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

APPELLEES' RESPONSE TO APPELLANTS' PETITION FOR REHEARING *EN BANC*

Steven A. Maddox
PROCOPIO
1901 L Street, NW
Suite 620
Washington, DC 20036
Tel.: 202.830.0707
Fax.: 202.830.0704

Counsel for Appellees

February 11, 2025

UNITED STATES COURT OF APPEALS FOR THE FEDERAL CIRCUIT

CERTIFICATE OF INTEREST

Case Number 2024-1936

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

Filing Party/Entity Amneal Pharmaceuticals of New York, LLC; Amneal Ireland Limited; Amneal Pharmaceuticals LLC; Amneal Pharmaceuticals, Inc.

Instructions:

1. Complete each section of the form and select none or N/A if appropriate.
2. Please enter only one item per box; attach additional pages as needed, and check the box to indicate such pages are attached.
3. In answering Sections 2 and 3, be specific as to which represented entities the answers apply; lack of specificity may result in non-compliance.
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5. Counsel must file an amended Certificate of Interest within seven days after any information on this form changes. Fed. Cir. R. 47.4(c).

I certify the following information and any attached sheets are accurate and complete to the best of my knowledge.

Date: February 11, 2025

Signature: /s/ Steven A. Maddox

Name: Steven A. Maddox

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
Amneal Pharmaceuticals of New York, LLC		See attached.
Amneal Ireland Limited		See attached.
Amneal Pharmaceuticals LLC		See attached.
Amneal Pharmaceuticals, Inc.		See attached.

☑ 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).

☐ None/Not Applicable ☐ Additional pages attached

Melissa Hatch O'Donnell, Robin P. Sumner, and Andrew P. Zappia of Troutman Pepper Hamilton Sanders LLC		
Rebekah R. Conroy and Shalom D. Stone of Stone Conroy LLC		

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)

If yes, concurrently file a separate Notice of Related Case Information that complies with Fed. Cir. R. 47.5(b). **Please do not duplicate information.** This separate Notice must only be filed with the first Certificate of Interest or, subsequently, if information changes during the pendency of the appeal. Fed. Cir. R. 47.5(b).

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).

☑ None/Not Applicable ☐ Additional pages attached

3. **Parent Corporations and Stockholders.** Fed. Cir. R. 47.4(a)(3).
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.

Amneal Pharmaceuticals of New York, LLC:
Wholly owned by Amneal Pharmaceuticals LLC

Amneal Ireland Limited:
Wholly owned by Amneal Pharmaceuticals Holding GmbH, which is wholly owned by Amneal UK Holding Company Ltd., which is wholly owned by Amneal Pharmaceuticals LLC

Amneal Pharmaceuticals LLC:
Wholly owned by Amneal Pharmaceuticals, Inc.

Amneal Pharmaceuticals, Inc.:
None/Not Applicable

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Amneal Pharmaceuticals LLC:
Wholly owned by Amneal Pharmaceuticals, Inc.

Amneal Pharmaceuticals, Inc.:
None/Not Applicable

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INTRODUCTION

The panel correctly held that none of the asserted pure device patents "claims the drug for which the applicant submitted the application," as required by the Listing Statute. 21 U.S.C. § 355(b)(1)(A)(viii)(I). The panel expressly and narrowly tailored its decision to the particular claims and facts before it. After finding that Teva's construction of the claims at issue does not particularly point out and distinctly claim what was approved in the NDA, the panel concluded: "We do not and need not decide more." Op. at 38.

This was a proper exercise of judicial restraint. Issues under the Listing Statute arising from different patent claims and different facts should be considered and addressed as they arise, on a case-by-case basis. Teva does not make any compelling showing as to why that ordinary course of common law development should not proceed. Nor could they, because *en banc* rehearing is not a mechanism for answering hypothetical questions or rendering advisory opinions.

