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 TO STAY INJUNCTION PENDING DECISION ON PETITION FOR REHEARING EN BANC

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January 13, 2025

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).

   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: January 13, 2025

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

Counsel for Appellants

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CONFIDENTIAL MATERIAL OMITTED

The material omitted in the text on pages 1 and 3 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.

INTRODUCTION

Amneal's perfunctory opposition is long on rhetoric but short on arguments. As Teva explained in detail, the balance of harms here is entirely one-sided. Teva would be immediately and irreparably harmed by lifting the stay, while Amneal will not be harmed *at all* by keeping the stay in place. Amneal barely even claims any harm, suggesting only that FDA is unpredictable and in theory *could* act at any time—notwithstanding Amneal's [redacted] status, and the [redacted] descriptor of FDA [redacted] noun needed as a result. On the other side of the scale, Teva has shown concrete, irreparable harm; Amneal just disagrees, without engaging with the facts or the agency regulations Teva presented. This Court already determined that the balance of harms weighs in favor of a stay, and in the interim Amneal's [redacted] noun have only moved the balance further in Teva's favor. Mot. 7.

Amneal's response fares no better on the merits. Teva's motion previewed the substantial arguments for rehearing en banc that it will make in its forthcoming petition, based both on conflicts with statutory text and precedent *and* on the importance of the issue. Amneal refutes neither.

First, Amneal's opposition (at 5-6) makes no meaningful effort to defend the panel's decision to ignore the FDCA's clear text, nor does it explain how the panel's interpretation of "claims" can be squared with fundamental principles of patent law.

Second, Amneal does not dispute the industry-wide significance of this

issue—which its own amici have already confirmed—or the repercussions that will flow directly from the panel decision. Instead, Amneal suggests that the importance of these issues is not relevant to the stay analysis. That misses the mark. As Teva explained, the importance of these issues—and the broad repercussions of the way in which the panel resolved them—heighten the case for rehearing en banc. For both reasons, Teva has shown the requisite likelihood of success on its rehearing petition—and the need to maintain the status quo pending resolution of that petition.

Amneal has no compelling reason to insist that the Court upend the status quo before the appellate process is complete. Teva faces certain, irreparable harm 14 days after a stay is lifted. Amneal and the public face no harm whatsoever during the pendency of rehearing. Given that, and given Teva's substantial arguments for rehearing en banc, continuing the stay is well warranted while the full Court considers those arguments.

ARGUMENT

I. Amneal's Opposition Underscores That the Balance of Harms Weighs Decisively in Teva's Favor.

A. Amneal Barely Disputes That It Will Face No Harm From a Stay.

Amneal's response regarding the harm it might face from a continued stay is best summarized as: Who knows? As it tellingly argues, the "harm to Amneal will be certain and irreparable *from the day that it receives tentative approval but remains unable to launch*." Opp. 9 (emphasis added). In other words, the claimed harm is

neither certain nor irreparable *today*, nor is there any reason to think it will materialize on any day between now and when the Court rules on the rehearing petition. Amneal muses that "there is no way of knowing for sure exactly when any ANDA will be approved." *Id.* That is sophistry. It is [redacted] for Amneal to [redacted], [redacted] its [redacted] *and* have FDA [redacted] its [redacted] (which FDA [redacted] will [redacted] "a [redacted] of FDA [redacted]") before this Court rules on the en banc petition. Those are the facts that matter to the harm question.

If, [redacted] the [redacted], Amneal receives tentative approval during the pendency of Teva's en banc petition, then Amneal can request that the Court lift the stay at that point. Amneal objects that this suggestion is not a "meaningful remedy" because relief on such a request would take "significant time." Opp. 9. That is not a serious argument. This Court rules on motions promptly, and it is absurd to suggest that this Court would be so slow to react to an actual change in the balance of harms that the Court should just dissolve the stay today, in case the balance might shift someday. What matters today is that Amneal has no approval or even tentative approval—in fact, in FDA's judgment, Amneal's ANDA product is currently [redacted].[1]

[1] Amneal separately argues that the public interest favors lifting a stay because it is beneficial to the public to have "Amneal's ANDA product on the market as soon as possible." Opp. 10. Even if Amneal could show that its product would benefit the

B. The Harm to Teva Would Be Irreparable, and Amneal's Proposed "Solutions" Are Illusory and Ineffective.

Amneal attempts to wave away Teva's harms as "speculative," Opp. 6-8, but there is nothing speculative about the loss of the 30-month stay. The loss of that statutory right is harm to Teva that is *certain* to occur 14 days after a stay is lifted—*and* Teva will be unable to regain that right even if it prevails before the full Court or the Supreme Court. Mot. 8-9. That is the opposite of speculative.

