No. 24-1936

TEVA BRANDED PHARMACEUTICAL PRODUCTS R&D, INC., NORTON (WATERFORD) LTD., TEVA PHARMACEUTICALS USA, INC.,
Plaintiffs-Appellants,

v.

AMNEAL PHARMACEUTICALS OF NEW YORK, LLC, AMNEAL IRELAND LTD., AMNEAL PHARMACEUTICALS LLC, AMNEAL PHARMACEUTICALS INC.,
Defendants-Appellees.

On Appeal from the United States District Court
for the District of New Jersey,
No. 23-cv-20964 (Hon. Stanley R. Chesler)

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Rasha Alhiary et al., *Delivery Device Patents on GLP-1 Receptor Agonists*,

2003, the Commission entered administrative consent orders requiring two pharmaceutical companies to delist improperly listed patents.[2] Additionally, the Commission has filed amicus briefs regarding improper Orange Book listings in numerous private lawsuits, including in the district court proceedings here.[3]

The Commission has also played a key role in advising Congress on amending the Hatch-Waxman scheme to prevent improper Orange Book listings and other abuses. In 2002, the Commission published a detailed study of Hatch Waxman-related anticompetitive practices that included recommendations for legislative action. *See* FTC, *Generic Drug Entry Prior to Patent Expiration: An FTC Study* ii-xii (July 2002).[4] In

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[2] Decision and Order, *In re Bristol-Myers Squibb Co.*, FTC Dkt. No. C-4076 (April 14, 2003); Decision and Order, *In re Biovail Corp.*, FTC Dkt. No. C-4060 (Oct. 2, 2002).

[3] *See Mylan Pharm. Inc. v. Sanofi-Aventis U.S. LLC*, No. 2:23-cv-00836, Dkt. No. 64 (W.D. Pa. Nov. 21, 2023); *Jazz Pharm., Inc. v. Avadel CNS Pharm., LLC*, No. 1:21-cv-691, Dkt. No. 227 (D. Del. Nov. 15, 2022); *In re Buspirone Patent Litig.*, No. 1:01-md-1410, Dkt. No. 31 (S.D.N.Y. Jan. 8, 2002); *SmithKline Beecham Corp. v. Apotex Corp.*, No. 99-cv-4304, Dkt. No. 92 (E.D. Pa. Jan. 29, 2003).

[4] *See also Caraco Pharm. Labs., Ltd. v. Novo Nordisk A/S*, 566 U.S. 399, 400, 408 (2012) (citing Commission study findings as "evidence … that some brands were exploiting [the Hatch Waxman] statutory scheme to prevent or delay the marketing of generic drugs").

Teva has violated the FTC Act through improper Orange Book listings—including those at issue in this case.[6]

Improper Orange Book listings have the potential to cause serious harm to competition. By listing a patent in the Orange Book, a brand pharmaceutical company can gain the ability to block generic competition for 30 months simply by filing a lawsuit, without having to respond to patent invalidity assertions or to show that a proposed generic product would actually infringe the brand company's patents. Brand companies thus have a powerful financial incentive to list patents regardless of whether the listing meets the statutory criteria Congress has established. That is why Congress—on the Commission's

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Release, Boehringer Ingelheim, *Boehringer Ingelheim caps patient out-of-pocket costs for its inhaler portfolio at $35 per month* (Mar. 7, 2024), https://shorturl.at/2K1cP; 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://shorturl.at/AP7h1. While the Commission welcomes voluntary reductions in patients' out-of-pocket costs, these are not substitutes for removing improper patent listings, as such listings may delay competition from generic products with lower prices.

[6] Teva has publicly disclosed the investigation in filings with the Securities and Exchange Commission. This brief is not based on any information that the FTC has learned in its investigation.

for publication in the Orange Book after NDA approval and providing that information on other patents "shall not be submitted").

