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 United States District Court for the District of New Jersey
Case No. 2:23-cv-20964, Judge Stanley R. Chesler

[NON-CONFIDENTIAL] APPELLEES' OPPOSITION TO APPELLANTS' MOTION TO STAY PENDING PETITION FOR REHEARING EN BANC

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January 6, 2025

UNITED STATES COURT OF APPEALS
FOR THE FEDERAL CIRCUIT

CERTIFICATE OF INTEREST

Case Number 2024-1936

Short Case Caption Teva Branded Pharmaceutical Products R&D, Inc. v. Amneal Pharmaceuticals of New York, LLC

Filing Party/Entity Amneal Pharmaceuticals of New York, LLC; Amneal Ireland Limited; Amneal Pharmaceuticals LLC; Amneal Pharmaceuticals, Inc.

Instructions:

1. Complete each section of the form and select none or N/A if appropriate.
2. Please enter only one item per box; attach additional pages as needed, and check the box to indicate such pages are attached.
3. In answering Sections 2 and 3, be specific as to which represented entities the answers apply; lack of specificity may result in non-compliance.
4. Please do not duplicate entries within Section 5.
5. Counsel must file an amended Certificate of Interest within seven days after any information on this form changes. Fed. Cir. R. 47.4(c).

I certify the following information and any attached sheets are accurate and complete to the best of my knowledge.

Date: 01/06/2025

Signature: /s/ Steven A. Maddox

Name: Steven A. Maddox

1. Represented Entities. Fed. Cir. R. 47.4(a)(1).	**2. Real Party in Interest.** Fed. Cir. R. 47.4(a)(2).	**3. Parent Corporations and Stockholders.** Fed. Cir. R. 47.4(a)(3).
Provide the full names of all entities represented by undersigned counsel in this case.	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. ☑ None/Not Applicable	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. ☐ None/Not Applicable
Amneal Pharmaceuticals of New York, LLC		See attached.
Amneal Ireland Limited		See attached.
Amneal Pharmaceuticals LLC		See attached.
Amneal Pharmaceuticals, Inc.		See attached.

☑ Additional pages attached

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).

☐ None/Not Applicable ☐ Additional pages attached

Melissa Hatch O'Donnell, Robin P. Sumner, and Andrew P. Zappia of Troutman Pepper Hamilton Sanders LLC		
Rebekah R. Conroy and Shalom D. Stone of Stone Conroy LLC		

5. Related Cases. Other than the originating case(s) for this case, are there related or prior cases that meet the criteria under Fed. Cir. R. 47.5(a)?

☑ Yes (file separate notice; see below) ☐ No ☐ N/A (amicus/movant)

If yes, concurrently file a separate Notice of Related Case Information that complies with Fed. Cir. R. 47.5(b). **Please do not duplicate information.** This separate Notice must only be filed with the first Certificate of Interest or, subsequently, if information changes during the pendency of the appeal. Fed. Cir. R. 47.5(b).

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).

☑ None/Not Applicable ☐ Additional pages attached

3. **Parent Corporations and Stockholders.** Fed. Cir. R. 47.4(a)(3).
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.

Amneal Pharmaceuticals of New York, LLC:
Wholly owned by Amneal Pharmaceuticals LLC

Amneal Ireland Limited:
Wholly owned by Amneal Pharmaceuticals Holding GmbH, which is wholly owned by Amneal UK Holding Company Ltd., which is wholly owned by Amneal Pharmaceuticals LLC

Amneal Pharmaceuticals LLC:
Wholly owned by Amneal Pharmaceuticals, Inc.

Amneal Pharmaceuticals, Inc.:
None/Not Applicable

3. **Parent Corporations and Stockholders.** Fed. Cir. R. 47.4(a)(3).
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.

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Wholly owned by Amneal Pharmaceuticals LLC

Amneal Ireland Limited:
Wholly owned by Amneal Pharmaceuticals Holding GmbH, which is wholly owned by Amneal UK Holding Company Ltd., which is wholly owned by Amneal Pharmaceuticals LLC

Amneal Pharmaceuticals LLC:
Wholly owned by Amneal Pharmaceuticals, Inc.

Amneal Pharmaceuticals, Inc.:
None/Not Applicable

TABLE OF CONTENTS

A description of the redacted information appears on the following page.

CONFIDENTIAL MATERIAL OMITTED

The material omitted in the text on pages 9 and 10 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.

