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 FOR AN IMMEDIATE ADMINISTRATIVE STAY AND TO STAY INJUNCTION PENDING DECISION ON PETITION FOR A WRIT OF CERTIORARI

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March 4, 2025

CERTIFICATE OF INTEREST

Counsel for Teva Branded Pharmaceutical Products R&D LLC, 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 LLC; 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 LLC: 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).

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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: March 4, 2025

/s/ *William M. Jay*
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CONFIDENTIAL MATERIAL OMITTED

The material omitted in the text on page 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

Appellants ("Teva") intend to seek review by the Supreme Court and respectfully request that the Court continue the stay of the district court's injunction pending Supreme Court review and stay its mandate for the same period. At a minimum, Teva requests that the Court grant an administrative stay and temporary stay of the mandate sufficient to permit the Court and, if necessary, the Circuit Justice to consider Teva's request for a stay pending certiorari. Teva suggests that the administrative stay last until 14 days following disposition of this motion, if this motion is denied. Finally, because appellee Amneal opposes this motion (including the request for an administrative stay) and intends to file a response, Teva requests that Amneal be directed to respond by Thursday, March 6, 2025. Teva would then reply by Friday, March 7.

This motion is highly time-sensitive because without a continued stay, Teva will have to submit papers to the FDA delisting its patents on Monday, March 17, 2025, and will suffer irreparable injury even if it were able to re-list its patents after that date. In light of those circumstances, this Court granted a stay pending appellate consideration and again pending consideration of rehearing. And since this Court first granted the stay, it has become even clearer that Amneal faces *no* cognizable harm from a stay for this short additional period. By contrast, without 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 and a balance of the equities that strongly favors Teva.

Teva should have the opportunity to request Supreme Court review of this decision *before* it suffers irreparable harm from delisting its patents. As this Court is well aware, which patents must be listed in the Orange Book is a contentious but critical issue in the pharmaceutical industry. This Court's decision announces a new construction of the Listing Statute that upends decades of settled FDA practice—a practice that Congress approved just five years ago. And because this Court has exclusive jurisdiction over all counterclaims seeking to delist patents from the Orange Book, its decision will in practice be treated as definitive. 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 an antitrust plaintiff will argue must be delisted under this Court's decision. As a result of this disincentive to litigate, this case is likely to be the Supreme Court's only opportunity to review this issue for some time. The stay standard asks whether there is a reasonable

prospect that the Supreme Court will grant certiorari and a fair chance of reversal. That standard is amply met here.

BACKGROUND

As the Court's opinion explains, the five patents at issue here[1] 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 through a New Drug Application ("NDA") 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 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.[2] Amneal counterclaimed for an injunction compelling Teva to delist the five patents

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[1] The five patents 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.

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

at issue from the Orange Book,[3] *see* 21 U.S.C. § 355(j)(5)(C)(ii)(I), and moved for judgment on the pleadings on those counterclaims.

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. The district court granted the alternative request for a 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 harm Amneal nor harm the public "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.

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

That same day, Teva filed an unopposed motion for an immediate administrative stay of the district court's order, explaining that it planned to file a petition for rehearing en banc and a motion to stay the injunction pending resolution of that petition. ECF No. 104. The Court granted Teva's request for an

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

administrative stay the next business day, December 23, 2024. ECF No. 105. Teva then filed its petition for rehearing en banc on January 21, 2025, and the next day, this Court granted Teva's opposed motion for a stay pending resolution of that petition. ECF Nos. 114, 116.

The Court denied Teva's petition for rehearing en banc yesterday, March 3, 2025, thereby lifting the stay. ECF No. 145.

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, absent a stay, Teva would have to submit papers to FDA delisting the five patents at issue from its ProAir HFA product by March 17, 2025. The case on Teva's underlying infringement case is proceeding in the district court. Op.16.