Amneal argues that Teva has "no authority" for its view that FDA will not reinstate the 30-month stay if Teva ultimately prevails on the merits. But Amneal ignores the statute, which requires that patents be listed in the Orange Book *before* an ANDA is filed in order for the 30-month stay to apply. 21 U.S.C. § 355(j)(5)(B)(iii); Mot. 9. Amneal, by contrast, has pointed to nothing to suggest that FDA will restore Teva's patents to the Orange Book on a *nunc pro tunc* basis—let alone restore the 30-month stay—if Teva prevails on the merits. That is precisely why Teva filed this stay motion: there is a substantial "likelihood" of irreparable harm (*i.e.*, that Teva cannot regain its statutory rights to lost 30-month stays) even if this Court reverses. *E.g.*, *Hollingsworth v. Perry*, 558 U.S. 183, 190 (2010) (per curiam).

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public in some way that the multiple existing generics do not, Amneal has no approval or even tentative approval for its ANDA product, as shown above. This argument fails for the same reason Amneal's claim of harm to itself fails.

Amneal next suggests that, if FDA will not reinstate the 30-month stay, Teva could obtain relief in its infringement suit. Opp. 7. What Amneal proposes is categorically different from the right Teva will lose. The 30-month stay is a statutory entitlement, not an exercise of equitable discretion. The 30-month stay therefore does *not* require satisfying the four-part test for a standard preliminary injunction, which involves an analysis of both the patent merits and the balance of harms. Amneal suggests the district court could "weigh the merits of Amneal's non-infringement and invalidity defenses," but that shows precisely why Amneal's proposed replacement is not an adequate substitute for loss of the statutory right. And while Amneal argues that "justice would be better served by such injunctive proceedings," the district court—the court that would have to adjudicate said injunctive proceedings—thought the exact opposite. As it explained, "[t]here is nothing worse than having to deal with complex legal and factual issues on an expedited basis" when a brand manufacturer "is compelled to seek a preliminary injunction." Appx1575. "It creates havoc with the court's docket and it delays handling other cases," and for that reason is "anathema" to the court. *Id.*

Finally, Amneal objects to Teva's assertions of harm with respect to Deva and other ANDA filers as, again, speculative. But there is nothing speculative about Teva's pending lawsuit (or 30-month stay) against Deva, and Deva has taken the position that all nine of the listed patents for ProAir HFA should be removed from

the Orange Book, including an additional patent asserted against Deva, but not Amneal. *See* ECF No. 29 at 2, *Teva Branded Pharm. Prods. R&D, Inc. v. Deva Holding A.S.*, Case No. 2:24-cv-04404-SRC-MAH ("*Deva* Order") (D.N.J. Aug. 28, 2024).

As for other generic applicants, Amneal suggests that it is unclear whether they would submit their ANDAs for this product while the Asserted Patents are delisted. Opp. 8. But if the Asserted Patents are delisted now, then any future filers who submit their ANDAs during the pendency of the en banc proceedings *will* be filing while the Asserted Patents are delisted. And while Amneal suggests that perhaps these ANDAs would be subject to infringement claims based on the other four patents currently listed in the Orange Book for ProAir HFA—though if they are similar to Amneal's, they presumably will not be—in all likelihood, anyone sued on those patents will argue that the panel's decision requires the delisting of those patents as well, and terminating any stay. Deva has already argued as much. *See Deva* Order at 2.

II. Amneal Does Not Seriously Dispute the Wide-Reaching Implications of the Panel's Decision.

This case presents a compelling case for en banc review because it involves "precedent-setting questions of exceptional importance"—*i.e.*, it is important precisely because of its certain impact on many other parties and patents. Fed. Cir. R. 40(c)(2). Amneal's effort to minimize the reach of the panel's decision is half-

hearted at best—Amneal makes no serious attempt to explain how the panel's reasoning could be cabined solely to the patents in this case. The decision broadly addresses the listing of patents for products approved as drugs that do not expressly recite the product's active ingredient in the claims, and therefore applies to far more than inhaler patents. More broadly, the panel's reasoning applies squarely to block listing of genus patents, patents that claim one of multiple active ingredients, and more. Mot. 16-18.

