a major overhaul, but rather feasible tweaks. The changes recommended could expand the biologic market, create greater competition with cheaper alternatives, and spur affordable pricing for lifesaving biologic drugs.

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I. INTRODUCTION

In a flurry of last-minute, behind-the-scenes negotiations in 2010, Congress established a historic pathway for the rapid entry of biosimilar medications.[1] The legislation was charmingly known as the BPCIA[2] (which this Article will refer to as the "Biosimilars Act"). The Act was intended to usher in an era of follow-on biologic drugs that would drive prices down for consumers.[3]

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1. In 2007, Senate Health, Education, Labor and Pensions (HELP) Committee members—Senators Edward M. Kennedy, Hillary Clinton, Orrin Hatch, and Mike Enzi—drafted a biosimilars bill, S. 1695, whose language largely parallels that of the later enacted Biosimilars Act. *See* Krista Hessler Carver, Jeffrey Elikan & Erika Lietzan, *An Unofficial Legislative History of the Biologics Price Competition and Innovation Act of 2009*, 65 FOOD & DRUG L.J. 671, 746 (2010). The following year, the Senate HELP committee reported S. 1695, but "[n]o committee report accompanied the reported bill, which was considered unusual." Many commentators, including the trade press, noted the curious timing of this action and speculated correctly that this bill might become a part of a larger healthcare package in the following Congress. *See id.* at 776–77; *see also* JOHN R. THOMAS, CONG. RSCH. SERV., R42890, THE ROLE OF PATENTS AND REGULATORY EXCLUSIVITIES IN PHARMACEUTICAL INNOVATION 8 (2013) (noting that the Biologics Price Competition and Innovation Act of 2009 was enacted as part of the larger Affordable Care Act); Erika F. Lietzan, *Biosimilar Law and Regulation: An Essential Guide*, at 13–14 (Food & Drug L. Inst., FDLI Monograph Ser. Vol. 2, No. 5, 2011), https://papers.ssrn.com/sol3/papers.cfm?abstract_id=2220857 (reporting that the White House was pushing for major changes in the biosimilar provisions of the Affordable Care Act even as the bill cleared both chambers of Congress and headed to conference); Tony Hagen, *AAM Makes a Plea to Save the BPCIA,* CTR. FOR BIOSIMILARS (May 27, 2020), https://www.centerforbiosimilars.com/view/aam-makes-a-plea-to-save-the-bpcia (noting a commentator's view that the Biosimilars Act was attached to the Affordable Care Act at the last moment); Patient Protection and Affordable Care Act, H.R. 3590, 111th Cong. (2009).

2. The Biologics Price Competition and Innovation Act of 2009 was originally proposed as stand-alone legislation. *See* Biologics Price Competition and Innovation Act of 2007, S. 1695, 110th Cong. (2007). However, after revision, the legislation ended up being enacted, without being formally re-introduced, as Subtitle A of Title VII of the Affordable Care Act of 2010. *See* Patient Protection and Affordable Care Act, Pub. L. No. 111–148, tit. VII, subtit. A, §§ 7001–03, 124 Stat. 119, 804–21 (2010) (Biologics Price Competition and Innovation Act of 2009 codified as amended at, *inter alia*, 42 U.S.C. § 262(k), (l), and 35 U.S.C. § 271(e)). For a complete discussion of the many bills and hearings regarding biosimilars that led up to S. 1695 and its development into the enacted legislation, see Carver, Elikan & Lietzan, *supra* note 1, at 716–806.

3. *See, e.g.*, Kasey E. Koballa, Note, *The Biologics Price Competition and Innovation Act: Is A Generic Market for Biologics Attainable*?, 9 WM. & MARY BUS. L. REV. 479, 483 (2018) ("In an effort to reduce the costs of biologics and provide pharmaceutical manufacturers with initiatives to strive continuously for innovation in biological therapies, President Barack

Biologic medicine plays an increasingly important role in this nation's health care system. The field of biologic medicine includes drugs such as Humira (the blockbuster treatment for rheumatoid arthritis), cancer therapeutics, a treatment for Crohn's disease, and the most effective COVID-19 vaccines. In general, the pharmaceutical industry has pivoted sharply towards biologics, particularly cancer therapeutics.[4] For example, oncology drugs constituted the largest number of all the new drugs launched in 2017.[5] Moreover, biologic medicines account for an increasing portion of spending on prescription medicine,[6] constituting 89% of Medicare Part B spending growth from 2008 to 2021.[7]

Thus, encouraging follow-on competition for biologics in a manner that will increase access and reduce prices remains a critical goal in the United States. Rather than heralding the Biosimilars Act's passage as historic, however, industry and commentators reacted with skepticism—some

Obama signed into law the [Biosimilars Act] . . . ."); Letter from Rep. Anna Eshoo et al. to President Barack Obama (Oct. 14, 2011), https://op.bna.com/hl.nsf/r?Open=bdmr-8msjms (noting that the Biosimilars Act was intended to lower the cost of drugs in the United States); Brendan McArdle, *Rumble in the BPCIA: Biologics vs. Biosimilars*, 17 HOUS. J. HEALTH L. & POL'Y 381, 386–88 (2017) (explaining that Congress intended for the Biosimilars Act to reduce prices and increase competition).

4. *See* Denise Roland, *Cancer-Drug Giant Roche Loses Edge as Rivals Grow*, WALL ST. J. (Apr. 28, 2019), https://www.wsj.com/articles/cancer-drug-giant-roche-loses-edge-as-rivals-grow-11556449201; Jared Hopkins, *Pfizer Pivots to Cancer Drugs for Growth*, WALL ST. J. (Jan. 27, 2019), https://www.wsj.com/articles/pfizer-pivots-to-cancer-drugs-for-growth-11548601200; Press Release, Sanofi, Sanofi Delivers 2018 Business EPS Growth of 5.1% at CER (Feb. 7, 2019), http://www.news.sanofi.us/2019-02-07-Sanofi-delivers-2018-business-EPS-growth-of-5-1-at-CER; Press Release, Merck, Merck to Acquire Peloton Therapeutics, Bolstering Oncology Pipeline (May 21, 2019), https://investors.merck.com/news/press-release-details/2019/Merck-to-Acquire-Peloton-Therapeutics-Bolstering-Oncology-Pipeline/default.aspx; Press Release, Novartis, Novartis Successfully Completes Acquisition of Endocyte (Dec. 21, 2018), https://www.novartis.com/news/media-releases/novartis-successfully-completes-acquisition-endocyte; *see also* Robin Feldman, *The Cancer Curse: Regulatory Failure by Success*, 21 COLUM. SCI. & TECH. L. REV. 82, 88–92 (2019) (describing the shift to cancer in terms of spending, research and development, and new drugs approved).

5. IQVIA INST., MEDICINE USE AND SPENDING IN THE U.S.: A REVIEW OF 2017 AND OUTLOOK TO 2022 33–34 (2018) (finding that cancer-related drugs made up the largest share of all new active substances launched in 2017).

6. Andrew Mulcahy, Christine Buttorff, Kenneth Finegold, Zeid El-Kilani, Jon F. Oliver, Stephen Murphy & Amber Jessup, *Projected US Savings from Biosimilars, 2021-2025*, 28 AM. J. MANAGED CARE 329, 329 (2022).

7. Nguyen X. Nguyen, T. Anders Olsen, Steven H. Sheingold & Nancy De Lew, U.S. DEP'T OF HEALTH AND HUM. SERVS., MEDICARE PART B DRUGS: TRENDS IN SPENDING AND UTILIZATION, 2008-2021, 1–2 (2023), https://aspe.hhs.gov/sites/default/files/documents/fb7f647e32d57ce4672320b61a0a1443/aspe-medicare-part-b-drug-pricing.pdf.

doubting that biosimilars would ever emerge as a major force in U.S. pharmaceuticals.[8]

Ten years out, the predictions of total failure have proven untrue. Nevertheless, the Biosimilars Act has failed to live up to its promise. Price reductions have been underwhelming at best, and the United States still lags well behind Europe in the introduction of follow-on biosimilars and in price reductions when those biosimilars enter.[9]

The experience of the first decade of the Biosimilars Act helps explain why the results have been so disappointing. Put simply, the incentives of the system are misaligned. The Act gives too much discretion and control to the involved parties, allowing them to navigate against society's interests and the goals of the legislation itself. The result is a highly constrained market, limited competition, and high prices.

Perhaps one indicator of the problems is the dearth of literature explaining the workings of the Biosimilars Act. The pathway is so complicated that few academics have even dared to tread its byways, let alone offer a detailed explanation of how it works and why it fails. Indeed, in 2015, the Federal Circuit, citing Winston Churchill, compared the Biosimilars Act to "a riddle wrapped in a mystery inside an enigma."[10] Stepping into the terrifying void, this Article explains how the system works in the abstract, how the parties are ignoring or reshaping the system, and why the system does not operate effectively either in the abstract or on the ground. Most important, this Article suggests that nudging the system into alignment does not require a major overhaul, but rather hovers tantalizingly within reach. The general choreography of the patent dance could remain, but in addition, the biosimilars regime could: (1) require that the brand biologic disclose (through the United States Food and Drug Administration (the FDA)) all patents related to a particular drug; and (2) standardize certain steps in the patent dance process.

8. *See, e.g.*, Yaniv Heled, *Follow-on Biologics Are Set Up to Fail*, 2018 U. ILL. L. REV. ONLINE 113, 114-15 (2018) (expressing skepticism about the likelihood of biosimilars becoming competitive in the United States, especially since the Biosimilars Act set up "an Industry-favorable, obstructed pathway for the approval of follow-on biologics"); Jason Kanter & Robin Feldman, *Understanding and Incentivizing Biosimilars*, 64 HASTINGS L.J. 57, 60–70 (2012) (asserting that the Biosimilars Act failed to provide sufficient incentives for biosimilar development); W. Nicholson Price II, *Regulating Secrecy*, 91 WASH. L. REV. 1769, 1798 (2016) (asserting that many brand biologics may never see any biosimilar competition, and even when biosimilars enter the market, the corresponding brand biologic may still remain expensive).

9. *See infra* Section II.D.

10. Sandoz Inc. v. Amgen Inc., 794 F.3d 1347, 1351 n.1 (Fed. Cir. 2015), *vacated in part*, *rev'd in part*, 582 U.S. 1 (2017), *remanded to* 877 F.3d 1315 (Fed. Cir. 2017).

With such changes, the Biosimilars Act, and the patent dance at its center, could create a more effective pathway to competition.

II. BACKGROUND

The most effective governmental systems generally provide incentives that encourage parties to act in alignment with the interests of society, instead of relying on pure altruism. Although the history of this line of logic is well-trodden,[11] it is worth dedicating a few words as a reminder of this path.

Adam Smith, widely deemed the father of modern economics, considered rational self-interest to be the main motivation of individual action and a far more reliable motivation than benevolence or public mindedness.[12] John Maynard Keynes, one of the foremost economists of the twentieth century, explained that government has a key role in directing this private self-interest towards public benefit.[13] For example, Keynes reasoned that it is appropriate for the government, at times, to artificially stimulate consumption or encourage investment, moving private interests into alignment with the public interest through tools such as taxation or interest rates.[14]

Later economic critiques, principally those by Robert Lucas, argued that such policies must be considered in terms of their impact on incentives at the

11. *See infra* notes 12–17 and accompanying text.

12. *See* ADAM SMITH, AN INQUIRY INTO THE NATURE AND CAUSES OF THE WEALTH OF NATIONS (Edwin Cannan ed., The Univ. of Chicago Press 1977) (1799) (Smith's seminal work, presenting the notion of rational self-interest as key to the success of an economy, and arguing that societal interests can be best furthered through the individual exercise of rational self-interest in a free and just economy); BERNARD MANDEVILLE, THE FABLE OF THE BEES: OR, PRIVATE VICES, PUBLICK BENEFITS 23 (Irwin Primer ed., Capricorn Books 1962) (1724) (arguing that what appear to be private vices are necessary to produce public benefits, and that in successful societies, "those very Vices, of every particular Person, by skillful Management, were made subservient to the Grandeur and worldly Happiness of the whole"); *see also* KENNETH J. ARROW & FRANK H. HAHN, GENERAL COMPETITIVE ANALYSIS vi (1971) (explaining that the success of *Wealth of Nations* in Smith's time and beyond led to "a long and fairly imposing line of economists from Adam Smith to the present" arguing for a conception of "economy motivated by self-interest").

13. *See* JOHN MAYNARD KEYNES, GENERAL THEORY OF EMPLOYMENT INTEREST AND MONEY 378 (1936) (referring to the State's "guiding influence on the propensity to consume," including "all manner of compromises and of devices by which public authority will co-operate with private initiative").

14. *Id.* at 377–78. *But see generally* Henry Farrell & John Quiggin, *Consensus, Dissensus, and Economic Ideas: Economic Crisis and the Rise and Fall of Keynesianism*, 61 INT'L STUDS. Q. 269 (2017) (recounting the debate among economists and policymakers about the need for Keynesian stimuli in addressing the 2008 Financial Crisis as well as noting briefly that whether and how Keynesian theory should be applied to economic volatility remains the subject of debate).

individual level, not by using macroeconomic models constructed under previous policies.[15] Though Lucas' emphasis differed from Keynes', Lucas maintained the principle that the government should seek to align private incentives with the interests of society.[16] Subsequent scholars have affirmed that the government, relying on the rational self-interest of market participants, should seek to regulate behavior through economic incentives and disincentives, in addition to legal restrictions.[17]

The goal of the Biosimilars Act is to increase competition and reduce prices, after an initial period of protection for biologic drugs. Following the logic that runs through the works of Smith, Keynes, Lucas, and their successors, the government's actions, as embodied in the Biosimilars Act, should seek to align industry's private incentives with the societal interests reflected in the goals of the Act.[18] If the Act instead leaves room for industry participants to operate against society's goals, incentives are improperly aligned, and the Act runs contrary to the underpinnings of Smith's work and its progeny. The following Section will provide the background for this discussion, describing the Hatch-Waxman system for rapid entry of generic drugs, the passage of the Biosimilars Act, the information desert resulting from the Biosimilars Act, and the disappointing performance of biosimilars in the United States.

A. HATCH-WAXMAN ACT

Enacted in 1984, the Hatch-Waxman Act was a piece of intricate, bipartisan legislation that created an easier approval pathway for generic

15. *See generally* Robert E. Lucas, Jr., *Econometric Policy Evaluation: A Critique*, 1 CARNEGIE-ROCHESTER CONF. SERIES ON PUB. POL'Y 19 (1976) (arguing that large-scale econometric models based on historical data may lead to misleading long-term forecasts as they fail to take into consideration how policy changes may affect the rational choices of individual actors).

16. *See generally id.*; Robert E. Lucas, Jr. & Thomas J. Sargent, *After Keynesian Macroeconomics*, in AFTER THE PHILLIPS CURVE: PERSISTENCE OF HIGH INFLATION AND HIGH UNEMPLOYMENT, at 49 (Fed. Rsrv. Bank Bos., Conf. Ser. No. 19, 1978) (proposing an alternative to Keynesian macro-econometric models but acknowledging that the goal of this model—analogous to the goals of Keynesian macro-econometric models—is to provide policymakers with scientific tools to align private incentives with societal interests).

17. *See, e.g.*, Norman J. Thomson, *Fiscal Incentives for Private Heritage Conservation*, 57 AUSTL. Q. 255 (1985) (describing how the Australian government could provide economic incentives to private citizens to put effort towards conservation of heritage assets, in which the public has an interest); Stephen K. Aikins, *Political Economy of Government Intervention in the Free Market System*, 31 ADMIN. THEORY & PRAXIS 403 (2009) (emphasizing the need for safeguards and controlled government intervention in the market, while acknowledging the importance of such intervention).

18. *See supra* notes 12–17 and accompanying text.

drugs.[19] Hatch-Waxman allows generic manufacturers to submit an "Abbreviated New Drug Application" (ANDA) instead of a "New Drug Application" (NDA) for approval. To qualify, the generic must be bioequivalent to an existing drug[20] with the same active ingredient(s), delivery methods, dosage, strength, labeling information, and indications.[21] Bioequivalence broadly means that there is no significant difference between the generic and the brand in the rate and extent to which the active ingredient(s) are dispersed in the target area.[22] If the generic manufacturer can prove bioequivalence, it can use safety and efficacy data from the brand drug's trials, greatly reducing the time and expense required for market entry.[23] Although generic products can enter the market only after the original drug patent expires, Hatch-Waxman allows generic manufacturers to begin development and start the FDA approval process before the brand patent's expiration. Thus, the generic can be ready to launch soon after the patent expires.[24]

In addition, Hatch-Waxman gave generics a way to resolve intellectual property claims without risking damages and the uncertainties of a jury trial.[25] Prior to Hatch-Waxman, companies wishing to challenge a patent had to enter

19. Drug Price Competition and Patent Term Restoration Act of 1984, Pub. L. No. 98-417, 98 Stat. 1585 (1984).

20. 21 U.S.C. § 355(j)(2)(A)(iv).

21. 21 U.S.C. § 355(j)(2)(A)(i)–(iii), (v); *see* ROBIN FELDMAN & EVAN FRONDORF, DRUG WARS: HOW BIG PHARMA RAISES PRICES AND KEEPS GENERICS OFF THE MARKET 26–27 (2017) (explaining the Hatch-Waxman Act's approval criteria for generic drugs and providing definitions for each criterion). The FDA, however, may grant a waiver allowing deviation from the listed criteria. 21 U.S.C. § 355(j)(2)(C) ("If a person wants to submit an [ANDA] which has a different active ingredient or whose route of administration, dosage form, or strength differ from that of a listed drug, such person shall submit a petition to the Secretary seeking permission to file such an application.").

22. *Orange Book Preface: Preface to the Forty Fourth Edition*, U.S. FOOD & DRUG ADMIN. (Jan. 25, 2024), https://www.fda.gov/drugs/development-approval-process-drugs/orange-book-preface ("Bioequivalence is the absence of a significant difference in the rate and extent to which the active ingredient or active moiety in pharmaceutical equivalents or pharmaceutical alternatives becomes available at the site of drug action when administered at the same molar dose under similar conditions in an appropriately designed study.").

23. FELDMAN & FRONDORF, *supra* note 21, at 28.

24. *Id.*

25. *See* Brian D. Coggio & Sandra A. Bresnick, *The Right to a Jury Trial in Actions Under the Hatch-Waxman Act*, 79 J. PAT. & TRADEMARK OFF. SOC'Y 765, 770-71 (1997); 35 U.S.C. § 271(e)(2), (4).

the market and face infringement litigation.[26] Entering the market meant that the company would become liable for the damages its product caused the brand by virtue of product sales. In contrast, Hatch-Waxman created a system of "artificial infringement" in which the mere action of filing for approval triggers the potential for a specialized infringement action—albeit without damages or a jury trial.[27] The prior pathway remains in place as an alternative. In what is known as "launching at risk," generics could obtain FDA approval, launch the product, forgo Hatch-Waxman's "artificial infringement" option, and invite litigation claims of actual infringement, with all the accompanying risks of damages and a jury trial.[28]

Hatch-Waxman also provides an incentive for generics to challenge improperly granted patents. The first generic to file for approval and successfully challenge a patent as either invalid or not infringed receives a six-month period in which no other generics can enter the market.[29] During the

26. Matthew Makowski, Comment, *Toward a Centralized Hatch-Waxman Venue,* 89 U. CHI. L. REV. 1837, 1838 (2022) (noting that Hatch-Waxman established a statutory scheme allowing the brand and generic to engage in patent infringement suits *before* the generic starts marketing).

27. Makowski, *supra* note 26, at 1845 ("[H]atch-Waxman creates an unusual cause of action for patent infringement that derives solely from a filing with a federal regulatory agency . . . . [T]he Supreme Court has called the Hatch-Waxman patent infringement scheme 'a highly artificial act of infringement that consists of submitting an ANDA.'").

28. For a fuller discussion of launching at risk, see *infra* note 166. Launching at risk has been relatively rare for generics. *See* Xiang Yu & Anjan Chatterji, *Why Brand Pharmaceutical Companies Choose to Pay Generics in Settling Patent Disputes: A Systemic Evaluation of Asymmetric Risks in Litigation*, 10 NW. J. TECH. & INTELL. PROP. 19, 34 (2011).

29. *See* 21 U.S.C. § 355(j)(5)(B)(iv) (describing the 180-day exclusivity period policy for generic drug applicants); *see also id.* § 355(j)(5)(D) (describing the circumstances in which a generic drug applicant forfeits its 180-day exclusivity period). Multiple scholars have discussed the impact of the 180-day, or six-month, exclusivity policy for generics. *See* Gregory H. Jones, Michael A. Carrier, Richard T. Silver & Hagop Kantarjian, *Strategies That Delay or Prevent Timely Availability of Affordable Generic Drugs in the United States*, 127 BLOOD F. 1398, 1399 (2016) (finding that the 180-day exclusivity results in a "short-term reduction in price"); C. Scott Hemphill & Mark A. Lemley, *Earning Exclusivity: Generic Drug Incentives and the Hatch-Waxman Act*, 77 ANTITRUST L.J. 947, 949 (2011) (noting that the 180-day exclusivity policy "is encouraging lots of *challenges* to [weak] patents"); Robin Feldman & Evan Frondorf, *Drug Wars: A New Generation of Generic Pharmaceutical Delay*, 53 HARV. J. ON LEGIS. 499, 508 (2016) (asserting that the six-month "exclusivity period can easily be worth hundreds of millions of dollars to a generic, representing a substantial majority of the potential profits to be gained from generic entry"). Two situations can lead to shared exclusivity for six months: (1) if multiple generics each file an ANDA with a Paragraph IV certification (i.e., a certification that the brand's patent is invalid or non-infringed under 21 U.S.C. § 355(j)(2)(A)(vii)(IV), (5)(B)(iv)(I)) concerning the same patent(s) on the same first day, or (2) if multiple generics each file an ANDA with a Paragraph IV certification for different dosage forms or strengths of the same brand drug. *See* David E. Korn, Erika Lietzan & Shaw W. Scott, *A New History*

six-month period, only the first-filing generic and the brand drug company are allowed on the market.[30]

Although Hatch-Waxman provided an easier and cheaper pathway for generic drugs to enter the market, these advantages did not extend to one category of drug products: biologics. Biologic drugs are produced using organic material and are far more chemically complex than non-biologic drugs.[31] Although non-biologic drugs often are referred to as "small molecule drugs," this Article will refer to the two categories of drugs as biologics and non-biologics, for ease of reading.

Biologic medicines are significantly more complex than their non-biologic counterparts. Although the active ingredients of non-biologic drugs typically consist of a few dozen atoms and can be replicated easily, biologic medicines are produced by using living cells. Among other things, they contain proteins, whole cells, and nucleic acids, each consisting of thousands of atoms. As a result, small variations in the manufacturing process or the host cells can drastically affect the purity, safety, and efficacy of the biologic, and it is highly

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and Discussion of 180-Day Exclusivity, 64 FOOD & DRUG L.J. 335, 342–43 (2009); *see also* Robin Feldman, *The Price Tag of "Pay-for-Delay,"* 23 COLUM. SCI. & TECH. L. REV. 1, 8 n.26 (2021).

30. 21 U.S.C. § 355(j)(5)(B)(iv)(I) ("[I]f the [abbreviated new drug] application contains a certification described in paragraph (2)(A)(vii)(IV) [i.e., a Paragraph IV certification, *see supra* note 29] and is for a drug for which a first applicant has submitted an application containing such a certification, the application shall be made effective on the date that is 180 days after the date of the first commercial marketing of the drug (including the commercial marketing of the listed drug) by any first applicant."). As the law is currently interpreted, the brand company, which has permission to market the drug, can choose to create its own generic version or authorize another company to market a generic version at any time, including during this six-month period. These are known as authorized generics or captive generics, and they can cut into the incentive for a generic company to enter the market. *See* Robin Feldman, *Captive Generics: The Wolf in Sheep's Clothing*, 59 HARV. J. ON LEGIS. 383, 390 (2022) (pinpointing the rise of captive generics with the explanation that "brand companies have addressed the problem of true generics by following the old adage, 'if you can't beat 'em, join 'em'"); *see also generally* Jay Hancock & Sydney Lupkin, *Drugmakers Master Rolling Out Their Own Generics to Stifle Competition*, KAISER HEALTH NEWS (Aug. 5, 2019), https://khn.org/news/ drugmakers-now-masters-at-rolling-out-their-own-generics-to-stifle-competition/ (stating that PDL's authorized generic version of Tekturna was timed to secure the company's benefit of being first to market). The intricate calculus of authorized generics has inspired complex settlement agreements between brands and generic challengers, which may not be in the public interest. *See* Feldman & Frondorf, *supra* note 29, at 523 (analogizing settlements between brands and generics that have no-authorized-generics clauses as similar to a schoolyard bully who takes lunch money in exchange for a promise not to hit kids and defends the action by saying, "[B]ut didn't you want me to stop hitting [the kids]?").

31. Favour Danladi Makurvet, *Biologics vs. Small Molecules: Drug Costs and Patient Access*, 9 MED. DRUG DISCOVERY 1, 1 (2021).

unlikely that two independent manufacturing processes can result in identical biologics.

Due to the complexity of biologic drugs and their sensitivity to minor changes during the manufacturing process, demonstrating bioequivalence is nearly impossible for biologic products.[32] Without bioequivalence, no generics could be made for biologic products under the Hatch-Waxman Act. Thus, a further pathway was needed to allow for abbreviated applications of later versions of biologics, known as biosimilars.

B. PASSAGE OF THE BIOSIMILARS ACT

In 2010, Congress sought to extend the benefits of Hatch-Waxman to the biologic realm, passing the Biosimilars Act as part of the Affordable Care Act.[33] The Biosimilars Act created an abbreviated pathway for the approval of biosimilars, but notably without the bioequivalence requirement present in Hatch-Waxman.[34] Instead, a biosimilar applicant must prove that its product is highly similar to the brand-name reference drug without meaningful clinical differences.[35] Moreover, the Biosimilars Act created a sub-category of biosimilar products: interchangeable biosimilars.[36] The standard for interchangeability generally is higher than for biosimilars. In addition to demonstrating no meaningful clinical differences from the original product, an interchangeable biosimilar must demonstrate that when patients alternate back and forth between the brand and the biosimilar, the biosimilar does not

32. *See, e.g.*, Robin Feldman, *Purple Is the New Orange*, 2024 U. ILL. L. REV. (forthcoming) (manuscript at 22–24) (on file with author); Martina Weise, *From Bioequivalence to Biosimilars: How Much Do Regulators Dare?*, 140 ZEITSCHRIFT FÜR EVIDENZ, FORTBILDUNG UND QUALITÄT IM GESUNDHEITSWESEN [ZEFQ] 58, 58 (2019) (Ger.).

33. *Implementation of the Biologics Price Competition and Innovation Act of 2009*, U.S. FOOD & DRUG ADMIN. (Feb. 12, 2016), https://www.fda.gov/drugs/guidance-compliance-regulatory-information/implementation-biologics-price-competition-and-innovation-act-2009 [hereinafter *BPCIA Implementation*].

34. *See* 42 U.S.C. § 262(k) (outlining the abbreviated pathway for biosimilar approval and omitting "bioequivalence" as a required criterion for showing biosimilarity); *see also* U.S. FOOD & DRUG ADMIN., BIOSIMILARS INFO SHEET (n.d.), https://www.fda.gov/media/154912/download (explaining that while non-biologic generics must show bioequivalence to the brand-name reference drug in order to gain approval, biosimilars need only show that they are highly similar to the reference brand biologic).

35. Anne Park Kim & Ross Jason Bindler, *The Future of Biosimilar Insulins*, 29 DIABETES SPECTRUM 161, 163 (2016); *see also* U.S. FOOD & DRUG ADMIN., *supra* note 34.

36. 42 U.S.C. § 262(k)(4) (enabling the FDA to designate a biosimilar as *interchangeable* if it meets additional safety and efficacy requirements).

produce decreased efficacy or increased risk.[37] Known as "switching studies," these studies are costly and time-consuming.[38] As with generic drugs, an interchangeable biosimilar can be substituted for the original product by a pharmacist, state law permitting, without consulting the physician who wrote the prescription.[39] The standard for interchangeability is so high that only seven biosimilars have been designated as interchangeable so far.[40]

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37. *BPCIA Implementation*, *supra* note 33; *see also* U.S. FOOD AND DRUG ADMIN., INTERCHANGEABLE BIOLOGICAL PRODUCTS (2017), https://www.fda.gov/media/151094/download#.

38. Benjamin P. Falit, Surya C. Singh & Troyen A. Brennan, *Biosimilar Competition in the United States: Statutory Incentives, Payers, and Pharmacy Benefit Managers*, 34 HEALTH AFFS. 294, 296 (2015) (noting significant expense of conducting large-scale switching study: "[Switching studies] can cost more than $50,000 per patient").

39. 42 U.S.C. § 262(i)(3) ("[An interchangeable] biological product may be substituted for the reference product without the intervention of the health care provider who prescribed the reference product."). Most states have adopted laws allowing automatic substitution of biosimilars that are interchangeable "without prescriber intervention." *See* Heled, *supra* note 8, at 126 ("[T]hirty-seven states and Puerto Rico have passed legislation addressing biologics substitution, with most of them imposing special pre-requisites for biologics substitution.").

40. The seven biosimilars that have been designated as interchangeable so far are: Rezvoglar (insulin glargine-aglr) and Semglee (insulin glargine-yfgn), both interchangeable with Lantus (insulin glargine); Cyltezo (adalimumab-adbm) and Abrilada (adalimumab-afzb), both interchangeable with Humira (adalimumab); Cimerli (ranibizumab-eqrn) and Byooviz (ranibizumab-nuna), both interchangeable with Lucentis (ranibizumab); and Wezlana (ustekinumab-auub), interchangeable with Stelara (ustekinumab). *See* Skylar Jeremias, *Rezvoglar Becomes Second Interchangeable Insulin Biosimilar*, CTR. FOR BIOSIMILARS (Nov. 23, 2022), https://www.centerforbiosimilars.com/view/rezvoglar-becomes-second-interchangeable-insulin-biosimilar#; *FDA Approves First Interchangeable Biosimilar Insulin Product for Treatment of Diabetes*, U.S. FOOD & DRUG ADMIN. (July 28, 2021), https://www.fda.gov/news-events/press-announcements/fda-approves-first-interchangeable-biosimilar-insulin-product-treatment-diabetes; *FDA Approves Cyltezo, the First Interchangeable Biosimilar to Humira*, U.S. FOOD & DRUG ADMIN. (Oct. 18, 2021), https://www.fda.gov/news-events/press-announcements/fda-approves-cyltezo-first-interchangeable-biosimilar-humira; *FDA Approves Coherus' Cimerli as Interchangeable Biosimilar to Ranibizumab*, CTR. FOR BIOSIMILARS (Aug. 3, 2022), https://www.centerforbiosimilars.com/view/fda-approves-coherus-cimerli-as-interchangeable-biosimilar-to-ranibizumab; *Abrilada Approved as Second Interchangeable Humira Biosimilar*, CTR. FOR BIOSIMILARS (Oct. 5, 2023), https://www.centerforbiosimilars.com/view/abrilada-approved-as-second-interchangeable-humira-biosimilar; *Eye on Pharma: New GI Data and Byooviz Interchangeability Propel Biosimilars into the Future*, CTR. FOR BIOSIMILARS (Oct. 25, 2023), https://www.centerforbiosimilars.com/view/eye-on-pharma-new-gi-data-and-byooviz-interchangeability-propel-biosimilars-into-the-future; *FDA Approves First Stelara Biosimilar, Wezlana*, CTR. FOR BIOSIMILARS (Nov. 1, 2023), https://www.centerforbiosimilars.com/view/fda-approves-first-stelara-biosimilar-wezlana; *see also FDA Roundup: September 15, 2023*, U.S. FOOD & DRUG ADMIN. (Sept. 15, 2023), https://www.fda.gov/news-events/press-announcements/fda-roundup-september-15-2023; Robert M. Califf, Commissioner, U.S. Food & Drug Admin., Remarks to the 2023 Food and Drug Law Institute (FDLI) Annual

Furthermore, although generic drugs are assigned the same nonproprietary name as their brand name counterpart, the FDA requires that all biosimilars' nonproprietary names must include a four-letter suffix that is "devoid of meaning."[41] The FDA believes that this naming convention will, among other things, facilitate monitoring of biologic and biosimilar drug use, along with detection of any safety issues.[42] Various stakeholders have noted, however, that the suffix might indicate to patients and physicians that the biosimilar differs in clinically meaningful ways from the brand biologic.[43] Indeed, one study found that when the nonproprietary name of a biosimilar included the four-letter suffix, participants were more skeptical about its similarity to the brand biologic than without the suffix.[44] In addition, the FDA's goal of improved monitoring and detection, through the use of the four-letter suffix, likely remains unachieved: One study found that out of more than 2,500 biosimilar-related adverse drug reports (ADRs), only 11 of the

Conference (May 17, 2023), https://www.fda.gov/news-events/speeches-fda-officials/remarks-commissioner-robert-califf-2023-food-and-drug-law-institute-fdli-annual-conference-05172023; Angela Maas, *Biosimilars Are Picking Up Market Share, but Some Uncertainties Still Exist*, PHARM. STRATEGIES GRP. (Sept. 8, 2022), https://www.psgconsults.com/blog/biosimilars-are-picking-up-market-share-but-some-uncertainties-still-exist.

41. U.S. FOOD & DRUG ADMIN., NONPROPRIETARY NAMING OF BIOLOGICAL PRODUCTS: GUIDANCE FOR INDUSTRY 1, 8, 10 (2017), https://www.fda.gov/media/93218/download.

42. U.S. FOOD & DRUG ADMIN., NONPROPRIETARY NAMING OF BIOLOGICAL PRODUCTS: UPDATE (2019), https://www.fda.gov/media/121316/download.

43. Fed. Trade Comm'n, FTC Comment to FDA 2019 Biologics Naming Guidance (May 6, 2019), https://www.ftc.gov/system/files/documents/advocacy_documents/ftc-staff-comment-fda-department-health-human-services-its-updated-guidance-industry-nonproprietary/ftc_comment_to_fda_2019_biologics_naming_guidance_5-6-19.pdf.

44. This study asked the participant to answer questions after viewing a print advertisement for a fictitious biologic drug. The study found that, absent any information about interchangeability, the presence of the four-letter suffix lowers the likelihood that participants will use that biosimilar. When the advertisement mentioned whether the biosimilar was interchangeable, the four-letter suffix did not significantly reduce the likelihood that the participants will use the biosimilar. But it still reduced the perceived similarity of the biosimilar to its reference brand biologic. Mariana P. Socal, Jace B. Garrett, William B. Tayler, Ge Bai & Gerard F. Anderson, *Naming Convention, Interchangeability, and Patient Interest in Biosimilars*, 33 DIABETES SPECTRUM 273, 274-77 (2020). *But see* Allison R. Kolbe, Aaron Kearsley, Lubna Merchant, Eva Temkin, Archita Patel, Jing Xu & Amber Jessup, *Physician Understanding and Willingness to Prescribe Biosimilars: Findings from a US National Survey*, 35 BIODRUGS 363, 369 (2021) (noting that "[t]he presence or absence of the suffix on the reference product's nonproprietary name did not have a significant effect on prescriber understanding or choice in the prescribing scenario," but cautioning that study depended on self-reported data from healthcare professionals).

reports used the suffix, while the rest of the reports were filed using the brand name only.[45]

Although the model of interchangeable biosimilars mirrors that of generic drugs, the Biosimilars Act differs from Hatch-Waxman in several critical respects. First, biosimilars that fail to meet the high standard for interchangeability cannot be substituted for the brand drugs at pharmacies, but must be specifically prescribed by providers in order to be used.[46] This limit on substitution reduces the price-alleviating potential of biosimilars relative to generics, which most state pharmacists can substitute for the brand drugs without contacting the prescribing physician for confirmation.[47]

Second, the Biosimilars Act provides a longer period of exclusivity to brands, creating a twelve-year exclusivity period for new biologics.[48] This exclusivity period is far longer than the five-year exclusivity period offered to new chemical entities under Hatch-Waxman.[49]

In explaining the longer period of protection, biologic companies reason that research and development for biologics is longer and more expensive than for non-biologic drugs.[50] Nevertheless, some scholars have argued that the

45. *See* Stanton R. Mehr, *If Four-Letter Suffixes Aren't Used in Biosimilar Tracking, What Use Are They?*, BIOSIMILAR DEV. (Nov. 6, 2018), https://www.biosimilardevelopment.com/doc/if-four-letter-suffixes-aren-t-used-in-biosimilar-tracking-what-use-are-they-0001.

46. *See* 42 U.S.C. § 262(i)(3) (stating that a biosimilar must be interchangeable in order to be substituted for the reference product without provider intervention).

47. U.S. FOOD & DRUG ADMIN., FYs 2013 – 2017 REGULATORY SCIENCE REPORT: ANALYSIS OF GENERIC DRUG UTILIZATION AND SUBSTITUTION (n.d.), https://www.fda.gov/drugs/generic-drugs/fys-2013-2017-regulatory-science-report-analysis-generic-drug-utilization-and-substitution (updated Feb. 16, 2018) (analyzing pharmacies' substitution of generic drugs for brand drugs without provider intervention, including an analysis of the possible barriers to substitution in certain populations).

48. Elizabeth Richardson, *Biosimilars*, HEALTH AFFS.: HEALTH POL'Y BRIEF 3 (Oct. 10, 2013), https://www.healthaffairs.org/do/10.1377/hpb20131010.6409/full/healthpolicybrief_100-1554749622899.pdf.

49. 21 U.S.C. § 355(c)(3)(E)(ii) (providing that within five years of the approval of a new drug, no generic substitution for it may be approved, unless the generic application contains a certification of patent invalidity or noninfringement (i.e., a Paragraph IV certification, *see supra* note 29), in which case the generic application may be approved after four years).

50. *See, e.g.*, Ryan Timmis, *The Biologics Price Competition and Innovation Act: Potential Problems in the Biologic-Drug Regulatory Scheme*, 13 NW. J. TECH. & INTELL. PROP. 215, 217 (2015) ("[B]iologic drugs are inherently more difficult and costly to manufacture than traditional pharmaceuticals . . . ."); Ude Lu, Note, *Biologics Price Competition and Innovation Act: Striking A Delicate Balance Between Innovation and Accessibility*, 15 MINN. J.L. SCI. & TECH. 613, 625 (2014) ("The cost to bring a biologic drug to the market is higher than that for a small-molecule drug."); BIO, THE TRANS-PACIFIC PARTNERSHIP AND INNOVATION IN THE BIOECONOMY: THE NEED FOR 12 YEARS OF DATA PROTECTION FOR BIOLOGICS 2 (n.d.), https://

research and development time for biologics is not sufficiently greater to warrant the longer exclusivity.[51] Research and development costs are higher for biologics than for non-biologic drugs, but the delta may not be of the magnitude that would explain the difference between five and twelve additional years of exclusivity.[52]

Finally, the Biosimilars Act specifies a far more complex patent litigation and rights-clearing process for biosimilars than Hatch-Waxman does for generics. Under Hatch-Waxman, a generic applicant applying for approval can submit what is known as a Paragraph IV certification,[53] attesting to circumstances that would permit immediate entry. Applicable circumstances include that the brand's listed patents are invalid or not infringed.[54] The generic

www.bio.org/sites/default/files/TPP%20White%20Paper%20_2_.pdf ("[It takes], on average, more than a decade and in excess of $1.2 billion to bring a biological product to market.").

51. *See* Reed F. Beall, Thomas J. Hwang & Aaron S. Kesselheim, *Pre-Market Development Times for Biologic Versus Small-Molecule Drugs*, 37 NATURE BIOTECH. 708, 708–09 (2019) (observing that the median pre-market development time was 12.4 years for both biologics and non-biologic drugs and casting doubt on the rationale that biologics need longer exclusivity due to their longer development time); Joel Lexchin, *Affordable Biologics for All*, 3 JAMA NETWORK OPEN 1, 1 (2020) (asserting that "there is no difference in the median premarket development time between biologics and small molecule drugs that would justify the 12 years of data exclusivity that the former group received in 2010"); *see also* Beall, Hwang & Kesselheim, *supra*, at 709 (finding that "although biologics are often thought to be more time-consuming to develop than small-molecule drugs, development times for biologics are similar to, or possibly somewhat shorter than, for small-molecule drugs," calling into question why biologics get a much longer exclusivity period than their non-biologic counterparts).

