No. 2024-1936

UNITED STATES COURT OF APPEALS
FOR THE FEDERAL CIRCUIT

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

Plaintiffs–Appellants,

v.

AMNEAL PHARMACEUTICALS OF NEW YORK, LLC, AMNEAL IRELAND LTD., AMNEAL PHARMACEUTICALS LLC, AMNEAL PHARMACEUTICALS, INC.,

Defendants–Appellees.

Appeal from the United States District Court for the District of New Jersey in No. 2:23-cv-20964, Judge Stanley R. Chesler

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UNOPPOSED MOTION OF PHARMACEUTICAL RESEARCH AND MANUFACTURERS OF AMERICA AND BIOTECHNOLOGY INNOVATION ORGANIZATION FOR LEAVE TO FILE A BRIEF AS *AMICI CURIAE* IN SUPPORT OF NEITHER PARTY ON PETITION FOR REHEARING

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CERTIFICATE OF INTEREST

I, Jeffrey P. Kushan, counsel for Pharmaceutical Research and Manufacturers of America and Biotechnology Innovation Organization, certify 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).

   Pharmaceutical Research and Manufacturers of America ("PhRMA") and Biotechnology Innovation Organization ("BIO").

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).

   PhRMA: None
   BIO: 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).

   PhRMA has no parent corporation and no publicly held corporation owns 10% or more of its stock.

   BIO has no parent corporation and no publicly held corporation owns 10% or more of its stock.

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).

PhRMA: None
BIO: None

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).

None.

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.

February 4, 2025

/s/ *Jeffrey P. Kushan*

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INTRODUCTION

Pursuant to Federal Rules of Appellate Procedure 29 and 40, and Federal Circuit Rule 40(i), Pharmaceutical Research and Manufacturers of America ("PhRMA") and Biotechnology Innovation Organization ("BIO") respectfully move this Court for leave to file the attached brief as *amici curiae* in support of neither party on petition for rehearing.

All parties have indicated that they do not oppose the relief sought in this motion.

STATEMENT OF INTEREST

PhRMA is a voluntary, nonprofit association representing the country's leading innovative biopharmaceutical research companies.[1] PhRMA member companies are laser-focused on developing innovative medicines that transform lives and create a healthier world, and PhRMA advocates for public policies encouraging innovation in life-saving and live-enhancing new medicines. PhRMA members make significant contributions to serve these goals and have led the way in the search for new cures.

[1] *See* www.phrma.org/about#members.

BIO is the principal trade association representing the biotechnology industry in the U.S. and abroad. BIO's more than 1,000 members range from small start-up companies and biotechnology centers to research universities and Fortune 500 companies. Most of BIO's members are small companies that have yet to bring products to market or attain profitability, with approximately 90% of BIO's corporate members having annual revenues below $25 million. These members rely heavily on venture capital and other private investment.

REASONS TO GRANT THE MOTION

Amici's members have a substantial interest in this case. They rely on a predictable, stable, and well-functioning patent system when making their substantial investments in the risky and unpredictable process of inventing new cures and bringing them to patients. *Amici*'s members rely, in particular, on clear rules governing which patents they must identify for listing in FDA's Orange Book when they submit their new drug applications, submitting only those patents they understand are required to be listed under the patent-listing statute, 21 U.S.C. § 355(b)(1)(A)(viii). *Amici* also have a strong interest in ensuring that these clear rules regarding patent listings remain consistent with

the straightforward language of the statute, as well as long-settled understandings and practices of both the FDA and pharmaceutical companies operating under this system. *Amici* seek leave to file a brief as *amici curiae* in order to advance and protect these interests and assist the Court.

CONCLUSION

Amici respectfully request that the Court grant their unopposed motion.

February 4, 2025

Respectfully submitted,

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CERTIFICATE OF COMPLIANCE

This motion complies with the type-volume limitation of Federal Rule of Appellate Procedure 27(d)(2)(A). The motion contains 378 words, excluding the parts 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 for Microsoft 365 MSO in 14-point Century Schoolbook font.

February 4, 2025

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BRIEF OF *AMICI CURIAE* PHARMACEUTICAL RESEARCH AND MANUFACTURERS OF AMERICA AND BIOTECHNOLOGY INNOVATION ORGANIZATION IN SUPPORT OF NEITHER PARTY ON PETITION FOR REHEARING

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None.

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Not Applicable.

