2024-1936

United States Court of Appeals for the Federal Circuit

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 in No. 2:23-cv-20964-SRC-MAH Honorable Stanley R. Chesler, Judge

BRIEF *AMICUS* OF DEVA HOLDING A.S. IN SUPPORT OF AMNEAL *ET AL.*, DEFENDANTS-APPELLEES

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Certificate of Interest

Per Fed. Cir. Rule 47.4, counsel for *amicus curiae* Deva Holding A.S. certifies the following:

1. The full names of all entities represented by undersigned counsel in this case: Deva Holding A.S.

2. The full names of all real parties in interest for the entities: N/A

3. The full names of all parent corporations for the entities and all publicly held companies that own 10% or more stock in the entities: EastPharma S.a.r.l., a Luxembourg based company, has controlling interest in Deva Holding A.S. and operates as a distinct corporate entity. No publicly-held company owns 10% or more of Deva Holding A.S.'s stock.

4. All law firms that have appeared for the entities: Shashank Upadhye; Yixin Tang; and Brent Batzer of Upadhye Tang LLP are counsel of record in the related case.

5. Related cases that meet the criteria of Rule 47.5(a): Teva Branded Pharm. Prods. R&D, Inc. et al. v. Deva Holding A.S., No. 2:24-cv-04404 (D.N.J.), but no Deva Holding A.S. case is on appeal to this Court.

6. Any information required under Rule 26.1(b) and 26.1(c): N/A

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Statement of Related Cases

There is one pending case that will be directly affected by this Court's decision in this appeal: *Teva Branded Pharm. Prods. R&D, Inc. et al. v. Deva Holding A.S.*, No. 2:24-cv-04404 (D.N.J.). Shortly after Judge Chesler issued his June 10, 2024 decision that is the subject of this appeal, Deva filed its opening motion to dismiss on June 20, 2024 (D.I. 11); Teva et al. filed its response on July 22, 2024 (D.I. 16); and Deva filed its reply on July 29, 2024 (D.I. 22). On Aug. 5, 2024, Judge Chesler ordered supplemental briefing to be filed by Aug. 19, 2024 (D.I. 23). He ordered the parties to brief that within the meaning of 35 U.S.C. §271(e)(2): "what is the definition of "drug" in the context of this statutory provision?" Both parties filed the supplemental briefing on Aug. 19, 2024 (D.I. 25, 26). On Aug. 28, 2024, Judge Chesler ruled that Deva's motion to dismiss was denied in part and reserved in part. His reservation is predicated on the disposition of this appeal. (D.I. 29). *See also*, *Teva Branded Pharmaceutical Products R&D, Inc. et al. v. Deva Holding A.S.*, 2024 WL 3966314, at *4 (D.N.J., 2024).

Statement of Interest of *Amicus Curiae* Deva Holdings SA

For over 65 years, Deva has researched, developed, manufactured, and marketed affordable pharmaceutical products. Each year, Deva adds new products to its portfolio and expand the therapeutic areas of its products. Deva's products are manufactured in EU GMP and US FDA approved manufacturing plants.

Deva filed its own Abbreviated New Drug Application (ANDA) #21-3818 with the US FDA seeking approval to market a generic version of Teva's ProAir® HFA (albuterol sulfate) Inhalation Aerosol (bearing NDA #02-1457) prior to the expiration of several patents, including the 9,463,289 patent that is the subject of this appeal.

Deva's *amicus* brief provides a different background that further illustrates why pure device patents are not properly listable in the Orange Book.[1]

[1] No counsel for a party authored this brief in whole or in part; no person other than *amicus* or its counsel contributed financially to fund its preparation or submission. Further all parties consented to the filing of this brief. Fed. R. App. P. 29(a)(2).

Introduction

The underlying appeal addresses a narrow point of law of whether a device patent can be listed in the Orange Book (OB). Teva's Blue Brief and other *amicus* briefs that support listing describe a parade of horribles based on an expansive reading of the law. This *amicus* brief does not point-for-point rebut the arguments made in the opening rounds. Rather it addresses many of the parade of horribles, myth-busts, and ultimately concludes that it is up to Congress, not the Courts, to fix any larger policy issues. This is because each side of the pharmaceutical industry – the brand and generic sides – have public policy arguments about the Hatch Waxman Act interpretation. *See*, Shashank Upadhye, *Generic Pharmaceutical Patent and FDA Law*, §1:4 "Caveats in the Hatch Waxman Act/Paragraph IV litigation" (2022 Ed.)(available in Westlaw GENPHARMA database)("Generic Pharma"):

