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' MOTION TO STAY INJUNCTION PENDING DECISION ON PETITION FOR REHEARING EN BANC

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 23, 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 23, 2024

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

Counsel for Appellants

TABLE OF CONTENTS

Page

CONFIDENTIAL MATERIAL OMITTED

The material omitted in the text on pages 2 and 7 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

Which patents must be listed in the Orange Book is a contentious but critical issue in the pharmaceutical industry. Patents like those owned by appellants ("Teva"), claiming components of drug-device combination products that were approved as drugs, have been listed in the Orange Book for decades. The panel has now ordered them out of the Orange Book and adopted its own new interpretation of the Listing Statute. And the implications of that interpretation sweep well beyond drug-device products. The result will be significant upheaval in the pharmaceutical industry and a potential mass delisting of hundreds of patents.

Teva should have the opportunity to request en banc review of this decision *before* it suffers irreparable harm from delisting its patents. As the Court necessarily recognized when granting a stay at the outset of the appeal, a stay will prevent great harm to Teva, yet cause no harm to Amneal during review. That balance of harms has not changed. Absent a stay, Teva will indisputably lose several of the statutory rights (to notice and a 30-month stay) that protect the owner of a listed patent when another company seeks to market a generic version of the drug for which the patent is listed, before the patent expires. The loss of that right will significantly harm Teva, as there is a grave risk that FDA, which administers the 30-month stay, will conclude that it cannot be restored. That amply shows a significant likelihood of irreversible, and therefore irreparable, harm. On the other side of the scale, Amneal

will suffer *no* harm from a continued stay of the decision, as Amneal does not have approval or tentative approval of its ANDA, and FDA recently [redacted] in Amneal's ANDA. While the panel has now ruled for Amneal on the merits, stays are not routinely lifted the same day as issuance of the merits decision—particularly where, as here, there has been absolutely no change in the balance of harms.

Teva also has a compelling case for en banc rehearing given the wide-reaching implications of the panel's decision. This Court has exclusive jurisdiction over all counterclaims seeking to delist patents from the Orange Book, and its decision will in practice be treated as definitive. And the FTC and private plaintiffs will threaten companies with antitrust liability if they do not immediately delist (or if they continue to list) patents that could be delisted under this Court's decision. As a result of this disincentive to litigate, this Court's decision is likely to be its last word on this issue for some time. Indeed, as the rehearing process is likely to highlight, companies and district courts (not to mention antitrust plaintiffs) are likely to read the panel's reasoning as sweeping well beyond drug-device patents, to preclude listing of several other categories of patents.

The Court today granted an administrative stay pending resolution of this motion. Given this imbalance of harms and the importance of this issue, the Court should extend that stay of the injunction pending Teva's forthcoming petition for

rehearing en banc. Amneal has informed Teva that it has not yet determined what position it will take on this motion, and that it expects to file a response.

BACKGROUND

As the Court's opinion explains,[1] the five patents at issue here[2] are listed in the Orange Book for Teva's ProAir® HFA (albuterol sulfate) Inhalation Aerosol ("ProAir HFA"), a drug product that includes a metered-dose inhaler to deliver the active ingredient. Op. 12-13. FDA reviewed and approved ProAir HFA under the statute and regulations governing New Drug Applications ("NDAs") because the product's primary mode of action is attributable to the drug. *Id*.

Amneal seeks to bring to market a generic version of Teva's ProAir HFA product before these five patents expire. Amneal submitted Paragraph IV certifications concerning all the patents listed in the Orange Book for ProAir HFA. Teva brought suit within 45 days of receiving Amneal's notice letter, creating a 30-month stay on FDA's ability to approve Amneal's ANDA that would expire in February 2026.[3] Amneal counterclaimed for an injunction compelling Teva to delist

---

[1] Teva provides only a succinct background given the Court's familiarity with the case.

[2] The five patents at issue are asserted in Teva's amended complaint: U.S. Patent Nos. 8,132,712 (the "'712 patent"), 9,463,289 (the "'289 patent"), 9,808,587 (the "'587 patent"), 10,561,808 (the "'808 patent"), and 11,395,889 (the "'889 patent") (collectively, the "Asserted Patents"). Op. 13.