Although Teva listed the patents at issue here as "drug product" patents, they do not meet either of the statutory criteria. They are drug-agnostic patents directed to mechanical devices—inhalers and dose counters for inhalers—and do not claim any particular active ingredient or any drug formulation or composition. Nor do the patents claim the approved product marketed by Teva—a metered dose inhaler containing the active ingredient albuterol sulfate. Indeed, Teva has listed these same patents for numerous other drug-device combination products, many containing entirely different active ingredients.

Teva advances an overbroad reading of the listing statute that invites gamesmanship to foreclose the very kind of competition the Hatch-Waxman Act was designed to promote. Notwithstanding the restrictions Congress placed in the statutory text, Teva asserts that the statute permits the listing of device and device component patents devoid of a relationship to any particular drug substance or formulation or composition. But that approach would allow brand manufacturers to turn a scheme that Congress designed to facilitate generic competition

into a means for perpetually forestalling generic entry—*i.e.*, by patenting narrow changes to the mechanical components of a device and listing the new patents in the Orange Book. Teva's proposed rewriting of the statute could thus impair the ability of millions of Americans to obtain life-saving drugs at affordable prices.

Manufacturers of branded inhalers face limited generic competition today. With large amounts of money at stake, branded manufacturers in this space have a strong financial incentive to abuse the statutory regime to block generic competition long after patent protection for the active ingredient(s) has expired. As outlined below, delays in generic entry for inhaler products—as with other drug products—can result in higher prices for consumers for lifesaving drugs.

The Court should enforce the statute Congress wrote and reject Teva's attempt to redraft that statute. To protect competition, it should affirm the order requiring delisting of Teva's improperly listed patents.

typically available at far lower cost. Congress enacted the Hatch-Waxman Act to "speed the introduction of low-cost generic drugs to market, thereby furthering drug competition." *FTC v. Actavis, Inc.*, 570 U.S. 136, 142 (2013) (cleaned up).

Under the Hatch-Waxman Act, a company seeking approval for a new drug must file a New Drug Application ("NDA"), a lengthy and costly process requiring evidence that the drug is safe and effective for its proposed use(s). 21 U.S.C. § 355(b). The NDA holder must submit information about certain patents relevant to the approved drug for listing in the FDA's Orange Book.[7] *Id.* § 355 (c)(2) *see also id.* §355(b)(1)(A)(viii). After an NDA is approved, another company may seek to market a generic version by filing an Abbreviated New Drug Application ("ANDA"). *Id.* § 355(j). The streamlined ANDA process lowers barriers to generic entry by eliminating the need to submit safety and efficacy studies. Instead, an ANDA filer must demonstrate that its generic product is bioequivalent to the referenced NDA drug product and meets certain sameness criteria—including that it contains

[7] The Orange Book's formal name is "Approved Drug Products with Therapeutic Equivalence Evaluations." *See* 21 U.S.C. § 355(b)(1)(A)(viii); 21 C.F.R. § 314.53(b).

the same active ingredient(s) in the same amount(s) and works in the body the same way.

If an ANDA filer seeks to market a generic product before the expiration of a patent listed in the Orange Book for the NDA reference drug prior to the ANDA filing, it must include a "paragraph IV" certification in its application asserting that the patent is invalid or will not be infringed by the generic product. 21 U.S.C. § 355(j)(2)(A)(vii)(IV). Such a certification is deemed an act of infringement. 35 U.S.C. § 271(e)(2)(A). If the patentee—typically, the brand company that holds the NDA—files suit within 45 days after receiving notice of the certification, FDA approval of the ANDA is stayed for 30 months, unless the lawsuit is resolved earlier. 21 U.S.C. § 355 (j)(5)(B)(iii).

Under this scheme, the owner of an Orange Book-listed patent has extraordinary rights that are not available to ordinary patentees.

