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 LTD., 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

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BRIEF OF AMICUS CURIAE ASTRAZENECA PHARMACEUTICALS LP IN SUPPORT OF NEITHER PARTY AND REHEARING EN BANC

Christopher N. Sipes
R. Jason Fowler
Michael K. Stern
Covington & Burling LLP
One CityCenter
850 Tenth Street NW
Washington, DC 20001-4956
(202) 662-6000

Counsel for Amicus Curiae AstraZeneca Pharmaceuticals LP

UNITED STATES COURT OF APPEALS
FOR THE FEDERAL CIRCUIT

CERTIFICATE OF INTEREST

Case Number 24-1936

Short Case Caption Teva Branded Pharmaceutical Products R&D, Inc. v. Amneal Pharmaceuticals of New York, LLC

Filing Party/Entity AstraZeneca Pharmaceuticals LP

Instructions:

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Date: 02/04/2025

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Name: Christopher N. Sipes

1. Represented Entities. Fed. Cir. R. 47.4(a)(1).	**2. Real Party in Interest.** Fed. Cir. R. 47.4(a)(2).	**3. Parent Corporations and Stockholders.** Fed. Cir. R. 47.4(a)(3).
Provide the full names of all entities represented by undersigned counsel in this case.	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. ☑ None/Not Applicable	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. ☐ None/Not Applicable
AstraZeneca Pharmaceuticals LP		AstraZeneca PLC

☐ Additional pages attached

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. Other than the originating case(s) for this case, are there related or prior cases that meet the criteria under Fed. Cir. R. 47.5(a)?

☐ Yes (file separate notice; see below) ☐ No ☑ N/A (amicus/movant)

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INTEREST OF AMICUS CURIAE

AstraZeneca Pharmaceuticals LP is a global, science-led, patient-focused biopharmaceutical company devoted to the discovery, development, and commercialization of prescription medicines across various therapy areas including oncology, respiratory and immunology, cardiovascular and metabolic, vaccines, and rare diseases.

AstraZeneca supports the balance that the Hatch-Waxman Act seeks between creating incentives for innovation and enabling access to lower-cost generic drugs. AstraZeneca makes business decisions that rely on the predictable application of the Hatch-Waxman Act consistent with its legislative purpose. As relevant here, AstraZeneca has a significant interest in ensuring that the patent-listing requirement is interpreted and applied in a consistent and predictable manner.[1]

INTRODUCTION

Departing from established principles of patent law, the panel concluded 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 Teva's NDA," but provided no further guidance that an NDA holder might rely on in determining whether a

[1] AstraZeneca certifies that this brief was not authored in whole or part by any party's counsel, and that no person or entity other than AstraZeneca or its counsel contributed financially to its preparation or submission. Pursuant to Federal Rule of Appellate Procedure 29(a)(3) and Federal Circuit Rule 40(i)(1), all parties consented to the filing of this brief.

particular patent claim is "too broad to particularly point out and distinctly claim" the approved drug product.

Because the panel did not limit its reasoning to the patents at issue, ambitious litigants could seek to extend the panel's decision to other broad categories of patents whose eligibility for listing has never been questioned. If uncertainty about the scope of the panel's decision were to cause NDA holders not to list these patents in the Orange Book (or, given uncertainty in the law, to take differing approaches where some companies list and some do not list certain categories of patents), the established Hatch-Waxman system for the orderly resolution of patent disputes would be threatened.

AstraZeneca supports granting panel or *en banc* rehearing to ameliorate the uncertainty the panel decision has created.

ARGUMENT

I. The panel's interpretation of "claims" has injected significant uncertainty into the Hatch-Waxman system.

Patent listing in the Orange Book is but one part of the "complicated scheme" embodied in the Hatch-Waxman Act designed to "strike[] a balance between the sometimes-competing policy interests of inducing pioneering research and development of new drugs and enabling production of low-cost, generic copies of those drugs." *Eli Lilly & Co. v. Teva Pharms. USA, Inc.*, 557 F.3d 1346, 1348 (Fed. Cir. 2009). For example, to compensate for regulatory delays incurred in obtaining FDA approval of a New Drug Application (NDA), Congress "included in the Hatch-Waxman Act a patent-term extension ('PTE') for patents claiming an FDA-

approved product." *Teva Branded Pharm. Prods. R&D, Inc. v. Amneal*, 124 F.4th 898, 904 (Fed. Cir. 2024). To be eligible for a term extension under the statute, the patent must, among other things, "***claim***[] a product, a method of using a product, or a method of manufacturing a product." 35 U.S.C. § 156(a) (emphasis added).