52. Oliver J. Wouters, Martin McKee & Jeroen Luyten, *Estimated Research and Development Investment Needed to Bring a New Medicine to Market, 2009-2018*, 323 JAMA 844, 12-13 tbl.3 (Supp. 2020), https://jamanetwork.com/journals/jama/fullarticle/2762311#supplemental-tab (observing that the median R&D cost, before adjusting for the cost of failures, is $391 million for biologics and $309 million for non-biologics); *see also* Joseph A. DiMasi & Henry G. Grabowski, *The Cost of Biopharmaceutical R&D: Is Biotech Different?*, 28 Managerial & Decision Econ. 469, 476–77 (2007) (observing that the average R&D cost, after adjusting for the capitalization cost and the cost of failures, is 1.24 billion for biopharmaceuticals—therapeutic recombinant proteins and monoclonal antibodies—and 1.31 billion for traditional small molecule drugs). Estimates vary widely for the R&D costs of a new drug, ranging from a few hundred million to a few billion. Michael Schlander, Karla Hernandez-Villafuerte, Chih-Yuan Cheng, Jorge Mestre-Ferrandiz & Michael Baumann, *How Much Does It Cost to Research and Develop a New Drug? A Systematic Review and Assessment*, 39 PHARMACOECONOMICS 1243, 1246 (2021) ("Estimates of the total average capitalized (pre-launch) R&D costs needed to bring a new compound to the market varied widely, from $161 million to $4.5 billion . . . .").

53. *See supra* notes 29–30.

54. *See* 21 U.S.C. § 355(j)(2)(A)(vii)(IV) (stating that the generic applicant must submit "a certification, in the opinion of the applicant and to the best of his knowledge, . . . that [each] patent is invalid or will not be infringed by the manufacture, use, or sale of the new drug . . .").

must notify the brand upon filing a Paragraph IV certification, and the brand then has 45 days to sue for patent infringement if it wishes to challenge the generic's attestation.[55]

In deciding whether to file a Paragraph IV certification, the generic company need only consider the specific and limited set of rights asserted by the brand company. When a brand company applies for approval of a non-biologic drug, the brand must list all of the patents and non-patent exclusivities[56] that it might assert in protection of the drug, updating that list with any new rights acquired.[57] The FDA publishes the list in what is known as the Orange Book.[58] When the generic certifies that its version does not infringe any relevant rights or that those rights are invalid, the generic need only certify to rights listed in the Orange Book.[59]

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55. *Id.* § 355(j)(5)(B)(iii) ("[B]efore the expiration of 45 days after the date on which the notice described in paragraph (2)(B) is received, an action is brought for infringement of the patent . . . ."). Brand companies may hold back their patents by not listing them in the Orange Book and then decide to sue outside the timeline mandated by the Hatch-Waxman Act. Celgene Corporation, for example, filed a complaint asserting three non-Orange Book patents against Sun Pharma, more than a year after Sun Pharma submitted its ANDA and sent a notice of its Paragraph IV certification to Celgene. *See* Complaint for Patent Infringement, Celgene Corp. v. Sun Pharma Glob. FZE, No. 19-10099 (SDW) (LDW) (D.N.J. Apr. 6, 2020).

56. In addition to patent rights, an FDA-approved non-biologic drug may be entitled to exclusive marketing or data rights for a predetermined period of time if certain statutory requirements are met. These include the orphan drug exclusivity and the new clinical investigation exclusivity, among others. These market exclusivities are colloquially called *non-patent exclusivities, regulatory exclusivities,* or simply *exclusivities*. Renu Lal, *Patents and Exclusivity*, FDA/CDER SBIA CHRONICLES (U.S. Food & Drug Admin., Silver Spring, MD), May 19, 2015*; see also* Robin Feldman, *Regulatory Property: The New IP*, 40 COLUM. J.L. & ARTS 53, 103 (2016) (providing a chart of approximately a dozen non-patent exclusivities available for biologic and non-biologic drugs); Richard B. Racine, *The Interplay Between U.S. Pharmaceutical Patents and FDA Law*, FINNEGAN: MANAGING INTELL. PROP. (Dec. 2010), http://www.finnegan.com/resources/articles/articlesdetail.aspx?news=ad4b058b-0150-4ec7-90f4-57e6641272a6 (describing the New Chemical Entity exclusivity and calling it a "non-patent exclusivity").

57. 21 U.S.C. § 355(b)(1)(A)(viii) (explaining FDA's mandate that new drug applicants must file with their application "the patent number and expiration date of each patent for which a claim of patent infringement could reasonably be asserted if a person not licensed by the owner of the patent engaged in the manufacture, use, or sale of the drug").

58. *Id.* § 355(c)(2) (requiring that new drug applicants must submit required patent information for listing in the Orange Book, and that the FDA must regularly update the Orange Book).

59. S. Sean Tu & Mark A. Lemley, *What Litigators Can Teach the Patent Office About Pharmaceutical Patents*, 99 WASH. U. L. REV. 1673, 1681 (2022); *see also supra* note 55 (noting authorities holding that brand's failure to list patent in NDA does not bar brand from suing generic for infringement of omitted patent); *infra* note 177 (same).

By contrast, the Biosimilars Act lays out an intricate patent litigation process known colloquially as the "patent dance."[60] The patent dance proceeds in two phases, with layers of notification and negotiation, both of which phases will be described in Part III, below.[61] In deciding whether to join the dance and enter the market, however, biosimilar companies face a troubling lack of information. The Section below describes that information desert.

C. THE INFORMATION DESERT

The biosimilar system suffers from a lack of information throughout the process, one that seriously impedes competitive entry. Consider the dearth of information facing a company contemplating whether to start down the road of producing a particular biosimilar. As a starting point, the company would want to know the answers to four simple questions: What is the drug? How do you make it? What patents apply? When do those patents expire? Each of these should be a relatively simple question to answer. Under the current system, however, they are not.

1. What Is the Drug?

The process of defining a particular drug is complicated for biologics. With a non-biologic drug like aspirin, one can identify the active ingredient of the

60. "Patent dance" refers to the intricately choregraphed exchange of patent-related information and the associated infringement litigation between the brand biologic and the biosimilar entrant. The dance commences when the FDA notifies the biosimilar entrant that its application has been accepted for review and the biosimilar, in turn, sends a copy of the application along with the manufacturing process information to the brand biologic. The brand and biosimilar then generate initial lists of patents that are arguably infringed by the biosimilar. After a complex process of exchanging lists, the two parties negotiate a single list of patents to be litigated in the first phase of litigation. If no such agreement can be reached, the parties exchange separate lists of patents to be litigated in the first phase. The brand then sues the biosimilar for infringement of the patents on the negotiated or separate lists. The second phase of the patent dance begins when the biosimilar notifies the brand, 180 days in advance, that the biosimilar will commence commercial marketing. At this point, the brand may start the second phase of litigation by initiating a suit against the biosimilar for infringement of any patent that was included in the initial lists but that was not included in the negotiated or separate lists. In this phase, the brand may move for a preliminary injunction blocking the biosimilar's commercial launch. *See* 42 U.S.C. § 262(l). For a detailed description of the patent dance, see *infra* Sections III.A.1, III.A.2. For flow charts breaking down the intricate steps of the patent dance, see *infra* Section VI.B.

61. *See* Alejandro Menchaca, *The Inner Workings of the BPCIA Patent Dance*, CTR. FOR BIOSIMILARS (July 24, 2021), https://www.centerforbiosimilars.com/view/the-inner-workings-of-the-bpcia-patent-dance; *see also infra* note 166 (noting that under both the Hatch-Waxman and Biosimilars Acts, a claim of actual infringement and damages entitles either party to a jury trial, while a claim of artificial infringement entitles neither party to a jury trial); *infra* Section III.A (describing the dance in detail).

drug by drawing its chemical structure.[62] Without too much difficulty, a generic company then can develop a sequence of chemical reactions that will lead to the chemical molecule.[63] Biologic drugs, however, are far too complex to draw—or even to understand their physical and chemical properties fully.[64]

Biologics are created through processes using living cells. While non-biologics may contain a few dozen atoms, biologics contain thousands or even millions of atoms that are folded into intricately complex, multi-layered shapes that cannot be captured in a two-dimensional drawing.[65] Scientists are not yet capable of completely identifying the structure, function, and composition of these biologically derived molecules.[66] Moreover, given that the processes involve living cells, every detail of the process matters. Small changes in everything from the cell line to the temperature and environment in which it is cultured, to the purification methods, can produce significant differences in the final molecule.[67] As a result, a biologic drug is identified, by proxy, through the process of making it. As is often said in the biologics field, "the process is

62. Pharmaceutical lingo refers to the active ingredient of a drug as the API, which stands for "the active pharmaceutical ingredient." *See generally* Vinod Kumar, Vasudha Bansal, Aravind Madhavan, Manoj Kumar, Raveendran Sindhu, Mukesh Kumar Awasthi, Parameswaran Binod & Saurabh Saran, *Active Pharmaceutical Ingredient (API) Chemicals: A Critical Review of Current Biotechnological Approaches*, 13 BIOENGINEERED 4309 (2022).

63. *See* Makurvet, *supra* note 31, at 1–4 (describing in detail the contrast between the creation of a generic and a biosimilar); *see also* Feldman, *supra* note 32 (explaining that with non-biologic drugs, "multiple chemical reactions involving different processes or different chemicals may yield the same molecule, and two companies using different pathways can be confident, nevertheless, that their products will be chemically indistinguishable").

64. Understanding the physical and chemical properties of a drug is referred to as "characterizing" the drug. *See Protein Characterization, Identification & Purification*, JORDI LABS, https://jordilabs.com/blog/protein-characterization-identification-purification/ (last visited Jan. 4, 2023).

65. *See* Makurvet, *supra* note 31, at 2; *see also* U.S. FOOD & DRUG ADMIN., BIOLOGICAL PRODUCT DEFINITIONS 1 (n.d.), https://www.fda.gov/files/drugs/published/Biological-Product-Definitions.pdf.

66. *See* Steven A. Berkowitz, John R. Engen, Jeffrey R. Mazzeo & Graham B. Jones, *Analytical Tools for Characterizing Biopharmaceuticals and the Implications for Biosimilars*, 11 NATURE 527, 527 (2012) (noting that for many "larger and more complex" biologics, "the extent to which existing analytical technologies can be used to support the likelihood of clinical comparability between a follow-on version and the original product is much more limited than for small-molecule drugs, and it is not possible to demonstrate that the two products are absolutely identical").

67. *See* Makurvet, *supra* note 31, at 1–2; W. Nicholson Price II & Arti K. Rai, *Manufacturing Barriers to Biologic Competition and Innovation*, 101 IOWA L. REV. 1023, 1033–34 (2016); Arti K. Rai & W. Nicholson Price II, *An Administrative Fix for Manufacturing Process Patent Thickets*, 39 NATURE BIOTECH. 20, 22 (2021).

the product."[68] This leads to the second, more important question: How do you make it?

2. How Do You Make It?

In theory, the question of how a particular drug is made should not be a problem with a biologic. First, the molecule itself would have been patented at the outset. A valid patent is required to include sufficient information that one skilled in the art can make, use, and sell the invention.[69] The requirement for adequate disclosure is society's due—the quid pro quo for receiving a patent.[70] In exchange for granting the powerful patent right, an inventor must teach future scientists who are skilled in the field of biologics enough information so that after the patent expires, others are able to make and use it.[71]

Unfortunately, the truth for biologic patents is far from the ideal. Inventors of biologics are able to satisfy the disclosure obligation by providing no more than approximations or ranges for a variety of elements, such as temperature, molecular composition, concentration, and reaction agent.[72] Other patents cite a wide variety of possible manufacturing processes through which the drug might be produced—listing, for example, bacterial, mammalian, yeast, and

68. H.R. REP. NO. 106-556, at 41 (2000); *see also* RAJ K. PURI, U.S. FOOD & DRUG ADMIN., CTR. FOR BIOLOGICS EVALUATION & RSCH., FDA'S PERSPECTIVES ON QUALITY AND NON-CLINICAL EVALUATION OF CELL/TISSUE-BASED PRODUCTS 6 (AUG. 26, 2010), https://www.pmda.go.jp/files/000153661.pdf; Yaniv Heled, *The Case for Disclosure of Biologics Manufacturing Information*, 47 J. MED. & ETHICS 54, 56 & n.40 (2019); *NCI Initiative Aims to Boost CAR T-Cell Therapy Clinical Trials*, NAT'L CANCER INST. (Apr. 23, 2020), https://www.cancer.gov/news-events/cancer-currents-blog/2020/car-t-cell-nci-manufacturing-clinical-trials.

69. *See* 35 U.S.C. § 112(a) ("The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same.").

70. A patent, of course, is no guarantee of a return, and many patent holders receive little value either directly from revenue or indirectly by serving to building a portfolio to defend territory around an innovation. Nevertheless, a patent provides an extraordinary opportunity to create value by excluding others. *See, e.g.*, Kewanee Oil Co. v. Bicron Corp., 416 U.S. 470, 484–85 (1974).

71. *See* 3 DONALD S. CHISUM, CHISUM ON PATENTS § 7.03 (2003) (explaining that since 1790, patent laws have mandated that an inventor provide sufficient information to teach a person in the same field to make and use the invention, even after the patent expires). *See generally* Robin Feldman, *The Inventor's Contribution*, 2005 UCLA J.L. & TECH 6.

72. *See* Jayson Singh Sohi, *Changes to the Best Mode Requirement: Weakening Enforcement Undermines the Purpose of Patent Law and Exacerbates an Ethical Patent Trilemma*, 17 INTELL. PROP. L. BULL. 157, 158 (2013); *see also* Robin Feldman, *Trade Secrets in Biologic Medicine: The Boundary with Patents*, 24 COLUM. SCI. & TECH. L. REV. 1, 27 n.139 (2022) (providing the example of Patent US 8,663,945 B2).

insect cells as types of host cells—without sorting any further among these.[73] Consider the biologic drug Enbrel, which treats rheumatoid arthritis. Enbrel's patent includes hundreds of techniques and materials that might be used to express the active protein, but scholars have pointed out that only a small subset of these would yield a compound biosimilar to Enbrel.[74]

Patents with these proverbial kitchen-sink claims may include more narrow claims as well,[75] but there is no guarantee the narrow examples are the ones that work. The narrow claims may be red herrings that serve to divert attention away from the process the company actually intends to use. In short, given the exquisite precision necessary to create a biologic drug, patents in the biologic space can easily fall short of fully teaching the invention so that it can be put into practice.

Patent timing plays a role as well. The patent on the initial molecule may issue many years before the related drug receives marketing authorization from the FDA, shortening the patent monopoly period to eleven to fourteen years.[76] By the time the drug reaches the market, the company will have developed and refined the method of making the drug in numerous ways and may continue to do so throughout the life of the drug. The original patent will contain none of that information.

If critical information is omitted from a biologic patent, the company can either keep that information private, keep it in the form of a trade secret, or file additional patent applications across time. Indeed, some biologic companies hold large numbers of patents related to a single drug,[77] far more than the average patents listed for non-biologic drugs in the Orange Book. For example, the biologic company that owns the rheumatoid arthritis drug

73. *See, e.g.*, Price & Rai, *supra* note 67, at 1050–51 (describing Enbrel manufacturing patents).

74. *See id.* at 1051 (describing Enbrel composition patent).

75. *See, e.g.*, U.S. Patent No. 8,343,737 B2 col. 95 ls. 7–13 (filed May 13, 2011) (with claim 2 listing "bacterial cells, yeast cells, insect cells and mammalian cells" as potential types of cells used in the cell culture but with additional claims narrowing the group).

76. *See* Robin Feldman, *Patent Term Extensions and the Last Man Standing*, 42 YALE L. & POL'Y REV. 1, 29 (2023) (finding that the monopoly period after FDA approval induced by the primary patents were, on average, 13.5 years for all drugs included in the study and 11.3 years for drugs that received patent term extensions on their primary patents); *see also* C. Scott Hemphill & Bhaven N. Sampat, *Evergreening, Patent Challenges, and Effective Market Life in Pharmaceuticals*, 31 J. HEALTH ECON. 327, 330 (2012) (finding that the average nominal patent protection term for drugs, including primary and secondary patents, is 15.9 years).

77. *See, e.g.*, Ryan Knox & Gregory Curfman, *The Humira Patent Thicket, the Noerr-Pennington Doctrine and Antitrust's Patent Problem*, 40 NATURE BIOTECH. 1761, 1761 (2022) (noting that AbbVie was granted 132 patents protecting Humira).

Humira holds more than 100 patents on the drug.[78] Each of a biologic's patents, however, may suffer from the inadequacy described above, in which the information offered fails to clarify precisely how to make the drug.

Given the FDA approval process, the brand biologic does give the FDA its precise information, which must be updated if the company changes its process. The FDA, however, respects the company's assertion that such information is confidential and does not make the information publicly available.[79]

Other information on making and using the product also remains bottled up at the FDA—information that Congress intended to make public. Both the Biosimilars Act and its muse, the Hatch-Waxman Act, anticipated enhancing market efficiencies by allowing producers of follow-on drugs, such as generics and biosimilars, to use the prior safety and effectiveness data developed by the brand.[80] Recreating the data would pose a significant financial burden to the generic and biosimilar manufacturers, without the promise of patent rights at the end to recoup those costs. The process of recreating that data also would raise ethical concerns, given that some patients would receive placebos despite the existence of safe and effective medications.[81]

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78. *Id.*; *see also* Mayor of Balt. v. AbbVie Inc., 42 F.4th 709, 711 (7th Cir. 2022) ("AbbVie, [Humira's] owner, obtained 132 additional patents related to [Humira] . . . .").

79. *See* 21 C.F.R. § 20.61(d) (2023) (allowing the brand biologic to designate part or all of the information submitted to the FDA as exempt from public disclosure); Christopher J. Morten & Amy Kapczynski, *The Big Data Regulator, Rebooted: Why and How the FDA Can and Should Disclose Confidential Data on Prescription Drugs and Vaccines*, 109 CALIF. L. REV. 493, 523–24 (2021) (explaining that FDA policy bars the FDA from disclosing any confidential commercial information and noting that the FDA allows pharmaceutical companies to designate clinical trial data as confidential commercial information with limited oversight and verification); *see also* 21 C.F.R. § 314.430(g)(1) (2023) (stating that the FDA does not disclose information about manufacturing methods or processes).

80. *See Review and Approval*, U.S. FOOD & DRUG ADMIN., https://www.fda.gov/drugs/biosimilars/review-and-approval (last visited Sept. 19, 2023) ("The goal of a biosimilar development program is to demonstrate biosimilarity between the proposed biosimilar and its reference product, not to independently establish the safety and effectiveness of the proposed biosimilar.").

81. 129 CONG. REC. 19,844–45 (1983) (statement of Rep. Waxman) ("The generic manufacturer need not conduct human clinical trials. Such retesting is unnecessary and wasteful because FDA has already determined that the drug is safe and effective. In fact, such retesting may be unethical because it requires that some sick patients take placebos and be denied treatment known to be effective."); FED. TRADE COMM'N, EMERGING HEALTH CARE ISSUES: FOLLOW-ON BIOLOGIC DRUG COMPETITION ii (2009) ("Duplication of safety and efficacy information is costly, an inefficient use of scarce resources, and, as the FDA has explained, raises ethical concerns associated with unnecessary human testing.").

The detailed information within the clinical trial data, however, is less important for generic companies than for biosimilar companies, which will need to do their own supplemental trials. Access to complete information on the prior clinical trials creates the pathway for the additional trials. Unfortunately, FDA processes frustrate that goal. The FDA defers to company assertions that clinical trial protocols and other information are protectible information that may not be circulated outside the agency.[82] Some courts have ruled that clinical trial information does not always qualify for trade secret protections,[83] but the FDA still fails to disclose it, on the theory that clinical trial information constitutes "confidential commercial information,"[84] which cannot be released under FDA regulations. The FDA also exempts clinical trial data from the Freedom of Information Act (FOIA), preventing anyone in the agency from revealing such information.[85]

In short, neither the patent system nor the FDA processes operate as legislators intended, providing too little of the information that biosimilar companies need to make follow-on versions of biologic drugs. As a result, biosimilar companies must spend seven to ten years of painstaking and expensive research to get to the point of bringing a drug to market.[86]

3. What Are the Patent Rights?

In the non-biologic space, the FDA's public list of drugs includes all patents associated with each drug.[87] However, in the biologic space, no public

82. *See* Feldman, *supra* note 72, at 32–33 ("[D]rug companies have long claimed clinical trial protocols and data (i.e., safety and efficacy data) as trade secrets, restricting their dissemination beyond the FDA.").

83. *Id.* at 42 n.238 (first citing Morten & Kapczynski, *supra* note 79, at 534; then citing Pub. Citizen Health Rsch. Grp. v. FDA, 964 F. Supp. 413, 416 (D.D.C. 1997); and then citing Pub. Citizen Health Rsch. Grp. v. FDA, 704 F.2d 1280, 1286 (D.C. Cir. 1983)).

84. *See* Morten & Kapczynski, *supra* note 79, at 522–24; *see also* 21 C.F.R. § 20.61(b)–(c) (2023) (defining confidential commercial information and barring the FDA from publicly disclosing any such information).

85. Feldman, *supra* note 72, at 42–43.

86. *See, e.g.*, Erwin A. Blackstone & Joseph P. Fuhr, Jr., *The Economics of Biosimilars*, 6 AM. HEALTH & DRUG BENEFITS 469, 471 (2013) ("It takes 7 to 8 years to develop a biosimilar . . . ."); *Comparison of the Cost of Development of Biologicals and Biosimilars*, GENERICS AND BIOSIMILARS INITIATIVE (Nov. 03, 2022), https://www.gabionline.net/reports/comparison-of-the-cost-of-development-of-biologicals-and-biosimilars (claiming that it take 8 to 10 years of research to bring a biosimilar to market); Miriam Fontanillo, Boris Kors & Alex Monnard, *Three Imperatives for R&D in Biosimilars*, MCKINSEY & CO. (Aug. 19, 2022), https://www.mckinsey.com/industries/life-sciences/our-insights/three-imperatives-for-r-and-d-in-biosimilars# ("[A] typical biosimilar [takes] six to nine years to go from analytical characterization to approval.").

87. *See supra* notes 56–58 and accompanying text.

list of all patents associated with each brand biologic drug exists. To assess the number or types of patents covering a biologic, a prospective biosimilar company would have to search the entire corpus of more than 3 million active patents in the United States.[88] Further, these patents do not necessarily include the name of the drug, the name of its active ingredient, or even the structure of the associated molecule. For example, they might simply describe lab methods related to molecule production in a way that would be difficult to associate with the drug. Thus, searching is a long, arduous, and often unfruitful process.[89]

As an alternative, biosimilar companies could search through the detailed court records from previous litigation. However, that process also has limitations. Not only would the process be tedious, but success would be contingent upon the existence of previous litigation, as well as the existence of sufficient litigation to cover all patents the company might assert or have acquired later on.[90]

If the case does not result in a judicial opinion related to a particular patent, the information may not exist in obtainable form. For example, if the parties settle, no obtainable litigation record may have formed. Also, the parties can influence the information that emerges through initial litigation choices. Although parties are barred from withholding patent information when discovery rules require production,[91] a party's choice of which patents to

88. In 2020, there were approximately 3,340,000 active patents in the United States. *See, e.g.*, Veera Korhonen, *Number of Patents in Force in the United States from 2004 to 2020*, STATISTA (June 2, 2023), https://www.statista.com/statistics/256738/number-of-patents-in-force-in-the-us/; Bruce Berman, *Too Many Patent Suits? The Data Suggests There Are Too Few*, IPWATCHDOG (Apr. 6, 2023), https://ipwatchdog.com/2023/04/06/many-patent-suits-data-suggests/id=159050. By May 2021, the United States Patent and Trademark Office (USPTO) issued more than 11 million utility patents. *Milestones in U.S. Patenting*, U.S. PAT. & TRADE OFF., https://www.uspto.gov/patents/milestones (last visited Feb. 23, 2024).

89. For example, in a sworn statement, an Amgen executive noted that Amgen owned more than 400 patents that might be relevant to the recombinant manufacturing and purification process used in their drug Neupogen® (filgrastim). He added that many of these 400 patents along with others from Amgen's collection of more than 1400 patents could be asserted against Zarxio®, a biosimilar to Neupogen® marketed by Sandoz. Declaration of Stuart Watt in Support of Amgen's Motion for a Preliminary Injunction at 3–5, Amgen Inc. v. Sandoz Inc., No. 3:14-CV-04741-RS (N.D. Cal. Feb. 5, 2015).

90. Charlotte Geaghan-Breiner, Note, *The Patent Trap: The Struggle for Competition and Affordability in the Field of Biologic Drugs*, 54 COLUM. J.L. & SOC. PROBS. 589, 595, 601–06, 610–11 (2021).

91. FED. R. CIV. P. 26(b)(1) ("[P]arties may obtain discovery regarding any nonprivileged matter that is relevant to any party's claim or defense and proportional to the needs of the case.").

litigate can nonetheless restrict the information that could be accessed by additional entrants who hope to learn from the prior litigation. Moreover, when court filings and document discovery contain information related to manufacturing processes and clinical trial protocols and data, companies often redact those details as confidential business information.[92] Companies try to redact the information unilaterally where possible (e.g., in document discovery), or by application to the court (e.g., in a motion to seal and to file a redacted a version) as even judicial opinions and orders may be redacted.[93] For all these reasons, litigation records are not a robust source of information.

As the discussion above makes clear, a prospective biosimilar company contemplating whether to enter the market has no idea what patent or other rights might be asserted. Nor can the company determine whether those patents or other rights are valid or might be validly applied to the version it will develop.

4. When Do Those Rights Expire?

This, perhaps, is the easiest of the four questions to answer, because there is no answer. If one does not know what patent rights exist, one cannot know when they will expire. Moreover, when the brand company can withhold critical information as a trade secret and then dribble out patent applications along the way, obtaining a clear picture of the potential rights that will be asserted becomes impossible.

In short, a prospective biosimilar company will be completely unable to answer any of the four basic questions of what the drug is, how it is made, what patent rights apply, and when those rights expire. Instead, a company trying to develop a biosimilar must stumble blindly through the information desert.

92. *See, e.g.*, Phase Four Indus., Inc. v. Marathon Coach, Inc., No. 04-4801 JW, 2006 WL 1465313, at *12 (N.D. Cal. May 24, 2006) ("Certain pages in the production have been redacted . . . on the basis of trade secret, proprietary and confidential business information.").

93. *See id.*; Defendants' Reply in Support of Motion to Dismiss Pursuant to Rule 12(B)(1) and 12(B) Redacted Version of Document Sought to be Sealed, Celltrion, Inc. v. Genentech, Inc., No. 4:18-cv-00274-JSW (N.D. Cal. Apr. 2, 2018) (emphasis added) (filing redacted version of document sought to be sealed); Mitze v. Saul, 968 F.3d 689, 692 (7th Cir. 2020) ("Even in cases involving substantial countervailing privacy interests such as . . . trade secrets, . . . courts have opted for redacting instead of sealing the order or opinion." (citing Hicklin Eng'g, L.C. v. Bartell, 439 F.3d 346, 348–49 (7th Cir. 2006), *abrogated on other grounds by* RTP LLC v. ORIX Real Est. Cap., 827 F.3d 689, 691–92 (7th Cir. 2016))).

D. FEW BIOSIMILARS, FEWER BARGAINS

The impact of the Biosimilars Act has been underwhelming, both in its facilitation of biosimilar development and in the actual price reductions resulting from biosimilar entry. As of 2020, a decade after the passage of the Biosimilars Act, only eighteen biosimilars, corresponding to seven biologics, had entered the U.S. market.[94] That is more of a trickle than a waterfall. Moreover, the United States lags behind Europe in biosimilar development, with half as many approvals and market entrants.[95] In a nation known for its pharmaceutical innovation, this gap is surprising and raises questions about the effectiveness of the Biosimilars Act in facilitating biosimilar entry.

Price reductions for biosimilars in the United States also have been disappointing from the perspective of percentage discounts. U.S. biosimilars have been marketed at an average of a 30% discount from brand biologics[96]—a much smaller percentage than the 80%–85% discount typically offered by generic versions of non-biologic drugs.[97] Some observers argue that these savings are more significant than generic discounts, given that biologics are priced an average of twenty-two times more than non-biologic drugs.[98] In other words, 30% of a vastly higher price represents more dollars saved than 85% of a far lower price. One could argue, however, that the amount of money saved is an incomplete metric, from the standpoint of affordability. A 30% discount on an exorbitant price will leave biosimilars nearly as unaffordable as brand biologics, whereas an 85% discount on generics sharply alters the financial implications of the treatment.

Although there are many contributing factors,[99] the impact of the Biosimilars Act has been particularly small in comparison to Hatch-Waxman,

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94. *See* Victor Van de Wiele, Aaron S. Kesselheim & Ameet Sarpatwari, *Barriers to US Biosimilar Market Growth: Lessons from Biosimilar Patent Litigation*, 40 HEALTH AFFS. 1198, 1199 (2021).

95. *See id.*

96. IQVIA INST., BIOSIMILARS IN THE UNITED STATES, 2020-2024: COMPETITION, SAVINGS, AND SUSTAINABILITY 2 (2020) ("Price declines for biosimilars range significantly but appear to reflect prior assumptions of roughly 30% discounts, though higher discounts have occurred and are possible in the future.").

97. *Generic Drugs: Questions & Answers*, U.S. FOOD & DRUG ADMIN. (Mar. 16, 2021), https://www.fda.gov/drugs/frequently-asked-questions-popular-topics/generic-drugs-questions-answers ("[Generic medicines] are typically sold at substantial discounts, an estimated 80 to 85% less, compared with the price of the brand-name medicine.").

98. *Id.* (noting that generics sell at a discount of 80–85% on average compared to name-brand drugs); Makurvet, *supra* note 31, at 4.

99. *See* Feldman, *supra* note 32 (arguing that the success of the Biosimilars Act has been limited by the dearth of patent disclosure in the biologics regime as well as the lack of

which substantially improved access to less-expensive drugs.[100] For example, prior to passage of the Hatch-Waxman Act in 1984, generic drugs accounted for only 19% of prescriptions dispensed in the United States, yet a dozen years later, generic drugs accounted for 43%,[101] and currently, they account for more than 87% of all non-biologic drugs dispensed in the United States.[102] In contrast, the Biosimilars Act falls short of that trajectory. A dozen years after passage of the Act, biosimilars accounted for less than 30% of biologic prescriptions sold in the United States.[103]

Moreover, with the greater precision needed to develop a biosimilar, along with the additional costs and uncertainties imposed by the system, biosimilar manufacturing is largely the sport of kings. In 2020, fourteen out of the twenty-two biosimilars on the U.S. market were developed and launched by seven large pharmaceutical companies, such as Sandoz and Pfizer.[104] Many biosimilars are made by biologic companies themselves, who enter the biosimilar market to challenge a biologic drug made by a different biologic company.[105]

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regulatory exclusivity for the first-filing biosimilar); Van de Wiele, Kesselheim & Sarpatwari, *supra* note 94, at 1199-1202 (arguing that non-compliance with the litigation process established by the Biosimilars Act and the large number of patents asserted by brand biologics are two main issues limiting the success of the Biosimilars Act).

100. *See* Aaron Kesselheim & Jonathan Darrow, *Hatch-Waxman Turns 30: Do We Need a Re-Designed Approach for the Modern Era?*, 15 YALE J. HEALTH POL'Y L. & ETHICS 293, 295 (2015) (noting that the Hatch-Waxman Act has been greatly impactful and that generics constituted eighty-four percent of all prescriptions dispensed in the United States in 2012).

101. CONG. BUDGET OFF., HOW INCREASED COMPETITION FROM GENERIC DRUGS HAS AFFECTED PRICES AND RETURNS IN THE PHARMACEUTICAL INDUSTRY, at ix (1998) ("In 1996, 43 percent of the prescription drugs sold in the United States [were] generic" but only "[t]welve years earlier, the figure was just 19 percent.").

102. Scott Biggs & Doug Long, *Insights Into the 2023 U.S. Pharmaceutical Market*, IQVIA (July 25, 2023), https://www.iqvia.com/locations/united-states/blogs/2023/07/insights-into-the-2023-us-pharmaceutical-market ("In 2022, 87.2% of small molecule drug prescriptions were dispensed as unbranded generics.").

103. ASS'N FOR ACCESSIBLE MED., THE U.S. GENERIC & BIOSIMILAR MEDICINES SAVINGS REPORT 25 (2022), https://accessiblemeds.org/sites/default/files/2022-09/AAM-2022-Generic-Biosimilar-Medicines-Savings-Report.pdf.

104. IQVIA INST., *supra* note 96, at 2, 6 (noting that as of publication, there were 22 biosimilars launched in the U.S. market and stating, "Of biosimilar products marketed in the United States, 14 were developed and launched by seven large pharma companies: Sandoz developed and launched three, while Pfizer developed three and also acquired and launched two more after their Hospira acquisition in 2015").

105. For example, in the rheumatoid arthritis space, Amgen's biologic drug Enbrel competes with AbbVie's biologic drug Humira. As for rheumatoid arthritis biosimilars, Amgen is launching a biosimilar to challenge AbbVie's biologic Humira, while Novartis is launching a biosimilar to challenge Amgen's Enbrel. *See* John Miller, *Big Pharma vs Big Pharma in Court*

Overall, these results are disappointing, particularly in comparison to the success of Hatch-Waxman. Without significant price reductions and widespread entry, the Biosimilars Act cannot deliver on its promise of increasing access and affordability in the United States, along with the many benefits that competition generates. To understand the factors leading to the underwhelming performance of the Biosimilars Act, one must examine the patent dance, which is the intricate, patent-litigation process at the center of the Act—and the moment of truth for would-be biosimilars.[106]

III. THE BIOLOGICS DANCE

A. DISPUTING INFRINGEMENT CLAIMS UNDER THE BIOSIMILARS ACT

The difficulties described above all factor into the strategic behaviors and choices that both brand and biosimilar companies make as they move through the process of approval and rights clearance in the Biosimilars Act. Nevertheless, at the heart of these difficulties lies the dispute resolution process, which is the core of the Biosimilars Act. Far more complex than the simple notice-and-lawsuit method in Hatch-Waxman, the biosimilar process consists of two phases, each involving several negotiations between the involved parties. As the following description of the process will demonstrate, its length and intricacy are driven, in part, by a lack of built-in patent disclosure in the biologic regulatory regime. Specifically, in Hatch-Waxman, both parties know prior to the filing of an application for generic manufacture, and even prior to the generic's decision whether to enter the market in the first place, which patents the brand can assert to protect its drug. In contrast, the litigation process outlined in the Biosimilars Act revolves around determining *which* biologic patents would even be at issue should a biosimilar come to market.

Many have used the phrase "patent dance" to refer to the exchanges between the parties that occur as part of the Biosimilars Act, with some referring only to the first phase as the dance and others describing the entire process as the dance.[107] Given that the entire exercise prompted by the

Battles Over Biosimilar Drugs, REUTERS (Oct. 2, 2016), https://www.reuters.com/article/us-pharmaceuticals-biosimilars/big-pharma-vs-big-pharma-in-court-battles-over-biosimilar-drugs-idUSKCN12208Q. Amgen, AbbVie, and Novartis are all large pharmaceutical companies that make biologic drugs.

106. *See supra* note 60 and accompanying text. For a detailed description of the patent dance, see *supra* Sections III.A.1–2.

107. *Compare* Michael A. Carrier & Carl J. Minniti III, *Biologics: The New Antitrust Frontier*, 2018 U. ILL. L. REV. 1, 17 (2018) (referring only to the first phase as the patent dance), *with* Michael A. Sanzo, *The Promise and Problem of Biologics*, 34 SANTA CLARA HIGH TECH. L.J. 78,

Biosimilars Act resembles an extended and intricately choreographed ballet, this Article uses "patent dance" to refer to every tiptoe of the process.

1. Phase One of the Patent Dance

a) The Dance Commences

The first phase of litigation begins when the FDA notifies the biosimilar company that the company's biosimilar application has been accepted for review.[108] Within twenty days, the biosimilar company must give the brand company a copy of that application, along with information describing the manufacturing process used to create the biosimilar.[109] With biologic medicines, the product generally is defined by describing the process of creating the drug,[110] and that process forms the basis for the key patent rights.

The design of these steps in the patent dance may have reflected the contemporary climate when Congress drafted the legislation. From the mid-2000s to the mid-2010s, concerns emerged regarding entities dubbed "patent trolls" or non-practicing entities.[111] Patent trolls produce no products. Their business model involves aggregating large patent portfolios and asserting those patents against companies in various markets, largely in the technology sector.[112] At the time, one could assert a patent against a company by simply

97–99 (2017) (using "patent dance" to refer to the entire process of litigation and patent dispute resolution outlined in the Biosimilars Act).

108. 42 U.S.C. § 262(l)(2).

109. *Id.* (stating that the biosimilar "shall provide to the [brand] a copy of the application submitted . . . and such other information that describes the process or processes used to manufacture the biological product").

110. *See supra* text accompanying notes 64–68 (describing the complexity of biologic molecules and the notion that "the process is the product").

111. *See* Adam Smith, Note, *Patent Trolls—An Overview of Proposed Legislation and a Solution that Benefits Small Businesses and Entrepreneurs*, 9 OHIO ST. ENTREPRENEURIAL BUS. L.J. 201 (2014). Other terms for patent trolls include non-practicing entities (NPEs)—reflecting the fact that, in patent lingo, they do not "practice" the patent but only assert it—and mass aggregators. *See* Michael Mazzeo, Jonathan H. Ashtor & Samantha Zyontz, *Do NPEs Matter? Non-Practicing Entities and Patent Litigation Outcomes*, 9 J. COMPETITION L. & ECON. 879, 880 (2013) (using "patent trolls" and "NPEs" interchangeably); Tom Ewing & Robin Feldman, *The Giants Among Us*, 1 STAN. TECH. L. REV. 1, 1, 15 (2012) (explaining that mass aggregators do not conduct research or manufacture products, but rather pursue other goals of interest to their founders and investors).

112. Ewing & Feldman, *supra* note 111, at 1–2. Debates around curbing patent trolls proliferated in the discussion leading up to the 2011 patent reform legislation known as the America Invents Act, with the life sciences industry opposing these reforms. *See* Robin Feldman & W. Nicholson Price II, *Patent Trolling: Why Bio & Pharmaceuticals Are at Risk*, 17 STAN. TECH. L. REV. 773, 776 (2014).

filing a patent infringement lawsuit and listing a patent.[113] This judicial process for patent litigation stood in contrast to the filing requirements for other types of litigation, in which those bringing suit were required to specify a sufficient basis for their claim or risk dismissal on an early motion.[114] As a result, scholars and commentators complained that patent trolls could extract settlements regardless of the merit of their claims simply because the expenses associated with pursuing the litigation exceeded the settlement amount demanded.[115]

Various pieces of legislation were introduced to address the problem.[116] In the runup to that legislation, the pharmaceutical industry opposed the

113. *See* FED. R. CIV. P. Form 18; Jun Zheng, *A New Era for Patent Infringement Pleading: Twombly, Iqbal, and the Demise of Form 18*, 24 TEX. INTELL. PROP. L.J. 15, 19–20 (2016) ("Form 18 requires the following information: (1) an allegation of jurisdiction; (2) a statement that the plaintiff owns the patent; (3) a statement that defendant has been infringing the patent 'by making, selling, and using [the device] embodying the patent'; (4) a statement that the plaintiff has given the defendant notice of its infringement; and (5) a demand for an injunction and damages."). In September 2014, a Judicial Conference committee unanimously approved a proposal to abrogate Form 18. This proposal was adopted by the Supreme Court in April 2015 and absent a Congressional objection, Form 18 was abrogated as of December 2015. *See* JUD. CONF. COMM. ON RULES OF PRAC. & PROC., REPORT OF THE JUDICIAL CONFERENCE COMMITTEE ON RULES OF PRACTICE AND PROCEDURE 13 (2014), http://www.uscourts.gov/uscourts/RulesAndPolicies/rules/Reports/ST09-2014.pdf; Zheng, *supra*, at 30–31.

114. Keith N. Hylton, *When Should a Case Be Dismissed? The Economics of Pleading and Summary Judgment Standards*, 16 SUP. CT. ECON. REV. 39, 41 n.9 (2008) (noting that for most litigation, "defendants challenge cases at the pleading stage by filing a motion to dismiss for failure to state a claim").

115. Eric Rogers & Young Jeon, *Inhibiting Patent Trolling: A New Approach for Applying Rule 11*, 12 NW. J. TECH. & INTELL. PROP. 291, 295 (2014); Robin Feldman, *Intellectual Property Wrongs*, 18 STAN. J.L. BUS. & FIN. 250, 283 (2013).

