No. 22-37

IN THE

Supreme Court of the United States

TEVA PHARMACEUTICALS USA, INC.,

Petitioner,

v.

GLAXOSMITHKLINE LLC AND
SMITHKLINE BEECHAM (CORK) LIMITED,

Respondents.

ON PETITION FOR WRIT OF CERTIORARI
TO THE UNITED STATES COURT OF APPEALS
FOR THE FEDERAL CIRCUIT

BRIEF OF 42 PROFESSORS OF LAW, ECONOMICS, BUSINESS, AND MEDICINE AS *AMICI CURIAE* IN SUPPORT OF THE PETITION

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INTEREST OF *AMICI CURIAE*

Amici curiae[1] are 42 professors of law, economics, business, and medicine. A list of signatories is attached in Appendix A. Their sole interest in this case is to ensure that patent law develops in a way that serves the public interest and public health by promoting competition.

SUMMARY OF ARGUMENT

The Federal Circuit's construction of inducement of patent infringement creates two serious conflicts with the federal statute on generic drug entry, in a way that is likely to be exploited widely in years to come to the detriment of United States health care, competition, and the federal government. Certiorari is warranted.

1. By permitting inducement of patent infringement to be premised on the content of a generic drug's approved labeling text, the Federal Circuit's decision creates two conflicts with the Hatch–Waxman statutory scheme on generic drug entry. First, Hatch–Waxman carefully balances the interests of drug patent holders, generic entrants, and the public. Key to that balance are the two distinct pathways for generic entrants to deal with drug patents during the regulatory approval process. The Federal Circuit's decision renders all but unusable one of those two pathways, the "skinny-label carve-

[1]Pursuant to Supreme Court Rule 37.2(a), all parties received appropriate notice of and consented to the filing of this brief. Pursuant to Rule 37.6, no counsel for a party authored this brief in whole or in part, and no counsel or party made a monetary contribution intended to fund the preparation or submission of the brief. No person or entity, other than *amici*, their members, or their counsel, made a monetary contribution to the preparation or submission of this brief.

out" procedure at the heart of this case, upsetting the legislatively designed balance.

Second, the Federal Circuit decision creates the untenable situation where Hatch–Waxman requires what patent law now prohibits. Under Hatch–Waxman, a generic drug is required to use the same labeling text as its patented counterpart product with only limited exceptions. But the Federal Circuit requires intricate, detailed editing of generic drug labels to avoid inducement—edits that the Food and Drug Administration ("FDA") likely and rightly would deem statutorily noncompliant. This bizarre double-bind cannot be correct as a matter of law.

2. Resolving these conflicts is not just necessary for the proper functioning of the law—it is a matter of tremendous national importance. As we find based on review of the FDA drug patent records, the number of method-of-use patents has exploded in recent decades. Under the Federal Circuit's decision, this mass of patents could be leveraged to stymie generic competition for years to come, greatly raising costs for American patients and the federal government. Certiorari is required to resolve the unnecessary statutory conflicts that the Federal Circuit has created, conflicts with major consequences for the American public.

ARGUMENT

I. The Federal Circuit Decision Creates a Statutory Conflict

In holding FDA-approved language in a generic drug label to be the basis for inducement under 35 U.S.C. § 271(b), the Federal Circuit created two distinct conflicts with the statutory regime for generic drug entry. *See* Hatch–Waxman Act, Pub. L. No. 98-417, 98 Stat. 1585

(1984). It rendered unusable half of the intricate two-pronged pathway for addressing patents in labels, and it made compliance with both the statute and patent law potentially impossible. This Court's review is required to resolve these conflicts.

A. The Decision Undermines Key Balance Provisions of the Hatch–Waxman Act

The decision conflicts with the balanced statutory scheme that Congress constructed in Hatch–Waxman. By design, the landmark statute of 1984 struck a balance between drug patent holders and generic manufacturers, in order to promote the entry of "low-cost, generic drugs for millions of Americans" and save American patients, states, and the federal government millions of dollars every year. 130 Cong. Rec. 24427 (1984) (statement of Rep. Henry Waxman); *see also* Michael A. Carrier, *Unsettling Drug Patent Settlements: A Framework for Presumptive Illegality*, 108 Mich. L. Rev. 37, 42 (2009). That balance is apparent throughout the legislation. For example, patent-holding drug innovators enjoy extensions of patent term and additional market exclusivity, *see* 35 U.S.C. § 156(c), (g)(6); Federal Food, Drug, and Cosmetics Act (FFDCA) § 505(j)(5)(F)(ii), (B)(iii), 21 U.S.C. § 355, while generic firms are granted incentives for challenging questionable patents and a simplified approval process at the FDA known as an Abbreviated New Drug Application ("ANDA"), *see* FFDCA § 505(j)(2), (5)(B)(iv).

