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 EXPEDITE

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June 27, 2024

CERTIFICATE OF INTEREST

Counsel for Appellants 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: June 27, 2024

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

Counsel for Appellants

CONFIDENTIAL MATERIAL OMITTED

The material omitted on pages 1, 5, 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.

While Amneal agrees with Teva that the appeal should be expedited, its proposed briefing schedule is unjustifiable. Amneal's insistence on a September argument date would burden the Court and Teva, and prejudice any potential amici. And because of the expected timing of FDA action, there is no reasonable justification for imposing those burdens for the sake of a September argument.

Amneal's premise is that it needs oral argument no later than September, time before FDA's most optimistic event, because argument in any later month would provide "no resolution until sometime after Amneal anticipates having FDA approval." Appellees' Partial Opposition ("Opp.") 2.[1] That premise is incorrect. Assuming (as Amneal appears to do) that this Court grants Teva's motion for a stay pending appeal,[2] the merits panel would be free to modify or dissolve the stay after hearing oral argument, if that were appropriate based on its consideration of the parties' arguments, the vote at conference, and any developments on Amneal's ANDA. *Cf. Insulet Corp. v. EOFlow Co., Ltd.*, No. 2024-1137, slip op. (Fed. Cir.

[1] If FDA requires an action, the goal date will not be until date.

[2] *See* Opp. 2 ("If argument is not held until the November session, Amneal would be subject to the potential harm of having obtained [tentative] approval, but nevertheless being prevented from entering the marketplace until the Court's disposition on the merits …."). As explained in Teva's motion for a stay, if the Court does not grant a stay and the patents are delisted, there will be no tentative approval and nothing preventing Amneal from entering the market—if FDA were to conclude that Amneal's ANDA is substantively approvable, Amneal would receive *final* approval.

June 17, 2024) (merits panel stayed preliminary injunction the day after oral argument); *Takeda Pharms. U.S.A. Inc. v. West-Ward Pharm. Corp.*, 785 F.3d 625, 628 (Fed. Cir. 2015) (merits panel vacated injunction pending appeal the day after oral argument). Amneal appears to believe that nothing can happen until the Court issues an opinion (and, presumably, a mandate). If that were so, even oral argument in September would not be likely to result in the issuance of an opinion and a mandate by the FDA goal date. Amneal's insistence that September is the latest feasible argument date is simply not correct.

Especially with that misconception cleared away, Amneal's proposed schedule—which it presented to Teva on a take-it-or-leave-it basis—cannot be justified given the costs it would impose on everyone except Amneal, starting with the Court.

Burden on the Court: As explained in its motion (at 5), Teva proposed a schedule that would have the appeal fully briefed and the appendix filed a few days before September 20, which is approximately when the Court would ordinarily issue the calendar for the November sitting.[3] Thus, consistent with the district court's admonition to the parties (*see* Teva Mot. Ex. 2 at 3), Teva's schedule would allow the merits panel the full usual time to prepare for oral argument. That level of

[3] It appears from its response that Amneal needs only 28 days for its response brief, whereas Teva had proposed giving Amneal 30 days, so the time might move back further.

preparation is fully warranted in this appeal, which involves complex statutory issues on which this Court has relatively little precedent (and only one decision involving a delisting injunction at all).

Amneal's schedule, by contrast, would not have the briefs finished and the appendix filed until August 16, just two and a half weeks before the September session begins. On Amneal's proposal, the case would be calendared around July 20, but the panel would not receive the response brief until August 2 or the reply brief until August 13. Amneal's proposed schedule might provide enough lead time for an October argument, but not a September one, at least not without forcing the merits panel into a degree of expedited preparation that cannot be justified here.[4] Amneal's response does not address the burden on the Court even though the point is flagged in Teva's motion.

If the Court were really inclined to schedule argument in this case just a few weeks after receiving the reply brief and appendix, then Teva's proposed schedule would permit oral argument in October. Amneal never gives any reason why

[4] The Court agreed to such an extraordinary turnaround in the *Jazz* appeal, but in that case, the defendant had already obtained tentative approval from the FDA. Jazz Mot. for Stay in No. 23-1186, at 5 & n.3. By contrast, any tentative approval for Amneal is months away at best. Amneal's suggestion (Opp. 4) that this Court should adopt a similar timetable—oral argument within three months after the district court order—ignores that key difference. Notably, despite the demonstrably lesser urgency, Amneal proposes imposing an even tighter deadline on Teva than Jazz faced—25 days from district court decision to opening brief, versus 28 for Jazz.

consideration in October would be insufficiently prompt *even if* all of Amneal's premises were correct. The *Jazz* appeal—Amneal's sole example of an expedited case—was decided in ten days.