None of Teva's arguments that the case is exceptionally important withstands scrutiny. Teva first argues that the FDA had an "understanding" that the Listing Statute should be interpreted to authorize the listing of a pure device patent, because it has not prevented pure device patents from being listed in the Orange Book, or removed them. Pet. at 5-6. This proves nothing, because the FDA has never policed the Orange Book, limiting itself to a purely "ministerial"

role in the listing of patents.

Teva next argues that Congress had the same "understanding" as FDA, based on a request in the OBTA that the GAO study listing practices regarding combination products. Pet. at 6. Teva reads far too much into this request. Merely gathering data about listing practices in no way implies (let alone constitutes) congressional approval of listing practices.

Moreover, Teva's petition is premised on the fallacy that the panel decision requires patents to *recite* the active ingredient by name. Pet. at 8. Specifically, Teva speculates that due to the alleged *recital* requirement, companies will delist *en masse* genus and other kinds of patents that do not recite the active ingredient.

But the panel did not hold or suggest that claims must *recite* the active ingredient. Rather, the panel held that in order to claim the active ingredient under the Listing Statute, the patent must particularly point out and distinctly claim the active ingredient, citing 35 U.S.C. § 112(b). That is not the same thing as requiring the patent to *recite* the active ingredient.

In the end, Teva's argument that the panel's decision is exceptionally important boils down to little more than unsupported claims that the sky is falling on the Hatch-Waxman Act and pharmaceutical industry. Teva's speculative parade of horribles allegedly flowing from the panel decision includes "a seismic effect on the Orange Book, far beyond combination products," an immediate "sea

change in the listing regime," and the removal of "hundreds of patents from the Orange Book." Pet. at 1, 2, 9. Such unsubstantiated hyperbole does not justify *en banc* review.

The Court likewise should reject Teva's argument that the panel decision conflicts with the law of indefiniteness under *Nautilus, Inc. v. Biosign Instruments, Inc.*, 572 U.S. 898 (2014). The panel decision does not address indefiniteness. Rather, it considers only the distinct issue of whether a claim meets the requirements of the Listing Statute for inclusion in the Orange Book. In any event, Teva again depends on the false premise that the panel requires a patent to *recite* the active ingredient in the claims in order to qualify for listing under the Listing Statute. The panel decision does not impose any such requirement.

Finally, Teva offers a summary re-hash of its proposed constructions of "claims" and "drug," taken and defined outside the context of the Listing Statute and the FDCA. But the panel's rejection of "claims" to mean "reads on" is well-supported by the structure of the Listing Statute, Section 112(b) and the case law analyzed by the panel in the decision. And the panel's rejection of "drug" to mean any "component" of an NDA product is well-supported by the full statutory language "claims the drug *for which the applicant submitted the application*," the cited sections of the FDCA, and the cited case law.

The petition should be denied.

ARGUMENT

I. The panel's decision is not exceptionally important or disruptive for the Hatch-Waxman regime.

A. The decision does not contravene any FDA or Congressional approval of listing pure device patents in the Orange Book.

Contrary to Teva's suggestion, the FDA has never approved or authorized the listing of pure device patents like the ones at issue here. Pet. at 5-6. This is because the FDA's role with respect to listing is exclusively ministerial. The FDA does not make any determination as to whether a patent submitted for listing complies with the Listing Statute. Accordingly, the prior listing of such patents by Teva and others does not evidence any sort of FDA approval, acceptance or understanding of compliance with the Listing Statute. Teva's argument simply ignores this reality.

Also contrary to Teva's suggestion, there is no evidence that Congress intended the OBTA to authorize listing of pure device patents such as those at issue. Pet. at 6. Teva offers only a speculative inference that Congress must have intended that authorization, because Congress directed the GAO to study listing practices for pure device patents on combination products. Teva fails, however, to offer any direct or actual evidence of why Congress requested the study, or Congress's opinion of the legality of any particular listing practice.

