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USA: Unpacking the shift – Heightened antitrust scrutiny on Orange Book listings

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USA: Unpacking the shift – Heightened antitrust scrutiny on Orange Book listings

ABSTRACT

The Federal Trade Commission has recently increased its scrutiny of pharmaceutical companies' patent listings in the Orange Book, challenging hundreds of device and delivery system patents through warning letters and policy statements over the last year. This enforcement shift coincides with significant judicial developments in the First and Second Circuits that changed the landscape for proving and defending antitrust claims based on alleged improper Orange Book listings. Standards now place the burden on pharmaceutical companies to prove their good faith in listing patents as an affirmative defense, rather than requiring antitrust plaintiffs to demonstrate bad faith. This article examines this convergence of regulatory and judicial developments against the backdrop of the Hatch-Waxman Act's framework for generic drug approval and the recent Orange Book Transparency Act of 2020. Further, it discusses the practical implications of this emerging standard, including challenges related to privilege waivers and proving causation of competitive harm, while raising questions about how courts in other circuits may approach these issues.

La Federal Trade Commission (FTC) a récemment intensifié son examen des inscriptions de brevets des entreprises pharmaceutiques dans l'Orange Book, contestant des centaines de brevets relatifs aux dispositifs et systèmes de délivrance via des lettres d'avertissement et des déclarations de politique au cours de l'année écoulée. Ce virage dans l'application des règles coïncide avec des évolutions judiciaires significatives dans les Premiers et Deuxièmes Circuits, qui ont modifié le cadre de la preuve et de la défense des réclamations en matière de concurrence déloyale fondées sur des inscriptions présumées abusives dans l'Orange Book. Les nouvelles normes imposent désormais aux entreprises pharmaceutiques la charge de prouver leur bonne foi dans l'inscription de brevets comme moyen de défense affirmatif, au lieu d'exiger des plaignants en droit de la concurrence qu'ils démontrent une mauvaise foi.

I. Introduction

1. Forty years ago, Congress passed the Hatch-Waxman Act,[1] which streamlined the generic drug approval process and revamped how patent infringement claims would be litigated against those prospective generic drug applicants. At the center of that complex regulatory scheme is a Food and Drug Administration (FDA) publication known as the "Orange Book."[2] As detailed below, sponsors of innovator (i.e., "branded") drugs are required by law to submit certain types of patents covering their drugs for publication in the Orange Book (although the precise scope of that requirement has been subject to much litigation over the years and recent statutory amendment). The Hatch-Waxman Act then provides valuable incentives to generic manufacturers to challenge Orange-Book-listed patents, and to do so quickly; but at the same time, the Act allows the patentee to assert those patents before the proposed generic enters the market, sometimes even years before. In fact, if a patentee files a suit in a timely manner, the FDA will delay final marketing approval for the generic product for up to two-and-a-half years to allow the patent suit to progress or even to conclude.

2. The Federal Trade Commission (FTC) has claimed for more than two decades that certain innovator companies have abused this Hatch-Waxman Act process by listing in the Orange Book patents that should not be listed. It is therefore hardly news that the FTC believes an innovator can unlawfully delay generic entry by improperly listing a patent in the Orange Book and by benefitting from the automatic stay of FDA approval that follows the later assertion of that patent. But in the last year, at the urging of certain members of Congress, the FTC has suddenly and dramatically shifted its regulatory attention and resources to these allegedly "improper" Orange Book listings. It has issued a policy statement threatening enforcement, even suggesting potential referral of responsible

* The views expressed in this article do not necessarily represent the views of Wilmer Cutler Pickering Hale and Dorr LLP or its clients. The authors thank Kevin Yurkerwich, PhD, for his feedback on drafts of this article while practicing at WilmerHale.

1 Drug Price Competition and Patent Term Restoration Act of 1984, Pub. L. No. 98-417 (codified at 21 U.S.C. § 355).

2 U.S. Dep't Health & Hum. Servs., Food & Drug Admin., Approved Drug Products with Therapeutic Equivalence Evaluations (44th ed. 2024).

individuals for criminal indictment.[3] It has sent waves of letters challenging hundreds of patent listings by more than a dozen innovators.[4] And it has filed multiple amicus briefs in pending private actions explaining what it believes to be the anticompetitive effects of improperly listed patents.[5]

3. This recent escalation of regulatory action and rhetoric has come in the wake of two federal appellate court decisions that have significantly lowered the bar for stating and prevailing on antitrust claims arising from allegedly improper Orange Book listings.[6] Those decisions, from the First and Second Circuit Courts of Appeals, have adopted a standard that does not require the antitrust plaintiffs to prove an improper listing was done in bad faith, but rather places the burden on the antitrust defendant to prove its good faith as an affirmative defense, potentially as a practical matter requiring disclosure of otherwise privileged legal advice to do so effectively. The confluence of these developments suggests that these initial regulatory salvos may be the beginning of a larger wave of government and private antitrust enforcement.

4. This article reviews recent developments concerning antitrust claims associated with allegedly improper Orange Book listings. It delves into the theories of competitive harm that underlie these claims, and the emerging legal standard that has recently developed for assessing whether such listings constitute actionable exclusionary conduct in violation of federal and state antitrust and unfair competition laws. The article then concludes by discussing the practical implications of the legal standard that is currently emerging, open questions that remain for future improper Orange Book claims, and challenges that enforcers and other plaintiffs may still face in proving their cases.

II. Background on the Orange Book and the generic drug approval process

5. Enacted in 1984, the Hatch-Waxman Act established a process by which the FDA would approve generic drugs. Congress aimed to strike a balance between two seemingly conflicting objectives: fostering generic competition, which would lower prescription drug prices, and continuing to incentivize pharmaceutical innovation, which would keep bringing new, beneficial therapies to market.[7] The legislation aimed to balance these dual objectives through a series of mechanisms, two of which are relevant to this article: (i) by reforming the procedures for disputing and enforcing pharmaceutical patents to promote prompt challenges while preserving the integrity of patent rights; and (ii) by regulating when the first generic challenger could launch (to incentivize innovation) and when subsequent generic applicants could launch (to reward the first-filer generic, i.e., the first patent challenger). Both mechanisms begin with the innovator drug company listing a patent in the Orange Book.

6. The Federal Food, Drug, and Cosmetic Act (FDCA) has long required a manufacturer of a new drug to obtain approval from the FDA to market the drug through a submission called a new drug application (NDA).[8] To obtain this approval, innovator drug companies submit NDAs, which must include data demonstrating that the proposed drug is safe and effective for its intended use, among other things.[9] Once the FDA approves the drug, the Hatch-Waxman Act requires an NDA holder to list patents that claim the drug or a method of using the drug.[10] Thereafter, each time the sponsor of the NDA acquires a new patent claiming the drug or a method of using the drug, the company is required to list the drug in the Orange Book within 30 days of patent issuance. Companies submit this information via a designated FDA form, Form 3542.[11] The FDA then lists those patents in a publication called the Approved Drug Products with Therapeutic Equivalence Evaluations, also known as the "Orange Book" because of its bright orange cover.[12] The FDA has repeatedly described its role with respect to Orange Book listings as "ministerial"—it has made clear it will not make any independent determination as to

3 Fed. Trade Comm'n, Statement Concerning Brand Drug Manufacturers' Improper Listing of Patents in the Orange Book (Sept. 14, 2023), https://www.ftc.gov/system/files/ftc_gov/pdf/p239900orangebookpolicystatement092023.pdf.

4 Press Release, Fed. Trade Comm'n, FTC Challenges More Than 100 Patents as 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; *see also* B. Sandburg, FTC's Rahul Rao On Why Agency Targeted Drug-Device Orange Book Patents, *Citeline's Pink Sheet* (Nov. 13, 2023) (stating that the FTC warns that it is "*continuing to review a wide array of patent listings*").