116. *See generally* Leahy-Smith America Invents Act, Pub. L. No. 112–29, § 34, 125 Stat. 284, 340 (2011) (allowing for greater access to the USPTO to deter patent trolls); Saving High-Tech Innovators from Egregious Legal Disputes Act, H.R. 845, 113th Cong. § 2 (2013) (enabling fee shifting to encourage challenging patent trolls); Patent Abuse Reduction Act, S. 1013, 133th Cong. § 2 (2013) (requiring use of claims charts during pleadings to discourage patent trolls); Patent Litigation and Innovation Act, H.R. 2639, 113th Cong. § 2 (2013) (likewise, requiring use of claims charts during pleadings to discourage patent trolls); End Anonymous Patent Act, H.R. 2024, 113th Cong. (2013) (mandating that issued patents disclose the patent owner(s) and parties in interest). Hearings and legislation tend to emerge as part of a long process that begins with at least a few years of public and private discussions. *See, e.g.*, *Patent Trolls: Fact or Fiction?: Hearing Before the Subcomm. on Cts., the Internet, & Intell. Prop. of the H. Comm. on the Judiciary*, 109th Cong. (2006); *Abusive Patent Litigation: The Impact on American Innovation and Jobs, and Potential Solutions: Hearing Before the Subcomm. on Cts., Intell. Prop., & the Internet of the H. Comm. on the Judiciary*, 113th Cong. (2013); *International Trade Commission and Patent Disputes: Hearing Before the Subcomm. on Intell. Prop., Competition, & the Internet of the H. Comm. on the Judiciary*, 112th Cong. (2012).

proposed reform,[117] likely because the reform restricted the extended discovery that was available, and the industry assertedly needed extensive discovery regarding a new entrant's processes to determine what patents to assert.[118] Although congressional legislation largely failed, the patent trolling problem has eased thanks to a procedure called *inter partes* review.[119] Streamlining the mechanism to challenge questionable patents, this procedure is conducted not by a federal court but instead by the Patent Trial and Appeal Board.[120] The pharmaceutical industry's concerns over obtaining information about an entrant's operations prior to filing suit are reflected in the first step of the Biosimilars Act patent dance, in which the biosimilar company must describe its manufacturing process.

b) The Back-and-Forth Tango

As described above, the patent dance begins when the biosimilar company gives the brand both a copy of its application for FDA approval and information describing the biosimilar's manufacturing process. Following that, the brand has sixty days to submit a list of patents that it believes can be reasonably asserted against the biosimilar. We refer to this list as the "Initial Brand List."[121]

In typical patent law fashion, the different stages of the patent dance are identified with a confusing mix of numbers, which are based on the sections of the law that outline this process.[122] To make the patent dance more accessible, this Article uses a simple language scheme for describing each step. The following table shows the correlation between the simple language and the numerical legal system. In addition, this Article includes an appendix with flowcharts breaking down the intricate steps of the patent dance.

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117. H.R. REP. NO. 113-279, at 93–94 (2013) (noting that several stakeholder groups, including the Biotechnology Industry Association (BIO) and the Pharmaceutical Research and Manufacturers Association (PhRMA), issued letters expressing opposition to the "Innovation Act").

118. *See id.* at 109–11 (noting that several pharmaceutical industry groups expressed concerns regarding the proposed provisions of the Innovation Act limiting discovery).

119. Carolyn Treasure & Aaron Kesselheim, *How Patent Troll Legislation Can Increase Timely Access to Generic Drugs*, 176 JAMA INTERNAL MED. 729, 729 (2016) (describing how *inter partes* review is "directed at patent trolls" but also "ha[s] an impact on brand and/or generic drug patent litigation").

120. *Id.*

121. 42 U.S.C. § 262(l)(3)(A)(i) ("[T]he [brand] shall provide to the [biosimilar] applicant . . . a list of patents for which the [brand] believes a claim of patent infringement could reasonably be asserted.").

122. *See id.* § 262(l)(3)(A)(i)–(5)(B)(i), (l)(7).

Table 1: Patent Dance Nomenclature

Numerical Legal Name	Simple Language Used in This Article
3A List[123]	Initial Brand List
3B List[124]	Biosimilar List
7AB List[125]	Supplemental Brand List
4AB List[126]	Negotiated List
5A Notice[127]	Number Notice
5B Lists[128]	Failed-Negotiation Lists
Subparagraph B Statement[129]	Biosimilar Detailed Statement
Paragraph 3(C) Statement[130]	Brand Detailed Statement

In response to receiving the Initial Brand List—that is, the patents the brand believes can be asserted against the biosimilar, the biosimilar company has sixty days to do two things. First, the biosimilar company may give the brand a list of patents that the *biosimilar* company believes the brand could assert as infringing (and that the biosimilar presumably believes are invalid or will not be infringed).[131] In other words, the biosimilar is saying to the brand, "we think you could throw these patents at us, as well, and we want them resolved as part of this process." The current Article refers to this list as the "Biosimilar List." Second, the biosimilar company must give the brand either: (1) a "detailed statement" (the "Biosimilar Detailed Statement") explaining why each patent listed in the Initial Brand List or the Biosimilar List is invalid or will not be infringed by the biosimilar; or (2) a statement declaring that the biosimilar will not enter the market until the listed patents have expired.[132]

123. *See id.* § 262(l)(3)(A).
124. *See id.* § 262(l)(3)(B).
125. *See id.* § 262(l)(7)(A)–(B).
126. *See id.* § 262(l)(4)(A)–(B).
127. *See id.* § 262(l)(5)(A).
128. *See id.* § 262(l)(5)(B).
129. *See id.* § 262(l)(3)(B)(ii)(I).
130. *See id.* § 262(l)(3)(C).
131. *Id.* § 262(l)(3)(B)(i) (stating that the biosimilar "may provide to the [brand] a list of patents to which the [biosimilar] applicant believes a claim of patent infringement could reasonably be asserted by the [brand]").
132. *Id.* § 262(l)(3)(B)(ii)(I), (II) (stating that the biosimilar "shall provide to the [brand], with respect to each patent listed [in the Initial Brand List] or [the Biosimilar List,] . . . a detailed statement that describes, on a claim by claim basis, the factual and legal basis of the opinion of the [biosimilar] applicant that such patent is invalid, unenforceable, or will not be infringed by the commercial marketing of the biological product . . . or . . . a statement that the [biosimilar] applicant does not intend to begin commercial marketing of the biological product before the date that such patent expires").

When the brand receives the Biosimilar Detailed Statement and the Biosimilar List, the brand has sixty days to provide its own "detailed statement" (the "Brand Detailed Statement") explaining why each patent addressed in the Biosimilar Detailed Statement either is *valid* or *will* be infringed.[133]

The Act also specifies dance steps to include if the brand receives more patents along the way. If the brand receives a new patent after providing the biosimilar company with an Initial Brand List, and the brand believes the new patent could serve as the basis for an infringement claim, the brand has thirty days after the patent issues to augment its Initial Brand List[134] with a

133. *Id.* § 262(l)(3)(C) ("[The brand] shall provide to the [biosimilar] applicant a detailed statement that describes, with respect to each patent described in subparagraph (B)(ii)(I), on a claim by claim basis, the factual and legal basis of the opinion of the [brand] that such patent will be infringed by the commercial marketing of the biological product . . . and a response to the statement concerning validity and enforceability.").

134. A brand could choose to omit patents from its Initial Brand List and Supplemental Brand List, in hopes of holding such patents in reserve and then springing them on the biosimilar after the biosimilar receives FDA marketing approval and begins marketing. Three factors deter a brand from engaging in that strategic behavior. First, the brand would lose an opportunity for a preliminary injunction. The Biosimilars Act authorizes the brand to move for a preliminary injunction during the second phase of the patent dance, after the biosimilar's notice of commercial marketing. *See infra* Section III.A.2. However, if the underlying patent was not on the Initial Brand List or Supplemental Brand List, the Act does not give the brand that authorization. *See id.*; *infra* notes 156, 158, 171, and accompanying text (citing 42 U.S.C. § 262(l)(8)). Second, the Biosimilars Act's "list it or lose it" provision expressly bars the brand from suing under 35 U.S.C. § 271 for infringement—through the Biosimilars Act pathway or through an ordinary infringement suit—of any patents omitted from the Initial Brand List and Supplemental Brand List that should have been included. *See* 35 U.S.C. § 271(e)(6)(C) ("The owner of a patent that should have been included in the [Initial Brand L]ist described in section 351(l)(3)(A) of the Public Health Service Act, including [in the Supplemental Brand List] as provided under section 351(l)(7) of such Act for a biological product, but was not timely included in such list, may not bring an action under this section [35 U.S.C. § 271] for infringement of the patent with respect to the biological product."). The provision is clear, although it has broad implications. Despite that clarity, there is some dispute concerning whether the provision reaches that broadly. *See* KEVIN J. HICKEY & ERIN H. WARD, CONG. RSCH. SERV., R46679, DRUG PRICES: THE ROLE OF PATENTS AND REGULATORY EXCLUSIVITIES 37–38 & nn.334–35 (2024); *cf.* Amgen Inc. v. Hospira, Inc., 866 F.3d 1355, 1361 (Fed. Cir. 2017); Amgen Inc. v. Apotex Inc., 827 F.3d 1052, 1058 (Fed. Cir. 2016), *cert. denied*, 580 U.S. 1030 (2016); Patient Protection and Affordable Care Act, Pub. L. No. 111-148, § 7002(c)(1), 124 Stat. 119, 816 (2010). Finally, in the negotiation phase, which is discussed next, the Biosimilars Act limits the Negotiated List (the first list in the negotiation phase) to patents included in the Initial Brand and Biosimilar Lists. *See* 42 U.S.C. § 262(l)(4)(A). (One would expect Congress to also limit subsequent lists in the negotiation phase, which are called Failed-Negotiation Lists, to patents included in the Initial Brand and Biosimilar Lists. Oddly, the Act fails to do so, which may have been a drafting error by Congress. Regardless, the hole left by that failure is plugged by the "list it or lose it" provision.)

Supplemental Brand List.[135] The biosimilar company then has thirty days to provide another statement to the brand about the validity and infringement potential of the patents on the Supplemental Brand List.[136]

c) Coming to a Compromise (or Not)

To recap, at this point, the brand has provided its Initial Brand List of infringed patents (augmented with a Supplemental Brand List of any new patents received).[137] The biosimilar company has responded with its (optional) Biosimilar List of patents it believes the *brand* both holds and might assert,[138] and with its (mandatory) Biosimilar Detailed Statement regarding each patent on the Initial Brand List or any Biosimilar List.[139] In turn, the brand has responded with a (mandatory) Brand Detailed Statement regarding each patent on the Biosimilar Detailed Statement.[140]

Now comes a negotiation phase. After the biosimilar company receives the Brand Detailed Statement, the parties have fifteen days to decide which patents from the Initial Brand and Biosimilar Lists belong on a "final and complete list," which we refer to as the "Negotiated List." Each of these patents will be included in an action for patent infringement.[141] If the parties cannot agree on which patents should constitute the Negotiated List, each party draws up a second set of lists, which we refer to collectively as the "Failed-Negotiation Lists."[142]

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135. 42 U.S.C. § 262(l)(7)(A)–(B) (stating that if a patent "is issued to, or exclusively licensed by, the [brand] after the date that the [brand] provided the list to the [biosimilar] applicant under paragraph (3)(A); and . . . the [brand] reasonably believes that, due to the issuance of such patent, a claim of patent infringement could reasonably be asserted by the [brand] . . . , the [brand] shall provide the [biosimilar] applicant a supplement to the list provided by the [brand]"). Note that the patents on the Supplemental Brand List are expressly included by the Biosimilars Act among the patents that may be litigated in the *second* phase of the patent dance. *See id.* § 262(l)(7). For further discussion of the Supplemental Brand List, see *infra* note 179 and accompanying text.

136. *Id.* § 262(l)(7) ("[T]he [biosimilar] applicant shall provide a statement to the [brand] in accordance with paragraph (3)(B).").

137. *See supra* notes 121, 134–135, and accompanying text.

138. *See supra* note 131 and accompanying text.

139. *See supra* note 132 and accompanying text.

140. *See supra* note 133 and accompanying text.

141. 42 U.S.C. § 262(l)(4)(A) ("[T]he [brand] and the [biosimilar] applicant shall engage in good faith negotiations to agree on which, if any, patents listed under paragraph (3) by the [biosimilar] applicant or [brand] shall be the subject of an action for patent infringement under paragraph (6).").

142. *Id.* § 262(l)(4)(B), (5)(B)(i) (stating that if within 15 days, there is a "[f]ailure to reach agreement," then "the [biosimilar] applicant and the [brand] shall simultaneously exchange . . .

In the Failed-Negotiation List process, the biosimilar company, as a general matter, gets to determine the *number* of patents it believes should be subject to an infringement action.[143] This restriction, in theory, allows the biosimilar company to control the patent litigation's scope, preventing the brand from flooding the biosimilar with claims of infringement.

The process begins when the biosimilar notifies the brand of the number of patents that will be on the biosimilar's Failed-Negotiation List. This notice is referred to here as the "Number Notice."[144] Within five days of the Number Notice, the biosimilar and the brand simultaneously exchange their Failed-Negotiation Lists, which list the patents they each believe should be included in an infringement action.[145] The number of patents on the brand's list cannot exceed the number of patents on the biosimilar's list.[146] At this point, the

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the list[s] of patents that" the brand and the biosimilar applicant each believe "should be the subject of an action for patent infringement").

143. *Id.* § 262(l)(5)(A) ("The [biosimilar] applicant shall notify the [brand] of the number of patents that [the biosimilar] applicant will provide to the [brand].").

144. *Id.* § 262(l)(5)(A).

145. *Id.* § 262(l)(5)(B)(i) ("[The biosimilar and brand] shall simultaneously exchange—the list[s] of patents that" each believe "should be the subject of an action for patent infringement.").

146. *Id.* § 262(l)(5)(B)(ii)(I) ("[T]he number of patents listed by the [brand] under clause (i)(II) may not exceed the number of patents listed by the [biosimilar] applicant under clause (i)(I).").

Section 262(l)(5)(A) and (B) clearly contemplate that the biosimilar's Number Notice (*see supra* text accompanying notes 144–145) should state the same number as the number of patents actually included in the biosimilar's Failed-Negotiation List. But it is unclear what happens if the biosimilar, after giving its Number Notice, provides a Failed-Negotiation List showing *fewer* patents, thereby duping the brand into giving a Failed-Negotiation List longer than the biosimilar's. In a litigation raising an analogous issue, the biosimilar did not negotiate the Negotiated List in good faith under section 262(l)(4) or comply with section 262(l)(5). The district court ruled that, consequently, the brand would not be limited to a reasonable royalty for damages, since that limitation of damages was intended as a benefit for the biosimilar's compliance with sections 262(l)(4) *and (5)*. *See* Janssen Biotech, Inc. v. Celltrion Healthcare Co., 239 F. Supp. 3d 328, 331–32 (D. Mass. 2017); *see also* GOODWIN PROCTER LLP, GUIDE TO BIOSIMILARS LITIGATION AND REGULATION IN THE U.S. § 4:19 & n.8 (2022) [hereinafter GOODWIN PROCTER GUIDE TO BIOSIMILARS LITIGATION].

In addition, the biosimilar's failure to comply with, among other provisions, Sections 262(l)(5)(A) and (B) entitles the brand to bring a declaratory judgment action for a declaration that any patent on the Initial Brand or Supplemental Brand List is valid, enforceable, or infringed. *See* 42 U.S.C. § 262(l)(9)(B); GOODWIN PROCTER GUIDE TO BIOSIMILARS LITIGATION § 4:19 & n.9. Without that right of action, the brand will have no real recompense for the biosimilar's noncompliance. However, none of the foregoing addresses the express statutory requirement that the number of patents on the brand's Failed-Negotiation List not exceed the number of patents on the biosimilar's Failed-Negotiation List. *See* 42 U.S.C. § 262(l)(5)(B)(ii)(I). Certainly, making the brand trim its list would be unfair to the brand,

negotiation process has finished, and the parties have narrowed down the universe of potentially litigable patents to a relatively short list of key patents that will be the focus of the ensuing litigation.

If, for whatever reason, the biosimilar does not include *any* patents on its list, the brand may include one patent on its list.[147] In either case, the brand has thirty days to bring an infringement action covering all the patents on the Negotiated List or (absent a Negotiated List) the Failed-Negotiation Lists.[148] As noted,[149] the number of patents on the brand's Failed-Negotiation List cannot exceed the number of patents on the biosimilar's list. This prevents the brand from flooding the litigation by listing hundreds of patents—regardless of whether the patents are valid or validly applied to the product—that the biosimilar will have to battle. Once again, the biosimilar controls the number of patents.

No later than thirty days after the brand's complaint is served, the biosimilar must provide a copy of the complaint to the FDA, which publishes notice of the complaint in the Federal Register.[150] So far, the Federal Register notices do not appear to have included the patents involved in the complaint.[151]

2. Phase Two of the Patent Dance

a) Phase Two Begins

Under the Biosimilars Act's sister act, Hatch-Waxman, the brand receives an automatic 30-month stay after filing litigation, during which the FDA is

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because the excess of patents on the brand's list was procured by the biosimilar's own wrongdoing. Perhaps the solution is to deem the biosimilar's list to include as many patents on the brand's list as are needed to make the two lists equal in number.

147. 42 U.S.C. § 262(l)(5)(B)(ii)(II) (noting the exception that "if a [biosimilar] does not list any patent under clause (i)(I), the [brand] may list 1 patent under clause (i)(II)").

148. *Id.* § 262(l)(6)(A)–(B) (providing that whether or not there is agreement on the patent list, "the [brand] shall bring an action for patent infringement with respect to each such patent").

149. *See id.*

150. *Id.* § 262(l)(6)(C)(i)–(ii) (stating that the biosimilar "shall provide the Secretary with notice and a copy of such complaint" for patent infringement within 30 days of when the complaint is served and that the "Secretary shall publish in the Federal Register notice of a complaint").

151. In the Federal Register notices that the authors could locate, none contains patent information. *See* 88 Fed. Reg. 14171 (Mar. 7, 2023); 87 Fed. Reg. 7844 (Feb. 10, 2022); 83 Fed. Reg. 46174 (Sept. 12, 2018); 82 Fed. Reg. 57279 (Dec. 4, 2017); 82 Fed. Reg. 55105 (Nov. 20, 2017); 82 Fed. Reg. 36150 (Aug. 3, 2017); 81 Fed. Reg. 64180 (Sept. 19, 2016); 81 Fed. Reg. 18858 (Apr. 1, 2016); 80 Fed. Reg. 51277 (Aug. 24, 2015).

barred from approving the generic's application for marketing.[152] The 30-month stay is included to give the courts time to resolve the patent disputes.

The Biosimilars Act does not contain an automatic stay in which the FDA is barred from granting the biosimilar's request for a license. However, the Act does contain a different timing device for market entry that similarly gives the courts time to resolve litigation issues.[153]

Specifically, the biosimilar must tell the brand the planned date of its first commercial marketing at least 180 days in advance. This notice marks the start of the second phase of litigation.[154]

The second phase of litigation gives the brand a chance to assert any remaining patents on any of the opening lists but not eventually litigated in the first phase.[155] To that end, after the biosimilar gives notice of commercial marketing, the brand may file suit and move for a preliminary injunction on any patents that were included in the Initial Brand List, Biosimilar List, and Supplemental Brand List but did not make it onto the Negotiated or Failed-Negotiation Lists.[156] The district court hearing a brand's preliminary injunction motion may limit the number of patents to be considered.[157]

A preliminary injunction would halt manufacture or sale of the biosimilar until the patent disputes are resolved in the second-phase lawsuit.[158] Note,

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152. *See infra* note 170.

153. For a different timing device in the Biosimilars Act, see *infra* notes 301–303 and accompanying text (describing the 12-year and 4-year exclusivities granted to the brand biologic).

154. 42 U.S.C. § 262(l)(8)(A) (noting that the biosimilar "shall provide notice to the [brand] not later than 180 days before the date of the first commercial marketing of the biological product").

155. *See* Carrier & Minniti, *supra* note 107, at 18.

156. 42 U.S.C. § 262(l)(8)(B)(i)–(ii) (providing that the brand "may seek a preliminary injunction"). The statutory text says only that in phase two the brand may seek a preliminary injunction, and does not say expressly that the brand also initiates a new lawsuit in which the preliminary injunction may be sought. *See id.* But the practice is clearly that if the brand in phase two seeks a preliminary injunction, it initiates a new lawsuit in which to file its preliminary injunction motion. *See, e.g.*, Second Amended Complaint ¶¶ 1, 11–15, 49–52, d, AbbVie Inc. v. Alvotech hf., 582 F. Supp. 3d 584 (N.D. Ill. Jan. 26, 2022) (lawsuit initiating second-phase litigation and seeking preliminary injunction).

157. *See, e.g.*, *In re* Katz Interactive Call Processing Pat. Litig., 639 F.3d 1303, 1310–13 (Fed. Cir. 2011) (holding that district courts hearing patent infringement claims may mandate the patent holder to select only representative claims against each defendant).

158. 42 U.S.C. § 262(l)(8)(B)(i)–(ii) (stating that the brand "may seek a preliminary injunction prohibiting the [biosimilar] applicant from engaging in the commercial manufacture or sale of such biological product until the court decides the issue of patent validity, enforcement, and infringement with respect to any patent that is . . . included in the list provided by the [brand] under paragraph (3)(A) or in the list provided by the [biosimilar]

however, that although the patent dance provisions of the Biosimilars Act authorize a preliminary injunction only in the second phase, other provisions of the Biosimilars Act might authorize injunctive relief in both phase one and phase two.[159]

If the court denies the brand's motion for a preliminary injunction in phase two, the biosimilar can enter the market, assuming the 180 days have expired.[160] With or without a preliminary injunction, the patent litigation will proceed to the merits. The only difference would be whether the biosimilar may enter the market while the litigation proceeds.[161]

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applicant under paragraph (3)(B); and . . . not included, as applicable, on . . . the list of patents described in paragraph (4); or . . . the lists of patents described in paragraph (5)(B)").

159. The patent dance provisions of the Biosimilars Act specify the potential for a preliminary injunction only in relation to phase two of the litigation. *See* 42 U.S.C. § 262(l)(6), (8) (specifying availability of a preliminary injunction during phase two of the litigation but remaining silent on the availability of a preliminary injunction in phase one). However, although much of the Biosimilars Act was codified in the part of federal law related to licensing biologic products (Title 42 of the U.S. Code), some of the Act's language required amendments to the Patent Act (Title 35 of the U.S. Code). Some courts and scholars suggest that the Biosimilars Act's amendments to the Patent Act make injunctive relief available in *both* phases, despite the absence in the patent dance sections of any language providing for injunctive relief in phase one. *See* AbbVie Inc. v. Alvotech hf., 582 F. Supp. 3d 584, 591–92 (N.D. Ill. 2022) (holding that because the Biosimilars Act authorizes the brand to bring an artificial infringement claim under 35 U.S.C. § 271(e)(2) in both phases, the Act also authorizes the brand to obtain injunctive relief under 35 U.S.C. § 271(e)(4) in both phases); Carl J. Minniti III, Sandoz v. Amgen*: Why Current Interpretation of the Biologic Price Competition and Innovation Act of 2009 Is Flawed and Jeopardizes Future Competition*, 97 J. PAT. & TRADEMARK OFF. SOC'Y 172, 177, 179 (2015) (discussing the Biosimilars Act's amendments to the Patent Act); *supra* note 2 (citing Patient Protection and Affordable Care Act, Pub. L. No. 111-148, tit. VII, subtit. A, §§ 7001–03, 124 Stat. 119, 804-21 (2010) which reflects the Biosimilars Act's amendments to the Patent Act); *cf.* GOODWIN PROCTER GUIDE TO BIOSIMILARS LITIGATION, *supra* note 146, § 4:58 (observing, even without reference to the Biosimilars Act's amendments to the Patent Act, that if a biosimilar provides notice of commercial marketing while phase-one litigation is still pending, a court could then enter a preliminary injunction on any patent being litigated in phase one to prevent entry into the market).

160. The exclusivities granted to brands under the Biosimilars Act also must have expired. *See infra* text accompanying notes 301–303 (describing those 12-year and 4-year exclusivities).

161. If there is no preliminary injunction, and the biosimilar launches while the merits are pending, the brand will be able to request damages. *See infra* note 166; *infra* text accompanying notes 166–169 (discussing the option to launch at risk).

b) The Biosimilar Gets Strategic Options

The biosimilar company does have some strategic options in addition to the ones listed above.[162] In particular, by creating two phases, the statute allows the parties to select key patents for litigation in the first phase and leave other patents for litigation in the second phase.[163] The intent may be to encourage the parties to focus on the key issues in the dispute, rather than wasting time going down every possible rabbit hole. More practically, the bifurcated phasing provides the biosimilar with strategic options, given that the biosimilar can choose when to initiate the second phase by deciding when to provide its notice of commercial marketing.[164]

Specifically, the Biosimilars Act does not require the first phase to finish before the second phase can be started.[165] Consider the circumstance in which, after the biosimilar has provided its notice of commercial marketing, there is no preliminary injunction halting the biosimilar's entry into the market. In

162. *See supra* text accompanying notes 131–132, 138–139, 143–146, 160.

163. *See* AbbVie, 582 F. Supp. 3d at 593 ("The BPCIA creates a procedure by which the parties can litigate the most contested and consequential patents immediately, *see* [42 U.S.C.] § 262(l)(6), giving both parties what is likely a definitive answer, with lower costs and on an expedited schedule.").

164. *See* Sandoz Inc. v. Amgen Inc., 582 U.S. 1, 10 (2017) ("Because the [biosimilar] applicant (subject to certain constraints) chooses when to begin commercial marketing and when to give notice, it wields substantial control over the timing of the second phase of litigation.").

165. *See* Thomas J. Sullivan, *The Patent Dance*, EUR. BIOPHARM. REV. 72, 74 (2018) ("A . . . mechanism to shorten a suit under the BPCIA would be to collapse the two phases of litigation into a single action in a scenario where the biosimilar applicant provides its 180-day notice of commercial marketing contemporaneously with its notification to the [brand drug-maker] of its [biosimilar application]."). By collapsing the two phases, the parties are effectively writing their own rules. Also, the fact that the second phase can be started before the first phase is complete is a boon to those biosimilars that prioritize getting to market over obtaining the brand's patent disclosure in the patent dance. The second biosimilar typically falls into this category. Unlike the second biosimilar, the first biosimilar has a relatively strong incentive to go through the patent dance: During its own patent dance, the first biosimilar will gain meaningful patent disclosure from the brand (as the brand makes *no* patent disclosure prior to the first biosimilar's patent dance), whereas the second biosimilar's patent dance is less likely to procure meaningful patent disclosure beyond what emerged from the first biosimilar's patent dance. Thus, the second biosimilar has a relatively strong incentive to start phase two immediately so that it can get to market as soon as possible (even if the first phase is so truncated as to generate little or no patent disclosure by the brand). The second biosimilar's conduct in these circumstances presents a variant of the free rider problem discussed below. *See infra* Section III.B.1. Note that while in theory the second biosimilar obtains meaningful disclosure from its patent dance with the brand, in practice the second biosimilar's need for disclosure is often satisfied, at least in significant part, from the disclosure generated by the first biosimilar's patent dance with the brand.

other words, imagine if the biosimilar provides notice of commercial marketing, launching the second phase, and the first phase of the dance has not even reached the point at which the brand *could* file a first-phase suit (let alone move for preliminary injunction). In addition, either 1) the brand's second-phase preliminary injunction motion is denied; 2) the brand doesn't move for a preliminary injunction in the second phase; or 3) the brand never even commences a second-phase suit. In those circumstances, nothing is blocking the biosimilar's entry, and thus the biosimilar has the strategic option of launching at risk.[166] To launch at risk, the biosimilar could simply obtain FDA approval, launch the product after the 180-day waiting period,[167] and invite a claim of actual infringement and damages.

166. *Cf. supra* text accompanying note 28 (describing launching at risk under the Hatch-Waxman Act); *see infra* note 197. Launching at risk under the Biosimilars Act is similar to launching at risk under the Hatch-Waxman Act. The added "risks" flow from the damages the brand will suffer when the generic or biosimilar actually enters the market. Once the generic or biosimilar enters the market and incurs damages liability, the brand can bring a claim for actual infringement and damages. When the brand claims actual infringement and damages, the parties have a right to jury trial. *See* Steven A. Nash & Rebecca Workman, *A New Pathway for Follow-on Biologics*, 20 FED. CIR. BAR J. 193, 216 n.160 (2010) ("Where no biosimilar launch has occurred, the [brand biologic] will be limited to equitable relief [such as an injunction]. Thus, similar to ANDA cases, there will be no right to a jury trial."); GOODWIN PROCTER GUIDE TO BIOSIMILARS LITIGATION, *supra* note 146, § 4:56 (concluding that right to jury trial arises when the brand claims actual infringement and damages, but not when the brand claims only artificial infringement: "As in the Hatch-Waxman context, the alleged infringement in a [Biosimilars Act] case may be prospective only where the biosimilar applicant has not yet commercially marketed any product. In this situation, the patentee typically only seeks injunctive relief because no money damages are at issue, and therefore the patentee's claim is not expected to trigger a right to a jury trial. . . . [But if] a biosimilar applicant were to obtain FDA approval for its product and launch its product prior to patent resolution, the [brand biologic] may allege infringement under § 271(a) and seek damages, triggering a right to a jury trial on infringement and validity of the patents at issue."). As a practical matter, jury trials will probably be more common in Biosimilars Act litigation than in Hatch-Waxman litigation, because biosimilars are more likely than generics to launch at risk, and thus to face a claim of actual infringement and damages. *See infra* note 196 (regarding greater likelihood that biosimilars will launch at risk); Ha Kung Wong & April Breyer Menon, *The State of Biosimilars in 2023*, JD SUPRA (Mar. 17, 2023), https://www.jdsupra.com/legalnews/the-state-of-biosimilars-in-2023-6368882/ (concluding that launching at risk is not uncommon under Biosimilars Act and noting that, of 40 approved biosimilars, 27 have been launched, and 11 of those launched—i.e., 40.7%—were launched at risk).

167. The biosimilar applicant wishing to market its drug commercially must give notice to the brand 180 days in advance. 42 U.S.C. § 262(l)(8)(A). During that period, the brand may move for a preliminary injunction against any commercial marketing of that drug. *Id.* § 262(l)(8)(B). If a preliminary injunction is granted, the commercial marketing of the drug is barred until the court's resolution of the validity, enforcement, and infringement of any patent that is "included in the [Initial Brand List] or the [Biosimilar List] and . . . not included, as

In the litigation that follows a biosimilar's launch at risk, the brand will allege an actual infringement, given that the biosimilar's commercial marketing constitutes actual infringement. In contrast, filing an application for *approval* of a biosimilar constitutes only artificial infringement, allowing the parties to resolve the patent issues before the biosimilar incurs liability for damages from actual infringement.[168] A biosimilar that launches at risk faces the added risk of damages and a potential jury trial. By declining to launch at risk and thus by engaging only in artificial infringement, the biosimilar can assure that a judge, rather than a jury, serves as the trier of fact.[169]

Waiting for the completion of all first-phase litigation, and then commercially marketing while second-phase litigation is ongoing, is not the only launch-at-risk option for a biosimilar. Nothing in the statute obligates the FDA to wait for completion of the dance (or any of its steps) before approving the application.[170] If the biosimilar provides notice of commercial marketing before the Negotiated List is finished or the Failed-Negotiation Lists are exchanged, then the parties likely would automatically enter the second phase. That second phase proceeds as an infringement litigation involving the patents on all existing lists—the Initial Brand List, Biosimilar List, and Supplemental Brand List.[171] If no launch has yet occurred (e.g., because a preliminary injunction against commercial marketing of the biosimilar was granted), the

applicable, on . . . the [Negotiated List] or . . . the [Failed-Negotiation Lists]." *Id.*; *see id.* § 262(l)(7) (making the Supplemental Brand List subject to 42 U.S.C. § 262(l)(8)); *supra* text accompanying notes 155–158. Note that if the court has not decided the preliminary injunction motion by day 180, the biosimilar is then free to begin commercial marketing of its drug and can continue unless and until the court grants the preliminary injunction motion.

As noted above, it is possible to collapse phases one and two if the biosimilar provides its notice of commercial marketing at the start of, or during, phase one. *See supra* note 159; *supra* notes 165–166 and accompanying text; *see also infra* text accompanying notes 171, 218. But collapsing phases one and two can lead to a dizzying number of interpretive problems depending on precisely when in phase one the notice of commercial marketing is provided. A full analysis of these issues and conflicts, however, is beyond the scope of this Article.

168. *See supra* note 166.

169. *See supra* note 166.

170. In contrast, the Hatch-Waxman Act includes a 30-month stay of approval once a patent infringement action is initiated within 45 days of when the generic manufacturer notifies the brand manufacturer that a Paragraph IV certification has been filed. *See* 21 U.S.C. § 355(c)(3)(C), (j)(5)(B)(iii).

171. 42 U.S.C. § 262(l)(8) (permitting brand to move for preliminary injunction against biosimilar's marketing of drug pending court's resolution of infringement claims with respect to any patent on Initial Brand or Biosimilar List that is not on Negotiated or Failed-Negotiation Lists); *id.* § 262(l)(7) (stating that any patent on Supplemental Brand List "shall be subject to [§ 262(l)](8)").

brand's claim is for artificial infringement; if the launch has occurred, the brand can bring a claim for actual infringement and damages.[172]

c) The Brand Also Gets Strategic Options

The Biosimilars Act also leaves room for strategic behavior by the brand. In particular, under the Biosimilars Act regime, if the brand's Initial Brand List does not list a relevant patent, the brand will face at least two consequences. First, the brand will face limitations on its ability to sue the biosimilar company in phase one and phase two. In phase one, the Negotiated List is limited to patents on the Initial Brand and the Biosimilar Lists.[173] A patent omitted from the Initial Brand List cannot be on the Negotiated List, unless, of course, the biosimilar put the patent on its Biosimilar List. Thus, the brand will not be able to sue in phase one for infringement of that patent.[174] Nor, in phase two, can the brand sue or obtain a preliminary injunction for infringement of any patent not litigated in phase one, unless the patent to be sued on was listed in the Initial Brand List (or the Biosimilar List).[175]

Second, the Biosimilars Act's "list it or lose it" provision creates an even more severe penalty.[176] This provision prevents the brand from bringing an ordinary suit under 35 U.S.C. § 271 for infringement of any patents that should have been, but were not, included in its Initial Brand List and Supplemental Brand List.[177]

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172. *See supra* text accompanying notes 27–28, 167–169.

173. *See* 42 U.S.C. § 262(l)(4)(A).

174. *See id.* § 262(l)(6); *cf. supra* note 134 (noting possible drafting error in statutory provision concerning Failed-Negotiation Lists).

175. *See* 42 U.S.C. § 262(l)(8)(B)(i); *supra* note 171; *see also supra* note 156 and accompanying text.

176. *See supra* note 134; *see also infra* text accompanying and following notes 177–178; KEVIN J. HICKEY, CONG. RSCH. SERV., IF11214, DRUG PRICING AND THE LAW: PHARMACEUTICAL PATENT DISPUTES 2 (2019).

177. *See supra* note 176. In contrast, under the Hatch-Waxman regime, if a brand's NDA fails to list a relevant patent, then the generic need not provide a Paragraph IV certification as to that patent. *See supra* note 59 and accompanying text. And absent that certification, the brand can sue the generic for infringement (if the brand can allege actual infringement unprotected by the safe harbor of 35 U.S.C. § 271(e)(1)) but cannot obtain a thirty-month stay in which the FDA cannot approve the generic. *See* HICKEY, *supra* note 176, at 2 (concluding that NDA's failure to list relevant patent bars brand from obtaining 30-month stay); Celgene Corp. v. Sun Pharma Glob. FZE, No. 19-10099 (SDW) (LDW), 2020 WL 1921700, at *2–3 (D.N.J. Apr. 6, 2020) (holding that NDA's failure to list relevant patent does not bar brand from suing generic for infringement of that patent (citing cases)); *see also infra* this footnote. To be clear, if the brand's NDA fails to list a relevant patent, although there may be implications related to the 30-month stay, the brand faces no fine, penalty, or restriction of its right to sue the generic for infringing that patent (though, again, the brand would have to allege actual

Despite this deterrent, the brand might still choose not to list certain patents in its Initial Brand List or Supplemental Brand List. The brand might be under the impression that it may still assert the patent in litigation against other biosimilars, and the company may have a strong incentive to hold back certain patents. Specifically, when a company alleges infringement of a patent in any type of litigation, the allegation puts that patent at risk. In response, the alleged infringer will immediately claim that the patent is invalid or does not apply to the drug at issue.

No company wants to risk its crown jewels unless absolutely necessary. Thus, the brand might ignore the "list it or lose it" provision and hold back its most important patent or patents, on the expectation that asserting other patents will be enough either to stop the biosimilar or to obtain a settlement that keeps the biosimilar off the market for a period of time.[178] If that strategy is successful, the brand's most important patents remain unchallenged and thus remain a possible deterrent to future biosimilar entry. Ultimately, however, the "list or lose it" provision may well be held to bar the brand from asserting those patents in future litigation against others trying to enter.

Even if the strategy fails—with the result that the biosimilar succeeds in knocking out the less important patents and enters the market—holding patents in reserve may still have value to the brand. Historically, average prices have dropped most sharply when several generics enter the market to challenge a brand. Although the brand has lost some market share with the entry of one biosimilar, holding some patents in reserve might help deter multiple entry, even if ultimately the "list it or lose it" provision will bar the brand from enforcing those patents.

Another strategic choice for the brand involves the Supplemental Brand List. The Biosimilars Act expressly includes the Supplemental Brand List within the patents that could be included in the second phase.[179] As described

infringement unprotected by the safe harbor of 35 U.S.C. § 271(e)(1)). *See* JOHN R. THOMAS, CONG. RSCH. SERV., R42354, PATENT INFRINGEMENT AND EXPERIMENTAL USE UNDER THE HATCH-WAXMAN ACT: CURRENT ISSUES 8 (2013); *Celgene*, 2020 WL 1921700, at *2–3. This stands in contrast to the Biosimilars Act as described in the text accompanying this note.

178. *See infra* Section III.B.3 (describing pay-for-delay settlements).

179. 42 U.S.C. § 262(l)(7). To be clear, both text and logic demonstrate that the Supplemental Brand List is part of the first phase (and not just the second). The textual evidence is twofold. First, the statutory provision creating the Supplemental Brand List is in paragraph 7 of § 262(l). The statutory provision creating the second phase is in paragraph 8 of § 262(l). Thus, the placement of the provision creating the Supplemental Brand List in paragraph 7 rather than paragraph 8 is evidence that the Supplemental Brand List is part of the first phase. Second, the statute calls the Supplemental Brand List a "supplement to the [Initial Brand L]ist," 42 U.S.C. § 262(l)(7)(B). Because the Initial Brand List is indisputably part

above,[180] if the brand, after providing the biosimilar with its initial list of relevant patents, receives a new patent that it believes could serve as a basis for an infringement claim, the brand has thirty days to send a Supplemental Brand List.[181] Sending the Supplemental Brand List in the second phase provides the *brand* with strategic choices comparable to those offered to the biosimilar through the bifurcated phasing. Specifically, if the brand can influence the timing of a patent approval by the U.S. Patent and Trademark Office (USPTO), the brand can time the sending of the Supplemental Brand List to reach the biosimilar at an inopportune moment for the biosimilar (e.g., close to the biosimilar's launch date).

Biosimilars would do well, however, to recall that the statute, while expressly making the Supplemental Brand List part of the second phase, also makes that list part of the first phase.[182] As a practical matter, the first phase could readily include a patent on the Supplemental Brand List as long as the Supplemental Brand List is provided before the Negotiated List is finished (or before the Failed-Negotiation Lists are exchanged).