Finally, Teva asserts that rehearing this case *en banc* will be this Court's last chance to address the Listing Statute. Pet. at 7. As Teva admits, however, actions

for delisting under the Listing Statute fall into this Court's exclusive jurisdiction. Teva's speculation as to the path of potential FTC antitrust litigation is unsupported and irrelevant.

B. Teva offers only a false premise and speculation that the panel decision will disrupt hundreds of patent listings.

The panel confined its decision to the claims of the Asserted Patents. Teva, however, seeks *en banc* rehearing based on hypothetical genus claims that were not before the panel. As *amici curiae* observed, "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."[1]

Specifically, Teva speculates that the panel's decision likely would prevent listing of unspecified hypothetical genus and other claims, none of which were before the panel. Teva bases this speculation on the premise that the panel decision requires the specific active ingredient to be *recited* in the claim language. Pet. at 8. That is a false premise. The panel made no such holding, as *amici curiae* acknowledge. "Indeed, the decision suggests that recitation of the active ingredient is not necessarily required."[2]

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[1] *See* Brief of *Amici Curiae* Pharmaceutical Research Manufacturers of America and Biotechnology Innovation Organization in Support of Neither Party on Petition for Rehearing, at 13.

[2] *See* Brief of *Amicus Curiae* AstraZeneca Pharmaceuticals LP in Support of Neither Party and Rehearing *En Banc*, at 7.

To support its claim that the panel held that the patent must expressly *recite* the active ingredient, Teva cites pages 33, 37 and 38 of the decision. Pet. at 8. But nothing on these pages supports Teva's claim. On page 33, the panel did not require recitation of the active ingredient by name. Rather, the panel concluded only that:

> To list a patent in the Orange Book, that patent must, among other things, claim the drug for which the application was approved. And to claim that drug, the patent must claim at least the active ingredient.

Op. at 33.

Similarly, on pages 37 and 38, the panel did not articulate any requirement that the claims must recite the active ingredient. Rather, the panel here addressed Teva's proposed construction of the claims at issue to require the presence of "an active drug."

The panel articulated the standard it was applying, without any reference to a requirement that the name of the active ingredient must be recited in the claims.

> As we explained above, to claim something, a patent must particularly point it out and distinctly claim what purports to be the invention. *See* 35 U.S.C. § 112(b). And to qualify for listing, a patent must claim at least the active ingredient in the application and the approved drug product.

Op. at 38. The panel then applied the standard to the particular facts of the case before it.

> 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. Teva's construction permits the presence of any active ingredient in any form. As a matter of law, Teva's construction does not particularly point out and distinctly claim what was approved – the ProAir HFA with albuterol sulfate as the active ingredient. We do not and need not decide more.

Op. at 38.

Thus, the panel expressly limited itself to holding that on the facts before it, Teva's construction of the claims at issue to require "an active drug" did not satisfy the requirement that a listable patent claim the drug approved in Teva's NDA. The panel did not hold that the active ingredient must be recited in the claim language.

II. The panel's interpretations of "claims" and "drug for which the applicant submitted the application" were proper and do not warrant *en banc* rehearing.

A. The panel's interpretation of "claims" does not conflict with Supreme Court or Federal Circuit precedent.

Teva asserts that the panel decision conflicts with the law of indefiniteness under *Nautilus, Inc. v. Biosign Instruments, Inc.*, 572 U.S. 898 (2014). The panel decision, however, does not address indefiniteness or patentability of any kind. Rather, it deals solely with the distinct issue of what is required for a patent to qualify under the Listing Statute for listing in the Orange Book. The panel decision does not conflict with *Nautilus* because the two decisions deal with different legal questions.

Further, Teva's argument with respect to *Nautilus* relies on the false premise that the panel decision requires patent claims to *recite* the active ingredient under the Listing Statute. Teva expressly relies on the alleged *recital* requirement to argue that there is a conflict between the panel decision and *Nautilus*.