5 Brief for the Fed. Trade Comm'n as Amicus Curiae, *Teva Pharmaceuticals USA, Inc. v. Amneal Pharmaceuticals, Inc.*, 23-cv-20964-JXNMAH (D.N.J. 2024), https://www.ftc.gov/system/files/ftc_gov/pdf/ftc_brief_as_amicus_curiae_teva_amneal.pdf; Brief for the Fed. Trade Comm'n as Amicus Curiae, *Mylan Pharmaceuticals, et al. v. Sanofi-Aventis, et al.*, 2:23-cv-00836-MRH (W.D. Pen. Nov. 20, 2023), https://www.ftc.gov/system/files/ftc_gov/pdf/p082105sanofiamicusbrief.pdf?utm_source=govdelivery; Brief for Fed. Trade Comm'n as Amicus Curiae, *Jazz Pharms., Inc. v. Avadel CNS Pharms.*, No. 1:21-cv00691 (D. Del. Nov. 10, 2022), https://www.ftc.gov/system/files/ftc_gov/pdf/P163500JazzPharmaAmicusBrief.pdf (arguing that a patent covering a system for implementing a REMS was not properly listed); Brief for the Fed. Trade Comm'n as Amicus Curiae, *SmithKline Beecham Corp. v. Apotex Corp.*, No. 99-CV-4304 (E.D. Pa. Jan. 29, 2003), https://www.ftc.gov/sites/default/files/documents/amicus_briefs/smithkline-beecham-corp.v.apotex-corp./smithklineamicus.pdf; Brief for the Fed. Trade Comm'n as Amicus Curiae, *In re: Buspirone Patent, Antitrust Litig.*, 185 F. Supp. 2d 363 (S.D.N.Y. 2002), http://www.ftc.gov/ogc/briefs/buspirone.pdf; Brief for the Fed. Trade Comm'n as Amicus Curiae, *American Bioscience, Inc. v. Bristol-Myers Squibb Co.*, No. CV-00-08577 WMB (AJWx) (C.D. Cal. Sept. 1, 2000), https://www.ftc.gov/legal-library/browse/amicus-briefs/american-bioscience-v-bristol-myers.

6 *In re Lantus Direct Purchaser Antitrust Litig.*, 950 F.3d 1, 3–4 (1st Cir. 2020); *United Food & Co. Workers Loc. 1776 & Participating Emps. Health & Welfare Fund v. Takeda Pharm. Co.*, 11 F.4th 118, 124 (2nd Cir. 2021).

7 *Mead Johnson Pharm. Group v. Bowen*, 838 F.2d 1332, 1333 (D.C. Cir. 1988).

8 21 U.S.C. §§ 301–392, 331(d), 355(a).

9 Ibid. at § 355.

10 Ibid. at §§ 355(b)(1)(A)(viii), 355(c)(1), (2).

11 *See* Food & Drug Admin., What's New with Forms FDA 3542 and 3542a, https://www.fda.gov/media/102040/download

12 21 U.S.C. § 355(b)(1); 21 C.F.R. § 314.53(e).

whether the patent is appropriate for listing in the Orange Book.[13]

7. In contrast to innovator drug companies, which must submit NDAs demonstrating safety and efficacy, prospective generic drug companies under the Hatch-Waxman Act submit an abbreviated new drug application (ANDA), which need not independently demonstrate the safety and efficacy of the proposed drug. Instead, ANDAs must demonstrate that the proposed generic drug is "bioequivalent" to an approved innovator drug (a so-called reference listed drug).[14] An ANDA relies on the safety and efficacy data described in the reference listed drug's NDA.[15] When submitting an ANDA, however, the generic manufacturer must address the Orange Book entry for the reference listed drug with one of four certifications. Where there are no patents listed in the Orange Book, the generic applicant submits a Paragraph I certification.[16] When all listed patents have expired, the generic applicant makes a Paragraph II certification.[17] When unexpired patents are listed, however, the generic applicant must certify, as to each patent, either that it will not seek final approval until after patent expiry (a "Paragraph III certification") or that the patent is invalid, unenforceable, or will not be infringed by the proposed generic product (a "Paragraph IV certification").[18] A Paragraph IV certification indicates that the generic applicant seeks to market its product prior to expiration of the patent, and the Hatch-Waxman Act requires the ANDA filer to provide notice of that to the NDA holder (a "Paragraph IV Notice").[19]

8. A Paragraph IV Notice is considered an "artificial" act of infringement, giving the Orange Book patent holder standing to bring patent infringement claims against the generic applicant, and to seek to enjoin the sale of the proposed generic drug, even before the generic applicant is close to reaching the market.[20] If the NDA holder files that patent infringement suit in federal district court within 45 days of receiving the Paragraph IV Notice, the FDA will stay final approval of the ANDA (thereby delaying commercial marketing of the generic drug) for 30 months to give time for the judicial process to progress.[21] This provision of the Hatch-Waxman Act thus effectively provides an automatic preliminary injunction (of up to two-and-a-half years) for Orange Book-listed patents, without the NDA holder having to make the customary preliminary injunction showings of risk of irreparable harm and likelihood of success on the merits. At the same time, the Hatch-Waxman Act provides countervailing incentives for prospective generic applicants to quickly challenge unexpired Orange Book-listed patents with Paragraph IV certifications. The first ANDA filer to submit a Paragraph IV certification (the "first-filer") is entitled to 180 days of generic "exclusivity," meaning the FDA will not approve a later Paragraph IV ANDA filer (a "secondary filer") until the first-filer has been on the market for 180 days (subject to certain forfeiture provisions).[22] As many courts have noted, this first-filer exclusivity can be extremely valuable to those generic applicants.[23]

9. Whether a patent can be listed in the Orange Book, however, has been the subject of significant litigation over the past twenty years. As initially enacted, the Orange Book listing provision of the Hatch-Waxman Act required NDA holders to submit for listing "*any patent which claims the drug for which the applicant submitted the application or which claims a method of using such drug and with respect to which a claim of patent infringement could reasonably be asserted if a person not licensed by the owner engaged in the manufacture, use, or sale of the drug*."[24] The FDA had promulgated regulations clarifying that NDA holders may submit only those patents that fell within the scope of that statutory provision.[25] Thus, the statute required submission of listable patents and the implementing regulations prohibited submissions of any other patents. But the scope of what was listable remained unclear to many. For example, litigation ensued as to whether an NDA may submit "method of use" patents claiming unapproved (i.e., off-label) uses of the drug.[26] As another example, over the course of many years, several different innovator companies sought guidance from the FDA as to whether patents covering a drug delivery device (but not the active ingredient) constituted a patent "*claim*[ing] *the*

13 *See Caraco Pharm. Lab'ys, Ltd. v. Novo Nordisk A/S*, 566 U.S. 399, 406–407 (2012) ("*The FDA* (. . .) *does not independently assess the patent's scope or otherwise look behind the description authored by the brand. According to the agency, it lacks 'both [the] expertise and [the] authority' to review patent claims; although it will forward questions about the accuracy of a use code to the brand, its own 'role with respect to patent listing is ministerial'*" (citing 68 Fed. Reg. 36683 (2003))).

14 21 U.S.C. § 355(d), (j)(2)(A)(iv).

15 Ibid. at § 355(j)(2)(A)(i).

16 Ibid. at § 355(j)(2)(A)(vii)(I).

17 Ibid. at § 355(j)(2)(A)(vii)(II).

18 Ibid. at § 355(j)(2)(A)(vii)(III), (IV). In addition, for patents that cover methods of use, the ANDA filer can alternatively certify that the ANDA is not seeking approval for the covered use. Ibid. at § 355(j)(2)(A)(viii).

19 Ibid. at § 355(j)(2)(B)(iii), (iv).

20 *See Eli Lilly & Co. v. Medtronic, Inc.*, 496 U.S. 661, 678 (1990) (stating that the Act creates "*a highly artificial act of infringement that consists of submitting an ANDA or a paper NDA containing the fourth type of certification*").

21 21 U.S.C. § 355(j)(5)(B)(iii).

22 Ibid. at § 355(j)(5)(B)(iii), (iv). *See In re Ciprofloxacin Hydrochloride Antitrust Litig.*, 261 F. Supp. 2d 188, 193 (E.D.N.Y. 2003) ("*The Hatch-Waxman Amendments provide an incentive to encourage generic drug manufacturers to challenge listed patents for brand-name drugs. As an incentive to incur 'potentially substantial litigation costs,' the first company to submit an ANDA IV is awarded a 180-day period of exclusive rights to market a generic formula of the pioneer drug*" (citing *Mylan Pharms., Inc. v. Shalala*, 81 F.Supp.2d 30, 33 (D.D.C. 2000))).

