No. 24-1936

UNITED STATES COURT OF APPEALS
FOR THE FEDERAL CIRCUIT

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

Plaintiffs-Appellant,

v.

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

Defendants-Appellees.

On Appeal from the United States District Court for the District of New Jersey

Civil Action No. 23-cv-20964 (SRC), Judge Stanley R. Chesler

BRIEF OF 14 PROFESSORS OF MEDICINE AND LAW AS AMICUS CURIAE IN SUPPORT OF DEFENDANTS-APPELLEES' RESPONSE TO APPELLANTS' PETITION FOR REHEARING *EN BANC*

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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 Professors of Medicine and Law: William B. Feldman, M.D., D.Phil., M.P.H.; Aaron S. Kesselheim, M.D., J.D., M.P.H.; S. Sean Tu, J.D., Ph.D.

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.
4. Please do not duplicate entries within Section 5.
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 25, 2025

Signature: /s/ Kristen A. Johnson

Name: Kristen A. Johnson

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
William B. Feldman, M.D., D.Phil., M.P.H.		
Aaron S. Kesselheim, M.D., J.D., M.P.H.		
S. Sean Tu, J.D., Ph.D.		
See full list of signatories at Section 4.		

☐ 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

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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)

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

Supplement to FORM 9. Certificate of Interest

Counsel represents plaintiffs in *In re Lantus Direct Purchaser Antitrust Litig.*, No. 16-cv-12652-LTS, ECF No. 466 (D. Mass. Mar. 6, 2023), an unrelated case which involves allegations that Sanofi- Aventis U.S. LLC (Amici Curiae in the present case) improperly listed device patents in the Orange Book for Lantus SoloStar.

Dated: February 25, 2025

/s/ *Kristen A. Johnson*
Kristen A. Johnson

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I. IDENTITY AND INTEREST OF *AMICUS CURIAE* [1]

Amici are professors of law and medicine who focus their research and teaching on the drug approval process, pharmaceutical pricing and policy, patent law, and the use and health outcomes of prescription drugs. A full list of amici is referenced at Section IV.

The first three signatories, William B. Feldman, M.D., D.Phil., M.P.H., Aaron S. Kesselheim, M.D., J.D., M.P.H., and S. Sean Tu, J.D., Ph.D guided the research, drafting, and editing of this brief. S. Sean Tu, J.D., Ph.D is a faculty member at the West Virginia University College of Law.[2] William B. Feldman, M.D., D.Phil., M.P.H. and Aaron S. Kesselheim, M.D., J.D., M.P.H. are members of the Program on Regulation, Therapeutics, and Law ("PORTAL") and its parent organization, the Division of Pharmacoepidemiology and Pharmacoeconomics of Harvard Medical School and Brigham & Women's Hospital. PORTAL brings together researchers, analysts, and trainees from the fields of medicine, law, epidemiology, and health policy

[1] Amici and their counsel are the sole authors of this brief. No party or counsel for a party authored any piece of this brief or contributed any money intended to fund its preparation or submission. (Amici are William B. Feldman, M.D., D.Phil., M.P.H., Aaron S. Kesselheim, M.D., J.D., M.P.H., S. Sean Tu, J.D., Ph.D., Jerry Avorn, MD, Reed F. Beall, PhD, Robyn T. Cohen MD, MPH, Ravi Gupta, MD, MSHP, Thomas R. Radomski, MD, MS, Reshma Ramachandran, MD, MPP, MHS, Rita F. Redberg, Benjamin N. Rome, MD, MPH, Joseph Ross, MD, MHS, S. Christy Sadreameli, MD, MHS, Olivier J. Wouters, PhD. Counsel are Kristen A. Johnson and Lauriane Williams, Hagens Berman Sobol Shapiro LLP). Fed. R. App. P. 29(a)(4)(E). Further, all parties have consented to the filing of this brief. Fed. R. App. P. 29(a)(2).