> But § 112(b) does not require explicit recitation. 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. Requiring a patent *recite* a particular active ingredient raises the bar above where the Supreme Court set it.

Pet. at 10-11. The panel decision does not require *recital* of a particular active ingredient to qualify under the Listing Statute to be listed in the Orange Book.

Teva repeats its argument that this Court in *Apotex, Inc. v. Thompson*, 347 F.3d 1335 (Fed. Cir. 2003), already held that "claims" in the Listing Statute must be construed to mean "reads on" a product. Specifically, Teva cites a portion of the *Apotex* decision that reads: "The listing decision thus requires what amounts to a finding of patent infringement, except that the 'accused product' is the drug that is the subject of the NDA." Pet. at 10 (quoting *Apotex*, 247 F.3d at 1344).

The panel properly rejected this argument because, as the panel observed, "Teva both takes the quotation from *Apotex* out of context and misreads it." Op. at 25. The language comes from a section of the opinion addressed to whether this Court had jurisdiction over a listing dispute, which depended on whether there was

a substantial question of patent law at play. "Beyond making that point, which established this court's jurisdiction, we did not need to, and did not, interpret the listing provision because we rejected Apotex's argument that the FDA had to police the Orange Book." Op. at 25. Further, "contrary to Teva's contention, we did not say in *Apotex* that, if something infringes a patent, then the patent claims it – i.e., that, to meet the requirement that a patent claims something, it suffices to show that thing infringes the patent." Op. at 25-26.

Finally, with respect to "claims," Teva takes issue with the panel's finding that the "problem with Teva's position is that the listing provision identifies infringing and claiming as two distinct requirements." Op. at 19. Teva reprises its argument that under the doctrine of equivalents a product can be subject to an action for infringement even if the claims do not literally read on the accused product. Pet. at 11. The panel correctly rejected Teva's doctrine of equivalents argument for several reasons:

> First, literal infringement and infringement under the doctrine of equivalents are better understood as separate 'theories of infringement' that are alternative ways of satisfying 'the statutory basis for direct infringement.'
>
> Second, as we explained above, *Hoechst-Roussel* rejected the argument that claiming and literal infringement are coextensive.
>
> Third, Teva's argument does not acknowledge that claiming and infringement have separate statutory bases and that the listing provision identifies both as separate

requirements.

Op. at 27 (cleaned up). Teva does not mount a challenge to any of these reasons.

B. The panel's interpretation of "drug for which the applicant submitted the application" is correct.

Contrary to Teva's suggestion, the panel did not rewrite the statutory definition of "drug." Rather it properly construed the statutory language of "drug for which the applicant submitted the application" in the context of the statutory language and the FDCA.

Teva once again argues that the FDCA defines the word "drug" to include "any 'component' of any 'article[]' used for the 'treatment[] or prevention of disease to 'affect . . . any function of the body.' 21 U.S.C. § 321(g)(B)(D)." Pet. at 12. Teva insists therefore that "a patent that claims a 'component' of the drug product claims the 'drug' and must be listed." *Id.* The panel properly rejected this argument on at least two grounds.

First, the panel found that Teva's "reliance on the FDCA's definition of drug fails to account for how the FDCA's other provisions inform and limit what kind of medical products within the FDA's purview are drugs." Op. at 28. After reviewing the FDCA's approval pathways for drugs and devices, the panel recognized that "[e]ven though the FDCA defines 'drug' broadly as something that treats disease, then, the statutory context demonstrates that a drug is a narrower class of medical product." Op. at 30.

The panel then turned to *Genus Med. Techs. LLC v. FDA*, 994 F.3d 631, 641 (D.C. Cir. 2023), which held that "what distinguished a drug from a device under the FDCA is that a device excludes a product that achieves its primary intended purposes through either chemical action or metabolization." Op. at 31. The panel explained that the FDCA refers to the part of a drug that supplies the chemical reaction or metabolization as the active ingredient. "And it is the presence of this active ingredient that makes a product approvable as a drug." Op. at 31.

