ANTICOMPETITIVE CONDUCT AND PATENTS LISTED IN THE ORANGE BOOK

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Branded pharmaceutical manufacturers are required by law to list all patents in the Orange Book that cover an approved drug product. However, over-inclusiveness of such listings can give rise to allegations of anticompetitive conduct. A review of recent rulings shows that courts have taken a statutory interpretation in ex post decisions regarding inappropriate patent listings. Additionally, to avoid determinations that such inappropriate listings constitute anticompetitive conduct, the burden appears to be on the manufacturer to demonstrate such listings were reasonable and in good faith. These decisions imply branded manufacturers may exclude certain patents in Orange Book listings going forward. Not listing patents on the Orange Book removes the assurance of exclusivity that is inherent in the current regulatory framework. Consequently, returns on research and development may decrease, leading to uncertainty regarding the impact on branded manufacturers' future investment decisions.

I. INTRODUCTION

Intellectual property ("IP") and antitrust issues frequently intersect in the life sciences industry. IP rights typically provide pharmaceutical manufacturers with market exclusivity for a period of time in order to encourage high-risk investments in developing new drugs. Antitrust laws promote competition and aim to protect consumers. The abuse of patents to improperly extend exclusivity may cause harm to consumers by depriving or delaying access to more affordable alternatives and be considered anticompetitive conduct.

A recent example of this intersection involves disputes regarding the appropriateness of patents listed in the Orange Book.[2] In May 2025, the Federal Trade Commission ("FTC") renewed its challenge against branded drug manufacturers listing "improper" patents and sent warning letters to five pharmaceutical manufacturers flagging over 200 patents it deemed improperly listed; this followed similar warning letters issued in 2023 and 2024.[3] Additionally, private litigations have alleged anticompetitive behavior from improper patent listings.[4] The FTC asserts that improperly listed patents can delay generic entry and lead to higher prices for prescription drugs and may constitute anticompetitive conduct.[5]

Recent cases have led to *ex-post* determinations of improperly listed patents and established a burden on branded manufacturers to demonstrate such listings were a legitimate attempt to follow legal requirements to avoid claims that such listings constitute anticompetitive conduct. These rulings, along with the FTC's focus on purportedly improper listings, have an unknown but potentially significant effect on the incentives to branded manufacturers to invest in certain types of development.

II. BACKGROUND

A. Drug Approval Pathways

Prescription pharmaceuticals in the U.S. are regulated by the FDA. New prescription pharmaceuticals require FDA approval before they can be marketed; brand manufacturers submit a New Drug Application ("NDA") to obtain approval.[6] Generic manufacturers seek approval to sell copies of branded products via an Abbreviated New Drug Application ("ANDA"). The ANDA must identify an approved drug product, referred to as a reference listed drug ("RLD"), and prove that the proposed generic drug product is bioequivalent to the RLD.[7]

An ANDA applicant must choose between one of four "certifications" regarding the RLD patents. The manufacturer asserts a RLD: (i) is not covered by any patents in a Paragraph I certification; (ii) the relevant patents have expired in a Paragraph II certification; or the manufacturer intends to wait to launch the generic until all relevant patents expire in a Paragraph III certification.[8] In a Paragraph IV certification, the generic manufacturer believes the patents are invalid, unenforceable, or not infringed.[9]

Manufacturers seeking Paragraph IV certification must serve notice to both the patent owner and the market authorization holder of the RLD.[10] The patent owner has 45 days from notice to file an infringement suit against the generic manufacturer, which triggers an automatic stay whereby the FDA cannot formally approve the generic manufacturer's product until the earliest of: (i) expiry of the patents at issue; (ii) final judgment in favor of the generic manufacturer; and (iii) 30 months from the filing date of the ANDA.[11] Notably, in order to encourage Paragraph

2 The Orange Book is the U.S. Food and Drug Administration's ("FDA") official list of approved drug products and includes related patents and exclusivity information (FDA, Orange Book Preface, available at https://www.fda.gov/drugs/development-approval-process-drugs/orange-book-preface).

3 FTC, FTC Renews Challenge of More Than 200 Improper Patent Listings (May 21, 2025) [hereinafter FTC 2025], available at https://www.ftc.gov/news-events/news/press-releases/2025/05/ftc-renews-challenge-more-200-improper-patent-listings.