625, 630 (Fed. Cir. 2015). The owner of an Orange Book-listed patent, however, can block FDA approval of a competing generic drug for 30 months simply by filing an infringement lawsuit, without showing that the proposed generic product is likely to infringe or responding to Brand's assertions. This ability to block generic competition for two

21 U.S.C. § 355(b)(1)(A)(viii) (hereinafter the "Listing Statute") (emphasis added); *see also id.* § 355(c)(2) (requiring submission of patent information after NDA approval). If a patent does not meet these requirements, it must not be submitted for listing in the Orange Book. *See id.* (information on other patents "shall not be submitted").

The FDA does not evaluate whether the patents submitted for listing in the Orange Book meet the statutory criteria, nor does it remove patent information without a request from the NDA holder. *See, e.g.*, *Jazz*, 60 F.4th at 1378. But there are several other routes by which other actors can redress improper listings, including delisting counterclaims by ANDA filers, *see* 21 U.S.C. § 355(j)(5)(C)(ii)(I); enforcement actions by the Commission under the FTC Act, *see supra* at 2-3; and lawsuits by private parties under the Sherman Act, *see United Food & Com. Workers Loc. 1776 v. Takeda Pharm. Co. Ltd.*, 11 F.4th 118, 134-38 (2d Cir. 2021) ("*UFCW*"); *Cesar Castillo, Inc. v. Sanofi-Aventis U.S., LLC* (*In re Lantus Direct Purchaser Antitrust Litig.*), 950 F.3d 1, 7-15 (1st Cir. 2020).

Teva holds an approved NDA for albuterol sulfate HFA Inhalation Aerosol, known as "ProAir HFA."[8] The approved product is a drug-device combination product: an inhaler device that delivers a metered dose of the active ingredient albuterol sulfate in aerosol form. Albuterol sulfate has been off patent since 1989, and Teva's Orange Book entry for this NDA currently lists only drug-agnostic device patents. Five of those patents (the "Asserted Patents") are at issue in this case. None of these patents is directed to a drug formulation or composition. Nor do the patents claim the approved product marketed by Teva—a metered aerosol containing the active ingredient albuterol sulfate.

> Patent No. 8,132,712 (the "'712 patent") claims a "dose counter for a metered dose inhaler" and a "metered dose inhaler" comprising the claimed dose counter.
>
> Patent No. 10,561,808 (the "'808 patent") claims a "dose counter for an inhaler," and Patent No. 11,395,889 (the "'889 patent") claims "an incremental dose counter for a metered dose inhaler."

[8] "HFA" refers to hydrofluoroalkane, which is used as a propellant.

ARGUMENT

I. Improper Orange Book Patent Listings Can Harm Competition and May Violate the Antitrust Laws.

health. 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, 1367-68 (2018). The ATS concluded that higher out-of-pocket expenses can increase stress, reduce medication adherence, and lead to worse health outcomes, including unnecessary hospitalizations, and noted that these problems have been "exacerbated by a paucity of generic alternatives"— i.e., lack of competition. Id. at 1367.

Lack of competition for asthma inhalers is particularly concerning. These potentially lifesaving products are used by millions of Americans. According to the American College of Allergy, Asthma, and Immunology, approximately 7.7% of Americans have asthma, including 20.2 million adults and 4.6 million children. [13] Although the patents on many of the active ingredients used in asthma inhalers have been expired for decades, only 5 of the 37 brand-name inhalers currently on

[13] See American College of Allergy, Asthma, and Immunology, Asthma Facts (2023), https://acaai.org/asthma/asthma-101/facts-stats/.

the U.S. market face independent generic competition. Lack of competition keeps prices high.