The Hatch-Waxman Act also incorporates Congress' decision "to create 'a new (and somewhat artificial) act of infringement' that would resolve patent disputes" prior to approval of a generic manufacturer's Abbreviated New Drug Application (ANDA). *Teva*, 124 F.4th at 904 (citing *Eli Lilly & Co. v. Medtronic, Inc.*, 496 U.S. 661, 676 (1990)). Specifically, the Hatch-Waxman Act makes the submission of an ANDA "for a drug ***claimed*** in a patent or the use of which is claimed in a patent" an act of infringement that allows litigation to commence prior to actual sale of the accused generic product. 35 U.S.C. § 271(e)(2)(A) (emphasis added); *Teva*, 124 F.4th at 904; *Vanda Pharms. Inc. v. West-Ward Pharms. Int'l Ltd.*, 887 F.3d 1117, 1126 (Fed. Cir. 2018).

These provisions, along with the patent-listing provision addressed by the panel decision, work together as part of the Hatch-Waxman "scheme" to bring generic drugs to the market more quickly. The panel's interpretation of "claims," however, has engendered significant uncertainty for the pharmaceutical industry not only for patent listing, but also for these other important provisions of Hatch-Waxman that turn on what a patent "claims."

II. The panel adopted a novel interpretation of "claims" in conflict with long-established principles of patent law.

The panel held that "claims," at least in the patent-listing context, means to "particularly point out and distinctly claim … at least the active ingredient in the application and the approved drug product." *See, e.g.*, *Teva*, 124 F.4th at 922. In so doing, the panel rejected the "reads on" standard, *id.* at 911, which was long-understood to apply to what a patent "claims," including in the patent-listing context, *see, e.g.*, *Allen Eng'g Corp. v. Bartell Indus., Inc.*, 299 F.3d 1336, 1345 (Fed. Cir. 2002); *Apotex, Inc. v. Thompson*, 347 F.3d 1335, 1344 (Fed. Cir. 2003).[2] Indeed, the statutory requirement that a patent "particularly point out and distinctly claim" subject matter has long been interpreted to require the patent to set forth clear boundaries of the claimed subject matter, *see, e.g., Nautilus, Inc. v. Biosig Instruments, Inc.*, 572 U.S. 898, 901 (2014), and hence a patent "particularly points out and distinctly claims" the subject matter encompassed within the boundaries drawn by the claims (that is, the subject matter on which the claim reads).

It was not disputed that Teva's patents "read on" its ProAir® HFA Inhalation Aerosol drug product, in that all the elements of the patent claims are found in that product. The panel concluded, however—even accepting that Teva's claims required the presence of "an active drug"—that those patents did not "claim" the drug product because the claims were "far too broad to particularly point out and distinctly claim

[2] The Patent Office too has long understood the term "claim" to mean "read on." For example, in interpreting the Hatch-Waxman statutory requirement that a patent must "claim" an approved product to be eligible for PTE, the Patent Office requires the patent to "read on" the approved product. *See* 37 C.F.R. § 1.710(a).

the drug approved in Teva's NDA." *Teva*, 124 F.4th at 922. According to the panel, the fact that the claims permit "the presence of any active ingredient in any form" means that the claims "as a matter of law … do not particularly point out and distinctly claim what was approved." *Id.* (cleaned up).

The panel decision thus appears to hold—at least in the context of patent listing—that a patent can, by claiming too much, claim nothing at all. Put differently, the decision seems to hold that a broad independent claim can fail to "claim" subject matter that its narrow dependent claim does "claim," simply by virtue of the broader claim being "too broad." The decision fails to provide any clarity, however, as to how broad is "too broad."

III. The panel's interpretation of "claims" creates significant uncertainty about the listing eligibility of broad categories of patents, including certain types of non-device patents that were long-understood to be subject to the listing requirement.