Key to this balance is Hatch–Waxman's intricate, two-pronged procedure for early resolution of patent issues during the generic approval process. Innovator firms must notify the FDA of patents relevant to their products. *See* FFDCA § 505(b)(1)(viii). If a generic firm seeks

approval of a drug having an in-force patent, the generic's ANDA must choose one of two options.

Under the first, called the "paragraph IV certification," the ANDA includes a certification alleging that the patent is invalid or not infringed. Paragraph IV is considered a "risk" to the generic applicant, due to "the hazard of sparking costly litigation." *Teva Pharm. USA, Inc. v. Sebelius*, 595 F.3d 1303, 1305 (D.C. Cir. 2010). The generic applicant must notify the patent holder of its application for approval, FFDCA § 505(j)(2)(B), the application is deemed a constructive act of infringement triggering immediate cause for a patent lawsuit, *see* 35 U.S.C. § 271(e)(5), and if litigation ensues, approval of the generic is stayed for up to 30 months, FFDCA § 505(j)(5)(B)(iii). To encourage generics to use this option despite the cost, Hatch–Waxman offers the first ANDA applicant a 180-day exclusivity period over other generics. *See* FFDCA § 505(j)(5)(B)(iv).

The alternative, called the "section viii carve-out" or colloquially the "skinny label," is reserved for patents on methods of using a drug. *See id.* § 505(j)(2)(A)(viii). Under this option, the generic drug's proposed labeling omits, to the FDA's satisfaction, uses of the drug that would infringe the method-of-use patent. *See id.*; *Caraco Pharm. Labs., Ltd. v. Novo Nordisk A/S*, 566 U.S. 399, 406 (2012). Section viii does not trigger the immediate consequences of paragraph IV: The ANDA applicant need not notify the patent holder, the 30-month stay does not apply, and a carve-out application does not give rise to constructive infringement and cause for immediate suit. *See AstraZeneca Pharm. LP v. Apotex Corp.*, 669 F.3d 1370, 1377–78 (Fed. Cir. 2012) (citing *Warner-Lambert Co. v. Apotex Corp.*, 316 F.3d 1348, 1356–60 (Fed. Cir. 2003)).

These features of the section viii carve-out evince a legislative intent to provide certainty: a well-defined procedure for generics to obtain approval on an otherwise off-patent drug covered by method-of-use patents, "so that a product . . . can quickly come to market." *Caraco*, 566 U.S. at 415. The immediate litigation consequences of paragraph IV are not needed for section viii because a carve-out of a method of use, double-checked in the approval process, provides certainty to the generic applicant and the FDA that the drug and its labeling do not infringe. *See id.* at 405 ("[T]he FDA cannot authorize a generic drug that would infringe a patent."). It is this certainty that makes section viii "an attractive route for generic manufacturers." *Purepac Pharm. Co. v. Thompson*, 354 F.3d 877, 880 (D.C. Cir. 2004); *see* Shashank Upadhye, *Generic Pharmaceutical Patent and FDA Law* § 26:11 (2020).

The Federal Circuit's decision eviscerates half of this balanced scheme. By allowing an inducement claim to proceed to damages here, the Federal Circuit puts every generic drug manufacturer using a carved-out label at risk of similar claims. Even for unmeritorious inducement claims, the time and expense of litigating those claims—combined with the risk of lost-profit damages exceeding the generic firm's revenues, as happened in the present case—render the certainty of section viii a nullity.

Hatch–Waxman's drafters almost certainly did not intend for one of its two distinct pathways for patent resolution to be carved out of the statute, but the Federal Circuit's decision has done so. Certiorari is warranted to resolve this conflict between patent law and Hatch–Waxman.