[2] *See* https://www.law.wvu.edu/faculty-staff/faculty/s-sean-tu.

to critically evaluate emerging issues on the regulation, use, and reimbursement of therapeutics (prescription drugs and medical devices).[3] PORTAL is one of the largest non-industry-funded research centers in the US devoted to pharmaceutical use, costs, regulations and outcomes.[4] In recent years, the program has carried out a series of studies to better understand how pharmaceutical manufacturers develop their drug patent portfolios.

Amici submit this second brief to provide the Court with additional context to counter the exaggerated consequences Teva purports will result from this Court's well-reasoned decision, which aligns with the Hatch-Waxman framework and the public interest. Teva's predictions—that the ruling will upend the Orange Book and trigger a flood of litigation—are unfounded and do not support a rehearing *en banc*. Instead, the decision (while constrained to the facts of this case) may contribute to expunging a small set of improperly listed device-only patents that have delayed lower-cost generics and hindered access to life-saving medications.

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[3] *See* PORTAL Program on Regulation, Therapeutics, and Law, About PORTAL - PORTAL: Program on Regulation, Therapeutics, and Law (portalresearch.org).

[4] Testimony of William Feldman, *Patent Thickets and Product Hops: How Congress Could Reward Legitimate Innovation While Facilitating More Timely Generic Competition*, United States Senate Judiciary Committee May 21, 2024, 1–12 https://www.judiciary.senate.gov/imo/media/doc/2024-05-21_-_testimony_-_feldman.pdf at 3.

II. ARGUMENT

A. Teva amplifies purported consequences of the panel's decision, but even so cannot show a "question of exceptional importance."[5]

Amici's long-standing research reveals that Teva's petition for a rehearing *en banc* is largely grounded in exaggerated statements made to support its contention that the panel's holding "involves a question of exceptional importance."[6] Amneal describes, and Amici agree, Teva's argument is "little more than unsupported claims that the sky is falling on the Hatch-Waxman Act and pharmaceutical industry."

Teva's unsubstantiated statements do not warrant the extraordinary measure of a rehearing *en banc*. A question is of exceptional importance if it creates "important systemic consequences for the development of the law and the administration of justice."[7] The purported consequences Teva identifies to support the conclusion that these issues are of exceptional importance fail to meet this standard.

1. The panel's decision will not dramatically reshape the Orange Book.

Teva argues first that this panel's decision would cause "a seismic effect" and "shrink the Orange Book dramatically."[8] This outcome is simply not supported by the

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[5] Federal Rule of Appellate Procedure 40; IOP 13(2).

[6] Pet. 5–7.

[7] *Athena Diagnostics, Inc. v. Mayo Collaborative Servs., LLC*, 927 F.3d 1333, 1370 (Fed. Cir. 2019) (Stoll, K., Wallach, E, dissenting) (quoting *Watson v. Geren*, 587 F.3d 156, 160 (2d Cir. 2009)).

[8] Pet. at 2, 9.

research Amici has conducted for years.

It is true that *manufacturers*' improper listing of device-only patents have become widespread for several classes of drug-device combinations.[9] Amici's first *amicus curiae* brief,[10] filed at the merits stage, points to the prevalence of listing device-only patents as a strategy to delay generic competition among manufacturers of inhalers[11]—such as Teva's ProAir HFA— glucagon-like peptide-1 receptor agonists,[12] and insulin injector pens.[13] Drug products containing insulin, however, were removed from the

[9] Although Teva sets forth that "the decisions rejects decades of FDA practice" and that Amici became involved in this case because "[f]or years FDA has *permitted* manufacturers to list the types of patents at issue" resulting in widespread component patents, Pet. at 6 (emphasis added), the FDA's "ministerial role" confers upon it an *obligation* to print each year all the patents submitted by manufacturers. As such, FDA does not endorse patents or give "permission" to list. *See* FDA Report to Congress, *The Listing of Patent Information in the Orange Book* at 5 (Jan. 2022).

[10] ECF No. 67.

