No. 18-1976, -2023

UNITED STATES COURT OF APPEALS
FOR THE FEDERAL CIRCUIT

GLAXOSMITHKLINE LLC and SMITHKLINE BEECHAM (CORK) LIMITED,

Plaintiffs-Appellants,

v.

TEVA PHARMACEUTICALS USA, INC.,

Defendant-Cross-Appellant.

Appeal from the U.S. District Court for the District of Delaware (Stark, C.J.)
No. 1:14-cv-00878-LPS-CJB

BRIEF OF AMICUS CURIAE FORMER CONGRESSMAN HENRY A. WAXMAN IN SUPPORT OF PETITION FOR REHEARING EN BANC

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Pursuant to Federal Circuit Rule 47.4, a completed Federal Circuit Form 9 has been filed along with this brief.

STATEMENT OF INTEREST[1]

Congressman Henry Waxman served on the U.S. House of Representatives' Committee on Energy and Commerce for his entire 40-year tenure in Congress, as Chair of its Subcommittee on Health and the Environment from 1979 to 1994, and as Chair of the Committee from 2008 to 2010. He has been described as "one of the most accomplished legislators of our time" with "remarkable legislative records in domains in which science is important, including health care and regulatory policy."[2]

One of Congressman Waxman's most significant accomplishments was the Drug Price Competition and Patent Term Restoration Act of 1984 (Hatch-Waxman Act), Pub. L. No. 98-417, 98 Stat. 1585 (1984), a landmark statute that created the modern generic drug industry. Congressman Waxman is submitting this brief in support of Teva Pharmaceuticals USA's petition for rehearing en banc because he believes both that the Majority's decision in this case is flatly inconsistent with the language of the Act and congressional intent, and that unless overturned it will have

[1] Under Federal Rule of Appellate Procedure 29(a)(4)(E), amicus curiae certifies that no party's counsel authored this brief in whole or in part; no party or party's counsel contributed money that was intended to fund preparing or submitting the brief; and no person—other than the amicus curiae, its members, or its counsel—contributed money that was intended to fund preparing or submitting the brief.

[2] Harold Varmus, *Winning Arguments on Capitol Hill*, 461 Nature 730, 730–31 (Oct. 8, 2009).

a devastating impact on the Hatch-Waxman Act's generic drug program, which has saved patients, the federal government, and other payers trillions of dollars.

ARGUMENT

Following extensive negotiations that included representatives of industry and consumers, in 1984 Congressman Waxman and Senator Orrin Hatch agreed to a grand compromise "between two competing sets of interests: those of innovative drug manufacturers, who had seen their effective patent terms shortened by the testing and regulatory processes; and those of generic drug manufacturers, whose entry into the market upon expiration of the innovator's patents had been delayed by . . . regulatory requirements." *Warner-Lambert Co. v. Apotex Corp.*, 316 F.3d 1348, 1358 (Fed. Cir. 2003).

For more than 35 years, the Hatch-Waxman Act has been instrumental in maintaining the availability of generic drugs. "Prior to the law, 35% of top-selling drugs had generic competitors after patent expiration; now almost all do."[3] By 2019, generic drugs comprised 90% of prescriptions filled in the United States, saving $313 billion, including $96.1 billion in Medicare savings and $48.5 billion in Medicaid savings.[4] The Majority decision in this case threatens to destroy the hard-

[3] Wendy H. Schacht & John R. Thomas, *The Hatch-Waxman Act: A Quarter Century Later*, Cong. Research Serv. 5 (Mar. 13, 2012).

[4] *Securing Our Access & Savings: 2020 Generic Drug & Biosimilars Access & Savings in the U.S. Report*, Ass'n for Accessible Medicines, 16, 20 (2020),

fought compromise at the heart of the Hatch-Waxman Act, undermining the availability of less expensive but equally safe and effective generic medicines.

A. Congress Considered the Scenario Presented in this Case and Passed Comprehensive Legislation Intended to Account for It.

"[I]n every case [courts] must respect the role of the Legislature, and take care not to undo what it has done. A fair reading of legislation demands a fair understanding of the legislative plan." *King v. Burwell*, 576 U.S. 473, 498 (2015). Congress passed the Hatch-Waxman Act after years of consideration and extensive negotiations. In reducing this agreement to legislative language, Congress attempted to foresee and close as many loopholes as possible. While it is never possible to foresee every potential way private parties may find to avoid the intent of the sponsors of legislation, in this case Congress anticipated the very scenario at issue and addressed it in legislative text. The Majority decision ignores this fact and, in so doing, directly undermines Congress's careful and considered "legislative plan."

