No. 24-1936

UNITED STATES COURT OF APPEALS
FOR THE FEDERAL CIRCUIT

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

Plaintiffs-Appellants,

v.

AMNEAL PHARMACEUTICALS OF NEW YORK, LLC, AMNEAL IRELAND LIMITED, AMNEAL PHARMACEUTICALS LLC, and AMNEAL PHARMACEUTICALS INC.,

Defendants-Appellees.

Appeal from the U.S. District Court
for the District of New Jersey
No. 23-cv-20964 (SRC), Judge Stanley R. Chesler

[NON-CONFIDENTIAL] APPELLANTS' REPLY IN SUPPORT OF THEIR MOTION FOR A STAY PENDING APPEAL

Daryl L. Wiesen
Christopher T. Holding
Jordan Bock
GOODWIN PROCTER LLP
100 Northern Ave.
Boston, MA 02210
(617) 570-1000

William M. Jay
GOODWIN PROCTER LLP
1900 N Street, N.W.
Washington, DC 20036
(202) 346-4000

Natasha E. Daughtrey
GOODWIN PROCTER LLP
601 South Figueroa Street
Los Angeles, CA 90017
(213) 426-2642

July 3, 2024

CERTIFICATE OF INTEREST

Counsel for Teva Branded Pharmaceutical Products R&D, Inc., Norton (Waterford) Ltd., and Teva Pharmaceuticals USA, Inc. (collectively "Teva" or "Plaintiffs"), certifies the following:

1. **Represented Entities.** Provide the full names of all entities represented by undersigned counsel in this case. Fed. Cir. R. 47.4(a)(1).

   Teva Branded Pharmaceutical Products R&D, Inc.; Norton (Waterford) Ltd.; and Teva Pharmaceuticals USA, Inc.

2. **Real Party in Interest.** Provide the full names of all real parties in interest for the entities. Do not list the real parties if they are the same as the entities. Fed. Cir. R. 47.4(a)(2).

   None

3. **Parent Corporations and Stockholders.** Provide the full names of all parent corporations for the entities and all publicly held companies that own 10% or more stock in the entities. Fed. Cir. R. 47.4(a)(3).

   Teva Branded Pharmaceutical Products R&D, Inc.: Teva Pharmaceutical Industries, Ltd.

   Norton (Waterford) Ltd.: Teva Pharmaceutical Industries, Ltd.

   Teva Pharmaceuticals USA, Inc.: Teva Pharmaceutical Industries, Ltd.

4. **Legal Representatives.** List all law firms, partners, and associates that (a) appeared for the entities in the originating court or agency or (b) are expected to appear in this court for the entities. Do not include those who have already entered an appearance in this court. Fed. Cir. R. 47.4(a)(4).

   Goodwin Procter LLP: Louis L. Lobel; Thomas V. McTigue IV

   Williams & Connolly LLP: Kathryn S. Kayali

   Walsh, Pizzi, O'Reilly, Falanga LLP: Liza M. Walsh, Selina M. Ellis, Hector D. Ruiz, Christine P. Clark

5. **Related Cases.** Provide the case titles and numbers of any case known to be pending in this court or any other court or agency that will directly affect or be directly affected by this court's decision in the pending appeal. Do not include the originating case number(s) for this case. Fed. Cir. R. 47.4(a)(5).

Teva Branded Pharm. Prods. R&D, Inc. v. Deva Holding A.S., No. 2:24-cv-04404 (D.N.J. complaint filed March 29, 2024).

6. **Organizational Victims and Bankruptcy Cases.** Provide any information required under Fed. R. App. P. 26.1(b) (organizational victims in criminal cases) and 26.1(c) (bankruptcy case debtors and trustees). Fed. Cir. R. 47.4(a)(6).

Not applicable

Dated: July 3, 2024

/s/ *William M. Jay*
William M. Jay

Counsel for Appellants

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CONFIDENTIAL MATERIAL OMITTED

The material omitted in the text on page 9 refers to confidential information regarding the timing and circumstances of FDA's tentative approval of Defendants-Appellees' product. This information is subject to a protective order in the district court.

