UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY

TEVA BRANDED PHARMACEUTICAL PRODUCTS R&D, INC., NORTON (WATERFORD) LTD., AND TEVA PHARMACEUTICALS USA, INC. Plaintiffs, v. AMNEAL PHARMACEUTICALS OF NEW YORK, LLC, AMNEAL IRELAND LIMITED, AMNEAL PHARMACEUTICALS LLC, AND AMNEAL PHARMACEUTICALS INC. Defendants.	Civil Action No. 2:23-cv-20964-JXN-MAH

FEDERAL TRADE COMMISSION'S BRIEF AS AMICUS CURIAE

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INTRODUCTION

Listing a patent in the Orange Book gives a brand pharmaceutical company a powerful tool—the ability to trigger a 30-month stay of approval of a generic competitor product. The Federal Trade Commission (FTC or Commission) has a long history of working to address improper Orange Book patent listings because of how those listings thwart competition from lower-cost generic drugs.

Amneal alleges that Teva's improper listing of patents for dose counters and inhaler devices in the Orange Book is delaying entry of its less expensive generic asthma inhalers from summer 2024 to early 2026.[1] Millions of Americans rely on asthma inhalers for life-saving treatment, and the patent on the active ingredient in many asthma inhalers—albuterol—expired in 1989. Although albuterol has long been off-patent, there remains little generic competition in the market for asthma inhalers, in part because brand manufacturers improperly list patents that claim device-related aspects of asthma inhalers, like dose counters, to block competition. As a result, asthma inhalers often cost hundreds of dollars, although they would likely cost significantly less in a more competitive market.

Because improper Orange Book listings can effectively block competition, Congress carefully prescribed what types of patents must be listed in the Orange

[1] *See* Def.'s Answer, Affirmative Defenses, and Countercl. to Pl.s' First Am. Compl., ECF No. 12 ¶¶ 121-22, 130 ("Amneal Countercl."). At this stage in the proceedings, these allegations are accepted as true.

Book, permitting only drug substance, drug product, and method of use patents on Food and Drug Administration (FDA) approved drugs to be listed. Here, however, Teva has triggered a 30-month stay based on inhaler and dose counter device patents that, on their face, are not specific to any FDA-approved drug. Indeed, one of the asserted patents (U.S. Patent No. 10,561,808) has been listed in the Orange Book for 21 different products spanning six separate new drug applications (NDA) and four active ingredients.[2]

In the FTC's view, device patents that do not mention any drug in their claims do not meet the statutory criteria for Orange Book listing, and a device patent that is improperly listed in the Orange Book must be delisted. Should a brand manufacturer not voluntarily delist an improperly listed device patent, it is well within the powers of a district court to compel delisting. Here, Teva has listed device patents in the Orange Book that do not mention any drug in their claims. If the Court agrees that such patents do not meet the listing requirements, it should grant Amneal's motion for judgment on the pleadings and order Teva to delist the patents at issue—clearing the way for Americans to access less expensive asthma inhalers.

[2] *See* U.S. Dep't Health & Hum. Servs., Food & Drug Admin., *Approved Drug Products with Therapeutic Equivalence Evaluations* ADA 7, 39-40, 178-188 (44th ed. 2024) ("Orange Book").

Teva's arguments opposing delisting are unavailing and inconsistent with the statute. Indeed, in a strikingly similar case, the First Circuit rightly held it improper to list a device patent that did not mention the active ingredient or the drug product in the claims. Moreover, Teva's novel argument that the delisting provision immunizes its conduct from the antitrust laws is wrong. Courts and the FTC, the expert body charged with protecting fair competition in pharmaceutical markets, have long recognized that improper Orange Book listings can be actionable under the antitrust laws.

INTEREST OF THE FEDERAL TRADE COMMISSION

The FTC is an independent agency charged by Congress with enforcing competition and consumer protection laws.[3] It exercises primary responsibility for federal antitrust enforcement in the pharmaceutical industry.[4] The Commission has substantial experience evaluating pharmaceutical competition under the Hatch-Waxman Act and has brought numerous enforcement actions challenging anticompetitive abuses of the Hatch-Waxman framework.[5]

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[3] 15 U.S.C. §§ 41-58.

[4] For a recent summary of the FTC's actions in the pharmaceutical industry, *see* Bradley S. Albert et al., Overview of FTC Actions in Pharm. Products and Distrib., Fed Trade Comm'n (Jan. 2024), https://www.ftc.gov/system/files/ftc_gov/pdf/Overview-Pharma.pdf.

[5] *See, e.g.*, *FTC v. Actavis, Inc.*, 570 U.S. 136 (2013); *King Drug Co. of Florence, Inc. v. Cephalon, Inc.*, 88 F. Supp. 3d 402 (E.D. Pa. 2015); *Impax Labs, Inc. v. FTC*, 994 F.3d 484 (5th Cir. 2021); *FTC v. AbbVie Inc.*, 976 F.3d 327 (3d Cir. 2020); *FTC v. Shkreli*, 581 F. Supp. 3d 579 (S.D.N.Y. 2022).

The FTC has long been concerned about abusive Orange Book listings because of how improper listings may delay and deter competition from less expensive generic drugs. The Commission first examined the effect of Orange Book listings on competition as part of a 2002 study, identifying numerous instances in which companies used the 30-month stay to block competition.[6] Around the same time, the FTC successfully settled an action under the antitrust laws against Biovail Corporation for, among other things, wrongfully listing a patent in the Orange Book to block generic competition.[7]

The FTC has also regularly filed amicus briefs in private litigation, explaining how improper Orange Book listings can violate the antitrust laws.[8] In September 2023, the FTC issued a policy statement, supported by the FDA, warning that improperly listing patents in the Orange Book may constitute illegal

[6] *See* Fed. Trade Comm'n, Generic Drug Entry Prior to Patent Expiration: An FTC Study, 39-52 (2002) ("FTC Study on Generic Drug Entry Before Patent Expiration"), https://www.ftc.gov/reports/generic-drug-entry-prior-patent-expiration-ftc-study.

[7] Decision & Order, *In re Biovail Corp.*, FTC Dkt. No. C-4060 8 (Oct. 2, 2002).

[8] *See* Mem. of Law for Fed. Trade Comm'n as Amicus Curiae, *In re: Buspirone Patent Litig.*, No. 1:01-md-1410, ECF No. 31 (S.D.N.Y. Jan. 8, 2002); Mem. of Law for Fed. Trade Comm'n as Amicus Curiae, *Jazz Pharms., Inc. v. Avadel CNS Pharms., LLC*, No. 1:21-cv-691, ECF No. 227 (D. Del. Nov. 15, 2022); Mem. of Law for Fed. Trade Comm'n as Amici Curiae, *Mylan Pharms. Inc. v. Sanofi-Aventis U.S. LLC*, No. 2:23-cv-00836, ECF No. 64 (W.D. Pa. Nov. 21, 2023).

monopolization under section 2 of the Sherman Act as well as an unfair method of competition under section 5 of the FTC Act.[9]

Last November, the FTC's Bureau of Competition sent warning letters to ten drug manufacturers notifying them of more than 100 Orange Book patent listings that FTC staff believes to be improper ("warning letters").[10] The warning letters identified patents listed on 13 inhaler products and four epinephrine injector pens, among other FDA-approved products. Two of the warning letters were sent to Teva and identified the five patents at issue in this case (the "asserted patents") as

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[9] *See* Fed. Trade Comm'n, Federal Trade Commission Statement Concerning Brand Drug Manufacturers' Improper Listing of Patents in the Orange Book, at 5-6 (Sept. 14, 2023) ("FTC Orange Book Policy Statement"), https://www.ftc.gov/system/files/ftc_gov/pdf/p239900orangebookpolicystatement092023.pdf; *see also* Fed. Trade Comm'n, Press Release, FTC Issues Policy Statement on Brand Pharmaceutical Manufacturers' Improper Listing of Patents in the Food and Drug Administration's 'Orange Book' (Sep. 14, 2023) ("FTC Press Release re: Orange Book Policy Statement"), https://www.ftc.gov/news-events/news/press-releases/2023/09/ftc-issues-policy-statement-brand-pharmaceutical-manufacturers-improper-listing-patents-food-drug ("The FDA appreciates and supports the FTC's efforts to examine whether brand drug companies are impeding generic drug competition by improperly listing patents in the Orange Book,' said FDA Commissioner Robert M. Califf, M.D.").