[11] Feldman WB, Bloomfield D, Beall RF, Kesselheim AS. *Patents And Regulatory Exclusivities on Inhalers for Asthma and COPD*, 1986-2020. Health Aff. (Millwood). June 2022; 41(6):787-96. doi:10.1377/hlthaff.2021.01874; Reddy S, Beall RF, Tu SS, Kesselheim AS, Feldman WB. *Patent Challenges and Litigation on Inhalers for Asthma and COPD. Health* Aff. (Millwood). Mar. 2023; 42(3):398–406. doi:10.1377/hlthaff.2022.00873.

[12] Alhiary R, Kesselheim AS, Gabriele S, Beall RF, Tu SS, Feldman WB., *Patents and Regulatory Exclusivities on GLP-1 Receptor Agonists. JAMA,* Aug. 15, 2023; 330(7):650-57. doi:10.1001/jama.2023.13872; Alhiary R, Gabriele S, Kesselheim AS, Tu SS, Feldman WB., *Delivery Device Patents on GLP-1 Receptor Agonists. JAMA*, Mar. 5, 2024; 331(9):794-96. doi:10.1001/jama.2024.0919.

[13] Olsen A, Beall RF, Knox RP, Tu SS, Kesselheim AS, Feldman WB. *Patents and regulatory exclusivities on FDA-approved insulin products: A longitudinal database study*, 1986–2019. PLoS Med. Nov. 2023; 20(11):e1004309. doi:10.1371/journal.pmed.1004309.

Orange Book as of March 23, 2020, given insulin's reclassification as a biologic.[14] And a review of all patents listed in the Orange Book from 1986 to 2024, which will be the basis for a forthcoming publication by Amici,[15] shows that although companies have impermissibly listed device patents on many classes of drugs—including transdermal patches, nasal sprays, ophthalmic implants, vaginal rings and other products—[16] these patents represent a very small fraction of overall patents listed in the Orange Book.

In its review, Amici applied a flexible definition of device patent to ensure it would capture an exhaustive variety of products—and included, for example, not just delivery device patents on inhalers, injector pens, transdermal patches, and implantable therapies but also patents on electronic tracking technology, nanotechnology, microparticles, and sustained release polymers in orally administered drugs. Even using that flexible definition, of the about 10,000 distinct patents listed in the Orange Book on products approved over the past 40 years, only roughly 10%

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[14] FDA, Press Release, Dec. 11, 2018, ("Biological products that have been approved under section 505 of the FD&C Act will be removed from the FDA's Orange Book on March 23, 2020, based on the agency's position that these products are no longer "listed drugs.") https://www.fda.gov/news-events/press-announcements/statement-fda-commissioner-scott-gottlieb-md-new-actions-advancing-agencys-biosimilars-policy.

[15] Teng T, Tu SS, Mooney H, Bendicksen L, Wouters OJ, Kesselheim AS, Feldman WB., *Tertiary patents on drug-device combinations approved by the FDA, 1985–2023*. (article in preparation).

[16] *Id.*

were device patents, of which around half (5%) were device-only patents.

The Court's holding will not dramatically reshape the Orange Book—it may, however, serve to help filter out the relatively few device-only patents that should never have been listed in the first place.

2. The panel's decision will not trigger a 'flood' of litigation.

Teva similarly raises overstated predictions that this decision will result in a flood of antitrust litigation, and that "FTC and private plaintiffs *will* threaten companies with antitrust liability if they do not immediately delist (or if they continue to list) patents that could be delisted *under this Court's decision*."[17]

Yet, despite this apparent newfound opportunity for antitrust enforcers,[18] challenges to these improperly listed patents have not been given a grand potential with this panel's decision—they have already occurred and are limited.

FTC, as Teva points out, *has* "been threatening antitrust liability" on manufacturers that improperly list device-only patents. In September 2023, the FTC issued a policy statement that warned it would be scrutinizing the improper

[17] Pet. 2–3 (emphasis added).