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INTRODUCTION

A stay is necessary to prevent certain, imminent, and irreparable harm to Teva: the loss of the 30-month stay, in this case and others, without the ability to regain it once this Court reverses. The district court was wrong to order Teva to delist these patents—but right to recognize that Teva has substantial arguments on the merits and faces irreparable harm. Amneal fails to show how the harm can be undone once Teva's patents are delisted, and likewise cannot defend the district court's refusal to apply the ordinary meaning of the verb "claims." The harm to Teva far outweighs any potential harm to Amneal, which this Court already minimized by expediting briefing and argument to likely outpace the FDA. All four factors support a stay for the brief period of this expedited appeal.

ARGUMENT

Considering the "magnitude of the threatened injury to the patent owner," it is clear a stay should issue. *Standard Havens Prods., Inc. v. Gencor Indus., Inc.*, 897 F.2d 511, 513 (Fed. Cir. 1990). As the district court recognized, Teva has at least a "substantial" argument on the merits—all that is required for a stay when the irreparable harm is great. In fact, Teva is likely to succeed on the merits. As in the only previous delisting appeal, this Court should stay the injunction for the short period until it can rule on the merits.

I. Amneal Ignores The Authority Demonstrating That Teva Is Likely To Succeed On The Merits.

The district court misread the statute, and its unduly narrow interpretation would dramatically remake the listing scheme. What a patent "claims" is not limited to what specific molecules it recites by name; rather, it extends to everything within the claim language, correctly construed. Mot. 9-14.

Amneal argues (at 10) that this Court has "rejected Teva's central premise," but ignores the cases that endorse that premise. In *Apotex, Inc. v. Thompson*, this Court explained that the "listing decision … requires what amounts to a finding of patent infringement, except that the 'accused product' is the drug that is the subject of the NDA." 347 F.3d 1335, 1344 (Fed. Cir. 2003). In other words, "a patent must be listed if it contains a product claim that reads on the drug that is the subject of the NDA." *Id.* Whether a claim reads on a product turns on "the tools and framework of patent law, including claim construction." *Jazz Pharms., Inc. v. Avadel CNS Pharms., LLC*, 60 F.4th 1373, 1379 (Fed. Cir. 2023). Amneal's discussion of the merits cites neither *Apotex* nor *Jazz*.[1]

Nor does Amneal respond to FDA's statements identifying "metered aerosols" as a "finished dosage form" that constitutes a "drug product" that a listable patent may claim. Mot. 4, 10-11; 68 Fed. Reg. 36,676, 36,680 (June 18, 2003);

[1] *Apotex* also precludes Amneal's argument (at 12) that a patent cannot be listed if it claims a component of the drug product.

FDA, *Approved Drug Products with Therapeutic Equivalence Evaluations*, app. at C-1 (44th ed. 2024). Here, the Asserted Patents claim the metered-dose inhaler. *See, e.g.*, '289 patent at claim 1 (ECF No. 7-1 at 46) (claiming "[a]n inhaler for metered dose inhalation, the inhaler comprising," *inter alia*, "a medicament canister").

Amneal ignores this point and relies instead on *Hoechst-Roussel Pharmaceuticals v. Lehman*, 109 F.3d 756 (1997). That reliance is misplaced. This Court confirmed that "claims" in the patent term extension (PTE) statute, 35 U.S.C. § 156, should be given its "well-known meaning and usage in the patent law." 109 F.3d at 760. That point helps Teva, not Amneal. Under that well-known meaning, the drug in *Hoechst* was not "claimed" for a unique reason: the PTE statute, unlike this one, has specific definitions requiring that a qualifying patent "claim" specifically "the active ingredient." *Id.* at 759 n.3; *see* 35 U.S.C. § 156(a)(1), (f)(1)(A), (f)(2). Hoechst's patent did not do that, because it claimed a metabolite instead; although administering the drug would *result* in infringement, under the PTE statute what mattered was whether it claimed the active ingredient. Here, by contrast, what matters is whether a patent claims the drug, including any "component." Mot. 10. Amneal tries to use *Hoechst* (Opp. 10) for the proposition that infringement can be broader than what is claimed—*e.g.*, under the doctrine of equivalents. 109 F.3d at 759 & n.2. But that was not what the district court here relied on: the drug product is within the metes and bounds of Teva's claims. Rather,

the district court insisted the drug was not claimed because *the active ingredient was not named*. That is at odds with the "well-known meaning" of "claims."[2]