1. *Background on the Hatch-Waxman Compromise*

"The road to Hatch-Waxman began decades before its enactment."[5] This was no haphazard, slapdash legislation; rather, it was a thoughtfully constructed and

https://accessiblemeds.org/sites/default/files/2020-09/AAM-2020-Generics-Biosimilars-Access-Savings-Report-US-Web.pdf.

[5] Rachel Sachs, *The New Model of Interest Group Representation in Patent Law*, 16 Yale J. L. & Tech. 344, 379 (2014); *see also, e.g.*, Ellen J. Flannery & Peter Barton Hutt, *Balancing Competition and Patent Protection in the Drug Industry:*

lengthily debated policy enactment, designed to resolve specific and significant problems. The Act "was designed to respond to two unintended distortions of the 17-year patent term [that existed in 1984,] produced by the requirement that certain products must receive premarket regulatory approval." *Eli Lilly and Co. v. Medtronic Inc.*, 496 U.S. 661, 669 (1990).

Senator Hatch, with the interests of brand pharmaceuticals and innovative drug development in mind, sought to resolve the first of the two issues, which "arose from the fact that an inventor ordinarily applies for patent protection for newly discovered drugs, or for methods for the use of new or existing drugs, well before securing regulatory approval." *Warner-Lambert*, 316 F.3d at 1357. Congressman Waxman, with the interests of the generic drug industry and lower drug prices in mind, sought to resolve the second issue, which "inhered in the need for a generic manufacturer . . . to provide its own safety and efficacy data," which was often prohibitively expensive, resulting "in a *de facto* extension of the patent term." *Id.*

The Hatch-Waxman Act gave brand sponsors patent extensions of up to five years and provided that "[g]eneric copies of any drugs may be approved if the generic is *the same as the original drug* or so similar that FDA has determined the differences do not require safety and effectiveness testing." H.R. Rep. No. 98-857(I)

The Drug Price Competition and Patent Term Restoration Act of 1984, 40 Food Drug Cosmetic L. J. 269, 271–76 (1985).

at 14–15 (emphasis added). The Act also established a regulatory scheme where there would be no gap between the expiration of applicable patents and the marketing of the generic version of the brand drug. Thus, it "provides that it is not an act of patent infringement for a generic drug maker to import or to test a patented drug in preparation for seeking FDA approval if marketing of the drug would occur after expiration of the patent." *Id.* at 15; *see also* 35 U.S.C. § 271(e)(1).

Finally, the Act provides that one of the four certifications that generic sponsors may file in support of their application is a Paragraph IV certification asserting that one or more of the brand's patents is invalid or will not be infringed. *See* 21 U.S.C. § 355(j)(2)(A)(vii)(IV). Congress made the generic's filing of the application for approval with a Paragraph IV certification an artificial act of infringement, allowing litigation over the validity of the patent before the generic drug reaches the market. *See* 35 U.S.C. § 271(e)(2)(A). In other words, the overall design of the statute is to give name-brand companies patent term extensions while giving generic companies a regulatory system that allows their drugs to be marketed immediately upon expiration of patents, or sooner in certain circumstances where patents are contested.

The Hatch-Waxman Act passed unanimously in the House and by voice vote in the Senate.[6] Congress intended for the Act to be as comprehensive as possible and

[6] Sachs, *supra* n.5, at 382.

to eliminate the loopholes Congress could foresee. This case involves just such a scenario, which Congress anticipated and accounted for in the statute.

2. *Congress Anticipated and Addressed the Issue Raised in this Case*

Importantly, in establishing this comprehensive regulatory scheme, Congress considered what would happen if a generic drug entered the market after a patent had expired but where one or more of the product's uses still remained under patent—just as occurred here. *See GlaxoSmithKline LLC v. Teva Pharm. USA, Inc.*, 976 F.3d 1347, 1359 (Fed. Cir. 2020) (Prost, C.J., dissenting) ("Congress contemplated the very circumstances this case presents, and plainly intended for the opposite outcome."). To address this situation, Congress adopted section viii of section 355(j)(2)(A), 21 U.S.C. § 355(j)(2)(A)(viii).