[10] *See* Fed. Trade Comm'n, Press Release, FTC Challenges More Than 100 Patents As Improperly Listed in the FDA's Orange Book (Nov. 7, 2023) (FTC Press Release re: Improper Orange Book Listings"), https://www.ftc.gov/news-events/news/press-releases/2023/11/ftc-challenges-more-100-patents-improperly-listed-fdas-orange-book.The patents identified in the warning letters should not be interpreted as an exclusive or exhaustive list of patents that the FTC believes are wrongfully listed, and companies that did not receive a letter in November 2023 should not assume the FTC views their listings as proper. The FTC continues to scrutinize whether additional patents are improperly listed, and all companies have an ongoing responsibility to ensure their listings are lawful.

well as 37 additional Teva patent listings on inhalers.[11] The letters notified Teva and other drug companies that the FTC was utilizing FDA's regulatory patent listing dispute process to challenge the improper listings, while retaining the right to take further action against the companies that the public interest may require, including investigating the conduct as an unfair method of competition under section 5 of the FTC Act.

In response to the warning letters, several companies, including GlaxoSmithKline, Kaleo, Inc., and Impax Laboratories LLC, delisted 14 patents across six NDAs. Meanwhile, AstraZeneca, Boehringer Ingelheim, and GlaxoSmithKline announced that they would reduce patient out-of-pocket costs for all of their asthma inhalers to $35 a month.[12] Following the warning letters,

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[11] *See* Letter from Rahul Rao, Dep. Dir., Bur. Competition, Fed. Trade Comm'n to Teva Branded Pharm. Prods. R&D, Inc. Regarding Improper Orange Book-Listed Patents for QVAR 40, ProAir HFA, ProAir DigiHaler (Nov. 7, 2023) ("Teva Warning Letter"), https://www.ftc.gov/system/files/ftc_gov/pdf/teva-branded-pharma-orange-book.pdf (disputing propriety of 35 patent listings, comprised of 18 patents across 3 inhaler products); Letter from Rahul Rao, Dep. Dir., Bur. Competition, Fed. Trade Comm'n to Norton (Waterford) Ltd. Regarding Improper Orange Book-Listed Patents for QVAR RediHaler (Nov. 7, 2023) ("Norton Warning Letter"), https://www.ftc.gov/system/files/ftc_gov/pdf/norton-orange-book.pdf (disputing propriety of 7 patent listings on 1 inhaler product).

[12] *See* Press Release, AstraZeneca, AstraZeneca caps patient out-of-pocket costs at $35 per month for its US inhaled respiratory portfolio (Mar. 18, 2024), https://www.astrazeneca-us.com/media/press-releases/2024/astrazeneca-caps-patient-out-of-pocket-costs-at-35-per-month-for-its-us-inhaled-respiratory-portfolio.html; Press Release, Boehringer Ingelheim, Boehringer Ingelheim caps patient out-of-pocket costs for its inhaler portfolio at $35 per month (Mar. 7,

numerous members of Congress also launched inquiries into the drug companies' Orange Book listings and other potentially anticompetitive practices.[13]

The warning letters to Teva explained FTC staff's belief that the patents at issue in this case—plus many others—are improperly listed in the Orange Book.

2024), https://www.boehringer-ingelheim.com/us/press-releases/boehringer-ingelheim-caps-patient-out-of-pocket-costs-inhaler-portfolio; Press Release, GlaxoSmithKline, GSK announces cap of $35 per month on U.S. patient out-of-pocket costs for its entire portfolio of asthma and COPD inhalers (Mar. 20, 2024), https://us.gsk.com/en-us/media/press-releases/gsk-announces-cap-of-35-per-month-on-us-patient-out-of-pocket-costs-for-its-entire-portfolio-of-asthma-and-copd-inhalers. While the Commission welcomes voluntarily reductions in patients' out-of-pocket costs, doing so is not a substitute for removing improper patent listings, as such listings may delay competition from generics with lower list prices.

[13] *See* Press Release, U.S. Sen. Comm. On Health, Educ. Labor and Pensions, Chairman Sanders, Baldwin, Luján, Markey Launch HELP Committee Investigation into Efforts by Pharmaceutical Companies to Manipulate the Price of Asthma Inhalers (Jan. 8, 2024), https://www.help.senate.gov/chair/newsroom/press/news-chairman-sanders-baldwin-lujan-markey-launch-help-committee-investigation-into-efforts-by-pharmaceutical-companies-to-manipulate-the-price-of-asthma-inhalers; Letter from Sen. Bernie Sanders et al. to Pascal Soriot, Exec. Dir. & Chief Exec. Off., AstraZeneca PLC (Jan. 8, 2024), https://www.sanders.senate.gov/wp-content/uploads/2024.01.08-HELP-Committee-Letter-to-AstraZeneca.pdf; Letter from Sen. Bernie Sanders et al. to Hubertus von Baumbach, Chairman of the Bd. Of Managing Dirs., Boehringer Ingelheim Int'l GmbH (Jan. 8, 2024), https://www.sanders.senate.gov/wp-content/uploads/2024.01.08-HELP-Committee-Letter-to-Boehringer-Ingelheim.pdf; Letter from Sen. Bernie Sanders et al. to Emma Walmsley, Chief Exec. Off., GSK (Jan. 8, 2024), https://www.sanders.senate.gov/wp-content/uploads/2024.01.08-HELP-Committee-Letter-to-Boehringer-Ingelheim.pdf; Letter from Sen. Bernie Sanders et al. to Richard Francis, Pres. & Chief Exec. Off., Teva Pharm. Indus. Ltd. (Jan. 8, 2024), https://www.sanders.senate.gov/wp-content/uploads/2024.01.08-HELP-Committee-Letter-to-Teva.pdf.

Rather than heed this warning, Teva re-certified the propriety of the 42 patent-listings identified in the warning letter, including each of the five patents listed for ProAir HFA that Teva asserts in this case.[14] Moreover, Teva re-certified those Orange Book listings despite the underlying device patents' failure to mention any drug at all in their claims. According to Amneal's counterclaims, Teva is using these improper Orange Book listings to restrict competition and delay Amneal from making less expensive generic inhalers available to the American public.[15]

The FTC submits this amicus brief because device patents improperly listed in the Orange Book can undermine fair competition, shutting out generics from the market and depriving Americans of access to lower-cost drugs.[16]

BACKGROUND

I. The Statutory and Regulatory Framework

Congress passed the Drug Price Competition and Patent Term Restoration Act of 1984, known as the Hatch-Waxman Act,[17] with the aim of "balanc[ing] two

[14] *See* Teva Warning Letter, *supra* note 11; Norton Warning Letter, *supra* note 11.
[15] Amneal Countercl., ECF No. 12 ¶¶ 101-05; 120-25.
[16] As the FTC stated in its policy statement, the Commission will "use all its tools to halt unlawful business practices that contribute to high drug prices." FTC Orange Book Policy Statement, *supra* note 9. In filing this amicus brief, the FTC does not disclaim or waive its right to bring an enforcement action against Teva or any other company that the FTC believes may continue to improperly list patents in the Orange Book.
[17] Pub. L. No. 98-417, 98 Stat. 1585 (1984).

competing interests."[18] On the one hand, the Hatch Waxman Act "encourag[es] research and innovation" by protecting brand drug companies' patent interests associated with drugs approved through the NDA.[19] On the other, the Act seeks to facilitate getting lower-cost "generic drugs on the market in a timely fashion"[20] through mechanisms like the abbreviated new drug application (ANDA), which provides an expedited pathway for approval of generic drugs.[21]

The Hatch-Waxman framework includes provisions "that encourage the quick resolution of patent disputes" for certain types of patents.[22] The Hatch-Waxman amendments and FDA regulations instruct brand manufacturers to submit information about certain patents for their NDA products to the FDA for publication in a compendium entitled "Approved Drug Products with Therapeutic Equivalence Evaluations," commonly referred to as the "Orange Book."[23] Listing a patent in the Orange Book can be extremely valuable because it gives brand

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[18] *In re Lantus Direct Purchaser Antitrust Litig.*, 950 F.3d 1, 5 (1st Cir. 2020) (citing Applications for FDA Approval to Market a New Drug: Patent Submission and Listing Requirements and Application of 30-Month Stays on Approval of Abbreviated New Drug Applications Certifying That a Patent Claiming a Drug Is Invalid or Will Not Be Infringed, 68 Fed. Reg. 36676 (June 18, 2003)

[19] *Id.*

[20] *Id.* at 11 (citing 68 Fed. Reg. at 36676).