4 See for example *Teva Branded Pharmaceutical Products R&D LLC et al v. Amneal Pharmaceuticals of New York, LLC et al*, in the U.S. District Court District of New Jersey, 2:23-cv-20964-SRC-MAH.

5 FTC 2025, *supra* note 3.

6 FDA, New Drug Application (NDA) (January 21, 2022), available at https://www.fda.gov/drugs/types-applications/new-drug-application-nda.

7 FDA, Guidance for Industry: Referencing Approved Drug Products in ANDA Submissions, at 2 (2020), *available at* https://www.fda.gov/media/102360/download.

8 FDA, Guidance for Industry: ANDA Submissions Amendments and Requests for Final Approval to Tentatively Approved ANDAs, at 3 (2024), available at https://www.fda.gov/media/119718/download.

9 *Ibid.* at 3.

10 *Ibid.* at 3-4.

11 *Ibid.* at 4.

IV certifications, the Hatch-Waxman Act provides a 180-day period of exclusivity to the first filer of a generic version of the pharmaceutical under an ANDA.[12]

B. The Orange Book

The Hatch-Waxman Act requires branded manufacturers to include as part of an NDA any patents that claims the drug and "is a drug substance (active ingredient) or drug product (formulation or composition) patent, or claims a method of using such drug" for which approval was granted by the FDA.[13] The patents identified by the manufacturer, including their respective expiry dates, are listed in the FDA publication, *Approved Drug Products with Therapeutic Equivalence Evaluations*, known as the *Orange Book*.[14]

In 2003, the FDA clarified "patent submission and listing requirements" to "reduce confusion and help curb attempts to take advantage of this process" and limited automatic 30-month stays to one per NDA.[15] Despite its rulemaking, the FDA does not have the resources or expertise to review patents included in an NDA filing for accuracy prior to publishing in the Orange Book.[16] Congress amended the Hatch-Waxman Act in 2003, allowing ANDA applicants to assert counterclaims for patents that do not claim either "the drug for which the application was approved" or "an approved method of using the drug;"[17] and formalized this rule with the passage of the Orange Book Transparency Act of 2020 ("OBTA").[18]

C. Role of IP Rights in the Pharmaceutical Industry

The current institutional and regulatory framework around branded and generic drug approvals represents an attempt to balance the need to incentivize the development of new branded products with the desire to increase the availability of lower cost prescription drugs.

The period from drug discovery to FDA approval is long, costly, and involves substantial risk. Drug developers rely on patent protection to ensure returns sufficient to justify costs required for those products that ultimately obtain approval and those that fail.[19] To incentivize the development of new pharmaceuticals, manufacturers that bring a product to market first are awarded a period of exclusivity in which they are the sole seller of a pharmaceutical product with a given active ingredient.[20]

III. IMPROPERLY LISTED PATENTS AND ANTICOMPETITIVE CONDUCT

A. Overview

The lack of scrutiny by the FDA regarding patents and statutory listing criteria has led to claims of improperly listed patents in the Orange Book. The listing of such patents may lead a generic manufacturer to seek approval through a Paragraph IV certification that could trigger an automatic stay of up to 30 months against any final generic approval for the first challenge to that NDA. It is primarily this automatic stay that has led to both the FTC and private litigants accusing brand manufacturers of engaging in anticompetitive conduct through the listing of knowingly "improper" patents in the Orange Book. As the introduction of competing generic products typically leads to significant price reductions to patients and payers, the harm of the purported anticompetitive products is through the higher branded pharmaceutical prices paid due to the delay of generic drug entry.

12 In general, the 180-day period of exclusivity begins once the "first-filer" launches its product, if it launches at-risk, or upon the date of a final decision of the court holding the relevant patent(s) invalid, unenforceable, or not infringed (21 U.S.C 355(j)(5)). After the 180-day period of exclusivity expires, other generic manufacturers would be free to enter, conditional upon final approval of their ANDAs.

13 21 U.S.C. § 355(b)(1)(A)(viii); FDA, Guidance for Industry: Orange Book: Questions and Answers, at 10 (2022), *available at* https://www.fda.gov/media/160167/download.

14 *Ibid.* at 1.

15 68 Fed. Reg. 36676 (June 18, 2003). For example, the FDA stated that "patents claiming packaging, intermediates, or metabolites" are ineligible for inclusion in the Orange Book. Conversely, patents that claim the same active ingredient but different structure or "polymorph," "must be submitted if the NDA holder has test data demonstrating that a drug product containing the polymorph will perform the same as the drug product described in the NDA" (*Ibid.*).