> But litigants and courts are again admonished to recall some basic principles. First, the Hatch Waxman Act, the Food Drug & Cosmetic Act, and the patent laws are statutory enactments. As such, interpretation of the statutes requires the time-honored and traditional tools of statutory construction. Courts should resist reading extra words or meanings into the statutory texts. Further, courts should resist injecting policy rationales into statutory

> interpretations. If dire consequences truly exist in a certain interpretation, then it is up to Congress to fix those infirmities in the statutes, presumably with input from all relevant stakeholders, agencies, associations, industry professionals, etc. As such, courts should be very sensitive to the typical "parade of horribles" arguments raised by parties on each side. A patent holder advocates for a position because a contrary position would devastate the incentive to conduct further research and development in pharma research; whereas the generic drug company advocates that a contrary position would deprive the public of cheaper alternatives.

Deva addresses the following points: (i) just because certain patents cannot be listed in the Orange Book does not mean those patents are worthless and have no value; (ii) there is one proper statutory construction and Congress knows how to fix the statutes to address policy issues; and (iii) patentees are in charge of their patent application drafting and any inability to list patents in the Orange Book are self-inflicted injuries that do not require Courts to remedy.

Argument

I. Non-Orange Book Patents Have Value Because They Can and Are Asserted In Court Cases

A. Despite Inability to List Device Patents, They Have Value

This appeal is about the listing of mechanical device patents that do not claim any drug substance, formulation, or composition into the Orange Book relating to Teva's albuterol sulphate inhaler product. There is no dispute that the patents do not mention any drug name, including albuterol sulphate. Teva did not discover albuterol. There is no dispute that the device patents do not claim a drug substance, a formulation, or a composition. Teva and its *amici* proponents assert that despite not naming any molecule, the device patents are listable in the Orange Book. A recurring but subtle theme is that without any OB listing, that somehow these patents don't have any value or have reduced value because they cannot be asserted at the outset and any enforcement would occur when competitive products are either approved or launched. Teva Blue Br. at 54; AstraZeneca *Amicus* Br. at 13 (Doc. #40); Sanofi *Amicus* Br. at 23 (Doc. #37).

B. Examples Where Non-OB Listed Patents Have Been Successfully Asserted

First, nothing suggests that the inability to list patents means that such patents cannot be asserted in court. Non-OB patents are asserted in courts. It is just a function of timing, not propriety. Old antibiotics are a prior example of timing. As discussed below, historically patents related to antibiotics were not OB listable. As such, generic drug companies filed the ANDA, obtained approval, decided whether to launch, and the brand company could sue for infringement (albeit post-approval). This situation was the norm for antibiotics. *See e.g.*, *Abbott Laboratories v. Sandoz, Inc.*, 500 F.Supp.2d 807, 814 (N.D.Ill. 2007)(describing how Abbott sued Sandoz for declaratory judgement infringement post-ANDA approval for non-Orange Book listed patents). And when that regime didn't work over the long term, Congress changed the law, as discussed below.

Second, there are other examples of non-OB patents being asserted. In *Abraxis Bioscience Inc. v. Navinta LLC*, Abraxis asserted

one OB listed patent that received the Paragraph IV certification,[2] and two other method of use patents that were not OB listed. The trial court determined that Navinta (the generic company) induced infringement of the two then-unlisted patents. Though the patents were later listed in the OB, it showed that the patentee could have and did assert non-OB patents. This Court reversed on standing grounds. *Abraxis Bioscience, Inc. v. Navinta LLC*, 625 F.3d 1359, 1360 (Fed. Cir. 2010).

Vanda Pharmaceuticals initially sued West-Ward Pharmaceuticals on the only listed OB patent based on West-Ward's Paragraph IV certification. *Vanda Pharmaceuticals Inc. v. West-Ward Pharmaceuticals International Ltd.*, 887 F.3d 1117, 1122 (Fed. Cir. 2018). Vanda obtained a second patent but sued West-Ward about 7 months later on this new second patent. And another 7 months elapsed before Vanda listed patent #2 in the OB. After patent #2 was finally listed in the OB, West-Ward tendered its second Paragraph IV certification. Because patent #2 was listed after West-Ward filed its ANDA, and despite being sued for infringement, Vanda could not earn

[2] For a description of the Paragraph IV process, see generally, *Generic Pharma*, §1:3 "Legal aspects of the generic drug development pathway for judges and lawyers".

new 30-month litigation stays to block ANDA approval. *Vanda*, 887 F.3d at 1128. *See*, *Generic Pharma* §27:3 "The Frozen Orange Book and Patents That Qualify For 30-Month Stays." Ultimately, the Federal Circuit affirmed patent #2 infringement and validity. This example further shows that a non-OB patent can block ANDA approvals even absent a 30-month stay.