Indeed, Amneal's own amici emphasize the broad significance of this issue. Five different groups of amici supported Amneal in this case precisely because they recognized that the "precedent set in *Teva v. Amneal* could have far-reaching consequences for pharmaceuticals in the US." Br. of 14 Professors at 28. The FTC, for one, explained that the questions presented are "not confined" to inhaler patents of the type at issue here. FTC Amicus Br. 19-20. To take just one of several examples, it identified "107 patents on GLP-1 delivery devices" for diabetes and weight loss medications that, in the FTC's view, are implicated by the arguments at play in the case. *Id.* at 20-21. Other amici likewise predicted that the Court's decision "could have far-reaching impact for other classes of drugs." Br. of 14 Professors at 26-28 (discussing the potential impact of a decision on injector pens, transdermal patches, intranasal drugs, and birth-control devices). And that is before considering the effects on genus patents and patents on one of several active

ingredients, among others. Given these ramifications, the full Court should have the opportunity to consider whether the statute actually requires overhauling the listing regime.

Unable to seriously counter this argument, Amneal pivots to suggesting that any broader implications are "irrelevant" because upheaval to the pharmaceutical industry "has no bearing on the merits of the Court's decision on the facts of this case." Opp. 4. That ignores the case's current posture: "the importance of the issues raised" is itself a reason *to grant en banc review*.[2] *Cloer v. Sec. of Health & Hum. Servs.*, 675 F.3d 1358, 1360 (Fed. Cir. 2012) (en banc), *aff'd*, 569 U.S. 369 (2013); *see* Mot. 11-16. As Teva explained at length, it is precisely this type of case—presenting exceptionally important questions that are the subject of reasonable debate and that future panels will likely not be able to revisit—that the Court should take en banc. Amneal does not argue otherwise.

Finally, despite extolling the supposed merits of its position, Amneal makes no substantive response to Teva's criticism of the panel's reliance on "statutory context"—in particular, that the panel entirely rejected the expressly applicable

[2] Amneal also criticizes Teva for failing to explain how the upheaval in the pharmaceutical industry will occur during the pendency of Teva's intended petition for rehearing en banc. Opp. 4-5. That confuses the issues. *Teva* will face irreparable harm if the Court does not grant a stay because it will be forced immediately to delist its patents. *See supra*, pp. 4-6. The harm to the pharmaceutical industry supports the separate point that this Court should grant en banc review.

statutory definition in 21 U.S.C. § 321(g)(1). Opp. 6; Mot. 18-20. Nor can Amneal dispute that the panel's statutory interpretation relied almost entirely on out-of-circuit caselaw cited by neither party.

For all of these reasons, Teva has shown a sufficient likelihood that it will succeed in its request for en banc review—which would set aside the panel's decision, including the portion dissolving the stay. Especially given the *im*balance of the equities here—with Teva facing irreparable harm and Amneal none—Teva has certainly shown the type of serious questions that justify continuing the stay through the rehearing stage. *See Standard Havens Prods., Inc. v. Gencor Indus., Inc.*, 897 F.2d 511, 513 (Fed. Cir. 1990) (where "the balance of hardships tips decidedly toward" the moving party, a stay is appropriate so long as there are "serious" "questions going to the merits") (quoting *Hamilton Watch Co. v. Benrus Watch Co.*, 206 F.2d 738, 740 (2d Cir. 1953)).

* * *

Amneal dismisses each of Teva's arguments with one adjective: speculative. But it is certain, not speculative, that lifting the stay will cause Teva to suffer the irreparable loss of a statutory right, while Amneal will face no harm at all. It is certain, not speculative, that the panel's decision will have significant repercussions for hundreds of patents, just as amici predicted. Given the combination of exceptionally important issues and a hugely lopsided balance of harms, this case

presents an exceedingly strong case for a continued stay while this Court resolves Teva's forthcoming petition for rehearing en banc.

CONCLUSION

The Court should stay the injunction pending resolution of Teva's forthcoming petition for rehearing en banc.

January 13, 2025

Respectfully submitted,

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CERTIFICATE OF COMPLIANCE

This motion complies with the type-volume limitations of Federal Rule of Appellate Procedure 27(d)(2)(A) because it contains 2,158 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: January 13, 2025

/s/ William M. Jay
William M. Jay

CERTIFICATE OF SERVICE

I hereby certify that on January 13, 2025, I electronically filed the foregoing using the Court's CM/ECF system, which will send notifications to all counsel registered to receive electronic notices.

/s/ William M. Jay
William M. Jay

UNITED STATES COURT OF APPEALS
FOR THE FEDERAL CIRCUIT

CERTIFICATE OF CONFIDENTIAL MATERIAL

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