Suppose, however, that a Supplemental Brand List is provided *after* completion of the Negotiated List (or *after* exchange of the Failed-Negotiation Lists) *but before* the second phase of the dance is triggered by the biosimilar

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of the first phase, a supplement to that list should be regarded as part of the first phase, too. True, paragraph 7 also expressly makes the Supplemental Brand List part of the second phase, but that fact does not weaken the conclusion that the Supplemental Brand List is part of the first phase *as well*. As a logical matter, any suggestion that the Supplemental Brand List may be part of the second phrase *exclusively*, *e.g.*, *Amgen Inc. v. Apotex Inc.*, 827 F.3d 1052, 1057 (Fed. Cir. 2016), should be rejected. An interpretation of paragraph 7 that makes the Supplemental Brand List part of the second phase *exclusively* would make no sense (aside from ignoring the clear textual evidence cited earlier in this note). Suppose that the brand provides its Initial Brand List to the biosimilar, and the next day obtains a new patent and immediately provides its Supplemental Brand List to the biosimilar—all well before the parties even attempt to negotiate the Negotiated List. Under those circumstances, an interpretation making the Supplemental Brand List exclusively part of the second phase would bar both the brand and the biosimilar from including the new patent in the negotiation of the Negotiated List, even though both parties were aware of the new patent before the negotiation, and both wished to include the new patent in the negotiation. That bar would be senseless. Worse yet, such an interpretation would prevent the brand from litigating the new patent—even though the brand informed the biosimilar of the new patent one day after providing the Initial Brand List—unless and until the biosimilar decides to commence the second phase with a notice of commercial marketing. Precluding the brand from having any *opportunity* to litigate the new patent unless the biosimilar so permits would be pointless and inequitable.

180. *See supra* text accompanying notes 134–135.

181. *See supra* text accompanying notes 134–135.

182. *See supra* note 179 (discussing textual and logical reasons why the Supplemental Brand List is part of the first phase as well as the second).

filing a notice of commercial marketing. In that circumstance, could the first phase include a patent on that Supplemental Brand List as a practical matter? The statutory language is unclear. The alternatives appear to be that (1) the parties agree to amend the Negotiated List to add the new patent, (2) the brand (assuming no Negotiated List was created) can amend its Failed-Negotiation List to add the new patent as long as the addition does not cause undue prejudice to the biosimilar, or (3) the parties begin a new first phase—supplementary to but independent of the existing first phase—addressing the new patent by itself.

In short, the patent dance is an intricate and astoundingly complex series of phases, steps within those phases, and strategic choices for both parties. Some of the steps, choices, and ramifications remain unclear almost fifteen years after President Obama signed the legislation. Moreover, the brand enters the dance in the dark, without knowing in advance what processes the biosimilar is using to make its drug. The biosimilar also enters in the dark, without a clear list of the patents that the brand may assert in protection of the drug. Just understanding the basic processes set forth in the statutory language burns through an enormous amount of ink. Therefore, the Biosimilars Act truly deserves the Federal Circuit's description as "a riddle wrapped in a mystery inside an enigma."[183] Given these frailties, it is not surprising that the Act has fallen short of expectations as a means of enhancing competition in the biologic drug markets and reducing drug prices for consumers.

B. GAMING THE PROCESS

As noted earlier, biologic patent dispute resolution owes its length and complexity to the fact that, prior to its initiation, the biosimilar has little concrete idea of the patents with which its gestating product must contend. Crucially, however, biologic patent litigation also places the responsibility to share relevant information squarely on the shoulders of drug-makers, conferring on them the authority to decide which patents to include on which lists.

Recall that information in the biologic realm—particularly patents and trade secrets relating to manufacturing processes—is extremely valuable to drug-makers given that biologic drug development is difficult, expensive, and incompletely understood. It should come as no surprise, then, that brand companies have the incentive to cooperate less than fully with a regulatory scheme whose objective is to hand that information over to a potential

183. *See supra* text accompanying note 10.

competitor. The following Sections describe how these incentives are playing out on the ground.

1. *Patent Disclosure, the Purple Book Continuity Act, and the Free Rider Problem*

As described in Section II.C, *The Information Desert*, the biosimilar system suffers from a severe lack of information. Unlike the system for generic drugs, the FDA does not publish a comprehensive list of the patents a brand company could reasonably assert in protection of each biologic drug. That lack of information combines with other information gaps related to biologic drugs—including gaps in biologics patents themselves and in the clinical trial data published by the FDA. As a result, a biosimilar company exploring whether to enter a particular market will be completely unable to answer any of the four basic questions: (1) what is the drug; (2) how is it made; (3) what patent rights apply; and (4) when do those rights expire.

Congress attempted to remedy the lack of patent transparency in the biologics space by amending the Biosimilars Act with the Purple Book Continuity Act, also known as the 2020 Transparency Act.[184] The Transparency Act mandates that the Secretary of Health and Human Services publish a listing of licensed biologic drugs and update it monthly. (In fact, the FDA of its own accord began publishing such a list on September 9, 2014,[185] but the Transparency Act formalized that FDA initiative.) Analogous to the Orange Book of non-biologic drugs, the publication, officially titled "Lists of Licensed Biological Products with Reference Product Exclusivity and Biosimilarity or Interchangeability Evaluations," is better known as the Purple Book.

More significantly, the 2020 Transparency Act mandated that the Purple Book include a list of patents appearing in any Initial Brand List and Supplemental Brand List provided during a patent dance, as well as the expiration dates of those patents.[186] (Note, however, that the 2020

184. The 2020 Transparency Act was enacted as section 325 (entitled "Biological Product Patent Transparency") of the Consolidated Appropriations Act, 2021. *See* Pub. L. No. 116-260, div. BB, tit. III, subtit. C, § 325, 134 Stat. 1182, 2936–38 (2020) (amending Public Health Service Act, 42 U.S.C. § 262(k), by adding new subsection (k)(9), which requires publication of Purple Book).

185. Kurt Karst, *The "Purple Book" Makes Its Debut*, FDA L. BLOG (Sept. 9, 2014), https://www.thefdalawblog.com/2014/09/the-purple-book-makes-its-debut.

186. *See* 42 U.S.C. § 262(k)(9)(A)(iii) ("Not later than 30 days after a list of patents under subsection (l)(3)(A), or a supplement to such list under subsection (l)(7), has been provided by the [brand] to the [biosimilar] applicant respecting a biological product included on the list published under this subparagraph, the [brand] shall provide such list of patents (or

Transparency Act does not call for the publication of any Biosimilar, Negotiated, or Failed-Negotiation Lists.) The new information must be included in the Purple Book within thirty days after the brand gives each relevant list to the biosimilar.

Although this requirement is a step in the right direction, it still grounds disclosure in the patent dance, allowing drug companies to control the information disclosed. Moreover, the requirement may have inadvertently created an additional disincentive for biosimilars by creating a potential "free rider" problem. Under the new regime, patent information does not enter the Purple Book until a biosimilar company has filed an application and the patent dance begins. The first biosimilar company to file an application, therefore, has a distinct disadvantage: It must develop and seek approval for its drug product with zero knowledge of the brand's patent holdings. Later biosimilar applicants preparing for market entry may obtain an advantage by reviewing patents revealed during the first filer's patent dance. Thus, subsequent filers benefit from the risk-taking of the first filer, essentially acting as free riders.

The disadvantage of first-filing biosimilars stands in stark contrast to the treatment of first-filing generics under the Hatch-Waxman Act. With Hatch-Waxman, the first-filing generic to successfully challenge a brand's patent receives the reward of 180 days of market exclusivity. On the other hand, the first-filing biosimilar receives nothing for its troubles but the prospect of hastening the entry of its competitors.[187]

The asymmetrical burden borne by the first-filing biosimilar not only discourages companies from developing biosimilars for markets, but also creates an incentive for first-filing biosimilars to engage in strategic behaviors that will avoid triggering the requirement for patent disclosure. Thus, it creates an alignment of interests between the brand and the biosimilar: Neither one wants to see patent disclosure, a fact that encourages collusion in pursuit of that goal.[188]

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supplement thereto) and their corresponding expiry dates to the Secretary, and the Secretary shall, in revisions made under clause (ii), include such information for such biological product. Within 30 days of providing any subsequent or supplemental list of patents to any subsequent [biosimilar] applicant under subsection (l)(3)(A) or (l)(7), the [brand] shall update the information provided to the Secretary under this clause with any additional patents from such subsequent or supplemental list and their corresponding expiry dates.").

187. With a first-filing interchangeable, however, the interchangeable receives a period of at least one year in which the FDA is barred from granting interchangeability status to a subsequent filer. *See infra* note 213 and accompanying and following text (describing the relevant provision and the varying time periods that may apply).

188. For a discussion of strategic behaviors to reach that goal, *see infra* Sections III.B.2–3.

Society's interests, of course, are the opposite. Low disclosure inhibits biosimilar development, and thus contributes to the cycle of high biologic prices and low biosimilar availability. Neither of those outcomes advances societal goals.

If society's incentive is to encourage information flow to induce competitive entry, the process fails to align incentives properly. Rather, we have established an enormously elaborate system in which no one's interests are aligned with those of the greater society. It is no wonder that the process has failed to induce significant competition. The following Sections describe strategic behaviors the parties utilize in the service of their interests.

2. Evading the Patent Dance

The possibilities for evasive and obfuscating tactics deployed by both brand biologics and biosimilar companies can take a range of forms. At the most basic level, the biosimilar can simply avoid the patent dance by refusing to provide its application and manufacturing information to the brand. This refusal would trigger only a narrow set of potential consequences. As the Supreme Court ruled in 2017 in *Sandoz v. Amgen*, a brand biologic cannot seek an injunction under federal law against a biosimilar for flouting the Biosimilars Act,[189] although injunctive relief may be possible under state law.[190]

The brand does have two options if the biosimilar company simply refuses to follow the patent dance. First, the language of the Biosimilars Act allows the brand to file a declaratory judgment action asking for a finding of infringement, validity, or enforceability of its patents.[191] Second, if the

189. When Sandoz filed for approval to bring into the market a biosimilar to filgrastim, marketed by Amgen under the brand name Neupogen®, Sandoz refused to provide Amgen with a copy of its biosimilar application, despite the requirement of 42 U.S.C. § 262(l)(2)(A). Amgen sought injunctive relief to force compliance, and the case went to the Supreme Court. In a unanimous opinion, the court held that when a biosimilar applicant fails to provide its application and manufacturing information to the brand, the only federal remedy available to the brand is to bring a declaratory judgment action for artificial infringement defined under 35 U.S.C. § 271(e)(2)(C)(ii). Sandoz Inc. v. Amgen Inc., 582 U.S. 1, 12–16 (2017).

190. *See* Sandoz, 582 U.S. at 6, 17–19 (holding that when a biosimilar fails to "provide its application and manufacturing information to the manufacturer of the biologic . . . an injunction is not available under federal law" and remanding on the question of whether an injunction is available under state law).

191. *Id.* at 11, 14–17; 42 U.S.C. § 262(l)(9)(C) ("If a [biosimilar] applicant fails to provide the application and information required under paragraph (2)(A), the [brand], but not the [biosimilar] applicant, may bring an action under section 2201 of title 28 for a declaration of infringement, validity, or enforceability of any patent that claims the biological product or a use of the biological product."); *see also infra* note 216 (describing the declaratory judgment option in greater detail).

biosimilar company has received approval and launched the product, the brand can file a good old patent infringement action, moving forward with the conventional patent litigation route that remains waiting in the wings.[192]

The *Sandoz* decision essentially renders participation in the patent dance optional for the biosimilar. More precisely, the Supreme Court held that a brand cannot get an injunction, under federal law, requiring a biosimilar to provide the application it submitted to the FDA or details about its manufacturing process.[193] On remand, the Federal Circuit held that the brand cannot get such an injunction under state law either due to preemption.[194] Nevertheless, the decision makes clear that a biosimilar's failure to provide its application and manufacturing information comes at a cost. When a biosimilar fails to provide its application and manufacturing information, it gives the brand "the control that the [biosimilar] applicant would otherwise have exercised over the scope and timing of the patent litigation." Instead, the brand will be able to file a declaratory judgment action under the Biosimilars Act on *any* number of patents it chooses to list.[195]

In addition, if the biosimilar company not only withholds its application and manufacturing details from the brand, but also proceeds with an "at risk" launch, it exposes itself not just to an actual infringement claim, but specifically to damages liability. In contrast, if the biosimilar company chooses not to launch at risk, the infringement litigation proceeds without the company incurring damages liability.[196] In short, if the biosimilar company launches at

192. Recall that the Hatch-Waxman and Biosimilars Acts provide pathways for a claim of artificial infringement, so that follow-on drug companies can resolve patent disputes without entering the market and risking a large damage award. *See supra* text accompanying note 27. However, the pathway of entering the market and taking the risk of a damage award remains. If the biosimilar refuses to follow the steps of the Biosimilar Act patent dance and chooses to launch at risk, the brand can sue for actual infringement in an ordinary patent lawsuit.

193. *See supra* note 190.

194. Amgen Inc. v. Sandoz Inc., 877 F.3d 1315, 1330 (Fed. Cir. 2017) ("Amgen's state law [claim for injunctive relief is] preempted on both field and conflict grounds.").

195. Sandoz, 582 U.S. at 3, 16.

196. The extent of damages liability is likely smaller for biosimilars than for generics, and thus biosimilars are more likely to launch at risk than are generics. Biosimilar drugs tend to sell at a smaller discount off the price of the brand drug than do generic drugs. *See supra* text accompanying notes 96–97; Zachary Silbersher, *When Do Biosimilars Launch at Risk?*, MARKMAN ADVISORS BLOG (Jan. 25, 2018), https://www.markmanadvisors.com/blog/2018/1/25/why-do-biosimilars-launch-at-risk; Kirke M. Hasson & Maria Salgado, *Biosimilars Enter the Courts: How Will Patent Infringement Settlements Be Tested for Validity Under Antitrust Laws*, A.B.A.: THE ANTITRUST SOURCE (Dec. 2016), https://www.americanbar.org/content/dam/aba/publishing/antitrust-magazine-online/dec16_hasson_12_12f.pdf. Thus, the profit made from a biosimilar drug that is launched at risk is closer in amount to the profit lost by the

risk, it exposes itself to patent litigation with the potential for a damages judgment.[197]

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brand drug as a consequence of the biosimilar's alleged infringement. As a result, the relatively high profit made by the biosimilar launched at risk gives the biosimilar maker a greater ability to pay a damages judgment. By contrast, generic drugs tend to sell at a much steeper discount off the price of the brand drug. Thus, the profit made by the generic drug launched at risk is much smaller in amount than the profit lost by the brand drug as a consequence of the generic's alleged infringement. That relatively low profit made by the generic launched at risk gives the generic relatively less ability to afford the damages liability. The bottom line is that, as commentators have observed, biosimilars are more willing and able to launch at risk than are generics, as the biosimilars are in a stronger position to pay any judgment for infringement damages. *See, e.g.*, Silbersher, *supra*; Hasson & Salgado, *supra*, at 8; *cf.* Wong & Menon, *supra* note 166 (noting that, of 27 launched biosimilars, 11 of them—i.e., 40.7%—were launched at risk, and none of those launched at risk has been ordered to pay damages, though most at-risk launches resulted in settlement). For a data-driven analysis of generic at-risk launches finding that at-risk launches in the dataset were common but that the rate of at-risk launches overall was low, see Keith M. Drake, Robert He, Thomas McGuire & Alice K. Ndikumana, *No Free Launch: At-Risk Entry by Generic Drug Firms*, 29 INT'L J. ECON. BUS. 301, 310–11 (2022).

197. A "launch at risk" occurs when the generic or biosimilar begins commercial marketing at any point during the period after the FDA's approval of the ANDA, or its biosimilar counterpart, becomes effective but before final resolution of the brand's infringement claims. Under the Hatch-Waxman regime, the brand can forestall a generic's launch at risk. If the generic files an ANDA with a Paragraph IV certification and gives notice to the brand, and within 45 days the brand sues the generic for infringement, then the FDA has 180 days to approve or disapprove the ANDA and must make any approval effective 30 months after that notice. 21 U.S.C. § 355(j)(5)(A), (B)(iii). This 30-month period is known informally as the "thirty-month stay"; it effectively bars the generic's launch for a period of time that should be sufficient for the court to rule on the brand's infringement claims. *See* CONG. RSCH. SERV., R44643, THE HATCH-WAXMAN ACT: A PRIMER 8 (2016). If the brand does not sue within 45 days, then the FDA's approval is effective immediately. 21 U.S.C. § 355(j)(5)(B)(iii). Once the FDA's approval is effective, the generic can launch; the launch is "at risk" if at the time of launch the brand's infringement claims have not yet been finally resolved.

Under the Biosimilars Act regime, a launch at risk can occur as early as phase one of the patent dance, when, for example, the parties are still negotiating which patents to put on the Negotiated List. It can also occur later, in the second phase, or even as late as after final judgment, as long as appeals are not yet exhausted.

More specifically, under the Biosimilars Act regime, much depends on whether the biosimilar provides a notice of commercial marketing. If the biosimilar provides a notice of commercial marketing and waits 180 days without the brand obtaining a preliminary injunction, then it can launch at risk. Alternatively, it can launch at risk, before the 180-day period ends, under two scenarios: (1) the brand files suit and moves for a preliminary injunction, the preliminary injunction is denied, but judgment in the underlying phase-two suit has not been entered, or (2) judgment in that suit has been entered for the biosimilar but appeals are not yet exhausted. If the biosimilar does not otherwise wait 180 days, or never provides a notice of commercial marketing, then it can launch at risk; but the brand can file a declaratory judgment action under 42 U.S.C. § 262(l)(9)(B) for a declaration of validity,

Engaging in the patent dance would require the biosimilar company to disclose valuable manufacturing information to the brand—information that the biosimilar may have spent years developing. The company may judge that such disclosure is a risk not worth taking. Although the Biosimilars Act limits the number of parties who can access the information released by the biosimilar and provides for immediate injunctive relief should those parties disclose it, the potential damage to the biosimilar could be difficult to truly remedy in case of a violation.[198] For example, Van de Wiele, Kesselheim, and Sarpatwari suggested that the brand could attempt to hinder the biosimilar company's efforts to avoid infringement by patenting the biosimilar company's manufacturing methods—ones that the biosimilar company has protected as trade secrets.[199] Even without the legal benefits of patent protection, the biologic company could find scientific value in the biosimilar company's methods and could later adopt those methods either when refining the drug at hand or when developing a future drug. A court order to stop disclosing information to unauthorized parties, or to terminate the employment of

infringement, or enforceability of any patent on the Initial Brand or Supplemental Brand List. The brand can also move for an injunction under 35 U.S.C. § 271(e)(4)(B) to enjoin infringement of any patent that is on the Initial Brand or Supplemental Brand List (or that could have been on the Initial Brand List if the biosimilar never provided its application and information to the brand). And, any time a biosimilar launches at risk, the brand can seek damages under 35 U.S.C. § 271(a) or § 271(e)(4)(C).

Note that launching at risk does not take the generic or biosimilar entirely out of the realm of the ANDA or its biosimilar counterpart. The premise of launching at risk is that the FDA has already approved the generic or biosimilar application. Only after approval can a launch at risk be even possible. Thus, launching at risk does not make the FDA withdraw its approval or require that the brand or generic conduct its own clinical trials. The main consequence of a launch at risk is that the generic or biosimilar knowingly shifts to actual infringement (with its risk of damages) from artificial infringement (with no risk of damages). But the issue raised by the brand's liability claim—does the generic or biosimilar drug infringe the brand's patent—stays the same. *See* Bristol Meyers Squibb Co. v. Mylan Pharmas. Inc., No. 17-379-LPS, 2017 WL 3980155, at *8 (D. Del. Sept. 11, 2017). That makes sense: A launch does not change the allegedly infringing drug's chemical compound or manufacturing process. The brand, however, may wish to amend to add a claim for damages and a jury trial, and possibly a claim for willful infringement. GOODWIN PROCTER GUIDE TO BIOSIMILARS LITIGATION, *supra* note 146, § 4:56 (damages and jury trial); Grace Lillian Wang, Teva v. Eisai*: What's the Real "Controversy"?*, 66 FOOD & DRUG L.J. 631, 638 n.46 (2011) (willful infringement).

198. Van de Wiele, Kesselheim & Sarpatwari, *supra* note 94, at 1200; 42 U.S.C. § 262(l)(1)(H).

199. Van de Wiele, Kesselheim & Sarpatwari, *supra* note 94.

violators, would do little to make up for the potentially long-lasting effects of such information leakage.[200]

Although brands could complain that the entire Biosimilars Act process similarly puts at risk the information that they have spent years developing, the circumstances are different. The brand has already received the benefit of excluding others from making, using, or selling the drug during the period of its patents. The disclosures required by patent law are the *quid pro quo* for receiving that valuable period of protection,[201] and any disclosures the brand must make under the Biosimilars Act regime help prevent the brand from extending its period of protection.[202]

After the *Sandoz* decision, some commentators optimistically predicted that conventional patent litigation resulting from a biosimilar manufacturer's refusal to participate in the patent dance would lead to improved transparency. Through discovery, the biosimilar company would "almost certainly" have to disclose its application and manufacturing information.[203] Similarly, the brand presumably would have to provide a list of all the patents it believes might be infringed by the biosimilar, including patent applications in process or recently purchased.[204] This perspective rested on several hopeful assumptions: that conventional patent litigation would achieve disclosure more readily than the patent dance, and that conventional litigation would not present its own opportunities for avoidance and collusion.

Life is rarely so rosy on the ground, and, indeed, the hopeful assumptions about the benefits of conventional patent litigation have proven false in practice. From the perspective of transparency, conventional patent litigation operates more poorly than the Biosimilars Act. Specifically, participation in the patent dance forces the brand biologic to disclose its patents or lose the right

200. *Id.* To the extent a biosimilar has any remedy for a brand's opportunistic use of information provided by the biosimilar, the solution appears to be a private agreement between the brand and the biosimilar, entered into before any disclosure is made by the biosimilar, in which the brand agrees not to base any patent application on (or otherwise use) the biosimilar's disclosure. *See infra* note 270.

201. *See* Feldman, *supra* note 72, at 8 (describing the classic analysis of patent disclosure as the quid pro quo for receiving a patent).

202. *See supra* note 24 and accompanying text (describing a goal of Hatch-Waxman, on which the Biosimilars Act is modeled, as preventing brands from artificially extending their period of monopoly by the amount of time a generic needs to obtain FDA approval after the brand's patent expires).

203. Jacob S. Sherkow, *The Science of Substitution: A Response to Carrier and Minniti*, 2018 U. ILL. L. REV. ONLINE 81, 87.

204. *Id.*

to assert them in litigation;[205] conventional patent litigation makes no such explicit requirement.[206] Thus, conventional patent litigation *removes* any transparency incentive. After all, in a conventional patent litigation, why show your hand when you can hold back patents to use in a future litigation against other parties[207] (and sometimes even against the same party[208])?

Since the *Sandoz* decision, biosimilar companies may have realized the drawbacks of refusing the patent dance. In the first year after *Sandoz*, most biosimilar companies involved in litigation failed to complete the patent dance; beyond that year, biosimilar companies have largely opted into the patent dance—from start to finish.[209]

What do the FDA and the brand do if the biosimilar opts not to comply with the patent dance? Standing first in the government's shoes, the FDA's approval of a biosimilar application technically does not depend on whether the biosimilar participates in the patent dance.[210] The picture is more nuanced,

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205. *See supra* note 134 (discussing consequences of brand's failure to list a relevant patent); *see also supra* notes 176–177 and accompanying and following text (same); *infra* note 240 and accompanying and following text (same). *But see* Brian D. Coggio, *Can Reference Sponsor Forfeit Right to Sue Under BPCIA?*, JD SUPRA (July 25, 2016), https://www.jdsupra.com/post/contentViewerEmbed.aspx?fid=eb404140-f7d8-44b8-aabf-3d08a5a11cc8 (arguing that "section" means "section" in 35 U.S.C. § 271(h), but it means "subsection" in "list it or lose it" provision, *see* 35 U.S.C. § 271(e)(6)(C), and thus, "list it or lose it" provision should be read narrowly); *cf.* CONG. RSCH. SERV., *supra* note 134, at 37–38 & nn.334, 335; Carrier & Minniti, *supra* note 107, at 40 n.353 (2018).

206. 35 U.S.C. § 271(e)(6); Yang Li, *Does It Still Take Two to Tango? A Modern Interpretation of the BPCIA's Patent Dance*, 9 N.Y.U J. INTELL. PROP. & ENT. L. 107, 126 (2019).

207. *But see supra* text accompanying notes 178–179 (describing ways that the brand may hold back patents even when participating fully in the Biosimilars Act patent dance).

208. Although application of res judicata in the context of patent infringement litigation is complex and highly fact-specific, there are circumstances in which res judicata will not likely bar a second action between the same parties concerning a different patent. For example, res judicata, while ordinarily barring claims that *could have been brought* in the first action, is less likely to bar the second action where the accused products in the two actions are different, where the infringing activity alleged in the second action occurred after judgment was entered in the first action, and where the first action was not fully litigated on the merits or did not involve the same issues as those litigated in the second action. *See* 6 ROBERT A. MATTHEWS, JR., ANNOTATED PATENT DIGEST § 38:14–16.50 (2023).

209. Between August 2, 2017 and March 8, 2018—the first year after the Supreme Court ruling in *Sandoz v. Amgen* on June 12, 2017—six of the eight biosimilars involved in litigation failed to complete the patent dance. Afterwards, however, only one of the eleven biosimilars involved in litigation between July 2, 2018 and April 27, 2021 failed to complete the patent dance. *See* Yun Dong, *Keep on Dancing: The Success and Failures of Patent Dance as Shown by BPCIA Litigation Cases Filed After* Sandoz v. Amgen, 83 U. PITT. L. REV. ONLINE 1, 17–19 tbl.1 (2022).

210. *See* KEVIN J. HICKEY, ERIN H. WARD & WEN W. SHEN, CONG. RSCH. SERV., R45666, DRUG PRICING AND INTELLECTUAL PROPERTY LAW: A LEGAL OVERVIEW FOR THE

however, given that other features of the Biosimilars Act, outside the patent dance, may restrict the FDA's ability to grant approval. The extent of the restriction will depend on how much time has passed between the brand drug's approval and the biosimilar applicant's request for approval, and whether other exclusivities, known as data exclusivities,[211] are in force. Recall that after the FDA approves the brand drug's license application, no biosimilar application may even be filed for four years, and the FDA is barred from approving a biosimilar application for twelve years.[212] Thus, if the biosimilar company opts out of the patent dance within that twelve-year period, the FDA cannot approve the biosimilar before the period ends (although note that the reason for lack of approval is not the biosimilar company's opt-out from the patent dance, but rather the brand's twelve-year exclusivity period). However, if the biosimilar company opts out of the patent dance *after* the brand's twelve-year exclusivity ends, then the FDA is free to approve or disapprove the biosimilar application, subject to one exception: If a first biosimilar has received a determination of interchangeability from the FDA, and the application of a second biosimilar relies on the same reference product that the first relied on, then there is a period of time in which the FDA may not make a determination that the second biosimilar is interchangeable.[213] In other words, the first interchangeable biosimilar receives an exclusivity period of at least one year (during which the FDA cannot grant approval to a second interchangeable)

116TH CONGRESS, at summary (2019) ("The patent dance does not affect FDA's ability to approve a biosimilar application."); *id.* at 30–32 (noting that while Hatch-Waxman Act bars FDA from approving generic application for 30 months after brand commences infringement litigation against generic, Biosimilars Act does not bar FDA from approving a biosimilar application while the patent dance is still ongoing); *id.* at 34 (FDA approval is not contingent on resolution of patent disputes).

211. This is commonly known as a "data exclusivity" from the perspective that it represents a benefit to the brand in exchange for giving biosimilars the ability to use the brand's clinical data. *See* Henry Grabowski, Genia Long & Richard Mortimer, *Data Exclusivity for Biologics*, 10 NATURE REV. DRUGS DISCOVERY 15 (2011).

212. *See* 42 U.S.C. § 262(k)(7)(A), (B).

213. In such a case, the FDA may not make a determination of interchangeability until the earlier of: one year after the first commercial marketing of the first interchangeable biosimilar, *see id.* § 262(k)(6)(A); 1.5 years after resolution of an infringement action brought in phase one of the patent dance against the applicant that submitted the application for that first interchangeable biosimilar, *see id.* § 262(k)(6)(B); 3.5 years after approval of the first interchangeable biosimilar if the applicant that submitted the application for that first interchangeable biosimilar has been sued for infringement in phase one of the patent dance and that suit is still ongoing within that 3.5-year period, *see id.* § 262(k)(6)(C)(i); or 1.5 years after approval of the first interchangeable biosimilar if the applicant that submitted the application for that first interchangeable biosimilar has not been sued in phase one of the patent dance, *see id.* § 262(k)(6)(C)(ii).

much as the brand receives a 12-year exclusivity period (during which the FDA cannot grant approval to any biosimilar). Note that the FDA may grant approval without the biosimilar even commencing the second phase of the patent dance, if neither the brand's exclusivity nor a first interchangeable's exclusivity is in force.[214]

Standing in the brand's shoes, once the FDA has approved the biosimilar, and the biosimilar company has opted out of the patent dance, the brand may sue the biosimilar company. The nature of the brand's claims depends on whether the biosimilar has launched at risk by the time of suit.[215] If the biosimilar has not launched at risk, the Biosimilars Act provides that the brand can bring a declaratory judgment action against the biosimilar for a declaration of infringement, validity, or enforceability.[216] If the biosimilar has launched at risk, the brand can bring conventional patent-infringement litigation against the biosimilar, including a claim for damages (e.g., lost profits).[217]

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214. *See* Sandoz Inc. v. Amgen Inc., 582 U.S. 1, 19 (2017) (holding that notice of commercial marketing can be given "before or after" FDA approval).

215. *See supra* note 197 (discussing launch at risk).

216. *See* 42 U.S.C. § 262(l)(9)(B), (C). When there is uncertainty surrounding the legal obligations or rights between two parties, a declaratory judgment resolves that uncertainty by using a binding court decision to define the legal relationship between parties and their legal rights. *See Declaratory Judgment*, CORNELL L. SCH. LEGAL INFO. INST., https://www.law.cornell.edu/wex/declaratory_judgment (last updated Sept. 2022). If the biosimilar opts out *ab initio* (i.e., without even providing its application or manufacturing information), the brand's declaratory judgment claim can allege infringement of any patent protecting the brand product. *See* 42 U.S.C. § 262(l)(9)(C). If the biosimilar opts out later in the patent dance (i.e., after providing its application and manufacturing information), the brand's declaratory judgment claim can allege infringement of any patent on the Initial Brand List or Supplemental Brand List. *Id.* § 262(l)(9)(B).

217. *See* 35 U.S.C. § 271(a) (providing for infringement liability in cases of actual infringement, namely, the making, use, offer to sell, or sale of the patentee's product); *id.* § 271(e)(4)(C) (providing that for an artificial infringement under 35 U.S.C. § 271(e)(2), courts may award damages and other monetary relief against the infringer if it engaged in the commercial manufacture, use, offer to sell, or sale of the patentee's product); AbbVie Inc. v. Alvotech hf., 582 F. Supp. 3d 584, 591–92 (N.D. Ill. 2022) (citing 35 U.S.C. § 271(e)(2), (4)); *cf.* Hasson & Salgado, *supra* note 196, at 4; *supra* note 28 and accompanying text (discussing damages liability following at-risk launch).

Note also that if a generic or biosimilar is launched at risk, then the brand is exempted from the price-negotiation provisions of the Inflation Reduction Act. *See* Inflation Reduction Act of 2022, Pub. L. No. 117-169, § 11001, 136 Stat. 1818, 1837, 1839 (2022) (adding, among other things, section 1192(c)(1) and (e)(1) to Title XI of Social Security Act); Danielle A. Duszczyszyn, Matthew J. Luneack & Jordan M. Gringauz, *Potential Implications of Inflation Reduction Act on Pharmaceutical Patent Litigation*, BLOOMBERG L. (May 2023), https://www.bloomberglaw.com/external/document/XA2O6QAO000000/patents-professional-perspective-potential-implications-of-infla ("In Hatch-Waxman or BPCIA litigation, if there

Although the Section above describes ways in which parties can choose to evade the patent dance, other parties are choosing to reshape the dance. According to some biosimilar practitioners, if their clients prioritize getting the drug to market quickly over obtaining patent disclosure from the brand, the practitioners simply collapse the two phases of the dance by filing a notice of commercial marketing at the same time as they give the brand the application for FDA approval.[218]

One should not lose sight of the impact of these puzzling provisions of the Biosimilars Act—an impact that extends far beyond courtrooms and the C-suites of pharmaceutical companies. In particular, the persistently high biologic prices continue to limit access and strain household budgets.[219] This result flows in part from the complexity of the patent dance,[220] the paucity of disclosures regarding intellectual property rights, [221] and the ample opportunities for gaming the process.[222] These factors combine to suppress the ability of the Biosimilars Act to encourage biosimilar entry[223] and to restrain any extended monopoly pricing for brand biologics.[224] The following Sections describe additional strategic behaviors that interact with Biosimilars Act provisions and hinder the effectiveness of the legislation.

3. Pay-for-Delay

Evasion of disclosure hardly ends with evasion of the patent dance. To conclude the litigation initiated by the biologic drug-maker, both the biologic and biosimilar makers may turn to the tried-and-true scheme of pay-for-delay. A common tactic in the non-biologic realm, pay-for-delay occurs when a brand

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is an 'at-risk' launch of a generic or biosimilar product, an otherwise eligible reference product will immediately become ineligible for selection under the IRA."); CTRS. FOR MEDICARE & MEDICAID SERVS., DEPT. OF HEALTH & HUM. SERVS., MEDICARE DRUG PRICE NEGOTIATION PROGRAM: REVISED GUIDANCE, IMPLEMENTATION OF SECTIONS 1191 – 1198 OF THE SOCIAL SECURITY ACT FOR INITIAL PRICE APPLICABILITY YEAR 2026 2, 6, 72–73, 101–02, 164–66 (June 30, 2023), https://www.cms.gov/files/document/revised-medicare-drug-price-negotiation-program-guidance-june-2023.pdf.

218. *See supra* Section III.A.2.b (explaining that the biosimilar has the option to collapse the two phases of the patent dance by filing its notice of commercial marketing before the conclusion of the first phase and that in such circumstances the biosimilar may launch at risk absent a preliminary injunction); *see also* cases cited *supra* notes 164–165 and accompanying and following text.

219. *See infra* notes 309–310 and accompanying text; *see also supra* Section II.D.

220. *See supra* Section III.A.

221. *See supra* Section III.B.1.

222. *See supra* Section III.B.

223. *See supra* Section II.D.

224. *See infra* text accompanying notes 231–232; *see also infra* Section III.C.

drug-maker and a generic drug-maker agree to settle a patent infringement suit such that the brand transfers cash or other source of value to the generic. In exchange, the generic agrees to stay out of the market for a designated period of time. The deal is also known as a "reverse payment settlement" because the flow of value moves atypically from the plaintiff to the defendant.

This type of deal serves the interest of both parties.[225] The consumer, however, suffers harm from any delay in which lower-priced versions fail to come to market. In the non-biologic context, the tactic has been enormously damaging, costing patients at least $6.2 billion per year between 2006 and 2017.[226]

Given the relatively recent enactment of the Biosimilars Act and the low number of biosimilar challenges mounted in the United States, there would have been limited opportunities for pay-for-delay settlements in the biologic realm. In fact, many scholars have speculated that pay-for-delay schemes may occur less frequently in connection with biologic patent litigation.[227] They point out that prohibitions on automatic substitution declaw the threat of biosimilar entry and that the 2011 introduction of *inter partes* review proceedings has enabled biosimilars to challenge biologic patents in a short and relatively inexpensive filing before the Patent Office, even before filing their applications.[228] Finally, these scholars assert that despite the looming prospect of trade secret disclosure in the Biosimilars Act patent dance, biologics would find paying for delay to be less than worthwhile.[229]

Unfortunately, evidence to the contrary has begun to trickle in. One analysis of all twenty-one lawsuits related to Biosimilars Act litigation filed through August 1, 2020 found that eleven—more than 50%—ended in

225. *See, e.g.*, C. Scott Hemphill, *Paying for Delay: Pharmaceutical Patent Settlement as a Regulatory Design Problem*, 81 N.Y.U. L. REV. 1553, 1575–76 (2006); Feldman & Frondorf, *supra* note 29, at 511 (2016); Michael A. Carrier, *Unsettling Drug Patent Settlements: A Framework for Presumptive Illegality*, 108 MICH. L. REV. 37, 39–40 (2009).

226. Feldman, *supra* note 32, at 32.

227. *See, e.g.*, Carrier & Minniti, *supra* note 107, at 21; Hasson & Salgado, *supra* note 196, at 5.

228. Carrier & Minniti, *supra* note 107, at 29, 30; Jennifer E. Struiale, *Hatch-Waxman Patent Litigation and Inter Partes Review: A New Sort of Competition*, 69 ALA. L. REV. 59, 85–86 (2017).

229. *See* Carrier & Minniti, *supra* note 107, at 21 ("Because of the more modest effects of biosimilar entry, biologics' first mover advantages, and increased use of IPR proceedings, settlements involving payment and delayed entry should be less likely in the biologic setting." (citations omitted)); Hasson & Salgado, *supra* note 196, at 4–5 (arguing that the lack of automatic substitution laws for biosimilars, the lengthy regulatory exclusivity period awarded to brand biologics, and the lack of exclusivity for the first non-interchangeable biosimilar will have the likely effect of reducing biologics' incentives to pursue pay-for-delay settlements).

settlement.[230] Although cases settle for many reasons, the number of settlements at least suggests the opportunity for collusive settlements.

Other indicators suggest the possibility of pay-for-delay. Of the eleven cases that settled, five resulted in lengthy delays between FDA approval of the biosimilar and its market entry, ranging from twenty-two months to several years.[231] Four more produced shorter delays of one to eleven months.[232]

Even if the settlements do not result in delay, they can be counter-productive to the public interest while serving the interests of the parties. Recall the free rider problem, in which the first-filing biosimilar takes on the effort and risk of developing a product and challenging the biologic with no knowledge of the biologic's patents while later-filing biosimilars get the benefit of seeing patents that were publicly disclosed through the first-filer's patent dance.[233] The biologic and biosimilar could cut a deal establishing a duopoly without trading patent lists. In this way, the biosimilar gets to enter the market without facilitating further biosimilar competition through public disclosure of those lists, and the biologic gets to prevent its patents from being challenged in this litigation. The biologic also gets to better protect those patents from the curious eyes of future biosimilar challengers, who would be able to plan for the patents that will be launched against them. In short, settlements can ensure that patents deserving of reassessment remain unchallenged and that prospective biosimilars continue to operate in the dark.

4. Other Disclosure Problems in the Biosimilars Regime

Another way of gaming the process is to exploit loopholes in other statutory disclosure requirements. Although the Hatch-Waxman Act requires generic applicants to report any settlements that arise from a Paragraph IV challenge,[234] the Biosimilars Act had no reporting requirements prior to 2018. In 2018, Congress amended the Biosimilars Act in an effort to introduce commensurate requirements.[235] As part of the amendment, a biosimilar

230. Van de Wiele, Kesselheim & Sarpatwari, *supra* note 94, at 1198, 1202.

231. *Id.*

232. *Id.*

233. *See supra* text accompanying notes 186–187.

234. Limin Zheng, *How Will Trump's New FTC/DOJ Reporting Requirements Impact Biosimilars?*, BIOSIMILAR DEV. (Nov. 13, 2018), https://www.biosimilardevelopment.com/doc/how-will-trump-s-new-ftc-doj-reporting-requirements-impact-biosimilars-0001; 21 U.S.C. § 355.

235. *See* Patient Right to Know Drug Prices Act, Pub. L. No. 115-263, § 3(2)(B), 132 Stat. 3672, 3674 (Oct. 10, 2018) (codified as 21 U.S.C. § 355 note); SUPPORT for Patients and Communities Act, Pub. L. No. 115-271, tit. IV, § 4004, 132 Stat. 3894, 3960–61 (Oct. 24, 2018) (codified as 21 U.S.C. § 355 note); AGATA DABROWSKA, VICTORIA R. GREEN & LISA

applicant must now report any settlements that occur after providing the Biosimilar Detailed Statement alleging that the patents in the Initial Brand List are invalid or not infringed.[236] As explained below, however, the new biosimilar requirements added in 2018 have had limited impact because they are entwined with the patent dance. In addition, collusive agreements between brand and biosimilar can evade these requirements, and they remain difficult to detect.