[21] *See* 21 U.S.C. § 355(j).

[22] *AbbVie*, 976 F.3d at 339.

[23] *See Caraco Pharm. Labs., Ltd. v. Novo Nordisk A/S*, 566 U.S. 399, 405-6 (2012).

manufacturers the power to trigger an automatic delay of FDA approval of competing generic products, generally for 30 months.

When a drug company seeks to market a generic version of a brand drug for which there are patents listed in the Orange Book, the company must provide a "certification" for each listed patent "which claims the listed drug . . . or which claims a use for such listed drug for which the applicant is seeking approval."[24] For non-expired patents, the generic company can file a "paragraph IV" certification asserting that the brand company's patent is invalid or will not be infringed by the generic drug.[25] Notice of the certification triggers an immediate right for the brand manufacturer to sue for infringement.[26] When a brand manufacturer brings such an infringement suit within 45 days after receiving notice for a patent that was submitted to FDA prior to the submission of the ANDA, as Teva did here, the FDA's approval of the generic manufacturer's ANDA is automatically stayed for

[24] 21 U.S.C. 355(j)(2)(A)(vii); *see also* 21 C.F.R. § 314.95(a).

[25] *See* 21 U.S.C. § 355(j)(2)(A)(vii). If the generic is not contending the patents are invalid or not infringed, it would simply file a "paragraph III" certification signifying it will wait to come to market until patent expiry. *See id.*

[26] There is no right to file an infringement suit in response to a paragraph IV certification if the patent was obtained by fraud on the U.S. Patent and Trademark Office or if the infringement suit would be objectively baseless. *See*, *e.g.*, *AbbVie Inc.*, 976 F.3d at 361 ("[W]e must not immunize a brand-name manufacturer who uses the Hatch-Waxman Act's automatic, 30-month stay to thwart competition. Doing so would excuse behavior that Congress proscribed in the antitrust laws.").

30 months.[27] Unlisted patents can still be enforced after the generic product launches.[28]

Given the significant consequences of listing a patent in the Orange Book, Congress put strict limits on the types of patents that may be listed. The Hatch-Waxman Act included Orange Book listing provisions that require brand manufacturers to submit listing information for specific types of patents.[29] For over two decades, FDA regulations have further specified that patents eligible for listing "consist of drug substance (active ingredient) patents, drug product (formulation and composition) patents, and method-of-use patents."[30] More recently, Congress enacted the Orange Book Transparency Act of 2020 (OBTA), which amended the listing provisions to state that a patent should be listed only if a "claim of patent infringement could reasonably be asserted" and the patent:

> (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

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[27] 21 U.S.C. § 355(j)(5)(B)(iii). If the patent is held infringed, that stay of approval is automatically extended until the patent's expiration date; *compare eBay Inc. v. MercExchange, L.L.C.*, 547 U.S. 388, 390-1 (2006) (holding prevailing patent plaintiff must normally meet traditional four-factor test to obtain permanent injunction).

[28] *See Bayer AG v. Biovail Corp.*, 279 F.3d 1340, 1350 (Fed. Cir. 2002) (denying collateral estoppel because "infringement under [35 U.S.C] § 271I(2)(A) by submission of an ANDA is not synonymous with infringement under § 271(a) by a commercial product").

[29] Pub. L. No. 98-417, Stat. 1585.

[30] 21 C.F.R. § 314.53(b)(1) (2003).

> (II) claims a method of using such drug for which approval is sought or has been granted in the application.[31]

Further, the listing provisions provide that information on patents that do not meet these requirements "shall not be submitted."[32]

NDA holders have a responsibility to ensure that Orange Book patent listings meet the statutory requirements. The FDA considers its role in this listing process to be "purely ministerial."[33] It does not "police the listing process by analyzing whether the patents listed by NDA applicants actually claim the subject drugs or applicable methods of using those drugs."[34]

Although the FDA does not independently evaluate the patents submitted for listing in the Orange Book, it provides a process under which any person may "dispute[] the accuracy or relevance of patent information submitted."[35] Under that process, the FDA relays the dispute statement to the brand manufacturer. The brand manufacturer must respond within 30 days by instructing the FDA to delist the patent or amend the patent information, or by re-certifying under penalty of

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[31] 21 U.S.C. § 355(b)(1)(A)(viii).
[32] *Id*. § 355(c)(2).
[33] *Organon Inc. v. Mylan Pharms., Inc.*, 293 F. Supp. 2d 453, 458-59 (D.N.J. 2003); *see also* U.S. Food & Drug Admin., Report to Congress: The Listing of Patent Information in the Orange Book, at 5 (Jan. 2022). https://www.fda.gov/media/155200/download ("FDA serves a ministerial role with regard to the listing of patent information").
[34] *Apotex v. Thompson*, 347 F.3d 1335, 1349 (Fed. Cir. 2003).
[35] 21 C.F.R. § 314.53(f).

perjury the propriety of the listings.[36] The FDA does not assess or take any other action on the dispute and will not change or remove the Orange Book listing unless the brand manufacturer instructs the FDA to do so in its response.[37]

In 2003, Congress authorized generic manufacturers that are sued for infringement of Orange Book-listed patents to bring a counterclaim seeking to remove the listing.[38] In addition to this delisting counterclaim, courts and the FTC have long recognized (both before and after the adoption of the delisting counterclaim provision) that improper Orange Book listings can also be actionable under the antitrust laws.[39] The FDA supports the FTC's efforts to examine whether brand drug companies are impeding generic drug competition by improperly listing patents in the Orange Book.[40]

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[36] *See id.*

[37] *See id.*

[38] *See* 21 U.S.C. § 355(j)(5)(C)(ii)(I).

[39] *See, e.g.*, *Lantus*, 950 F.3d at 6-7, 15 (finding improper listing of component device patent may support Section 2 Sherman Act claim); *In re Loestrin 24 Fe Antitrust Litig.*, 433 F. Supp. 3d 274, 315 (D.R.I. 2019) (ruling "sham Orange Book listing claim" under Section 2 of the Sherman Act may proceed to trial); *In re Remeron Antitrust Litig.*, 335 F. Supp. 2d 522, 531 (D.N.J. 2004) ("there exists no regulatory scheme [for Orange Book listings] so extensive as to supplant antitrust laws"); *see also* FTC Study on Generic Drug Entry Before Patent Expiration, *supra* note 6, at 1; FTC Orange Book Policy Statement, *supra* note 9, at 1.

[40] *See* FTC Press Release re: Orange Book Policy Statement, *supra* note 9.

II. Teva Continues to Improperly List Patents in the Orange Book—Including the Asserted Patents—Despite FTC Staff Warnings

In November 2023, the FTC's Bureau of Competition sent letters to ten brand manufacturers informing them that FTC staff have opted to use the FDA's process to dispute over 100 Orange Book listings.[41]

In response, four brand drug manufacturers requested that the FDA remove from the Orange Book virtually all their patent listings identified by the FTC.[42] Several of those companies delisted asthma inhaler device patents and device component patents with claims that resemble the asserted patents in this case (i.e., device or device component patents that do not mention the active ingredient or the drug product that is the subject of the NDA in the patent claims).[43]

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[41] FTC Press Release re: Improper Orange Book Listings, *supra* note 10.

[42] *See* U.S. Food & Drug Admin., *Patent Listing Disputes* (current through Mar. 8, 2024), https://www.fda.gov/media/105080/download (noting changes in the patent listings for Kaleo Inc., Impax Laboratories LLC, GlaxoSmithKline Intellectual Property Development Limited, and Glaxo Group Limited). All told, these four manufacturers voluntarily delisted fourteen patents across six NDAs, with one patent being listed for three different applications.