In this situation, Congress provided that the generic applicant may make a "section viii statement." In providing for such a procedure, "Congress recognized that a single drug could have more than one indication and yet that the [generic] applicant could seek approval for less than all of those indications." *Warner-Lambert*, 316 F.3d at 1360; *see also* H.R. Rep. No. 98-857(I) at 22 (explaining that a "listed drug may be approved for two indications. If the [generic] applicant is seeking approval only for Indication No. 1, and not Indication No. 2 because it is protected by a use patent, then the applicant must make the appropriate certification and a statement explaining that it is not seeking approval for Indication No 2").

If a company seeks approval for a method of use for a generic drug in such a scenario, "it will propose labeling for the generic drug that 'carves out' from the brand's approved label the still-patented methods of use." *Caraco Pharm. Labs., Ltd. v. Novo Nordisk A/S*, 566 U.S. 399, 405 (2012) (citing 21 C.F.R. § 314.94(a)(8)(iv)). Such a label is commonly referred to as a "skinny label." From there, "[t]he FDA may approve such a modified label as an exception to the usual rule that a generic drug must bear the same label as the brand-name product." *Id.* (citing 21 C.F.R. § 314.127(a)(7); 21 U.S.C. §§ 355(j)(2)(A)(v), (j)(4)(G)). Critically, "FDA acceptance of the carve-out label allows the generic company to place its drug on the market . . . , but only for a subset of approved uses—*i.e.*, those not covered by the brand's patents." *Id.*

Congress thus plainly anticipated the exact situation involved in this case, as has been recognized by both this Court and the Supreme Court. "[A]s Congress understood[], a single drug may have multiple methods of use, only one or some of which a patent covers. The Hatch-Waxman [Act] authorize[s] the FDA to approve the marketing of a generic drug for particular unpatented uses; and section viii provides the mechanism for a generic company to identify those uses, *so that a product with a label matching them* can quickly come to market." *Id.* At 414–15 (emphasis added). As the Supreme Court has stated, "[t]he statutory scheme, in other words, contemplates that one patented use will not foreclose marketing a generic

drug for other unpatented ones." *Id.* at 415; *see also Takeda Pharm. U.S.A., Inc. v. West-Ward Pharm. Corp.*, 785 F.3d 625, 630 (Fed. Cir. 2015); *Warner-Lambert*, 316 F.3d at 1360.

In addition, Congress also knew that once a drug is approved, even if only for limited uses, physicians may prescribe the drug for any use (including unapproved uses). In fact, two years prior to passage of the Hatch-Waxman Act, the FDA had clarified that the Food, Drug, and Cosmetic Act "does not, however, limit the manner in which a physician may use an approved drug. Once a product has been approved for marketing, *a physician may prescribe it for uses or in treatment regimens or patient populations that are not included in approved labeling*." 12 FDA Drug Bulletin 1, 4–5 (April 1982), http://www.circare.org/fda/fdadrugbulletin_041982.pdf (emphasis added). Indeed, "[o]ff-label use is not only legal and ethical, but is a common and integral feature of medical practice."[7]

B. The Majority Decision Goes Against the Statute and Will Have Major, Adverse Implications.

The Majority's decision cannot be reconciled with the plain statutory text and congressional intent. That decision allows proof of induced patent infringement

[7] James M. Beck & Elizabeth D. Azari, *FDA, Off-Label Use, and Informed Consent: Debunking Myths and Misconceptions*, 53 Food & Drug L. J. 71, 79 (1998).

every time a generic uses a skinny label. *See GlaxoSmithKline LLC*, 976 F.3d at 1366 (Prost, C.J., dissenting) ("By finding inducement based on Teva's skinny label, which was not indicated for—and did not otherwise describe—the patented method, the Majority invites a *claim of inducement* for almost *any generic* that legally enters the market *with a skinny label*. That is directly contrary to Congress's intent.") (emphasis in original).