16 59 Fed. Reg. 50338, 50345 (October 3, 1994).

17 Pub. L. No. 108-173, sec. 1101(a), § 505(j), 117 Stat. 2066, 2452; 21 U.S.C. § 355(j)(5)(C)(ii)(I). This amendment was part of the Medicare Prescription Drug, Improvement, and Modernization Act.

18 Pub. L. No. 116-290, 134 Stat. 4889 (2021).

19 See, e.g. Scherer, F.M., "Pharmaceutical Innovation," *Harvard University Working Paper*, February 2007.

20 Congressional Research Servies, The Role of Patents and Regulatory Exclusivities in Drug Pricing, *available at* https://www.congress.gov/crs-product/R46679. Patent terms may be extended to compensate the patent owner for delays in commercial marketing due to the regulatory review process (35 U.S.C. § 156).

B. FTC Warning Letters

The FTC's 2023 policy statement ("Policy Statement") asserts that the listing of improper patents in the Orange Book "may constitute an unfair method of competition … because it is not competition on the merits of drug quality or price, and it tends to negatively affect competitive conditions by impeding opportunities for generic rivals to compete, thus limiting consumer choice" and the "improper listing of patents in the Orange Book may also constitute illegal monopolization."[21] In conjunction with these assertions, the FTC sent warning letters to branded manufacturers identifying patents it deemed improperly listed and informing recipients that the FDA's regulatory dispute process to challenge said patents had been initiated.[22] Branded manufacturers then had 30 days to either withdraw, amend, or certify that their patents comply with "applicable statutory and regulatory requirements."[23] The vast majority of the patents flagged by the FTC relate to patents associated with products that combine active ingredients with a device to assist in drug delivery, often referred to as "combination products."[24]

Many branded manufacturers rejected the assertion that their patents were improperly listed in the Orange Book and raised several arguments in response, including:[25]

- Noting the procompetitive nature of the Orange Book, including clarity to generic manufacturers of the patents that apply to a drug; a mechanism for litigating patent disputes; and a 180-day exclusivity period for the first generic manufacturer(s) that obtain approval through a Paragraph IV certification;[26]
- Asserting the FTC ignored examples of instances in which the branded manufacturer did not challenge infringement of the allegedly improper patents and trigger a 30-month stay;[27]
- Highlighting regulatory risk to the brand from its failure to include patents in the Orange Book, required by law;[28] and
- Emphasizing both the complexity and critical role of the device component of drug-device combination products, including the significant research and development ("R&D") that goes into the development of such products.[29]

C. Recent Cases

Three recent decisions shed light on the requirements regarding patents that should and should not be listed in the Orange Book and the ability to claim harm from anticompetitive conduct.

1. *In Re Lantus Direct Purchaser Antitrust Litigation*

In Re Lantus Direct Purchaser Antitrust Litigation is a matter brought by direct purchasers (e.g. wholesalers and other entities who directly purchase pharmaceuticals from a manufacturer) against Sanofi-Aventis U.S. LLC ("Sanofi"). Plaintiffs alleged Sanofi engaged in anticompetitive conduct through improperly listed patents in the Orange Book and harmed the direct purchasers through higher prices from the delayed market entry of competing insulin glargine products. The asserted patents covered the disposable injector component in Sanofi's drug Lantus SoloSTAR (insulin glargine injection).[30]

21 FTC, Federal Trade Commission Statement Concerning Brand Drug Manufacturers' Improper Listing of Patents in the Orange Book, at 5 (2023) *available at* https://www.ftc.gov/system/files/ftc_gov/pdf/p239900orangebookpolicystatement092023.pdf.

22 FTC 2025, *supra* note 3.

23 *Ibid.*

24 See for example *Ibid.*; FTC, FTC Expands Patent Listing Challenges, Targeting More Than 300 Junk Listings for Diabetes, Weight Loss, Asthma and COPD Drugs (April 30, 2024), *available at* 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.