[3] Another generic company, Deva Holding A.S. ("Deva"), has likewise submitted an ANDA with Paragraph IV certifications to the same patents. Teva timely filed a separate suit against Deva, No. 2:24-cv-04404 (D.N.J.), creating a 30-month stay on

the five patents at issue from the Orange Book,[4] *see* 21 U.S.C. § 355(j)(5)(C)(ii)(I), and moved for judgment on the pleadings on those counterclaims under Rule 12(c).

The district court concluded that these five patents must be delisted, and issued an injunction directing Teva to do so. Appx24-40. Teva moved the district court to stay the injunction pending this appeal or, in the alternative, for 30 days to permit this Court to consider a stay application. After a hearing, the district court granted the alternative request for a 30-day stay to permit this Court to resolve a motion for stay pending appeal. ECF No. 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.

Teva timely appealed the district court's delisting injunction. Op. 16-17. The parties both sought expedited consideration, and Teva also moved to stay the injunction pending this appeal. The Court expedited the appeal and stayed the district court's order "until further notice of this court." ECF No. 32; Op. 17. The case is proceeding in the district court on Teva's underlying infringement case. Op. 16.

The issue in this appeal is whether these five patents must be delisted from

---

FDA approval of Deva's ANDA as well. Three of the four patents being pursued against Deva are among those ordered delisted here.

[4] Amneal also asserted antitrust counterclaims not at issue on appeal.

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). On December 20, 2024, the Court affirmed the district court's delisting order and "now lift[ed] the stay." Op. 3.

On the same day as this Court's opinion lifting the stay, Teva filed an unopposed motion for an immediate administrative stay of the district court's order, ECF No. 104. The Court today granted that motion and accepted the parties' proposed briefing schedule. ECF No. 105. Under that schedule, any opposition to this motion from Amneal is due by Monday, January 6; and Teva's reply is due by Monday, January 13. Amneal has not yet taken a position on the stay sought in this motion.

FDA regulations give Teva 14 days from the date of a court order to delist its patents from the Orange Book. 21 C.F.R. § 314.53(f)(2). Thus, if the administrative stay were dissolved, Teva would have to submit papers to FDA delisting the five patents at issue from its ProAir HFA product within 14 days.

ARGUMENT

The test for a stay involves four factors: "(1) whether the stay applicant has made a strong showing that [it] 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 interested in the proceeding; and (4) where

the public interest lies." *Nken v. Holder*, 556 U.S. 418, 433-34 (2009) (citation omitted). When "the [nonmerits] factors militate in movant's favor," it need only show "a substantial case on the merits." *E.g.*, *Standard Havens Prods., Inc. v. Gencor Indus., Inc.*, 897 F.2d 511, 513 (Fed. Cir. 1990) (emphasis and citation omitted).

The panel already concluded that these factors weighed in favor of a stay at the outset of the appeal—and, in particular, necessarily determined that the harm to Teva outweighs any harm to Amneal. Subsequent developments have only confirmed that the balance of harms tips sharply in Teva's favor. And although Amneal has prevailed on the merits before the panel, the stay should continue to protect Teva against irreparable harm long enough for the full Court to consider Teva's petition for rehearing en banc. Lifting a stay before the appellate mandate issues is the exception, not the rule, and it makes particularly little sense to lift the stay in the middle of *these* proceedings, as there has been no change in the balance of the harms: a continued stay will result in no harm to Amneal but irreparable harm to Teva.

The panel should reinstate the stay and preserve the status quo pending the Court's resolution of Teva's forthcoming petition for rehearing en banc.

I. There Has Been No Change In The Balance Of Harms.

A. A Continued Stay Will Result In No Harm To Amneal Because It Still Does Not Have Tentative Approval.

Teva and others will be irreparably harmed absent a stay (as discussed below), but Amneal will almost certainly face *no* harm from a continued stay pending

consideration of rehearing en banc. Amneal's generic product still does not have even tentative approval and remains unmarketable at this time. Indeed, the case for harm to Amneal is weaker now than when the Court first granted the stay, ECF No. 32; Op. 17, given the recent FDA correspondence concerning Amneal's ANDA, ECF No. 101.