In a different scenario, this Court addressed the impact of a non-Paragraph IV patent and its potential enforcement. Amarin Pharmaceuticals sued Hikma Pharmaceuticals in a "run-of-the-mill induced infringement case arising under" Section 271(b). *Amarin Pharma, Inc. v. Hikma Pharmaceuticals USA Inc.*, 104 F.4th 1370, 1377 (Fed. Cir. 2024). Hikma initially filed its ANDA in Sept. 2016 with Paragraph IV certifications and Amarin sued on 6 patents. The trial court ruled against Amarin in March 2020 and this Court summarily affirmed. *Amarin Pharma Inc. v. Hikma Pharmaceuticals USA Inc.*, 819 Fed.Appx. 932 (Sept. 2020). In March 2020, Amarin obtained 3 new patents and listed them in the OB. Hikma filed so-called Section viii

statements to those 3 patents.[3] Hikma obtained final ANDA approval in May 2020 and launched the product in Nov. 2020. Because of facts learned after the launch, Amarin sued Hikma in Nov. 2020 for inducement to infringe the 3 new patents. This Court remanded the trial court's dismissal ruling stating that Amarin can proceed on its inducement counts. *Amarin*, 104 F.4th at 1372. This shows that even post-launch, a patentee can assert patents, even to those that did not beget any Paragraph IV certification, based on facts learned after ADNA approval and launch.

In yet another post-launch scenario, a patentee won over $200 million in damages. Teva was the defendant. Teva filed its ANDA in March 2002, with a Paragraph III certification to patent #1, and a Paragraph IV certification to patent #2. The Paragraph III certification blocked the launch until patent #1 expired in March 2007. GSK did not sue Teva on patent #2. Instead, GSK put patent #2 into reissue proceedings in Nov. 2003. The PTO reissued the patent #2 in Jan. 2008,

[3] The Section viii Statement, 21 U.S.C. §355(j)(2)(A)(viii), is sometimes known as the skinny label or label carve-out. *Generic Pharma* §26:11 to §26:15; *Amarin Pharma, Inc. v. Hikma Pharmaceuticals USA Inc.*, 104 F.4th 1370, 1377-78 (Fed. Cir. 2024).

which maintained its expiration date in June 2015. GSK replaced the original patent #2 in the OB with the new reissued patent. When patent #1 expired in March 2007, Teva later launched its product in Sept. 2007. GSK sued in July 2014 based on new facts learned well after launch. This Court affirmed the infringement and the jury award. *GlaxoSmithKline LLC v. Teva Pharmaceuticals USA, Inc.*, 7 F.4th 1320, 1341 (Fed. Cir. 2021). This is another example where post-launch consideration can result in enforcement and damages years later.

Currently before this Court is yet another example (*Astellas Pharma Inc. v. Sandoz, Inc. et al*, CAFC Docket No.: 23-2032/ -2063/ -2089). Originally, Astellas sued generic drug companies based on the first ANDA filings. Astellas settled with the generic companies for a launch date in the future. Astellas then obtained the '780 patent on Nov. 24, 2020 and immediately sued the generic companies again. At the time of the suit, the '780 patent was not an OB listed patent; the '780 listed later in Dec. 2020. A few generic companies went to trial and won invalidity of the '780 patent. *Astellas Pharma Inc. v. Sandoz Inc.*, 2023 WL 3934386, at *2 (D. Del. 2023). Those few generic companies launched their products pending appeal. Meanwhile Astellas obtained

the ‘451 patent on July 25, 2023, sued the generic companies that launched on July 28, 2023. *Astellas Pharma Inc. v. Lupin Ltd.*, 2024 WL 1832483, at *3 (D. Del., 2024). The ‘451 patent later listed in Aug. 2023. Again, this another example of a brand company’s ability to assert patents pre- and post- launch.

Finally, Lundbeck v. Lupin is proof that even a categorically excludable OB patent can be enforced. In Lundbeck, aside from other patents in suit, Lundbeck sued Lupin for infringing the ‘626 patent, which is non-OB listed because it claims a process. Notwithstanding its non-OB listing status, Lundbeck proved infringement of the ‘626 process patent. *H. Lundbeck A/S v. Lupin Ltd.*, 87 F.4th 1361, 1374 (Fed. Cir. 2023).