TABLE OF AUTHORITIES

Page(s)

Cases

INTRODUCTION

Contrary to Teva's opening suggestion, the sky will not fall on the pharmaceutical industry if the Court denies this motion. There is no evidence to support Teva's insinuation that allowing the delisting order to take effect in this case will cause "significant upheaval in the pharmaceutical industry and a potential mass delisting of hundreds of patents." (Teva Br. at 1.)

Moreover, Teva's speculative prophecy of industry upheaval is irrelevant to the narrow legal issue presented by this motion. That issue is whether the Court should reinstate the stay pending Teva's petition for rehearing en banc in this case. The controlling legal framework are the four factors articulated in *Nken v. Holder*, 556 U.S. 418 (2009). Those factors do not include any alleged industry upheaval.

Teva's predictions of industry chaos and disruption are a mere theatrical distraction from Teva's inability to make the showings required under *Nken*. Beginning with the first *Nken* factor, Teva does not even seriously attempt to argue that it has made the requisite "strong showing" of "likely success" on the merits. After all, Teva has seen its arguments rejected by every court to have considered them, including the unanimous merits panel of this Court.

Accordingly, Teva claims to have made a showing of only a "substantial case" on the merits, based on its predicted industry upheaval and what amounts to the Court's refusal to offer advisory opinions on claims and facts not before it. Yet

Teva fails to cite any authority for the legal sufficiency of such grounds to establish even a "substantial case" on the merits. Teva simply declares those grounds to be "substantial enough." (Teva Br. at 11.)

As to the second *Nken* factor, Teva returns to speculation that the sky will fall if the stay is not granted and Amneal receives tentative approval while the petition for rehearing is pending. In fact, the Rules of Civil Procedure provide a ready remedy in those circumstances. Teva can seek to protect itself by moving for a preliminary injunction.

Teva's argument as to the third *Nken* factor – harm to Amneal from reinstating the stay – is equally speculative. Teva speculates that Amneal will not likely receive tentative approval during the pendency of the petition for rehearing, and so will not suffer any harm from the stay. Neither Teva nor Amneal knows for sure when the FDA will approve Amneal's ANDA. The fact remains, however, that whenever Amneal does receive tentative approval, it is certain to begin suffering irreparable harm if barred by the stay from launching its product immediately. Moreover, the Rules of Civil Procedure do not afford Amneal a remedy for such harm.

As to the fourth *Nken* factor – where the public interest lies – there can be no reasonable dispute that the public's interest lies in getting access to lower-cost

medicines as soon as possible. Reinstating the stay would be squarely contrary to that public interest.

The Court should deny the motion.

LEGAL STANDARDS

"A stay is an intrusion into the ordinary processes of administration and judicial review, and accordingly is not a matter of right, even if irreparable injury might otherwise result to the appellant." *Nken v. Holder*, 556 U.S. 418, 427 (2009). Thus, the party requesting a stay bears the burden of showing that the particular circumstances of the case justify an exercise of judicial discretion based on four factors:

> (1) whether the stay applicant has made a strong showing that he is likely to succeed on the merits; (2) whether the applicant will be irreparably injured absent a stay; (3) whether issuance of the stay will substantially injure the other parties…; and (4) where the public interest lies.

Id. at 433-34 (2009); *ePlus, Inc v. Lawson Software, Inc.*, 431 Fed.Appx. 920 at *1 (Fed. Cir. July 14, 2011).

Importantly, the first two factors are the most critical, and neither is satisfied by mere possibilities. *Nken*, 556 at 434-35 (stating that "more than a mere possibility of relief is required" and "simply showing some possibility of irreparable injury fails to satisfy the second factor") (cleaned up).

ARGUMENT

I. Teva Has Not Made a "Strong Showing" that it Is Likely to Succeed on the Merits.

Teva has not made the requisite "strong showing" of likely success on the merits. Indeed, Teva does not make any serious attempt to make such a showing. Instead, Teva argues that its petition for rehearing will be "substantial enough" on the merits. (Teva Br. at 11.) Whatever Teva subjectively deems to be "substantial enough" is a far cry from the "strong showing" of *Nken.*

Teva attempts to demonstrate its "substantial case" on the merits by arguing that the sky will fall on the entire pharmaceutical industry if the stay is not re-instated. Teva speculates that the decision will disrupt hundreds of patent listings throughout the pharmaceutical industry, and will upend the Hatch Waxman Act system. Teva simply declares that the decision "will require revisiting" hundreds of patents. (Teva Br. at 11.) Teva even speculates that the decision will result in "a breakdown of the orderly Hatch-Waxman procedure for litigating the validity and infringement of these patents before launch." (Teva Br. at 14.)