ARGUMENT

A stay pending a petition for certiorari is appropriate when there is "(1) a reasonable probability that four Justices will consider the issue sufficiently meritorious to grant certiorari; (2) a fair prospect that a majority of the Court will vote to reverse the judgment below; and (3) a likelihood that irreparable harm will result from the denial of a stay." *Hollingsworth v. Perry*, 558 U.S. 183, 190 (2010). The Court also balances the equities, including assessing "the relative harms" to the parties seeking and opposing the stay. *Trump v. Int'l Refugee Assistance Project*, 137 S. Ct. 2080, 2087 (2017). This Court applies similar factors to a motion to stay the mandate

pending certiorari, with success on the merits referring to the chances of obtaining review and reversal by the Supreme Court. Fed. R. App. P. 41(d)(1); *American Axle & Mfg., Inc. v. Neapco Holdings LLC*, 977 F.3d 1379, 1380-81 (Fed. Cir. 2020) (citing *Hollingsworth*).[4]

The panel already concluded that these factors weighed in favor of a stay both at the outset of the appeal *and* pending resolution of Teva's petition for rehearing en banc. Teva still faces imminent, irreparable harm if it is forced to delist the patents—which it must do within 14 days without a stay. And the balance of harms still tips sharply in Teva's favor—indeed, developments during this appeal have made clear that Amneal faces no cognizable harm during the period of a stay. Accordingly, the Court should continue to preserve the status quo and protect Teva against irreparable harm long enough for the Supreme Court to consider Teva's forthcoming petition for a writ of certiorari, which has a reasonable likelihood of success.

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

Teva will be irreparably harmed absent a stay, whereas Amneal will almost certainly face *no* harm from a continued stay pending resolution of Teva's

[4] Unlike most cases in which a litigant seeks to stay this Court's mandate, here it is not the issuance of the mandate itself that would cause Teva irreparable harm—it is the dissolving of this Court's stay of the injunction. Teva seeks a stay of the mandate simply to ensure that any stay this Court separately grants can remain in place; ordinarily a stay dissolves when the mandate issues.

forthcoming cert petition. "The balancing" of the equities is "quite easy" when there is "no irreparable harm"—indeed, no harm—"that granting the stay would produce." *Barnes v. E-Systems, Inc. Group Hospital Medical & Surgical Ins. Plan*, 501 U.S. 1301, 1305 (1991) (Scalia, J., in chambers).

A. A Continued Stay Will Not Harm Amneal Because It Still Does Not Have Tentative Approval.

The patents' continued presence in the Orange Book is not causing Amneal any current harm. 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'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.

Specifically, Amneal's ANDA is [redacted: status] include [redacted: noun] as [redacted: descriptor] *See* Ex. 1 at 8-10 ([redacted: requirements]); *see also* ECF No. 13, at 17 n.8 & Ex. 8 (discussing prior FDA action). FDA [redacted: verb] Amneal's request for [redacted: action]. *See* Ex. 2 at 1-3.

In the highly unlikely event that Amneal does obtain tentative approval from FDA while the stay remains in place, it could ask this Court to revisit the stay at that time. By contrast, if this 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 delisted from the Orange Book, Teva will lose statutory rights that it cannot regain *even if* it prevails before the Supreme Court. As the panel necessarily recognized when granting Teva's request for a stay pending en banc review, the harm to Teva outweighs any harm to Amneal. That balance has not shifted: while the harm to Amneal is nonexistent, 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 2, *supra*) associated with the delisted patents *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*, 558 U.S. at 195 (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 the ongoing patent 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 an ANDA filing 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. 8-9, *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 prevails. 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 Case Presents a "Reasonable Probability" of Supreme Court Review.

The scope of the Listing Statute is "an important question of federal law that has not been, but should be, settled by [the Supreme] Court." Sup. Ct. R. 10(c). And in reaching its own interpretation, this Court interpreted aspects of the statute in ways that conflict with "relevant decisions" of the Supreme Court. *Id.* Both are well-established bases for the Supreme Court to grant review in a patent-related case from this Court. There is both a "reasonable probability" that the Supreme Court will review this case and a "fair chance" that, upon review, the Court will reverse.

To start, within the past five years, both FDA *and* Congress have confirmed that the Listing Statute extends to patents for products approved as drugs under the FDCA's combination-product provision (21 U.S.C. § 353(g)(1)), regardless of whether those patents recite the drug's active ingredient. This Court nevertheless upended decades of settled FDA practice and adopted the position of the FTC—an

agency with no experience with patent law. The ramifications will be extensive. The panel's decision implicates a wide range of patents, including hundreds of patents on similar combination products, not to mention genus patents, patents on drugs with multiple active ingredients, and others. And because delisting can *only* be litigated in a statutory counterclaim that falls within this Court's exclusive, nationwide jurisdiction, parties will view this Court's ruling as authoritative as to the scope of any antitrust liability for improper listing.