These above examples illustrate situations where patents that are not in the Orange Book at the time of the original or first ANDA filing; get listed later into the OB; or are issued post-launch can be enforced. These examples show that patents that do not beget a Paragraph IV certification at the time the first ANDA’s are filed can be asserted.[4]

[4] Other examples include *Novartis Pharmaceuticals Corp. v. Alembic Pharmaceuticals Ltd*, 2023 WL 6387975, at *1 (D. Del., 2023)(indicating

They have value. And because they have enforcement value, there is no reason to contort the statutory language to allow for listing device patents.

II. Device Patent Listing Disputes Require Congressional Action, Not Court Action

As stated earlier, courts should hesitate to involve themselves in policy issues. Another recurring theme in the blue brief and supporting *amici* is that without device patent listing, it would disrupt the Hatch Waxman Act balance. This is precisely why Congress should step in, instead of the Courts, to fix any perceived imbalance.

A. Congress Intentionally Differentiated Between Listable and Non-Listable Patents

First, Congress intentionally created differentiation between listable and non-listable patent categories. Per, 21 U.S.C. §355(b)(1)(A)(viii), Congress stated that patentees can only list:

> (viii) the patent number and expiration date of each patent for which a claim of patent infringement could reasonably be asserted

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that the '918 patent claiming an amorphous form was not OB listed); and *Celgene Corporation v. Sun Pharma Global FZE*, 2020 WL 1921700, at *1 (D. N.J., 2020)(denying dismissal motion based on 3 non-OB listed patents that did not even receive any Paragraph IV certification).

> if a person not licensed by the owner of the patent engaged in the manufacture, use, or sale of the drug, **and that**—
>
> (I) claims the drug for which the applicant submitted the application **and** is a drug substance (**active ingredient**) patent or a drug product (**formulation or composition**) patent; or
>
> (II) claims a method of using such drug for which approval is sought or has been granted in the application. (emphasis added).

The Sanofi Br. at 2 and 12, appears to crop the statutory language of subsection (I) by stopping the quote at "… submitted the application." Indeed, as shown below, stopping there reads out completely the new additions in subsections (I) and (II). The plain language of the statute imposes the listing conditions and should be read in its entirety, including a focus on the word "and" where it appears.

The statute defines the categories of listable patents. First, the patent has to be one that an unauthorized person could be reasonably sued for infringement under subsection (viii). Second, the kinds of patent are more specifically identified in subsections (I) and (II), and therefore further define the language of subsection (viii) because section (viii) includes an "and that" before subsections (I) and (II). Therefore, it

is improper to stop analysis at just the introduction subsection (viii) without diving into subsections (I) and (II).

Subsection (I) states that two kinds of listable patent; one is for the drug substance, which the statute immediately defines as the "active ingredient" in the parenthesis. The second kind of patent is for the drug product that is immediately defined as the "formulation or composition" in the parenthetical. There are, therefore, 2 conditions embedded within subsection (I). First is that the patent "claims the drug for which the applicant submitted the application" and the second is that the patent is either a drug substance or drug product.

Moreover, stopping at the phrase "(I) claims the drug for which the applicant submitted the application…" ignores the "and" right after. And what comes after the "and" modifies what just came before, shown here with square brackets collecting the drug substance and drug product together:

> Proper Interpretation: 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]]

Listing Proponents Interpretation: 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~~

Devices are not the drug substance. And while some may believe a device is approved as part of the drug product, it does not mean devices are "formulations or compositions".[5] Further the parentheticals do not include broadening language that implies breadth. The parentheticals

[5] Teva's Br. at 1 and 12, suggests that the trial court erred for failing to conduct any claim construction. Teva's aspersions of the judge for failing to conduct any claim construction is not error. This is an appeal on statutory construction, not claim construction. Teva's Br. at 18 identifies the standard of review as being of statutory construction, not an abuse of discretion for failing to conduct any claim construction. Moreover, Amneal's Counterclaims (D.I. 12, docket 23-cv-20964, filed Dec. 1, 2023) Paras. 84, 85 state that none of the patents use the words "albuterol" or "albuterol sulfate." Amneal's Counterclaim Para. 187 states that "[n]one of the claims of the '289 patent recite "albuterol," "albuterol sulfate," "propellant HFA-134a," or "ethanol."" Para. 188 states that "[t]he '289 patent does not recite any of the following words or phrases: "albuterol," "albuterol sulfate," "HFA-134a," "ethanol," "ingredient," "formulation," or "bronchospasm."" And Para. 189 states that "[o]ther than reciting the name of the assignees and applicants "Ivax Pharmaceuticals Ireland," and "Teva Pharmaceuticals Ireland," the '289 patent does not recite the words "pharmaceutical," "pharmaceuticals," "pharmacological," "pharmacy," or "pharmaceutics.""

do not have expansive language, such as: "(e.g., active ingredient)" or "(e.g., formulation or composition)" or "(formulation or component, etc.)".