[43] For example, GSK removed listings for patents on an "actuation indicator" (U.S. Patent No. 7,500,444), a "dose counter for use with a medicament dispenser" (U.S. Patent No. 8,113,199), a "medicament dispenser" (U.S. Patent No. 8,161,968), and a "manifold for use in a medicament dispenser" (U.S. Patent No. 8,534,281). *Compare* Letter from Rahul Rao, Dep. Dir., Bur. Competition, Fed. Trade Comm'n to GlaxoSmithKline Intell. Prop. Dev. Ltd (Nov. 7, 2023), https://www.ftc.gov/system/files/ftc_gov/pdf/glaxosmithkline-orange-book.pdf, *and* Letter from Rahul Rao, Dep. Dir., Bur. Competition, Fed. Trade Comm'n to Glaxo Group Ltd (Nov. 7, 2023), https://www.ftc.gov/system/files/ftc_gov/pdf/glaxo-group-orange-book.pdf, *with*

Teva, however, did not delist or amend any of the 42 patent-listings disputed by the FTC, including the asserted patents in this case.[44] Each of the asserted patents were listed in the Orange Book during the period from 2012 to 2022.[45] The patents are device or device component patents that claim a dose counter or an inhaler that includes a dose counter.[46] On their face, none of these patents mention any drug in their claims, much less the active ingredient in ProAir HFA, albuterol sulfate.[47] Notably, the patent covering albuterol sulfate expired in 1989.[48]

Patent No.	Patent Title	List Date
8,132,712	Metered-dose inhaler	Mar. 27, 2012
9,463,289	Dose counters for inhalers, inhalers and methods of assembly thereof	Nov. 8, 2016
9,808,587	Dose counter for inhaler having an anti-reverse rotation actuator	Nov. 16, 2017
10,561,808	Dose counter for inhaler having an anti-reverse rotation actuator	Mar. 19, 2020
11,395,889	Dose counter for inhaler having an anti-reverse rotation actuator	Aug. 19, 2022

U.S. Food & Drug Admin., *Patent Listing Disputes*, *supra* note 42, and *Delisted Patents*, U.S. Food & Drug Admin., https://www.accessdata.fda.gov/scripts/cder/ob/search_patent.cfm?listed=delisted (last updated Mar. 20, 2024).

[44] *Compare* Teva Warning Letter, *supra* note 11 and Norton Warning Letter, *supra* note 11 *with* U.S. Food & Drug Admin., *Patent Listing Disputes*, *supra* note 42.

[45] Pl.'s Am. Compl., ECF No. 7, Exs. A-E.

[46] *See id.*

[47] *See id.*; *see also* Orange Book (44th ed. 2024), *supra* note 2, at ADA 7(listing active ingredient of ProAir HFA as albuterol sulfate).

[48] Orange Book AD 6 (7th ed. 1987) (referencing U.S. Patent No. 3,644,353) (on file with Hyman, Phelps, & McNamara PC, *The Orange Book Archives, 1987, 7th Ed.*, https://thefdalawblog.com/wp-content/uploads/2020/06/OB-Annual-1987-7th-Ed.pdf).

Each of the asserted patents is also listed in the Orange Book for other Teva products.[49] For example, Teva has listed U.S. Patent No. 10,561,808 on a dose counter in the Orange Book for *21 different approved drugs*, many of which contain entirely different active ingredients from ProAir HFA.[50]

Despite receiving warning letters from the FTC's Bureau of Competition, Teva continues to list device and device component patents that, on their face, do not mention any drug in their claims. As a result, Teva can trigger—and here, has in fact triggered—a 30-month stay that blocks competition from less expensive generic inhalers solely based on these patents. In this case, Amneal submitted its ANDA seeking approval to market a generic version of ProAir HFA on August 24, 2023, and alleges that absent the 30-month stay, it could launch its less expensive competitor asthma inhaler as early as this summer.

ARGUMENT

The FTC believes this Court should grant Amneal's motion for a judgment on the pleadings as to counterclaim counts 1-5 regarding Teva's improper Orange Book listings. To aid the court in its analysis of the other federal law counterclaims, the FTC also explains how improper Orange Book listings harm

[49] Amneal Countercl., ECF No. 12 ¶ 86.
[50] *See* Orange Book (44th ed. 2024), *supra* note 2, at ADA 7, 39-40, 178-188.

fair competition and can trigger antitrust liability, and why *Trinko* does not apply to Amneal's counterclaims.

I. Drug Manufacturers Cannot Lawfully List Device Patents That Are Not Limited to Either the Active Ingredient or the Approved Product

The statutory listing provisions and related regulations require that, to be properly listed in the Orange Book, a patent must "claim[] the drug for which the applicant submitted the [NDA]" and also be either "a drug substance (active ingredient) patent or a drug product (formulation or composition) patent."[51] Alternatively, the patent may claim a "method of using such drug for which approval is sought or has been granted in the application."[52] Here, Teva listed the asserted patents in the Orange Book as "drug product" patents,[53] and it is undisputed that these patents are not "drug substance" or "method of use" patents.

Teva contends that the asserted patents qualify for the second category—drug product. However, a device or device component patent that does not mention any drug in its claims is not a "drug product (formulation or composition) patent." Rather, FDA regulations instruct manufacturers to "submit information only on those patents that claim the drug product, as is defined in [21 C.F.R.] § 314.3, that

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[51] 21 U.S.C. § 355(b)(1)(A)(viii). *See also* 21 C.F.R. § 314.53(b)(1).

[52] *Id.*

[53] Pl.'s Br. In Supp. Mot., ECF No. 28, at 6 ("There are nine unexpired patents listed in the Orange Book for ProAir® HFA, each listed as a drug product patent.") ("Teva Br.").

is described in the pending or approved NDA."[54] In turn, § 314.3 defines "drug product" as "a finished dosage form, e.g., tablet, capsule, or solution, *that contains a drug substance*, generally, but not necessarily, in association with one or more other ingredients."[55] Together, these provisions mean that brand drug manufacturers may list as "drug product (formulation or composition) patents" only those that claim the finished dosage form containing the drug substance of the relevant NDA.[56] The asserted patents do not meet this criterion because they are device and device component patents untethered from any drug—much less the ProAir HFA albuterol sulfate formulation.[57]

As the FDA stated in its 2003 rulemaking on patent submissions and listing requirements, for drug product patent listings, "[t]he *key factor* is whether the patent being submitted claims the finished dosage form of the approved drug

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[54] 21 C.F.R. § 314.53(b)(1).

[55] 21 C.F.R. § 314.3(b) (emphasis added).

[56] 21 C.F.R. § 314.53(b)(1). The FDA's 2016 regulations made some "Technical Corrections to Regulatory Concepts" including modifying the text of § 314.53(b)(1) to reference "the drug product" instead of "a drug product." This was intended "to clarify that for patents that claim a drug product, the applicant must submit information only on those patents that claim the drug product, as is defined in § 314.3, that is described in the pending or approved NDA." *See* Abbreviated New Drug Applications and 505(b)(2) Applications, 81 Fed. Reg. 69580, 69631 (Oct. 6, 2016).

[57] Amneal argues device patents are not listable in the Orange Book. Def.'s Br. In Supp. Mot., ECF No. 48, at 14-21 ("Amneal Br."). Setting aside for present purposes whether device patents are *ever* listable, the FTC's view is that device and device component patents that do not claim the active ingredient or drug product that is the subject of the NDA are not listable.

product."[58] Here, the drug substance that was the subject of Teva's NDA for ProAir HFA is albuterol sulfate, and its finished dosage form is "metered aerosol."[59] The claims of the asserted patents mention neither albuterol sulfate nor the ProAir HFA albuterol sulfate metered aerosol. A comparison to one of Teva's actual formulation patents—which expired long ago—is illuminating. For example, claim 2 of U.S. Patent No. 5,695,743 claims "[a]n aerosol formulation comprising: (a) a therapeutically effective amount of [albuterol]; and (b) a propellant . . . comprising 1,1,1,2-tetrafluoroethane . . . ." This patent appears to have been properly listed, as this claim specifies the particular drug product—a metered aerosol formulation including the drug substance—for which Teva received approval. In contrast, the asserted patents do not even mention any elements of the formulation.

The First Circuit's decision in *In re Lantus Direct Purchaser Antitrust Litigation*, which similarly considered a device component patent and held its listing improper, is instructive.[60] In *Lantus*, the First Circuit considered an Orange Book listing for a combination drug/device product called Lantus SoloSTAR, a

[58] 68 Fed. Reg. at 36680 (emphasis added).

[59] *Orange Book: Approved Drug Products with Therapeutic Equivalence Evaluations, Product Details for NDA 021457*, U.S. Food & Drug Admin., https://www.accessdata.fda.gov/scripts/cder/ob/results_product.cfm?Appl_Type=N&Appl_No=021457#22991 (last visited Mar. 21, 2024).

[60] 950 F.3d at 1.

