

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] MOTION TO EXPEDITE

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June 19, 2024

FORM 9. Certificate of Interest

Form 9 (p. 1)
March 2023

**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 Teva Branded Pharmaceutical Products R&D, Inc.; Norton (Waterford) Ltd.; Teva Pharmaceuticals USA, 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: 06/19/2024

Signature: /s/ William M. Jay

Name: William M. Jay

FORM 9. Certificate of Interest

Form 9 (p. 2)
March 2023

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
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.

☐ Additional pages attached

FORM 9. Certificate of Interest

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March 2023

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

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

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Goodwin Procter LLP

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Connolly LLP

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

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

CONFIDENTIAL MATERIAL OMITTED

The material omitted in the text on pages 2, 4, and 6 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

This is an appeal from an injunction requiring appellants (collectively “Teva”) to remove five patents from FDA’s Orange Book. Under FDA regulations, the injunction would have required Teva to delist its patents by Monday, June 24.¹ But the district court recognized that this Court would need time to consider Teva’s motion to stay the injunction pending appeal and the opposition papers to be filed by appellees (collectively “Amneal”). The district court therefore granted a limited stay lasting through Monday, July 15, and directed the parties to present an expedited briefing schedule to this Court. The parties have agreed on expedited schedules for the stay motion and they jointly request that the Court accept the proposed schedule. The parties also agree that the appeal should be expedited but disagree on the schedule for expediting. This motion sets forth Teva’s proposed schedule; Amneal opposes the specifics of the schedule and intends to file a response.

Motion to Stay: The parties jointly propose the following. Teva will file its motion to stay by Friday, June 21.² Amneal will file its opposition by Friday, June 28. Teva will file its reply by 2:00 p.m. on Wednesday, July 3. That will give this Court seven business days to consider the parties’ submissions and decide whether to extend the stay before Teva must file the delisting papers with FDA.

¹ See 21 C.F.R. § 314.83(f)(2)(i) (14 days to remove a patent after a court order).

² Teva was prepared to file a day sooner, but due to a scheduling conflict, Amneal’s counsel requested that the schedule move back one day.

Merits Briefing and Oral Argument: The parties jointly request that this Court expedite its consideration of this appeal, but disagree on the proposed schedule. Teva respectfully requests that this Court expedite the appeal and schedule oral argument for November 2024. Teva proposes to file its opening brief by July 30. Teva proposed to have Amneal file its response brief by August 30, although Amneal is free to file earlier if it chooses. Teva proposes to file its reply brief 14 days after the response brief (September 13 on this schedule), and to file the appendix no more than two business days after the reply brief (September 17 on this schedule). That would have all briefing completed in time for the Court to schedule oral argument for the November argument session. As explained below, that would permit the appeal to be submitted for decision before FDA action on Amneal's generic drug application is likely.

BACKGROUND

Briefly, Teva holds the NDA for ProAir® HFA (albuterol sulfate) Inhalation Aerosol, a metered-dose aerosol product. Teva has listed nine patents in the Orange Book for ProAir® HFA, including the five patents at issue in this case. Amneal has filed a Paragraph IV ANDA with the FDA, seeking authorization to market a generic of ProAir® HFA before the expiration of those patents. The FDA expects to review Amneal's **submission** to its ANDA by either **date** or **date**.

Teva timely sued Amneal on the five patents at issue, which has the effect of precluding FDA from approving Amneal's ANDA for thirty months. *See* 35 U.S.C. § 355(j)(5)(B)(iii). Amneal counterclaimed for an order to delist those five patents from the Orange Book. *See id.* § 355(j)(5)(C)(ii)(I). If the patents are delisted, the 30-month stay would terminate.

On June 10, 2024, the district court granted Amneal's motion for judgment on the pleadings on its counterclaim and entered an injunction directing Teva to delist the five patents from the Orange Book. If not stayed, that order would have required Teva to act by June 24, 2024. *See* note 1, *supra*.

The day after the injunction entered, Teva moved to stay that injunction pending appeal or, in the alternative, for a 30-day stay to permit this Court to resolve a stay motion. The district court granted the alternative motion and stayed its order until July 15 at 11:59 p.m., and directed the parties to propose a briefing schedule "which will grant the Federal Circuit more than adequate time to consider your positions and evaluate the merits of your claims." Ex. 1 at 19-20; Ex. 2.

ARGUMENT

I. Briefing Schedule for Motion to Stay Pending Appeal

The parties have agreed to a schedule for briefing Teva's motion for a stay that will have the motion fully briefed before the Independence Day holiday weekend. The district court's temporary stay expires at the end of the day on July

REDACTED pursuant to protective order

15. The timelines (including the 7-day period for Amneal to respond) are consistent with this Court's usual practice for expedited motions. The parties jointly propose the following schedule for briefing the motion to stay pending appeal:

- Teva's motion to stay: June 21, 2024
- Amneal's opposition: June 28, 2024
- Teva's reply: July 3, 2024 (by 2 pm)
- District Court Stay Expires: 11:59 pm, July 15, 2024³

II. Expedited Appeal

The parties also submit that there is good cause to expedite consideration of the merits of this appeal. Whether a stay is granted or denied, expedited consideration will increase the likelihood that the Court will be able to hear and decide the merits of this appeal before the status of the five patents at issue becomes directly relevant to Amneal's ability to obtain FDA approval of its ANDA.

The district court noted at the stay hearing its understanding that "the possibility of [Amneal's] receiving tentative approval [from the FDA] is either **date** of **date** or **date** of **date** depending on whether or not they have to do an **action** of the **location**." Ex. 1 at 12. For that reason, Teva has proposed a briefing schedule that would permit the Court to hear oral argument in November

³ If this Court determines it needs additional time to decide the motion for stay pending appeal, it can enter an administrative stay pursuant to the All Writs Act.