[18] Previous arguments about a theoretical "flood of litigation" have not been well received by this Court. *See Ritz Camera & Image, LLC v. SanDisk Corp.*, 700 F.3d 503, 508 (Fed. Cir.2012) (quoting *Walker Process Equip., Inc. v. Food Mach. & Chem. Corp.*, 382 U.S. 172 (1965).

submission of patents for listing in the Orange Book.[19] On November 7, 2023, FTC issued a press release announcing they challenged "more than 100 patents as improperly listed in the FDA's Orange Book" by sending notice letters to ten drug manufacturers. FTC also notified FDA that it disputes the accuracy or relevance of the listed information for these patents, "which may require that the manufacturers remove the listing or certify under penalty of perjury that the listings comply with applicable statutory and regulatory requirements."[20] The patents identified by the FTC included "specific asthma and other inhaler devices."[21] In early 2024, FTC announced that "Kaleo Inc., Impax Labs, GlaxoSmithKline, and Glaxo Group delist[ed] patents in response to FTC's [November] warning letters," and resulted in "AstraZeneca, Boehringer Ingelheim, and GlaxoSmithKline [announcing] commitments to cap inhaler out-of-pocket costs at $35."[22]

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[19] Federal Trade Commission, *Federal Trade Commission Statement Concerning Brand Drug Manufacturers' Improper Listing of Patents in the Orange Book*, https://www.ftc.gov/system/files/ftc_gov/pdf/p239900orangebookpolicystatement092023.pdf

[20] Federal Trade Commission, *FTC Challenges More Than 100 Patents as Improperly Listed in the FDA's Orange Book* (Nov. 7, 2023), https://www.ftc.gov/news-events/news/press-releases/2023/11/ftc-challenges-more-100-patents-improperly-listed-fdas-orange-book.

[21] *Id.*

[22] Federal Trade Commission, *FTC Expands Patent Listing Challenges, Targeting More Than 300 Junk Listings for Diabetes, Weight Loss, Asthma and COPD Drugs* (Apr. 30, 2024), https://www.ftc.gov/news-events/news/press-releases/2024/04/ftc-expands-patent-listingchallenges-targeting-more-300-junk-listings-diabetes-weight-loss-asthma.

Similarly, private plaintiffs have *already* taken action to delist those patents, with only three wrongful listing cases or similar filed over the last eight years, involving the drugs Lantus SoloStar (insulin glargine in an injector pen), Qvar (beclomethasone in an inhaler), and Actos (pioglitazone).[23] Setting aside that statutes of limitations likely precludes antitrust liability for a majority of these wrongfully listed patents, two of these three cases resulted in rulings from the First and Second Circuits consistent with this panel's holding,[24] the earlier of which issued in 2020. Teva warns of a deluge of litigation—which potential *already* existed—that simply has not and will not happen.

In short, the panel's decision does not signal an industry-wide upheaval or a tsunami of litigation—and thus does not support Teva's basis for its claim that this decision is a question of exceptional importance. Instead, this court's panel is simply the most recent actor, after the First and Second Circuit and the FTC, to take action against the improper listing of device-only patents in the Orange Book.

B. The panel's decision supports important public policy and public interest and need not be revisited.

Amici filed a brief with this Court at the merits stage to emphasize the far-reaching impact of improperly listing device-only patents, including consequences

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[23] *Iron Workers District Counsel of New England Health and Welfare Fund et al. v. Teva Pharmaceutical Industries Ltd. et al,* 1:23-cv-11131, ECF No. 31 (D. Mass); *see*, *infra*, n. 23.

