

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'
PARTIAL OPPOSITION TO MOTION TO EXPEDITE**

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June 25, 2024

**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: 06/25/2024

Signature: /s/ Steven A. Maddox

Name: Steven A. Maddox

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

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

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

CONFIDENTIAL MATERIAL OMITTED

The material omitted in the text on pages 2 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.

TABLE OF AUTHORITIES

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Cases

Jazz Pharmaceuticals, Inc. v. Avadel CNS Pharmaceuticals, LLC, 60 F.4th 1373 (Fed. Cir. 2023) 4

INTRODUCTION

Appellees (collectively “Amneal”) submit this partial opposition to the motion of appellants (collectively “Teva”) to expedite the merits briefing of this appeal. Amneal agrees with Teva that Amneal’s pending Abbreviated New Drug Application warrants expedition of the merits briefing schedule. However, the parties could not reach agreement on the specific dates of such a schedule.

Amneal seeks expedited briefing to be completed in time for the Court to hear argument in the September 2024 session. Teva seeks to delay argument until the November session. In this brief submission, Amneal outlines why its proposed schedule with argument in September is the better course.

BACKGROUND

This appeal arises from the district court’s ruling of judgment on the pleadings with respect to the infringement claims brought by Teva against Amneal under the Hatch Waxman Act. The district court held that the asserted patents failed to meet the statutory requirements for listing in the Orange Book.

Accordingly, on June 10, 2024, the district court issued an order requiring Teva to request the FDA to de-list the patents from the Orange Book. The district court subsequently granted a 30-day stay for the purpose of allowing the orderly presentation of arguments for a stay and expedited schedule to this Court. That temporary stay expires on July 15, 2024.

The parties agreed to, and jointly requested, an expedited briefing schedule for submission of whether that stay is to be extended pending a resolution on the merits. Under that proposed agreed schedule, briefing on the question of a further stay would be complete on July 3, 2024.

ARGUMENT

The Court should enter Amneal's proposed schedule for the September session because it would mitigate the potential harm to Amneal of being kept out of the marketplace prior to a resolution of the merits. In contrast, Teva has not identified any potential harm it would suffer by having oral argument in the September session, as opposed to the November session. For Teva, this scheduling dispute is a matter of convenience -- *and* a matter of an additional two months in which Amneal may be kept out of the marketplace.

Amneal anticipates receiving tentative approval from the FDA on or before the **DATE** of **DATE**. If argument is not held until the November session, Amneal would be subject to the potential harm of having obtained approval, but nevertheless being prevented from entering the marketplace until the Court's disposition on the merits sometime in December, January or later. As a practical matter, delaying oral argument until the November session would virtually ensure no resolution until sometime after Amneal anticipates having FDA approval.

If the case is heard in the September session, the risk of harm to Amneal is at least mitigated. It is more likely that the Court will have time to deliberate and issue a decision on the merits before Amneal’s anticipated approval.

Further, holding oral argument in the September session would not subject Teva to any risk of harm. Teva’s arguments are based on speculation and convenience – not any kind of potential harm.

Teva speculates that Amneal will not receive tentative approval on or before [REDACTED]. Teva basis this speculation on the assertion that that “there is no suggestion that the FDA will provide an ‘approval’ as of” the [REDACTED] of [REDACTED]. Teva Br. at 6. Teva fails, however, to cite any support for its implicit assumption that such FDA communications typically contain any indication one way or another as to a date of approval. Accordingly, the absence of any such indication in FDA’s communications to Amneal is not probative of whether Amneal will receive tentative approval on or before [REDACTED].

Teva complains that it would be inconvenient to have to work on its merits brief at the same time it is working on the stay motion that Teva itself decided to file. Teva Br. at 6. Teva also appears to complain that Amneal’s proposed schedule would interfere with its observance of the Fourth of July. *Id.*

Teva even asserts the alleged inconvenience of *amici curiae*. Teva Br. at 7. Teva speculates that Amneal’s “extraordinarily rapid schedule” would “foreclose

amicus participation” and “potentially prejudice the presentation of arguments to this Court.” *Id.* Teva does not cite any specifics or supporting facts.

Finally, contrary to Teva’s suggestion, this Court *does* have prior experience in reviewing orders to de-list patents, such as the order in this case. In *Jazz Pharmaceuticals, Inc. v. Avadel CNS Pharmaceuticals, LLC*, 60 F.4th 1373 (Fed. Cir. 2023), the Court affirmed a similar order to de-list an Orange Book patent. Notably, the Court issued that affirmance approximately three months after the district court had issued its de-listing order. *Id.* at 1373, 1375.

Amneal proposes the following schedule leading to oral argument in the September session, approximately three months from the district court’s June 10, 2024 order at issue:

Opening brief by Teva: July 5, 2024

Response brief by Amneal: August 2, 2024

Reply brief by Teva: August 13, 2024

Appendix filed: August 16, 2024

CONCLUSION

The Court should adopt Amneal’s proposed schedule for briefing on the merits, and set oral argument for September 2024.

Respectfully submitted,

/s/ Steven A. Maddox

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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 860 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 June 25, 2024 the foregoing document was filed with the Court, and served on counsel of record for Defendants-Appellees via electronic mail at the addresses listed below.

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/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**Instructions:** When computing a confidential word count, Fed. Cir. R.

25.1(d)(1)(C) applies the following exclusions:

- Only count each unique word or number once (repeated uses of the same word do not count more than once).
- For a responsive filing, do not count words marked confidential for the first time in the preceding filing.

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- This number exceeds the maximum permitted by Federal Circuit Rule 25.1(d)(1), and the filing is accompanied by a motion to waive the confidentiality requirements.

Date: 06/25/2024Signature: /s/ Steven A. MaddoxName: Steven A. Maddox