Separately, this Court's decision conflicts with multiple Supreme Court decisions, providing an entirely independent reason for the Supreme Court to grant review. By relying on the "broader statutory context," Op.28, rather than the statutory definition of "drug," the panel ignored both the Supreme Court's interpretation of "drug" and its directive to apply the statutory term as written. *See United States v. Generix Drug Corp.*, 460 U.S. 453, 459 (1983); *United States v. Article of Drug … Bacto-Unidisk*, 394 U.S. 784, 794 (1969).

On top of that, this Court's decision conflicts with *Nautilus, Inc. v. Biosig Instruments, Inc.*, 572 U.S. 898 (2014), one of the Supreme Court's foundational patent decisions. Supreme Court Rule 10(c). Patent law's definiteness standard, 35 U.S.C. § 112(b), requires that a patent's claims "particularly point[] out and distinctly claim[] the subject matter which the inventor … regards as the invention." Under *Nautilus*, that requires "inform[ing] those skilled in the art about the scope of

the invention with reasonable certainty." 572 U.S. at 910. It decidedly does *not* require the standard the Court imposed here—namely, that to "particularly point[] out and distinctly claim[]" a drug, the patent must *recite* a particular active ingredient.

A. This Court's decision will have broad implications for both pharmaceutical regulations and antitrust liability.

For years FDA has permitted manufacturers to list precisely the types of patents at issue here. As Amneal's own amici detailed, there are hundreds of patents in the Orange Book for an array of products that were similarly approved as drugs under the FDCA's combination provision. *See* FTC Amicus Br. 19-20 (discussing, as just one example, "107 patents on GLP-1 delivery devices" for diabetes and weight loss medications); 14 Professors Amicus Br. 26-28 (discussing patents on injector pens, transdermal patches, intranasal drugs, and birth-control devices).

FDA is well-aware of the focus on these patents. Seeking additional assurance that these patents could properly be listed, 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. FDA denied those requests 15 years later. When it did, FDA did not suggest that these patents should be delisted; to the contrary, it 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. FDA thus strongly implied—if not affirmatively confirmed—that it views these patents as properly listable under the current statutory scheme.[5]

Just a few years ago, Congress "codif[ied] current FDA regulations and practice regarding" Orange Book listings through the Orange Book Transparency Act of 2020 ("OBTA"). Op.11 (quoting H.R. Rep. No. 116-47 at 6 (2019)) (brackets in original). OBTA tellingly 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). Had Congress viewed the second category as not properly listable, it would make no sense to direct GAO to study the listing of those very same patents.

The FTC has taken a different view—at least recently. The agency, which has no patent expertise and no jurisdiction over the listing regime, twice filed amicus

[5] While FDA takes a "ministerial" approach to the listing of specific patents in the Orange Book, 68 Fed. Reg. 36,676, 36,683 (June 18, 2013), it could of course issue guidance on which patents are listable. GAO Report 24.

briefs in the proceedings below urging the court to hold that the Asserted Patents are not listable. Straying far outside its ken, FTC argued that what it describes as "drug-agnostic device patents such as the Asserted Patents are ineligible for submission for listing in the Orange Book." FTC Amicus Br. 21. Notably, the FTC has only recently come to this position. In its amicus brief in a previous case raising this question, the FTC argued that "claims" should be given its ordinary meaning in patent law. *See* FTC's Br. as Amicus Curiae at 16, *Jazz Pharms., Inc. v. Avadel CNS Pharms., LLC*, No. 1:21-cv-00691 (D. Del. Nov. 15, 2022), ECF No. 227 ("To 'claim[] the drug for which the NDA was submitted,' a patent must 'contain[] a product claim that reads on the drug that is the subject of the NDA …'"). And yet the FTC suggested in its amicus brief in this matter that a patent "claims" the drug only if it explicitly mentions the name of the drug. FTC Amicus Br. at 19-21, 28-31.

Against this backdrop, this Court enshrined the FTC's newly adopted position. In so doing, the Court resolved a significant inter-agency conflict in favor of the agency with no relevant expertise or jurisdiction. That alone would create a strong case for Supreme Court review, but that case is all the stronger because this Court's decision will work a massive change in FDA practice and the Hatch-Waxman 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 pre-

launch determination of patent validity and infringement on which the industry depends. The Hatch-Waxman Amendments implement the process of patent listing and the accompanying Paragraph IV procedures, which enable the parties to obtain patent certainty *before* launch. Under the Hatch-Waxman scheme, parties avoid both the expense and the risk of a jury trial and time-consuming preliminary injunction proceedings—both of which will clog the district court dockets, contrary to the express purpose of Hatch-Waxman.