FDA has verb review of Amneal's ANDA. It is status status in its descriptor status; category include descriptor category classified as descriptor *See* Ex. 1 at 8-10 (verb adj task; time requirement); *see also* ECF No. 13, at 17 n.8 & Ex. 8 (discussing prior FDA action).

As the district court recognized when granting the initial stay, "[t]here is no harm to Amneal" when "they can't conceivably go on the market." Appx1575. Amneal remains unable to go on the market. If Amneal does obtain tentative approval from FDA during this stay, then this Court would be able to revisit the stay at that time—at which point this Court will likely have resolved Teva's petition for rehearing en banc. By contrast, if the Court denies the stay and the Asserted Patents are delisted, there will *be* no tentative approval because there will be no 30-month stay—FDA will simply issue a decision on Amneal's ANDA when it has completed its review. *See* 21 C.F.R. § 314.3(b) ("tentative approval" applies only when final approval is blocked by a 30-month stay, a period of exclusivity, or a court order).

B. Teva Will Face Irreparable Harm As Soon As Its Patents Are Delisted.

Delisting these patents will have irreparable consequences, for this litigation and others. Once the patents are actually delisted from the Orange Book, Teva will lose statutory rights that it cannot regain *even if* it prevails before the full Court or the Supreme Court. As the panel necessarily recognized when granting the initial stay, the harm to Teva outweighs any harm to Amneal. That balance has not shifted: while the harm to Amneal has, if anything, decreased as explained above, the harms to Teva remain precisely the same.

Chief among these harms is the statutory 30-month stay, which Teva would lose with respect to Amneal *and* Deva (*see* note 3, *supra*) *and* any additional ANDA filer—and which Teva could not regain even if the patents were relisted. 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").

The 30-month stay currently prevents FDA from approving Amneal's ANDA before February 2026, unless Amneal prevails in the litigation before then, because Teva timely sued Amneal on Orange Book-listed patents. *See* 21 U.S.C. § 355(j)(5)(B)(iii). Amneal has already taken the position that delisting the patents will itself immediately extinguish the 30-month stay. *See* ECF No. 28 at 4; D. Ct. Dkt. No. 48 at 31; D. Ct. Dkt. No. 108 at 2, 5. Delisting all of the patents-in-suit

would also permit Amneal to withdraw its Paragraph IV certification, *see* Op. 15, allowing FDA to approve the ANDA without regard to the Asserted Patents or the outcome of this litigation. *See* 21 C.F.R. §§ 314.94(a)(12)(viii)(B), 314.107(b)(1)(i).

If the patents are delisted, then even if Teva is ultimately successful in overturning the delisting injunction and restoring the patents to the Orange Book, the protections of the 30-month stay would already be irreversibly lost in this and other cases. 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 and Deva's ANDAs are both on file already. For those two ANDA filers—and any more generics that file applications after the patents are delisted—FDA would not recognize a 30-month stay if Teva resubmitted the patents after a reversal and FDA listed them effective at that time. 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). Thus, Teva has shown that a stay is needed to avoid injury that is concrete, non-speculative, imminent, and irreparable: as against both Amneal and Deva, and possibly others, once the Asserted Patents are removed from

the Orange Book, they can *never* be the basis for a 30-month stay again.

It also appears that any company with an ANDA on file would not even need to *certify* to the Asserted Patents if they were restored to the Orange Book. *See* 21 C.F.R. § 314.94(a)(12)(vi). A generic company is under no obligation to notify the patent owner of the filing of an ANDA unless it contains a Paragraph IV certification to at least one listed patent. And if there is no 30-month stay, court order, or exclusivity restricting the timing of FDA approval, FDA will simply approve the ANDA when it is ready.