B. The Decision Holds Patent Law to Prohibit what Hatch–Waxman Requires

The Federal Circuit's reading of inducement conflicts with Hatch–Waxman in another way: It prohibits under patent law activity that the generic approval statute mandates. Under that statute, an ANDA can only be approved if the labeling for the generic drug under consideration is "the same as the labeling approved for" the patent-holding innovator firm's equivalent product. FFDCA § 505(j)(2)(A)(v); *accord* 21 C.F.R. § 314.127(a)(7). But the import of the Federal Circuit's decision is that generic applicants must revise their labels to avoid inducement liability. That decision thus creates a serious dilemma of satisfying both Hatch–Waxman's same-labeling requirement and § 271(b)'s different-labeling requirement.

To be sure, the statute and the FDA make allowances for labeling edits in view of section viii carve-outs, but only to the extent that the FDA agrees that "such differences do not render the proposed drug product less safe or effective." 21 C.F.R. § 314.127(a)(7). This is straightforward when whole sections on drug indications are omitted, but the Federal Circuit seemingly required more: detailed, intricate, scattered line edits across the labeling, including in sections on dosage and administration. Such edits would almost certainly prompt the FDA to question safety and efficacy under the whittled-down label. *See* Ctr. for Drug Evaluation & Research, FDA, *ANDA Submissions—Refuse-to-Receive Standards* 13 (2d rev. Dec. 2016), *available online* (describing dosing regimen alterations as reason for the FDA to reject an ANDA).[2]

[2]Locations of authorities available online are shown in the Table of Authorities.

And given that the patent-holding drug manufacturer itself writes the text of the labeling that generics must copy, it has every incentive to draft that text cleverly such that edits to avoid inducement will prompt an FDA rejection.

The conflict arises because the Federal Circuit failed to interpret § 271(b) in the context of Hatch–Waxman "in a way that preserves the purposes of both." *Zenith Elecs. Corp. v. Exzec, Inc.*, 182 F.3d 1340, 1347 (Fed. Cir. 1999) (quoting *Vornado Air Sys. v. Duracraft Corp.*, 58 F.3d 1498, 1507 (10th Cir. 1995)). *SmithKline Beecham Consumer Healthcare, LP v. Watson Pharmaceuticals, Inc.* presents an instructive contrast. There, the Second Circuit considered whether a generic drug label, being identical in text to that of the reference product, was an infringement of copyright. *See* 211 F.3d 21, 23–24 (2d Cir. 2000). The generic manufacturer in fact had attempted to revise the label to avoid copyright concerns, but the FDA rejected the proposed alterations, requiring virtually identical label text in view of Hatch–Waxman's same-labeling requirement. *See id.* at 24. Determining that "[t]he purposes of the Hatch–Waxman Amendments would be severely undermined if copyright concerns were to shape the FDA's application of the 'same' labeling requirement," the Second Circuit declined to hold the generic label an infringement of copyright. *Id.* at 29. Given that Hatch–Waxman was later in time, more specific, and more likely to have its purposes frustrated, the court concluded that the Copyright Act was required to yield, such that copying of drug labels for ANDA approvals was noninfringing. *See id.* at 28 & n.3.

For analogous reasons, there is a serious question of how the panel's construction of § 271(b) interacts with

Hatch–Waxman. Scattered editing throughout a label to avoid inducement, like editing of labels to avoid copyright infringement, does not simply create a risk of the FDA rejecting the label but also frustrates the purposes behind the same-labeling requirement itself, namely conserving FDA resources and enabling speedy introduction of generic drugs. *See SmithKline*, 211 F.3d at 28.[3] And as with the Copyright Act, § 271(b) is older in time and far broader in scope than Hatch–Waxman.

Despite this stark incompatibility between the Federal Circuit's construction of § 271 and the same-labeling requirement of Hatch–Waxman, despite the damaging double-bind for generic drug entrants that it creates, and despite nearly every Federal Circuit judge's acknowledgment of the statutory discrepancy, the appellate court failed to rectify or even address the conflict. This Court should do so.