Listing of device patents directed solely to the mechanical components of an inhaler— i.e., patents that do not claim the active ingredient or a drug formulation or composition—appears to be widespread. A recent study examined all 53 asthma and chronic obstructive pulmonary disease ("COPD") inhaled medications approved by the FDA from 1986 to 2020 and found that 39 of these products collectively listed 137 device patents, many claiming inhaler components such as the nozzle, canister, valve, piston pumping system, and dose counter. Brandon J. Demkowicz et al.,

longest period of protection extending over 21 years past the last to expire non-device patent. Id. at 454, 457. [14]

These tactics and harms are not confined to inhaled asthma/COPD medications. The Commission's Bureau of Competition has identified hundreds of drug-agnostic device patent listings for other lifesaving medications, including epinephrine injector pens and treatments for diabetes and weight loss. [15] Researchers have similarly documented such device patent listings with respect to medications for diabetes and weight loss. See Rasha Alhiary et al., Delivery Device Patents on GLP-1 Receptor Agonists, 331 JAMA 794, 794-96 (2024). For example, they found that NDA-holders listed a total of 107 patents on

[14] A recent academic study of FDA-approved asthma/COPD inhaled medications shows that brand companies can continue to earn large profits long after patents on their drugs' active ingredients expire if they have secondary patents, including device and device component patents. See William B. Feldman et al., Manufacturer Revenue on Inhalers After Expiration of Primary Patents, 2000-2021, 329 J. Amer. Med. Assoc. 1, 1-3 (2023).

[15] See, Press Release, FTC, FTC Expands Patent Listing Challenges, Targeting More Than 300 Junk Listings for Diabetes, Weight Loss, Asthma and COPD Drugs (April 30, 2024), https://www.ftc.gov/legal-library/browse/warning-letters/85231; Press Release, FTC, FTC Challenges More Than 100 Patents as Improperly Listed in the FDA's Orange Book (Nov. 7, 2023), https://www.ftc.gov/legal-library/browse/warning-letters/81927.

GLP-1 delivery devices, none of which included claims mentioning active ingredients, chemical structures, or therapeutic classes. Id. at 794. The researchers observed that removal of these device patents from the Orange Book "may substantially reduce barriers to generic entry by decreasing the number of patents that generic firms must contest ahead of FDA approval." Id.

II. Teva's Device and Device Component Patents Do Not Meet the Listing Criteria Established by Congress.

Enforcing the OBTA's limits on Orange Book listings would protect competition as Congress intended. Under the plain language of the Listing Statute, drug-agnostic device patents such as the Asserted Patents are ineligible for submission for listing in the Orange Book. A non-method-of-use patent that may be infringed by a generic product is listable only if (1) it is "a drug substance (active ingredient) patent or a drug product (formulation or composition) patent" and (2) it "claims the drug for which the [NDA] applicant submitted the application." 21

U.S.C. § 355(b)(1)(A)(viii)(I); see also id. § 355(c)(2).[16] Under the plain language of the statute, both criteria must be satisfied.

The district court held that the Asserted Patents are not listable because they do not "claim" ProAir HFA, without addressing whether they are "drug product (formulation or composition) patents." Appx33. In fact, Teva's drug-agnostic device patents do not satisfy either prong of the test. That does not mean that Teva is unable to enforce its device patents against a potentially infringing generic product. It simply means that Teva is not entitled to list those patents in the Orange Book and obtain a 30-month stay on that basis.

A. Drug-Agnostic Device Patents Are Not "Drug Product (Formulation or Composition)" Patents.

By enacting the OBTA, Congress made clear that not all patents that might be infringed by the manufacture, use, or sale of a generic drug are properly listable in the Orange Book. A non-method-of-use patent is listable only if it is directed to a "drug substance (active ingredient)" or a "drug product (formulation or composition)." 21 U.S.C.

[16] A patent is also listable if it "claims a method of using such drug for which approval is sought or has been granted in the application," 21 U.S.C. § 355(b)(1)(A)(viii)(II), but that provision is not at issue here.

