No. _____

IN THE
Supreme Court of the United States

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

Applicants,

v.

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

Respondents.

On Application for Extension

APPLICATION FOR AN EXTENSION OF TIME TO FILE A PETITION FOR A WRIT OF CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE FEDERAL CIRCUIT

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Dated: May 22, 2025

PARTIES TO THE PROCEEDING

All parties appear in the caption of the case on the cover page.

RULE 29.6 STATEMENT

Teva Pharmaceutical Industries, Ltd. is the parent corporation of applicants Teva Pharmaceutical Products R&D LLC, Norton (Waterford) Ltd., and Teva Pharmaceuticals USA, Inc. Teva Pharmaceutical Industries Ltd. is the only publicly traded company that owns 10% or more of applicants.

RELATED PROCEEDINGS

U.S. District Court for the District of Delaware:

Teva Branded Pharmaceutical Products R&D, Inc. v. Amneal Pharmaceuticals of New York, LLC, No. 23-20964 (SRC) (June 10, 2024)

U.S. Court of Appeals for the Federal Circuit:

Teva Branded Pharmaceutical Products R&D, Inc. v. Amneal Pharmaceuticals of New York, LLC, No. 24-1936 (Dec. 20, 2024), *reh'g denied* (Mar. 3, 2025)

To the Honorable John G. Roberts, Jr., Chief Justice of the United States and Circuit Justice for the Federal Circuit:

Pursuant to this Court's Rule 13.5, applicants Teva Branded Pharmaceutical Products R&D LLC, Norton (Waterford) Ltd., and Teva Pharmaceuticals USA, Inc. (collectively, "Teva") respectfully request a 60-day extension of time, to and including August 1, 2025, within which to file a petition for a writ of certiorari. The United States Court of Appeals for the Federal Circuit issued its opinion and entered judgment on December 20, 2024. A copy of the opinion is attached as Exhibit A. The court of appeals denied Teva's timely petition for rehearing on March 3, 2025. A copy of that order is attached as Exhibit B. This Court's jurisdiction would be invoked under 28 U.S.C. § 1254(1).

Absent an extension, a petition for a writ of certiorari would be due on June 2, 2025 (a Monday). This application is being filed more than 10 days in advance of that date.

1. Teva seeks review of a decision of the Federal Circuit that rewrites the statutory definition of "drug" in the Federal Food, Drug and Cosmetic Act ("FDCA"), *see* 21 U.S.C. § 321(g)(1)(D), and misconstrues the statutory provision governing listing of patents in the "Orange Book" administered by the Food and Drug Administration ("FDA"). Due to these errors, the Federal Circuit's decision conflicts with this Court's decisions in *Nautilius, Inc. v. Biosig Instruments, Inc.*, 572 U.S. 898 (2014), *United States v. Generix Drug Corp.*, 460 U.S. 453, 459 (1983), and *United States v. Article of Drug … Bacto-Unidisk*, 394 U.S. 784, 794 (1969).

2. "To facilitate the approval of generic drugs as soon as patents allow, the Hatch-Waxman Amendments and FDA regulations direct brand manufacturers to file information about their patents," which FDA publishes in a volume known as the "Orange Book." *Caraco Pharm. Labs., Ltd. v. Novo Nordisk A/S*, 566 U.S. 399, 405-06 (2012); 21 C.F.R. § 314.53(e). Specifically, the brand manufacturer "shall submit":

> the patent number and expiration date of each patent for which a claim of patent infringement could reasonably be asserted if a person not licensed by the owner of the patent engaged in the manufacture, use, or sale of the drug, and that –
>
> (I) claims the drug for which the applicant submitted the application and is a drug substance (active ingredient) patent or a drug product (formulation or composition) patent; or
>
> (II) claims a method of using such drug for which approval is sought or has been granted in the application.

21 U.S.C. § 355(b)(1)(A)(viii) (the "Listing Statute"). Submission is not discretionary: if a patent meets either prong of the definition, it *must* be submitted for listing in the Orange Book.

If there are patents listed in the Orange Book for a drug, then any company that seeks approval to market a generic version of that drug must certify to FDA why its proposed generic drug will not infringe the listed patents. *Caraco*, 566 U.S. at 406-07. One pathway is to certify that the generic applicant believes a listed patent either "is invalid or will not be infringed" by the generic product (or both), and that the generic therefore should be able to be approved before the patent expires; that certification is known as a "Paragraph IV" certification. 21 U.S.C.

§ 355(j)(2)(A)(vii)(IV). The generic applicant must send notice of filing the Paragraph IV certification to the brand manufacturer and patent owner, along with an explanation of why the patent is invalid or would not be infringed. Receiving such a notification allows the patent owner immediately to sue the generic applicant for infringement, paving the way for invalidity and/or infringement to be adjudicated while FDA is completing its review of the generic application. *See* 35 U.S.C. § 271(e)(2)(A).

If the brand company files suit within 45 days of receiving notice from the generic company, the FDA generally may not approve the generic company's application (which is called an Abbreviated New Drug Application, or ANDA) right away. Rather, approval is not allowed for a 30-month period (a period often referred to as a 30-month stay) to allow the infringement or invalidity issues to be litigated in court; if the generic company wins on either infringement or invalidity before that time, the 30-month stay dissolves and the ANDA may be approved. *See* 21 U.S.C. § 355(j)(5)(B)(iii).