23 *See*, e.g., *King Drug Co. of Florence v. SmithKline Beecham Corp.*, 791 F.3d 388, 404 (3d Cir. 2015) (explaining that the "*180-day exclusivity period is 'possibly "worth several hundred million dollars,"' and may be where the bulk of the first-filer's profits lie*").

24 21 U.S.C. § 355(b)(1) (2020).

25 21 C.F.R. § 314.53(b).

26 *See Organon Inc. v. Mylan Pharms., Inc.*, 293 F. Supp. 2d 453, 460 n.8 (D.N.J. 2003) (noting ambiguity in the regulations such that the "*section is capable of two equally plausible interpretations*" that would "*not have been inconsistent with the broad language of 21 U.S.C. §§ 355(b)(1) & (c)(2)*").

drug."[27] These companies' requests for advisory opinions remained pending for several years, until the FDA ultimately declined to provide a substantive response.[28]

10. The Orange Book Transparency Act of 2020 (OBTA) aimed to provide clarity on the categories of patents that NDA holders could include in the Orange Book. The OBTA amended the language of the Orange Book listing provision to specify that the patent must (i) be one "*for which a claim of patent infringement could reasonably be asserted if a person not licensed by the owner of the patent engaged in the manufacture, use, or sale of the drug*" and (ii) claim either (a) "*the drug for which the applicant submitted the application and is a drug substance* (. . .) *or a drug product* (. . .) *patent*" or (b) "*a method of using* [the] *drug*." The amendment made clear that a patent must both be of a type that can be listed (claiming the drug or method of using the drug) and separately be one for which a reasonable claim of infringement could be made against an unlicensed copycat drug. The revised language, and implementing regulations, provided further specification as to the type of drugs that could be listed. To "claim the drug," the OBTA further requires that the patent claim either the "*drug substance*," i.e., "*the active ingredient*," or a "*drug product*," i.e., a "*formulation or composition*." FDA regulations further spell out that "[p]*rocess patents, patents claiming packaging, patents claiming metabolites, and patents claiming intermediates* (. . .) *must not be submitted to FDA*."[29] For "method of use" patents, the OBTA requires the patent to claim a use "*for which approval is sought or has been granted in the application*."[30] FDA regulations now state that patents that claim unapproved uses of an approved drug may not be listed in the Orange Book.[31] Finally, if a patent listed in the Orange Book is later found by a court or the Patent Trial and Appeal Board (PTAB) to be invalid, the patent holder or the sponsor of the drug product must update the Orange Book to delist the patent within 14 days.[32]

III. The Federal Trade Commission's action against allegedly improper Orange Book listings

11. In fall 2023, the FTC released its Statement Concerning Brand Drug Manufacturers' Improper Listing of Patents in the Orange Book (the "FTC Policy Statement"), in which it warned that it was prepared to take enforcement action against companies that have improperly listed patents in the Orange Book.[33] The Commission declared that "[i]*mproper Orange Book listings may have played a role in distorting pharmaceutical markets for decades*."[34] The FTC stressed that those allegedly improper listings "*may constitute an unfair method of competition in violation of Section 5 of the FTC Act*."[35] The FTC's focus was on innovator companies that have listed patents that do not (in the FTC's view) either "claim the drug" or an approved "method of use" within the meaning of the listing statute. According to the FTC, "[b]*rand drug manufacturers are responsible for ensuring their patents are properly listed. Yet certain manufacturers have submitted patents for listing in the Orange Book that claim neither the reference listed drug nor a method of using it. When brand drug manufacturers abuse the regulatory processes set up by Congress to promote generic drug competition, the result may be to increase the cost of and reduce access to prescription drugs*."[36]

12. In addition to potentially constituting an "unfair method of competition" under Section 5 (the statutory provision the FTC enforces), the Commission added that improper Orange Book listings may also constitute unlawful monopolization under Section 2 of the Sherman Act, which can be enforced by private plaintiffs such as generic manufacturers or purchasers. The FTC further announced in its statement that it may refer potential criminal violations to the Department of Justice where individual liability for wrongful listings might exist.[37]

13. A claim under either Section 2 or Section 5 requires showing that the Orange Book listing impaired

27 GlaxoSmithKline, *Request for Advisory Opinion Concerning "Orange Book" Listing of Patents*, Docket No. FDA-2005-A-0476 (Jan. 10, 2005); Ropes & Gray on behalf of AstraZeneca, *Request for Advisory Opinion Concerning "Orange Book" Listing of Patents*, Docket No. FDA-2006-A-0063 (Aug. 10, 2006); Ropes & Gray on behalf of AstraZeneca, *Request for an Advisory Opinion–"Orange Book" Listings of Patents*, Docket No. FDA-2007-A-0099 (June 21, 2007); Finnegan on behalf of Forest Laboratories, Inc., *Request for Advisory Opinion Regarding Patents Listable in the Orange Book in connection with NDA No. 202-450*, Docket No. FDA-2011-A-0363 (May 12, 2011); Novo Nordisk Inc., *Request for Advisory Opinion*, Docket No. FDA-2012-A-1169 (Nov. 26, 2012).

28 FDA CDER Response to Request for Advisory Opinions re: Docket Nos. FDA-2005-A-0476, FDA-2006-A-0063, FDA-2007-A-0099, FDA-2011-A-0363, and FDA-2012-A-1169 (June 1, 2020).

29 21 C.F.R. § 314.53(b).

30 21 U.S.C. § 355(b)(1)(A)(viii). The section states in full: "*(viii) the patent number and expiration date of each patent for which a claim of patent infringement could reasonably be asserted if a person not licensed by the owner of the patent engaged in the manufacture, use, or sale of the drug, and that—(I) claims the drug for which the applicant submitted the application and is a drug substance (active ingredient) patent or a drug product (formulation or composition) patent; or (II) claims a method of using such drug for which approval is sought or has been granted in the application.*"

31 21 C.F.R. § 314.53(b), (c)(2). The OBTA further clarifies that "*a method of using the drug*" requires FDA approval, whether already granted or pending. 21 U.S.C. § 355(b)(1)(A)(viii).

32 21 U.S.C. § 355(j)(7)(D)(i). This requirement applies to "*decision*[s] (. . .) *issued on or after the date of enactment of th*[e OBTA]" (Jan. 5, 2021).

33 Fed. Trade Comm'n, Statement Concerning Brand Drug Manufacturers' Improper Listing of Patents in the Orange Book, *supra* note 3.

34 Ibid. at 3.

35 Ibid. at 5.

36 Ibid. at 1.

37 *See* ibid. at 6 ("*Individuals who submit or cause the submission of improper Orange Book patent listings, including those who certify compliance under 21 C.F.R. § 314.53(c)(2)(ii)(R), may be held individually liable. Further, if the FTC encounters false certifications filed under 21 C.F.R. § 314.53(c)(2)(ii)(R) that may constitute a potential criminal violation for the submission of false statements, the Commission may refer such cases to the U.S. Department of Justice for further investigation*").

competition.[38] In a pair of amicus briefs the FTC filed in the wake of the FTC Policy Statement, the FTC spelled out its theory of competitive harm. At the heart of the theory is what many in the antitrust plaintiffs' bar call the "patent cliff."[39] The "patent cliff" refers to the traditional pattern of generic impact on brand sales. In most cases, predominantly due to state substitution laws that allow and, in some cases, require pharmacies to dispense generics when available, brand-name drugs quickly lose a vast majority of their sales to less expensive generic alternatives within several weeks to a few months.[40] According to the FTC, an "improper" Orange Book listing has the effect of delaying this "patent cliff," thereby causing purchasers to pay what the FTC considers an anticompetitive overcharge during the period of generic delay. The FTC stressed in its Policy Statement that, "[g]*iven the enormous profit margins of many branded drugs, even small delays in generic competition can generate substantial additional profits for brand companies at the expense of patients*."[41]

14. The FTC advances two theories for how allegedly improper Orange Book listings lead to this generic delay. First, the FTC explains: "*By listing a patent in the Orange Book and then filing an infringement suit, a brand can block competition for up to two-and-a-half years* [i.e., 30 months] *regardless of the scope or validity of the patent and regardless of whether it meets the statutory listing criteria*."[42] Under this theory, the combination of patent listing and subsequent assertion in a Hatch-Waxman patent litigation triggers the automatic FDA stay of approval and therefore an unwarranted delay of generic entry. Second, the FTC posits that an improper Orange Book listing "*may* [also] *work a more subtle harm*"; specifically, "[f]*aced with a 30-month lag on receiving a return on investment, a generic company may elect to pursue an alternative generic drug*."[43] Under this alternative theory, the mere listing itself, irrespective of any later enforcement, would prevent a prospective competitor from even pursuing approval for a generic alternative.

