

**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

**APPELLANTS' UNOPPOSED MOTION
FOR AN ADMINISTRATIVE STAY**

Daryl L. Wiesen
Christopher T. Holding
Louis L. Lobel
Jordan Bock
Thomas V. McTigue IV
GOODWIN PROCTER LLP
100 Northern Ave.
Boston, MA 02210
(617) 570-1000

December 20, 2024

William M. Jay
GOODWIN PROCTER LLP
1900 N Street, N.W.
Washington, DC 20036
(202) 346-4000

Natasha E. Daughtrey
GOODWIN PROCTER LLP
601 South Figueroa Street
Los Angeles, CA 90017
(213) 426-2642

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: December 20, 2024

/s/ William M. Jay

William M. Jay

Counsel for Appellants

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INTRODUCTION

Appellants (“Teva”) respectfully request an immediate administrative stay of the district court’s order, reinstating the stay that a motions panel of this Court previously granted. This motion is unopposed but time-sensitive.

The district court’s order requires Teva to delist several patents from the Orange Book. In its opinion filed today, the Court lifted the stay. If that stay is not reinstated, Teva will have to submit papers to the FDA delisting its patents on Friday, January 3, 2025, and will suffer irreparable injury even if it were able to re-list its patents after that date. Teva intends to file a separate motion on Monday, December 23, requesting that the Court reinstate the stay until the full Court rules on Teva’s forthcoming petition for rehearing en banc. The parties have agreed to a briefing schedule for that motion. In this motion, Teva requests that the Court reinstate the stay at least until the Court rules on Teva’s stay motion. Such an administrative stay will give the parties time to brief the stay motion and the Court time to consider it.

Appellees (“Amneal”) do not oppose this motion for an administrative stay and will not file a response. Amneal is still determining whether to oppose the forthcoming motion for a stay pending rehearing.

The parties have agreed to the following briefing schedule for the stay motion: Teva to file its motion on **Monday, December 23**; Amneal to file any opposition by **Monday, January 6**; Teva to reply by **Monday, January 13**. Teva requests that

the Court enter that briefing schedule if it grants the administrative stay. The proposed deadline for Amneal's filing reflects a modest extension of the standard 10-day period to oppose a motion, primarily to accommodate the Christmas and New Year's holidays.

The Court should grant this motion sufficiently in advance of the January 3 deadline to spare the parties from the need to take urgent action on the eve of that deadline. Because the deadline comes from FDA regulations, the parties to this case cannot simply agree between themselves to postpone it: a stay from this Court is necessary to avert the irreparable consequences of delisting the patents on that date. If it does not grant this motion, the Court should expedite briefing on Teva's stay motion to permit a decision on that motion before January 3, and to permit Teva to apply for a stay to the Circuit Justice if necessary.

ARGUMENT

1. As the Court's opinion explains, the five patents at issue here are listed in the Orange Book for Teva's product ProAir[®] HFA Inhalation Aerosol, which was approved pursuant to a New Drug Application. Op. 12-13. The issue in this appeal is whether those patents must be delisted from the Orange Book on the ground that they do not "claim . . . the drug for which the application was approved." 21 U.S.C. § 355(j)(5)(C)(ii)(I)(aa). The district court concluded that they must, and it issued an injunction directing Teva to delist the patents. Appx24-40. The district court

concluded, however, that it should grant an administrative stay of its injunction for 30 days to permit this Court to resolve a motion for stay pending appeal. ECF 12-4 (D. Ct. Dkt. No. 98). The district court recognized that such a stay would neither cause any harm to Amneal nor harm the public interest “in any way, shape, or form.” Appx1575.

This Court then granted the stay pending appeal. ECF No. 32; Op. 17.

2. Amneal has confirmed to Teva that it does not oppose granting the administrative stay and does not intend to file a response to this motion. That position confirms that Amneal will not suffer any prejudice during the pendency of this administrative stay—just as the district court recognized that it would not suffer any prejudice during the stay that court previously granted. Appx1575. Amneal still does not have FDA approval or even tentative approval to market its ANDA product.¹ (Amneal has submitted two sealed updates to the Court regarding FDA actions with respect to its ANDA, most recently on December 12, 2024. ECF Nos. 93, 101.) And the administrative stay would last only while the underlying stay motion is briefed and considered by the Court.

Far from causing Amneal any prejudice, the administrative stay would *benefit* Amneal by ensuring that its counsel have adequate time to assess and respond to

¹ See <https://www.accessdata.fda.gov/scripts/cder/daf/index.cfm> (select “Drug Approval Reports by Month” for recent approvals and tentative approvals).

Teva's forthcoming motion for a stay pending consideration of rehearing en banc. The administrative stay would likewise ensure that Teva will not be harmed by agreeing to Amneal's short but reasonable extension of time to respond, which accommodates the fact that Amneal will be working on its response during the Christmas and New Year's holidays. Without an administrative stay, by contrast, Teva would have to seek highly expedited consideration of its stay motion to ensure that it is decided before the expiration of the 14-day period after which, as discussed below, Teva will suffer irreparable harm.