2024. This Court ordinarily would release the calendar for that session on approximately September 20, 2024. Teva has therefore proposed shortening the standard briefing schedule for all three briefs and the appendix in order to allow the appeal to be fully briefed and paper copies filed before that date.

Teva proposes the following briefing schedule:

- Opening brief by Teva: July 30, 2024
- Response brief by Amneal: No later than August 30, 2024
- Reply brief by Teva: September 13, 2024 or 14 days after the response
- Appendix filed: September 17, 2024 or 2 business days after the reply

By contrast, if the Court does not expedite the appeal, further emergency filings could well become necessary if Amneal receives tentative or final approval of its ANDA—which could well occur before a merits panel of this Court is in a position to rule definitively on the merits of the appeal. For that reason, both parties submit that it is in the interest of all parties and the Court to have the case ready for submission to a merits panel on an expedited basis. A November argument provides the parties with a reasonable amount of time to brief their positions and the Court to consider the issues once briefing is complete.

Amneal has refused to agree to Teva’s proposed schedule; it seeks to expedite the appeal even more and to schedule it for argument as early as September. That request should be rejected. Although Amneal is free to file its brief as rapidly as it

REDACTED pursuant to protective order

likes, there is no need to shorten Teva's briefing schedule to the degree Amneal has proposed (giving Teva only 23 days from docketing of the appeal to write its brief—while also filing and arguing the stay motion in the district court and filing the stay motion and reply in this Court—and making the brief due the Friday after the Independence Day holiday). Amneal currently does not have even tentative approval. The next “event” for FDA action, to provide a response to Amneal's most submission, is date. Even then, there is no suggestion that the FDA will provide an “approval” as of that date. To the contrary, Amneal requested that the FDA action its time to respond to the most submission and action the submission as only “descriptor.” The FDA refused, continuing to treat the submission as “descriptor.” The need to consider this descriptor submission is the basis for the event for FDA action of no earlier than date date. Accordingly, holding oral argument in November would permit the merits panel to decide whether to continue or dissolve a stay, before any action is expected by FDA.

Moreover, this appeal presents the first opportunity for this Court to consider a claim for delisting of patents from the Orange Book as requested by an ANDA filer. The Court should ensure that the parties, and potential amici, have sufficient time to prepare comprehensive briefing on this important matter. Unusually, there was amicus briefing in the district court, and there is certain to be great interest by

amici now that the case is in the court of appeals with nationwide jurisdiction over delisting claims.⁴ Amneal's suggestion that briefing be completed on an extraordinarily rapid schedule would require the briefing to be so expedited as to potentially prejudice the presentation of arguments to this Court, including the potential participation of amici who are likely to have helpful views on these issues. And as noted, the status of Amneal's ANDA does not justify a rush that would foreclose amicus participation.

CONCLUSION

The Court should expedite the appeal, set the requested deadlines for the briefing on the motion to stay, adopt Teva's proposed schedule for the briefing on the merits, and set oral argument for November 2024.

⁴ Teva has already received inquiries concerning the case schedule from potential amici.

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 1,615 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/ William M. Jay

William M. Jay

CERTIFICATE OF SERVICE

I, William M. Jay, hereby certify that on June 19, 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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FORM 31. Certificate of Confidential Material

Form 31
July 2020

**UNITED STATES COURT OF APPEALS
FOR THE FEDERAL CIRCUIT**

CERTIFICATE OF CONFIDENTIAL MATERIAL

Case Number: No. 24-1936

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.

The limitations of Fed. Cir. R. 25.1(d)(1) do not apply to appendices; attachments; exhibits; and addenda. *See* Fed. Cir. R. 25.1(d)(1)(D).

The foregoing document contains 15 number of unique words (including numbers) marked confidential.

- ☒ This number does not exceed the maximum of 15 words permitted by Fed. Cir. R. 25.1(d)(1)(A).
- ☐ This number does not exceed the maximum of 50 words permitted by Fed. Cir. R. 25.1(d)(1)(B) for cases under 19 U.S.C. § 1516a or 28 U.S.C. § 1491(b).
- ☐ 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: 06/19/2024

Signature: /s/ William M. Jay

Name: William M. Jay

Exhibit 1

(Confidential Filed Under Seal)

Exhibit 2

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**UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY**

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

Plaintiffs,

v.

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

Defendants.

Civil Action No. 23-cv-20964-SRC-
MAH

**ORDER GRANTING IN
PART MOTION TO STAY THE
COURT'S JUNE 10, 2024 ORDER**

Filed Electronically

THIS MATTER having been brought before the Court upon Plaintiffs Teva Branded Pharmaceutical Products R&D, Inc., Norton (Waterford) Ltd., and Teva Pharmaceuticals USA, Inc.'s (collectively, "Teva" or "Plaintiffs") Motion to Stay the Court's June 10, 2024 Order (D.E. 88) pending the resolution of Teva's appeal, or in the alternative, a 30-day stay to permit resolution of Teva's application to the United States Court of Appeals for the Federal Circuit for a stay pending appeal; and the Court having

ORDERED, for the reasons set forth on the record on June 13, 2024, that Plaintiffs' alternative request in its Motion for a 30-day stay to permit resolution of an application to the United States Court of Appeals for the Federal Circuit for a stay pending appeal is **GRANTED**; and it is further

ORDERED that the parties shall meet and confer and propose to the Federal Circuit a briefing schedule for Teva's application for a stay and a briefing schedule for the appeal.

Hon. Stanley R. Chesler, U.S.D.J.