3. This process of litigating the invalidity or infringement of patents listed in the Orange Book—and, in turn, what patents must be listed there—is the linchpin of a carefully calibrated statutory scheme that balances pharmaceutical innovation with the availability of generic drugs. That scheme includes a provision for a generic defendant to challenge whether a patent asserted against it should be listed in the Orange Book. Under 21 U.S.C. § 355(j)(5)(C)(ii), an ANDA applicant sued for patent infringement "may assert a counterclaim seeking an order

requiring" the brand company to remove or change an Orange Book listing, "on the ground that the patent does not claim … the drug for which the application was approved." 21 U.S.C. § 355(j)(5)(C)(ii)(I). Because such de-listing counterclaims are brought in an existing suit for patent infringement, the Federal Circuit has exclusive, nationwide jurisdiction over all such counterclaims. *See* 28 U.S.C. § 1295(a)(1).

4. Teva is a pharmaceutical company that holds the approved NDA for ProAir® HFA (albuterol sulfate) Inhalation Aerosol ("ProAir HFA"), a pressurized metered-dose inhaler with the active ingredient albuterol sulfate, indicated to treat bronchospasm (a breathing difficulty that may be caused by asthma, bronchitis, or various other factors). In August 2023, respondent Amneal notified Teva that it had submitted an ANDA seeking approval for a generic version of ProAir HFA. The ANDA included Paragraph IV certifications for the nine unexpired patents listed in the Orange Book for ProAir HFA, all of which are listed as drug product patents under prong I of the statutory definition. Teva brought suit on five of those patents within 45 days of receiving Amneal's notice letter, creating a 30-month stay on FDA approval of Amneal's ANDA that would expire in February 2026. *See* 21 U.S.C. § 355(j)(5)(B)(iii).

Amneal counterclaimed for an injunction compelling Teva to delist the asserted patents from the Orange Book. The district court granted judgment for Amneal on the delisting counterclaims, and entered an injunction ordering Teva to delist the Asserted Patents.

5. The Federal Circuit affirmed the district court in a precedential opinion on December 20, 2024. The basic dispute between the parties concerned whether the patents "claim[] the drug for which the applicant submitted the application," as required by prong I of the Listing Statute. Teva argued that the "drug" is the entire approved inhaler product, including all of its components; that each of the patents "claims" aspects of the drug product, including "an active drug"; and that disputes about what the patents "claim[]" should be resolved through the process of claim construction.

The panel held that, "to qualify for listing, a patent must claim at least the active ingredient in the application and the approved drug product." Ex. A at 38. The panel further rejected Teva's reliance on the statutory definition of "drug" in the FDCA, *see* 21 U.S.C. § 321(g)(1). Citing "the FDCA's broader statutory context," the panel held that, "'for a patent to claim[] the drug for which the applicant submitted the application,' such a patent must claim at least the active ingredient identified in the application." *Id.* at 28-29.

6. The Federal Circuit denied Teva's petition for rehearing en banc on March 3, 2025. Ex. B at 3. It also lifted its stay of the injunction, requiring Teva to de-list the patents from the Orange Book.

7. The panel's decision implicates nationally important issues that Congress, the FDA, and other key stakeholders have studied for years. FDA has listed hundreds if not thousands of patents that, like Teva's, do not meet the Federal Circuit's new definition of what it means to "claim" the relevant "drug." No

percolation is possible: the Federal Circuit's interpretation is immediately binding nationwide on every district court entertaining a de-listing request like Amneal's.

The panel's new interpretation refuses to apply the statutory definition of "drug" based on non-textual policy considerations, in conflict with this Court's pronouncements on that precise definition. The panel notably did not dispute that, applying the statutory definition of "drug," the Asserted Patents are listable. Ex. A at 28. Nor could it, given this Court's caselaw interpreting the FDCA's definition of "drug." *United States v. Generix Drug Corp.*, 460 U.S. 453, 459 (1983) (recognizing that § 321(g)(1)(D) must encompass all components of a drug, not just active ingredients). Rather than accept this outcome, the panel turned to the "broader statutory context," which, it concluded, should be read to "limit[]" the term "drug" to require "at least the active ingredient identified in the application." Ex. A at 28-29. That is wrong, and flies directly in the face of this Court's precedent making clear that it is error for lower courts to "refus[e] to apply the [FDCA's drug definition] as written." *United States v. Article of Drug … Bacto-Unidisk*, 394 U.S. 784, 794 (1969).

The panel's interpretation of "claims" also conflicts with a foundational patent decision from this Court: *Nautilus, Inc. v. Biosig Instruments, Inc.*, 572 U.S. 898 (2014). 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 standard 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 panel imposed here—that to "particularly point[] out and distinctly claim[]" a drug, the patent must *recite* a particular active ingredient. The panel's rewriting of the indefiniteness standard is itself a sufficient reason to grant review.

Given these significant conflicts with this Court's precedent and the importance of the Listing Statute to pharmaceutical innovation, the correct interpretation of the Listing Statute presents a substantial question worthy of this Court's review.

8. Teva respectfully requests a 60-day extension of time to file a petition for a writ of certiorari, to and including August 1, 2025. Teva's counsel of record is heavily engaged with other matters and has other commitments that make the preparation of a petition for a writ of certiorari by the existing deadline impracticable. These commitments have included multiple recent oral arguments in the courts of appeals on April 8 and 30 and May 9 and, in the coming weeks, will include a certiorari-stage reply brief due in this Court on May 27, an expedited brief in the Ninth Circuit due June 18, responding to a preliminary injunction motion at the end of June, and a brief in the First Circuit likely to be due in late June. In addition, this case is proceeding in the district court with a pretrial order due July 8 and a final pretrial conference set for July 22. In light of these commitments, the additional time is warranted to enable Teva to determine whether to seek certiorari and to prepare and print the petition.

For the foregoing reasons, Teva respectfully requests that the time to file a petition for a writ of certiorari be extended to and including August 1, 2025.

Respectfully submitted.

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