§ 355(b)(1)(A)(viii)(I). Teva concedes that the Asserted Patents are not "drug substance (active ingredient)" patents. But they do not qualify as "drug product (formulation or composition)" patents either. [17] Teva's argument that drug-agnostic patents directed to inhaler devices meet this criterion disregards the statutory language and would enable even minor device inventions unrelated to the actual medicine in a drug to

product"; thus a patent is properly listable under this prong only if it is

5,695,743, which expired in 2014, is directed to an "aerosol formulation" comprising (a) a "therapeutically effective amount of" salbutamol (another name for albuterol) or other specified active ingredients and (b) HFA as a propellant. This is an example of a "drug product (formulation or composition) patent" because it is directed to a mixture of chemical substances, one of which is the active ingredient of ProAir HFA.

Even setting aside the words "formulation or composition," Teva's drug-agnostic device patents still could not be classified as "drug product" patents. The term "drug product" originates in FDA regulations, which define "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." 21 C.F.R. § 314.3(b) (emphasis added). A "dosage form" is "the physical manifestation containing the active and inactive ingredients that delivers a dose of the drug product." Id. The definitions of "drug product" and "dosage form" include an active ingredient. Accordingly, the Asserted Patents, which do not recite any active ingredient in their claims, are not directed to a "drug product."

Furthermore, the words "a drug substance (active ingredient) patent or a drug product (formulation or composition) patent"—which Congress specifically added to the statute in 2020—must mean something different than a patent that "claims the drug for which the applicant submitted the application." 21 U.S.C. § 355(b)(1)(A)(viii)(I). Courts "generally presum[e] that statutes do not contain surplusage," Obduskey v. McCarthy & Holthus LLP , 586 U.S. 466, 476 (2019), and a reading that would nullify the OBTA amendments should be rejected.

Teva is also incorrect in suggesting that under the Commission's reading, there would have been no need for Congress to distinguish between a "drug substance (active ingredient) patent" and a "drug product (formulation or composition) patent." Teva Br. 53. The two categories are distinct. A "drug substance (active ingredient) patent" is directed to an active ingredient. A "drug product (formulation or composition) patent," as discussed above, is directed to a mixture of substances that includes at least one active ingredient. A device patent that does not recite any species or genus of active ingredient in its claims is neither a drug substance nor a drug product patent within the meaning of the Listing Statute.

Contrary to Teva's argument (Teva Br. 53-54), no claim construction is required to resolve whether the Asserted Patents are listable. The "drug product (formulation or composition) patent[s]" prong of the statute limits the types of patents that are listable. No claim construction is needed here to conclude that on their face, the Asserted Patents are device and device component patents not "drug product (formulation or composition) patents."

B. Drug-Agnostic Device Patents Do Not Claim the NDA Product.

Because the Asserted Patents are not "drug product (formulation or composition) patents," they are not properly listable regardless of whether they "claim the drug for which [Teva] submitted the [NDA]." 21 U.S.C. § 355(b)(1)(A)(viii)(I). But the district court correctly held that the Asserted Patents do not satisfy the "claims the drug" requirement either. As the district court held, a device patent that does not recite any active ingredient in its claims cannot be said to "claim" a particular drug product.

Teva attempts to rewrite the language of the Listing Statute in arguing that a patent "claims the drug" approved in the NDA if it "reads on" the NDA drug— i.e., if the unauthorized use, manufacture, or

sale of the NDA drug would infringe the patent—even if the patent claims do not mention an active ingredient. Teva Br. 21. The First Circuit correctly disposed of this precise issue in Lantus , which involved an injector pen containing a type of insulin. See 950 F.3d at 5-10. The court held that a patent on the drive mechanism component of the pen device did not "claim the drug" for which the brand's application was approved because the patent "neither claims nor even mentions insulin glargine or the Lantus SoloSTAR"—the active ingredient and the approved drug product, respectively. Id . at 10. The same analysis applies here, where the Asserted Patents do not mention albuterol sulfate, any genus of compounds that includes albuterol sulfate, or indeed, any active ingredient at all, and are listed across many different NDAs for products with different active ingredients.