Accordingly, Congress chose to limit the listable patents under subsection (viii) to the active ingredient, formulation, or composition, and nothing else. To be doubly sure, as discussed below regarding the Orange Book Transparency Act, Congress chose to add prescriptive language in 21 U.S.C. §355(c)(2) to ensure that non-eligible patents are not listed.[6]

FDA implemented the statute in 21 C.F.R. §314.53(b)(1). There it repeats that, "[f]or purposes of this part, such patents consist of drug substance (active ingredient) patents, drug product (formulation and composition) patents, and method-of-use patents." It repeats the parenthetical that the drug product is only the formulation or composition. And the regulation now states categories that cannot be listed: "Process patents, patents claiming packaging, patents claiming metabolites, and patents claiming intermediates are not covered by this

[6] The prescriptive language added by the OBTA is at the end of section 355(c)(2): "Patent information that is not the type of patent information required by subsection (b)(1)(A)(viii) shall not be submitted under this paragraph."

section, and information on these patents must not be submitted to FDA." This repeats essentially the prescriptive language of Section 355(c)(2). The same statutory constructs apply in regulatory interpretation.

Now device patent listing proponents argue that device patents that don't even claim the underlying drug product or substance, where such patents can cover myriad different products, are still listable and Congress knew that. But in examining the categories of patents that cannot be listed, it becomes clear that generalized device patents are not listable.

The list of excludable categories includes patents that are highly tied to or intertwined with the exact underlying drug product. For example, patents on processes of making that exact drug product are excludable. Patents claiming the exact packaging of the drug product are excluded. Patents claiming the metabolite of the drug substance, which occurs upon ingestion of the exact drug, are excluded. Finally, patents claiming intermediates of making the drug substance (the active ingredient) are excluded. Notably, as part of the drug approval process, FDA approves the process of manufacturing the active

ingredient via complete assessment approval of the Drug Master File (DMF). FDA also approves the manufacturing process for the final dosage form. FDA also approves the packaging. 21 U.S.C. §355(b)(1)(A). Despite the FDA approving of manufacturing methods and packaging, patents claiming these are not listable.

So, what is more likely? That patents claiming devices that do not recite or even mention the actual drug product are clearly listable but patents that are so highly connected and intertwined to the drug substance or drug product are not listable? It makes no sense.

B. Congressional Amendments to the Orange Book Statutes Demonstrate Congressional Ability to Fix Problems

As stated earlier, Congress knows how to fix Orange Book listing issues, and has done so. Prior antibiotic patents were not eligible to be OB listed because these old antibiotics were approved under prior Section 507 of the Food Drug Cosmetic Act, not under Section 505 (a/k/a 21 U.S.C. §355). Under Section 125 of Title 1 of the Food & Drug Administration Modernization Act of 1997 (Pub. L. 105-115) (a/k/a FDAMA), Congress repealed Section 507, thereby new antibiotics were approved now under Section 505, and hence eligible for OB listing. Congress provided the fix.

Deva discussed §355(b)(1)(A) above, which is the modern version. In the Orange Book Transparency Act of 2020 (Pub. L. 116-290)(OBTA), Congress amended §355(b)(1) to add the two new and very specific subsections in (I) and (II):

Before the OBTA of 2020	**After**
"any patent which claims the drug for which the applicant submitted the application or which claims a method of using such drug and with respect to which a claim of patent infringement could reasonably be asserted if a person not licensed by the owner engaged in the manufacture, use, or sale of the drug."	"(viii) the patent number and expiration date of each patent for which a claim of patent infringement could reasonably be asserted if a person not licensed by the owner of the patent engaged in the manufacture, use, or sale of the drug, and that— —(I) claims the drug for which the applicant submitted the application and is a drug substance (active ingredient) patent or a drug product (formulation or composition) patent; or —(II) claims a method of using such drug for which approval is

	sought or has been granted in the application."