There are currently hundreds of Subject Patents, *see* p. 13, *supra*, all of which were listed by FDA in line with decades of established practice. Any of those patents could be the target of delisting counterclaims following the Federal Circuit's decision. Removing these patents from the Orange Book merely because they do not expressly recite the active ingredient—or, in the case of products with multiple active ingredients, because they do not recite *all* the active ingredients—will destabilize the Hatch-Waxman regime and create significant uncertainty in the pharmaceutical industry. Patents not listed in the Orange Book may not be readily known to the public; may not be asserted until a generic launch is imminent or has already occurred; and may well result in preliminary injunction proceedings, a post-launch jury trial, and an award of money damages—all significant risks that disincentivize generics to challenge patents, which will delay patients' access to lower-cost medicines and likely inhibit lower prescription drug prices. Thus, a series

of amici—even amici who did not support Teva—explained at the rehearing stage that this Court's decision "has injected significant uncertainty into the Hatch-Waxman system." AstraZeneca Amicus Br. 2; *see also* Sanofi Amicus Br. 6 ("Unfortunately, the panel's decision works as a drastic rewriting of the statute that will fundamentally alter current listing practices and undermine Congress's aims.").

This Court's decision also has extensive antitrust implications. As this case—and the FTC's Amicus Brief—amply demonstrate, a party that improperly lists a patent faces a significant threat of antitrust liability. *See* note 3, *supra*; *see also* FTC Amicus Br. 15-21 (explaining its view that improper listing runs afoul of the antitrust laws); Sanofi Amicus Br. 9-10 (describing the antitrust implications of the decision, including the "significant follow-on consequences for innovative manufacturers—and, by extension, for patients"). And, critically, this case is likely the only opportunity for the Supreme Court to adjudicate this issue. Given this Court's jurisdiction over patent issues, its interpretation of the Listing Statute will be taken as authoritative, with two important consequences. First, parties that currently list patents subject to this Court's decision may well decide to delist those patents to avoid facing claims of antitrust liability for purportedly inhibiting competition through the listing of improper patents. FTC Amicus Br. 15-16. Second, parties that would list these patents in the future will decline to do so, again to avoid a threat of antitrust liability. The result: There will be no further disputes over this aspect

of the Listing Statute, and therefore no opportunity for the Supreme Court to address this issue.[6]

Finally, this case is an ideal vehicle for the Supreme Court to address the scope of the Listing Statute. This appeal presents one issue: the proper interpretation of the Listing Statute. And it arose in the posture Congress envisioned for resolving listing disputes: a delisting counterclaim under 21 U.S.C. § 355(j)(5)(C)(ii) (allowing an ANDA applicant sued for patent infringement to "assert a counterclaim seeking an order requiring the holder to correct or delete the patent information submitted by the [NDA] holder … on the ground that the patent does not claim … the drug for which the application was approved"). This case thus squarely raises the key issue that needs to be resolved regarding the scope of the Listing Statute.

B. This Court's Decision Conflicts with Multiple Supreme Court Decisions.

This case is also a compelling candidate for certiorari because this Court's decision conflicts with several Supreme Court opinions. First, the panel's definition of "drug" cannot be squared with either *Generix Drug Corp.*, 460 U.S. at 459, or

[6] While two other courts have also addressed the interpretation of the Listing Statute in the context of antitrust claims, both parties and courts will almost certainly abide by the Federal Circuit's interpretation of the Listing Statute given the Federal Circuit's jurisdiction over questions of patent law. *See United Food & Commercial Workers Local 1776 v. Takeda Pharmaceutical Co.*, 11 F.4th 118 (2d Cir. 2021); *In re Lantus Direct Purchaser Antitrust Litig.*, 950 F.3d 1 (1st Cir. 2020).