Any injuries stemming from loss of the 30-month stay will not be compensable by monetary damages. The 30-month stay operates as a restraint on FDA, not directly on the ANDA applicants. FDA is not liable for damages because it has sovereign immunity, and the ANDA applicants also would not be liable for the loss of the 30-month stay even if this Court's decision were later overturned and it became clear the loss of the stay was erroneous. (Generic applicants are liable only for infringement, a distinct question.) Furthermore, the harm to Teva will extend well beyond its particular dispute with Amneal, *see* pp. 8-10, *supra*; even if Amneal could be answerable in damages for some of it, the full harm still would not be compensable.

Thus, once the patents are delisted, Teva faces harm that cannot be reversed or repaired even if it ultimately wins this case. That is a strong reason by itself not

to put that harm into effect prematurely. And given the lack of *any* harm to Amneal at this stage, the balance of harms decisively favors a continued stay.

II. This Appeal Presents An Exceptionally Compelling Case For En Banc Rehearing.

This appeal raises multiple "precedent-setting questions of exceptional importance," Fed. Cir. R. 40(c)(1), as the panel's interpretation of the Listing Statute will work a massive change in FDA practice and the Hatch-Waxman regime. At a minimum, Teva's petition for rehearing en banc will be substantial enough to justify continuing the stay so that the full Court can consider those questions.

A. The Panel's Decision Rejects Decades of Listing Practice And Will Unsettle Hundreds of Patent Listings

Manufacturers have for decades listed precisely these types of patents. As a result, the Court's new interpretation of the Listing Statute will require revisiting a wide range of patent listings, likely covering hundreds of patents. And the Court may not have the opportunity to refine its interpretation in subsequent appeals from delisting injunctions. As the FTC has made clear in this case, both the FTC and private antitrust plaintiffs will not hesitate to threaten antitrust liability against any manufacturer that does not delist patents; as a result, the direct impact of the Court's decision is likely to include many delisting decisions that occur quietly, without litigating a delisting counterclaim like this one. Furthermore, as discussed below—and as the Court will likely hear from amici at the rehearing stage—the Court's

reasoning appears to call into question other well-established listing practices well beyond the context of drug-device combination products.

Patents on drug-device combination products have been listed for decades regardless of whether they mention the active ingredient. *See, e.g.*, ECF No. 62 (FTC Amicus Br.) at 19 (noting that listing of similar component patents is "widespread"). This practice accords with FDA regulations. For "drug product (formulation or composition) patents," FDA regulations require "the applicant [to] submit information only on those patents that claim the drug product, as is defined in § 314.3, that is described in the pending or approved NDA." 21 C.F.R. § 314.53. The cross-referenced regulation, in turn, defines "drug product" as "a finished dosage form, e.g., tablet, capsule, or solution, that contains a drug substance, generally, but not necessarily, in association with one or more other ingredients." *Id.* § 314.3. And "dosage form" is defined as "the physical manifestation containing the active and inactive ingredients that delivers a dose of the drug product." *Id.*; *see also* 68 Fed. Reg. 36, 676, 36,680 (June 18, 2003) ("The key factor is whether the patent being submitted claims the finished dosage form of the approved drug product."). Notably, FDA expressly categorizes metered aerosols as a dosage form, and metered aerosols are therefore included in the Orange Book's list of current dosage forms for approved drug products. 68 Fed. Reg. at 36,680; Orange Book, Appendix C, at C-1 (44th ed. 2024).

Seeking additional assurance, in 2005 drug manufacturers "submitted formal requests to FDA for clarification on which device-related patents to list in the Orange Book." U.S. Gov't Accountability Off., GAO-23-105477, Generic Drugs: Stakeholder Views on Improving FDA's Information on Patents ("GAO Report") 24 (2023), https://bit.ly/4dcVPtR. The FDA denied those requests in 2020, suggesting, 15 years later, that these issues "should be examined as part of a broader effort to seek comment on the subject of patent listings in the Orange Book." *Id.* at 25. It therefore invited public comment, but so far has only convened "a multidisciplinary working group within the Agency to evaluate whether additional clarity is needed regarding" the listing regime. FDA, *The Listing of Patent Information in the Orange Book* 24 (2022), https://bit.ly/4fHFGxy.