The 2018 amendment tied its disclosure requirements to a key step in the patent dance—the furnishing of the Biosimilar Detailed Statement alleging that the brand's patents are invalid or not infringed.[237] Although the Biosimilar Detailed Statement would appear to be analogous to the generic's Paragraph IV certification—both documents make assertions about whether the reference product's patents are valid or infringed—the crucial difference lies, once again, in the difference between the two regimes. Under Hatch-Waxman, if a generic applicant wants to enter the market before the patents expire, it must submit a Paragraph IV certification challenging each patent related to the brand drug that has not expired at the time of filing for approval.[238] Thus, submitting Paragraph IV certifications is part and parcel of the generic's application for FDA approval, which makes reporting of settlements difficult to avoid. This is not the case for biosimilar drug-makers; they are obligated to report a settlement only if the parties engage in the patent dance and complete at least its first few steps. If the parties settle before the biosimilar provides the Biosimilar Detailed Statement, or if the biosimilar chooses not to submit a statement, the settlement will not be reported. Thus, parties can continue to make collusive agreements with the authorities none the wiser.[239]

One could argue that the contrast between the requirement to report settlements to competition authorities under the two regimes flows from the difference in the disclosure requirements. The biosimilar company cannot submit a statement about invalidity or noninfringement of patents from the outset of filing for approval because there is no public listing of patents that the brand might assert. After all, a biosimilar company cannot allege that the brand's patents are invalid or not infringed when the biosimilar company

N. SACCO, CONG. RSCH. SERV., R45405, THE SUPPORT FOR PATIENTS AND COMMUNITIES ACT (P.L. 115-271): FOOD AND DRUG ADMINISTRATION AND CONTROLLED SUBSTANCE PROVISIONS 27 (2018).

236. *See supra* note 235.

237. *See supra* notes 235–236 and accompanying text.

238. Zheng, *supra* note 234; *Patent Certifications and Suitability Petitions*, U.S. FOOD & DRUG ADMIN. (Apr. 20, 2021), https://www.fda.gov/drugs/abbreviated-new-drug-application-anda/paragraph-iv-drug-product-applications-generic-drug-patent-challenge-notifications.

239. *See supra* notes 236–237 and accompanying text.

doesn't even know what those patents are. Thus, the biosimilar company can file its application for approval, triggering notice to the brand, and the parties can settle without ever incurring the obligation to report the settlement to competition authorities.

In theory, a brand and a generic in the Hatch-Waxman arena could manage to settle before the generic files an application—the point at which a Paragraph IV certification would be needed—and thereby avoid triggering the requirement to report the settlement. Such a scenario, however, would be less likely. The generic would have to reach out to the brand saying, "Hey, we are about to file for approval; want to settle?" Alternatively, the brand could figure out which companies are getting close to developing a competing product and reach out to them proactively, but one would expect generics to keep such competitive information under wraps.

The strategies considered thus far in this Section largely follow from the biosimilar's initiative not to participate in the patent dance. The brand, however, has games to play as well. For example, noncompliance with the Biosimilars Act is far from the sole domain of the biosimilar. Given that brand biologics are not required to identify patents at the time of filing for approval, as brand non-biologics are in the Hatch-Waxman realm, biologics have their own reasons to avoid the patent dance. As a result, they may choose not to send the Initial Brand List of patents to a prospective biosimilar maker in order to avoid having that list included later in the Purple Book. Of course, certain statutory provisions disincentivize this brand behavior—the "list it or lose it" provision and the provision limiting preliminary injunction motions to patents that were on the Initial Brand List or Supplemental Brand List (but not the Negotiated or Failed-Negotiation Lists).[240] The extent to which courts will enforce those provisions, however, remains to be seen.

5. *Using 28 U.S.C. § 1782 to Circumvent the Confidentiality Protecting the Biosimilar's Disclosures*

By statutory command, both the biosimilar application and the manufacturing information that the biosimilar developer gives the brand at the outset of the patent dance are accorded confidential treatment.[241] The recipients and the use of those materials are severely limited.[242] Although the Biosimilars Act allows the brand and its inside and outside counsel to receive the materials, the Act bars those recipients from disclosing the materials to

240. *See supra* note 134.
241. *See* 42 U.S.C. § 262(l)(1)(A)–(D).
242. *Id.*

anyone else, including other brand employees, outside scientific consultants, or other outside counsel.[243] Nor can the brand or its inside or outside counsel use the materials for any purpose other than determining whether the brand could bring a claim for infringement of the brand's patent(s) if the biosimilar manufactured or sold the drug at issue in the biosimilar application.[244]

Nevertheless, in one recent case, the brand arguably succeeded in sidestepping these confidentiality strictures. Amgen sells osteoporosis drugs, whose active ingredient is denosumab, and owns patents on denosumab. Sandoz filed an application with the FDA for approval of a denosumab biosimilar. Amgen and Sandoz engaged in the patent dance, pursuant to which Sandoz gave its biosimilar application (though not its manufacturing information)[245] to Amgen. Amgen then brought a phase-one infringement suit against Sandoz and two of its European affiliates in the District of New Jersey.[246]

Although the Court's ultimate decision is silent on Amgen's motivation,[247] Amgen apparently realized that it could use the biosimilar's application to support a preliminary injunction motion in European courts against the biosimilar's European affiliates, which were about to manufacture their own denosumab biosimilar. However, the patent dance's statutory confidentiality strictures barred the use of any document received in the patent dance. Thus, Amgen needed a way, independent of the patent dance, to obtain a statutorily unrestricted copy of the biosimilar application.

The solution Amgen found was 28 U.S.C. § 1782.[248] That provision authorizes any interested party who seeks documents for use in a foreign

243. *Id.* § 262(l)(1)(B)–(C).

244. *Id.* § 262(l)(1)(D).

245. *See* Memorandum of Law in Support of Amgen Inc.'s *Ex Parte* Application Pursuant to 28 U.S.C. § 1782 for an Order Compelling Discovery for Use in a Foreign Proceeding at 2 n.3, *In re*: Request from Vienna, Misc. No. 23-mc-258-CFC (D. Del. Sept. 26, 2023), ECF No. 2.

246. *In re*: Request from Vienna, Misc. No. 23-mc-258-CFC, 2023 WL 6278815, at *1 (D. Del. Sept. 26, 2023) (citing Amgen Inc. v. Sandoz Inc., No. 2:23-cv-020406, D.I. 1 (D.N.J. May 1, 2023).

247. *See id.*

248. *See id.* at *6. Section 1782 provides in relevant part: "The district court of the district in which a person resides or is found may order him to . . . produce a document . . . for use in a proceeding in a foreign or international tribunal . . . . The order may be made . . . upon the application of any interested person . . . . To the extent that the order does not prescribe otherwise, . . . the document or other thing [shall be] produced[] in accordance with the Federal Rules of Civil Procedure. A person may not be compelled . . . to produce a document . . . in violation of any legally applicable privilege."

proceeding to apply to the federal district court, in the district where the person possessing the documents resides, for an order compelling production. Amgen reasoned that if it obtained the biosimilar application, not through the statutory patent-dance provisions (which include the confidentiality strictures described above), but rather through Section 1782, the patent dance's confidentiality strictures would not apply. According to this reasoning, Amgen could freely use the biosimilar application in the European courts. Thus, in *In re: Request from Vienna*,[249] Amgen applied to the District Court for the District of Delaware, where Sandoz resides, for an order under Section 1782 compelling Sandoz to produce its biosimilar application.[250]

When ruling on a Section 1782 application, the judge's decision is discretionary, not mandatory.[251] As the Supreme Court has explained, the statute sets forth criteria that applicants must meet to be eligible for a favorable exercise of discretion; if the applicant meets the criteria, then the district court must consider discretionary factors when ultimately determining whether to grant or deny the application.[252] The District Court ruled that Amgen met the eligibility requirements[253] and also ruled in favor of Amgen on the discretionary factors.[254]

The court also rejected Sandoz's argument that the statutory confidentiality protecting documents provided in the patent dance barred Amgen's Section 1782 application.[255] The court held that those statutory

249. *In re*: Request from Vienna, 2023 WL 6278815. While this discussion of *In re*: *Request from Vienna* is based on court filings, the fullness of the discussion is limited by the facts that many of those filings are under seal or redacted, and that, because the case is still ongoing, new filings continue to appear on the docket even as this Article goes to press.

250. *Id.* at *1–2. More precisely, Amgen sought an order permitting it to serve Sandoz with a subpoena for several categories of documents, including the biosimilar application. *Id.*

251. Intel Corp. v. Advanced Micro Devices, Inc., 542 U.S. 241, 255 (2004).

252. *Id.* at 255–66; *In re*: Request from Vienna, 2023 WL 6278815, at *2. The eligibility criteria are: the person from whom the documents are sought "resides or is found" within the district; the documents are "for use in a proceeding before a foreign or international tribunal"; and the application is made by an "interested person." 28 U.S.C. § 1782(a). Discretionary factors identified by the Supreme Court are: "whether the person from whom discovery is sought is a participant in the foreign proceeding since such a person may possess evidence unobtainable absent § 1782(a) aid"; "the nature of the foreign tribunal, the character of the foreign proceedings, and the receptivity of the foreign court to federal judicial assistance"; "whether the request conceals an attempt to circumvent foreign proof-gathering restrictions"; and "whether the request is unduly intrusive or burdensome." *In re:* Request from Vienna, 2023 WL 6278815, at *5 (internal quotation marks omitted) (quoting *Intel*, 542 U.S. at 264–65).

253. *In re*: Request from Vienna, 2023 WL 6278815, at *2–4.

254. *Id.* at *5.

255. *Id.* at *6.

provisions, by their terms, accord confidentiality only to documents obtained during the patent dance.[256] They do not apply, the court held, to documents obtained through discovery tools independent of the patent dance.[257]

On the one hand, the decision does not significantly weaken the Biosimilars Act. Rather, the decision applies only in limited circumstances, given that Section 1782 is applicable only where a foreign proceeding is reasonably contemplated.[258] Moreover, a federal district court decision does not constitute binding precedent.[259]

On the other hand, the decision chips away at the Biosimilars Act's confidentiality protections,[260] and thus will discourage biosimilar companies from giving their biosimilar applications and manufacturing information to brands during future patent dances. The decision also upholds what is indisputably an end-run around the Biosimilars Act, and thereby encourages other efforts to circumvent the Act's provisions.[261] Indeed, it was undisputed

256. *Id.*

257. *Id.*

258. More concretely, the circumstances apply only where a biosimilar's foreign affiliate is manufacturing or marketing an analogous biosimilar that may infringe foreign patents analogous to the brand's U.S. patents.

259. *See, e.g.*, Colby v. J.C. Penney Co., 811 F.2d 1119, 1124 (7th Cir. 1988) (holding that district court decisions in federal system cannot be binding precedent: "[D]istrict judges in this circuit must not treat decisions *by other district judges,* in this and *a fortiori* in other circuits, as controlling . . . . Such decisions will normally be entitled to no more weight than their intrinsic persuasiveness merits. The reasons we gave for giving some though not controlling weight to decisions of other federal courts of appeals do not apply to decisions of other district courts, because the responsibility for maintaining the law's uniformity is a responsibility of appellate rather than trial judges and because the Supreme Court does not assume the burden of resolving conflicts between district judges whether in the same or different circuits. Federal district judges in Detroit do not make law that is binding on federal district judges in Chicago." (emphasis in original)).

260. While the decision does indeed chip away at the statutory confidentiality protections, biosimilars can still protect themselves through carefully drafted protective orders. Indeed, after Amgen served its subpoena on Sandoz, the parties entered into a stipulated protective order that restricts Amgen's use of confidential materials received from Sandoz. *See* Stipulated Protective Order ¶ 25, *In re*: Request from Vienna, Misc. No. 23-mc-258-CFC (D. Del. Nov. 14, 2023), ECF No. 39 (limiting use of confidential materials to instant action and to patent infringement proceedings brought in European courts by Amgen, and barring use of those materials for patent prosecution or other commercial use).

261. Furthermore, any attempted circumvention of *domestic* law should counsel reluctance by the court to grant § 1782 relief. *See, e.g.*, *In re* Pishevar, No. 21-mc-105, 2023 WL 2072454, at *4 (D.D.C. Feb. 17, 2023) ("Nothing in the record indicates that Mr. Pishevar is seeking discovery here via Section 1782 to circumvent the proof-gathering rules or policies of either *this Court* or the courts of England." (emphasis added)). Note that the list of discretionary factors identified in the Supreme Court's principal holding interpreting § 1782 was broader

that Amgen had received Sandoz's application during the patent dance.[262] Amgen, therefore, was restricted by statutory confidentiality from using that document in the European litigation and sought a way to circumvent the restriction.[263] Arguably, that circumvention alone warranted denial of the Section 1782 relief sought by Amgen.[264]

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than the District of Delaware's paraphrase of that holding: The Supreme Court held that, in deciding the scope of any § 1782 relief, "a district court could consider whether the § 1782(a) request conceals an attempt to circumvent foreign proof-gathering restrictions or other policies of a foreign country *or the United States*." Intel Corp. v. Advanced Micro Devices, Inc., 542 U.S. 241, 264-65 (2004) (emphasis added); *cf. In re*: Request from Vienna, 2023 WL 6278815, at *5 ("whether the request 'conceals an attempt to circumvent foreign proof-gathering restrictions'" (quoting *Intel*, 542 U.S. at 265)). Even if the Supreme Court had not so mentioned circumvention of domestic law, a district court could still consider such circumvention to be a relevant discretionary factor: The Supreme Court's list of factors was non-exhaustive, as the Court held that it was listing "factors" rather than "the factors." *Intel*, 542 U.S. at 264 ("We note below factors that bear consideration in ruling on a § 1782(a) request."). Nevertheless, the decision to grant § 1782 relief here will lessen that reluctance.

262. *In re*: Request from Vienna, 2023 WL 6278815, at *1 ("[During the patent dance,] Sandoz Inc. provided Amgen a copy of its [Biologics License Application ('BLA')], which contains certain information about the processes Sandoz Inc. uses to manufacture its denosumab biosimilar.").

263. *Id.* at *6 (ruling that while the Biosimilars Act prohibited the use of BLAs obtained as a part of the patent dance in foreign litigation, it does not bar Amgen from using BLAs obtained through other means, including a § 1782 application).

264. The last point bears expansion. Amgen *already possessed* the biosimilar application sought by the § 1782 application. Thus, insofar as the § 1782 application sought that same document, there was a question as to whether the § 1782 application presented a genuine case or controversy. True, a party that already possesses a document may use federal litigation to obtain an identical version of the same document from a witness—be it an adversary or a third party—because the witness's *act of producing* the document has evidentiary value independent of the document's content. *Cf.* United States v. Doe, 465 U.S. 605, 613, 617 (1984) (holding that the "act of producing the [subpoenaed] documents would involve testimonial self-incrimination," and accordingly that "the act of producing the documents at issue in this case is privileged and cannot be compelled without a statutory grant of use immunity"); Lorraine v. Markel Am. Ins. Co., 241 F.R.D. 534, 552–53 (D. Md. 2007) (holding that act of production constitutes "evidence sufficient to support a finding that the matter in question is what its proponent claims" (citation and internal quotation marks omitted)). However, nothing in *In re: Request from Vienna* indicates any reliance by Amgen on an act-of-production theory. It appears that the only reason Amgen sought Sandoz's biosimilar application under § 1782 was that the Biosimilars Act's confidentiality restrictions prevented Amgen from using, in the European litigation, the identical version that Amgen had received from Sandoz in the patent dance. Yet, under § 1782, whether a document is usable in the foreign proceeding is beyond the scope of the court's inquiry. *See In re*: Request from Vienna, 2023 WL 6278815, at *5. The only issue for the court to decide under § 1782 is whether the § 1782 applicant—here, Amgen—can *obtain* certain documents, not whether it can actually *use* those documents in a foreign proceeding. Although the eligibility criteria required that Amgen *desire* to use the

C. PATENT ABUSES

The second phase of biologic patent dispute resolution also offers the brand biologic an opportunity to prolong the negotiation and litigation process. Each additional day, week, or month spent engaged in the process reaps the brand another day, week, or month of monopoly profits. As a general matter, monopoly profits can be significant enough to justify strategic behavior to create such delay.[265]

As noted earlier, the second phase begins when the brand notifies the biologic that marketing of the biosimilar will begin in 180 or more days.[266] At this point, the brand may seek a preliminary injunction blocking the manufacture and/or sale of the biosimilar until resolution of the infringement status of any patents that were on the Initial Brand or Biosimilar Lists but were omitted from the Negotiated or Failed-Negotiation Lists.[267] These omitted patents may include new patents that were issued after the Initial Brand List was provided to the biosimilar manufacturer, and, therefore, must be included in the Supplemental Brand List.[268]

The Supplemental Brand List must be provided to the biosimilar within 30 days of a new patent's issuance.[269] However, the brand can continue to apply for and receive new patents after the Initial Brand List is provided,[270] creating

documents in a foreign proceeding, the court was barred under § 1782 from deciding whether Amgen could actually *use* the documents in that foreign proceeding.

In short, with respect to the biosimilar application, Amgen's § 1782 application could not have gotten Amgen any evidence that Amgen did not already have. The issue of whether Amgen could use that evidence in the European litigation should be decided not by the District of Delaware (where the § 1782 action was pending), but rather either the District of New Jersey (where the phase-one litigation was pending) or the European courts (where Amgen was intending to seek preliminary injunctive relief). But insofar as Amgen's § 1782 application sought Sandoz's biosimilar application, it would appear that Amgen already had all the relief it was entitled to obtain.

265. For example, one drug that received a five-month delay was able to earn over $600 million in monopoly sales, roughly $120 million per month. FELDMAN & FRONDORF, *supra* note 21, at 96–97. Even if there are other drugs available to treat the same issue addressed by the monopoly drug, the effects of those available substitutes are already reflected in the sales statistics.

266. *See supra* note 154 and accompanying text.

267. *See supra* note 156 and accompanying text.

268. Carrier & Minniti, *supra* note 107, at 37.

269. *Id.* at 18 n.162.

270. Rai & Price, *supra* note 67, at 20. In practice, the biosimilar can guard against sharp practice by requiring the brand to enter into a private confidentiality agreement with an anti-prosecution provision. *See* Van de Wiele, Kesselheim & Sarpatwari, *supra* note 200; *cf.* 42 U.S.C. § 262(l)(1)(A) (authorizing parties to agree on supplemental confidentiality rules for the patent dance's exchange of information).

the potential opportunity for an eleventh-hour delay of the biosimilar's entry to market. This type of behavior rewards a brand's efforts to abuse the patent system, which can take the form of cultivating patent thickets and using late-issued patents. The following Sections will describe how these behaviors play out in greater detail.

1. Patent Thickets

Patent thickets, a technique familiar in the non-biologic space, develop when firms amass large numbers of overlapping patents to increase risk of infringement for competitors.[271] Patent thickets serve to deter generic and biosimilar applicants through the threat of endless litigation, and some of the patents may extend the lifespan of the brand's patent protection in relation to the product.[272] Drug-makers create patent thickets by seeking protection for minor or frivolous modifications and patenting those modifications rather than by making legitimate innovations related to the drug.[273] The dearth of a comprehensive public list of all biologic patents related to drugs in the Purple Book[274] makes patent thickets particularly difficult for biosimilar applicants and antitrust regulators to detect. In addition, their deployment in the biologic patent dispute resolution process can be devastating.[275]

Lack of transparency prevents the biosimilar company from confirming the existence of a thicket prior to engagement in the patent dance. In addition, the two-phase structure of patent dispute resolution ensures that, one way or

271. Carl Shapiro, *Navigating the Patent Thicket: Cross Licenses, Patent Pools, and Standard Setting*, *in* 1 INNOVATION POLICY AND THE ECONOMY 119, 120 (Adam B. Jaffe, Josh Lerner & Scott Stern eds., 2001) ("[A patent thicket is] a dense web of overlapping intellectual property rights that a company must hack its way through in order to actually commercialize new technology."); KEVIN J. HICKEY & ERIN H. WARD, CONG. RSCH. SERV., R46679, THE ROLE OF PATENTS AND REGULATORY EXCLUSIVITIES IN DRUG PRICING 52–53 (2024) ("[Patent thicket may] describe one incumbent manufacturer's practice of amassing a large number of patents relating to a single product, with the intent of intimidating competitors from entering the market, or making it too costly and risky to do so.").

272. In a practice known as "evergreening," drug manufacturers that have already patented a drug's base compound obtain additional patents covering different aspects of the drug in an effort to prolong their market control for that drug. *See generally* Robin Feldman, *May Your Drug Price Be Evergreen*, 5 J.L. & BIOSCIS. 590 (2018); Robin Feldman, *Understanding 'Evergreening': Making Minor Modifications of Existing Medications to Extend Protections*, 41 HEALTH AFFS. 801 (2022).

273. Jeffrey Wu & Claire Wan-Chiung Cheng, *Into the Woods: A Biologic Patent Thicket Analysis*, 19 CHI.-KENT J. INTELL. PROP. 93, 138 (2019).

274. *See supra* Section III.B.1.

275. *See infra* text accompanying notes 276–283.

another, each patent in the thicket has a chance to lengthen the biosimilar's time to market.

Of course, these threats hinge on the biosimilar company's decision to continue with the patent dispute resolution process set out in the Biosimilars Act once the existence of a patent thicket becomes apparent. Daunted by both the literal and temporal cost of bringing each patent in a thicket to court, the biosimilar may well choose to settle instead—thereby opening the door to pay-for-delay and other collusive agreements, as described above.

Litigation surrounding AbbVie's Humira (adalimumab), a biologic used to treat rheumatoid arthritis, provides an illustration of these tactics. In 2014, two years before Humira's primary patent would expire, AbbVie began to file aggressively for additional patents on the drug: Out of the 247 patent applications filed on Humira, 220 were filed at least one year after its commercial launch[276] and 122 of them—approximately 50% of all applications filed—were applied for after 2013, two years before the primary patent's expiration.[277] One analysis found that AbbVie asserted at least 20 method-of-manufacturing patents against biosimilar applicants that were filed more than a year after Humira was launched[278] and thus were of dubious validity.[279] Furthermore, AbbVie's patent thicket protecting Humira was significantly thicker in the United States than in Europe—AbbVie had accumulated more than three times the number of patents in the United States than in Europe.[280]

When biosimilars emerged on the drug, AbbVie asserted large numbers of patents against them.[281] By reaching settlements with every challenging biosimilar maker since 2016, AbbVie effectively delayed until 2023 the market entries of all six adalimumab biosimilars that have received FDA approval.[282]

276. W. Nicholson Price II & Arti K. Rai, *How Logically Impossible Patents Block Biosimilars*, 37 NATURE BIOTECH. 862, 862 (2019).

277. I-MAK, OVERPATENTED, OVERPRICED: HUMIRA 3–4 (2021), https://www.i-mak.org/wp-content/uploads/2021/09/i-mak.humira.report.3.final-REVISED-2021-09-22.pdf.

278. Price & Rai, *supra* note 276, at 862.

279. *See id.* (arguing that the method-of-manufacturing patents that were filed more than a year after Humira launched were invalid if that method was already used in manufacturing Humira or improperly asserted in blocking biosimilar entry, as biosimilars can find an alternative method that is not covered in the asserted patent).

280. Stacie Ropka, Ted Mathias & Chantelle Ankerman, *Failure to Launch: The Patent Thicket Delay of US Biosimilars*, LAW360 (Oct. 9, 2019), https://www.law360.com/articles/1206946/failure-to-launch-the-patent-thicket-delay-of-us-biosimilars.

281. *Id.*

282. Jason Laday, *Market Gears Up for Biosimilar Boom in 2023 as Humira Exclusivity Draws to a Close*, HEALIO (June 18, 2021), https://www.healio.com/news/rheumatology/20210617/

Although the specific financial terms of the settlements have not been disclosed to the public, commentators have asserted that Humira's patent thicket fostered a legal environment perfect for pay-for-delay.[283]

AbbVie may have created a patent thicket to buy itself time—seven years—for a "product hop." With a product hop, a brand extends its monopoly over a particular market with the introduction of a newly patented formulation for the same condition and shifting the market to the new product.[284] Indeed, in 2019, AbbVie released two new rheumatoid arthritis drugs to which the company may aim to shift Humira's consumer base. This would discourage customers from trying biosimilars that may come to market.[285]

As exemplified by AbbVie's strategic actions, patent thickets may hinder biosimilar entry even more effectively than they hinder generic entry due to a combination of opacity and brand control over the patent dispute resolution process.[286]

2. Late-Issued Patents

Late-issued patents present another way for brands to use the patent dispute resolution process to their advantage. Recall that the brand submits a Supplemental Brand List of patents if any relevant patents are issued after the brand has submitted its Initial Brand List.[287] The brand must furnish the biosimilar with its Supplemental Brand List no later than thirty days after the brand receives the new patent.[288] The biosimilar then has thirty days to return a statement to the brand asserting whether the patent is invalid or not infringed by the biosimilar's product.[289]

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market-gears-up-for-biosimilar-boom-in-2023-as-humira-exclusivity-draws-to-a-close (reporting that AbbVie reached settlements with all six FDA approved adalimumab biosimilars, delaying their market entry until 2023); *see also* I-MAK, *supra* note 277, at 8 (stating that the first biosimilar alternative to Humira would not enter the U.S. market until 2023); Robin C. Feldman & Prianka Misra, *The Fatal Attraction of Pay-for-Delay*, 18 CHI.-KENT J. INTELL. PROP. 249, 278–79 (2019) (providing examples of cases where Humira reached settlements with potential biosimilar entrants, delaying biosimilar market-entry until 2023).

283. Feldman & Misra, *supra* note 282, at 277–79.

284. Laday, *supra* note 282.

285. *Id.*

286. Wu & Cheng, *supra* note 273, at 167.

287. *See supra* notes 134–135 and accompanying text.

288. *See supra* notes 134–135 and accompanying text.

289. Although 42 U.S.C. § 262(l)(7) ambiguously describes when the patents on the Supplemental Brand List can be litigated, at least one practitioner suggests that patents on the Supplemental Brand List can be litigated only in phase two. *See* APRIL ABELE ISAACSON, THOMSON REUTERS PRAC. L., BIOLOGICS PRICE COMPETITION & INNOVATION ACT

These conditions incentivize the brand biologic to hold off on filing for some patents, or to engage in any behavior with the USPTO that could delay granting the patent, until after the relevant product faces the prospect of biosimilar competition. After the biosimilar has applied for approval and the first few exchanges of patent lists have concluded, the brand can then apply for and obtain additional patents and submit a Supplemental Brand List.[290] Thus, even if every single patent the brand includes on its Initial Brand List is successfully invalidated by the biosimilar in phase one, the brand is not without options in phase two: The brand can stop the biosimilar from making or selling its product on the grounds that its freshly issued patents, listed on the Supplemental Brand List, have not yet been litigated. In this way, even patents that the brand knows will not stand up to challenge can be a source of monopoly profit as they stall the biosimilar's entry to market.

This method of late filing represents an update to the use of "submarine patents," patents that experienced years of delay between filing and issuance due to the filer's intentional manipulation of their processing at the USPTO. Firms deployed submarine patents in their heyday to surprise new innovators with infringement claims, often after an industry that had been in its nascence at the time of filing became more established. Submarine patenting worked because prior to 1995, patent lifespans in the United States began when the patents were issued, rather than when the patent applications were filed, as is the case today. In addition, prior to 1995, all patents remained secret until issuance, enabling filers to keep any patents-in-progress hidden from

(BPCIA): LITIGATION CONSIDERATIONS 6 (2022), https://ktslaw.com/en/Insights/Publications/2022/3/Biologics-Price-Competition-Innovation-Act-BPCIA-Litigation-Considerations. However, as noted above, if the Supplemental Brand List is provided before the Negotiated List is negotiated (or the Failed-Negotiation Lists are exchanged), a textual and logical analysis concludes that patents on the Supplemental Brand List can be litigated in phase one as well, especially given that the Biosimilars Act characterizes the Supplemental Brand List as a "supplement" to the Initial Brand List. *See supra* notes 179–182 and accompanying and following text. The only standard a patent must meet in order to qualify for inclusion on the Supplemental Brand List is to be worthy of the biologic's "[reasonable]" belief that "a claim of patent infringement could reasonably be asserted" on its basis. *See* 42 U.S.C. § 262(l)(7)(B) (providing that any patents that were issued after provision of the Initial Brand List and that the brand reasonably believes to be assertable against the biosimilar applicant shall be included in the Supplemental Brand List).

290. 42 U.S.C. § 262(l)(7). If a new patent is issued to the biologic manufacturer during the patent dance, the manufacturer must inform the biosimilar applicant within 30 days. However, this 30-day requirement applies when a patent is *issued*, not when the patent application is *filed*, meaning patents that are obtained after the Initial Brand List is provided could still have been applied for beforehand.

competitors.[291] Applicants, therefore, could engage in various tactics of regulatory manipulation to delay the issuance of their patent, allowing them to choose a time for the patent to issue that would afford them competitive advantages in the market.[292] However, in December 1994, Congress enacted the Uruguay Round Agreements Act, incorporating into law the agreements from the Uruguay Round of the General Agreement on Tariffs and Trade.[293] The following year, the United States joined the World Trade Organization.[294] Under the Uruguay Round Agreements Act and other subsequent statutory reforms, patent terms were modified to end twenty years from the date when patent applications were filed rather than seventeen years from the date when the patents were issued,[295] and patent applications were made public after eighteen months.[296] These reforms effectively killed the ability to create new submarine patents.[297]

Although late-issued patents introduced during the biologic patent litigation process cannot strictly be deemed submarine patents, they work in an analogous manner to stymie biosimilar innovators with unexpected infringement claims. This new form of submarine patent can do the greatest

291. Carrier & Minniti, *supra* note 107, at 38.

292. *Id.*; *see also* Minniti, *supra* note 159, at 172–73, 186–90 (noting the severity of the threat of submarine patents for biosimilars specifically, due to the multitude of patents involved and the new emergence of the sector).

293. Uruguay Round Agreements Act, Pub. L. No. 103-465, 108 Stat. 4809 (1994).

294. *U.S. in the World Trade Organization*, LIBR. OF CONG., https://guides.loc.gov/united-states-trade-policy/world-trade-organization (last visited Mar. 1, 2024).

295. Uruguay Round Agreements Act § 532(a); 35 U.S.C. § 154(a)(2). *See* Karin L. Tyson & Robert W. Bahr, *Patent Term Guarantee Overview*, U.S. PAT. & TRADEMARK OFF. (Aug. 10, 2011), https://www.uspto.gov/patents/laws/american-inventors-protection-act-1999/patent-term-guarantee-overview ("[T]he Uruguay Round Agreements Act amended 35 U.S.C. § 154 in June of 1995 to change the term of utility and plant patents from ending seventeen years from the date of patent grant to ending twenty years from the filing date of the application . . . .").

296. 35 U.S.C. § 122(b)(1)(A); American Inventors Protection Act of 1999 (AIPA), Pub. L. No. 106-113, § 4502, 113 Stat. 1501, 1501A-561 (1999).

297. Many true submarine patents filed before 1995 took decades to make their way through the USPTO. *See* Dennis Crouch, *Old-School Submarine Patents*, PATENTLY-O (Dec. 14, 2010), http://patentlyo.com/patent/2010/12/old-school-submarine-patents.html. As of 2014, 450 remained pending with the USPTO, some of which were for biologic drugs. Dennis Crouch, *Old Application; New Patents*, PATENTLY-O (Jan. 18, 2014), https://patentlyo.com/patent/2014/01/old-patents.html; *see also* Minniti, *supra* note 159, at 187–88 (describing the threat to biosimilars posed by the 450 submarine patents pending at USPTO as of 2014, and noting that a recent case involved a biologic for which a patent application was filed in 1995 but patents did not issue till 2011 and 2012).

damage in the second phase of the patent dance as the basis for preliminary injunction motions.

IV. RE-ALIGNMENT: SHIFTING THE STEPS

Multiple factors may be contributing to the slow entry and uptake of biosimilars in the United States. On the subject of pricing, some evidence suggests that middle players may be contributing to higher biosimilar prices in the United States in comparison to Europe.[298] For example, some biosimilars reportedly have tried to launch at lower prices in the United States, but were subsequently forced to raise their prices.[299] Middle players refused to contract for the drugs at the substantially lower prices because of insufficient ability to extract revenue.[300] In theory, that insufficiency may stem from the inability to extract revenue from rebates, or from fees based on the higher pre-rebate price of the drug, or both. The Biosimilars Act did not anticipate or address supply-chain issues such as these.

Similarly, other areas of the Biosimilars Act, outside of intellectual property disclosure and the patent dance, also contribute to sluggishness in this market. The length of the data exclusivity that the Biosimilars Act grants to brand biologics in the first place is one such area.[301] During this twelve-year period,

298. *See* Sarah J. Tribble, *Why The U.S. Remains The World's Most Expensive Market For 'Biologic' Drugs*, CAL. HEALTHLINE (Jan. 28, 2019), https://californiahealthline.org/news/why-the-u-s-remains-the-worlds-most-expensive-market-for-biologic-drugs/ (noting that biosimilars on average cost higher in the United States than in Europe and asserting that tactics like rebate traps can artificially decrease biosimilar intake and increase prices).

299. Sandoz initially launched Omnitrope, a follow-on protein to Amgen's Genotropin (somatropin), at a substantial price discount. But Sandoz tried to sell Omnitrope through "specialty pharmacies," which, unlike managed care organizations, make profit as a percentage of a drug's sales price. As a result, the low price of Omnitrope adversely affected the revenue of the specialty pharmacies. So Sandoz had to *increase* the price of Omnitrope to achieve market penetration. Some years later, after the Biosimilars Act created the biosimilar pathway, Sandoz sought approval for Zarxio (filgrastim-sndz), a biosimilar to Amgen's Neupogen (filgrastim). As to whether Zarxio would be priced lower than Neupogen, a Sandoz executive said simply that the subject of price was "challenging" and that his company learned its lesson from Omnitrope. *See* Sue Sutter, *Biosimilar Pricing: Sandoz Vows Not to Make* Omnitrope *'Mistake' with Filgrastim*, PINK SHEET (Dec. 22, 2014), https://pink.citeline.com/PS056542/Biosimilar-Pricing-Sandoz-Vows-Not-To-Make-emOmnitropeem-Mistake-With-Filgrastim.

300. *See* Sutter, *supra* note 299.

301. 42 U.S.C. § 262(k)(7)(A) ("Approval of [a biosimilar application] may not be made effective by the Secretary until the date that is 12 years after the date on which the reference product was first licensed under [42 U.S.C. § 262](a)."); *Background Information: List of Licensed Biological Products with Reference Product Exclusivity and Biosimilarity or Interchangeability Evaluations (Purple Book)*, U.S. FOOD & DRUG ADMIN., https://www.fda.gov/drugs/biosimilars/

the FDA may not approve any biosimilar application that uses the brand biologic as its reference product.[302] Furthermore, the Biosimilars Act provides the brand with four years of regulatory exclusivity during which a biosimilar may not even apply for approval.[303] Finally, all of the patent disclosure in the world will not help if the patents themselves do not provide the necessary information.[304] Nevertheless, the patent dance remains at the heart of the Biosimilars Act, and it fails to function in an effective manner. Those failings can be remedied.

At the outset, we would note that the logic of trying to focus the parties on what matters among the avalanche of patent rights and numerous claims within those patents may make sense. In fact, some patent judges and jurisdictions try to streamline portions of patent cases by asking the parties to focus on a subset of the possible issues first, in the hopes that resolving these will bring the parties closer to a resolution.[305] Nevertheless, the appeal of encouraging two particular parties to resolve a dispute ignores the broader interests of society, which reach well beyond those two parties and that moment of time. Rather, society's interests center on encouraging a broad range of competitors to prepare to enter the field, both when the brand's patents expire and across time.

Entry preparation, however, requires full and complete rights information. To that end, the Hatch-Waxman Act provides a model that can be adapted to the biologic circumstances.[306] For example, we suggest that brand biologic

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background-information-list-licensed-biological-products-reference-product-exclusivity-and (last updated Aug. 3, 2020).

302. 42 U.S.C. § 262(k)(7)(A).

303. *Id.* § 262(k)(7)(B) ("A[biosimilar application] may not be submitted to the Secretary until the date that is 4 years after the date on which the [brand] product was first licensed under [42 U.S.C. § 262](a).").

304. *See supra* Sections II.C, III.B (describing insufficiency of biologic patent disclosure).

305. A number of district courts have adopted local rules limiting the number of claim terms that may be submitted to the court for claim construction in a single case. *E.g.*, N.D.N.Y. PAT. R. 4.4(b) ("No more than ten (10) patent terms or phrases may be presented to the Court for construction, absent prior leave of Court upon a showing of good cause."); D. MASS. R. 16.6(e)(1)(C) ("The parties may jointly present to the court no more than 10 claim terms for construction . . . ."); N.D. CAL. PAT. R. 4-1(b) ("The parties shall also jointly identify the 10 terms likely to be most significant to resolving the parties' dispute, including those terms for which construction may be case or claim dispositive."). In jurisdictions where no specific local patent rule limits the number of claim terms that the court will construe, certain judges may impose their own limits. *See, e.g.*, Hearing Components, Inc. v. Shure, Inc., No. 9:07CV104, 2008 WL 2485426, at *1 (E.D. Tex. June 13, 2008) ("In order to secure the just, speedy and inexpensive determination of this action pursuant to Fed.R.Civ.P. 1, the court ORDERS that the parties shall elect no more than ten (10) disputed claim terms for construction.").

306. *See* Drug Price Competition and Patent Restoration Act of 1984, *supra* note 19.

companies could be required to submit all patent and exclusivity rights to the FDA at the time of the drug's approval, along with a requirement to supplement that information with any new rights acquired. The FDA, in turn, could be required to publish that information in the Purple Book. The system could be structured in a use-it-or-lose-it form, such that biologic companies could not assert rights in relation to a drug if they failed to list those rights. This would give prospective biosimilars a more robust view of the potential rights at the time when they are contemplating entering the fray.

Providing disclosure upfront would remove some of the temptations that parties have to maneuver the patent dance so that information is not released to future competitors. If the information is already out there, the benefit of hiding loses its power to distort choices along the way.

For enacting such a reform, the general choreography of the patent dance could remain in place. The litigation structure could continue to allow the biosimilar to choose how many patents would become the focus of the litigation. This limits the brand's ability to overwhelm the biosimilar with endless numbers of legal claims, each of which may be of questionable validity.

In addition, the Biosimilars Act should provide some advantage for the first-moving biosimilar that gets FDA approval and gets to market. One could model such a provision after the 180-day exclusivity that is available under Hatch-Waxman for first-filing generics who successfully challenge rights.[307] Although policy makers would be well advised to learn from and adjust to the Hatch-Waxman history of pay-for-delay agreements, a first-mover advantage could be designed to avoid the strategic behaviors that developed to tiptoe around the Hatch-Waxman Act's language and provisions.

A simpler and cleaner solution than trying to design around the strategic behaviors of pay-for-delay could be a period of exclusivity for the first-moving biosimilar to get FDA approval, regardless of whether any rights-challenging occurs. Currently, the first interchangeable to get FDA approval receives a period of exclusivity, which protects it against entry by subsequent interchangeables.[308] That provision could be expanded to all first biosimilars who get FDA approval.

Finally, additional small adjustments could be made to ensure a functioning patent dance, including standardizing whether injunctive relief—preliminary or otherwise—is available. Disincentives also could be created for parties who

307. 21 U.S.C. § 355(j)(5)(B)(iv) (describing the 180-day exclusivity period for the first-filing generics with a Paragraph IV certification).

308. 42 U.S.C. § 262(k)(6) (stipulating the length and nature of "[e]xclusivity for first interchangeable biological product").

would move outside the process. These could deter parties from finding the need and incentive to sidestep the systems created.

Together, these changes could provide a pathway for moving forward with a more successful Biosimilars Act. Although it may be tempting to scrap the entire patent dance, starting from scratch would wipe away all that we may have learned about the goals and strategic behaviors of the parties. Sometimes the devil you know may be better than the devil you don't. By leaving the essential process in place while making a few key changes, the Biosimilars Act, with its central feature of the patent dance, could become a more effective conduit for bringing competition to the increasingly important market for biologic medicine.

V. CONCLUSION

As numerous commentators have asserted, biologics are currently a driving force behind high drug prices. According to the most recently available information,[309] biologics account for only 2% of all prescriptions in the United States but 37% of the drug spending.[310] Combating these prices and ensuring more affordable access to medications will require greater competition in the biologic market from cheaper alternatives. Congress attempted to achieve this objective by passing the Biosimilars Act in 2010 to create an easier market entry pathway for follow-on drugs known as biosimilars. The Biosimilars Act, however, has proven to be much less successful than the older cousin on which it was patterned, the Hatch-Waxman Act. A key part of this dismal performance can be traced to the control over patent disclosure that the Biosimilars Act vests in drug companies. To avoid disclosure of patent and manufacturing information to other drug companies, biologic and biosimilar makers alike can easily evade the disclosure contemplated by the Biosimilars Act.

