

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

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I. INTRODUCTION

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

10. *Id.*

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

12. *Id.*

II. BACKGROUND

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

A. THE HATCH-WAXMAN ACT

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

1. *New Drug Applications*

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

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

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

15. *Id.*

16. 21 U.S.C. § 355(j).

17. 21 U.S.C. § 355(a).

18. 21 U.S.C. § 355(b)(1)(A).

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

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

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

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

19. *Id.*

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

21. 21 U.S.C. § 355(j).

22. 21 U.S.C. § 355(j)(2)(A).

23. 21 U.S.C. § 355(j)(5)(B)(iv).

24. 21 U.S.C. § 355(j)(2)(A)(vii).

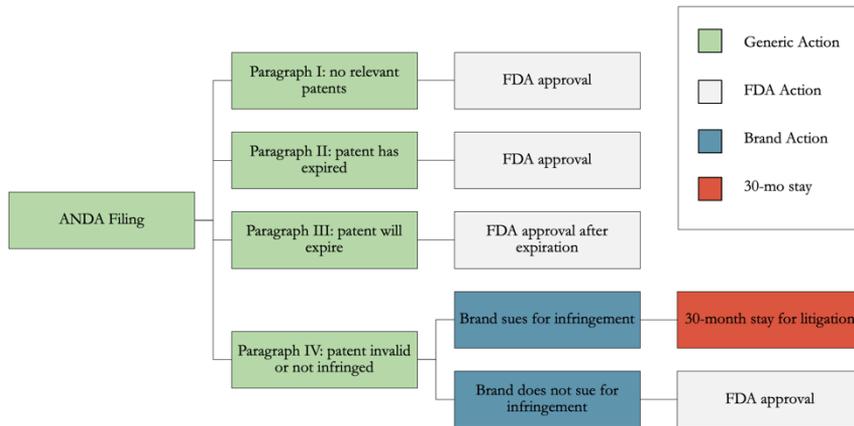
25. 21 U.S.C. § 355(j)(2)(A)(vii). Paragraph IV certifications are named after the subsection of the ANDA filing requirements it falls under.

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

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

27. 21 U.S.C. § 355(j)(2)(B)(iv).

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



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

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

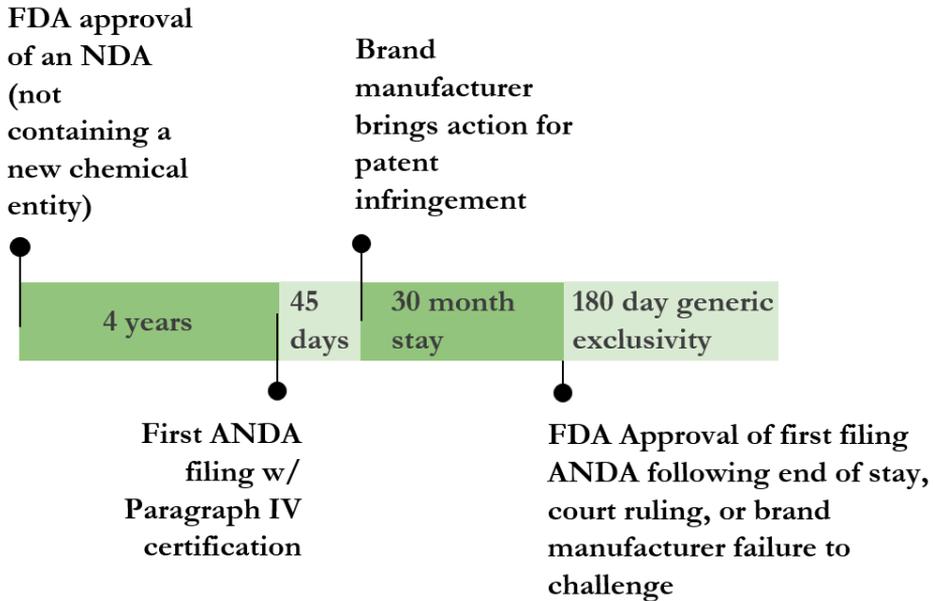
29. 21 U.S.C. § 355(j)(5)(B)(iii). *See supra* Figure 1 for further reference.

30. 21 U.S.C. § 355(j)(5)(B)(iii).

31. 35 U.S.C. § 271(e)(2).

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

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



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

33. 21 U.S.C. § 355(j)(5)(B)(iii)(I).

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

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

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

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

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

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

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

38. *Id.*

39. *Id.* at 48–49.

40. *Id.* at ivv.

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

42. 21 C.F.R. § 314.53(d)(2)–(3).

43. 21 C.F.R. § 314.94(a)(12)(vi).

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

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

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

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

45. 44 Fed. Reg. 2932-2933.

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

47. *See generally* ORANGE BOOK.

48. *Id.*

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

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

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

1. *Listing Rules for Orange Book Patents*

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

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

50. 21 C.F.R. § 314.53(b)(1).

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

52. 21 C.F.R. § 314.53(f).

53. 21 C.F.R. § 314.53(b)(1).

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

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

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

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

56. *Id.*

57. *Lantus*, 950 F.3d at 8–10.