In passing the Orange Book Transparency Act ("OBTA"), Congress did not change these practices: to the contrary, as the Court acknowledged, "Congress adopted this language to 'codify current [FDA] regulations and practice'" regarding Orange Book listings. Op. 11 (quoting H.R. Rep. No. 116-47 at 6 (2019)) (brackets in original). In fact, Congress directed the Government Accountability Office ("GAO") to study listing practices for two types of patents: those "that claim the active ingredient or formulation of a drug in combination with a device that is used for delivery of the drug" and those "that claim a device that is used for the delivery of the drug, but do not claim such device in combination with an active ingredient

or formulation of a drug." Orange Book Transparency Act of 2020, Pub. L. No. 116-290, § 2(f), 134 Stat. 4889, 4892 (Jan. 5, 2021). This language makes clear that Congress was trying to determine, of listed patents claiming a device, how many also explicitly claim the active ingredient. In other words, Congress was gathering information on the current practice of listing these types of patents—not changing that practice. The industry therefore expected that the legal regime governing listings was stable.

The panel's new interpretation has upended that expectation, and it threatens significant harm to the Hatch-Waxman listing regime. Listing patents in the Orange Book for each product that the patents claim not only provides transparency to the public, but also allows for the type of early, pre-launch determination of patent validity and infringement on which the industry depends. Parties avoid the threat of money damages and the expense and risk of both a jury trial and a time-consuming preliminary injunction proceeding. But as the Court acknowledges (Op. 11), the Listing Statute leaves no room between floor and ceiling: a patent either must be listed or it may not be listed. The Court's decision will create a significant segment of patents that claim the brand-name drug product, that will be infringed by any generic version, but that will no longer be disclosed to the public in the Orange Book. The result will be a breakdown of the orderly Hatch-Waxman procedure for litigating the validity and infringement of these patents before launch. The resulting

uncertainty will, perversely, *disincentivize* generic drug development.

These effects will be felt immediately. Given this Court's exclusive, nationwide jurisdiction over delisting counterclaims, its interpretation of the Listing Statute will be taken as authoritative. And the FTC has made clear that it will threaten antitrust liability against any pharmaceutical company that lists a patent that the FTC thinks should not be listed. Even if the FTC were to forbear, private plaintiffs often bring equivalent antitrust claims. Thus, patent owners will face immediate external pressure to delist, and not to list in the future, any patent that this Court's reasoning seems to implicate, rather than to pursue the issue by litigating a delisting counterclaim up to this Court. The result: This Court will have limited opportunity in the future to address the implications of its decision—both the express application to patents like Teva's here, and the application of its reasoning to other, equally important types of patents that have also been listed for decades (*see* Section B, *infra*).

In short, even those who disagree about the right answer to the questions presented here should be able to agree that those questions are exceptionally important ones that are the subject of reasonable debate. Indeed, the Court itself went beyond the arguments of the parties in crafting its own interpretation. This one judicial decision will alter hundreds of future listing decisions—in ways that likely will not be litigated back up to this Court. This is precisely the type of case in which

a party—and, likely, amici from throughout the industry—should be allowed the additional opportunity to convince the Court to alter or reconsider its decision before the mandate issues.

B. The Panel's Reasoning Has Broad Implications That The Decision Does Not Address.

The decision elides the ramifications of its interpretation—ramifications that should be addressed by the full Court. To start, the panel opinion concludes that, "to qualify for listing, a patent must claim at least the active ingredient in the application and the approved drug product," where "to claim" means to "particularly point out and distinctly claim" the invention. Op. 38. Even accepting the panel's conclusion that "claim" does not mean literally infringe (a conclusion that Teva disputes), the panel never explains why "claim" or "particularly point out and distinctly claim" are effectively coextensive with explicitly "recite." That conclusion, however, has critical implications for the listing regime—implications the panel does not address. The full Court should have the opportunity to consider the significant ambiguity surrounding what can or cannot be listed in the Orange Book.