In particular, the strategies employed by brand companies adapt some of the forms of gameplaying familiar in the non-biologic space to the conditions of biologic manufacture and patent dispute resolution, as well as taking on

309. Josh Nathan-Kazis, *'Biosimilars' Were Supposed to Tame Costs for Drugs Like Humira. It Isn't Working.*, BARRON'S (Feb. 21, 2023), https://www.barrons.com/articles/biosimilar-drug-costs-humira-a5f42f37.

310. *Id.*; David L. Carl, Yannic Laube, Miquel Serra-Burriel, Huseyin Naci, Wolf-Dieter Ludwig & Kerstin N. Vokinger, *Comparison of Uptake and Prices of Biosimilars in the U.S., Germany, and Switzerland*, 5 JAMA NETWORK OPEN (2022) (noting the statistically disproportionate level of spending on biologics in the United States); Avik Roy, *Biologic Medicines: The Biggest Driver of Rising Drug Prices*, FORBES (Mar. 8, 2019), https://www.forbes.com/sites/theapothecary/2019/03/08/biologic-medicines-the-biggest-driver-of-rising-drug-prices/?sh=66bfc61c18b0 (describing biologics as a primary driver of high drug prices).

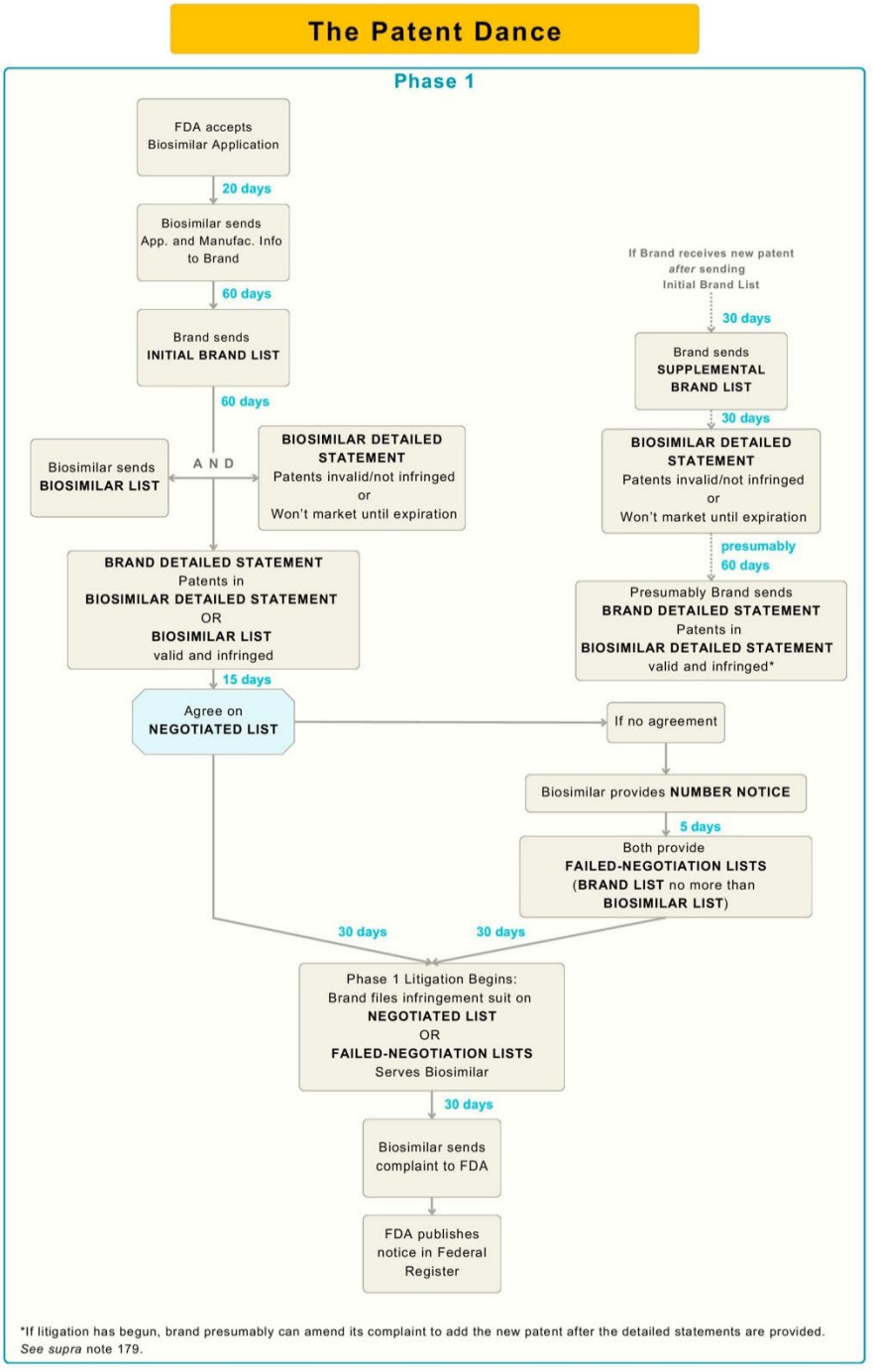
entirely new strategic behaviors. All of these behaviors will remain enticing to drug-makers as long as the biologic regulatory regime not only incentivizes brands to shroud their patents in darkness but offers them ample opportunity to continue to do so.

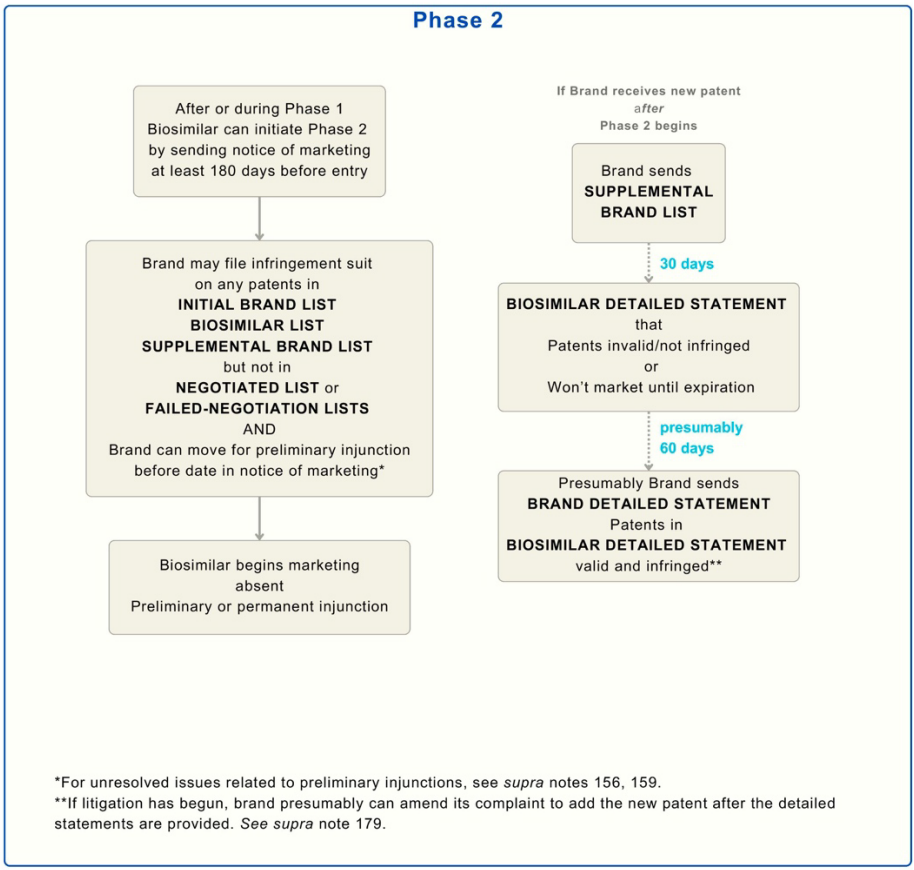
VI. APPENDIX

A. PATENT DANCE NOMENCLATURE

Numerical Legal Name	**Simple Language Used in This Article**
3A List	Initial Brand List
3B List	Biosimilar List
7AB List	Supplemental Brand List
4AB List	Negotiated List
5A Notice	Number Notice
5B Lists	Failed-Negotiation Lists
Subparagraph B Statement	Biosimilar Detailed Statement
Paragraph 3(C) Statement	Brand Detailed Statement

B. PATENT DANCE FLOWCHART





*For unresolved issues related to preliminary injunctions, see *supra* notes 156, 159.
**If litigation has begun, brand presumably can amend its complaint to add the new patent after the detailed statements are provided. *See supra* note 179.

THE "CEREMONIAL USE" DEFENSE TO INFRINGEMENT OF PSYCHEDELIC PATENTS

Forrest Tahdooahnippah[†]

ABSTRACT

A psychedelic "renaissance" has led to renewed interest in the medical uses of psychedelics, particularly to assist in treatment of substance use disorders. This "renaissance" has included attempts to patent methods of using or synthesizing psychedelics. Long before this "renaissance," however, indigenous peoples of the Americas used psychedelic plants in their religious rites, including using psychedelic plants to treat substance abuse disorders such as alcoholism. Therefore, indigenous peoples have raised concerns that the recent trend of patenting psychedelics will lead to the patenting of their traditional knowledge and impede their free exercise of religion. A current proposed solution to address such concerns is to create traditional knowledge repositories. Such repositories prevent the patenting of traditional knowledge that qualifies as "prior art" under the patent laws. However, due to the secret nature of religious ceremonies and oral transmission of religious instruction, prior indigenous uses of psychedelics may not qualify as "prior art." Moreover, market forces may compel indigenous communities to substitute patented varieties of psychedelics for traditional varieties. Accordingly, a "ceremonial use" defense should also be recognized to provide a defense to patent infringement claims for indigenous communities and their members.

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I. INTRODUCTION

Psychedelic plants—cohoba, ayahuasca, psilocybin mushrooms, peyote—have long been used sacramentally by indigenous peoples of the Americas.[1] Initially targeted for suppression as part of colonial efforts to Christianize indigenous peoples, psychedelics enjoyed brief interest by the psychiatric community before being criminalized under the Controlled Substances Act in 1970.[2] Recently, shifting attitudes towards psychedelics have spurred renewed interest in their medical applications among researchers, particularly in using psychedelics to assist with psychotherapy for alcoholism and other substance use disorders.[3] This, in turn, has led to the filing of several patent applications relating to such use of psychedelic plants, or the alkaloids within them.[4]

1. Chike Pilgrim, *Communicating with Spirits, Getting High: The Wooden Artefacts of the Caribbean Indigenous Cohoba Ceremony*, NAT'L TRUST OF TRINIDAD AND TOBAGO, https://nationaltrust.tt/home/wooden-artefacts-cohoba-ceremony/?v=df1f3edb9115 (Apr. 28, 2021); Melanie J. Miller, Juan Albarracin-Jordan, Christine Moore & José M. Capriles, *Chemical Evidence for the Use of Multiple Psychotropic Plants in a 1,000-year-old Ritual Bundle from South America*, 116 PNAS 11207 (May 6, 2019), https://www.pnas.org/doi/10.1073/pnas.1902174116; Giorgio Samorini, *The Oldest Archeological Data Evidencing the Relationship of Homo Sapiens with Psychoactive Plants: A Worldwide Overview*, 3 J. OF PSYCHEDELIC STUDIES 63, 64 (2019); Dustin Marlan, *Beyond Cannabis: Psychedelic Decriminalization and Social Justice*, 23 LEWIS & CLARK L. REV. 851, 865 (2019).

2. Benjamin Breen, *The Failed Globalization of Psychedelic Drugs in the Early Modern World*, 65 HISTORICAL J. 12, 13–23 (2022); Arnaud Exbalin, *Discovering Hallucinogenic Mushrooms in Mexico*, CONVERSATION (Apr. 11, 2019), https://theconversation.com/discovering-hallucinogenic-mushrooms-in-mexico-115033; MIKE JAY, MESCALINE: A GLOBAL HISTORY OF THE FIRST PSYCHEDELIC 40, 131, 193–198 (2019)**;** Rick Strassman, DMT: THE SPIRIT MOLECULE A DOCTOR'S REVOLUTIONARY RESEARCH INTO THE BIOLOGY OF NEAR-DEATH AND MYSTICAL EXPERIENCES 25, 49 (2001); Controlled Substances Act, 21 U.S.C. § 812 (outlawing certain hallucinogenic substances, including dimethyltryptamine, mescaline, peyote, and psilocybin).

3. Mason Marks & I. Glenn Cohen, *Patents on Psychedelics: The Next Legal Battlefront of Drug Development*, 135 Harv. L. Rev. F. 212, 212–15 (2020) (noting growing research on psychedelics to treat "drug overdose epidemic" and stating "[i]n the past few decades, pioneering researchers rekindled interest in the therapeutic use of psychedelic substances."); *Psychedelic Drug Therapy May Help Treat Alcohol Addiction*, NYU LANGONE HEALTH (Aug. 24, 2022) https://nyulangone.org/news/psychedelic-drug-therapy-may-help-treat-alcohol-addiction; Brendan Borrell, *The Next Big Addition Treatment*, N.Y. TIMES (Mar. 31, 2022) https://www.nytimes.com/2022/03/31/well/mind/psilocybin-mushrooms-addiction-therapy.html.

4. *See, e.g.*, Antidepressant-Psilocybin Co-treatment to Assist Psychotherapy, Application Pub. No. US 2022/0387456 (filed Mar. 10, 2022); Mescaline Derivatives with Modified Action, Application Pub. No. US 2022/0267252 (filed Feb. 20, 2022) (discussing use of mescaline derivatives for use in substance-assisted therapy); Effects of Mescaline and of Mescaline Analogs (Scalines) to Assist Psychotherapy, Application Pub. No. US 2022/0265582 (filed Feb. 18, 2022); Methods and Systems for Enhancing Clinical safety of Psychoactive Therapies, Application Pub. No. US 2023/0162851 (filed Mar. 9, 2021)

Indigenous religions, however, have long used psychedelics as sacraments in ceremonies that seek to address those same ills.[5] Attempts to patent psychedelics, or methods of using psychedelics, have stoked fears among indigenous communities that patent laws will be the new tool of colonial suppression, preventing indigenous people's free exercise of religion.[6]

Currently, researchers have primarily proposed using traditional knowledge repositories to prevent the patenting of indigenous religious practices.[7] While no traditional knowledge repository has been adopted in the United States,[8] where such repositories do exist, researchers aim for repositories to improve patent examiners' access to traditional knowledge by translating and consolidating that knowledge into a searchable database.[9] Improved access to traditional knowledge enables such knowledge to be found during "prior art" searching.[10] Patent examiners use "prior art" searches to prevent patents from being erroneously granted on existing practices.[11] The content of the "prior art" is a question of patent validity—if a supposed

(discussing methods and systems for enhancing clinical safety of psychoactive therapies, including psilocybin therapy).

5. JAY, *supra* note 2, at 208; OMER C. STEWART, PEYOTE RELIGION: A HISTORY 157, 220–21 (1987).

6. Simon Spichak, *Psychedelics are Surging—at the Expense of Indigenous Communities*, DAILY BEAST, (Dec. 26, 2022), https://www.thedailybeast.com/psychedelics-are-surging-at-the-expense-of-indigenous-communities (expressing concerns that patents will make psychedelics used by indigenous people for ceremonial purposes inaccessible, and describing the patenting of psychedelics as "biopiracy" and part of a "colonial process").

7. Marks & Cohen, *supra* note 3, at 231–32.

8. *See Online Databases and Registries of Traditional Knowledge and Genetic Resources*, WIPO, https://www.wipo.int/export/sites/www/tk/en/resources/pdf/gr_table.pdf (listing WIPO members states with databases for traditional knowledge and genetic resources and showing United States has only adopted databases concerning genetic resources, not traditional knowledge) (last access Feb. 21, 2024).

9. Jay Erstling, *Using Patents to Protect Traditional Knowledge*, 15 TEX. WESLEYAN L. REV. 295, 319–20 (2009).

10. Murray Lee Eiland, *Patenting Traditional Medicine*, 89 J. PAT. & TRADEMARK OFF. SOC'Y 45, 64–65 (2007) ("A TM [traditional medicine] database would put information in the public domain. It would allow patent examiners to identify what is novel in reference to TK [traditional knowledge]. If a patent application were the same as what was recorded in the database, it would be denied.").

11. Patrick Nolan & Leonard Change, *Understanding the Patent Examination Process*, OFFICE OF PATENT TRAINING, U.S. Patent & Trademark Office at 7 (July 2020) https://www.uspto.gov/sites/default/files/documents/InventionCon2020_Understanding_the_Patent_Examination_Process.pdf (stating that patent examiner responsibilities include searching "existing technology for claimed invention").

invention was already publicly disclosed, it is not patentable.[12] In other words, examiners use "prior art" searches to ensure the novelty and nonobviousness of a patent application.[13] Therefore, the focus of traditional knowledge repositories is patent validity—the content of existing public disclosures. Such repositories do not concern patent infringement, where claims compare an accused device or method to the patented invention.

The focus on patent validity has several drawbacks. Indigenous religious practices using sacramental psychedelics may not qualify as "prior art" under existing law. The definition of "prior art" focuses on whether the invention was previously disclosed to the public (either in writing or by its public use) or was on sale to the public.[14] However, because indigenous religious practices are often secret, non-commercial, and transmitted through oral tradition, they may not qualify as "prior art." Moreover, modern science has already created new (and often commercialized) varieties of non-psychedelic plants traditionally used by the indigenous peoples of the Americas, and some of these new varieties of plants have been patented.[15] Economic forces favor these new varieties to their traditional counterparts, and the scarcity of the traditional varieties has already compelled indigenous people to substitute the more available nontraditional varieties in their religious and cultural practices.[16] Similar forces could compel indigenous people to rely on patented versions of psychedelics for their religious rites if traditional psychedelic plants become scarce. Prior art repositories do not address these substitution concerns.

Accordingly, courts (or Congress) should recognize an affirmative defense to patent infringement for the religious practices of indigenous communities—a defense I will refer to herein as the "ceremonial use" defense. Similar to the "prior user rights" defense, the "ceremonial use" defense would permit continued use of patented technologies for an original (albeit secret) user. However, the "ceremonial use" defense is applied in a religious rather than a

12. *Prior Art Research*, LEXISNEXIS IP BLOG (Sept. 20, 2021) https://www.lexisnexisip.com/resources/prior-art-research/ ("It is the job of patent examiners to comb through and evaluate an invention's novelty and nonobviousness based on all prior art in the world (a tall order, we know).").

13. *Id.*

14. 35 U.S.C. § 102(a).

15. *See, e.g.*, Hugh Murphy, *Foods Indigenous to the Western Hemisphere*, AM. INDIAN HEALTH AND DIET PROJECT, https://aihd.ku.edu/foods/corn.html (last visited Aug. 4, 2023) (noting traditional Native American use of corn); Paul Harris, *Monsanto Sued Small Farmers to Protect Seed Patents-Report*, GUARDIAN (Feb. 2013), https://www.theguardian.com/environment/2013/feb/12/monsanto-sues-farmers-seed-patents (noting patent protection for corn varieties).

16. Carling Malouf, *Gosiute Peyotism*, 44 AM. ANTHROPOLOGIST 93, 97 (1942), https://www.jstor.org/stable/662831?seq=1 at 99 n.12 (noting use of canned sweet corn in peyote ceremony).

commercial context. The "ceremonial use" defense goes further than the "prior user rights" defense in permitting substitution of new and novel variants of psychedelics that were inspired by prior ceremonial use of psychedelic plants. In this way, the "ceremonial use" defense would be similar to the "shop rights" doctrine, which allows an employer to use inventions developed by its employees when fairness and equity so require. The owners of the rights to the "ceremonial use" defense should be federally recognized Indian Tribes, pre-existing indigenous religious organizations, and others authorized to perform religious ceremonies under tribal custom.

II. BACKGROUND

A. RELIGIOUS PRACTICES OF INDIGENOUS PEOPLES OF THE AMERICAS INSPIRED SCIENTIFIC RESEARCH INTO PSYCHEDELICS

Psychiatric researcher Humphry Osmond coined the term "psychedelics" to the world at a 1956 conference and in a 1957 article.[17] Osmond combined the Greek words *psyche* ("mind" or "soul") and *delein* ("to make manifest") to create a new word that meant "mind manifesting."[18] He needed new vocabulary to describe the effects he experienced from mescaline (an alkaloid found in peyote) and lysergic acid diethylamide (LSD).[19] Certain chemicals are considered to be "classic" psychedelics due to a long history of use and research into them during the 1950s and 1960s, during the emergence of the field of molecular neuroscience.[20] These "classic" psychedelics are psilocybin, LSD, dimethyltryptamine (DMT), and mescaline.[21] The "classic" psychedelics fall within one of two general chemical categories—tryptamines (LSD, psilocybin, and DMT) and phenethylamines (mescaline).[22]

With the exception of LSD, the long history of use of "classic" psychedelics includes ancient use by indigenous peoples of the Americas.[23]

17. Steven J. Novak, *LSD before Leary: Sidney Cohen's Critique of the 1950s Psychedelic Drug Research*, 88 ISIS 87, 95 (1997); Marlan, *supra* note 1, at 857 & n.1.

18. Marlan, *supra* note 1, at 857.

19. JAY, *supra* note 2, at 257 n.17; John Cloud, *When the Elite Loved LSD*, TIME (Apr. 23, 2007), https://content.time.com/time/nation/article/0,8599,1613675,00.html.

20. Matthew W. Johnson, Peter S. Hendricks, Frederick S. Barrett & Roland R. Griffiths, *Classic Psychedelics: An Integrative Review of Epidemiology, Therapeutics, Mystical Experience, and Brain Network Function*, 197 PHARMACOLOGY & THERAPEUTICS 83, 85 (2019).

21. James J.H. Rucker, Jonathan Iliff & David J. Nutt, *Psychiatry & the Psychedelic Drugs. Past, Present & Future*, 142 NEUROPHARMACOLOGY 200, 201 (2018).

22. Johnson, *supra* note 20, at 84.

23. *See* Marlan, *supra* note 1, at 861 regarding the use of ayahuasca, psilocybin mushroom, and peyote in the Americas dating back millennia. In contrast, LSD was not synthesized until 1938.

While ancient cultures in other parts of the world used psychoactive plants that contained "classic" psychedelics (particularly psilocybin), the context in which these plants were used has been lost to history; the only record of their use that remains is the archeological evidence.[24] In contrast, the religious use of psychedelics by Native Americans began in ancient times, but it has persisted to the present day.[25] With the exception of LSD, "classic" psychedelics come from plants that were used in a religious context by Native Americans. Mescaline, for instance, is found in cacti species native only to the Americas—the peyote cactus and San Pedro cactus.[26] "Evidence suggests that Native Americans have been using peyote as long ago as 5,700 years."[27] Indigenous South Americans have been using San Pedro for religious purposes since 1500 BCE.[28] Similarly, psilocybin is found in a genus of mushroom (psilocybe).[29] Psilocybin mushrooms were used in the religious practices of indigenous peoples in the Americas as far back as 1000 BCE,[30] and their use continued until the Spanish conquest.[31]

DMT is a molecule that naturally occurs throughout the plant and animal kingdom: it is found in mammals (including humans), toads and frogs, as well as in grasses, molds, barks, roots, and other plants and animals.[32] Importantly, DMT is found in the seeds of the cohoba tree.[33] Indigenous peoples of the

24. The archeological record indicates the use of psilocybin mushrooms by humans in the Sahara Desert between 6,000 and 4,500 B.C., and in Spain around 4,000 B.C. Samorini, *supra* note 1, at 70. Rock art also suggests potential psilocybin mushroom use in Australia and Tanzania. David E. Nichols, *Psychedelics*, 68 PHARMACOLOGICAL REVIEWS 264, 268 (2016). However, it was not until F. Gordon Wasson published an article in *LIFE* magazine about the existence of *velada* ceremonies making use of mushrooms in Mexico was the existence of continued use of mushrooms publicized to Western society. Nicky Kvitsinski, *Fungus Among Us: A Juxtaposition of the Psychological Benefits of Psilocybin Use and Its Federal Classification as a Schedule I Drug*, 50 W. ST. L. REV. 65, 67–68 (2023).

25. JAY, *supra* note 2, at 41; Strassman, *supra* note 2, at 22; Konstantin Gerber, Inti García Flores, Angela Christina Ruiz, Ismail Ali, Natalie Lyla Ginsberg & Eduardo E. Schenberg, *Ethical Considerations about Psilocybin Intellectual Property*, 4 ACS PHARMACOL. & TRANSL. SCI. 573 (2021), https://www.ncbi.nlm.nih.gov/pmc/articles/PMC8033603/ (discussing resilience of Mazatec mushroom ceremonies in face of centuries of persecution).

26. JAY, *supra* note 2, at 8, 15, 18.

27. Marlan, *supra* note 1, at 865.

28. F.J. Carod-Artal & C.B. Vázquez-Cabrera, *Mescaline and the San Pedro Cactus Ritual: Archeological and Ethnographic Evidence in Northern Peru*, 42 REVISTA DE NEUROLOGIA (2006), https://pubmed.ncbi.nlm.nih.gov/16625512/.

29. Marlan, *supra* note 1, at 860.

30. Samorini, *supra* note 1, at 64.

31. Gastón Guzmán, *Hallucinogenic Mushrooms in Mexico: An Overview*, 32 ECONOMIC BOTANY 404, 405–10 (2008).

32. Strassman, *supra* note 2, at 42.

33. Pilgrim, *supra* note 1.

Caribbean have used cohoba powder as snuff for hundreds of years.[34] In fact, the very first European work describing the ethnology of the New World by Ramone Pane (who accompanied Christopher Columbus on his second voyage) noted the use of cohoba by indigenous peoples in 1496.[35]

Initial scientific research into psychedelics focused on schizophrenia, and researchers investigated any possible links between psychedelic compounds and the disease.[36] Mescaline was the first psychedelic chemically isolated[37] by German chemist Arthur Heffter in 1897.[38] The chemist Ernst Späath then synthesized Mescaline in a laboratory in 1919.[39] This led to the use of mescaline for psychiatric research, and mescaline experiments became widespread in the field of psychiatry by 1940.[40]

The effects of mescaline inspired further scientific research into other psychedelics, such as LSD. For instance, when Albert Hoffman famously administered LSD on himself on April 19, 1943 (the first-ever human experience with LSD), he recognized that its effects were "not new to science," but were similar to mescaline.[41] LSD then went on to be used in psychiatry, often by researchers who had been experimenting with mescaline, and it eventually surpassed mescaline in popularity with researchers.[42]

In 1954, psychiatrists Humphry Osmond and Abram Hoffer began experimenting with giving alcoholics LSD.[43] This research was inspired by their experience attending a ceremony of the Native American Church (the name given to the peyote religions of indigenous North Americans in 1918) in Canada, where they learned of the success of the Church in combating alcoholism.[44] Over the next half-decade, the research into LSD as a treatment for alcoholism led it to be known as "a miracle cure."[45] The research into psychedelic drug therapy proliferated, with a thousand clinical papers, dozens

34. *Id.*
35. William Edwin Safford, *Identity of Cohoba, the Narcotic Snuff of Ancient Haiti*, 6 J. OF THE WASH. ACAD. OF SCIS. 547, 549–50 (1916).
36. *See, e.g.*, JAY, *supra* note 2, at 193–195; Strassman, *supra* note 2, at 25, 49.
37. *See* Rucker, et al, *supra* note 21, at 201.
38. *Id.*; JAY, *supra* note 2, at 257 n.17.
39. JAY, *supra* note 2, at 131.
40. *Id.* at 103–05, 132–46, 178.
41. *Id.* at 189.
42. *Id.* at 189–98.
43. Novak, *supra* note 17, at 97.
44. JAY, *supra* note 2, at 208.
45. Novak, *supra* note 17, at 98.

of books, and six international conferences on the topic between 1950 and the mid-1960s.[46]

As another example, biochemist Alexander Shulgin's use of mescaline inspired him to look for other psychoactive phenethylamines, eventually leading to his synthesis of 3,4-Methylenedioxymethamphetamine (MDMA), which had been previously synthesized but never made available for research.[47] Shulgin took MDMA and, noting its effects, introduced it to a psychotherapist for use with clients.[48] MDMA then "spread rapidly through California's psychotherapeutic community."[49] Today, MDMA is on the verge of FDA approval for use in treatment of post-traumatic stress disorder.[50]

Mescaline also indirectly inspired scientific interest in DMT. In 1953, Hungarian physician and chemist Stephen Szara was hoping to use LSD in his research regarding schizophrenia.[51] However, Sandoz Laboratories refused to provide him with LSD because the drug company did not want to risk such a powerful drug being used in a communist country.[52] In search of an alternative, Szara began experimenting with mescaline.[53] Encouraged by his experience with mescaline, Szara looked to other indigenous medicines and, after learning of cohoba, began exploring DMT.[54]

Similarly, although psilocybin mushrooms are found throughout the world and were used in antiquity,[55] it was the use of these mushrooms by Mazatec Indians in Mexico that famously caught the attention of R. Gordon Wasson, who published a 1957 article in *Life* magazine[56] regarding the indigenous use of mushrooms.[57] Wasson, a bank executive and an amateur mushroom

46. Marlan, *supra* note 1, at 866 (quoting LESTER GRINSPOON & JAMES B. BAKLAR, PSYCHEDELIC DRUGS RECONSIDERED 192 (1997)).

47. JAY, *supra* note 2, at 243–44.

48. *Id.* at 244–45.

49. *Id.* at 245.

50. Katie Brown, *Legalizing MDMA for PTSD Treatment: Phase 3 Clinical Trial Results*, PSYCHIATRSIT.COM (May 23, 2023), https://www.psychiatrist.com/news/legalizing-mdma-for-ptsd-treatment-phase-3-clinical-trial-results/.

51. Andrew R. Gallimore & David P. Luke, *DMT Research from 1956 to the Edge of Time*, REALITY SANDWICH (Oct. 15, 2015), https://realitysandwich.com/dmt-research-from-1956-to-the-edge-of-time/; *see also Stephen Szara*, PSYCHEDELIC SCI. REV., https://psychedelicreview.com/person/stephen-szara/ (last visited July 24, 2023).

52. *Stephen Szara*, *supra* note 51; Strassman, *supra* note 2, at 44–45.

53. Strassman, *supra* note 2, at 44–45.

54. *Id.*

55. Samorini, *supra* note 1, at 64, 70.

56. R. Gordon Wasson, *Seeking the Magic Mushroom*, LIFE (May 13, 1957), at 102–09.

57. *See* Kathryn L. Tucker, *Psychedelic Medicine: Galvanizing Changes in Law and Policy to Allow Access for Patients Suffering Anxiety Associated with Terminal Illness*, 21 QUINNIPIAC HEALTH L.J. 239, 241 (2018).

enthusiast, and his wife Valentina, a pediatrician and scientist, gained admission to a Mazatec mushroom ceremony (called a *velada*) based on Wasson's lie that he was seeking help for his son.[58] Wasson's participation in the *velada* was conditioned on secrecy, although he would later breach his secrecy obligations by writing about the ceremony.[59] After participating in the Mazatec ceremony in Mexico, Wasson returned with samples of mushrooms from Mexico that he sent to Albert Hofmann (the same Swiss chemist that invented LSD).[60] In 1958, Hoffman used the samples to synthesize psilocybin, leading to its use in psychiatric studies.[61] Wasson also influenced Timothy Leary, a psychology professor who read Wasson's *Life* article and "became highly interested in the experiences" described.[62] In 1959, Leary joined the faculty at Harvard and, in 1960, inspired by Wasson, Leary traveled to Mexico to partake in psilocybin mushrooms.[63] Afterward he and another professor, Richard Alpert, started the Harvard Psilocybin Project, "which aimed to document psilocybin's effects on human consciousness."[64]

B. LEGAL HISTORY OF THE SUPPRESSION OF PSYCHEDELICS

Scientific research into the "classic" psychedelics came to a screeching halt in the 1960s, as psychedelics became outlawed, as part of a growing "moral panic" that culminated in the "War on Drugs."[65] The use of psychedelics, however, had long been controversial and was subject to legal efforts to suppress their use even before the 1960s. Due to their use as a religious

58. James Stephen, *R. Gordon Wasson & Maria Sabina: First Contact with Magin Mushrooms: The Troubled Rediscovery of Psilocybin Mushrooms*, TRUFFLE REP. (Nov. 10, 2020) https://truffle.report/maria-sabina-and-r-gordon-wasson-psychedelic-first-contact-warning/; Amy Bartlett and Monnica T. Williams, *The Cost of Omission: Dr. Valentina Wasson and Getting Our Stories Right*, CHACRUNA (Nov. 11, 2020) https://chacruna.net/dr-valentina-wasson-and-getting-our-stories-right/.

59. Gerber et al., *supra* note 25, at 573.

60. Zachary LeCompte, *Not Groovy Man: Psilocybin's Long and Complicated History with the Law, and Its Potential to Treat the Growing Mental Health Crisis in America*, 90 U. CIN. L. REV. 1113, 1138 (2022).

61. Tucker, *supra* note 57, at 241; LeCompte, *supra* note 60, at 1138–39.

62. Scott Houghton, *From Medicine to Poison: The Magic Mushroom in 1960s America*, COLLECTOR (Dec. 5, 2021) https://www.thecollector.com/magic-mushrooms-1960s-america/; *see also* Carolyn Gregoire, *Inside the Movement to Decolonize Psychedelic Pharma*, PROTO.LIFE (Oct. 29, 2020), https://proto.life/2020/10/inside-the-movement-to-decolonize-psychedelic-pharma/.

63. LeCompte, *supra* note 60, at 1140; Houghton, *supra* note 62; Leary v. United States, 383 F.2d 851, 857 (5th Cir. 1967), 395 U.S. 6 (1969) (noting Leary testified that he ingested psychedelic mushrooms by travelling to Mexico in 1960).

64. LeCompte, *supra* note 60, at 1140; Houghton, *supra* note 62.

65. LeCompte, *supra* note 60, at 1142.

sacrament, these efforts have often been countered by arguments regarding free exercise of religion.

The religious use of psychedelics by indigenous peoples was the subject of colonial suppression. The first Europeans to encounter the indigenous use of these "classic" psychedelics were the Spanish—who had colonies in South America, Central America, and Mexico (which at that time included Texas, where the peyote cactus grows).[66] The Spanish condemned and prohibited the use of psychedelic plants as a form of witchcraft or necromancy.[67] In 1620, an Inquisitorial edict officially banned "peyote and other herbs . . . [that] cause images, fantasies, and representations . . . on which divinations are based."[68] The Spanish referred to peyote as the "devilish root" (*raiz diabolica*) and between 1620 and 1779, the Inquisition heard seventy-four peyote cases.[69] Despite its suppression, near the northern borders of Mexico, where the Spanish presence was limited to "main roads," "mining towns," and "scattered and poorly supported missions," "peyote traditions clung on."[70] Likewise, although suppressed, the psilocybin mushroom traditions in Mexico were able to continue.[71]

In 1845, Texas became a state,[72] and the United States had to confront the use of psychedelics (peyote in particular) amongst indigenous people in the new state. The initial policy of the U.S. federal government was suppression.[73] In 1888, the Bureau of Indian Affairs forbade the use of peyote, later classifying peyote as "liquor" in 1890.[74] The rationale for this classification was entirely paternalistic—the Bureau of Indian Affairs Special Agent forbidding

66. *New Spain and Spanish Colonization*, ENCYCLOPEDIA.COM https://www.encyclopedia.com/history/encyclopedias-almanacs-transcripts-and-maps/new-spain-and-spanish-colonization (last accessed Feb. 23, 2024); *ELSI Research Report, State Regulation of Psilocybin: Recommendations for the Oregon Health Authority*, 1 https://www.oregon.gov/oha/PH/PREVENTIONWELLNESS/Documents/ELSI%20Report%20Draft-%20Historical%20and%20Indigenous%20Use.pdf ("the modern history of psilocybin usually begins with the Spanish discovery of Aztec ceremonies in the New World.").

67. Breen, *supra* note 2, at 13–23; Arnaud Exbalin, *Discovering Hallucinogenic Mushrooms in Mexico*, CONVERSATION (Apr. 11, 2019), https://theconversation.com/discovering-hallucinogenic-mushrooms-in-mexico-115033.

68. Breen, *supra* note 2, at 69.

69. JAY, *supra* note 2, at 40.

70. JAY, *supra* note 2, at 41.

71. *See* Strassman, *supra* note 2, at 22.

72. H.R.J. Res. 46, 9 Stat. 108 (Mar. 1, 1845).

73. Stewart, *supra* note 5, at 128 ("When the use of peyote became apparent to missionaries and Indian agents of the federal government, they immediately sought to suppress it.").

74. Varun Soni, *Freedom from Subordination: Race, Religion, and the Struggle for Sacrament*, 15 TEMP. POL. & CIV. RTS. L. REV. 33, 39–40 (2005).

its use remarked, it "is for the good of the Indians—many of whom are being destroyed by the use of this bean."[75] However, in 1916, a U.S. District Court Judge in South Dakota held that peyote "is neither an intoxicating liquor nor a drug."[76] In response and in order to continue to prohibit the use of peyote by Native Americans, a bill was introduced that same year in Congress to prohibit the interstate "traffic" of peyote.[77] The bill failed, as did bills introduced in 1917, 1918, 1919, 1921, 1922, 1924, 1926, and 1937.[78] On October 10, 1918,[79] peyotists from several Tribes in Oklahoma incorporated the "Native American Church" under state law in order to bolster the legitimacy of their use of peyote as a religion.[80] Peyote practitioners in other states—e.g., Nebraska, Montana, South Dakota, Wisconsin—soon incorporated similar organizations.[81] In 1944, these various chapters confederated into a single national organization: the Native American Church of the United States (later renamed the Native American Church of North America).[82]

Despite this early religious opposition to laws forbidding peyote, the federal government eventually prohibited peyote and all other psychedelics, after questions were raised regarding the validity of the scientific (not indigenous) community's use of psychedelics.[83] Infamously, LSD researchers started using LSD for recreational parties rather than legitimate research.[84] Leary and Alpert, the founders of the Harvard Psilocybin Project, were dismissed after complaints surfaced that the two were using psilocybin along with their research subjects and promoting recreational use of psilocybin.[85] The pair became countercultural icons, with President Nixon declaring Leary to be the "most dangerous man in America" in 1971.[86] Concern about the diversion of LSD led Congress to pass the 1962 Kefauver-Harris Amendments to the

75. *Id.* (citing Stewart, *supra* note 5, at 128-129).
76. *Id.* at 41.
77. *Id.* at 42; *see also* WESTON LA BARRE, THE PEYOTE CULT 223–24 (5th ed. 1989)
78. LA BARRE, *supra* note 77, at 224.
79. Soni, *supra* note 73, at 45.
80. Stewart, *supra* note 5, at 222.
81. LA BARRE, *supra* note 77, at 171.
82. Stewart, *supra* note 5, at 239–40.
83. *See* Marlan, *supra* note 1, at 867–68 (describing early 1960s criticism of Harvard Research Project using psychedelics, 1962 Amendments to 1938 Food, Drug, and Cosmetics Act that tightened FDA scrutiny of psychedelics, and Drug Abuse Control Amendments of 1965 that prohibited drugs with "hallucinogenic effect").
84. Novak, *supra* note 17, at 99.
85. LeCompte, *supra* note 60, at 1140–41.
86. *Id.* at 1141.

Federal Food, Drug, and Cosmetics Act of 1938 to tighten control on research.[87]

Increasing bad publicity led Congress to enact the Drug Abuse Control Amendments of 1965, prohibiting drugs found by the Secretary of Health, Education and Welfare to have a "hallucinogenic effect."[88] By January 1966, LSD, DMT, mescaline, and psilocybin were all subject to such findings.[89] The legislation initially prohibited peyote as well, but the federal government quickly provided a regulatory exemption after several courts found that members of the Native American Church had a First Amendment right to use peyote—a regulatory exemption that persists to the present day.[90] In 1969, Congress enacted the Comprehensive Drug Abuse Prevention and Control Act of 1970.[91] Title II of the Act is the "Controlled Substances Act," under which the Attorney General has the authority to classify drugs into different "schedules."[92] All the "classic" psychedelics (LSD, DMT, psilocybin, mescaline) are listed as Schedule I,[93] with an exemption for peyote used in "bona fide ceremonies" of the Native American Church.[94] This legal prohibition largely led to the cessation of medical research into psychedelics. The Food and Drug Administration began shutting down research projects relating to LSD and mescaline.[95] Pharmaceutical companies also stopped distributing LSD.[96] However, the Native American Church's ceremonial use of peyote was not curtailed under federal law due to the specific exemption for its own "bona fide ceremonies."[97] Nevertheless, peyote was still illegal under some state laws, an issue that eventually made its way to the Supreme Court in 1990.[98]

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87. Marlan, *supra* note 1, at 867.