15. Based on these theories, FTC Chair Lina Khan declared in a release that accompanied the FTC Policy Statement that "[a] *pharmaceutical company can weaponize the Orange Book to protect monopoly rights to a medical product—even if those monopoly rights are invalid*."[44] In her statement, Chair Khan provided the example of one pharmaceutical company that had listed a patent covering a drug's risk management process (a risk evaluation and mitigation strategy or "REMS" patent).[45] She cited, as another example, pharmaceutical companies that had listed patents covering drug delivery devices, but not the medication itself. In those cases, Chair Khan asserted that the listed patents "*had nothing to do with the drug itself or an approved method of using the drug*."[46]

16. Less than two months after its Policy Statement, and for the first time, the FTC sent warning letters to ten companies challenging over 100 patents with claims covering inhalers and medical devices, including epinephrine autoinjectors.[47] The FTC stated that it "*notified FDA that it disputes the accuracy or relevance of the listed information for these patents, which may require that the manufacturers remove the listing or certify under penalty of perjury that the listings comply with applicable statutory and regulatory requirements*."[48] FDA Commissioner Dr. Robert M. Califf expressed support for the FTC's challenges—despite the FDA's historical ministerial role in overseeing the accuracy of Orange Book listings.[49] Commissioner Califf stated: "*The FDA reminds all NDA holders they are obligated to ensure that patent listings comply with statutory and regulatory requirements and to substantively respond to statements of dispute provided under the FDA's patent listing dispute process* (. . .)*. The FDA will continue its longstanding engagement with FTC to help protect American consumers*."[50]

17. After the FTC's warning letters, three companies delisted certain patents that had been challenged, following letters from Senator Elizabeth Warren and Representative Pramila Jayapal requesting compliance

38 Policy Statement Regarding the Scope of Unfair Methods of Competition Under Section 5 of the Federal Trade Commission Act, Commission File No. P221202 (Nov. 10, 2022), https://www.ftc.gov/system/files/ftc_gov/pdf/P221202Section5PolicyStatement.pdf.

39 *New York ex rel. Schneiderman v. Actavis PLC*, 787 F.3d 638, 647 (2d Cir. 2015) ("*A brand drug's exclusivity period is significant because when that period ends and generic versions enter the market, the brand drug often loses more than 80 to 90% of the market within six months. This period following the end of patent exclusivity has been referred to in this litigation and throughout the industry as the 'patent cliff.'*").

40 Ibid. at 644–645 ("[A]*ll 50 states and the District of Columbia have drug substitution laws.* (. . .) [D]*rug substitution laws either permit or require pharmacists to dispense a therapeutically equivalent, lower-cost generic drug in place of a brand drug absent express direction from the prescribing physician that the prescription must be dispensed as written*.").

41 Fed. Trade Comm'n, Statement Concerning Brand Drug Manufacturers' Improper Listing of Patents in the Orange Book, *supra* note 3, at 4.

42 Brief for the Fed. Trade Comm'n as Amicus Curiae, *Mylan Pharmaceuticals, et al. v. Sanofi-Aventis, et al.*, *supra* note 5, at 12.

43 Ibid.

44 Statement of Chair Lina M. Khan at the September Open Commission Meeting on Brand Drug Manufacturers' Improper Listing of Patents in the Orange Book Commission File No. P233900 (Sept. 14, 2023), at 1, https://www.ftc.gov/system/files/ftc_gov/pdf/2023.09.14-statement-of-chair-lina-m-khan-at-sept-ocm-re-orange-book.pdf.

45 A REMS patent pertains to technologies or methods specifically designed to comply with the FDA's risk evaluation and mitigation strategies (REMS) requirements for drugs. These patents typically focus on systems for monitoring and managing drug safety and adherence.

46 Statement of Chair Lina M. Khan, *supra* note 44, at 2.

47 Press Release, *supra* note 4.

48 Ibid.

49 Ibid.

50 Ibid. The FDA's process for disputing patent listings in the Orange Book, outlined in Section 314.53(f)(1), allows individuals to challenge the accuracy or relevance of listed patents. Once a dispute is filed, the FDA posts information about the dispute and whether the NDA holder has responded. The NDA holder then has 30 days to either withdraw the patent, amend the listing, or certify its accuracy. The FDA then updates the Patent Listing Dispute List with details on the disputed patent and the related drug product. FDA, Approved Drug Products with Therapeutic Equivalence Evaluations | Orange Book, Orange Book, Patent & Exclusivity Information, https://www.fda.gov/drugs/drug-approvals-and-databases/approved-drug-products-therapeutic-equivalence-evaluations-orange-book#:~:text=Section%20314.53(f)(1,information%20and%20the%20disputed%20patent. The FDA keeps an active list of disputed patents here: https://www.fda.gov/media/105080/download?attachment.

with the FTC's warnings.[51] Five companies declined to delist their patents.[52] On March 22, 2024, the FTC took a position on the merits of the claims in *Teva Pharmaceuticals USA, Inc. v. Amneal Pharmaceuticals, Inc.* The asserted patents in that case included the NDA holder's inhaler patents for its ProAir HFA that had been challenged by the FTC.[53] The generic challenger argued that the patents were improperly listed in the Orange Book, and moved the court to compel the NDA holder to delist the patents. The FTC's amicus brief urged the court to order delisting, and alerted the court that the patents asserted in the case were among those patents identified by the FTC as improperly listed.[54] The district court granted the motion to delist, and the FTC has recently submitted an amicus brief to the U.S. Court of Appeals for the Federal Circuit urging affirmance.[55]

18. On April 30, 2024, the FTC sent another round of warning letters to ten companies covering over 300 listed patents for injectable drugs, inhalers, and nasal sprays.[56] Four of these companies were not targets of the first round of letters. On March 6, 2024, the first putative class action was filed against one of the innovator companies the FTC had targeted in its letters.[57] Referencing the FTC's and lawmakers' initiatives, the Fund alleges that the NDA holder "*improperly submitted 23 device patents to the Orange Book as claiming Combivent Respimat*," as well as another 16 "*as claiming Spiriva Respimat*."[58] Similarly, on April 29, 2024, another putative class action complaint accused the same innovator company of a similar "scheme."[59]

51 *See* Company Responses to Senator Warren and Rep. Jayapal's Dec. 13, 2023, Letters to Pharmaceutical Companies (Jan. 10, 2024), https://www.warren.senate.gov/imo/media/doc/Drug%20Companies'%20Responses%20to%20Warren%20re%20Orange%20Book%20Patents.pdf; Press Release, Warren, Jayapal Announce Three Drug Manufacturers Pulled Sham Patents after Warnings, Urge FDA to Continue Fight Against Big Pharma Companies' Patent Abuse (Feb. 16, 2024), https://jayapal.house.gov/2024/02/16/jayapal-warren-announce-three-drug-manufacturers-pulled-sham-patents-after-warnings-urge-fda-to-continue-fight-against-big-pharma-companies-patent-abuse/.

52 Company Responses to Senator Warren and Rep. Jayapal's Dec. 13, 2023, Letters to Pharmaceutical Companies, *supra* note 51.

53 Brief for the Fed. Trade Comm'n as Amicus Curiae, *Mylan Pharmaceuticals, et al. v. Sanofi-Aventis, et al.*, *supra* note 5 (taking no position on whether the Lantus patents were improperly listed).

54 Brief for the Fed. Trade Comm'n as Amicus Curiae, *Teva Pharmaceuticals USA, Inc. v. Amneal Pharmaceuticals, Inc.*, *supra* note 5.

55 Brief for the Fed. Trade Comm'n as Amicus Curiae, *Teva Pharmaceuticals USA, Inc. v. Amneal Pharmaceuticals, Inc.*, No. 23-cv-20964 (Fed. Cr. Sept. 6, 2024), https://www.ftc.gov/system/files/ftc_gov/pdf/62-AMICUS-CURIAE-BRIEF-FILED.pdf.