Take genus patents. There is no dispute that a genus encompasses every species in the genus without mentioning any one of them—and the panel would presumably agree that it can therefore "claim" a group of active ingredients without explicitly reciting any of them. *See Amgen Inc. v. Sanofi*, 143 S.Ct. 1243, 1254 (2023) (noting that in some circumstances, "a patent *claims* an entire class of

processes, machines, manufactures, or compositions of matter" (emphasis added)). As this Court recently recognized, such a "pharmaceutical genus claim" can be a company's "most valuable inventive asset." *Allergan USA, Inc. v. MSN Labs. Priv. Ltd.*, 111 F.4th 1358, 1371 (Fed. Cir. 2024).

Yet the panel's decision calls into question whether many genus patents could be listed. Indeed, asked at oral argument about "the genus problem" that Amneal's position creates by precluding the listing of genus patents, Amneal candidly acknowledged that it cannot "solve that problem." Oral Arg. at 35:12-35:34. Nor has the panel's decision solved that problem. To the contrary: The decision states that "[t]o list a patent in the Orange Book, that patent must, among other things, claim the drug for which the applicant submitted the application and for which the application was approved. And to claim that drug, the patent must claim at least the active ingredient." Op. 33; *see* Op. 38. The panel further concluded that these patents would have to claim "albuterol sulfate" as the active ingredient, because FDA "approves a specific active ingredient at a specific concentration" and albuterol sulfate is the active ingredient in the approved ProAir HFA product. Op. 38. But a patent that claims a class of drugs—whether by function, by structure, or by other chemical classification—does not point out any specific active ingredient, and would therefore appear not to be listable on the panel's reading of the statute. That is a highly significant result that the full Court

should have the opportunity to address, rather than leaving these critical questions unanswered.

The panel's decision likewise raises significant questions surrounding the common circumstance in which the approved drug contains multiple active ingredients, and FDA has approved a specific combination of such active ingredients. Can a patent that claims just one of multiple active ingredients be listed in the Orange Book? Under the panel's reasoning, the answer appears to be no. Such a patent might claim "a" drug for which the applicant submitted the application, but not "the" combination of active ingredients. Op. 38 (explaining that FDA "approves a specific active ingredient at a specific concentration if that active ingredient, in combination with other features of the drug product, is safe and effective"). Both brand and generic companies need certainty on these issues, and the panel's decision provides none.

The panel's errors are not confined to the "claims the drug" phrase. The panel also bypassed the express definition of "drug" in 21 U.S.C. § 321(g)(1)—and notably based on caselaw Amneal never raised. As Amneal did not dispute, and the panel at least nominally accepted, "drug" takes its definition from the broad statutory definition in 21 U.S.C. § 321(g)(1). Op. 28. But the panel ultimately concluded that "drug" does not mean "drug" as defined, but rather "active ingredient" (which FDA calls a "drug substance"). In the panel's view, "though the FDCA defines 'drug'

broadly as something that treats disease … the statutory context demonstrates that a drug is a narrower class of medical product." Op. 30. In other words, while there is an applicable statutory definition of "drug," the panel jettisoned that definition based on its nebulous concerns about statutory context and citing regulatory cases addressing other aspects of the drug-approval statute. *See* Op. 32-33 (discussing *Sandoz Inc. v. Becerra*, 57 F.4th 272, 280 (D.C. Cir. 2023), and *Ipsen Biopharmaceuticals, Inc. v. Becerra*, 108 F.4th 836 (D.C. Cir. 2024)). Drawing on the statutory requirements for drug approval (such as the labeling requirements), the panel determined that "what makes something approvable as a drug is the presence of an active ingredient," and a patent must therefore claim the active ingredient in order to "claim[] something that the FDA could not have properly regulated as a drug in the first place." Op. 32-33.