"pre-filled drug delivery system" that dispenses insulin glargine to the patient—i.e., an insulin injector pen.[61] That patent claimed "aspects of a 'drive mechanism' that serves as a part of the SoloSTAR drug injector pen."[62] The claims of the patent listed in the Orange Book for SoloSTAR did not mention the active ingredient insulin glargine or the drug product for which the NDA was submitted, Lantus SoloSTAR.[63] The First Circuit held that Sanofi's patent was improperly listed, reasoning that "[t]he 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 a patent that "neither claims nor even mentions the [active ingredient] or the [approved drug], does not fit the bill."[64] The Teva listings at issue here are strikingly similar to those the First Circuit held improper in *Lantus*.

The Second Circuit recently followed *Lantus*'s reasoning in a case where a brand manufacturer listed patents claiming methods of treatment using a combination of two active ingredients, even though the relevant NDA product contained only one of those two active ingredients.[65] The Second Circuit concluded that under *Lantus* "[a] patent claim that fails to explicitly include the

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[61] *Id.* at 4, 7.
[62] *Id.* at 5.
[63] *Id.* at 10.
[64] *Id.*
[65] *United Food & Com. Workers Loc. 1776 & Participating Emps. Health & Welfare Fund v. Takeda Pharm. Co. Ltd.* (*Actos*), 11 F.4th 118, 127, 134-35 (2d Cir. 2021).

drug actually makes *neither* type of claim on the drug" permitted under the listing provisions.[66]

Teva's other arguments that its patents are properly listed are unavailing. First, Teva contends that the OBTA undermined *Lantus* by adding "component" or "composition" in ways that changed the meaning of § 355.[67] The OBTA did no such thing. Each instance of "component" in § 355 was already included in the statute before OBTA was enacted.[68] And "composition" was added to the listing provisions only to further specify the *limits* on the scope of listable patents—codifying limits that existed in FDA regulations (but not the statute) pre-OBTA.[69]

Second, Teva argues that even though the asserted patents do not claim the drug substance listed in the NDA (albuterol sulfate), or even the drug product listed in the NDA (ProAir HFA Inhalation Aerosol), the Court should find its Orange Book listings proper because "[t]he Listing Statute Broadly Requires Listing All Patents that 'Claim the Drug,'" and the asserted patents purportedly "read on" the ProAir HFA inhaler—meaning that the ProAir HFA's inhaler meets each claim element of at least one claim of the asserted patents.[70] But Teva's

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[66] *Id.* at 134-35 (citing *Lantus*, 950 F.3d at 8).
[67] Teva Br., ECF No. 28, at 13-14 (citing 21 U.S.C. §§ 355(b)(1)(A)(ii), (iii), (v), (viii).
[68] 21 U.S.C.S. §§ 355(b)(1) (LexisNexis 2019); *see also* Amneal Br., ECF No. 48, at 25.
[69] 21 U.S.C. § 355(b)(1)(A)(viii)(I); *cf* 21 C.F.R. § 314.53(b)(1) (2003).
[70] Teva Br., ECF No. 28, at 9, 14-16.

argument ignores the statutory text. Even assuming *arguendo* that the ProAir device can be considered a part of the "drug," under the statutory text, it is not a sufficient condition for proper listing that the patent "claims the drug." The statutory text allows only listing of a patent that "claims the drug . . . *and* is a drug substance (active ingredient) patent or a drug product (formulation or composition) patent," or else claims an approved method of using the drug.[71] Here, Teva's device and device component patents are none of those three types.[72]

Third, Teva argues that "patents claiming drug products *or their components* must be listed in the Orange Book."[73] Teva claims that the definition of "dosage form" in 21 C.F.R. § 314.3 takes into account "such factors" as "[t]he way the product is administered" and "[t]he design features that affect frequency of dosing;" thus, Teva argues, it must list "patents covering any of the components . . . that contribute" to ProAir HFA's "finished dosage form" if they "relat[e] to 'the way the product is administered' and 'design features that affect frequency of dosing.'"[74] According to Teva, these include device and device component patents.

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[71] 21 U.S.C. § 355(b)(1)(A)(viii)(I) (emphasis added).

[72] Teva cites *Apotex*, 347 F.3d at 1343-44 for its dictum that "[t]he listing decision thus requires what amounts to a finding of patent infringement, except that the 'accused product' is the drug that is the subject of the NDA." Teva Br., ECF No. 28, at 21. But that statement only occurred in the Court's analysis of its subject-matter jurisdiction, and in any event is no longer accurate in view of the OBTA amendments to the listing provisions.

[73] Teva Br., ECF No. 28, at 16 (emphasis added).

[74] *Id*. at 16-17.

In the FTC's view, this argument stretches the FDA's guidance well beyond a fair reading. As explained above (at 19), the FDA's guidance on whether to list a "drug product" patent stated the "*key factor* is whether the patent being submitted *claims* the finished dosage form."[75] Teva offers no authority or even explanation for widening the FDA's guidance to allow listing of device or device component patents that "contribute" in some way to the finished dosage form (rather than claiming it), or that "relat[e]" to the factors the FDA uses to determine a drug's dosage form.[76]

Indeed, in *Lantus*, the First Circuit rejected virtually the same argument that Teva now makes. There, Sanofi argued it could list its device component patent—claiming the drive mechanism of an insulin injector pen—because it was required to list patents on "integral components" of the approved drug product.[77] Noting a "gap between [Sanofi's] reading of the law and its filing of a patent that does not claim the listed drug," the First Circuit concluded there was "nothing in the statute or regulations that welcomes such a further expansion of the already stretched statutory terms, whereby an integral part of an injector pen becomes the pen itself, and in turn is a drug."[78] The First Circuit ultimately held that the patent was

[75] 68 Fed. Reg. at 36680 (emphasis added).
[76] Teva Br., ECF No. 28, at 16-17.
[77] *Lantus,* 950 F.3d at 8.
[78] *Id.*

improperly listed because, even "assum[ing] for the sake of argument that the Lantus SoloSTAR is a drug under the statute, there is still a vital link missing: the '864 patent does not claim or even mention the Lantus SoloSTAR."[79] The same logic applies here.[80]

Under Teva's reading of the statute, drug companies could list any patent—and obtain a 30-month stay of FDA approval of a generic competitor—where the patent covers even one minor component of a drug-device combination product. The limits Congress imposed on Orange Book listings reflect a desire to avoid such an absurd result, in which patents on even minor device components trigger a stay of FDA approval and delay competition from less expensive generic drug products. Indeed, Teva's interpretation is inconsistent with the language of the listing provisions and would impermissibly render the "drug substance" category in the

[79] *Id.*

[80] Teva briefly argues that any patent not expressly excluded in the listing regulation may be listed. Teva Br., ECF No. 28, at 17 *quoting* 21 C.F.R. § 314.53(b)(1) ("Process patents, patents claiming packaging, patents claiming metabolites, and patents claiming intermediates are not covered by this section, and information on these patents must not be submitted to FDA.") (emphasis omitted). This sweeping argument lacks merit for the reasons identified by Amneal. Amneal Br., ECF No. 48, at 18 n.7. In addition, 21 C.F.R. § 314.53(b) imposes numerous requirements for listing drug substance, drug product, and method-of-use patents that Teva's argument would read out of the regulation by collapsing all of § 314.53(b) into its final sentence. Teva's argument would similarly make redundant the OBTA's adoption of the "drug substance" and "drug product" requirements in 21 U.S.C. § 355(b)(1)(A)(viii)(I).

listing provisions surplusage.[81] Specifically, if any patent on a "component" of the drug product—including the active ingredient—is listable as a drug product patent, then there would be no reason to have a separate "drug substance (active ingredient)" category.[82] The active ingredient is undoubtedly a "component" of the "drug product," along with the inactive ingredients.[83] Thus, the existence of a separate category of "drug substance" for the active ingredient indicates that "drug product" patents are not listable unless they claim the entire drug product, not just components.

In short, the Hatch-Waxman Act does not authorize the listing of the asserted patents because they do not mention any drug in their claims and are therefore not "drug product (formulation or composition) patent[s]" under the listing provisions, as Teva claims.

II. Improper Orange Book Patent Listings Harm Competition

Improper Orange Book listings harm competition by deterring and delaying entry of lower-cost generics. As discussed, the Hatch-Waxman framework gives brand drug manufacturers with patents listed in the Orange Book the ability to

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[81] *Arlington Cent. Sch. Dist. Bd. of Educ. v. Murphy*, 548 U.S. 291, 299 n.1 (2006) (statutory interpretation presumes that "statutes do not contain surplusage").