56 Press Release, 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.

57 Complaint, *Massachusetts Laborers' Health & Welfare Fund v. Boehringer Ingelheim*, No. 24-cv-10565-DJC (D. Mass. Mar. 6, 2024), ECF No. 1, https://fingfx.thomsonreuters.com/gfx/legaldocs/gdvzdbjwxvw/BOEHRINGER%20PATENT%20LAWSUIT%20complaint.pdf.

58 Ibid.

59 Complaint, *1199SEIU National Benefit Fund et al. v. Boehringer Ingelheim Pharmaceuticals Inc. et al.*, No. 3:24-cv-00783 (D. Conn. Apr. 29, 2024), ECF No. 1, https://casefilingsalert.com/wp-content/uploads/2024/09/Boehringer-Ingelheim-Accused-of-Monopoly.pdf.

IV. The developing antitrust standard for allegedly improper Orange Book listings

19. This sudden and expansive regulatory action and the follow-on private class action complaints come after a recent pro-plaintiff shift in the legal standard applying to antitrust claims arising from allegedly improper Orange Book listings. Under the antitrust standard that is currently emerging from the First and Second Circuits, once a court makes a *de novo* and *ex post* determination that a patent should not have been listed, the burden shifts to the NDA holder—the antitrust defendant—to prove as an affirmative defense that it acted reasonably and in good faith in listing the challenged patent. The antitrust plaintiff need not prove any predatory intent or bad faith as part of its prima facie showing for an improper Orange Book listing to be deemed exclusionary for purposes of a monopolization claim. Before addressing the ramifications of this emerging standard, we briefly discuss the development of the law and the rationales underlying these holdings.

1. The application of antitrust immunities to Orange Book listings

20. In the early 2000s, during the initial wave of antitrust claims arising from allegedly improper Orange Book listings, courts grappled with the question whether such listings were entitled to some form of antitrust immunity, especially *Noerr-Pennington* immunity. The *Noerr-Pennington* doctrine provides that firms are immune from antitrust liability for any impact legitimate government petitioning has on competitors or competition.[60] The immunity derives from the First Amendment of the U.S. Constitution, which enshrined the right "*to petition the Government for a redress of grievances*."[61] To ensure the risk of antitrust liability does not chill the exercise of that right, *Noerr-Pennington* has been broadly extended to efforts to petition the legislative, executive, and judicial branches, including the initiation of litigation, but it does not extend to so-called sham petitions.[62] In the context

60 *United Mine Workers of Am. v. Illinois State Bar Ass'n*, 389 U.S. 217, 222 (1967); *Eastern Railroad Presidents Conference v. Noerr Motor Freight, Inc.*, 365 U.S. 127 (1961); *United Mine Workers v. Pennington*, 381 U.S. 657 (1965).

61 *United Mine Workers*, 389 U.S. at 222 (observing that the right to petition government for a redress of grievances is "*among the most precious of the liberties safeguarded by the Bill of Rights*").

62 *Prof. Real Estate Investors, Inc. v. Columbia Pictures Indus., Inc.*, 508 U.S. 49, 60 (1993).

of litigation, an antitrust plaintiff seeking to recover for injuries suffered from sham litigation must show, first and as a threshold matter, that the lawsuit was "*objectively baseless*," i.e., "*no reasonable litigant could realistically expect success on the merits*," and, second, that it was brought with the "*subjective motivation*" to use the litigation process "*as an anticompetitive weapon*."[63] Under this sham exception, the Supreme Court emphasized that a litigant's subject motivations should be examined only after the antitrust plaintiff proves the challenged litigation was "*objectively baseless*."[64] Another recognized exception to *Noerr-Pennington* immunity, specific to the patent context, is the *Walker Process* fraud exception, which applies when a patentee knowingly asserts a patent that had been procured by fraud on the Patent and Trademark Office.[65] To satisfy the *Walker Process* fraud exception to *Noerr-Pennington*, the elements of fraud (i.e., specific intent to deceive and materiality) must be proven by the antitrust plaintiff with clear and convincing evidence.[66]

21. In *In re Buspirone Patent Litigation* ("*Buspirone*"), a court in the U.S. District for the Southern District of New York was the first to address the question whether *Noerr-Pennington* applied to Orange Book listings such that antitrust plaintiffs would need to satisfy either the two-part sham test or the *Walker Process* fraud test.[67] There, the defendant NDA holder faced antitrust claims from both generic drugmakers and direct purchasers of buspirone.[68] The plaintiffs alleged that the NDA holder improperly listed a patent in the Orange Book less than one day before generic market entry was expected, and then immediately brought suit against generic producers, triggering Hatch-Waxman's automatic stay provision.[69] The plaintiffs claimed that the innovator company knew the late-listed patent did not qualify for Orange Book listing because it did not cover the approved use of buspirone and would have been invalid if it did.[70] The NDA holder moved to dismiss the federal and state antitrust claims, arguing that its patent filing to the FDA (i.e., submitting Form 3542 to the FDA) was protected conduct under the *Noerr-Pennington* doctrine.[71]

22. The district court held that an Orange Book listing is not a "*petitioning activity*" and therefore not protected under *Noerr-Pennington* because the FDA's role with respect to the Orange Book is "*merely ministerial.*"[72] The court found it was "*critical to distinguish between activities in which the government acts or renders a decision only after an independent review of the merits of a petition and activities in which the government acts in a merely ministerial or non-discretionary capacity in direct reliance on the representations made by private parties*."[73] It reasoned that *Noerr-Pennington* applies only when the anticompetitive effect results from private parties first "*convincing the government of the merits of their views and* (. . .) *obtaining a valid and independent governmental decision*."[74] The court also rejected the NDA holder's alternative argument that the Orange Book listing was "*inextricably bound up with its subsequent patent infringement suits,*" which are undoubtedly entitled to *Noerr-Pennington* immunity. The court concluded that the "*listing activity*" was "*distinct from its subsequent litigation both analytically and as a practical matter*," explaining the NDA holder "*could have listed* [the patent] *in the Orange Book without subsequently bringing infringement suits* (. . .)*, and* [it] *could have brought these suits without relying on its Orange Book listing*."[75]

23. Following *Buspirone*, at least two district courts rejected challenges to Orange Book listings, holding instead that it was the *Noerr-Pennington*-protected initiation of litigation that proximately caused the complained-of generic delay (from the 30-month stay), not the predicate Orange Book listing.[76] Most courts, however, followed *Buspirone* in holding that a party's decision to list a patent in the Orange Book does not enjoy *Noerr-Pennington* immunity.[77]

24. *Noerr-Pennington* immunity, however, was not the only type of antitrust immunity addressed in *Buspirone*. The NDA holder in that case also asserted that "*patent* [holders] *enjoy a qualified immunity when they act in good*

63 Ibid. at 60–61 (citing *City of Columbia v. Omni Outdoor Advertising, Inc.*, 499 U.S. 365, 380(1991)).

64 Ibid.

65 The Federal Circuit characterizes *Walker Process* as one of two ways (in addition to the sham exception) of piercing a patentee's *Noerr-Pennington* immunity. *See Nobelpharma AB v. Implant Innovations, Inc.*, 141 F.3d 1059, 1068 (Fed. Cir. 1998). In *Walker Process*, the Supreme Court held that a patentee may be liable under the Sherman Act if it maintains and enforces a patent obtained by fraud. *Walker Process Equip., Inc. v. Food Machinery & Chem. Corp.*, 382 U.S. 172, 176–177 (1965). The *Walker Process* holding, however, was not rooted in First Amendment principles. Rather, as Justice Harlan explained in his famous concurrence, the holding was "*aimed* (. . .) *at achieving a suitable accommodation* (. . .) *between the differing policies of the patent and antitrust laws*." Ibid. at 179 (Harlan, J., concurring). Justice Harlan explained that a finding of fraud was necessary for the imposition of antitrust liability because exposing patentees to the risk of treble damages merely because they sought to enforce a patent that was later found to be invalid "*might well chill the disclosure of inventions through the obtaining of a patent because of fear of the vexations or punitive consequences of treble damage suits*." Ibid. at 180.