Thus, granting an administrative stay would benefit the Court and both parties, ensure sufficient time to consider Teva's forthcoming stay motion, and prejudice no one.

3. With the lifting of the stay, FDA regulations give Teva 14 days to delist its patents from the Orange Book. 21 C.F.R. § 314.53(f)(2). For that reason, this Court's intervention is necessary before the 14-day period expires: without a stay, *even with Amneal's agreement*, Teva would not be able to avoid its obligation to submit the delisting amendment to the Orange Book. And once the patents are delisted, a number of irreparable consequences will follow.

Chief among these is the statutory 30-month stay, which Teva would lose with respect to the five delisted patents and which it could not regain. An order to take action that is both irreversible and not compensable is the very definition of

irreparable harm. *See Hollingsworth v. Perry*, 558 U.S. 183, 195 (2010) (harm is irreparable when it “would be difficult—if not impossible—to reverse”). For a 30-month stay to apply, the patents must be listed in the Orange Book *before* the ANDA is filed. 21 U.S.C. § 355(j)(5)(B)(iii). Amneal’s ANDA is on file already. So is that filed by another generic company, Deva, which is also subject to a 30-month stay based on the lawsuit Teva filed on these and other patents. For those two ANDA filers, FDA would not recognize a 30-month stay on the delisted patents, even if Teva prevailed in this case on rehearing en banc or certiorari and resubmitted those patents. The same is true for any more generics that file ANDAs after the patents are delisted—indeed, those generics would not even have to *certify* to the patents and provide Teva with the notice letter that Hatch-Waxman otherwise requires, 21 U.S.C. § 355(j)(2)(B)(ii), even if the patents were later restored to the Orange Book. *See* 21 C.F.R. § 314.94(a)(12)(vi). The permanent loss of such a “statutory entitlement ... is a harm that [is] sufficiently irreparable” to support a stay because “[o]nce the statutory entitlement has been lost, it cannot be recaptured.” *Apotex, Inc. v. FDA*, No. Civ.A. 06-0627, 2006 WL 1030151, at *17 (D.D.C. Apr. 19, 2006) (citing *Mova Pharm. Corp. v. Shalala*, 140 F.3d 1060, 1067 (D.C. Cir. 1998)), *aff’d*, 449 F.3d 1249 (D.C. Cir. 2006). Nor are there any money damages available to compensate Teva for the loss of these important statutory rights, which are distinct from the rights conferred by the patents themselves.

4. This is a highly significant case that has already garnered a high degree of attention—as the Court observed on taking the bench for oral argument and seeing the courtroom packed on a Friday afternoon. Because of this Court’s nationwide jurisdiction over delisting claims, the Court’s decision will have repercussions far beyond the parties to this case.

The merits of Teva’s petition for rehearing en banc are beyond the scope of this motion for an administrative stay, which is being filed the same day as the Court’s decision; Teva will address the standards for rehearing en banc in the stay motion it will file on Monday. Rather, the question at this stage is only whether to grant the administrative stay necessary to permit *consideration* of rehearing en banc beyond the 14-day period imposed by FDA regulations. The Court should not pretermitt the rehearing process by denying an administrative stay to which both parties have agreed, because denying the administrative stay would benefit no one and granting the stay would benefit the Court as well as the parties.

CONCLUSION

For the foregoing reasons, and in light of Amneal’s non-opposition, Teva respectfully requests that this Court grant an administrative stay of the district court’s injunction pending consideration of Teva’s forthcoming motion to stay. If the Court grants the administrative stay, Teva also requests that the Court enter the requested briefing schedule: Teva to file its motion to stay on **Monday, December 23**; Amneal

to file any opposition by **Monday, January 6**; Teva to reply by **Monday, January 13**.

December 20, 2024

Daryl L. Wiesen
Christopher T. Holding
Louis L. Lobel
Jordan Bock
Thomas V. McTigue IV
GOODWIN PROCTER LLP
100 Northern Ave.
Boston, MA 02210
(617) 570-1000
Fax.: 617.523.1231

Natasha E. Daughtrey
GOODWIN PROCTER LLP
601 South Figueroa Street
Los Angeles, CA 90017
(213) 426-2642

Respectfully submitted,

/s/ William M. Jay
William M. Jay
GOODWIN PROCTER LLP
1900 N Street, N.W.
Washington, DC 20036
(202) 346-4000

Counsel for Appellants

CERTIFICATE OF COMPLIANCE

This motion complies with the type-volume limitations of Federal Rule of Appellate Procedure 27(d)(2)(A) because it contains 1,508 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: December 20, 2024

/s/ William M. Jay
William M. Jay

CERTIFICATE OF SERVICE

I hereby certify that on December 20, 2024, 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