This analysis improperly conflates "drug" and "drug substance." In enacting the Listing Statute, Congress asked whether a patent "claims the *drug* for which the applicant submitted the application"—not the "drug substance" and not the "active ingredient." 21 U.S.C. § 355(b)(1)(A)(viii)(I) (emphasis added). Congress knew how to define "drug" as "active ingredient" when it wanted to: That is precisely what it did in the Patent Term Extension Statute, adopted at the same time and discussed in *Hoechst-Roussel Pharmaceuticals, Inc. v. Lehman*, 109 F.3d 756 (Fed. Cir. 1997), a case this Court emphasized. *See* 35 U.S.C. §§ 156(f)(1)(A), (f)(2)

(limiting "product" to "the active ingredient" of a drug). The same is true for the statute governing combination products, which defines "approved drug" to "mean[] an active ingredient" that satisfies certain requirements. 21 U.S.C. § 353(g)(5)(B); *see also* Op. 35 (discussing this statute). But here, Congress solely used the term "drug," and therefore clearly intended the statutory definition of that term. *See Digital Realty Tr., Inc. v. Somers*, 583 U.S. 149, 160 (2018) (an "explicit definition" in the statute controls).

Not only does the panel rewrite the statute, it does so on a basis that the parties did not brief. Amneal never argued that the FDA's requirements for drug approval mandate interpreting "drug" as "drug substance," in direct contravention of the actual statutory language. It would be particularly inappropriate to require Teva to delist the patents, thereby cutting off the possibility of any meaningful future relief, *see* pp. 8-10, *supra*, without providing it an opportunity to respond to the panel's particular approach to these issues.

* * *

This case is both difficult and important, with far-reaching implications. And as the panel already recognized, the balance of harms tips decidedly in Teva's favor: Leaving the panel's prior stay in place for the pendency of proceedings before this Court will cause no harm to Amneal, but lifting the stay will cause irreparable harm to Teva. Against that backdrop, a stay is well-warranted

notwithstanding the panel's decision in favor of Amneal. The panel should re-enter the stay, facilitating a full and fair exposition of the legal issues in this case.

CONCLUSION

The Court should stay the injunction pending resolution of Teva's forthcoming petition for rehearing en banc.

December 23, 2024

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

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

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: 12/23/2024

Signature: /s/ William M. Jay

Name: William M. Jay

CERTIFICATE OF COMPLIANCE

This motion complies with the type-volume limitations of Federal Rule of Appellate Procedure 27(d)(2)(A) because it contains 5,024 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 23, 2024

/s/ William M. Jay
William M. Jay

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

DECLARATION OF WILLIAM M. JAY IN SUPPORT OF APPELLANTS' MOTION TO STAY INJUNCTION PENDING DECISION ON PETITION FOR REHEARING EN BANC

December 23, 2024

I, William M. Jay, hereby declare:

1. I am over the age of twenty-one, of sound mind, and competent to make this declaration. I am also qualified to give testimony under oath. Each of the facts listed below is within my personal knowledge and is true and correct.

2. I am a partner with the law firm Goodwin Procter LLP, counsel of record for Appellants Teva Branded Pharmaceutical Products R&D, Inc., Norton (Waterford) Ltd., and Teva Pharmaceuticals USA, Inc. (collectively, "Teva") in this matter. I make this declaration from personal knowledge and, if called to testify, I could and would testify competently thereto.

3. Attached hereto as Exhibit 1 is a true and correct copy of correspondence from FDA to Amneal Pharmaceuticals of New York, LLC, produced to Teva pursuant to the protective order entered in the proceedings below.

4. Exhibit 1 is being filed under seal because it refers to confidential information regarding the timing and circumstances of FDA's tentative approval of Amneal's product. This information is subject to a protective order in the proceedings below.

I declare under penalty of perjury that the foregoing is true and correct.
Executed on December 23, 2024.

/s/ William M. Jay
William M. Jay

INDEX TO THE DECLARATION OF WILLIAM M. JAY IN SUPPORT OF APPELLANTS' MOTION TO STAY INJUNCTION PENDING DECISION ON PETITION FOR REHEARING EN BANC

Exhibit No.	Description
1	Correspondence from FDA to Amneal Pharmaceuticals of New York, LLC

EXHIBIT 1

(CONFIDENTIAL FILED UNDER SEAL)