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, 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 [CORRECTED]

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October 27, 2021

CERTIFICATE OF INTEREST

Pursuant to Federal Circuit Rule 47.4, counsel for amicus curiae Former Congressman Henry A. Waxman certify the following:

1. Every entity represented by undersigned counsel in this case:

   Former Congressman Henry A. Waxman.

2. All real parties in interest for the entity: None. (Same as the entity.)

3. All parent corporations and all publicly held companies that own 10% or more stock in the entity: None.

4. All law firms, partners, and associates that have not entered an appearance in the appeal and appeared for the entity in the lower tribunal or are expected to appear for the entity in this court: None. (All have entered appearances.)

5. 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: *GlaxoSmithKline LLC v. Glenmark Pharmaceuticals Inc., USA*, No. 1:14-cv-877 (D. Del.).

6. All information required by Federal Rule of Appellate Procedure 26.1(b) and (c) that identifies organizational victims in criminal cases and trustees in bankruptcy cases: Not applicable.

Date: October 27, 2021

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STATEMENT OF INTEREST[1]

Congressman Henry Waxman served on the U.S. House of Representatives' Committee on Energy and Commerce for 40 years, 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, Pub. L. No. 98-417, 98 Stat. 1585 (1984) (Hatch-Waxman Act), a landmark statute that created the modern generic drug industry. Congressman Waxman is submitting this brief in support of Teva Pharmaceuticals USA's (Teva's) petition for rehearing en banc because he believes both that, just like its prior decision, the Majority's decision in this case is flatly inconsistent with the language of the Act and congressional intent, and that unless

[1] Amicus curiae certifies that no party's counsel authored this brief in whole or part, and no party or party's counsel contributed money intended to fund preparing or submitting the brief. Arnold Ventures and West Health Institute contributed money to fund the brief. Counsel for amicus conferred with the parties in this matter: Teva Pharmaceuticals consents to and GlaxoSmithKline does not oppose the filing of this brief. A motion for leave to file accompanies this brief.

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

overturned it will devastate the Hatch-Waxman Act's generic drug program, which has saved patients, the federal government, and other payers trillions of dollars.[3]

ARGUMENT

Following extensive negotiations that included representatives of industry and consumers, in 1984 Congressman Waxman and Senator Orrin Hatch developed 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 decades the Hatch-Waxman Act has been instrumental in maintaining the availability of less expensive but equally safe and effective generic medicines. By 2019, generic drugs comprised 90% of prescriptions filled nationally, saving $313 billion, including $96.1 billion in Medicare savings and $48.5 billion in Medicaid savings.[4] The Majority decision threatens to destroy the hard-fought compromise at

[3] Congressman Waxman also filed an amicus brief in support of Teva's original petition for rehearing en banc. ECF No. 170.

[4] *Securing Our Access & Savings: 2020 Generic Drug & Biosimilars Access & Savings in the U.S. Report*, Ass'n for Accessible Meds., 16, 20 (2020), https://accessiblemeds.org/sites/default/files/2020-09/AAM-2020-Generics-Biosimilars-Access-Savings-Report-US-Web.pdf.

the heart of the Act. *See GlaxoSmithKline LLC v. Teva Pharm. USA, Inc.*, 7 F.4th 1320, 1361 (Fed. Cir. 2021) (Prost, J., dissenting) ("This new opinion does little to assuage, and even exacerbates, concerns raised by the original.").

A. Congress Considered and Accounted for the Scenario in this 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). In the Hatch-Waxman Act, Congress attempted to foresee and close loopholes and in so doing anticipated the very scenario at issue in this case and addressed it. The Majority decision ignores the legislative text and undermines Congress's careful and considered "legislative plan."

1. *Background of the Hatch-Waxman Compromise*

The Hatch-Waxman 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 . . . 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 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) at 14–15 (1984). 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 drug. *See id.* at 15; *see also* 35 U.S.C. § 271(e)(1).

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

Importantly, Congress considered what would happen if a generic drug entered the market after the patent on the product's basic compound had expired but where one or more of the product's specific uses remained under patent—just as occurred here. In this situation, the generic applicant may provide a "section viii statement." *See* 21 U.S.C. § 355(j)(2)(A)(viii). In developing 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.