Amneal next turns to decisions from outside this Circuit to support its cramped reading of "claims." The First Circuit in *In re Lantus* held that if a patent "do[es] not *mention* the drug for which the sNDA was submitted, the patent does not 'claim the drug'" under the Listing Statute. 950 F.3d 1, 8 (1st Cir. 2020) (emphasis added). That court's reductionist approach cannot be squared with *this* Court's approach in cases like *Apotex* and *Jazz*.

Amneal also points (at 11-12) to *United Food*, but it supports Teva. As the Second Circuit explained, a patent "claims" a product when "each of the claim limitations 'reads on,' or in other words, is found in" the product. 11 F.4th at 132. There the brand was seeking a *broader* reading of "claims" to justify listing combination patents that, *unlike the NDA product*, combined the active ingredient with other substances; the Second Circuit applied the ordinary rule—irrelevant

[2] Amneal separately argues (at 11) that the Court should not apply the ordinary meaning of "claims" because the statute also requires that a listable patent be one "for which a claim of patent infringement could reasonably be asserted" against unlicensed use of the drug. 21 U.S.C. 355(b)(1)(A)(viii). But the phrases have different objects. The "claims the drug" phrase asks whether the patent claims the NDA product (*i.e.*, the brand drug). The "infringement could be asserted" phrase refers more broadly to infringement through the "manufacture, use, or sale of a competing product"—which, like the metabolite patent in *Hoechst*, might not be a patent claiming the brand drug itself. *See United Food & Com. Workers Loc. 1776 v. Takeda Pharm.*, 11 F.4th 118, 134 (2d Cir. 2021) (describing the "space between" the two phrases).

here—that "a combination patent, in general, does not 'claim' its constituent parts." *Id.* at 124, 131. Amneal instead says the court held that "a patent claim that fails to explicitly include the [NDA] drug" does not "claim the drug." Opp. 11-12 (citing language appearing at 11 F.4th at 134-35). But the court was simply stating that a generic can infringe a patent that does not "claim the drug." 11 F.4th at 134-35.

Turning to the text, Amneal argues that Teva ignores the requirement that the patent "claim *the* drug for which the applicant submitted the application," and "ignores that the Listing Statute says nothing about listing patents claiming only a *device component* of a drug product." Opp. 12. To start, Amneal ignores Teva's claims directed to the *entire* inhaler product. Conspicuously, Amneal does not address that this Court discussed this very statutory phrase in *Apotex*. 347 F.3d at 1343-44. Amneal's argument turns on an interpretation of "drug" that even the district court rejected. Mot. Ex. 3 at 11. The statute defines "drug" to cover the entirety (including any "component") of an "article[]" used for the "treatment[] or prevention of disease." 21 U.S.C. § 321(g)(1)(B), (D).

Amneal alludes (at 13) to an irrelevant D.C. Circuit decision, *Genus Medical Technologies LLC v. FDA*, 994 F.3d 631 (2021), about the difference between drugs and devices. As Teva has explained, Amneal misunderstands the regulation of combination products. Mot. 3-4; ECF No. 42 at 9-11 (addressing *Genus Medical* specifically). *Genus Medical* did not address combination products. 994 F.3d at

640, 644. ProAir® HFA was approved as a drug. Mot. 3-4.

Pivoting, Amneal argues (at 13-15) that the Asserted Patents are also not "drug product" patents—which is not a ground on which the district court ruled. It is notable that Amneal is pointing to an issue the district court did not reach. Amneal is also wrong.