25 Authors' analysis of FDA list of disputed patents and NDA holder responses (*See* FDA, "Patent Listings Disputes" (October 10, 2025), available at https://www.fda.gov/media/105080/download.) See also Letter from AstraZeneca Pharmaceuticals LP to Sen. Elizabeth Warren and Rep. Pramila Jayapal (Feb. 7, 2024) [hereinafter AstraZeneca Letter]; Letter from Boehringer Ingelheim USA Corporation to Sen. Elizabeth Warren and Rep. Pramila Jayapal (Jan. 15, 2024) [hereinafter BI Letter]; Letter from GlaxoSmithKline to Sen. Elizabeth Warren and Rep. Pramila Jayapal, "December 13, 2023 Letter Concerning GlaxoSmithKline's Orange Book Patent Listing", (Jan. 12, 2024); Letter from AbbVie, Inc. to Sen. Elizabeth Warren and Rep. Pramila Jayapal (Jan. 15, 2024) [hereinafter AbbVie Letter]; Letter from Viatris Inc. to Sen. Elizabeth Warren and Rep. Pramila Jayapal (Jan. 12, 2024); Letter from Kaleo, Inc. to Sen. Elizabeth Warren and Rep. Pramila Jayapal (Jan. 12, 2024); Letter from Teva Pharmaceutical Industries Ltd. to Sen. Elizabeth Warren and Rep. Pramila Jayapal (Jan. 12, 2024) [hereinafter Teva Letter].

26 AstraZeneca Letter; GSK Letter; Teva Letter.

27 GSK Letter; AbbVie Letter; AstraZeneca Letter.

28 AstraZeneca Letter.

29 AstraZeneca Letter; BI Letter; AbbVie Letter; Teva Letter.

30 Amended and Consolidated Complaint and Demand for Jury Trial, *In Re Lantus Direct Purchaser Antitrust Litigation*, No. 1:16-cv-12652-JGD-LTS (D.M. March 6, 2023), at ¶¶ 1-15, 468-477.

In an initial ruling, the district court dismissed Plaintiffs' claims, stating that Sanofi's decision to list an asserted patent was reasonable and not "objectively baseless."[31] Plaintiffs appealed this decision, and the U.S. Court of Appeals for the First Circuit issued two rulings. First, it reversed the district court's finding and asserted that Sanofi inappropriately listed the asserted patent in the Orange Book; stating that "statute and regulations clearly require that only patents that claim the drug for which the NDA is submitted should be listed in the Orange Book," and the asserted patent "neither claims nor even mentions insulin glargine or the Lantus SoloSTAR" and was thus not eligible for listing.[32]

Second, the First Circuit found that Sanofi can be held liable under antitrust laws for any injury caused by its improper submission of the asserted patent in the Orange Book.[33] However, the First Circuit rejected the assertion that the reasoning behind Sanofi's conduct is irrelevant, noting that such carve-outs exist in other regulatory settings.[34] Accordingly, the First Circuit established a test to preclude antitrust liability from the listing of the improper patent; specifically, if the brand manufacturer can demonstrate that "the submission was the result of a reasonable, good-faith attempt to comply with the Hatch-Waxman scheme."[35]

At the time of this writing, the district court has yet to rule on whether Sanofi's inclusion of the asserted patent was "reasonable" and in "good faith," nor has the court ruled whether Plaintiffs have demonstrated the inclusion of the asserted patent led to harms suffered by the Plaintiffs.

2. *In Re Actos Antitrust Litigation*

In Re Actos Antitrust Litigation is a set of class actions from direct purchasers and end-payors (e.g. patients and health insurers) against Takeda Pharmaceutical Company Limited ("Takeda"), alleging Takeda engaged in a monopolization scheme in violation of Section 2 of the Sherman Act through improperly listed patents in the Orange Book covering Takeda's drug Actos (pioglitazone). In particular, Plaintiffs allege Takeda improperly listed patents involving a combination that includes insulin sensitivity enhancers.[36]

The district court rejected Takeda's arguments that the asserted "combination patents" cover the underlying product in accordance with the contemporaneous regulations and that Plaintiffs must show the listing of the patents was made in "bad faith" to demonstrate anticompetitive conduct.[37] Takeda appealed and the U.S. Court of Appeals for the Second Circuit affirmed the district court's ruling: the asserted combination patents do not claim the underlying drug and that to allege a monopolization claim, Plaintiffs "need only have plausibly alleged that Takeda had market power and that it incorrectly listed its combination patents as claiming ACTOS, causing their antitrust injuries."[38] The classes in *In Re Actos* were certified in September 2024. The matter is currently awaiting trial.[39]

3. *Teva v. Amneal*

In 2023, Amneal Pharmaceuticals ("Amneal") filed a Paragraph IV Certification for a generic version of Teva Branded Pharmaceuticals, Inc's ("Teva") inhaler ProAir HFA (albuterol sulfate) Inhalation Aerosol. In response, Teva sued Amneal for infringement of five patents listed in the Orange Book that relate to device components of the inhaler and had yet to expire.[40] Additionally, the FTC sent a letter to Teva in November 2023 stating that the patents claiming ProAir HFA (and other branded Teva products) are improperly listed in the Orange Book and that they have

31 U.S. Court of Appeals for the First Circuit Decision, *In Re Lantus Direct Purchaser Antitrust Litigation*, No. 18-2086 (February 13, 2020) at 11.