58. *Id.* at 7.

59. *Id.* at 5.

60. *Id.*

61. *Lantus*, 950 F.3d at 8–10.

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

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

64. *Id.* at 1367.

65. *Id.* at 1376–77.

66. *Id.* at 1379–80.

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

2. *The Orange Book Dispute and Delisting Process*

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

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

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

67. *Id.* at 1382.

68. 21 C.F.R. § 314.53(f).

69. 21 C.F.R. § 314.53(f)(1).

70. *Id.*

71. *Id.*

72. 21 C.F.R. § 314.53(f)(1)(i).

73. *Id.*

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

75. *Id.* at 5–6.

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

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

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

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

76. 15 U.S.C. § 45(a)(2).

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

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

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

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

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

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

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

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

2. Section 2 of the Sherman Act: Illegal Monopolization

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

82. *Id.*

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

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

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

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

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

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

89. 15 U.S.C. § 45(a)(2).

90. 15 U.S.C. § 44.

91. 15 U.S.C. § 45(b).

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

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

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

93. 15 U.S.C. § 2.

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

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

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

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

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

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

100. *Id.*

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

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

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

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

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

104. *Id.* at 232.

105. *Id.*

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

107. *Id.* at 1106–10.

108. *Id.* at 1092.

109. *Id.* at 1095.

110. *Id.* at 1102.

111. *Id.* at 1103.

112. *Id.* at 1102.

113. *Id.* at 1104.

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

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

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

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

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

114. *Id.* at 1106.

115. *Id.* at 1109–10.

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

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

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

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

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

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

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

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

122. *Id.* at 366.

123. *Id.*

124. *Id.* at 368.

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

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

127. *Id.*

128. *Id.* at 368.

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

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

129. *Id.* at 371–73.

130. *Id.*

131. *Id.* at 374.

132. *Id.* at 375.

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

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

135. *Id.* at 525.

136. *Id.* at 526–27.

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

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

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

137. *Id.* at 532.

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

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

140. *Id.*

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

142. *Id.*

143. *Id.* at 397.

144. *Id.* at 397–98.

145. *Id.* at 401.

146. *Id.*

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

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

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

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

147. *See id.*

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

149. *Lantus*, 950 F.3d at 7–10.

150. *Id.*

151. *Id.* at 14–15.

152. *Id.* at 13.

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

154. *See Lantus*, 950 F.3d at 13–15.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

163. *Id.* at 8–9.

164. *Id.* at 9.

165. *Id.* at 10, 16.

166. *Id.* at 12.

167. *Id.* at 14.

168. *Id.* at 18–19.

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

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

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

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

169. *Id.* at 22–23.

170. *Id.* at 23–24.

171. *Id.*

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

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

174. *Id.* at 59.

175. *Id.* at 62.

176. *See id.*

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

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

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

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

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

177. *Id.* at 60.

178. *Id.*

179. *Id.* at 64–65.

180. *Id.*

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

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

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

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

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

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

184. *Id.* at 229.

185. *Id.*

186. *Id.*

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

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

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

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

191. *Id.* at 28–29.

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

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

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

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

193. *Id.* at 9.

194. *Id.* at 3–4.

195. *Id.* at 4–5.

196. *Id.*

197. *Id.* at 15.

198. *Id.*

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

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

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

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

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

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

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

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

202. *Id.* at 917.

203. *Id.* at 921–22.

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

205. *Id.* at 2.

206. *Id.*

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

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

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

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

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

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

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

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

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

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

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

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

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

212. 15 U.S.C. § 45(a)(2).

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

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

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

216. *Id.* at 845.

217. *Id.* at 842–43.

218. *Id.*

219. *Id.*

220. *Id.* at 865.

221. See *id.* at 842–43.

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

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

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

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

223. *Id.* at 400–01.

224. *Id.* at 371.

225. *Id.* at 374–75.

226. *Id.* at 371–75.

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

228. *See id.*; 15 U.S.C. § 45.

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

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

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

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

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

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

233. *Id.* at 7.

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

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

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

237. *Id.*

238. *Id.*

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

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

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

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

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

241. 21 C.F.R. § 314.53(f)(1)(i).

242. *Id.*

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

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

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

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

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

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

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

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

247. 15 U.S.C. § 53(b).

248. *Id.*

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

257. 59 Fed. Reg. 50342–43.

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

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

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

258. 59 Fed. Reg. 50342.

259. 59 Fed. Reg. 50343.

260. 68 Fed. Reg. 36683.

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

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

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

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

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

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

265. *Id.*

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

267. *Id.*

268. *Id.* at 23–24.

269. *Id.*

270. *Id.* at 24.

271. *Id.* at 27.

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

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

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

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

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

273. 35 U.S.C. § 2(a).

274. *Id.*

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

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

277. *Id.* at 1691–92.

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

279. *Id.* at 1689–90.

280. *See* 35 U.S.C. § 2.

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

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

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

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

281. *Id.*

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

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

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

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

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

284. 35 U.S.C. § 8.

285. *See* 35 U.S.C. § 2.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

V. CONCLUSION

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

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

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

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