The OBTA of 2020 also amended §355(c)(2) to: (i) add a timing requirement of when patent listing must occur; (ii) referred to the newly added subsections (I) and (II); and (iii) specifically added the statement: "Patent information that is not the type of patent information required by subsection (b)(1)(A)(viii) shall not be submitted under this paragraph." Pub. L. 116-290, Section 2(b). The OBTA of 2020 also required patentees to delist patents based on invalidity court judgments. Pub. L. 116-290, Section 2(d), adding new subsection 21 U.S.C. §355(j)(7)(D). This last amendment shows Congress was aware that PTAB-IPR/PGR decisions, which were issued after the 2012 AIA, could lead to final invalidity, and thus required delisting patents as appropriate. Finally, the OBTA of 2020 required the OB to list certain exclusivities and exclusivity expiration date. 21 U.S.C. §355(j)(7)(A)(iv). Congress knew how to fix the Orange Book.

C. Congress Chose to Limit 30-Month Stays in the 2003 MMA

Device patent listing proponents argue that patentees are entitled to the litigation 30-Month stay because of patent listings. Congress

actually thought and acted oppositely. Congress curtailed 30-month stays. Prior to the Medicare Modernization Act (MMA) of 2003, (Pub. L. 108-173, 117 Stat. 2066), patentees could obtain and list new patents, force a pending ANDA litigant to certify Paragraph IV to that newly listed patent, sue within the 45-day deadline after receiving the Notice Letter, and obtain yet another 30-month stay. This pummeled ANDA litigants with repetitive or "evergreening" 30-month stays. *Apotex, Inc. v. Thompson*, 347 F.3d 1335, 1340-41 (Fed. Cir. 2003). That presented a policy problem. Section 1101(a)(2) of the MMA amended the statute that now only allows for one 30-month stay. Here, rather than allow patentees to continue with repetitive 30-month stays, Congress chose to limit patentees to just one 30-month stay. *Apotex*, 347 F.3d at 1341; *Generic Pharma*, §27:3 (on frozen Orange Book). In other words, Congress expressly limited patentee rights.

These Congressional fixes demonstrate that to the extent that device patent listing is controversial, Congress is to fix any policy reasons. *SCA Hygiene Products Aktiebolag v. First Quality Baby Products, LLC*, 580 U.S. 328, 345 (2017)("First Quality and its

supporting *amici* also make various policy arguments, but we cannot overrule Congress's judgment based on our own policy views.").

D. Other Policy Reasons by Device Listing Proponents Are Myths That Are Myth-Busted

As to other policy reasons, proponents argue that OB listing facilitates due diligence by the generic company and is more efficient. First, allowing device patents untethered from an underlying drug (that is because the drug is not claimed) introduces the slippery slope leading to broader swath of device patent listings. This increases due diligence burdens and is less efficient because of more costs. Second, efficiency is not really a concern because patent searching is not unduly difficult nowadays; and generic companies still must search for other excluded categories such as processes, packages, polymorphs (if not the same polymorph as the branded drug product, *see* 21 C.F.R. §314.53(b)(1), (2)), etc. Generic companies use patent search tools to find OB excluded and OB included patents, and evaluating those search results.

Finally, proponents argue that waiting for approval and launches raises the specter of so-called at-risk launches. It's true that full approval can surprise the NDA holder who then must marshal resources to file TRO's and/or PI's to block the launch. But just because

an ANDA filer obtains full approval to the surprise of the NDA holder does not justify a wrong reading of the statute nor mean that a launch is also imminent. It can happen that upon ANDA approval or near-approval, the ANDA sponsor files its own Declaratory Judgment action to clear the way of possible patents. ANDA sponsors can also file PTAB proceedings to clear the way. These options de-risk the launch-at-risk. After all, a patentee, to avoid being a DJ defendant, could tender a covenant not-to-sue to deprive DJ jurisdiction and the ANDA sponsor now has no risk.

The AstraZeneca Br. at 15 suggests that at-risk launches can result in billion-dollar verdicts, citing to an article that describes the Teva/Sun-Pfizer case. The passage suggests it was based on non-OB listable patents because that's what this appeal is about. In that case, Teva and Sun were involved in typical Paragraph IV litigation. The relevant patents were OB listed and received Paragraph IV certifications, and earned a 30-month stay until August and Sept. 2007. After the stay expired and subject to FDA approval, the generic companies could launch. The plaintiff filed a preliminary injunction to block the launches in June 2007 before the stay expired. Teva launched

in Dec. 2007. Ultimately, this Court affirmed the denial of the injunction on potential patent invalidity grounds. *Altana Pharma AG v. Teva Pharmaceuticals USA, Inc.*, 566 F.3d 999, 1002 (Fed. Cir. 2009). The trial continued and in April 2010, a jury upheld the patent validity, thereby now making Teva and Sun liable for potential damages. The case settled wherein damages were paid. *Altana Pharma AG et al. v. Teva Pharmaceuticals USA Inc. et al.*, (DNJ 2:04-02355, Doc. #1384, dated June 12, 2013). The case posture does not support the brief's suggestion that non-OB patents generate potential damages.