The example given by the First Circuit in Lantus is illustrative. Suppose a patent contains claims reciting a transmission system for use in automobiles. The patent would "read on" a car that incorporated that transmission system. But one would not say the patent on the transmission "claims" the car. See Lantus, 950 F.3d at 8 ("One would not think . . . that a patent claiming only a transmission system must

this second requirement in the statute, which the Asserted Patents do not meet. See supra Section II.A.

Teva's reliance on dicta from Apotex, Inc. v. Thompson, 347 F.3d 1335 (Fed. Cir. 2003) (Teva Br. 24-25) is misplaced. In that case, the Court never reached the issue of whether the patents were properly listed. Id. at 1349. The court's discussion of the phrase "claims the drug" as part of its antecedent jurisdictional analysis does not suggest that a patent claiming only the device components of a drug-device combination product, with no mention of an active ingredient, can be said to claim the NDA drug.

Contrary to Teva's assertion (Teva Br. 45-48), no claim construction is required with respect to this prong either. The claims in the Asserted Patents recite only structural elements and do not mention any chemical or biological substances whatsoever, and thus cannot plausibly be construed to claim a metered aerosol of albuterol sulfate.[21] This Court's recent decision in Jazz is not to the contrary. Jazz observed

[21] Teva proposes claim constructions of the Asserted Patents that would read in new limitations reciting the use of an unspecified "active drug," Teva Br. 45-46, but it is black letter law that new limitations cannot be imported into the claims. See Phillips v. AWH Corp., 415 F.3d 1303, 1323 (Fed. Cir. 2005) (en banc).

that what the patent "claimed" "should be derived using the tools and framework of patent law, including claim construction ," 60 F.4th at 1379, but it did not conduct a detailed claim construction analysis. Instead, it held that claims to a "system" could not properly be construed as claiming a "method." Id. at 1380. Nor was claim construction needed in UFCW; on their face, the listed patents there did not "claim" the NDA drug, because they claimed a combination of two active ingredients, but the NDA drug contained only one of them. UFCW, 11 F.4th at 124, 132.

Finally, Teva's argument that the term "drug" may include "articles intended for use as a component" of a drug does not support its position. SeeTeva Br. 29 (quoting 21 U.S.C. § 321(g)(1)(D)). Lantus properly rejected an argument identical to Teva's. 950 F.3d at 9. As the First Circuit explained, the "plain wording" of the Listing Statute requires not only that the listed patent "claims a drug," but that it 0.0004 Tc 0.0 0 09

these components are not "the" drug for which Teva submitted the NDA because the components may be made and used without albuterol sulfate. Indeed, Teva has listed the same patents in connection with several other NDAs containing different active ingredients.

C. The Court Should Enforce the Policy Choices Congress Made in the OBTA To Prevent Improper Orange Book Listings.

Teva conjures a parade of horribles that will supposedly ensue if courts enforce the statutory criteria for Orange Book listing. Teva Br. 54-56. It is not the role of this Court to second-guess Congress's policy judgment. In enacting the OBTA, Congress clarified that the protection of the 30-month stay does not extend to every patent that an ANDA product may infringe, but only to specific types of patents. Patents that merely claim a mechanism for delivering a drug do not qualify.

In any event, Teva's suggestion that a plain text application of the listing criteria will effectively nullify the Hatch-Waxman Act and thereby disincentivize companies from trying to launch generics (Teva Br. 54-55) is groundless. Brand companies will still be required to list patents that claim their approved product and are directed to the relevant drug substance or a formulation or composition of the drug

product (or patents that claim a method of use approved in the NDA), and they will still be entitled to a 30-month stay if a competitor subsequently files an ANDA seeking to market a generic before expiration of these properly listed patents. Enforcement of the listing criteria simply means the statute will function as Congress intended.

CONCLUSION

The district court's judgment should be affirmed.

September 6, 2024

Respectfully submitted,

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