February 4, 2025

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INTEREST OF *AMICI CURIAE*[1]

The Pharmaceutical Research and Manufacturers of America ("PhRMA") is a voluntary, nonprofit association representing the country's leading innovative biopharmaceutical research companies.[2] PhRMA member companies are laser-focused on developing innovative medicines that transform lives and create a healthier world, and PhRMA advocates for public policies encouraging innovation in life-saving and live-enhancing new medicines. PhRMA members make significant contributions to serve these goals and have led the way in the search for new cures.

The Biotechnology Innovation Organization ("BIO") is the principal trade association representing the biotechnology industry in the U.S. and abroad. BIO's more than 1,000 members range from small start-up companies and biotechnology centers to research universities and Fortune 500 companies. Most of BIO's members are small companies that have yet to bring products to market or attain

[1] No counsel for any party authored this brief in any part, and no party, counsel, or person other than amicus contributed money to fund the preparation and submission of this brief. *See* Fed. R. App. P. 29(a)(4)(E).
[2] *See* www.phrma.org/about#members.

profitability, with approximately 90% of BIO's corporate members having annual revenues below $25 million. These members rely heavily on venture capital and other private investment.

Amici's members have a substantial interest in this case. They rely on a predictable, stable, and well-functioning patent system when making their substantial investments in the risky and unpredictable process of inventing new cures and bringing them to patients. *Amici*'s members rely, in particular, on clear rules governing which patents they must identify for listing in FDA's Orange Book when they submit their new drug applications, submitting only those patents they understand are required to be listed under the patent-listing statute, 21 U.S.C. § 355(b)(1)(A)(viii). *Amici* also have a strong interest in ensuring that these rules regarding patent listings remain consistent with the straightforward language of the statute, as well as long-settled understandings and practices of both the FDA and pharmaceutical companies operating under this system.

INTRODUCTION

Innovators seeking to market a new drug are required to seek FDA approval by filing a New Drug Application. When innovators do so, the patent-listing statute requires that they identify to FDA certain patents "for which a claim of patent infringement could reasonably be asserted" if someone without a license were to make, use, or sell the drug. 21 U.S.C. § 355(b)(1)(A)(viii). The statute then instructs that innovators must identify any patent within this set that (I) "claims the drug…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." *Id.* The patents meeting these criteria must be listed in FDA's Orange Book. This disclosure and listing process is a critical part of the balanced, comprehensive scheme created by the Hatch-Waxman Amendments to the Federal Food, Drug, and Cosmetic Act for efficiently resolving patent disputes before generic versions of new drugs enter the market. *See generally* Drug Price Competition and Patent Term Restoration Act, Pub. L. No. 98-417, 98 Stat. 1585 (1984).

This case is about whether Teva's patents that "focus" on "device components" of an inhaler fall within the scope of the statutory

obligation to identify and list any patent that "claims the drug" and "is a drug substance (active ingredient) patent or a drug product (formulation or composition) patent."[3] *Amici* take no position on that narrow question. But the panel opinion's interpretive analysis reflects certain foundational errors that overcomplicate what should be a straightforward statutory inquiry. And that unnecessary complexity has led Teva, at least, to suggest that the ultimate holding in this device-patent case disrupts settled understandings regarding other kinds of patents that are routinely and correctly listed in the Orange Book. *Amici* respectfully submit that rehearing is warranted to allow the panel or the *en banc* Court to revisit its statutory analysis and to further underscore that the ultimate holding in this case is limited to the narrow question presented by Teva's patents.

ARGUMENT

I. The Panel Opinion's Approach to the Patent Listing Statute Reflects a Foundational Error That Overcomplicates the Interpretive Analysis.

The panel's statutory analysis begins by taking on the first of Teva's "key interpretive moves"—that "claims" in the phrase "claims the

[3] The Teva patents are not asserted to claim "a method of using [a] drug." 21 U.S.C. § 355(b)(1)(A)(viii)(II).

drug" should be read to mean "reads on." (Op. 18.) The panel opinion rejects Teva's infringement-based interpretation of "reads on," because it results in what the panel calls a "stunning" redundancy. (Op. 19–20.) In the panel's view, the term "claims" within the phrase "claims the drug" cannot mean something like "infringing," because the statute separately specifies that listable patents are those "for which a claim of patent infringement could reasonably be asserted." (*Id.*)

There is no redundancy, however. The two phrases in question do independent work: the phrase "claims the drug" (along with "claims a method using such drug") further limits the set of patents "for which a claim of patent infringement could reasonably be asserted." This can be readily appreciated by reading the phrases of the statute in their defined context:

> **(vii)** [The applicant 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) (emphases added).