Burden on Teva: Amneal proposed a schedule that would allow Teva 23 days from the date of docketing to file its opening brief (a period that also encompasses arguing the stay motion in district court, plus preparing and filing the stay motion *and* the motion to expedite *and* the replies on each of them in this Court). By contrast, Amneal allotted itself 28 days to file the response brief. That lopsided briefing schedule is inequitable on its face, especially compared to the standard times of 60 days for Teva's opening brief and 40 days for Amneal's response.

The allotment of only 11 days—half the standard time—to prepare and file the reply brief is also unjustifiable, especially because Amneal knows full well that it expects at least one amicus filing 7 days after the due date for its own brief—by a government agency that filed a brief below and that does not need consent or permission to file in this Court. Fed. R. App. P. 29(a)(2).

Amneal dismisses these considerations as mere "convenience," but such a significant reduction in the amount of time allowed to write the briefs and respond to amicus briefs would affect a party's ability to present its arguments even if that party had nothing else to do during that period. As for convenience, Amneal's chosen July 5 due date for Teva's opening brief bears some emphasis: as Amneal is

no doubt aware, it imposes more than just routine inconvenience to insist that an adversary file a 14,000-word expedited brief on the Friday between a federal holiday and a weekend, immediately after filing an expedited stay reply the day *before* the holiday. Teva will adhere to any briefing schedule the Court sets; the question is whether the timing consideration Amneal raises—*possible* FDA action in [redacted] date, which may or may not be favorable to Amneal—warrants this type of unequal and burdensome briefing schedule. It does not.

Amicus participation: Amicus briefs are due seven days after the parties' filings. Amneal says (at 4) that Teva does not cite any "specifics" suggesting this is a case that will warrant amicus participation, but ignores the specific fact Teva already provided: *this case has already featured amicus participation in the district court*. The concern is particularly acute for Teva, because Amneal's schedule would require that any amici supporting Teva file about two weeks from now—likely too quickly for many to participate—whereas amici supporting Amneal can file in early August. Teva has already received expressions of interest from amici, who are understandably concerned about whether they could file in two weeks.

Amneal's uncertain prospects of approval: As shown above, Amneal's proposed schedule would be overkill even if Amneal were correct to assert that it "anticipates receiving tentative approval from the FDA on or before the FDA [redacted] event [redacted] event of [redacted] date [redacted]." Opp. 2. But Amneal offers nothing more than the [redacted] event

event itself to support that critical foundation for its scheduling proposal. And FDA's setting a event for action does not mean Amneal can expect *good* news by that date. Indeed, FDA's refusal to action Amneal's recent status from descriptor to descriptor (Mot. 6) suggests otherwise. Amneal also acknowledged below that the event will be later if an action is required. Mot. Ex. 1 at 12. Nor does Amneal provide examples of ANDAs, especially of such complex inhalation products, approved on the expedited timeline Amneal suggests. To the contrary, Amneal's own counterclaim suggests approval will take much longer. For example, Amneal discusses an ANDA for ProAir® HFA filed in 2012, but not approved by the FDA until 2020. *See* Amneal Counterclaims (ECF No. 12) ¶¶ 60, 63. And Amneal itself originally claimed it expected approval in the "summer of 2024," *id.* ¶ 121, but acknowledges that FDA action now will not come until later. Teva's proposed schedule provides an appropriate balance between the time needed by this Court and the parties to address the important issues raised by this appeal, and expedited resolution to minimize any risk of harm to Amneal, in light of Amneal's failure to establish that it reasonably expects approval in such a short time period.

Teva will, of course, file its briefs and appear for argument at any times set by the Court. Our goal is to have this complex case briefed in time for this Court's thorough consideration. Both sides support expedited consideration. Teva opposes only a degree of expedition that is both unjustified and burdensome.

CONCLUSION

Teva respectfully requests that the Court expedite the appeal, adopt the briefing schedule Teva proposed in its Motion to Expedite, and set oral argument for November 2024.

June 27, 2024

Respectfully submitted,

/s/ William M. Jay

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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 1,621 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: June 27, 2024

/s/ William M. Jay
William M. Jay

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:

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- For a responsive filing, do not count words marked confidential for the first time in the preceding filing.

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Date: 06/27/2024

Signature: /s/ William M. Jay

Name: William M. Jay