88. *Id.* at 868.

89. *Hallucinogens*, 68 COLUM. L. REV. 521, 544 (1968).

90. Memorandum Opinion for the Chief Counsel, Drug Enforcement Administration on the Peyote Exemption for Native American Church (Dec. 22, 1981) (on file with U.S. Dep't of Just.) at 405, available at https://www.justice.gov/file/22846/download; *see also* 21 C.F.R. § 1307.31 (2023).

91. Comprehensive Drug Abuse Prevention and Control Act of 1970, Pub. L. No. 91-513, 84 Stat. 1236.

92. Controlled Substances Act, 84 Stat. 1242, 1245. The law remains the same today. 21 U.S.C. § 811 (2023).

93. 21 C.F.R. §§ 1308.11(d)(19), (22), (24), (29) (2023).

94. 21 C.F.R. § 1307.31 (2023).

95. Marlan, *supra* note 1, at 868–69.

96. Marlan, *supra* note 1, at 869.

97. 21 C.F.R. § 1307.31 (2023).

98. Employment Div., Dept. of Human Resources of Or. v. Smith, 494 U.S. 872, 877–90 (1990).

C. THE PSYCHEDELIC "RENAISSANCE"

The 1990s saw a renewed interest in psychedelics—particularly plant medicines used by indigenous peoples of the Americas, after their religious use came to the forefront of policy discussions in the courts and Congress. Many states adopted an exemption for the religious use of peyote by the Native American Church (often modeled on the federal regulatory exemption).[99] Oregon failed to adopt such an exemption—a failure that reached the Supreme Court in 1990.[100] In *Employment Division v. Smith*, the Supreme Court considered whether Oregon's prohibition on the use of peyote was invalid under the Free Exercise Clause.[101] The Court held that the Free Exercise Clause of the First Amendment does not exempt an individual from compliance with criminal laws of general applicability.[102] This decision challenged prior understandings of the First Amendment,[103] and Congress responded swiftly by enacting not one, but two, legislative fixes: the Religious Freedom Restoration Act of 1993 (RFRA)[104] and the American Indian Religious Freedom Act Amendments of 1994 ("AIRFA Amendments").[105] RFRA reinstated the "compelling interest" test used prior to *Smith* to evaluate the validity of a law (even of general applicability) that substantially burdens religious practices. The AIRFA Amendments preempt any state laws that prohibit the use, possession, or transportation of peyote by members of federally recognized Indian Tribes for "bona fide traditional ceremonial purposes."[106]

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99. LA BARRE, *supra* note 77, at 265. *Compare* 21 C.F.R. § 1307.31(providing exemption for "nondrug use of peyote in bona fide religious ceremonies of the Native American Church") *with*, *e.g.*, Kansas Stat. § 65-4116(c)(9) (providing exemption for members of Native American Church in "bona fide religious ceremonies of the Native American Church"); Minn. Stat. § 152.02 subd. 2(e) (providing exemption for "the nondrug use of peyote in bona fide religious ceremonies of the American Indian Church"); Wis. Stat. § 961.115 (providing exemption for "nondrug use of peyote and mescaline in the bona fide religious ceremonies of the Native American Church").

100. Employment Div., Dept. of Human Res. of Or. v. Smith, 494 U.S. 872 (1990).

101. *Id.* at 874–76.

102. *Id.* at 877–90.

103. *See, e.g.*, Fraternal Order of Police Newark Lodge No. 12 v. City of Newark, 170 F.3d 359, 362 (3d Cir. 1999) ("In 1990, however, the legal landscape changed dramatically when the Supreme Court handed down its decision in [*Smith*]" (full citation omitted)); Black v. Snyder, 471 N.W.2d 715, 719 (Ct. App. Minn. 1991) ("The Supreme Court's most recent free exercise decision, [*Smith*], effected a significant change in first amendment law" (full citation omitted)); *see generally* Kenneth Marin, Note, Employment Division v. Smith: *The Supreme Court Alters the State of Free Exercise Doctrine*, 40 AM. U. L. REV. 1431 (1991).

104. 42 U.S.C. § 2000bb(a)(4).

105. 42 U.S.C. § 1996a(a)(4).

106. 42 U.S.C. § 1996a(b)(1).

Peyote was not the only psychedelic that garnered attention. From 1990 to 1995, Dr. Rick Strassman led research into the effects of DMT,[107] which was the first government-funded psychedelics research in over two decades.[108] Strassman was inspired in part by Terrance McKenna,[109] an advocate of psychedelics who famously theorized that consumption by human primate ancestors of psilocybin mushrooms was a step in human evolution.[110] McKenna also brought tales of ayahuasca to the masses in the 1980s.[111]

Indigenous people in South America use a combination of plants called ayahuasca in religious ceremonies.[112] Archeological evidence shows that the religious use of ayahuasca in the Amazon dates back to at least 1,000 BCE.[113] The law concerning religious use of psychedelics came full circle when ayahuasca laws were challenged under RFRA. An ayahuasca-using church, O Centro Espirita Benficiente Uniao do Vegetal (UDV), challenged the government's ban on importation of the plants used to make ayahuasca.[114] The case, G*onzalez v. O Centro Espirita Beneficiente Uniao do Vegetal*, eventually reached the Supreme Court, where the Court invalidated the importation prohibition under the RFRA.[115]

The renewed interest in psychedelics has spurred additional research and legislative reforms. In 2006, a study on the psychological effects of psilocybin reported that volunteers' experiences with psilocybin had "substantial personal meaning and spiritual significance" and that they "attributed to the experience sustained positive changes in attitudes and behavior."[116] In 2019, Denver,

107. Strassman, *supra* note 2, at xv-xvi.

108. Strassman, *supra* note 2, at xv.

109. *Id.* at 349 n.11; *see also id.* at 187, 358 n. 2.

110. Douglas Martin, *Terence McKenna, 53, Dies; Patron of Psychedelic Drugs*, N.Y. TIMES (Apr. 9, 2000).

111. Strassman, *supra* note 2, at 349 n.11; *see also* Ariel Levy, *The Drug of Choice in the Age of Kale*, NEW YORKER (Sept. 5, 2016), https://www.newyorker.com/magazine/2016/09/12/the-ayahuasca-boom-in-the-u-s (describing McKenna's influence on use of ayahuasca in United States).

112. Ayahuasca is typically prepared by combining the vine Banisteripsis caapi with Psychotria viridis leaves. Psychotria viridis contains DMT, while the B. caapi allows the DMT to become orally active. Marlan, *supra* note 1, at 864.

113. Miller, et al., *supra* note 1.

114. The church referred to its sacrament as "hoasca," as does the Court in its opinion. "Hoasca" is the Portuguese transliteration of ayahuasca. *See* O Centro Espirita Beneficiente Uniao Do Vegetal v. Ashcroft, 342 F.3d 1170, 1174 (10th Cir. 2003). For the sake of consistency, ayahuasca is used herein.

115. Gonzalez v. O Centro Espirita Beneficente Uniao do Vegetal, 546 U.S. 418, 428–39 (2006).

116. R.R. Griffiths, W. A. Richards, U. McCann & R. Jesse, *Psilocybin Can Occasion Mystical-type Experiences Having Substantial and Sustained Personal Meaning and Spiritual Significance*, 187 PSYCHOPHARMACOLOGY 268–83 (2006).

Colorado became the first city in the United States to decriminalize psilocybin.[117] Several cities (including Washington, D.C., Oakland (CA), Santa Cruz (CA), Ann Arbor (MI), Detroit (MI), Somerville (MA), Cambridge (MA), Seattle (WA), and San Francisco (CA)), alongside Oregon and Colorado, have since followed suit.[118] Patents concerning the use of "classic" psychedelics—such as mescaline and psilocybin—in psychotherapy have been filed with the U.S. Patent and Trademark Office (USPTO) and World Intellectual Property Organization (WIPO).[119]

Some of these patent applications are drafted broadly enough to cover religious practices. For example, one application sought to patent treatment of substance use disorder by using mescaline to induce a psychedelic state in an individual.[120] As originally drafted, this patent would have been infringed by the existing practice of convening a Native American Church ceremony to cure alcoholism.[121] The claims in the application were later amended and would now require that the treated individual previously have had an adverse effect from psilocybin or LSD.[122] Accordingly, a Native American Church ceremony convened to pray for someone struggling with addiction would still infringe upon the applied-for claims if that person previously used psilocybin or LSD with an adverse effect (which is not improbable for someone dealing with

117. Marlan, *supra* note 1, at 872.

118. *Where Are Psychedelics Legal in the U.S. (or Decriminalized)?*, MICRODOSE (June 18, 2023), https://microdose.buzz/news/where-are-psychedelics-legal-in-the-u-s-or-decriminalized/.

119. *See, e.g.*, N,N-Dimethyltryptamine and Related Psychedelics and Uses Thereof, Application Pub. No. US 2023/0212119 (filed Feb. 23, 2023) (relating to derivatives of DMT); Psilocybin and O-Acetylpsilocin, Salts and Solid State Forms Thereof, Application Pub. No. US 2023/0151036 (filed Dec. 28, 2022) (claiming crystalline forms of psilocybin); Mescaline for the Treatment of Substance Use Disorders, Application No. PCT/US2022/031423 (filed May 27, 2022); N,N-Dimethyltryptamine Compositions and Methods, Application Pub. No. US2022/0339139 (filed Apr. 26, 2022) (discussing method of treating neurological diseases using DMT); Antidepressant-Psilocybin Co-treatment to Assist Psychotherapy, Application Pub. No. US 2022/0387456 (filed Mar. 10, 2022); Mescaline Derivatives with Modified Action, Application Pub. No. US 2022/0267252 (filed Feb. 20, 2022) (discussing use of mescaline derivatives for use in substance-assisted therapy); Effects of Mescaline and of Mescaline Analogs (Scalines) to Assist Psychotherapy, Application Pub. No. US 2022/0265582 (filed Feb. 18, 2022); Methods and Systems for Enhancing Clinical Safety of Psychoactive Therapies, Application Pub. No. US 2023/0162851 (filed Mar. 9, 2021) (discussing methods and systems for enhancing clinical safety of psychoactive therapies, including psilocybin therapy).

120. Effects of Mescaline and of Mescaline Analogs (Scalines) to Assist Psychotherapy, Application Pub. No. US 2022/0265582 (filed Feb. 18, 2022).

121. JAY, *supra* note 2, at 208; Stewart, *supra* note 5, at 157, 220–21.

122. Attorney Docket No 0614.00100 (Feb. 23, 2024), Effects of Mescaline and of Mescaline Analogs (Scalines) to Assist Psychotherapy, Application Pub. No. US 2022/0265582 (filed Feb. 18, 2022).

addiction).[123] Similarly, another patent application that has been granted covers crystalline psilocybin with certain characteristics.[124] If natural psilocybin becomes scarce or indigenous communities are priced out of obtaining it, substitution of this crystalline psilocybin into a *velada* ceremony will constitute infringement.

The shifting attitudes towards psychedelics has been dubbed the "psychedelic renaissance."[125] Many scholars have criticized this "renaissance" for exploiting the indigenous communities that inspired the use of psychedelics in the first place. Indeed, for some scholars the term "renaissance" rings too *apropos*. As one critic noted, "[t]he European Renaissance did not simply coincide with the imperial expansionism . . . the riches plundered from the so-called Third World and what are now the contemporary settler states of Canada, the United States, Mexico, New Zealand, and Australia fueled the creativity, learning, and economic growth associated with the European Renaissance."[126] These critics note that psychedelics have become a billion-dollar industry, with the potential to be magnitudes larger if legalized, and yet little to no benefits have been shared with indigenous peoples.[127] In the words of one journalist: "It's a tale as old as colonialism itself: European settlers and explorers come into [i]ndigenous lands, pillage their natural resources, and patent new medicinal compounds based on those resources, furthering modern medicine while bringing destruction to Indigenous habitats and ways of life."[128]

In particular, critics of the psychedelic renaissance have voiced concern about potential disruption to indigenous communities by increased commercialization of psychedelics. This includes a scarce supply of

123. *See* Brittany Killion, Audrey Hang Hai, Abdulaziz Alsolami, Michael G. Vaughn, P. Sehun Oh & Christopher P. Salas-Wright, *LSD Use in the United States: Trends, Correlates, and a Typology of US*, 223 DRUG & ALCOHOL DEPENDENCE 108715, 2 (June 2021) (noting that lifetime hallucinogen use is highly comorbid with other substance use); Bheatrix Bienemann, Nina Stamato Ruschel,Maria Luiza Campos,Marco Aurélio Negreiros & Daniel C. Mograbi, *Self-Reported Negative Outcomes of Psilocybin Users: A Quantitative Textual Analysis*, 15 PLoS ONE 1, 10 (Feb. 21, 2020) (noting that use of psilocybin with other substances may increase negative outcomes).

124. Psilocybin and O-Acetylpsilocin, Salts and Solid State Forms Thereof, Application Pub. No. US 2023/0151036 (filed Dec. 28, 2022) issued as U.S. Patent No. 11,851,452.

125. *See, e.g.*, Emily Witt, *The Science of the Psychedelic Renaissance*, NEW YORKER (May 29, 2018), https://www.newyorker.com/books/under-review/the-science-of-the-psychedelic-renaissance.

126. Keith Williams, Osiris Sinuhé González Romero, Michelle Braunstein & Suzanne Brant, *Indigenous Philosophies and the "Psychedelic Renaissance,"* 33 ANTHROPOLOGY OF CONSCIOUSNESS 506, 508 (2022).

127. *Id.*

128. Gregoire, *supra* note 62.

psychadelics for indigenous communities, caused by increased prices, over-harvesting, or use of habitat.[129] Due to these concerns about habitat for peyote, several members of the Native American Church advocate that peyote should not be included in psychedelic decriminalization initiatives,[130] and the National Congress of American Indians accordingly passed a resolution opposing the legalization or decriminalization of peyote.[131] More broadly, patenting of psychedelics poses a threat to the practice of all indigenous religions that use psychedelic sacraments. Critics argue that commercial interests may exclude indigenous communities and that patent examiners may not accurately evaluate whether psychedelic patents are entitled to patent protection.[132]

III. THE CONFLICT BETWEEN PSYCHEDELIC PATENTS AND RELIGIOUS FREEDOM

The law of psychedelics presently finds itself at the intersection of intellectual property and religious freedom. This intersection raises two concerns: (1) whether indigenous communities should have a property right to their religious practices that is infringed when others use their sacramental psychedelics, and (2) whether the intellectual property rights recognized by the dominant society will impede the free exercise of religion of indigenous peoples using sacramental psychedelics. This Article concerns the latter, dwelling on the rights that indigenous peoples possess when others obtain patent protection for purported inventions involving psychedelics that have been used in indigenous religious rites.

Patents are property that provide an *exclusive* right to make, use, sell, offer for sale, or import patent technology for a limited duration of time.[133] Accordingly, the purpose of patenting psychedelic-related technology is to obtain a limited term monopoly on a particular psychedelic or use of psychedelics. Where an invention relates to medicinal plants (or their naturally occurring chemical components) used by indigenous communities for hundreds or thousands of years, a possibility exists that a patent grant could

129. *Id.*; Spichak, *supra* note 6.

130. Louis Sahagún, *Why are Some Native Americans Fighting Efforts to Decriminalize Peyote?*, L.A. TIMES (Mar. 29, 2020), https://latimes.com/environment/story/2020-03-29/native-americans-want-mind-bending-peyote-cactus-removed-from-efforts-to-decriminalize-psychedelic-plants.

131. *The National Congress of American Indians Resolution ECWS-22-009*, NAT'L CONG. OF AM. INDIANS, https://ncai.assetbank-server.com/assetbank-ncai/assetfile/913.pdf.

132. Spichak, *supra* note 6; Marks & Cohen, *supra* note 3, at 231–32.

133. 35 U.S.C. § 271(a); 35 U.S.C. § 154; *see also* Horne v. Dept. of Agric., 576 U.S. 350, 359 (2015) ("[A patent] confers upon the patentee an exclusive property in the patented invention . . . .") (alterations in original).

cover an ancient practice *or* prohibit modern adaptation of ancient rites. Therefore, an acute fear exists that issuance of patents pertaining to medicinal plants used by indigenous communities—such as psilocybin mushrooms, peyote, ayahuasca—or patents pertaining to use of the molecular compounds, such as psilocybin, mescaline, or DMT, will impose a barrier to the free exercise of religion of indigenous peoples.

This fear is significant because American law places immense value on both religious freedom and intellectual property. Each is given particular treatment in the Constitution.[134] Yet, the interplay between the two has seldom been considered—each is conceived as operating within a separate and distinct sphere of society. Religious freedom concerns private worship practices, typically ones that have a long history and are noncommercial; while intellectual property concerns the latest technological advancements, frequently for use in a commercial setting. This is particularly true of patent law, which by its nature requires a novel invention.[135] Today, as the psychedelic industry draws inspiration from the religious practices of indigenous peoples, these two spheres overlap in ways seldom previously considered.

Consequently, there is no guidance on what, if any, religious rights a person has to justify patent infringement . The First Amendment to the Constitution, of course, provides that "Congress shall make no law respecting an establishment of religion, or prohibiting the free exercise thereof . . ."[136] Due to the historic suppression of indigenous peoples' religions, specific laws have been enacted to address religious freedom for indigenous peoples. This includes laws that specifically address the right of indigenous peoples to use psychedelics as a religious sacrament. In particular, the AIRFA Amendments forbid state and federal governments from prohibiting the use, possession, or transportation of peyote by members of federally-recognized Indian Tribes in connection with the practice of a "traditional Indian religion."[137] The RFRA provides that the federal government "shall not substantially burden a person's exercise of religion even if the burden results from a rule of general applicability," except if the government demonstrates that application of the burden to the person "(1) is in furtherance of a compelling governmental interest; and (2) is the least restrictive means of furthering that compelling governmental interest."[138]

134. U.S. CONST., art. I, § 8; U.S. CONST. amend. I.
135. 35 U.S.C. § 102.
136. U.S. CONST. amend. I.
137. 42 U.S.C. § 1996a(b).
138. 42 U.S.C. § 2000bb-1.

This law has been applied to prevent the federal government from banning the importation of ayahuasca.[139] All of these laws are drawn in terms of providing a negative right—the government has a duty to avoid action that prohibits the free exercise of religion, prohibits use, possession, or transportation of peyote, or that substantially burdens religion. The United States has not recognized that indigenous people have a positive right that requires the government to ensure the survival of their religious practices.

When religious practices come into conflict with property rights, property rights have often prevailed. For instance, in *Lyng v. Northwest Indian Cemetery Protective Association*, a Native American organization, individual Native Americans, and others, challenged the decision of the U.S. Forest Service to build a paved road and allow timber harvesting near a sacred site.[140] The Supreme Court held that the First Amendment's promise of free exercise was not even implicated because the land at issue was federal land, and therefore the government's decisions regarding its use was an "internal affair[]" and not action that "penalize[d] religious activity by denying any person an equal share of the rights, benefits, and privileges enjoyed by other citizens."[141]

Likewise, it could be held that the decision to grant a patent concerning psychedelics is not a decision designed to "penalize religious activity" at all but is simply a secular recognition of property rights. Indeed, in the analogous context of trademark law, courts have recognized that they may properly adjudicate the right to use a religious mark so long as they rely on "secular principles of property."[142]

IV. CURRENT PROPOSALS TO RESOLVE TENSION BETWEEN INTELLECTUAL PROPERTY LAWS AND RELIGIOUS FREEDOM FOCUS ON ENHANCING ACCURACY OF PATENT OFFICE DECISIONS

The concern that an outsider would co-opt existing inventions of indigenous people and then monopolize them through intellectual property laws is not new. International discussions on the rights of indigenous peoples have long recognized the existence of "traditional knowledge."[143] No single definition of "traditional knowledge" exists but it is defined by the WIPO

139. Gonzalez v. O Centro Espirita Beneficente Uniao do Vegetal, 546 U.S. 418, 428–39 (2006).

140. 485 U.S. 439, 442–43 (1988).

141. *Id.* at 449.

142. Maktab Tarighe Oveyssi Shah Maghsoudi, Inc. v. Kianfar, 179 F.3d 1244, 1249 (9th Cir. 1999).

143. *See* Erstling, *supra* note 9, 296 (2009).

Intergovernmental Committee on Intellectual Property and Genetic Resources, Traditional Knowledge and Folklore (IGC) as

> the content or substance of knowledge that is the result of intellectual activity and insight in a traditional context, and includes the know-how, skills, innovations, practices and learning that form part of traditional knowledge systems, and knowledge that is embodied in the traditional lifestyle of a community or people, or is contained in codified knowledge systems passed between generations. It is not limited to any technical field, and may include agricultural, environmental and medicinal knowledge, and knowledge associated with genetic resources.[144]

The discussions concerning "traditional knowledge" have also recognized the need to protect such knowledge from so-called "biopiracy." Biopiracy is the exploitation of traditional knowledge, such as through patenting inventions based on traditional knowledge without the consent of knowledge holders or payment of compensation.[145]

The patent system theoretically has built-in guardrails to protect against direct biopiracy: patents are required by statute to be novel (that is, a new invention, not a pre-existing invention of others) and nonobvious.[146] Indeed, in an error-free world, a patent should never cover pre-existing traditional knowledge, especially a religious practice that dates back millennia, because that patent would not be novel. However, there are several infamous examples where errors in patent examination led to the patenting of traditional knowledge. One such example is a 1995 patent that was granted on the use of turmeric for wound healing.[147] That use of turmeric, however, was not novel in 1995. People in India have been using turmeric to heal wounds for centuries, and such use constitutes traditional knowledge in India.[148] India's Council of Scientific and Industrial Research challenged the patent, and submitted prior art references in languages such as Sanskrit, Urdu, and Hindi concerning the traditional medicinal uses of turmeric.[149] After re-examination of the patent, the USPTO rejected all its claims as obvious and anticipated by that prior art.[150]

144. *Id.* at 295, 296.

145. *Id.* at 300.

146. 35 U.S.C. §§ 102,103.

147. U.S. Patent No. 5,401,504 (filed Mar. 28, 1995); K.S. Jayaraman, *US Patent Office Withdraws Patent on Indian Herb*, 389 NATURE 6 (1997).

148. Jayaraman, *supra* note 147.

149. Anusree Bhowmick, Smaranika Deb Roy & Mitu De, A Brief Review on the Turmeric Patents Case with its Implication on the Documentation of Traditional Knowledge, 1 NDC E-BIOS 83, 86 (2021), https://www.ndcebios.in/v1n1/2021010110.pdf.

150. *Id.*

As another example concerning traditional knowledge from India, it has been known for millennia in India that the neem tree is a source of medicine that can be used as insect repellent.[151] A company filed patent applications covering an oil extract of the neem tree for use as an insecticide and fungicide.[152] The patent was rejected in the European Union but upheld in the United States and New Zealand.[153]

In response to these well-publicized failures of Western patent systems to prevent the patenting of traditional knowledge, scholars and the WIPO have advocated for the adoption of "traditional knowledge repositories."[154] Patent examiners often lack access to traditional knowledge. This lack of access may be due to language barriers,[155] or because traditional knowledge is often described in sources unfamiliar to a patent examiner, such as historical texts or anthropological works, as opposed to prior patent applications and the general scientific literature routinely searched by patent offices.[156] Another obstacle to access is that traditional knowledge may not be described in writing at all, but may instead exist in an unrecorded oral tradition.[157] A potential solution to prevent patenting of traditional knowledge is to create prior art repositories that contain translations and transcriptions of works describing traditional knowledge.[158] This proposal has been implemented in India, where an online repository—known as the Traditional Knowledge Digital Library—was created to translate traditional knowledge into international languages familiar to patent examiners.[159] Several other countries (such as Finland, New Zealand, Peru, the Philippines, South Korea, South Africa, and Venezuela) have adopted traditional knowledge repositories of some kind.[160]

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151. Eiland, *supra* note 10, at 62.

152. *Id.*

153. *Id.* at 62–64.

154. *Id.* at 65; s*ee generally* Erstling, *supra* note 9; *Recognition of Traditional Knowledge Within the Patent System*, WIPO, Intergovernmental Committee on Intellectual Property and Genetic Resources, Traditional Knowledge and Folklore, Thirteenth Session, WIPO/GRTKF/IC/13/7 (Oct. 13–17, 2008).

155. *See* Erstling, *supra* note 9, at 320 (noting that Indian Traditional Knowledge Digital Library includes translations of references into languages understood by patent examiners and also contemporary names of medicinal plants, diseases, and processes).

156. *Recognition of Traditional Knowledge Within the Patent System*, *supra* note 154, at 20.

157. Javier Garcia, *Fighting Biopiracy: The Legislative Protection of Traditional Knowledge*, 18 BERKELEY LA RAZA L.J. 5, 6, n.8 (2007).

158. *See generally* Erstling, *supra* note 9; *Recognition of Traditional Knowledge Within the Patent System*, *supra* note 154; Eiland, *supra* note 10, at 65.

159. *About the Traditional Knowledge Digital Library*, WIPO, https://www.wipo.int/meetings/en/2011/wipo_tkdl_del_11/about_tkdl.html (last visited Aug. 4, 2023).

160. *Online Databases and Registries of Traditional Knowledge and Genetic Resources*, *supra* note 8, (listing WIPO members states with databases for traditional knowledge and genetic resources

Indigenous religious rites using sacramental psychedelics are a subspecies of traditional knowledge: these religious rites include knowledge on how to harness the power of potent plant medicines. Therefore, one proposed solution to strike a balance between intellectual property rights, such as patents, and religious freedom is to create repositories of traditional uses of psychedelics.[161] Repositories may alleviate some concerns about direct attempts to copy indigenous religious ceremonies known in the literature. This is particularly true for existing descriptions of indigenous religious practices that are not in scientific literature generally searched by patent examiners. However, for practitioners of religious ceremonies—which may involve an element of secrecy and have survived despite a long history of attempted suppression—the proposal to deposit details of the use of psychedelic plants in a searchable, and potentially public,[162] database is not inviting.

Indeed, repositories have several limitations. One previously discussed limitation is that repositories burden indigenous communities with the obligation (and associated costs) of cataloging their traditional knowledge.[163] Another limitation of repositories is that they are intended for "traditional knowledge" generally, and not religious practices specifically. As discussed below, religious freedom includes additional considerations for which addressing patent validity alone is insufficient. Repositories do not address the problem of how to weigh conflicting rights where a properly granted patent prevents religious free exercise. Proper weighing of that conflict requires providing a defense to infringement for indigenous religions, in addition to increasing accuracy of patenting decisions.

V. FOCUS ON PATENT VALIDITY ALONE IS INSUFFICIENT—A DEFENSE TO INFRINGEMENT FOR TRADITIONAL SACRAMENT USE OF PSYCHEDELICS SHOULD BE RECOGNIZED

A claim for patent infringement requires both that a patent be valid and that a patent be infringed.[164] While repositories are valuable in addressing validity, repositories do not address the issue of infringement. Other proposals

and showing United States has only adopted databases concerning genetic resources, not traditional knowledge).

161. Marks & Cohen, *supra* note 3, at 231–32.

162. Erstling, *supra* note 9, at 318.

163. *Id.*

164. *See, e.g.*, Five Star Mfg., Inc. v. Ramp Lite Mfg., Inc., 14 F. Supp. 2d 1228, 1231 (D. Kan. 1998) ("The two necessary elements to the patent infringement claim are (1) the validity of the patent, and (2) the infringement of the patent.").

such as tightening of patentability requirements also address validity alone.[165] One proposal that does address infringement is for patent owners to make voluntary "pledges" not to assert patents against certain people or communities.[166] Whether these "pledges" are binding is untested, and these "pledges" are voluntary in any event. Therefore, a more robust defense to infringement for indigenous communities making religious use of psychedelics is needed.

The lack of proposals concerning the infringement half of the analysis may be because at first blush it seems contradictory that a newly granted patent could be used to prevent practice of age-old religions, such as those of indigenous peoples of the Americas. However, there is an appreciable risk that existing indigenous religious practices could be found to infringe valid psychedelic patents for at least three reasons: (1) the belief systems of indigenous peoples may prevent their religious rites from qualifying as "prior art" for patents, (2) evidentiary requirements for "prior art" may make it difficult to prove indigenous religious rites are "prior art" even if they are, and (3) market forces may force substitution of patented technology for non-patented technology in religious rites.

A. INDIGENOUS RELIGIOUS PRACTICES MAY NOT QUALIFY AS "PRIOR ART" DUE TO RELIGIOUS BELIEFS CONCERNING THOSE PRACTICES

The religious requirements of indigenous religions themselves create a risk that patents could be granted covering those rites. Patent law generally does not permit a secret inventor to obtain patent protection.[167] Part of the policy rationale for patent laws is a *quid pro quo*—an inventor discloses his or her invention to the world and in exchange, receives a limited duration monopoly.[168] Whether a patent should be issued or not turns on the content of the "prior art"—that is, whether the invention was previously disclosed to the public, or is obvious in light of what was previously disclosed to the

165. Marks & Cohen, *supra* note 3, at 232.

166. *Id.* at 232–33.

167. Instead, industrial secrets obtain intellectual property protection through trade secrets law. Trade secrets law, however, does not protect religious rites, as its protection is limited to information with "economic value." UNIF. TRADE SECRETS ACT § 1(4)(i) (UNIF. L. COMM'N 2000).

168. "Patent monopolies are granted in order to stimulate invention of useful devices, protect investments required to produce invention, and encourage the disclosure of trade secrets." 1 DONALD S. CHISUM, 1A CHISUM ON PATENTS § 3.01 (2023); *see also* W.L. Gore & Assocs. v. Garlock, Inc., 721 F.3d 1540, 1550 (Fed. Cir. 1983) ("Early public disclosure is a linchpin of the patent system.").

public.[169] The Patent Act (as amended by the America Invents Act of 2011 (AIA)), currently provides that

> A person shall be entitled to a patent unless—(1) the claimed invention was patented, described in a printed publication, or in public use, on sale, or otherwise available to the public before the effective filing date of the claimed invention.[170]

None of these categories of prior art cleanly apply to indigenous religious practices.

The first category of prior art—other patents—is frequently the type of art cited by patent examiners.[171] It is also inapplicable to indigenous religions—indigenous communities have not sought patent protection on their practices, and likely would not want to make a public disclosure of their religious practices due to the confidentiality considerations discussed above with respect to traditional knowledge repositories.

The next category of prior art—described in a printed publication—is unlikely to apply to many indigenous religious practices due to cultural norms around secrecy. The requirement of secrecy of indigenous religious practices is well-documented.[172] These established secrecy requirements have led to several administrative accommodations, such as permitting Native Americans to omit information about religious practices when applying for eagle feathers for religious use or to withhold information concerning religious and cultural properties during tribal-federal consultations under the National Historic Preservation Act.[173] Moreover, even where the ceremonial procedures of

169. 35 U.S.C. §§ 102,103.

170. 35 U.S.C. § 102(a).

171. James Yang, *What is Prior Art?*, OC Patent Lawyer (June 25, 2022), https://ocpatentlawyer.com/what-is-prior-art/ ("Patents and pre-grant publications are the most common types of prior art.").

172. *See* Jody Neal-Post, *Sacred Sites and Federal Land Management: An Analysis of the Proposed Native American Free Exercise of Religion Act of 1993*, 34 NAT. RESOURCES J. 443, 461 (1994) ("Certain Native American religious traditions prohibit disclosure of information relating to their beliefs and practices."); *see also* Glen Stoht, *The Repercussions of Orality in Federal Indian Law*, 31 ARIZ. ST. L.J. 679, 680 (1999) ("[T]he use of Native American or anthropological experts is fraught with difficulties, including the common situation in which sacred knowledge is secret and may not be shared with non-tribal members."); Connie Rogers, *Native American Consultation in Resource Development on Federal Lands*, 31 COLO. L. (Jan. 2002), at 113 ("for both protective and religious reasons, Native Americans usually have a profound need for secrecy about their beliefs and sacred sites.").

173. U.S. Fish and Wildlife Service, *Eagle Parts for Native American Religious Purposes Permit Application*, https://www.reginfo.gov/public/do/DownloadDocument?objectID=3384501 (permitting name of ceremony, required by regulation 50 C.F.R. § 22.22, to be omitted if providing name would violate religious beliefs); 36 C.F.R. § 800.4(a)(4); U.S. Department of Transportation, *Federal Highway Administration, Tribal Transportation*, https://

indigenous religions are well-documented by social scientists—as is the case for the Native American Church[174]—the level of generality of the description may be insufficient to invalidate new psychedelic patents.

The threshold for being "described in a printed publication" is high: "'each and every element of the claimed invention' must be disclosed either explicitly or inherently, and the elements must be 'arranged or combined in the same way as in the claim.'"[175] Therefore, the law is intrinsically biased in favor of prior patents and applications, rather than social science sources, because patents are required to include a written description of the invention,[176] and are therefore more likely to meet the bar of disclosing each element of a claimed invention. In contrast, social science sources are likely to focus on elements of cultural interest (song, language, etc.), and may gloss over the elements of a ceremony that produce a result notable to medical science, such as the exact mechanism used to cure alcoholism or substance abuse.

The third category of prior art—public use—also may not apply to indigenous religious practices. Previously, "public use" was required to be "in this country," but that language was eliminated by the AIA.[177] Other than the elimination of the territorial limitation, prior case law will likely inform the meaning of "public use" in the current statute.[178] Under such case law, the test for whether an invention was in "public use" prior to the patent application was "whether the purported use: (1) was accessible to the public; or (2) was commercially exploited."[179] The Federal Circuit has further clarified that "[c]onsideration of public use includes analysis of, inter alia, the nature of and public access to activities involving the invention; confidentiality obligations imposed upon observers; commercial exploitation; and the circumstances surrounding testing and experimentation."[180]

Under this standard, psychedelic patents that cover indigenous religious practices may be invalid as the religious practices were in "public use." Indeed, the general public's participation in ceremonies, especially South American

www.fhwa.dot.gov/tribal/topics/historic/tcqa.htm#:~:text=The%201992%20Amendments%20to%20the,on%20or%20off%20Tribal%20lands (last visited Aug. 4, 2023).

174. *See generally* Stewart, *supra* note 5; LA BARRE, *supra* note 77.

175. MPEP (9th Edition Rev. July 2022) § 2152 (citing *In re* Gleave, 560 F.3d 1331, 1334 (Fed. Cir. 2009); Eli Lilly & Co. v. Zenith Goldline Pharms., Inc., 471 F.3d 1369, 1375 (Fed. Cir. 2006); Net MoneyIN, Inc. v. VeriSign, Inc., 545 F.3d 1359, 1371 (Fed. Cir. 2008); *In re* Bond, 910 F.2d 831, 832–33 (Fed. Cir. 1990)).

176. 35 U.S.C. § 112(a).

177. MPEP (9th ed. Rev. July 2022) § 2152.

178. *Id.*

179. Am. Seating Co. v. USSC Grp., Inc., 514 F.3d 1262, 1267 (Fed. Cir. 2008).

180. *Id.*

ayahuasca ceremonies, has generated criticism for its commercialism and has been dubbed "psychedelic tourism."[181] Such ceremonies would likely be considered as "public use"—however, these ceremonies have also been criticized for their lack of authenticity as indigenous religious expression.[182] More authentic religious ceremonies may be subject to stricter limitations on participation. For instance, ceremonies of the Native American Church are not open to the public but rather accessible only to members of federally-recognized Indian Tribes.[183] Similarly, Mazatec mushroom ceremonies—despite being the subject of Wasson's well-known *Life* magazine article—are subject to confidentiality obligations (which Wasson breached).[184]

The WIPO has expressed concern that such limitations may prevent traditional knowledge from being deemed in "public use."[185] An important factor in the "public use" use analysis is the existence of confidentiality obligations.[186] Accordingly, to the extent that religious obligation requires confidentiality, the use is likely not "public." Moreover, indigenous communities may not wish to argue that their religious practices are "public." Wasson's *Life* article is illustrative as to why. The use of psilocybin mushrooms in Mexico was the subject of violent suppression by the Spanish, and survived only by remaining hidden to outsiders.[187] After Wasson breached his secrecy

181. Inti García Flores, Rosalía Acosta López & Sarai Piña Alcántara, *Niños Santos, Psilocybin Mushrooms and the Psychedelic Renaissance*, CHACRUNA (Nov. 12, 2020), https://chacruna.net/mazatec_mushroom_ceremony_psychedelic_tourism/ (discussing commercialization of Mazatec ceremony by inauthentic "neoshamans").

182. *See id.* (discussing commercialization of Mazatec ceremony by inauthentic "neoshamans").

183. Peyote Way Church of God, Inc. v. Thornburgh, 922 F.2d 1210, 1215–16 (5th Cir. 1991) ("We hold that the record conclusively demonstrates that NAC membership is limited to Native American members of federally recognized tribes who have at least 25% Native American ancestry . . .").

184. Gerber et al., *supra* note 25 (discussing Mazatec secrecy requirements surrounding velada ceremony, persecution during Inquisition, and that secrecy requirements that were disregarded by Gordon Wasson for his LIFE article); *see also* Flores, et al., *supra* note 183 (noting that mushroom ceremony is secret and if it is not kept secret, the "ceremony is useless").

185. *See, e.g.*, WIPO, Intergovernmental Committee on Intellectual Property and Genetic Resources, Traditional Knowledge and Folklore, *supra* note 153, at 24 ("Generally, information which is held confidential is not considered prior art. In the case of [traditional knowledge] the term 'the public' has been particularly scrutinized with respect to the question whether a teaching has been disclosed to 'the public' when it has been used in a traditional community, but not outside.").

186. Dey, L.P. v. Sunovion Pharms., Inc., 715 F.3d 1351, 1355 (Fed. Cir. 2013).

187. Kaleb R. Smith, Modeling the Flesh of God: Semantic Hyperpriming and the Teonancátl Cults of Mexico, 14 NEUROQUANTOLOGY 297, 298 (2016); Gerber et al., *supra* note 25, at 573.

obligations, the rush of outsiders to the Sierra Mazateca was so overwhelming that it altered the community and prompted retaliation against the leader of the ceremony in which Wasson had participated.[188] Indigenous communities would likely wish to enforce the confidentiality obligations that their religions impose where possible, and may reject the label of "public" for their ceremonies out of concern that it would comprise enforcement of confidentiality obligations.

Similar considerations exist for the so-called "on sale" category of prior art. The "on sale" bar requires that a product is the subject of a commercial offer for sale.[189] Despite growing concerns of psychedelic tourism (which, as discussed above, are largely for inauthentic versions of indigenous religious ceremonies),[190] a tenet of many indigenous religions using psychedelics continues to be that the religious experience is not for sale—a commercial exchange of psychedelics may be prohibited.[191] In other instances, the religious experience may have some commercial elements—such as a culture of gift exchange[192]—but it would be repugnant to religious practitioners to refer to this as being "on sale." The cultural values of indigenous religions prohibit the use of traditional knowledge for profit or self-gain.[193] To view a gift provided for a religious purpose as commercial sale would be blasphemy.[194] Therefore,

188. Smith, *supra* note 187, at 299-300 (2016); Flores, et al., *supra* note 181.

189. Pfaff v. Wells Elecs., 525 U.S. 55, 67 (1998) (construing pre-AIA statute); *see also* Helsinn Healthcare S.A. v. Teva Pharms. USA, Inc., 139 S. Ct. 628, 630 (2019) (holding that "on sale" has the same meaning pre- and post-AIA).

190. Flores, et al., *supra* note 181; Carlos Suarez Alvarez, *Why You Will Never Get a Traditional Ayahuasca Treatment*, CHARCUNA (Aug. 10, 2017), https://chacruna.net/you-will-never-get-traditional-ayahuasca-treatment/.

191. Anna Lutkajtis, *Lost Saints: Desacralization, Spiritual Abuse, and Magic Mushrooms*, 14 FIELDWORK IN RELIGION 118, 130 (2020) ("[S]ome older, more traditional healers will not charge a fee for their services as they believe that if they accept money the mushrooms will not have a curative effect.").