66 *Nobelpharma AB v. Implant Innovations, Inc.*, 141 F.3d at 1073 (applying clear and convincing evidence standard).

67 *In re Buspirone Patent & Antitrust Litig.*, 185 F. Supp. 2d 363, 372–373 (S.D.N.Y. 2002).

68 Ibid. at 366.

69 Ibid.

70 Ibid.

71 Ibid. at 367.

72 *See* ibid. at 371 (finding that "*the FDA's actions are non-discretionary and do not reflect any decision as to the validity of the representations in an Orange Book listing*").

73 Ibid. at 369.

74 Ibid. at 370; *see also Allied Tube & Conduit Corp. v. Indian Head, Inc.*, 486 U.S. 492, 499 (1988) ("'[W]here a restraint upon trade or monopolization is the result of valid governmental action, as opposed to private action,' those urging the governmental action enjoy absolute immunity from antitrust liability for the anticompetitive restraint." (quoting *E. R. R. Presidents Conf. v. Noerr Motor Freight, Inc.*, 365 U.S 127, 136 (1961)).

75 *In re Buspirone*, 185 F. Supp. 2d at 372.

76 *Twin City Bakery Workers & Welfare Fund v. Astra Aktiebolag*, 207 F. Supp. 2d 221, 225 (S.D.N.Y. 2002); *In re Relafen Antitrust Litig.*, 360 F. Supp. 2d 166, 176 n.3 (D. Mass. 2005).

77 *See*, e.g., *Organon Inc. v. Mylan Pharmaceuticals, Inc.* ("*Remeron*"), 293 F. Supp. 2d. 453, 458 (D.N.J. 2003); *Rochester Drug Co-op., Inc. v. Braintree Lab'ys*, 712 F. Supp. 2d 308, 321 n.14 (D. Del. 2010) ("[T]*he court notes its agreement with the caselaw holding that 'improper listing' in the FDA's Orange Book is not an act of petitioning for Noerr–Pennington purposes*"). X

faith to protect their patent rights," relying on *Zenith Elecs. Corp. v. Exzec, Inc.*[78] In *Zenith*, the Federal Circuit had addressed the application of § 43(a) of the federal Lanham Act to non-petitioning, marketplace statements by a patentee concerning infringement of its patents.[79] The Federal Circuit focused on the tension between the Lanham Act's restrictions on misleading marketplace conduct and the patent law's preservation of a patentee's right to exercise patent rights.[80] In reaching what it described as a "*suitable accommodation*" (alluding to Justice Harlan's famous concurrence in *Walker Process*, see note 65), the Federal Circuit injected an additional "bad faith" requirement to a § 43(a) claim (which did not otherwise require a showing of bad faith).[81] The court ruled that "*imposing* [§] *43(a) liability on a patentee for marketplace statements regarding infringement and scope of its patent, assuming such statements otherwise satisfy the elements of* [§] *43(a), does not impermissibly conflict with the patent laws as long as the statements are proven to have been made in bad faith*."[82] The court in *Zenith* relied heavily on the Ninth Circuit's decision in *Handgards, Inc. v. Ethicon, Inc.*[83] That case, decided before the Supreme Court's decision extending *Noerr-Pennington* to all forms of litigation, held that antitrust liability could arise from patent enforcement only if were shown by clear and convincing evidence that the patentee acted in bad faith.[84] The Ninth Circuit dubbed this clear and convincing bad faith standard as the "proper balance" in the "*clash between the policies of patent and antitrust laws*."[85]

25. The district court in *Buspirone,* however, declined to dismiss the antitrust claims under this qualified patent immunity described in *Zenith* because, in the court's view, plaintiffs had alleged bad faith and that those allegations "*if proven, would be sufficient to strip* [the defendant] *of any qualified patent immunity*."[86] Thus, while the district court in *Buspirone* apparently concluded that the plaintiffs need not meet the recognized exceptions to *Noerr-Pennington* immunity, it seemingly contemplated that the plaintiffs would still need to prove the NDA holder acted in bad faith. The case eventually settled the following year, in November 2003.[87]

78 182 F.3d 1340, 1343 (Fed. Cir. 1999). Indeed, as discussed above, *supra* note 65, the *Walker Process* standard, requiring fraud on the Patent Office before subjecting a patentee to antitrust liability for enforcing a patent later invalidated, was based on a desire not to chill the exercise of patent rights, not the right to petition.

79 Ibid. at 1353.

80 Ibid.

81 Ibid.

82 Ibid. at 1354; *Fisher Tool Co., Inc. v. Gillet Outillage*, 530 F.3d 1063, 1069 (9th Cir. 2008) ("*But the Federal Circuit has held that where Lanham Act claims and state tort claims are based on a defendant's representation that someone infringed his patent, plaintiff must show that defendant's representation was made in bad faith. We adopt these holdings*"(citation omitted)).

83 601 F.2d 986 (9th Cir. 1979).

84 Ibid. at 996.

85 Ibid. at 995–996.

86 *In re Buspirone Patent Litig.*, 185 F. Supp. 2d 363, 377 (S.D.N.Y. 2002).

87 *See In re Buspirone Antitrust, et al.*, No. 1:01MD01413, ECF No. 171 (S.D.N.Y. Nov. 18, 2003).

2. The development of the governing standard

26. A year after *Buspirone*, a court in the U.S. District for the District of New Jersey, after agreeing that *Noerr-Pennington* did not provide antitrust immunity for Orange Book listings, nevertheless dismissed the antitrust claim after holding that the NDA holder had an objectively reasonable basis for listing the challenged patent.[88] In that case, the NDA holder allegedly listed a patent covering an unapproved ("off-label") use of its drug, Remeron.[89] The court held that the FDA regulations at the time were "*capable of two equally plausible interpretations*," one of which would require listing a patent covering even an off-label use of the approved drug.[90] That interpretation, according to the court, would "*not have been inconsistent*" with the broad language of the Orange Book listing statute in effect at the time, which simply required the listing of a patent that "*claims a method of using*" the approved drug.[91] The court in *Remeron* concluded: "[G] *iven the statutory and regulatory language at the time it submitted* [the patent] *for listing in the Orange Book,* [the NDA holder] *had a reasonable basis for the submission, and therefore,* [its] *listing was not improper*."[92]

27. Few courts after *Remeron* had occasion to address the standard applicable to improper Orange Book claims until, nearly fifteen years later, a court in the U.S. District for the District of Massachusetts applied the same objective reasonableness standard to dismiss antitrust claims directed at an Orange Book listing after concluding that the listing statute and relevant regulatory guidance created genuine ambiguity around whether the patent at issue should have been listed.[93] In that case, the NDA holder listed a patent claiming the "*drive mechanism*" of its Lantus Solostar product, an insulin glargine injector pen.[94] The question at that time, prior to the 2020 OBTA amendments to the listing statute, was whether the patent "*claimed the drug*."[95] While the court observed that the FDA had provided guidance that patents covering drug "*packaging*" should not be listed, it noted that the Lantus Solostar had received FDA approval as a "*drug delivery system*" inclusive of the patented drive mechanism, and that the FDA had required listing of patents claiming "*pre-filled drug delivery systems*."[96] The plaintiffs argued that the patent claiming the drive mechanism alone was not listable because it included no claim directed to the

88 *Remeron*, 293 F. Supp. 2d. at 458.

89 Ibid. at 455.

90 Ibid. at 460.

91 Ibid. at 459–460.

92 Ibid. at 460.

93 *In re Lantus Direct Purchaser Antitrust Litig.*, 284 F. Supp. 3d 91, 107 (D. Mass. 2018).

94 Ibid. at 99.

95 Ibid. at 97.

96 Ibid. at 104.

"*finished dosage form*."[97] The court, however, noted significant uncertainty in the industry over how to apply FDA guidance on this precise issue, leading several firms publicly to seek clarification from the FDA, which the FDA never provided.[98] The district court concluded: "*While this court makes no determination as to the correct interpretation of the FDA Comments, it is clear from these requests that the issue whether the '864 patent should have been listed is an open question in the industry*."[99] As a result, the court held the listing was "*reasonable*" and dismissed the antitrust claims premised on it.[100]

28. In February 2020, the U.S. Court of Appeals for the First Circuit reversed the district court.[101] The court in *Lantus* addressed the regulatory question first: "*whether, under the facts alleged by the plaintiffs, it was proper for* [the NDA holder] *to submit* [the patent] *for listing in the Orange Book*."[102] Interpreting the statute and regulations, the court concluded that, to "*claim the drug*" within the meaning of the statute, the patent must have a claim directed at the drug substance itself, which the drive mechanism patent at issue did not.[103] Having concluded the patent should not have been listed, the court then turned to the antitrust question. The defendant's position, adopted by the district court, was that an NDA holder cannot face antitrust liability for a patent listing that was objectively reasonable, even if incorrect.[104] The plaintiffs urged that the court hold that "*reasonableness is not a defense*."[105] The court of appeals charted a middle ground.