[82] 21 U.S.C. § 355(b)(1)(A)(viii).

[83] *See Ben Venue Lab. v. Novartis Pharm. Corp.*, 10 F. Supp. 2d 446, 458 (D.N.J. 1998) ("There can therefore be no serious question that, under 21 C.F.R. § 314.53(b), a 'drug substance' or 'active ingredient' may be a 'component' of a drug product . . . .").

initiate patent infringement litigation against would-be generic competitors before the FDA approves their ANDAs, which can lead to a 30-month stay of approval, regardless of whether the patent is properly listable.[84] Purchasers, like patients, hospitals, and health plans, are harmed each day that competition is delayed beyond the point the FDA would have otherwise approved a generic challenger's ANDA product. These potential harms—both in terms of higher drug prices and patient health—are serious.

When generic drugs enter a market, prices tend to fall dramatically. The following graph from an FDA study illustrates the effects of increased competition on generic drug prices relative to the brand drug price before entry.[85] Researchers have found that with robust competition, most drug prices "eventually fall[] to 80–85% below the original brand-name cost."[86]

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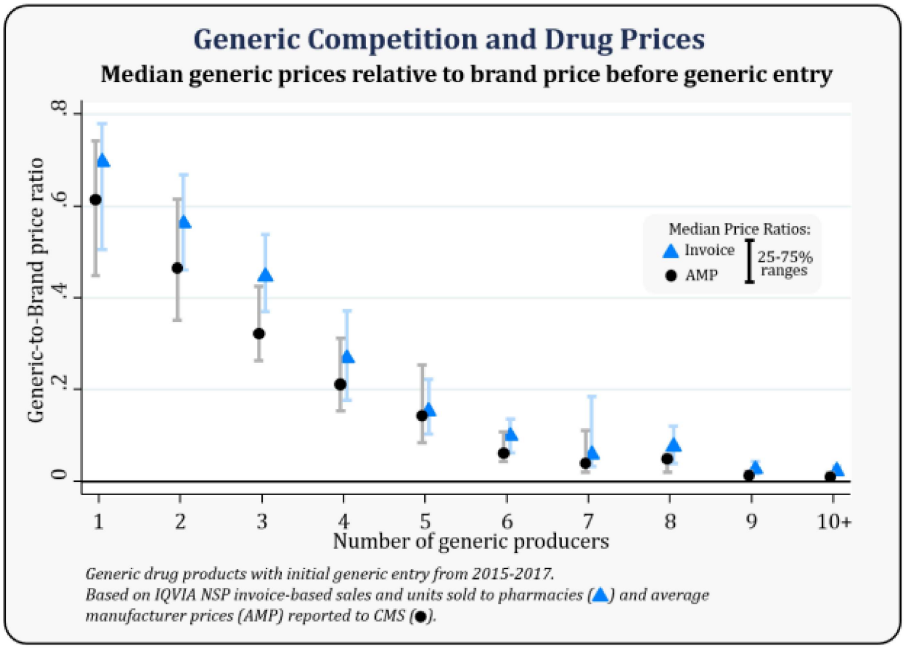
[84] This is true unless the generic competitor prevails in litigation sooner. *But see Lantus*, 950 F.3d at 4 ("[W]hile [the] thirty-month period may be shortened by resolution of the infringement action or order of the court [], the status quo, the allocation of burdens, and the life-span of patent litigation can all work against any such shortening.").

[85] U.S. Food & Drug Admin., Generic Competition and Drug Prices: New Evidence Linking Greater Generic Competition and Lower Generic Drug Prices 2 (Dec. 2019), https://www.fda.gov/media/133509/download.

[86] Robin Feldman et al., *Empirical Evidence of Drug Pricing Games—A Citizen's Pathway Gone Astray*, 20 Stan. Tech. L. Rev. 39, 46 (2017); *see also* Herbert Hovenkamp, *Antitrust and the Patent System: A Reexamination*, 76 Ohio St. L.J. 467, 491 (2015) ("[C]ompetition among generics drives prices to the competitive level," which can be "as little as 20% of pre-generic-entry prices.").



In this case, because the asserted patents have been listed in the Orange Book, Teva's suit has triggered the 30-month stay of approval on Amneal's ANDA product until February 2026.[87] If not for this 30-month stay, Amneal alleges the FDA could approve its ANDA product as early as next month, April 2024,[88] and pleads that if approved it could come to market as early as this summer.[89] Absent this Court granting judgment on the pleadings as to counterclaim counts 1–5 and ordering the asserted patents delisted, Amneal's product—and the price competition it would bring—may be delayed by nearly two years.[90]

[87] This is true unless Amneal prevails in this litigation sooner.
[88] Amneal Br., ECF No. 48, at 3.
[89] Amneal Countercl., ECF No. 12 ¶ 122.
[90] The entry of Amneal's product would also increase patient choice.

In addition to raising prices, delayed competition from improper Orange Book listings may in turn harm patient health. In 2018, the American Thoracic Society (ATS) issued a policy statement observing that the high cost of inhalers and other medicines for patients with asthma and COPD has led to higher out-of-pocket expenses and harmed patient health.[91] Based on its review of the academic literature, the ATS concluded that higher out-of-pocket expenses can increase stress, reduce medication adherence, and lead to worse health outcomes, including unnecessary hospitalizations.[92] The ATS also noted that these problems have been "exacerbated by a paucity of generic alternatives"—i.e., by a lack of competition.[93]

Improper Orange Book listings appear to be part of a widespread problem, particularly with inhaler device and device component patents. As explained above, the FTC's Bureau of Competition's November 2023 warning letters disputed over 100 Orange Book listings by ten brand drug manufacturers across 13 inhaler products and four epinephrine injector pens.[94] With respect to even just Teva alone, the letters disputed a total of 42 patent-listings across four inhaler

[91] Minal R. Patel et al., *Improving the Affordability of Prescription Medications for People with Chronic Respiratory Disease: An Official American Thoracic Society Policy Statement*, 198 Amer. J. of Respiratory & Critical Care Med. 1367 (2018).
[92] *Id.* at 1368.
[93] *Id.* at 1367.
[94] *See* FTC Press Release re: Improper Orange Book Listings, *supra* note 10.

products.[95] Additionally, a study published just last year examined all 53 asthma and COPD inhalers approved by the FDA from 1986 to 2020 and found that 39 of these products collectively listed 137 device patents in the Orange Book, the majority of which (105, or 77%) failed to reference an active ingredient.[96]

Further, improper Orange Book listings create barriers to entry that may deter generic competitors from entering the market in the first place. Faced with the prospect of a 30-month delay of FDA-approval, a generic competitor may forgo entry altogether, harming competition.

The revenue generated by brand drug companies from delays in competition caused by improper Orange Book listings and other practices can be significant. A recent academic study of FDA-approved asthma/COPD inhalers calculated the revenue generated by brand manufacturers before and after patents on the active ingredients expired.[97] As illustrated in the graph below, the study found that over

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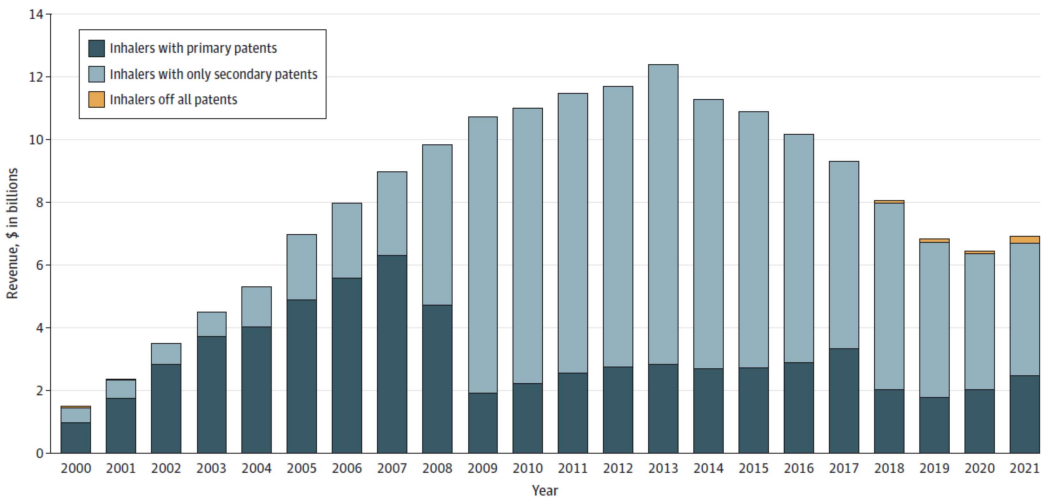
[95] *See* Teva Warning Letter, *supra* note 11; Norton Warning Letter, *supra* note 11.