In a similar context, this Court held that allowing a name-brand pharmaceutical company to prove induced infringement based *only* on evidence that a generic company marketed its drug using a skinny label "would, in practice, vitiate § 355(j)(2)(A)(viii) by enabling . . . infringement claims despite the fact that [the generic company's] Section viii statements and corresponding proposed labeling explicitly and undisputedly carve out all patented indications for [the drug]." *AstraZeneca Pharm. LP v. Apotex Corp.*, 669 F.3d 1370, 1380 (Fed. Cir. 2012); *see also id.* (finding "unpersuasive" argument of induced infringement merely because "pharmacists and doctors will nonetheless substitute the generic for all indications once it becomes available").

Indeed, allowing the skinny label to be considered evidence of inducement would allow the brand drug company "to maintain its exclusivity merely by regularly filing a new patent application claiming a narrow method of use not covered by its NDA . . . and was not what Congress intended." *Warner-Lambert*, 316 F.3d at 1359.

The Majority opinion, if left standing, "would allow a pioneer drug manufacturer to maintain de facto indefinite exclusivity over a pharmaceutical compound by obtaining serial patents for approved methods of using the compound and then wielding [the threat of infringement actions] 'as a sword against any competitor's [application] seeking approval to market an off-patent drug for an approved use not covered by the patent. Generic manufacturers would effectively be barred altogether from entering the market.'" *AstraZeneca*, 669 F.3d at 1380 (quoting *Warner-Lambert*, 316 F.3d at 1359).

This Court reiterated the point in *Takeda Pharmaceuticals U.S.A., Inc. v. West-Ward Pharmaceuticals Corporation*, where it stated that "[t]he principles that can be distilled from these [infringement] cases are applicable in the Hatch-Waxman Act context where, as here, it is alleged that the drug label induces infringement by physicians. The label must encourage, recommend, or promote infringement." 785 F.3d at 631. As Congress recognized by enacting section viii, a skinny label does no such thing; yet the Majority decision holds otherwise. "This requirement of inducing acts is particularly important in the Hatch-Waxman Act context because the statute was designed to enable the sale of drugs for non-patented uses even though this would result in some off-label infringing uses." *Id.*

The Majority's decision thus threatens to decimate the compromise at the heart of the Hatch-Waxman Act, which in turns threatens to undermine the generic

pharmaceutical industry. Generic drugs saved the United States "nearly $2.2 trillion" over the past ten years,[8] but if the Majority's decision stands, name-brand companies like GlaxoSmithKline will be encouraged to file serial patents for novel methods of use and effectively bar generics from entering the market indefinitely. Such a fear is not misplaced—a recent study of the top 12 drugs by gross U.S. revenue found that there were 125 patent applications filed and 71 patents granted per drug.[9] GlaxoSmithKline also waited seven years to file its infringement suit and sought nearly $750 million in damages. *See GlaxoSmithKline*, 976 F.3d at 1350, 1363.

Unless overturned, the Majority's ruling will encourage other name-brand pharmaceutical companies to follow suit, effectively barring entry to the market for all generics and undermining the Hatch-Waxman Act. Indeed, another lawsuit has already been filed in the wake of the Majority's decision. *See Amarin Pharma, Inc. v. Hikma Pharm. USA Inc.*, No. 20-cv-1630, (D. Del. Nov. 30, 2020).

CONCLUSION

For the foregoing reasons, the petition for rehearing en banc should be granted.

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[8] *Securing Our Access & Savings*, *supra* n.4, at 18.

[9] *Overpatented, Overpriced: How Excessive Pharmaceutical Patenting Is Extending Monopolies and Driving up Drug Prices*, I-MAK (2020), https://www.i-mak.org/wp-content/uploads/2018/08/I-MAK-Overpatented-Overpriced-Report.pdf.

Dated: December 16, 2020

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CERTIFICATE OF SERVICE

I, William B. Schultz, hereby certify that on December 16th, 2020, I caused to be served electronically the foregoing Brief of Amicus Curiae Former Congressman Henry A. Waxman in Support of Petition for Rehearing En Banc.

/s/ William B. Schultz
William B. Schultz

CERTIFICATE OF COMPLIANCE

I, William B. Schultz, hereby certify that the foregoing Brief of Amicus Curiae Former Congressman Henry A. Waxman in Support of Petition for Rehearing En Banc complies with the relevant type-volume limitation of the Federal Rules of Appellate Procedure and Federal Circuit Rules because the filing has been prepared using a proportionally-spaced typeface and includes 2,535 words.

Date: December 16, 2020

/s/ William B. Schultz
William B. Schultz