The first requirement is that the patent be one "for which a claim of patent infringement could reasonably be asserted." This requirement does not impose restrictions as to what subject matter is being claimed, and it thus encompasses patents that FDA has long excluded from listing, such as patents covering a drug's packaging or the manufacturing processes used to make it. *See* 21 C.F.R. § 314.53(b)(1).

The separate requirement that a listable patent be one that "claims the drug" or "claims a method of using such drug" serves the purpose of further limiting the set of listable patents to certain specific types of patents. It, for example, includes patents covering the drug product, including composition and formulation patents, or those covering the active ingredient in it, but excludes things like packaging or manufacturing-process patents. This narrowing function is served regardless of whether "claims" in subparagraphs (I) and (II) is interpreted to mean "reads on," which is a natural reading of the statutory language. Accordingly, an infringement-based reading of "claims" can be readily understood and applied, and does not render the "claims the drug" requirement in § 355(b)(1)(A)(viii)(I) redundant. The

panel's interpretive framing, which seeks to differentiate what a claim "reads on" from what it "particularly points out and distinctly claims…as the invention" introduces unnecessary confusion. (Op. 18.)

With respect to "the drug" in the phrase "claims the drug," *Amici* respectfully submit that its scope is best understood in the context of the rest of § 355(b)(1)(A)(viii)(I), as amended by the Orange Book Transparency Act, Pub. L. No. 116-290, 134 Stat. 4889 (2021). A listable patent under this provision must not only claim "the drug" but also be "a drug substance (active ingredient) patent or a drug product (formulation or composition) patent." 21 U.S.C § 355(b)(1)(A)(viii)(I). At a minimum, then, the statute makes clear that innovators must list any valid patent that reads on the active ingredient of the drug (a "drug substance") *or* a drug's formulation or composition (a "drug product").

The panel's opinion chose to assess the question whether Teva's patents claim "the drug" *without* considering whether they were "drug substance" or "drug product" patents. (*See* Op. 36–37.) This, too, unnecessarily complicated the panel's analysis. These further limitations critically inform what "the drug" means in the patent-listing statute, as amended by the Orange Book Transparency Act.

II. The Statute's Straightforward Interpretation Is Supported by the Policies of Hatch-Waxman.

The clear and straightforward approach to the patent-listing statute outlined above is consistent with the policies that animate the broader Hatch-Waxman scheme.

The patent-listing requirement is integral to achieving Hatch-Waxman's aim "to facilitate the resolution of patent-related disputes over pharmaceutical drugs by creating a streamlined mechanism for identifying and resolving patent issues related to the proposed generic products"—*before* generic drugs enter the market. *Apotex, Inc. v. Thompson*, 347 F.3d 1335, 1338 (Fed. Cir. 2003). It does so in several ways.

First, it ensures that generic manufacturers are put on notice of the patents that are likely to be infringed by the marketing of their generic version of a new drug product before they invest in developing it.

Second, it links specific patents to the statutory scheme for early dispute-resolution before the generic product enters the market, and creates a process for courts to hear disputes over those patents. *See id.* at 1339 ("To facilitate judicial resolution of the question whether the

generic drug would infringe a pertinent patent, the Hatch-Waxman Act treats the act of filing a paragraph IV certification as an act of patent infringement." (citing 35 U.S.C. § 271(e)(2)(A)).)

And third, it allows generics to litigate specific patent issues without having to "launch at risk," and without the risk of actual and possibly treble damages that would stem from such launches.

The opportunity to resolve specific patent disputes before the generic product enters the market is critically important to innovators, generic manufacturers, and the public alike. For innovators, it helps to protect the legitimate exclusivity provided by valid patents. For generic manufacturers, it provides an opportunity to expeditiously resolve patent-related risks of launching a product—without the economic risks that potential infringers are exposed to via patent litigation outside of the system—if they can show that the patents are invalid or would not be infringed by their generic products. And for the public, this system of early resolution of patent disputes helps to avoid market disruptions associated with removal of a generic drug from commercial channels if it is found later to be infringed.