29. As a preliminary matter, the court recited long-standing precedent that, for a monopoly maintenance claim under Section 2 of the Sherman Act, courts "*examine the effects of a monopolist's improper conduct, rather than the reasons why it engaged in such conduct*," citing case law holding the "*focus*" in a Section 2 claim "*is upon the effect of* [the] *conduct*."[106] But the court went on to survey cases recognizing a regulatory compliance defense.[107] In particular, the court discussed Seventh Circuit law, developed in cases involving telecommunication regulations, holding that an antitrust defendant "*is entitled both to raise and to have the jury consider its good faith adherence to regulatory obligations as a legitimate antitrust defense*."[108] While the NDA holder had advocated for a standard requiring plaintiffs to establish that the listing was unreasonable, the court of appeals adopted the Seventh Circuit approach, which placed the burden on the antitrust defendant to prove, as an affirmative defense, that the regulated conduct was both reasonable and done in good faith.[109] As to reasonableness, the court of appeals explained that regulatory ambiguity and industry custom and practice are relevant, but stressed that the district court must scrutinize intent, nonetheless.[110] The First Circuit in *Lantus* then remanded the case back to the district court to proceed in accordance with that standard.

30. In 2021, the U.S. Court of Appeals for the Second Circuit largely aligned itself with the First Circuit's analysis, affirming a district court's conclusion that an antitrust plaintiff, after sufficiently alleging that the challenged patent was wrongly listed, need not plead or prove that the NDA holder acted in bad faith by listing it.[111] There, the district court concluded (as the First Circuit would several months later, see *supra*) that, to the extent good faith supplied a defense to the NDA holder, it would be an affirmative defense for which the defense bore the burden.[112] In that case, the district court concluded, after extensive analysis, that patents covering combination therapies should not have been listed as "claiming the drug" where the drug at issue (Actos) comprised just one of the active ingredients in the patented combination.[113] The Second Circuit agreed.[114] The Second Circuit also agreed with the district court that "*bad faith*" is not an element of plaintiffs' prima facie antitrust case.[115] The Second Circuit rooted its affirmance in the basic elements of a Section 2 monopoly maintenance claim, which requires only "*(1) the possession of monopoly power in the relevant market and (2) the willful acquisition or maintenance of that power as distinguished from growth or development as a consequence of a superior product, business acumen, or historic accident*."[116] Based on these elements, the court of appeals rejected the NDA holder's argument that plaintiffs' "*claim fails because they cannot show* (. . .) *that the listing decision was unreasonable*."[117] The court reasoned that "*willfulness*" under Section 2 requires only "*mere intent to do the act*," and that "*benign intent does not shield anticompetitive conduct*

97 Ibid.

98 Ibid.

99 Ibid. at 107.

100 Ibid.

101 *In re Lantus Direct Purchaser Antitrust Litig.* ("*Lantus*"), 950 F.3d 1, 3–4 (1st Cir. 2020).

102 Ibid. at 7.

103 Ibid. at 8.

104 Ibid. at 10.

105 Ibid.

106 Ibid. at 10 (citing *United States v. Microsoft Corp.*, 253 F.3d 34, 60 (D.C. Cir. 2001)).

107 Ibid. at 12.

108 Ibid. (quoting *MCI Commc'ns Corp. v. Am. Tel. & Tel. Co.*, 708 F.2d 1081, 1109–1010 (7th Cir. 1983)).

109 Ibid. at 13 (citing *MCI Commc'ns*, 708 F.2d at 1138 (framing the defense as requiring the antitrust defendant to prove that it "'*at the time had a reasonable basis in regulatory policy to conclude, and in good faith concluded' that its actions were required by regulation*")).

110 Ibid. at 13–14.

111 *United Food & Co. Workers Loc. 1776 & Participating Emps. Health & Welfare Fund v. Takeda Pharm. Co.* ("*United Food*"), 11 F.4th 118 (2d Cir. 2021), *affirming In re Actos End-Payor Antitrust Litig.* ("*Actos*"), 417 F. Supp. 3d 352 (S.D.N.Y. 2019).

112 *Actos*, 417 F. Supp. 3d at 372.

113 Ibid. at 369.

114 *United Food*, 11 F.4th at 136.

115 *Actos*, 417 F. Supp. 3d at 370.

116 *United Food*, 11 F.4th at 137 (quoting *United States v. Grinnell Corp.*, 384 U.S. 563, 570–571 (1966)).

117 Ibid. at 136.

from liability" in a monopolization claim.[118] Thus, the court of appeals in *Actos* concluded plaintiffs need only to allege that the NDA holder "*had market power and that it incorrectly listed its combination patents as claiming ACTOS, causing their antitrust injuries*" to state a claim and survive dismissal.[119]

V. The emerging antitrust standard: Implications and open questions

31. As discussed above, the emerging standard from the First and Second Circuits 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, and if the plaintiff establishes the other substantive elements of the claim (for example, in the context of a private antitrust claim for damages, the possession of monopoly power, causation, and antitrust injury), 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. Although antitrust claims premised on allegedly improper Orange Book claims are not new, this appellate standard is. The extent to which this emerging standard will be adopted by courts outside the First and Second Circuits, or how it will be applied to different fact patterns even within those circuits, remains unclear. But as these initial cases—*Lantus* and *Actos*—proceed at the district court on remand, some important implications of this emerging standard have become clear. We conclude by briefly discussing these observations.

1. Adoption of the *Lantus* and *Actos* standards

32. It remains to be seen whether the antitrust defense bar will be able to blunt the momentum currently behind the emerging standard. To date, no other court of appeals has weighed in on the proper standard to apply when determining whether an Orange Book listing is actionable exclusionary conduct, but recently, on May 24, 2024, a court in the U.S. District for the District of Delaware followed the Second Circuit's *Actos* decision and held that the antitrust plaintiff in that case need not allege the NDA holder "*lacked a reasonable basis for listing*" the challenged patent.[120] In so holding, the court noted the in-circuit 2003 *Remeron* decision, but found that decision unpersuasive because "*the court in* [*Remeron*] *did not explain why a defendant's reasonable basis for listing means that such a listing was 'proper.'*"[121]

33. Despite that current momentum, a circuit split may yet develop. As discussed above, the emerging standard is premised on the predicate conclusions that (i) Orange Book listings are not "petitioning activity" within the meaning of the First Amendment right to petition, (ii) the standard prima facie elements of monopoly maintenance and unfair competition claims do not include bad faith or intent, and (iii) the regulatory compliance defense has developed as an affirmative defense for which the antitrust defendant bears the burden. At the same time, however: (i) *Walker Process*, *Handgards* and *Zenith* have based antitrust immunity not on the right to petition under the First Amendment, but rather on the importance of not chilling the exercise of patent rights more generally;[122] (ii) the Federal Circuit has injected a "bad faith" element that did not otherwise exist into another federal statute (the Lanham Act) to preserve those patent rights in that context; and (iii) the burden-shifting approach historically applied to the regulatory compliance defense did not involve regulations that concerned the exercise of patent rights. Certainly, imposing a "bad faith" element would not bar the FTC from reaching the type of regulatory "*abuse*" and "*weaponiz*[ation]" it addressed in its Policy Statement.