[24] *In re Lantus Direct Purchaser Antitrust Litig.*, 950 F.3d 1, 10 (1st Cir. 2020); *United Food & Com. Workers Loc. 1776 & Participating Emps. Health & Welfare Fund v. Takeda Pharm. Co. Ltd.*, 11 F.4th 118, 134–36 (2d Cir. 2021).

ranging from violating the Hatch-Waxman regime to harming patients.[25] Teva argues that "the panel has now upended Congress's and FDA's understanding, threatening instability and material harm to the Hatch-Waxman regime."[26] But the public policy goals of the Hatch-Waxman Act include: "getting safe and effective generic substitutes on the market as quickly as possible after the expiration of the patent."[27] Teva similarly mischaracterizes that FDA has an "understanding" that manufacturers may list the patents at issue here.[28] According to FDA "if the patent claims the drug product as defined in § 314.3, the patent must be submitted for listing," "Section 314.3 defines a 'drug product' as '* * * a finished dosage form, for example, tablet, capsule, or solution, that contains a drug substance, generally, but not necessarily, in association with one or more other ingredients,'" and "[t]he key factor is whether the patent being submitted claims the finished dosage form of the approved drug product."[29] FDA's understanding, in fact, is in line with this panel's decision. And, as discussed above, FDA has never endorsed or "permitted" manufacturers to list device patents.[30]

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[25] ECF No. 67.

[26] Pet. at 6.

[27] H.R. Rep. No. 98-857, pt. 2, 98th Cong. 2d sess. 9 (1984).

[28] Pet. at 5.

[29] FDA response to 2003 comments, FDA 2003 Final Rule, 68 Fed. Reg. at 36,680.

[30] *See, supra,* § II, n.9.

An amicus brief submitted in support of Teva suggests that this panel's decision "undermines Hatch-Waxman," harms generic and brand manufacturers,[31] and, "by extension," patients.[32] The opposite is true. Delisting device patents will have positive outcomes for patients. This Court's finding ensures that improperly listed patents will not delay access to lower-cost generic alternatives. This is especially critical for life-saving, chronic medications such as inhalers.[33] Submitting patents for listing in the Orange Book and suing the generic manufacturer who chooses to challenge those patents generates an automatic 30-month stay that prevents the FDA from approving the generic for two-and-a-half years.[34] These 30-month stays also give the brand-name firm leverage to extract favorable settlements that are detrimental for patients.

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[31] Removing impermissibly listed patents could push drug manufacturers towards more meaningful innovation. Minor patent-protected tweaks on delivery devices currently allow manufacturers to earn billions of dollars in extended revenue on their products (as seen, for example, in the case of inhalers). *See* Feldman WB, Tu SS, Alhiary R, Kesselheim AS, Wouters OJ., *Manufacturer Revenue on Inhalers After Expiration of Primary Patents*, 2000–2021. *JAMA*. Jan. 3 2023; 329(1):87-89.doi:10.1001/jama.2022.19691; Wouters OJ, Feldman WB, Tu SS. *Product Hopping in the Drug Industry - Lessons from Albuterol.* New Eng. J. Med., Sept. 29 2022; 387(13):115356. doi:10.1056/NEJMp2208613; Feldman WB., *How the makers of inhalers keep prices so high*, https://www.washingtonpost.com/opinions/2023/06/01/inhaler-cost-drug-company-prices/.

[32] Pet. at 7, 10.

[33] Edwards J., *Man dies of asthma attack after inhaler cost skyrockets to more than $500*, https://www.washingtonpost.com/business/2025/02/10/inhaler-cost-death-optum-rx-walgreens/.

[34] 21 U.S.C. § 355(c)(3)(C) (NDAs); 21 U.S.C. § 355(j)(5)(B)(iii) (ANDAs).

III. CONCLUSION

Far from the catastrophic upheaval Teva predicts, this decision realigns the patent system with Congressional intent and the public interest—paving the way for genuine innovation and improved access to life-saving medications. Teva's petition for rehearing *en banc* should be denied.

IV. SIGNATORIES[35]

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Dated: February 25, 2025

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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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Name: Kristen A. Johnson

CERTIFICATE OF SERVICE

I hereby certify that I electronically filed the foregoing on the Court's CM/ECF system, which will send a notification of such filing to counsel of record.

Dated: February 25, 2025

/s/ Kristen A. Johnson
Kristen A. Johnson