[96] Brandon J. Demkowicz et al., *Patenting Strategies on Inhaler Delivery Devices*, 164 Chest 450, 452 (2023). This is consistent with a prior study that examined Orange Book patents on asthma/COPD inhalers, epinephrine injectors, and insulin injectors and concluded that 90% of the drug products studied were protected by device patents. *See* Reed F. Beall et al., *Is Patent "Evergreening" Restricting Access to Medicine/Device Combination Products?*, 11 PLOSE ONE 3 (2016).

[97] *See* William B. Feldman et al., *Manufacturer revenue on inhalers after expiration of primary patents, 2000-2021*, 329 J. Amer. Med. Assoc. 1, 3 (2023). This study did not measure the revenue obtained from delays in generic approval specifically due to improper Orange Book listings, but it demonstrates the

the 2000–2021 period, brand manufacturers generated $67.2 billion in revenue while their active ingredient patents were in effect compared with $110.3 billion after the active ingredient patents expired and the inhalers were protected only by later-filed secondary patents, including device and device component patents.[98]

Figure. Revenue Earned in the US on Brand-Name Inhaler Lines Approved by the US Food and Drug Administration, 2000-2021



III. Improper Orange Book Listings May Constitute Illegal Monopolization Under Section 2 of the Sherman Act

Contrary to Teva's arguments in its motion to dismiss, the FTC and courts have long recognized that improper submission of patents for listing in the Orange Book may constitute illegal monopolization—as well as an illegal course of monopolistic conduct—under section 2 of the Sherman Act.[99]

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enormous value for brand drug manufacturers in delaying generic competition through any means—including obtaining 30 month stays through improper listings.

[98] *Id.* at 1.

[99] As the FTC's policy statement explains, improper Orange Book listings are also actionable under section 5 of the FTC Act, which prohibits unfair methods of

Monopolization requires proof of "the willful acquisition or maintenance of [monopoly] power as distinguished from growth or development as a consequence of a superior product, business acumen, or historic accident."[100] To establish a section 2 violation, a plaintiff must show "(1) that the defendant possesses monopoly power in the relevant market, and (2) that the defendant has acquired or maintained that power by improper means."[101]

Here, Teva seeks dismissal only with respect to the latter "improper means" element.[102] Demonstrating acquisition or maintenance of monopoly power by improper means requires proof that the defendant has engaged in anticompetitive conduct "to foreclose competition, to gain a competitive advantage, or to destroy a competitor."[103] As described above, improper Orange Book listings can foreclose competition and patient access to affordable medications by enabling brand companies to block generic competition generally for 30 months—regardless of whether the listed patent is valid or infringed by the competitor's product. Moreover, improper Orange Book listings can deter generic drug companies from

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competition. *See* FTC Orange Book Policy Statement, *supra* note 9, at 5-6. There is no federal private right of action to enforce Section 5; this case focuses on Section 2 of the Sherman Act alone.

[100] *United States v. Grinnell Corp.*, 384 U.S. 563, 570-71 (1966).

[101] *Lantus*, 950 F.3d at 7 (quoting *Town of Concord v. Bos. Edison Co.*, 915 F.2d 17, 21 (1st Cir. 1990)) (additional citation and internal quotation omitted).

[102] *See* Teva Br., ECF No. 28, at 24.

[103] *Eastman Kodak Co. v. Image Tech. Servs., Inc.*, 504 U.S. 451, 482-83 (1992) (quoting *United States v. Griffith*, 334 U.S. 100, 107 (1948)).

entering a market at all, thereby foreclosing competition and depriving patients of lower-priced competing drugs. Courts (and the FTC) have consistently recognized that improperly listing patents in the Orange Book may constitute an improper means of maintaining or acquiring monopoly power—and they have done so both before and after 2003 when Congress enacted the counterclaim for a delisting injunction in 21 U.S.C. § 355(j)(5)(C)(ii).[104]

In this case, Amneal counterclaims that Teva improperly listed the asserted patents in the Orange Book, thus unlawfully maintaining its monopoly power.[105] As described above, these improper listings have enabled Teva to trigger the 30-month stay of approval, effectively delaying entry of Amneal's ANDA product

[104] *See Lantus*, 950 F.3d at 1, 7, 11-15 (reversing dismissal and holding allegations regarding improper listing of device patent could support actionable Sherman Act section 2 claim); *Actos*, 11 F.4th at 134-138 (affirming denial of motion to dismiss and remanding for consideration of whether brand drug manufacturer incorrectly listed patents in Orange Book causing antitrust harm); *Loestrin 24 Fe*, 433 F. Supp. 3d at 315 (ruling "sham Orange Book listing claim" may proceed to jury trial); *In re Gabapentin Pat. Litig.*, 649 F. Supp. 2d 340, 360 n.23 (D.N.J. 2009) (recognizing improper Orange Book listing allegations could support monopolistic scheme allegations); *Remeron*, 335 F. Supp. 2d at 532 (allowing plaintiffs to present facts concerning improper listing in support of monopolistic scheme allegations); Decision & Order, *Biovail*, FTC Dkt. No. C-4060 (settling an action under the antitrust laws against Biovail Corporation for, among other things, wrongful Orange Book listing); FTC Study on Generic Drug Entry Before Patent Expiration, *supra* note 6 at App. H (discussing "three categories of patents that raise Orange Book listability questions"); FTC Orange Book Policy Statement, *supra* note 9.

[105] Amneal Countercl., ECF No. 12 ¶ ¶ 120-25, 134-270.

from as early as this summer to February 2026.[106] These facts, which at the motion to dismiss stage must be accepted, establish a plausible violation of section 2.

IV. The Narrow *Trinko* Exception Does Not Immunize Improper Orange Book Listings From Antitrust Scrutiny

Verizon Commc'ns, Inc. v. Trinko, LLP[107] cannot immunize Teva from antitrust liability for improper Orange Book listings. In *Trinko*, the Supreme Court declined to expand Section 2 of the Sherman Act to capture conduct that was "not a recognized antitrust claim under this Court's existing refusal-to-deal precedents,"[108] particularly where the federal and state regulatory "regime was an effective steward of the antitrust function."[109] The antitrust claims and the regulatory framework at issue here are nothing like those considered in *Trinko*. As explained below, *Trinko* is inapplicable because Amneal's counterclaims are not an expansion of antitrust law, the FDA does not directly police the Orange Book, and the statutory amendment to add a delisting counterclaim does not transform a patent enforcement framework into an antitrust regulatory scheme.

This Court rightly rejected Teva's argument, explaining that "there exists no regulatory scheme [for Orange Book listing] so extensive as to supplant antitrust

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[106] *See supra* Background §§ I, II; Amneal Br., ECF No. 48, at 3; Amneal Countercl., ECF No. 12 ¶¶ 121-22, 130.
[107] 540 U.S. 398 (2004).
[108] *Id*. at 410.
[109] *Id.* at 413.

laws."[110] As Judge Hochberg explained, "[n]o authority has been cited to support the proposition that the antitrust laws have been superseded by the Hatch-Waxman Act or by FDA regulations. *Trinko* does not bar the instant antitrust claims."[111]

First, Amneal does not ask the Court to "recognize an expansion of the contours of §2" beyond existing precedents.[112] Courts have consistently recognized that lawsuits based on improperly listed Orange Book patents may constitute an "improper means" of maintaining or acquiring monopoly power.[113] Even before the Hatch-Waxman Act, courts recognized that improper use of a patent to exclude competitors can violate Section 2.[114]

Second, the FDA's ministerial role in Orange Book listings is nothing like the extensive scheme of Federal Communications Commission (FCC) regulation of telecommunications competition considered in *Trinko*. In *Trinko*, the local phone incumbent, Verizon, allegedly provided poor network access to prospective rivals,

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[110] *Remeron*, 335 F. Supp. 2d at 531.