34. Furthermore, even if courts are persuaded by the rationale behind the First and Second Circuit decisions as applied to the Orange Book claims at issue in those, they may not be when confronted with different fact patterns. The FTC's recent enforcement focus and the allegations in both *Lantus* and *Actos* involve patents of a type that allegedly should not be listed (i.e., because those patents allegedly did not claim the drug or a method of using the drug within the meaning of the relevant statute and regulations). But private litigants have historically, although certainly less frequently, challenged Orange Book listings on the grounds that a "reasonable claim of infringement" could not be made, even if the patents were otherwise of a type that should be listed. For example, private plaintiffs have alleged that patents were improperly listed in the Orange Book because they were allegedly known to be invalid or procured by fraud on the Patent and Trademark Office (PTO).[123] In normal cases, antitrust plaintiffs bear the high burden of proving those types of allegations with clear and convincing evidence before antitrust liability can attach.[124] Courts may well balk at changing that in the context of pharmaceutical patent litigation.

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118 Ibid. at 137 (citing *In re Lipitor Antitrust Litig.*, 868 F.3d 231, 263 (3d Cir. 2017)).

119 Ibid. at 138.

120 *Jazz Pharmaceuticals, Inc. v. Avadel CNS Pharmaceuticals, LLC*, 2024 WL 2700031 (D. Del. May 24, 2024).

121 Ibid. at *3.

122 *See Handgards, Inc. v. Ethicon, Inc.*, 601 F.2d 986, 998 (9th Cir. 1979).

123 *See*, e.g., *In re DDAVP Indirect Purchaser Antitrust Litig.*, 903 F. Supp. 2d 198, 217 (S.D.N.Y. 2012).

124 *Microsoft Corp. v. i4i Limited Partnership*, 564 U.S. 91 (2011).

2. Privilege waivers under the emerging standard

35. Under the emerging standard, once a court retroactively decides a patent should not have been listed in the Orange Book, the burden shifts to the antitrust defendant to prove that the listing was both objectively reasonable and subjectively done in good faith. The need to prove affirmatively one's good faith (as opposed to denying bad faith) may, from a practical matter, lead the antitrust defendant to feel obligated to waive the privilege to demonstrate its good faith. After all, in both *Lantus* and *Actos*, the courts assessed the correctness of the patent listing through some combination of patent claim construction and statutory and regulatory interpretation. Because patent listing questions turn on those types of determination, it should be no surprise that most patent listing decisions are infused with legal advice.

36. In *Lantus*, on remand, the NDA holder decided voluntarily to waive privilege so that it could properly assert the regulatory compliance defense. This waiver resulted in litigation over the scope of the privileged information the NDA holder must turn over in discovery. The NDA holder sought to cabin its waiver to any advice from regulatory counsel, and not litigation counsel.[125] The plaintiffs argued that the waiver also necessarily included advice from litigation counsel because, among other things, improper listing was at issue in one of the three underlying infringement litigation and litigation counsel and opinion counsel consulted each other.[126] The court ultimately held that Sanofi must turn over documents from litigation counsel, but only as to the underlying infringement litigation.[127]

37. In *Actos*, the NDA holder similarly proceeded with a regulatory compliance defense, asserting "*the advice of counsel that the pre-2003 listing regulations applied to* [its] *listing decision*," but sought to withhold some categories of documents on the grounds that they were not within the scope of their waiver.[128] The plaintiffs moved to compel production of "*all documents relating to* [the NDA holder's] *state of mind* (. . .) *including its actual motives or intent*" with regard to the challenged conduct.[129] Specifically, they sought documents regarding: (i) patent analysis, i.e., documents reflecting the NDA holder's analysis of Actos-related patents, the regulations governing their listing and description, and the consequences of the NDA holder's listings on generic entry; and (ii) prior patent litigation and settlement strategy/negotiations.[130] The NDA holder responded that the documents at issue went beyond the narrow scope of its subject matter waiver because they implicated other subjects distinct from its compliance with the pre-2003 regulations. The court agreed with plaintiffs in part and ordered broader production of all privileged communications concerning the decision to list and subsequent decisions to affirm listing.

38. But the court rejected the plaintiffs' waiver arguments concerning litigation strategy, patent infringement analysis, and advice concerning Paragraph IV certifications and other regulatory requirements for the NDA. It explained that limiting the scope of the waiver as the NDA holder defined would prejudice plaintiffs by "*potentially shield*[ing] *communications at the heart of whether* [the NDA holder] *acted in good faith, which* [it] *has placed at issue in its regulatory compliance defense*."[131] The court held that the NDA holder's voluntary, express waiver required the production of "*all documents which formed the basis for the legal advice regarding this subject matter, all documents considered by counsel in rendering that advice, and all reasonably contemporaneous documents reflecting discussions by counsel or others concerning that advice* [and] (. . .) *all documents that would otherwise have been protected under the work product doctrine that reflect or concern the subject matter of its waiver*."[132]

39. According to the court, "*fairness considerations*" required that the scope of the waiver also include "*any communications, as well as any documents reflecting communications, between* [the NDA holder] *and its counsel, relating to* [its] *decision to list the '584 Patent and '404 Patent as claiming ACTOS and subsequent decisions to reaffirm the listings for such patents*."[133]

40. Thus, these two initial cases proceeding under the emerging standard have demonstrated that defendants asserting the regulatory compliance defense likely will find it necessary to waive privilege, that plaintiffs will aggressively seek to expand the scope of the privilege waiver, and courts are reluctant to endorse excessively narrow waivers of privilege.

3. Causation may still prove a challenge to plaintiffs

41. The focus of the relevant case law has been on whether a patent listing should be deemed "improper" and thereby actionable under the antitrust laws, but there will always remain the distinct question whether an allegedly improper Orange Book had or will have any impact on competition. A plaintiff seeking damages for alleged monopolization must establish that the Orange Book listing caused it to suffer antitrust injury—e.g., that the listing delayed the entry of generic competition, causing lost profits (to the generic) or overcharge pricing

125 *In re Lantus Direct Purchaser Antitrust Litig.*, 578 F. Supp. 3d 211, 213 (D. Mass. 2021).

126 Ibid. at 215–216.

127 Ibid. at 213.

128 *In re Actos Antitrust Litig.*, 628 F. Supp. 3d 524, 532 (S.D.N.Y. 2022) (citation omitted).

129 Ibid. at 531.

130 Ibid. at 536.

131 Ibid. at 537.

132 Ibid. at 535.

133 Ibid. at 536.

(to purchasers). Even if judged "improper," however, it remains possible (and, indeed, may often be the case) that the single patent listing in the Orange Book had no impact on when generics ultimately enter the market.

42. As discussed above, the FTC's primary theory of competitive harm (and the theory of causation and antitrust injury in most private rights of action) is that, but for the improper Orange Book listing, the automatic regulatory litigation stay would not have delayed generic entry. But an allegedly improper Orange Book listing may be one of many unexpired patents listed in the Orange Book, meaning the 30-month litigation stay would have been invoked even if the challenged patent had not been listed. Similarly, the generic applicant or applicants may have encountered other bars to regulatory approval (such as manufacturing issues). The FTC's alternative theory of competitive harm—that the mere presence of the patent (or the additional patent) in the Orange Book would serve as a disincentive for the prospective generic even to invest in the product opportunity— may be difficult to prove as anything more than speculation. Indeed, there may be scenarios where generic applicants are more likely to challenge patents if they are listed in the Orange Book and thus can be litigated before the generic launches its product and incurs substantial exposure in the form of patent damages.[134]

VI. Conclusion

43. The FTC's recent and intense focus on Orange Book listings has and will continue to have the intended effect of causing innovator companies to scrutinize their own patent listings. The wave of private litigation likely to follow, combined with the currently emerging standard from the First and Second Circuits, will also elevate the risk of litigation and potential exposure. Nevertheless, even though antitrust claims premised on Orange Book listings are not new, the focus and governing precedent are, and much remains to be seen as to how the law will develop and how these cases will be litigated. ■

134 *In re Ciprofloxacin Hydrochloride Antitrust Litig.*, 261 F. Supp. 2d 188, 251 (E.D.N.Y. 2003) ("*Because of the Hatch-Waxman scheme, Barr's exposure in the patent litigation was limited to litigation costs, but its upside—exclusive generic sales—was immense*"); *In re Lipitor Antitrust Litig.*, 2013 WL 4780496, at *2 (D.N.J. Sept. 5, 2013) (noting that the Hatch-Waxman litigation process "*allows the generic manufacturer to litigate patent validity and infringement to avoid facing an 'at risk' product launch and exposure to substantial damages*"), *rev'd and remanded*, 868 F.3d 231 (3d Cir. 2017).

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