II. Resolving the Conflict Is Important

Petitioner notes the many serious economic and individual harms that would result from letting the Federal Circuit's decision stand, for patients, individuals, competition, and the federal government. These harms are the result of the decision's potential to cut off the tremendous economic, health, and welfare boon that generic drug competition has offered. *See, e.g.*, Gov't Accountability Office,

[3] *Syngenta Crop Protection, LLC v. Willowood, LLC* is distinguishable because this Court found that the statute at issue there "does not require a me-too applicant to ensure that its product label is identical." 944 F.3d 1344, 1357 (Fed. Cir. 2019). Importantly, the *Syngenta* court agreed that Hatch–Waxman differed from that statute in that the former "requires" same-labeling, such that "generic applicants faced a double-bind." *Syngenta*, 944 F.3d at 1357 & n.4 (quoting *SmithKline*, 211 F.3d at 25).

Report GAO-12-371R, Drug Pricing: Research on Savings from Generic Drug Use 4 (Jan. 31, 2012), *available online* (finding savings of over $1 trillion over 12 years due to generic drugs). To provide insight into the breadth of those harms, *amici* present empirical data on the potential volume of patent litigation to which the Federal Circuit has opened the door.

We use data from the FDA's annual listing of patents on approved drugs, published in *Approved Drug Products with Therapeutic Equivalence Evaluations*, colloquially known as the "Orange Book."[4] The listing identifies, for each drug product approved as of the year of publication, all patents that the product's manufacturer has identified as covering the product. For patents directed to methods of using the product, the listing also identifies a "use code," which we use to distinguish method-of-use patents from patents directed to the drug product as a whole.

The 1988 Orange Book listed 340 unique patents and 61 distinct use codes. Method-of-use patents were generally rare: The average Orange Book patent in 1988 identified 0.18 use codes. By 2019, however, method-of-use patents were prevalent. There were 7,919 distinct codes listed in the Orange Book, for 4,790 unique patents. The average patent in 2019 was associated with 1.65 use codes—over a ninefold increase compared to 1988.

The number of use codes associated with an active ingredient also provides a useful metric for the effect of the Federal Circuit's decision. As of 2019, each active ingredient listed in the Orange Book was associated with 3.17 use

[4] *See* Food & Drug Admin., *Approved Drug Products with Therapeutic Equivalence Evaluations (the Orange Book)* (42d ed. 2022), *available online.*

codes on average. This is almost a fivefold increase from 2001, when the average active ingredient had 0.70 use codes. Put another way, the average generic firm seeking to enter the market will have to contend, on average, with slightly over three potential allegations of inducement of patent infringement. Each allegation could result in substantial litigation costs, delays, and damages.[5]

This substantial increase in method-of-use patents suggests that a large number of generic drugs may be at risk of accusations of violating § 271(b) in view of the Federal Circuit's decision. More importantly, the large number of method-of-use patents in force today means that drug patent holders have a tremendous arsenal for frustrating generic entry. The patented drugs that skinny-label generics typically compete with reap millions of dollars in revenue *per day*,[6] so those drugs' patent holders have every incentive to engage in costly, time-consuming inducement litigation to the fullest extent. Saddling the lion's share of future generic entrants with this litigation, indeed likely deterring them from entering markets at all, will have costs measured not just in billions of dollars but also in human lives.[7]

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[5] A single patent may have several associated use codes, but since each of those use codes could give rise to a distinct theory of patent infringement that the generic firm will have to litigate, it is more appropriate to count the number of use codes rather than distinct patents.

[6] *See* Bryan S. Walsh et al., *Frequency of First Generic Drug Approvals With "Skinny Labels" in the United States*, 181 JAMA Internal Med. 995, 995 (2021); *see also* Lisa Urquhart, *Top Companies and Drugs by Sales in 2021*, 21 Nature Reviews: Drug Discovery 251, 251 (2022) (noting multi-billion dollar annual revenues on multiple drugs).

[7] *See* Xcenda AmersourceBergen, *Modeling the Population Outcomes of Cost-Related Nonadherence: Model Report* 13 tbl.6 (2020), *available online*.

Such costs are the unnecessary result of a Federal Circuit decision that ignores conflicts with federal statutes and stymies the generic drug entry scheme. Resolving this case and these errors of statutory interpretation is a matter of immediate national importance.

CONCLUSION

For the foregoing reasons, the petition for a writ of certiorari should be granted.

Respectfully submitted,

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[8]The brief presents the views of the individual signers. Institutions are listed for identification purposes only.

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