The panel decision provides no guidance for determining when a claim is "too broad to particularly point out and distinctly claim" the approved drug. Nor does patent law provide the tools to figure this out. It was, until the panel decision, black-letter law that a broad claim also "claims" everything that is "claimed" by a narrower claim that is entirely within its scope.

For example, 35 U.S.C. § 112(d) states that a dependent claim "specif[ies] a further limitation of the subject matter claimed." "By definition, an independent clam is broader than a claim that depends from it, so if a dependent claim reads on a particular embodiment of the claimed invention, the corresponding independent claim must cover that embodiment as well." *Littelfuse, Inc. v. Mersen USA EP Corp.*,

29 F.4th 1376, 1380 (Fed. Cir. 2022); *see also Intamin Ltd. v. Magnetar Techs., Corp.*, 483 F.3d 1328, 1335 (Fed. Cir. 2007).[3] It is thus a foundational principle of patent law that a narrower claim cannot literally claim subject matter that is not also claimed by a broader claim encompassing it.

This Court had never before suggested that, under the principles of patent law, a narrow claim could literally claim something that a broader claim does not. Yet under the standard adopted by the panel, a broad independent claim can perversely claim less, not more, than a narrower dependent claim.[4] The standard announced and applied by the panel is thus inconsistent with the fundamental principles underlying Sections 112, 251, 271, and 305 of the Patent Code.

The panel's departure from established patent-law principles in defining what "claims" means for patent-listing purposes casts a cloud of uncertainty on how the listing requirement applies to various patents, such as non-device genus patents, a category of patents whose eligibility for listing has never been questioned. Under the standard adopted by the panel, is a genus or sub-genus claim encompassing the approved drug product ineligible for listing if the claim language does not expressly

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[3] Similarly, the prohibition on broadening reissue and reexaminations in Sections 251 and 305 of the Patent Code are understood to require that the claims obtained in reissue or reexamination claim no subject matter outside the original claims—a test at odds with the panel's holding that a narrower claim may claim subject matter (e.g., the approved drug) that is not claimed by a broader claim encompassing it. *See, e.g., Quantum Corp. v. Rodime, PLC*, 65 F.3d 1577, 1581 (Fed. Cir. 1995).

[4] Equally perverse is that, under the standard applied by the panel, a patent can be literally infringed by a product that it does not claim.

identify "the active ingredient in the application and the approved drug product"? *Teva*, 124 F.4th at 922.

The panel decision likewise creates uncertainty with respect to the listing of other types of patents that do not expressly recite the active ingredient, such as platform patents and drug-formulation patents. For example, a platform or drug-formulation claim directed to a specific set of inactive ingredients that enable the extended release of an active ingredient would be considered to "claim" a drug product that incorporates each limitation in the claim, even without an express recitation of the product's active ingredient. The panel's sweeping statements about the meaning of "claims," however, create uncertainty about when such patents are subject to the listing requirement.

The applicability of the listing requirement to these types of patents has never been questioned in public discussions about the scope of the listing requirement. *See, e.g.*, GAO, Generic Drugs: Stakeholder Views on Improving FDA's Information on Patents (Mar. 2023) (GAO Report); FDA, Listing of Patent Information in the Orange Book; Establishment of a Public Docket; Request for Comments, 85 Fed. Reg. 33,169 (June 1, 2020).

The level of specificity required to claim a drug also remains unclear under the panel's decision, as the panel did not specify what claim language—aside from the literal recitation of the active ingredient itself—would meet the requirement to "particularly point out and distinctly claim the drug." Indeed, the decision suggests that recitation of the active ingredient in the claim is not necessarily required. *See Teva*, 124 F.4th at 913. But the panel's determination that Teva's claims—which the

panel assumed required the presence of "an active drug"—are "far too broad to particularly point out and distinctly claim the drug" creates great uncertainty about what, short of reciting the active ingredient, is sufficient under the panel's standard.