At a minimum, the district court could not reject this argument without construing the claims at issue to determine whether an active ingredient is required. Amneal suggests that Teva forfeited this argument, but Teva expressly asked the court to "deny Amneal's Rule 12(c) Motion at least to engage in claim construction proceedings if necessary to determine the scope of what the Asserted Patents claim." ECF No. 64 at 35. Amneal then returns (at 14) to the argument that a patent is properly listed only if its claims recite albuterol sulfate, the active ingredient in ProAir® HFA. That is wrong, *see supra*, pp. 3-4, and further shows why claim construction is required if the Court disagrees with Teva that the Asserted Patents claim the metered-dose inhaler on their face. Amneal argues that the Court need not engage in claim construction to determine if the claims explicitly mention albuterol sulfate. True, but if the Court disagrees with Amneal' s exceedingly narrow "magic words" approach, then claim construction is required. Properly construed, these patents claim the complete metered-dose inhaler, and therefore are drug product patents. *See supra*, p. 3.

II. Delisting Will Cause Teva Immediate, Irreparable Harm.

The district court recognized the "substantial" harm to Teva from prematurely delisting its patents from the Orange Book. Mot., Ex. 1 at 18. Amneal never disputes that delisting would terminate the 30-month stay in its case. The loss of that statutory right is harm to Teva and certain to occur without a stay. The only question is whether that harm is likely to be irreparable. Amneal asserts it may not be—but cites nothing in support. There is no law providing for the restoration of patents to the Orange Book *nunc pro tunc* or the restoration of a 30-month stay once terminated. Teva showed, citing the relevant regulations, that there is a grave risk that FDA—which administers the 30-month stay—will conclude no stay applies. That is more than sufficient to show a "likelihood" of irreparable harm, which is all the stay standard requires. *E.g., Hollingsworth v. Perry*, 558 U.S. 183, 190 (2010) (per curiam). Nor is Amneal's proposed alternative, a district-court injunction, a substitute.

Amneal asserts (at 4) that Teva cited "no authority" but never addresses the cited regulations, whose plain text shows: (1) Amneal must change its ANDA to withdraw its Paragraph IV certification once the patents are delisted; (2) once the certification is changed, there is no 30-month stay; and (3) thereafter, "patent information" that is "submit[ted]" to the Orange Book after the ANDA is already on file will not be the basis for a 30-month stay. No 30-month stay means that FDA

can approve the ANDA at any time, with no prior notice, skipping the "tentative approval" that FDA uses when a patent bars final approval.

Amneal posits that perhaps the district court could grant an injunction for the term of the 30-month stay—*i.e.*, not a standard preliminary injunction, which lasts until final judgment on the merits, but some never-before-seen variant. It appears Amneal is envisioning an injunction based on likelihood of success on the patent merits. Opp. 5. That is exactly what the 30-month stay is not, as the district court correctly recognized, Mot., Ex. 1 at 19. A defendant can defeat a preliminary injunction by identifying a substantial defense; it cannot lift the 30-month stay unless it prevails on the merits. 21 U.S.C. § 355(j)(5)(B)(iii)(I)(aa). Amneal's supposed substitute remedy is no substitute at all.

Amneal also does not dispute that delisting will affect the 30-month stay against other ANDA applicants. Instead, Amneal argues Teva has other patents listed for this product besides the ones at issue here. As Teva explained, it may well be unable to assert those patents against other ANDA filers, including in the pending action against Deva. Amneal calls that "speculation," Opp. 7, but that is exactly what happened in this case: after reviewing Amneal's ANDA, Teva was able to assert only these patents. Mot., Ex. 1 at 8. Teva was compelled to sue Deva before reviewing its ANDA, *id.* at 10, and all Amneal can offer to support its assertion that other patents will remain in the case against Deva is—speculation.

Amneal hints that maybe FDA would be willing to "reinstitute the 30-month stay." Opp. 4. The regulations suggest otherwise, but no one knows for certain what view FDA will take, because this situation has not previously arisen. It is abundantly clear, though, that relisting the patents will not affect Amneal if Amneal has already gotten an early approval thanks to the dissolution of the 30-month stay. And even if Amneal's ANDA were still pending, there would still be no 30-month stay unless FDA relisted the patents *nunc pro tunc*—something it has never done. That is precisely why Teva filed this stay motion: there is a substantial likelihood that Teva cannot regain any lost 30-month stays even if this Court reverses.