The argument that patent infringement actions should be conducted in a single upfront action is false because there are countless cases where generic drug companies are pummeled with "waves" of patent suits. The waves occur because brand companies obtain new patents and assert them. This situation is described above referring to the *Astellas v. Sandoz et al*. case. Another example is the enalapril case, now in its 3rd wave. *Azurity Pharmaceuticals, Inc. v. Bionpharma Inc.*, 2023 WL 5664278, at *1 (E.D.N.C., 2023)(describing the 6-year war over 3 waves). Teva is a defendant in litigation with patentee Corcept Therapeutics since March 2018 in 5 waves of 9 new patents, with the

most recent complaint filed in March 2023. *See Corcept Therapeutics Inc. v. Teva Pharmaceuticals USA Inc.,* District of NJ Dockets: 18-cv-03632; 19-cv-05066; 19-cv-21384; and 23-cv-01505. Deva takes no position whether companies can obtain new patents and assert them, but use these examples only to rebut that litigations must be done in single actions.

Other policy reasons exist to deny generalized device patents from OB listing. Suppose a new ink-maker develops a new inventive and patented ink. That ink is used by a sticker/labeling printer who prints information on the sticker/labeling. The labeling/sticker is then placed on standard bottles. The bottles are used to package the pills when the drug product is approved. It makes no sense for the ink-maker to list the ink patent. Suppose a company invents and patents a new pharmaceutical ingredient. Dozens of companies use that ingredient in those respective formulations in both branded and generic formulations. Because FDA approves the drug product including the ingredients, will that ingredient patent be OB listable? Again, it makes no sense.

Device listing proponents also suggest that by listing patents in the Orange Book, it comports with a generic company's desire to file a

Paragraph IV certification to the patent and obtain so-called 180-Day exclusivity. That's wrong on many levels. First, suppose a product has no patents in the Orange Book. The ANDA sponsor can file its ANDA and within 10-11 months obtain final approval and launch the product.[7] The ANDA sponsor is not subject to any 30-month stays that extend possible launches for an additional 20 months nor spend millions in patent litigation. When left with a choice, a reasonable ANDA sponsor would opt for no litigation, no money spent, and fast approval. Will an ANDA sponsor not file the ANDA hoping one day that a patent will list, then file the ANDA to secure any 180-Day Exclusivity, that itself may be forfeited?[8]

Second, to the extent that a drug product has no patents listed, an ANDA sponsor may indeed qualify for a different kind of 180-Day exclusivity under the Competitive Generic Therapy (CGT) program. *See*,

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[7] GDUFA Reauthorization Performance Goals and Program Enhancements Fiscal Years 2023-2027, pg. 4 (visited Aug. 29, 2023: https://www.fda.gov/media/153631/download?attachment)("Assess and act on 90 percent of standard original ANDAs within 10 months of the date of ANDA submission, subject to any adjustments to the goal dates described in section I(A)(3).").

[8] An ANDA sponsor can forfeit the 180-Day Exclusivity under 6 different provisions. 21 U.S.C. §355(j)(5)(D).

Generic Pharma §30:1 to 30:3 ("180-Day Market Exclusivity Under Competitive Generic Therapy Initiative"). CGT exclusivity can be earned when no OB patents are listed. 21 U.S.C. §355(j)(5)(B)(v)(III)(aa)(BB). Therefore, an ANDA sponsor can earn the 180-Day exclusivity through the CGT pathway, saving time and money.

Moreover, it is true that certain brand drug products have only one first-filed ANDA that may qualify for the Paragraph IV based 180-Day Exclusivity. But there are brand drug products that have 29 ANDA's filed on the same day (dimethyl fumarate NDA 20-4063, ANDA's filed on March 27, 2017); 25 ANDA's (apixaban NDA 20-2155, ANDA's filed on Dec. 28, 2016); and 20 ANDA's (dapagliflozin NDA 20-2293, ANDA's filed on Jan. 8, 2018). In each case, the 20+ ANDA sponsors are all "first" and all share the 180-Exclusivity.

This Court should read the statute as it is and leave policy decisions to the policymakers. *Romag Fasteners, Inc v. Fossil, Inc.*, 590 U.S. 212, 219 (2020)("As these things go, *amici* amplify both sides' policy arguments. Maybe, too, each side has a point. But the place for reconciling competing and incommensurable policy goals like these is

before policymakers. This Court's limited role is to read and apply the law those policymakers have ordained, and here our task is clear.").