32 *Ibid.* at 20.

33 *Ibid.* at 1.

34 *Ibid.* at 25.

35 *Ibid.* at 30.

36 U.S. Court of Appeals for the Second Circuit Decision, *United Food & Com. Workers Local 1776; Meijer, Inc. v. Takeda Pharm. Co.*, No. 20-1994-cv; 20-2002-cv (September 15, 2021) at 5, 12, 16.

37 *Ibid.* at 19-20.

38 *Ibid.* at 3, 37-39.

39 Both Plaintiffs' and Takeda's submissions for summary judgement on "regulatory compliance" (i.e. whether Takeda's listing of the patent in the Orange Book was a "reasonable mistake in good faith") were denied (Opinion and Order, *In Re Actos Antitrust Litigation*, No. 13-cv-9244 (RA) (S.D.NY March 31, 2025) at 1-2, 64).

40 First Amended Complaint, Teva v. Amneal, No. 23-cv-20964-JXN-MAH (D.N.J. October 27, 2023), at ¶¶ 1, 67-71; U.S. Court of Appeals for the Federal Circuit Decision, *Teva v. Amneal*, No. 23-cv-20964-SRC-MAH (December 20, 2024) at 2-3, 13.

subsequently submitted patent listing dispute communications to the FDA.[41] In December 2023, Amneal responded to Teva's lawsuit with counterclaims alleging that the asserted patents are invalid because they "do not meet the statutory requirements to be listed in the Orange Book" and sought to have the asserted patents delisted.[42] Amneal stated in its counterclaims that but-for improper Orange Book listings, they would have submitted a Paragraph I Certification and not a Paragraph IV Certification, thus a 30-month stay would not have been triggered.[43] Amneal alleged Teva was engaging in anticompetitive conduct and causing Amneal harm in the form of lost future sales and profits.[44]

In June 2024, the district court ordered Teva to delist the asserted patents.[45] Teva appealed the decision. The U.S. Court of Appeals for the Federal Circuit affirmed the decision, ruling that even for drug-device combinations "to qualify for listing, a patent must claim at least what made the product approvable as a drug in the first place—its active ingredient."[46] Since the device patents do not claim the active ingredient and are instead directed to components of the inhaler device, both the district court and Federal Circuit concluded the patents were inappropriately listed in the Orange Book.

In July 2025, following the Federal Circuit's ruling, the parties jointly applied for a Consent Order of Dismissal and all asserted claims and counterclaims were dismissed without prejudice.[47]

4. Summary

It is apparent that the courts have taken a statutory interpretation in deciding the appropriateness of listing a patent in the Orange Book, requiring a nexus between a product's FDA approval and the patent claims. However, improper listings alone may not imply anticompetitive conduct. The decisions in *In Re Lantus* and *In Re Actos* have been referred to as an:

> emerging standard … for determining whether an Orange Book listing is actionable under a monopolization or unfair competition theory turns on an *ex-post* determination whether the patent should not have been listed. If so … the burden would shift to the defendant to prove that the listing was objectively reasonable (relying upon statutory and regulatory ambiguity and/or industry custom and practice) and subjectively made in good faith.[48]

We are not aware of any existing case law/precedent that illuminates how courts determine whether an improper Orange Book listing constitutes anticompetitive conduct. Instead, the burden appears to be placed on the branded manufacturer to demonstrate its listing decision was "reasonable" and in "good faith" to preclude claims of anticompetitive conduct.

IV. IMPACT OF RECENT RULINGS ON ORANGE BOOK LISTINGS

The Orange Book, as a centralized source of patents associated with approved drugs, is expected to be procompetitive as is consistent with the objectives of the Hatch-Waxman Act. For branded manufacturers, R&D gives rise to patents that are listed in the Orange Book and provides an assurance of exclusivity, thereby protecting returns on R&D and encouraging further innovation. The Orange Book also provides clarity on the patents that claim a drug product and can incentivize manufacturers to design around valid patents, thus increasing innovation and creating competition. For both brand and generic manufacturers, it triggers the statutory mechanism for litigating patent disputes such that claims are addressed prior to FDA approval of the generic drug.