Teva's arguments are mere speculation. But even if they had any basis in fact, they would still be irrelevant to the issue before the Court on this motion – that is, whether to reinstate the stay pending Teva's petition for rehearing en banc. Teva's doomsday scenario has no bearing on the merits of the Court's decision on the facts of this case. And Teva does not even attempt to explain how this hypothetical parade

of horribles will occur in the timeframe at issue in this motion – that is, during the pendency of Teva's intended petition for rehearing en banc.

Instead, Teva pivots to arguing a "substantial case" on the merits based on speculative "broad implications" of the decision. (Teva Br. at 16-20.) Teva criticizes the Court for not addressing itself to whether hypothetical patents containing undefined genus patent claims would be listable under Court's decision. (Teva Br. at 16-17.) As Teva acknowledges, however, the patent claims before the Court in this case were not genus claims. Teva's criticism amounts to an argument that the Court erred by not issuing an advisory opinion with respect to hypothetical undefined claims that were not before it.

Similarly, Teva criticizes the Court for not addressing a circumstance in which the product at issue contains more than one active ingredient. (Teva Br. at 18.) Here again, Teva acknowledges that the case before the Court did not present any such circumstance. The product at issue contains only one active ingredient. Again, Teva takes the Court to task for appropriately refraining from offering an advisory opinion on facts not before it.

Next, Teva speculates that "the Court may not have the opportunity to refine its interpretation in subsequent appeals from delisting injunctions." (Teva Br. at 11.) Based on that speculation, Teva seems to argue that neither it nor the pharmaceutical industry should have to wait for opinions regarding claims and facts that are not

before the Court in this case. Teva fails to cite any authority for this extraordinary proposition.

Finally, in the last two pages of its brief, Teva summarily declares that the Court's rejection of Teva's argument was based on mere "nebulous concerns about statutory context." (Teva Br. at 19.) There is, however, nothing "nebulous" about the Court's statutory analysis in the opinion. In addition, Teva asserts that the Court's opinion "rewrites the statute . . . on a basis that the parties did not brief." (Teva Br. at 20.) This is incorrect. The statutory construction adopted by the Court is in fact the statutory construction for which Amneal argued in its brief.

The first *Nken* factor weighs in favor of denying the motion.

II. Teva Has Failed to Show Irreparable Harm if the Stay Is Not Reinstated.

Turning to the second and third *Nken* factors, Teva has not shown that it will suffer irreparable harm if the five Asserted Patents are delisted while the petition for rehearing en banc is pending. Teva's arguments are at best speculative. Speculation about potential harm is not sufficient to establish that this factor favors a stay. *Nken v. Holder*, 556 U.S. 418, 434-35 (2009) (holding that it is not sufficient to simply show "some possibility of irreparable injury"); *Koninklijke Philips N.V. v. Thales USA, Inc.*, 39 F.4th 1377 (Fed. Cir. 2022) (noting that it is not sufficient to show a "mere possibility or speculation of harm") (citing *Winter v. Nat. Res. Def. Council, Inc.*, 555 U.S. 7, 20 (2008)).

As to Amneal's ANDA, Teva has not shown that it would be irreparably harmed if Amneal's 30-month stay is dissolved before this Court decides Teva's intended petition for rehearing en banc. As an initial matter, Teva provides no authority for its fatalist proposition that FDA would refuse to reinstitute the 30-month stay if Teva ultimately succeeded. Even if the FDA did not reinstitute Amneal's 30-month stay, that could be repaired by an injunction. Specifically, if it is ultimately determined that the Asserted Patents are listable, Teva could seek to enjoin Amneal from selling its ANDA product until the original expiration date of the 30-month stay. To the extent Amneal had not yet sold any of its ANDA product by then, such an injunction would restore the *status quo ante*, repairing the alleged harm. To the extent Amneal had already been selling its ANDA product, the injunction could prevent further sales. And if Amneal were ultimately found liable for those sales, damages would be a sufficient remedy.

Indeed, justice would be better served by such injunctive proceedings. Injunctive proceedings necessarily would be more robustly informed than Teva's motion to stay, as the case would be in a more advanced stage, and the briefing could be less truncated. Moreover, with injunctive proceedings, the court would have the opportunity to weigh the merits of Amneal's non-infringement and invalidity defenses, not just the merits of Amneal's delisting arguments.