[111] *Id.* at 531. Other courts have similarly rejected attempts to extend *Trinko* to preclude antitrust claims in other contexts. *See, e.g., Steward Health Care Sys., LLC v. Blue Cross & Blue Shield*, 997 F. Supp. 2d 142, 153 n.6 (D.R.I. 2014) (rejecting argument that "the heavily regulated nature of health care markets makes it improper for courts to intervene on antitrust grounds," explaining "[w]hereas the telecommunications industry at issue in *Trinko* was the subject of extensive antitrust regulation, it cannot be said that the same level of antitrust-focused regulation exists in health care markets").

[112] *Trinko*, 540 U.S. at 412.

[113] *See supra* note 105.

[114] *See, e.g.*, *SmithKline Corp. v. Eli Lilly & Co.,* 575 F.2d 1056, 1065 (3rd Cir. 1978).

leaving them unable to consistently serve the phone customers they sought to take from Verizon. The Telecommunications Act of 1996 "sought to 'uproot' the incumbent [local phone company's] monopoly and to introduce competition in its place."[115] "Central to the scheme of the Act [was] the incumbent [phone company's] obligation … to share its network with competitors," along with "a complex regime for monitoring and enforcement" by the FCC.[116] The New York Public Service Commission imposed similar network sharing conditions.[117] After Verizon's competitors complained about its conduct,[118] New York and the FCC opened parallel investigations; within months, New York issued orders requiring Verizon to pay $10 million to its rivals, and Verizon paid $3 million under an FCC consent decree.[119]

The Supreme Court gave "particular importance" to this "regulatory structure designed to deter and remedy anticompetitive harm" when it declined the *Trinko* plaintiffs' request to expand Section 2.[120] In *Trinko*, the FCC—an agency

[115] *Trinko*, 540 U.S. at 402 (quoting *Verizon Communications Inc. v. FCC*, 535 U.S. 467, 488 (2002)).
[116] *Id.* at 401-02 (citations omitted).
[117] *Id.* at 398.
[118] *Id.* at 403.
[119] *Id.* at 403-04.
[120] *Id.* at 412.

with longstanding competition expertise and statutory enforcement authority[121]—and New York "provided a strong financial incentive for [Verizon's] compliance."[122] When Verizon failed to meet its obligations, the regulators responded quickly, "impos[ing] a substantial fine" and onerous, "*daily* reporting requirements" to ensure compliance.[123] Collectively, this regulatory "regime was an effective steward of the antitrust function."[124]

Here, however, the FDA's "purely ministerial" role with Orange Book patent listings is starkly different from the FCC's role in *Trinko*.[125] "The FDA's mission is to protect the public by ensuring that drugs are safe and effective," not to "resolve economic disputes about the coverage of patent claims."[126] And the

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[121] *See Steward,* 997 F. Supp. 2d at 153 n.6 ("the telecommunications industry at issue in *Trinko* was the subject of extensive antitrust regulation"); *Competition Policy Division, Wireline Competition Bureau*, Fed. Commc'n Comm'n., https://www.fcc.gov/general/competition-policy-division-wireline-competition-bureau (last visited Mar. 20, 2024) ("Our primary mission is to foster competition…"); Judge Douglas Ginsburg & Josh Wright, *Reimagining Antitrust Institutions: A (Modest?) Proposal* (George Mason L. & Econ. Rsch. Paper No. 23-22, at 14, 2023) (forthcoming, Rev. L. Econ.) (explaining "[s]ome sectoral regulators also have sector-specific analogs to the [FTC] Section 5 authority to prevent 'unfair methods of competition.' Agencies with such authority include the FCC, over cable operators…").

[122] *Trinko*, 540 U.S. at 413 (citations omitted).

[123] *Id.*

[124] *Id.*

[125] *Organon*, 293 F. Supp. 2d at 458-59.

[126] *Remeron*, 335 F. Supp. 2d at 531-32 (quoting Fed. Defs.' Mem. in Opp'n to Pls.' Mot. for Prelim. Injunction, *Mylan v. Thompson*, 139 F. Supp. 2d 1 (D.D.C. 2001)).

FDA has stated that it "lack[s] the resources, authority, or expertise to police patent claims" that delay the entry of generic drugs.[127] As the Federal Circuit has explained, the FDA does not "police the listing process by analyzing whether the patents listed by NDA applicants actually claim the subject drugs or applicable methods of using those drugs."[128] The FDA supported the FTC's efforts to scrutinize improper Orange Book patent listings under the antitrust laws.[129]

Nor does the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA) create a regulatory structure that supplants the need for the antitrust laws to address anticompetitive harm, as Teva asserts.[130] By its plain terms, the MMA merely provides a mechanism for courts to require delisting of improper Orange Book patents—i.e., an injunctive relief counterclaim—and does not limit or displace the availability of antitrust liability, including for damages.[131]

Specifically, Subclause I of the relevant provision established a counterclaim for an ANDA filer to seek removal of an improperly listed patent from the Orange Book during patent infringement litigation brought under the Hatch-Waxman

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[127] Br. for the U.S. as Amicus Curiae, *Caraco Pharm. Labs., Ltd. v. Novo Nordisk A/S*, No. 10-844, 2011 WL 3919720, at *17, 27 (U.S. Sept. 6, 2011); *see also Caraco*, 566 U.S. at 424 (noting "the FDA's determination that it cannot police patent claims.").

[128] *Apotex*, 347 F.3d at 1349.

[129] *See* FTC Press Release re: Orange Book Policy Statement, *supra* note 9.

[130] Teva Br., ECF No. 28, at 28.

[131] *See* Amneal Br., ECF No. 48, at 39-40 (quoting H.R. Rep. No. 108-391, at 836 (2003)).

Act.[132] Subclause II specifies that the "claim described in subclause (I)" may only be brought as a counterclaim to a patent infringement suit.[133] Nothing in the statute preempts, or even mentions, the well-established antitrust claims raised by Amneal here—which are claims authorized by the Sherman Act that in no way depend on the authority to bring "the claim described in subclause (I)" of the MMA.

Moreover, the MMA counterclaim does not offer any means to remedy the types of harm to competition from improper Orange Book listings that antitrust liability addresses. For one, the MMA counterclaim cannot lead to monetary damages; it may only correct the Orange Book listing and does not allow for any other remedy.[134] Additionally, the counterclaim arises only if and when a branded drug manufacturer sues a generic drug manufacturer for infringement of a product covered by an Orange Book listing. Thus, the counterclaim cannot address the chilling effect of improper patent listings that discourage would-be competitors from even attempting to enter the market—harming competition and consumers. Such a mechanism does not constitute a comprehensive antitrust regulatory regime.

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[132] 21 U.S.C. § 355(j)(5)(C)(ii)(I) ("If an owner of the patent … brings a patent infringement action against the applicant, the applicant may assert a counterclaim seeking an order requiring the holder to correct or delete the patent information...").

[133] 21 U.S.C. § 355(j)(5)(C)(ii)(II) ("Subclause (I) does not authorize the assertion of a claim described in subclause (I) in any civil action or proceeding other than a counterclaim described in subclause (I).").

[134] *See Id.* § 355(j)(5)(C)(ii)(II) (Applicants "not [] entitled to damages").

Indeed, even after the enactment of the MMA counterclaim, courts have repeatedly and consistently recognized that improper Orange Book listings can violate Section 2.[135] The FTC is not aware of any case extending *Trinko* to preclude antitrust liability for improper Orange Book listings. This Court should reject Teva's invitation to become the first. Notably, in a case alleging sham litigation under the Hatch Waxman Act, the Third Circuit rejected a branded drugmaker's *Noerr-Pennington* argument, holding that courts "must not immunize a brand-name manufacturer who uses the Hatch-Waxman Act's automatic, 30-month stay to thwart competition. Doing so would excuse behavior that Congress proscribed in the antitrust laws."[136] Courts have long recognized that antitrust exemptions are "strongly disfavored and have only been found in cases of clear repugnancy between the antitrust and regulatory provisions."[137] No such conflict exists here.

CONCLUSION

For the foregoing reasons, the Court should grant Amneal's motion for a judgment on the pleadings as to counterclaim counts 1-5 and order the asserted patents delisted. The Court should evaluate the issues consistent with the principles

[135] *See supra* note 105.
[136] *AbbVie Inc.*, 976 F.3d at 361.
[137] *Otter Tail Power Co. v. United States*, 410 U.S. 366, 372 (1973).

described above, including that improper Orange Book listings may cause substantial harm to competition and may violate the antitrust laws.

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