The panel found this statutory focus on the active ingredient to be reinforced by *Sandoz Inc. v. Becerra*, 57 F.4th 272 (D.C. Cir. 2023), and *Ipsen Biopharmaceuticals, Inc. v. Becerra*, 108 F.4th 836 (D.C. Cir. 2024). Op. at 32. Teva's attacks on these cases fall far short of undermining that conclusion. Teva merely quibbles that *Sandoz* reflects that the FDA also reviews inactive ingredients in the drug. Pet. at 14. Yet, *Sandoz* itself explains: "While the FDA approves [a] drug as a whole, assessment and study of the active ingredient is central to the new drug approval process." *Sandoz*, 57 F.4th at 280.

As to *Ipsen*, Teva observes only that that the case did not address the § 321(g)(1)(D) component provision. Pet. at 15. That, however, is irrelevant to the point for which the panel cited *Ipsen* – namely, that "classification as a drug or biological product depended on 'the active ingredient,' not the 'dosage form.'" Op. 33 (citing *Ipsen*, 108 F.4th at 844).

After thoroughly reviewing the FDCA framework and associated case law, the panel concluded:

> [W]hat makes something approvable as drug is the presence of an active ingredient. Thus, to claim the drug for which the applicant submitted the application and for which the application was approved, a patent must claim an invention containing the active ingredient. Otherwise, a patent claims something that the FDA could not have properly regulated as a drug in the first place.

Op. at 33.

Second, the panel rejected Teva's "component" definition argument because it sought to construe the word "drug" in isolation, rather than in the full context of the statutory language "the drug for which the applicant submitted the application." "Teva's invocation of 'components,' with respect to the question before us, ignores the requirement that listable patents must claim the drug for which approval is sought. That requires claiming an active ingredient." Op. at 33.

Finally, Teva again argues that every part of the ProAir HFA combination product is a drug because the product was reviewed and approved as an NDA under the FDA pathway for review of drugs, as opposed to devices. Pet. at 15. But as the panel explained: "[A] drug device combination product being approved with an NDA does not make the device parts a drug. The fact that the combination product was approved with an NDA just means that the drug mode of action predominated." Op. at 36. The panel concluded:

> On the facts of this case, the drug for which the application was submitted and approved is thus not every component of Teva's ProAir HFA. Instead, it is the part of the drug-device combination that made it regulatable as a drug in the first place. And that is the active ingredient.

Op. at 36.

CONCLUSION

The petition should be denied. The panel's decision is confined to the claims and facts before it, and is neither exceptionally important nor in conflict with Supreme Court or Federal Circuit precedent. *En banc* review is not appropriate to render the advisory opinions Teva and *amici* seek on claims and facts not before the panel. The Court should allow its jurisprudence on the Listing Statute to develop on a case-by-case basis, in the normal course of common law development.

Respectfully submitted,

/s/ Steven A. Maddox

Steven A. Maddox
Jeremy J. Edwards
Brett M. Garrison
PROCOPIO
1901 L Street, NW
Suite 620
Washington, DC 20036
Tel.: 202.830.0707
Fax.: 202.830.0704

Counsel for Appellees

CERTIFICATE OF COMPLIANCE

This filing complies with the type-volume limitation of Federal Rule of Appellate Procedure 27(d)(2). This filing contains 3,503 words.

This brief 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). This brief has been prepared in a proportionally spaced typeface, 14-point Times New Roman font, using Microsoft Word 2016.

CERTIFICATE OF SERVICE

I hereby certify that on February 11, 2025, I electronically filed the foregoing with the Clerk of the Court for the United States Court of Appeals for the Federal Circuit using the Court's CM/ECF system. Counsel for all parties to the case are registered CM/ECF users and will be served by the CM/ECF system.

/s/ Steven A. Maddox
Steven A. Maddox