III. An "Empty" Device Patent Claim Is A Self-Inflicted Injury

An "empty" device patent claim, that is one that contains no claim limitation to the drug substance or even a drug formulation, is a self-inflicted injury. A patentee is master of the patent application at the start. When a patent applicant fails to even mention any drug product, drug formulation, or drug name, then it's clear that the invention is only to a mechanical device, not to a drug product at all. Otherwise, if the patent applicant is a traditional pharma company that is also developing its own unique device in parallel with its drug substance, then the applicant could have written the drug substance names therein. And that's the applicant's fault. Or when a drug company with no device development skills is developing a new formulation of an existing drug, then must begin hunting around for suitable devices, the company has to suffer the consequences that the device patentee failed to include any drug names in their patents or have no patent claim to the drug name. For the drug company knowing that in-licensed device patents do not have drug names or drug name claims, then this is a

contract issue between the drug company and the device company. And the inability to list device patents becomes a business term among them.

Other patentees know how to claim a device + drug name. For example, US Patent No.: 8,871,241 is listed in the OB for FLUOCINOLONE ACETONIDE (ILUVIEN) IMPLANT, NDA #20-1923. See here, https://www.accessdata.fda.gov/scripts/cder/ob/patent_info.cfm?Product_No=001&Appl_No=201923&Appl_type=N

The '241 patent claims an implant device (describing tubes, membranes, cylindrical shape) and specifically names the fluocinolone acetonide drug name:

> 1. A cylindrical drug delivery device shaped and sized for injection through a needle or cannula having a size from about 30 gauge to 23 gauge comprising:
>
> a core including an effective amount of **fluocinolone acetonide**, wherein the core comprises a matrix of **fluocinolone acetonide** particles and one or more polymers;

a polymeric tube, impermeable to **fluocinolone acetonide**, longitudinally surrounding the core, the tube comprising polyimide;

at least one diffusion membrane, permeable or semi-permeable to the passage of **fluocinolone acetonide**, disposed at an end of the delivery device.

Accordingly, where a device patentee fails to include any mention of any drug product name, or fails to claim the drug name in any claim, that is a self-inflicted injury. And where any injury is self-inflicted, it is not appropriate to contort statutory interpretation to save the injury.

IV. Delisting These Patents Do Not Undermine Teva's Monopoly Because Other Generic Versions Are Approved and Marketed

Teva admits, as it must, that its NDA product is not the branded product that typically exists in Paragraph IV litigation. That is, in a typical case, the branded product is still the monopoly and the generic company is seeking to be the first generic version. Teva's Blue Brief implies that its product is still the branded monopoly product. Teva Br. at 9. In this underlying Teva v. Amneal case, Teva's complaint actually reveals the full story. Teva admits that it no longer markets the brand

product but sells its own product as an authorized generic. Complaint, Para. 46 (D.I. 1)(DNJ Docket #23-cv-20964). According to Amneal's Answer and Counterclaim, Paras. 61-63 (D.I. 12), Lupin Pharmaceuticals filed its ANDA, got sued, settled, and now launched on Feb. 26, 2020. The FDA database shows that at least Lupin has ANDA approval for the generic equivalent of Teva's ProAir®. *See*, https://www.accessdata.fda.gov/scripts/cder/daf/index.cfm?event=overview.process&ApplNo=021457

Essentially, the market is already genericized by Teva itself and with at least Lupin. Accordingly, any implication that the ProAir® HFA market is still a branded monopoly should be rejected.

Conclusion

Deva, as *amicus curiae*, respectfully requests that this Court affirm the underlying trial court decision because the trial court made no error of law in statutory interpretation; made no error of fact because facts are undisputed here; no error in failing to conduct any claim construction as no claim construction was necessary; and for the reasons set out above, no reversible error exists.

Respectfully submitted,

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Certificate of Compliance

I hereby certify that this brief complies with the typeface requirements of Rule 32(a)(5); the type-style requirements of Rule 32(a)(6); and the type-volume limitations of Rules 29(a)(5), 29(b), and 32(b)(1), because this brief is in proportional spaced font, has a typeface of 14-point Century Schoolbook font, and contains 5,713 words, excluding the parts of the brief exempted by Rule 32(f) and Rule 32(b)(2).

Date: September 3, 2024

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Certificate of Service

I hereby certify that I electronically filed the foregoing on the CM/ECF system, which will send a notification of such filing to the appropriate counsel.

Date: September 3, 2024

/s/ Shashank Upadhye

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