Bacto-Unidisk, 394 U.S. at 794. In *Generix* the Supreme Court explained that nothing in the text of § 321(g)(1)(D) limits "components" to active ingredients. 460 U.S. at 459. To the contrary, the Supreme Court explained that "subsections (A), (B), and (C) [of § 321(g)(1)] are plainly broad enough to include more than just active ingredients," and "they *must* do so unless subsection (D) is to be superfluous." *Id.* The panel eschewed this definition, relying instead on the "broader statutory context" to reach its preferred outcome. Op.28-29. The Supreme Court rejected that approach in *Bacto-Unidisk*, explaining that "drug" in the FDCA "encompass[es] far more than the strict medical definition of the word." 394 U.S. at 793. Had the panel properly applied the statute's "literal" definition, a "drug" under § 321(g)(1)(D) need not include an active ingredient. *See id.* at 798.

Separately, this Court's decision also conflicts with the Supreme Court's decision in *Nautilus*. The panel defined "claims the drug" as "particularly points out and distinctly claims the drug." Op.18 (emphasis added). This interpretation cannot be squared with the Supreme Court's well-established approach to indefiniteness under § 112(b). According to this Court, a construction permitting "the presence of any active ingredient" does not, "[a]s a matter of law," "particularly point out and distinctly claim" the approved drug. Op.38. Rather, to "particularly point out and distinctly claim" a particular drug, the patent must recite that drug's active ingredient—here, albuterol sulfate. *Id.*

But § 112(b) has an established meaning, and it is not recite. Under *Nautilus*, "particularly pointing out and distinctly claiming" requires "inform[ing] those skilled in the art about the scope of the invention with reasonable certainty." 572 U.S. at 910. The requirement that a patent recite a particular active ingredient is a far higher bar and, as this Court itself recognized post-*Nautilus*, "breadth is not indefiniteness." *BASF Corp. v. Johnson Matthey Inc.*, 875 F.3d 1360, 1367 (Fed. Cir. 2017); see also MPEP § 2173.04 ("[A] genus claim that covers multiple species is broad, but is not indefinite because of its breadth, which is otherwise clear."). These well-established principles cannot be squared with this Court's conclusion that "a claim requiring the presence of 'an active drug' is far too broad to particularly point out and distinctly claim the drug approved in" an NDA." Op.38.

* * *

As this Court has recognized throughout this litigation, it would make little sense to allow irreparable harm to Teva before the resolution of the important and far-reaching legal issues in this case when there is absolutely no risk of harm to Amneal. And while this Court has denied the petition for rehearing en banc, this case is a reasonable—indeed, compelling—candidate for Supreme Court review given the ongoing agency disagreement, the conflict between this Court's decision and several Supreme Court precedents, and the risk of widespread upheaval to the Hatch-Waxman regime. In short, the panel should maintain the status quo—with

zero harm to Amneal—while the Supreme Court reviews Teva's petition for a writ of certiorari.

CONCLUSION

Teva respectfully requests that this Court stay the injunction, and its mandate, pending the timely filing and disposition of Teva's petition for certiorari. Given the 14-day timeline for Teva to delist its patents without a stay, and the need to permit a reasonable time for review by the Circuit Justice if this Court denies the stay, Teva also requests that the Court grant an immediate administrative stay during consideration of this motion and lasting until 14 days after its decision on this motion, if this motion is denied. Finally, Teva requests that the Court direct Amneal to file its opposition to this motion by March 6, 2025, with Teva's reply to follow on March 7, 2025.

March 4, 2025

Respectfully submitted,

/s/ William M. Jay

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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).
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Date: 03/04/2025

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 5,161 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: March 4, 2025

/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 FOR AN IMMEDIATE ADMINISTRATIVE STAY AND TO STAY INJUNCTION PENDING DECISION ON PETITION FOR A WRIT OF CERTIORARI

March 4, 2025

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 LLC, 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. Attached hereto as Exhibit 2 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.

5. Exhibits 1 and 2 are being filed under seal because both refer 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 March 4, 2025.

/s/ William M. Jay
William M. Jay

INDEX TO THE DECLARATION OF WILLIAM M. JAY IN SUPPORT OF APPELLANTS' MOTION FOR AN IMMEDIATE ADMINISTRATIVE STAY AND TO STAY INJUNCTION PENDING DECISION ON PETITION FOR A WRIT OF CERTIORARI

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

EXHIBIT 1

(CONFIDENTIAL FILED UNDER SEAL)

EXHIBIT 2

(CONFIDENTIAL FILED UNDER SEAL)