III. Amneal's Suggested Harms Are At Best Highly Speculative.

The Court has now set this case for oral argument in November, in time to avert harm to Amneal. FDA's earliest goal date for action is descriptor date. Mot., Ex 1 at 12.[3] Amneal speculates that *if* FDA's action is favorable (which is unlikely, *see* Mot. to Expedite 6), Amneal would be "stuck with tentative approval" for "indeterminate periods." Opp. 17-18. That is wrong: the merits panel would be free to modify or dissolve the stay based on any developments on Amneal's ANDA,

[3] Amneal suggests "FDA could approve the ANDA *at any time*." Opp. 17. That is not just speculative but wrong. FDA explained that it would "strive to act prior to a goal date when the assessment is complete and there are no outstanding status." Mot. Ex. 8, at 2. That is not the case here—the basis for FDA's date goal date is its need to consider Amneal's outstanding descriptor status. *Id.*

with the benefit of briefing and oral argument. Amneal cannot show a significant risk of harm based on a string of speculations (including Amneal's unreliable predictions for when it might have approval).

IV. Amneal Has Failed To Identify Harm To The Public Interest.

The Hatch-Waxman scheme is carefully designed to avoid a rushed preliminary-injunction fight, but that is exactly how Amneal suggests the parties handle their patent dispute. Notably, the district court—the forum that would be saddled with preliminary-injunction proceedings—found this theory "anathema." Mot., Ex. 1 at 19. Contrary to Amneal's suggestion, the issue is not "Teva and its competitors," Opp. 19, but the delays for other cases caused by the "havoc" preliminary injunctions wreak on dockets. Mot. 19. Amneal also argues it is beneficial to have Amneal's ANDA product on the market "as soon as possible," Opp. 18, but acknowledges there is no such harm until it obtains FDA approval. The expedited appeal means that any stay is unlikely to delay Amneal's ability to launch even if it obtains approval. *See supra*, p. 9.

CONCLUSION

Teva respectfully requests that this Court stay the injunction pending appeal. If needed, Teva respectfully requests that the Court administratively extend the district court's stay of the injunction until this Court rules on the motion. If the Court were to deny the stay, Teva requests that at a minimum the stay be extended for three

business days after this Court's ruling, to permit Teva to evaluate an application to the Circuit Justice.

July 3, 2024

Respectfully submitted,

/s/ William M. Jay

William M. Jay
GOODWIN PROCTER LLP
1900 N Street, N.W.
Washington, DC 20036
(202) 346-4000

Counsel for Appellants

Daryl L. Wiesen
Christopher T. Holding
Jordan Bock
GOODWIN PROCTER LLP
100 Northern Ave.
Boston, MA 02210
(617) 570-1000
Fax.: 617.523.1231

Natasha E. Daughtrey
GOODWIN PROCTER LLP
601 South Figueroa Street
Los Angeles, CA 90017
(213) 426-2642

CERTIFICATE OF COMPLIANCE

This motion complies with the type-volume limitations of Federal Rule of Appellate Procedure 27(d)(2)(A) because it contains 2,599 words, excluding the parts of the motion exempted by Federal Rule of Appellate Procedure 32(f) and Federal Circuit Rule 32(b)(2).

This motion complies with the typeface requirements of Federal Rule of Appellate Procedure 32(a)(5) and the type style requirements of Federal Rule of Appellate Procedure 32(a)(6). The motion has been prepared in a proportionally spaced typeface using Microsoft Word 365 in 14-point Times New Roman font.

Dated: July 3, 2024

/s/ William M. Jay
William M. Jay

UNITED STATES COURT OF APPEALS
FOR THE FEDERAL CIRCUIT

CERTIFICATE OF CONFIDENTIAL MATERIAL

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