192. *See* Osiris Sinuhe Gonzalez Romero, *Maria Sabina, Mushrooms, and Colonial Extractivism*, CHACRUNA (May 27, 2021), https://chacruna.net/maria-sabina-mushrooms-and-colonial-extractivism/ (noting that Maria Sabina did not charge a fixed amount of money for ceremonies with sacred mushrooms); Alvarez, *supra* note 190 (noting that traditionally an ayahuasca healer would receive food, work, merchandize, or money); Stewart, *supra* note 5, at 69 (noting that for a peyote ceremony there "was not a set fee, and payment was always viewed as a gift").

193. Testimony of Jon Brady, Arikara MHA Nation, President Native American Church of N. Am., U.S. House of Representatives Committee on Appropriations, Subcommittee on Interior, Environment, and related Agencies, 118th Cong. 3 (2023) (statement of Jon Brady, President of Native American Church North America), https://docs.house.gov/meetings/AP/AP06/20230309/115414/HHRG-118-AP06-Wstate-BradyJ-20230309.pdf.

194. For example, Mazatec curandera Maria Sabina accepted voluntary donations for her ceremonies. Maria Sabina, *A Most Facinating Mexican Healer*, FAENA ALEPH, https://

even if religious use of psychedelics could theoretically be said to have been "on sale," indigenous religious communities may again resist such a classification for cultural reasons and purposefully forgo such argument.

The AIA recently added a final category of prior art—a "catch-all" that reads "otherwise available to the public."[195] Due to the relative newness of this provision, little case law exists to elucidate its meaning. In considering the phrase's impact on interpretation of the on-sale bar, the Supreme Court noted that the phrase "otherwise available to the public," like other catch-all phrases, "captures material that does not fit neatly into the statute's enumerated categories but is nevertheless meant to be covered."[196] Accordingly, the meaning of the word "public" would likely be interpreted in a similar manner for this phrase—meaning that secrecy, confidentiality obligations, disclosure to non-members would likely weigh against finding prior technology was "otherwise available to the public." Therefore, for all the reasons discussed above, a risk exists that indigenous religious practices could be found to not be "otherwise available to the public," despite their continuous practice for hundreds or thousands of years.

B. EVEN IF INDIGENOUS RELIGIOUS PRACTICES ARE "PRIOR ART," EVIDENTIARY HURDLES TO PROVING INVALIDITY ARE HIGH

Moreover, even if indigenous psychedelic religious practices could be prior art—such as if they could qualify as in "public use," or "on sale," or "otherwise available to the public" due to their sustained use since time immemorial—evidentiary hurdles may make proving the *content* of these religious rites practically difficult. First, the threshold for proving patent invalidity is higher than for infringement. In litigation, patent invalidity must be proven by clear and convincing evidence.[197] Second, indigenous cultures often rely on oral tradition. Therefore, when religious practices are fully disclosed, such as to a member of the community for the express purpose of transmitting knowledge of the ceremonial rites, such disclosures are generally made orally rather than in writing.

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www.faena.com/aleph/maria-sabina-a-most-fascinating-mexican-healer (last accessed Feb. 22, 2024). However, local residents of the Sierra Mazateca (along with tourists and anthropologist) may consider obtaining profit from psilocybin mushrooms as a "desecration." Marcos Garcia de Teresa, *Seeking a True Shaman in the Sierra Mazateca*, CHACRUNA (Mar. 8, 2021), https://chacruna.net/mazatec-shaman-authenticity/.

195. 35 U.S.C. § 102(a)(1); MPEP (9th ed. Rev. July 2022) § 2152.

196. Helsinn Healthcare S.A. v. Teva Pharms. USA, Inc., 139 S. Ct. 628, 634 (2019) (holding that the phrase "otherwise available to the public" had no impact on the interpretation of the on-sale bar).

197. Microsoft Cop. v. i4i P'ship, 564 U.S. 91, 95 (2011).

This presents an evidentiary problem. Oral testimony alone is insufficient to invalidate a patent under the clear and convincing evidence standard required in court.[198] Indeed, the Federal Circuit has specifically noted that "uncorroborated oral testimony, particularly that of interested persons recalling long-past events, does not, of itself, provide the clear and convincing evidence."[199] Instead, "oral testimony must be corroborated by some other evidence," under a "rule of reason" analysis.[200] The "rule of reason test" examines "all pertinent evidence . . . in order to determine whether [the oral testimony] is credible."[201] The test places greater weight on contemporaneous documentary evidence.[202] However, as discussed above, indigenous religious practices are often transmitted orally, with confidentiality obligations imposed, and do not fit within the type of framework generally seen by courts in evaluating "clear and convincing" evidence of patent invalidity.

Indigenous religious practices do not come with user manuals, unlike the industrial devices for which patent laws were designed. Accordingly, due to these biases in the law, it is possible that a psychedelic patent could be issued that reads on an ancient indigenous religious practice. This is particularly true given the emergent nature of the field in the context of the patent office. Few patents have been issued concerning psychedelics. Prior patents and patent applications are the form of prior art most likely to be cited by patent examiners.[203] Therefore, with few prior patents or applications, from the perspective of an examiner engaging in prior art searching, the field of psychedelics appears to be relatively open; there is little prior art from which patentees must distinguish their technologies in order to demonstrate the novelty of their inventions.

However, in truth, the field is crowded with the ancient practices of indigenous peoples, where knowledge is transmitted orally from one practitioner to the next. For instance, the decision to grant a patent that broadly covers the use of psychedelics to treat substance abuse disorders or to improve mental health may not be erroneous in a technical sense, since no clear and convincing evidence admissible in a court of law exists to prove prior disclosure of the invention in patents, printed publications, public use, offer for sale, or other availability to the public. Nonetheless, such a patent could tread on the religious rites of indigenous peoples that have been used for a

198. 1 DONALD S. CHISUM, 1A CHISUM ON PATENTS § 3.05 (2023).

199. Woodland Trust v. Flowertree Nursery Inc., 148 F.3d 1368, 1369 (Fed. Cir. 1998).

200. Transweb, LLC v. 3M Innovative Props. Co., 812 F.3d 1295, 1301 (Fed. Cir. 2016).

201. Mosaic Brands, Inc. v. Ridge Wallet LLC, 55 F.4th 1354, 1363 (Fed. Cir. 2022).

202. Transweb, LLC v. 3M Innovative Props. Co., 812 F.3d 1295, 1301 (Fed. Cir. 2016)

203. Yang, *supra* note 171 ("Patents and pre-grant publications are the most common types of prior art.").

long time in a clandestine manner (secrecy that may itself have been compelled due to colonial suppression efforts). Therefore, addressing validity alone is insufficient, and an infringement defense for indigenous communities is required.

C. RELIGIOUS FREEDOM REQUIRES SOME ABILITY TO SUBSTITUTE NEW TECHNOLOGIES, AS MARKET FORCES FREQUENTLY FORCE SUCH SUBSTITUTION

An infringement defense is needed because the commercialization of psychedelics may force indigenous peoples to substitute modern versions of psychedelics into their religious practices, creating infringement via this substitution of the new for the ancient. History has demonstrated a pattern of indigenous peoples forced to adopt new or westernized versions of their own innovations. Consider, for instance, non-psychedelic medicinal plants used by indigenous peoples of the Americas such as tobacco or corn. Historically, indigenous people used a variety of wild plants from the tobacco family.[204] Indigenous people also historically cultivated domestic maize of several varieties.[205] Indigenous peoples often had religious beliefs, customs, and rituals that went along with their usage of the varieties of maize or tobacco.[206]

Today, tobacco and maize are commercial crops whose dominant production has interfered with Native American religious practices. About 202,000 acres of land in the United States is used for the commercial cultivation of tobacco.[207] "[A]lmost all commercial production of tobacco" is a single crop variety: *Nicotiana tabacum*.[208] For corn, a whopping 94.1 million

204. Alan Boyle, *Molecular Analysis Turns Up Unexpected Twist in Smoking Habits of Ancient Tribes*, GEEK WIRE (Oct. 29, 2018), https://www.geekwire.com/2018/tobacco-smoking-habits-ancient-tribes/#:~:text=quadrivalvis%20(Indian%20tobacco)%20and%20N,ornamental%20plant%20for%20Northwest%20gardens); Sojouner Ahebee, *Sacred Tobacco and American Indians, Tradition and Conflict*, WHYY (May 14, 2021), https://whyy.org/segments/keep-it-sacred-smoking-indigenous-people-tradition-and-conflict/; *see also* Spichak, *supra* note 6.

205. American Indian Health and Diet Project, *supra* note 15.

206. *Id.*; Dina Fine Maron, *The Fight to Keep Tobacco Sacred*, SCI. AM. (Mar. 29, 2018), https://www.scientificamerican.com/article/the-fight-to-keep-tobacco-sacred/.

207. *Area of Tobacco Harvested in the U.S. from 2001 to 2022 (in acres)*, STATISTA, https://www.statista.com/statistics/192012/area-of-tobacco-harvested-in-the-us-since-2000/#:~:text=About%20202%20thousand%20acres%20of,the%20United%20States%20in%202022.

208. *Nicotiana tabacum*, UNIV. OF KENTUCKY MARTIN-GATTON COLLEGE OF AGRICULTURE, FOOD AND ENVIRONMENT, https://burleytobaccoextension.ca.uky.edu/content/nicotiana-tabacum#:~:text=Nicotiana%20tabacum%20is%20the%20species,are%20varients%20of%20this%20species.

acres is used for cultivation in the United States.[209] Some 86 percent of this corn comes from seeds subject to patent protection.[210] Most of this corn is not cultivated for human consumption, but is instead used for animal feed and ethanol.[211] The vast majority of corn available for purchase in grocery stores are "super sweet" varieties developed only since 1953 that have better shelf life than other varieties.[212] Therefore, the colonization of the Americas has led to dominance in the agricultural industry of the corn species with highest profit margins due to the market preferences of the dominant society. This has forced indigenous peoples to adopt some of these species into their religious practices due to the scarcity of other varieties of plants. For instance, in Native American Church ceremonies, participants may use commercial tobacco at the beginning of the ceremony and commercial sweet corn at the conclusion of the ceremony.[213] These commercial variants have replaced traditional plant species originally used in religious rites. While the religious tradition of the Native American Church is to use traditional (rather than commercial) products, it is often the case today that commercial products must be purchased and substituted into the ceremony in order for Native American Church members to continue to practice their religion.

The fear, of course, is that a similar substitution process will take place with respect to the sacraments of indigenous religions. Patents require novelty, so several patent applications have already been submitted on synthetic versions of compounds found within sacramental plants used by indigenous peoples.[214] However, patent protection has already been granted for some

209. USDA, *Acreage* (June 2023), https://downloads.usda.library.cornell.edu/usda-esmis/files/j098zb09z/hh63v8465/zg64w269x/acrg0623.pdf

210. Paul Harris, *Monsanto Sued Small Farmers to Protect Seed Patents-Report*, GUARDIAN (Feb. 2013), https://www.theguardian.com/environment/2013/feb/12/monsanto-sues-farmers-seed-patents.

211. Mauricio Espinoza, *"All Corn Is the Same," and Other Foolishness about America's King of Crops*, OHIO STATE UNIV., COLL. OF FOOD, AGRIC., AND ENV'T SCIS. (Apr. 2, 2015), https://cfaes.osu.edu/news/articles/%E2%80%98all-corn-is-the-same%E2%80%99-and-other-foolishness-about-america%E2%80%99s-king-crops.

212. Debra Levey Larson, *Supersweet Corn: 50 Years in the Making*, UNIVERSITY OF ILLINOIS URBANA-CHAMPAIGN, NEWS BUREAU (Aug. 7, 2003), https://news.illinois.edu/view/6367/212406 (noting that percent of acreage for super sweet corn in Florida went from 2% to 90%, a trend that also occurred nationwide).

213. *See* George Morgan, *The Native American Church: Recollections of the Peyote Road*, UPCOUNSEL, https://www.upcounsel.com/lectl-the-native-american-church-recollections-of-the-peyote-road (last visited Aug. 4, 2023) (noting that Bull Durham tobacco is used); Malouf, *supra* note 16, at 97 (noting use of Bull Durham tobacco); *id.* at 99 n.12 (noting use of canned sweet corn).

214. *See, e.g.*, N,N-Dimethyltryptamine and Related Psychedelics and Uses Thereof, Application Pub. No. US 2023/0212119 (filed Feb. 23, 2023) (relating to derivatives of DMT);

sacramental plants. In 1986, a patent was granted under the Plant Patent Act, for a specific variety of Banisteriopis caapi—a vine used to make ayahuasca.[215] A request for reexamination of this patent, which noted the religious use of the vine, was filed in 1999.[216] Ultimately, the USPTO found that the species of vine was entitled to patent protection, avoiding any discussion of religious use, and focusing on the ability to asexually reproduce the vine and its differing leaf size and shape from other varieties of the vine.[217] If the same were to happen with other species of ayahuasca, or other sacramental plants, such as mescaline, peyote, psilocybin mushrooms (or the alkaloids within them), it is possible that the dominant society's appetite for such plants would force indigenous communities to turn to substitutes, as corn and tobacco.[218]

This concern is heightened by the current widespread interest in psychedelics by the dominant society. Oregon, Colorado, and many cities have decriminalized psychedelics. The potential use of psychedelics to treat mental health disorders has entered popular culture. For example, author Michael

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Psilocybin and O-Acetylpsilocin, Salts and Solid State Forms Thereof, Application Pub. No. US 2023/0151036 (filed Dec. 28, 2022) (claiming crystalline forms of psilocybin); Mescaline for the Treatment of Substance Use Disorders, Application No. PCT/US2022/031423 (filed May 27, 2022); Mescaline Derivatives with Modified Action, Application Pub. No. US 2022/0267252 (filed Feb. 20, 2022) (discussing use of mescaline derivatives for use in substance-assisted therapy).

215. U.S. Patent No. Plant 5,751 (filed June 17, 1986); Marlan, *supra* note 1, at 864.

216. Detailed Statement in Support of Request for Reexamination of U.S. Plant Patent No. 5,751, https://www.ciel.org/wp-content/uploads/2015/06/ReexaminationofUSPlantPatent5751.pdf.

217. Notice of Intent to Issue Reexamination Certificate, https://www.ciel.org/wp-content/uploads/2015/06/PTO_Examiner_Transcript.pdf.

218. A countervailing substitution effect could also occur. The current prohibition of psychedelics may motivate some to falsely claim religious beliefs in order to consume psychedelics for which religious exemptions to the drug laws currently exist. *See* LA BARRE, *supra* note 78, at xiii (discussing "Neo-American Church" making use of mescaline under false guise of religion). If psychedelics were legalized, such users may abandon pretext and simply consume potent synthetic psychedelics, like LSD, outside of a religious context, leaving greater supply for religious users. However, the history of religious use by indigenous peoples is part of the allure of some psychedelics to the non-indigenous user For instance, author Carlos Castañeda wrote several books falsely claiming to have been taught indigenous knowledge regarding peyote. LA BARRE, *supra* note 77, at 270-75, 307-08. This is part of a broader, and well-documented, phenomenon of "playing Indian." *See, e.g.*, Arlene Hirschfelder and Paulette F. Molin, *I is for Ignoble: Stereotyping Native Americans*, JIM CROW MUSEUM OF RACIST IMAGERY (Feb. 22, 2018), https://jimcrowmuseum.ferris.edu/native/homepage.htm. It is thus my opinion that the magnitude of substitution away from sacramental psychedelic plants is likely to be small compared to those that would seek out psychedelic plants due to their history of religious use. Indeed, La Barre observed that Castañeda's books caused an increase of peyote poaching, to the detriment of supply to the Native American Church. LA BARRE, *supra* note 77, at 290.

Pollan created a Netflix series based on his novel *How to Change Your Mind*, which details the use of psychedelics.[219] In June 2023, an estimated 12,000 people attended the Multidisciplinary Association for Psychedelic Studies (MAPS) conference in Denver, Colorado—the largest psychedelics conference ever.[220] If, as it appears may be the case, psychedelics are legalized, the market demand for psychedelics could be astronomical. The obvious market incentive, therefore, will be to dedicate habitat for psychedelic plants, not to the pre-existing wild varieties of plants, but instead to patented products with high profit margins. The familiar result will be the dominance of newer varieties of plants to the detriment of the heirloom varieties used for religious practices. Shrinking habitat and waning availability will then necessitate (again) substitution towards commodified and potentially patented protected versions of sacramental plants in order to sustain the practice of indigenous religions.

This concern is particularly pronounced for peyote, for which habitat pressures have existed for years. In the United States, peyote grows only in a small area of South Texas.[221] The local economy in that region includes cattle and energy, both of which pose threats to peyote plants. Root plowing for cattle grazing is the largest threat to peyote plants currently.[222] Energy development from both oil exploration and wind energy necessitates road infrastructure and energy pads that further contribute to the loss of peyote habitat.[223] The limited habitat for peyote raises substantial concern that commercialization of patented varieties of peyote will lead to dedication of this habitat to these patented varieties. This result would force the Native American Church to substitute these newer varieties to continue practicing their religion.

Similar market dynamics could influence the decisions of practitioners of other indigenous religions. For instance, natural habitat for the ayahuasca vine or certain varieties of psilocybin mushrooms exist only outside the United

219. *How to Change Your Mind* (Netflix 2022).

220. Alejandro A. Alonso Galva & Jenna McMurtry, *"Psychedelics is About Healing": Thousands Gather in Denver for Largest Psychedelic Conference to Date*, CPR NEWS (June 25, 2023), https://www.cpr.org/2023/06/25/denver-psychedelic-mushrooms-conference-health-and-policy/.

221. Stewart, *supra* note 5, at 10, map 2; *id.* at 15, map 3.

222. *Known Challenges to Lophophora*, CACTUS CONSERVATION INST., https://www.cactusconservation.org/CCI/ch/hi.html (June 17, 2018); Alexander Lekhtman, *National Indigenous Church Urges Congress to Protect Peyote Habitat*, FILTER (Sept. 20, 2022), https://filtermag.org/indigenous-church-protect-peyote/.

223. *Lophophora Williamsii*, NATURESERVE EXPLORER (Oct. 7, 2020), https://explorer.natureserve.org/Taxon/ELEMENT_GLOBAL.2.139920/Lophophora_williamsii.

States in Mexico, South, and Central America.[224] Therefore, availability of these sacramental plants in the United States depends on domestic cultivation or importation. If these plants are commercialized, the preference in cultivation or importation for higher profit margin and patented varieties could limit the supply of traditional varieties domestically. Even in Mexico, the commercialization of the market for psilocybin mushrooms for tourists has contributed to shortages of mushroom sacrament.[225] If traditional varieties of these religious sacraments are in short supply, the only means for indigenous people to continue to practice their religions will be to substitute patented varieties into their religious practices. However, using a patented invention is infringement—notwithstanding the prior use of a similar and unpatented plant variety. Accordingly, focus on patent validity alone is insufficient and must be augmented by infringement defenses for indigenous communities making use of psychedelic sacraments.

VI. THE PROPOSED "CEREMONIAL USE" DEFENSE

The religious freedom of indigenous communities is presently on a collision course with the attempts by the biotech industry to patent uses of psychedelics or patent varieties of psychedelics themselves. This is especially true as it concerns the use of psychedelics to combat alcoholism and other substance use disorders. It has been long observed that traditional indigenous religions had success in combating such disorders,[226] and many of the pending psychedelic patents concerning the use of psychedelic-assisted psychotherapy also relate to treatment of such disorders.[227] In resolving this collision of rights,

224. *See* O Centro Espirita Beneficiente Uniao Do Vegetal v. Ashcroft, 342 F.3d 1170, 1175 (10th Cir. 2003) (noting that plants in ayahuasca "do not grow in the United States" and therefore were "prepared in Brazil by Church officials and exported to the United States"); Anya Ermakova, *Psychoactive Mushrooms in Mexico: Overview of Ecology and Ethnomycology*, CHACRUNA (Nov. 12, 2021), https://chacruna.net/psychoactive-mushrooms-in-mexico-overview-of-ecology-and-ethnomycology/ (noting that while some species of mushrooms are widespread, others are endemic only to Mexico with highly localized habitat).

225. Flores, et al., *supra* note 181.

226. JAY, *supra* note 2, at 208; Stewart, *supra* note 5, at 157, 220–21.

227. Mescaline for the Treatment of Substance Use Disorders, Application No. PCT/US2022/031423 (filed May 27, 2022); Novel N,N-Dimethyltryptamine Compositions and Methods, Application Pub. No. US2022/0339139 (filed Apr. 26, 2022) (discussing method of treating neurological diseases using DMT); Antidepressant-Psilocybin Co-treatment to Assist Psychotherapy, Application Pub. No. US 2022/0387456 (filed Mar. 10, 2022); Mescaline Derivatives with Modified Action, Application Pub. No. US 2022/0267252 (filed Feb. 20, 2022) (discussing use of mescaline derivatives for use in substance-assisted therapy); Effects of Mescaline and of Mescaline Analogs (Scalines) to Assist Psychotherapy, Application Pub. No. US 2022/0265582 (filed Feb. 18, 2022); Methods and Systems for Enhancing Clinical Safety of Psychoactive Therapies, Application Pub. No. US 2023/0162851 (filed Mar. 9, 2021)

courts (or Congress) should provide an infringement defense to indigenous communities making sacramental use of psychedelics. Indigenous communities need such a defense due to the shortcomings of focusing solely on patent validity for the reasons discussed above. This defense finds precedent in similar defenses for prior commercial users of patented inventions and the "shop rights" doctrine that allows employers to use inventions of their employees. Indeed, the social value placed on religious freedom is much weightier than either the interest in prior commercial users of an invention or the interests of an employer.

A. ELEMENTS OF DEFENSE

I have coined the "ceremonial use" defense to describe the defense to patent infringement based on prior religious use of psychedelics, acknowledging the ceremonial context in which psychedelics are used as a sacrament by indigenous peoples. The elements of such a defense are inspired by the "prior user rights" and "shop rights" defenses, discussed below, and are shaped to provide a narrow defense for authentic religious exercise of indigenous peoples. The elements of this defense should be:

1. Prior religious use of a plant;
2. Current use of a patented variety of that plant, patented method of cultivating that plant, patented variant of an alkaloid within that plant, or patented method of synthesizing an alkaloid within that plant; and
3. Other than substitution of patented plant varieties or alkaloids, substantial similarity between infringing use and prior religious practices.

The purpose of this defense is to ensure that patented uses of psychedelics plants, patented varieties of psychedelic plants or patented uses or versions of their alkaloids, do not prevent the free exercise of pre-existing religions.

Further contours of this defense are shaped by its inspirations—the "prior user rights" defense and "shop rights" doctrine. For example, the "prior user rights" defense for commercial uses is nontransferable, except with the transfer of an entire enterprise or line of business.[228] Making the "ceremonial use" defense non-transferrable could reassure the biotech industry that their intellectual property will be protected. However, just as the "prior user rights defense" is transferrable in the case of an assignment of an entire line of

(discussing methods and systems for enhancing clinical safety of psychoactive therapies, including psilocybin therapy).

228. 35 U.S.C. § 273(e)(1).

business, the "ceremonial use" defense should be transferable in the case of a split of a church (or similar organization) or in the event that the ability to lead ceremonies is transferred from person to person in accordance with tribal customs, discussed further below.

B. PRECEDENTIAL JUSTIFICATION—PRIOR USER RIGHTS AND SHOP RIGHTS DOCTRINES

A "ceremonial use" defense is not currently recognized, but courts and Congress have both acted to recognize similar defenses in less compelling circumstances than religious free exercise—"prior user rights" and "shop rights." One reason a "ceremonial use" defense is needed is to respect the confidentiality obligations attendant to indigenous religious practices. Congress has enacted a "prior use rights" defense for a similar reason—to provide a defense for businesses whose trade secrets are patented by others. A "ceremonial use" defense can also be justified to allow fairness and equity—scientific research into psychedelics was inspired by ceremonial uses in the first place, and it would be inequitable to allow patents to deprive society of the continued ceremonial use of psychedelics. Fairness is the base justification is for the judicially-created "shop rights" doctrine. And, just as the "shop rights" doctrine allows employers to use inventions created by their employees using the employer's resources, the "ceremonial use" defense would allow indigenous communities to use the inventions created by psychedelic researchers drawing on traditional knowledge and use of psychedelics for inspiration.

The "prior user rights" doctrine owes its genesis in the United States to the Federal Circuit's 1998 decision in *State Street Bank & Trust v. Signature Financial Group*.[229] In that case, the Federal Circuit held that no "business method" exception exists for patentable subject matter.[230] This holding raised a concern because many business methods are maintained as trade secrets: what if a competitor properly obtained a patent on a method previously used in secret by another?[231] In response to such concerns, Congress created the "prior user rights" defense in 1999.[232]

Later, the AIA was passed into law and the United States moved from a first-to-invent system to a first-to-file system—again raising the specter of the unjust outcome of a person infringing a patent by merely continuing to use

229. 149 F.3d 1368, 1375–77 (Fed. Cir. 1998).

230. *Id.*

231. Aleksey Khamin, *America Invents Act's Prior User Defense: Lessons from Global Patent Regimes and Legislative History*, 15 U. PITT. J. TECH. L. POL'Y 132, 143 (2015).

232. *Id.*; Patrick M. Boucher & Daniel J. Sherwinter, *The America Invents Act*, 41 COLO. LAW.1,47, 54 (2012).

their own previously used but undisclosed invention.[233] Accordingly, Congress again acted to expand the "prior user rights" defense beyond business methods. The current iteration of the "prior user rights" defense is as follows:

> A person shall be entitled to a defense under section 282(b) with respect to subject matter consisting of a process, or consisting of a machine, manufacture, or composition of matter used in a manufacturing or other commercial process, that would otherwise infringe a claimed invention being asserted against the person if—
>
> (1) such person, acting in good faith, commercially used the subject matter in the United States, either in connection with an internal commercial use or an actual arm's length sale or other arm's length commercial transfer of a useful end result of such commercial use; and
>
> (2) such commercial use occurred at least 1 year before the earlier of either—
>
> (A) the effective filing date of the claimed invention; or
>
> (B) the date on which the claimed invention was disclosed to the public in a manner that qualified for the exception from prior art under section 102(b).[234]

The statute may not apply to indigenous religious practices due to its limitation to "commercial" uses. Nonetheless, it is an important confirmation that good policy, equity, and fairness require that continued secret uses are a defense to allegations of patent infringement. Therefore, to address concerns about the confidentiality requirements, as well as other reasons that indigenous religious practices may not qualify as "prior art" under the Patent Act, such as oral transmission and closure to the public, this defense should be extended from the commercial context to the religious context in the form of the "ceremonial use" defense.

A "ceremonial use" defense that permits continued religious use of psychedelics (which are still patentable because prior religious use was in secret) is important. However, the "ceremonial use" defense should go further to permit ceremonial use of patented psychedelics that are novel. Permitting use of novel versions of psychedelics is important to account for the potential coerced substitution of these psychedelics due to market forces. As discussed above, history has already shown that profit-incentives cause land-use to shift toward commercial varieties of plants with ceremonial uses. Particularly given the limited (as in the case of peyote) or remote (as in the case of ayahuasca)

233. Khamin, *supra* note 231, at 146–47.
234. 35 U.S.C. § 273(a).

habitat for psychedelics, a real threat exists that the burgeoning psychedelics industry will shift production to patented psychedelics at the expense of access of indigenous communities.

Allowing royalty-free religious production and use of patented psychedelics has existing analogies in the law. Under the judicially-created "shop rights" doctrine, an employer has a defense to an infringement action brought by an employee in certain circumstances.[235] The exact rationale behind the "shop rights" doctrine is a bit elusive, but courts have reiterated that the doctrine is motivated by equity and fairness.[236] Courts recognize that it is inequitable for an employee to use the resources of their employer to test and develop an invention without providing rights to the employer to use that same invention.[237]

The same rationale can be extended to indigenous peoples' religious use of psychedelics. Their religious use of psychedelics has inspired an entire "renaissance." It was the use of peyote by indigenous peoples that led to the first ever scientific study of a psychedelic—mescaline.[238] Mescaline further inspired scientific exploration of LSD once the similarity of psychoactive effects between the two was discovered.[239] The Native American Church's use of peyote to cure alcoholism further inspired the current research into psychedelics for substance abuse disorders.[240] Mescaline further inspired experimentation with other psychedelics such as MDMA, which the FDA could soon approve as a treatment for post-traumatic stress disorder..[241] Use of cohoba and ayahuasca further inspired the scientific community's interest

235. Exela Pharma Scis., LLC v. Lee, 781 F.3d 1349, 1356 (Fed. Cir. 2015) (noting judicially created); McElmurry v. Ark. Power & Light Co., 995 F.2d 1576, 1580–82 (explaining doctrine).

236. McElmurry, 995 F.2d at 1580–82; *see also* 1 DONALD S. CHISUM, 1A CHISUM ON PATENTS § 22.03 (2023) ("the equity basis is probably a more accurate description of what the courts actually do, to wit, make a case by case determination of whether it is fair for the employee to have all rights, given the parties' respective contributions to the conception, reduction to practice, and commercial development of the idea.").

237. *See* United States v. Dubilier Condenser Corp., 289 U.S. 178 (1933) ("[Under the shop rights doctrine] where a servant, during his hours of employment, working with his master's materials and appliances, conceives and perfects an invention for which he obtains a patent, he must accord his master a nonexclusive right to practice the invention. . . . This is an application of equitable principles. Since the servant uses his master's time, facilities, and materials to attain a concrete result, the latter is in equity entitled to use that which embodies his own property and to duplicate it as often as he may find occasion to employ similar appliances in his business.").

238. JAY, *supra* note 2, at 74–88, 98–100.

239. *Id.* at 189.

240. *Id.* at 208.

241. *Id.* at 243–45; Brown, *supra* note 25.

in DMT.[242] Strassman, who revived government-funded research into psychedelics after two decades of inactivity, acknowledges the impact of sacramental use by indigenous peoples: "New World aboriginal people used, and continue to use, a wide range of mind-altering plants and mushrooms. Most of what we know about psychedelics comes from investigating chemicals first found in Western Hemisphere materials: DMT, psilocybin, mescaline, and several LSD-like compounds."[243] And, many of the patent applications recently filed regarding also acknowledge the contributions of indigenous peoples.[244]

In such circumstances, fairness and equity demand that indigenous peoples be able to share in the benefits of the scientific advancements they themselves inspired. Indeed, non-indigenous usage of psychedelics has already impacted indigenous religious practices. For example, since the 1960s, tourists have flocked to the Sierra Mazateca, disrupting the Mazatec community and altering religious practices.[245] In South America, ayahuasca tourism led to an increasing mestizo impact on indigenous traditions.[246] Similarly, after peyote reached mainstream popularity (due in part to writers such as Carlos Castañeda touting its use), psychedelic tourists flocked to Texas looking for peyote.[247] The resulting trespass by these tourists led to stricter laws concerning peyote that were enforced against Native American Church members, largely ending their ability to find peyote in the wild and forcing them to purchase from DEA-licensed dealers.[248]

Notably, the proposal for a "ceremonial use" defense is modest compared to other alternatives, such as providing a property right for indigenous communities in their traditional knowledge.[249] Some scholars have advocated for a property right in traditional knowledge, which would enable indigenous

242. Strassman, *supra* note 2, at 44–45, 349 n.11; Levy, *supra* note 111.

243. Strassman, *supra* note 2, at 22.

244. *See, e.g.*, Novel N,N-Dimethyltryptamine Compositions and Methods, Application Pub. No. US2022/0339139 (filed Apr. 26, 2022) at [0004] (noting that naturally occurring psychedelics "have been used for centuries by indigenous cultures in ritualistic or sociocultural context, and in the context of religious sacraments"); Effects of Mescaline and of Mescaline Analogs (Scalines) to Assist Psychotherapy, Application Pub. No. US 2022/0265582 (filed Feb. 18, 2022) at [0080] ("Indigenous tribes across northern and southern parts of America have used mescaline for centuries for ethnomedical purposes."). Troublingly, not all patents on psychedelics acknowledge the contributions of indigenous peoples to the art.

245. Flores, et al., *supra* note 181.

246. Xavier Francuski, *The "Traditional" Ayahuasca Ceremony is Probably a Recent Invention*, KAHPI (Mar. 22, 2019), https://kahpi.net/traditional-ayahuasca-ceremony-recent-invention/.

247. LA BARRE, *supra* note 77, at 290.

248. *Id.*

249. This is not to be construed as opposition to such alternatives, on which I take no position.

communities to prevent use of their traditional knowledge and potentially eliminating the ability of others to innovate based on indigenous knowledge altogether.[250] In this case, such innovations would include novel synthesis of mescaline, DMT, or psilocybin. Indeed, the Native American Church of North America has taken the position that mescaline is a "heritage molecule" that is being appropriated by the pharmaceutical industry.[251] However, the "ceremonial use defense," like the "shop rights" doctrine, is not a property right entitling the owner to exclude others, but rather an affirmative defense to infringement. Just as the employer whose materials, tools, and workspace formed the building blocks of an inventor's innovation receives an affirmative defense to infringement of a resulting patent,[252] so too should indigenous communities—whose traditional knowledge have formed the building blocks for later innovation in the science of psychedelics—receive an affirmative defense to infringement of resulting psychedelic patents.

Patenting of psychedelics will certainly impact indigenous communities in unforeseen ways. At a minimum, it will likely cause a shift of production to patented psychedelics for commercial purposes. To ensure that the religious practices of indigenous communities are not prohibited by patents, an infringement defense must be recognized. Indeed, given that religious freedom is at issue, the rationale for such a defense is much higher than for the "shop rights" doctrine. The interests of an employer in the inventions of an employee are nowhere near as compelling as the needs of indigenous communities to continue their religious practices. This is particularly true given that these religions have already been subject historically to suppression efforts. For this reason, international conversations are already underway regarding the rights of indigenous peoples to "benefit sharing" for the use by the dominant society

250. *See*, *e.g.*, J. Janewa OseiTutu, *A Sui Generis Regime for Traditional Knowledge: The Cultural Divide in Intellectual Property Law*, 15 MARQ. INTELL. PROP. L. REV. 147, 154-55 (2011) (discussing proposal for sui generis regime to protect traditional knowledge that would include others from making use of intergenerational knowledge without consent); Gregory Younging, *Traditional Knowledge Exists; Intellectual Property Is Invented or Created*, 36 U. PA. J. INT'L L. 1077, 1083-85 (2015) (criticizing Western intellectual property system's placement of traditional knowledge in public domain where it can be used in violation of indigenous customary law); Eliana Torelly de Carvalho, *Protection of Traditional Biodiversity-Related Knowledge: Analysis of Proposals for the Adoption of a Sui Generis System*, 11 MO. ENVTL. L. & POL'Y REV. 38, 63 (2003) (noting proposals for perpetual property right on innovations derived from traditional knowledge and arguing such proposals are overly broad).

251. Annette McGivney, *Peyote is the Darling of the Psychedelics Renaissance. Indigenous Users Say it Co-Opts a "Sacred Way of Life,"* GUARDIAN (Dec. 19, 2023), https://www.theguardian.com/us-news/2023/dec/19/indigenous-communities-protecting-psychedelics-peyote-corporations.

252. McElmurry v. Arkansas Power & Light Co., 995 F.2d 1576, 1582 (Fed. Cir. 1993).

of their traditional knowledge.[253] At minimum, a "benefit" that indigenous peoples should enjoy is to be able to continue their religious practices without threat of patent infringement.

C. OWNERSHIP OF "CEREMONIAL USE DEFENSE"

One potential criticism of recognizing a "ceremonial use" defense for indigenous communities is that "indigenous communities" is itself a nebulous concept and that identifying the proper community to own the right to this defense may be difficult. In some contexts, it may be correct that identifying the owner of such a right may prove to be difficult (although it is doubtful it will be any more difficult than many of the factual issues that the judiciary is called upon to resolve every day). However, several pre-existing organizational structures exist that can be used to determine ownership of such a defense. Federally-recognized Indian Tribes are one such organizational structure that can be used. Another pre-existing organizational structure that can be used to determine ownership of the defense are the church organizations that formed to resist the historical suppression of sacramental psychedelic use. These organizations formed to assert First Amendment and religious free exercise claims—and accordingly already have developed sufficient structure to be reliably identified as the owner of a "ceremonial use" defense that requires prior religious use of psychedelic sacraments. Other owners may be determined to be owners of such a defense on a case-by-case basis in reference to tribal law and custom.

In the context of religious use of peyote by indigenous communities in the United States, identification of the proper "indigenous" community should be straightforward given their pre-existing organizational structure. First and foremost, the United States already recognizes the existence of certain tribal governments, and tribal governments are already recognized as the holders of many rights guaranteed by treaties as well as federal statutes. Plants and traditional medicines used by federally-recognized Indian Tribes, such as peyote, should be considered community property of those Tribes, and Tribes should be recognized as one class of owners of the "ceremonial use" defense for peyote.

Second, the history of indigenous resistance to the suppression of the religious use of peyote led to the formation of the Native American Church in 1918. Like many churches, the Native American Church has spawned several

253. *See, e.g.*, *Nagoya Protocol on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits Arising From their Utilization to the Convention on Biological Diversity*, SECRETARIAT OF THE CONVENTION ON BIOLOGICAL DIVERSITY MONTREAL (Oct. 29, 2010), https://www.cbd.int/abs/doc/protocol/nagoya-protocol-en.pdf (last visited Aug. 4, 2023).

more churches—organizations such as the Native American Church of North America and the Azee Bee Nahaga of Dine Nation (ABNDN).[254] However, just like with other churches, the ecclesiastical lineage of these churches can be traced to the original 1918 Native American Church, and thus entitlement to a "ceremonial use" defense can be verified.

The same is true for churches making use of ayahuasca as a sacrament, although such churches generally have a more recent vintage. Several ayahuasca using churches, the UDV, Church of the Holy Light of the Queen, and Ceu da Divina Rosa, brought successful religious free exercise challenges under RFRA in the early 2000s regarding their importation of ayahuasca tea.[255]

Now, as psychedelics are becoming mainstream and the subject of intellectual property, those pre-existing structures may be used to determine ownership of the proposed "ceremonial use" defense. In particular, courts may reference ecclesiastical customs to determine when the rights to perform ceremonies using psychedelic sacraments have been validly transferred to new churches or congregations. While such determinations may be complicated by the secrecy obligations, discussed above, unlike patented "prior art," which is public, most courts have mechanisms for sealing records in cases where confidentiality is required.[256] And, transfer of the right to perform indigenous ceremonies should not be held to the "clear and convincing" standard that creates evidentiary issues in assessing "prior art" in the context of patent validity, as discussed above.

For other indigenous communities without a history of litigation nor federal recognition, such as Mexican indigenous communities making use of psilocybin mushrooms, no domestic structures exist. Nonetheless, courts often are required to make determinations of foreign law, and their determination of ownership of the "ceremonial use" defense may be made with reference to tribal law and custom.

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254. Stewart, *supra* note 5, at 240, 311–12 (discussing formation of Native of American Church of North America and Native American Church of Navajoland); Rima Krisst, *"Our Way of Healing": Azee' Bee Nahagha Working to Protect Peyote from State Decriminalization*, NAVAJO TIMES (Aug. 11, 2023), https://navajotimes.com/reznews/our-way-of-healing-azee-bee-nahagha-working-to-protect-peyote-from-state-decriminalization/ (noting that Azee Bee Nahaga of Dine Nation formerly known as Native American Church of Navajoland).

255. Gonzalez v. O Centro Espirita Beneficente Uniao do Vegetal, 546 U.S. 418, 429–39 (2006); Church of the Holy Light of the Queen v. Mukasey, 615 F. Supp. 2d 1210, 1212, 1219–21 (D. Or. 2009), *rev'd for narrower injunction*, 443 F. App'x 302 (9th Cir., 2011).

256. *See, e.g.*, United States v. Pickard, 733 F.3d 1297, 1300 (10th Cir. 2013) ("A court has authority to seal documents before it, based upon the court's inherent supervisory authority over its own files and records."); *see also* FED. R. CIV. P. 26(c) (permitting protective orders for discovery in federal litigation).

VII. CONCLUSION

The "psychedelic renaissance" in the scientific community has been inspired by the religious practices of the indigenous peoples of the Americas. The patenting of psychedelics will create conflict between intellectual property laws and religious freedom laws in ways never previously considered. Prior proposals to address the issuance of invalid patents, such as traditional knowledge repositories, should be adopted. An infringement-based solution is also needed in light of the limitations of patent validity arguments. Therefore, at a minimum, a "ceremonial use" defense to infringement should be recognized in order to give proper weight to religious freedom in the context of the patent laws.