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41 Letter from FTC, Office of the Director Bureau of Competition to Teva Branded Pharmaceutical Products R&D, Inc. (November 7, 2023), available at https://www.ftc.gov/system/files/ftc_gov/pdf/teva-branded-pharma-orange-book.pdf.

42 Counterclaims to Plaintiffs' First Amended Complaint, Teva v. Amneal, No. 23-cv-20964-JXN-MAH (D.N.J. December 1, 2023), at ¶ 15.

43 *Ibid.* at ¶ 102.

44 *Ibid.* at ¶ 127. Amneal also alleged harm in the form of litigation costs; a "delay in Amneal's ability to recoup its investment in filling and packaging lines and device components for the Amneal ANDA Products"; and a loss of investment "in device components that will expire before expiration of the 30-month stay" (*Ibid.* at ¶ 127.).

45 U.S. Court of Appeals for the Federal Circuit Decision, *Teva v. Amneal*, No. 23-cv-20964-SRC-MAH (December 20, 2024) at 2-3.

46 *Ibid.* at 18.

47 Kass, Dani, "Teva, Amneal End Case Over Listing Inhaler IP In Orange Book," Law360 (July 29, 2025), available at https://www.law360.com/articles/2370314/teva-amneal-end-case-over-listing-inhaler-ip-in-orange-book.

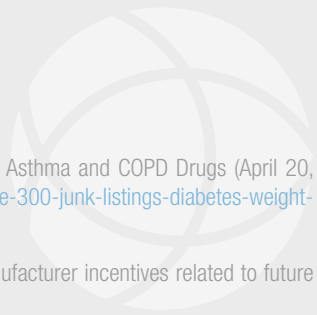
48 Ford, Mark et al., *USA: Unpacking the shift – Heightened antitrust scrutiny on Orange Book listings*, 4 Concurrences 242, 251 (2024).

The procompetitive aspects of Orange Book listings are in contrast to the anticompetitive allegations asserted in the cases above. Further, the recent court rulings on the inappropriateness of Orange Book listings could have broader implications if branded manufacturers are unable to capture the benefits that arise from listing certain patents in the Orange Book.

Consistent with the anticompetitive allegations, the FTC has referred to the asserted patents as "junk patents," in the context of appropriateness for Orange Book listings.[49] If a patent were "junk," its inclusion in the Orange Book would not be procompetitive and its listing may harm generic manufacturers (and thereby also consumers) due to an inappropriate delay in generic entry. In contrast, to the extent that asserted patents reflect innovation, prohibiting their inclusion in the Orange Book may lead to a suboptimal change in the behavior of branded manufacturers. The inability to include certain patents in the Orange Book could decrease the expected return from investments in R&D. Accordingly, branded manufacturers may respond by reducing or reallocating future investments in R&D, particularly around drug-device combination products.[50]

V. CONCLUSION

Over the past few years, there has been an increase in assertions of improperly listed patents in the Orange Book, including claims of anticompetitive conduct due to delayed generic entry. Recent court decisions have found that based on a strict reading of the relevant regulations, certain patents were inappropriately listed in the Orange Book. Further, the burden appears to be placed on the branded manufacturer to demonstrate its listing decision was "reasonable" and in "good faith" in order to preclude claims of anticompetitive conduct. These decisions imply certain patents may not be eligible for listing in the Orange Book, even if they claim aspects of the product. At this time, it is unclear how manufacturers will respond to courts' interpretation of listing requirements and there are questions regarding the extent to which branded manufacturers may adjust their R&D plans. The resolution to such issues lies at the intersection of IP rights and antitrust laws where the current regulatory framework attempts to both incentivize innovation in drug development and ensure access to lower cost generic drugs.



49 See for example FTC, FTC Expands Patent Listing Challenges, Targeting More Than 300 Junk Listings for Diabetes, Weight Loss, Asthma and COPD Drugs (April 20, 2024), *available at* 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.

50 The FTC's opinion on these questions is unknown. In their Policy Statement, the FTC does not discuss any impact on branded manufacturer incentives related to future innovation.

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