IV. The Court should clarify the contours of eligibility for patent listing.

If a patent meets the requirements for listing, then listing is mandatory, and NDA holders must comply with the listing requirement or face significant potential repercussions. It is equally important to generic manufacturers to have all eligible patents timely listed in the Orange Book, as that listing provides notice of relevant patents, the 180-day-exclusivity incentive to bring patent challenges, and a statutory mechanism for resolving patent disputes in advance of generic approval in lieu of the generic manufacturer launching "at risk," thereby preventing undesired litigation and liability for damages for patent infringement. *See* Letter from Sen. Bill Cassidy, M.D., to Robert Califf, M.D., FDA (Sept. 30, 2024), https://www.statnews.com/wp-content/uploads/2024/09/Cassidy-Letter-to-FDA_Orange-Book-1.pdf; *see also* Association for Accessible Medicines (AAM) Comment at 16, Docket No. FDA-2020-N-1069-0013 (Aug. 31, 2020).

If the panel's definition of "claims" and its corresponding uncertainty result in some NDA holders removing patents from the Orange Book or not listing patents that would have otherwise been listed (e.g., non-device genus patents), while other NDA holders interpret the panel's decision as more limited, the Orange Book will not serve its intended purpose of notifying generic applicants of patents covering the approved drug that should be taken into consideration in developing a generic product. *See, e.g.*, GAO Report, at 15–16. Indeed, the non-listing of patents that

would have otherwise been listed increases the likelihood that litigation will occur only after a generic product launches,[5] litigation that will inevitably include adjudication of requests not typically needed in Hatch-Waxman litigation such as for injunctive relief and, eventually, damages.[6] This outcome would be contrary to a key objective of the Hatch-Waxman Act, i.e., to "permit[] the commencement of a legal action for patent infringement before the generic drug maker has begun marketing" and thus before "damages and other monetary relief and injunctive relief may be awarded for the infringement …." H.R. Rep. No. 98-857, pt. 1, at 28, 46 (June 21, 1984).

* * *

AstraZeneca asks the Court to grant Teva's petition for rehearing en banc to (1) clarify the interpretation of "claims" in the listing provision to be consistent with longstanding and well-understood principles of patent law; and (2) tailor the opinion in this case to the specific facts and issues presented, *see Air Courier Conf. of Am. v. Am. Postal Workers Union AFL-CIO*, 498 U.S. 517, 531 (1991) (Stevens, J. concurring).

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[5] If no patents are listed in the Orange Book, the NDA holder's first notice of the generic product may occur when the generic manufacturer launches it.

[6] The non-listing of these patents, if no other patents are listed in the Orange Book, would also eliminate the incentive given to first-filer generic applicants of 180-day exclusivity vis-à-vis other generic applicants for challenging an NDA holder's patents, thus further deterring generic manufacturers from developing new generic drugs. *See, e.g.*, GAO Report, at 15–16.

Without such clarification or tailoring of the panel's decision, it is not apparent whether or when the Court might have another opportunity to ensure that the patent-listing requirement is applied in a consistent and predictable manner. An appeal that raises these issues in the context of a patent delisting counterclaim will be less likely if NDA holders implement the panel decision by listing (and maintaining the listing of) only those patents that qualify for listing under the strictest interpretation of the panel decision. Further judicial interpretation of the patent-listing statute might be more likely to occur in antitrust cases that are beyond this Court's jurisdiction.

Moreover, the panel's decision might cause the FDA to cease any further efforts to develop an interpretation of the patent-listing statute that best aligns with the legislative purpose for specific types of patents. In the absence of any further administrative policy development by the FDA, the public would be deprived of an opportunity to provide input through notice-and-comment rulemaking or a guidance development process, and the FDA's expert views would not be reflected in the prevailing interpretation of the patent-listing requirement.

CONCLUSION

The Court should grant Teva's petition for rehearing en banc for the reasons discussed above.

Dated: February 4, 2025

Respectfully submitted,

/s/ Christopher N. Sipes

Christopher N. Sipes
R. Jason Fowler
Michael K. Stern
Covington & Burling LLP
One CityCenter
850 Tenth Street NW
Washington, DC 20001-4956
(202) 662-6000

Counsel for Amicus Curiae
AstraZeneca Pharmaceuticals LP

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July 2020

UNITED STATES COURT OF APPEALS
FOR THE FEDERAL CIRCUIT

CERTIFICATE OF COMPLIANCE WITH TYPE-VOLUME LIMITATIONS

Case Number: 24-1936

Short Case Caption: Teva Branded Pharmaceutical Products R&D, Inc. v. Amneal Pharmaceuticals of New York, LLC

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