As to the Deva ANDA, Teva cannot show irreparable harm, because merely delisting the five Asserted Patents will not dissolve Deva's 30-month stay. Teva acknowledges that only three of the four patents it has asserted against Deva would be subject to the delisting order. (Teva Br. at 3 n.3.) To dissolve Deva's 30-month stay, all four of the patents asserted against Deva would have to be delisted. Thus, Teva has secured a 30-month stay as to Deva's ANDA that will not be affected by implementation of the delisting order. Accordingly, the delisting order does not pose any risk of irreparable harm to Teva. In any event, even if the Deva stay were dissolved and Teva thereafter prevailed in this appeal, that harm could be repaired by an injunction and/or a damages award, as explained above.

As to Teva's hypothetical future ANDA filers (Teva Br. at 8-10), Teva is piling speculation on top of speculation. First, Teva speculates that possibly other ANDA filers could be lurking. Teva doubly speculates that those hypothetical filers might submit their ANDAs while the Asserted Patents are delisted. Teva's hypothetical also assumes (without any basis or explanation) that those other hypothetical ANDAs would be subject to infringement assertions on only the five delisted patents, and not on any of the other four patents listed in the Orange Book for ProAir HFA. Teva is counting angels on the head of a pin, not demonstrating irreparable harm.

Even in Teva's speculative hypothetical scenario (where it ultimately only asserted the five Asserted Patents), and it could not obtain or keep a 30-month stay, Teva could seek to repair such alleged harm by injunction, as explained above.

The second *Nken* factor weighs in favor of denying the motion.

III. The Harm to Amneal in Reinstating the Stay Is Certain and Irreparable.

The harm to Amneal in reinstating the stay outweighs the harm to Teva. The harm to Amneal will be certain and irreparable from the day that it receives tentative approval but remains unable to launch by virtue of the stay. Where Teva could remedy any alleged harm by use of preliminary injunction, the rules of civil procedure do not afford Amneal any such remedial vehicle. Teva's suggestion that Amneal could file a special application in this Court (Teva Br. at 7) is not a meaningful remedy because it merely ensures that significant time will elapse between Amneal obtaining tentative approval and any potential relief, while the harm to Amneal would mount daily.

Finally, Teva devotes a substantial portion of its brief to speculation as to whether Amneal will obtain tentative approval during the pendency of Teva's petition for rehearing en banc. The fact is that the FDA approval process is largely unpredictable, and there is no way of knowing for sure exactly when any ANDA will be approved. Amneal is [redacted] action

action submitted by Teva, and will continue action until the FDA issues tentative approval.

The third *Nken* factor weighs in favor of denying the motion.

IV. The Public Interest Favors Lifting the Stay

The public has a strong interest in speeding and maximizing access to critical, affordable asthma medication. Having Amneal's ANDA product on the market as soon as possible serves this public interest by increasing access to this medication and driving healthy competition, which will likely drive down the cost of this medication for patients. A stay pending the petition for rehearing erects an unjustified barrier to delisting the Asserted Patents and thus runs contrary to the public interest.

The fourth and final *Nken* factor weighs in favor of denying the motion.

CONCLUSION

The motion should be denied.

January 6, 2025

Respectfully submitted,

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CERTIFICATE OF COMPLIANCE

This filing complies with the type-volume limitation of Federal Rule of Appellate Procedure 27(d)(2). This filing contains 2,185 words.

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). This motion has been prepared in a proportionally spaced typeface, 14-point Times New Roman font, using Microsoft Word 2016.

/s/ Steven A. Maddox

Steven A. Maddox

CERTIFICATE OF SERVICE

I, Steven A. Maddox, hereby certify that on January 6, 2025 the foregoing document was filed with the Court using the Court's CM/ECF systems, which will send notifications to all counsel registered to receive electronic notices.

/s/ Steven A. Maddox
Steven A. Maddox

UNITED STATES COURT OF APPEALS
FOR THE FEDERAL CIRCUIT

CERTIFICATE OF CONFIDENTIAL MATERIAL

Case Number: 2024-1936

Short Case Caption: Teva Branded Pharmaceutical Products R&D, Inc. v. Amneal Pharmaceuticals of New York, LLC

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Date: 01/06/2025

Signature: /s/ Steven A. Maddox

Name: Steven A. Maddox