Consistent with Hatch-Waxman's goals of enabling both innovators and generic manufacturers to facilitate early resolution of patent disputes, Congress made listing specific types of patents *mandatory*. An innovator's failure to submit timely information regarding a patent frees generic manufacturers from having to submit a certification relating to the patent, 21 C.F.R. § 314.94(a)(12)(vi), which can result in the loss of the innovator's ability to trigger a 30-month stay of FDA approval.[4] The mandatory listing scheme helps to effectuate Hatch-Waxman's purposes, as omissions of patents subject to mandatory listing from the Orange Book could otherwise delay the expeditious resolution of patent disputes before generic products enter the market, and thereby increase uncertainty for all parties and the public. Additionally, when litigation regarding an unlisted patent does arise, innovators may rely increasingly on emergency filings, requests

[4] Referring to the prohibition on FDA granting final approval of an ANDA pending an ongoing litigation involving infringement of a listed patent under 35 U.S.C. § 271(e)(2)(A) as imposing an unconditional "30-month stay" is inaccurate. The stay on approval remains in effect until the earlier of an adverse disposition of the validity or infringement of the patent or a period of 30 months has expired, measured from receipt of notice of the paragraph IV certification, and only one such stay is available against the ANDA as filed.

for injunctive relief, and requests for significant damages (potentially enhanced for willfulness), all of which not only can burden courts, but also can discourage investment in the development of generic drugs.

In 2003, Congress paired the mandatory listing requirements with a novel "de-listing" action to allow generics to seek the removal from the Orange Book of patents that do *not* claim the approved drug or an approved method of use. *See* 35 U.S.C. § 355(j)(5)(C)(ii)(I). (Op. 9.) Taken together, these provisions reflect a statutory scheme designed to incentivize the listing of patents that must be listed and discourage the listing of those that may not be listed. *See* H.R. Rep. No. 116-47, at 3–4 (2019) (noting, in connection with then-proposed Orange Book Transparency Act, problems of both under-listing and over-listing). In short, the Hatch-Waxman scheme reflects an understanding that *either* "under-listing" or "over-listing" interferes with the optimal functioning of the system.

Amici's members depend on clear and stable rules to guide their conduct when submitting patent information for listing in the Orange Book. The straightforward approach to the statute set forth above furthers this objective, as it comports with longstanding practice and

FDA regulations, and implies a clear set of rules of what must be listed and must not be listed. Following such an approach helps to ensure that generics have notice of and can trigger pre-launch litigation to resolve disputes regarding *all* of the patents that Congress saw fit to require listing under Hatch-Waxman. The panel's opinion highlights potential problems with "over-listing" (*e.g.*, Op. 7–8), but does not account for the risks of "under-listing" or the need for clarity in this domain.

III. The Panel Should Grant Rehearing to Simplify Its Analysis and Underscore the Narrow Scope of Its Holding.

The panel's interpretive approach reflects a foundational error—based on an asserted "redundancy"—that led to an overcomplicated statutory analysis. That is reason enough to warrant vacating the panel decision and granting panel or *en banc* rehearing. Leaving the existing opinion in place could lead to unnecessary confusion in the lower courts, including as to questions not presented by this case.

Teva's own petition includes arguments that illustrate how future litigants may misunderstand (or misuse) the panel's decision to sow confusion. For example, Teva asserts that the panel's decision has "implications" for a "broad range of patents," including "genus patents" directed to a class of compounds that may include the active ingredient

in a drug. (Pet. 8.) *Amici* do not read the panel's decision as Teva does: the panel said that it was not deciding more than the case before it, which involved claims focused on a device.[5] (Op. 38.) The panel did not have any reason to call into question the established practice of listing genus patents, and *Amici* do not read its opinion as doing so. Nonetheless, innovators, generic manufacturers, and the public would benefit from a more focused analysis that makes clear what the Court is deciding—whether a patent focusing on a device component "claims a drug" and is a "drug substance" or "drug product patent"—and what it is not.

Amici thus respectfully submit that, at a minimum, the panel opinion should be vacated and replaced with a revised opinion that is expressly limited to device-related patents.

CONCLUSION

Rehearing is warranted.

[5] The patents at issue in this case raise a narrow question relevant to listing; whether claims defining an inhaler device with a "medicament canister," (Op. 15), that *may* contain a drug substance or drug product "claims the drug" within the meaning of the statute.

February 4, 2025

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