With a section viii statement, the generic company certifies that it will market the drug with labeling "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, 406 (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, the generic company relies on the brand company's "description of any method-of-use patent it holds" when it "assure[s] the FDA that its proposed generic drug will not infringe the brand's patents." *See id.* at 405–07.

Congress thus plainly anticipated this exact situation. As the Supreme Court recognized, "[t]he 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); *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.

Additionally, Congress was aware that the approval of a generic drug as therapeutically equivalent to the brand drug means that it may be safely substituted

for all uses, including those that are carved out of the labeling. *See Takeda*, 785 F.3d at 631 ("[T]he statute was designed to enable the sale of drugs for non-patented uses even though this would result in some off-label infringing uses."). Congress thus intended that, without more, a generic would not be liable for infringement if a physician prescribes generic drugs for patented off-label uses.

B. The Majority Decision Is Inconsistent with the Statute and Will Have Major, Adverse Implications.

The Majority decision cannot be reconciled with the plain statutory text and congressional intent. It creates significant uncertainty as to how generic companies can comply with the Hatch-Waxman Act and avoid patent infringement lawsuits such as this one, because the opinion permits skinny labels to be proof of induced infringement. *See GlaxoSmithKline LLC*, 7 F.4th at 1360 (Prost, J., dissenting) ("[I]t's unclear what Teva even did wrong—or, put another way, what another generic in its shoes should do differently.").

The Hatch-Waxman Act created a regulatory scheme that provides a clear and considered roadmap for generics to avoid infringement. "If a generic wanted to avoid patented uses, it had the simple expedient of omitting from its label the uses the brand identified. And if a brand wanted to block a skinny label containing a use it thought was patented, it had the simple expedient of including that use in its FDA patent declaration." *Id.* at 1361 (Prost, J., dissenting); *see also* 21 C.F.R. § 314.53(b)(1) (2003) ("For approved applications, the applicant submitting the

method-of-use patent *shall identify with specificity the section of the approved labeling* that corresponds to the method of use claimed by the patent submitted.") (emphasis added);[5] 68 Fed. Reg. 36,676, 36,682 (June 18, 2003) ("In determining whether [generic] can 'carve out' the method of use, [the FDA] will rely on the description of the approved use provided by the . . . patent owner").

The Majority decision destroys that roadmap. The Majority "presume[s] the jury found that Teva sold carvedilol with a label that instructed physicians to use it in an infringing manner," and claims that "[w]e do not hold that an AB rating[6] in a true section viii carve-out (one in which a label was produced that had no infringing indications) would be evidence of inducement." *GlaxoSmithKline*, 7 F.4th at 1334, 1335 n.7. But the decision effectively rescinds the protection Congress intended the section viii statement to confer when a generic "play[s] by the rules" and "carve[s] out exactly what [the brand] said would infringe," as Teva did here. *Id.* at 1342, 1357 (Prost, J., dissenting); *see id.* at 1350 ("Teva asked to carve out GSK's patented uses, and the FDA in return used GSK's representations to provide Teva with a carved-

[5] The regulation currently states: "For approved [new drug applications], the [entity] submitting information on the method-of-use patent must identify with specificity the section(s) and subsection(s) of the approved labeling that describes the method(s) of use claimed by the patent submitted." 21 C.F.R. § 314.53(b)(1).

[6] An "AB rating" means the FDA considers the drug "therapeutically equivalent" to another drug. *Orange Book Preface*, FDA, § 1.7 (41st ed. 2021), https://www.fda.gov/drugs/development-approval-process-drugs/orange-book-preface.

out label."); J.A. 6908–51 (FDA's instruction for what to omit from label, showing pages of excised language).

The Majority decision provides no direction for how to avoid infringement with a skinny label. *See GlaxoSmithKline*, 7 F.4th at 1328–31 (identifying "substantial evidence" that Teva's label "was not a [true] skinny label"). GlaxoSmithKline's patented indication for congestive heart failure (CHF) "claimed a method of administering a combination of [the drug] and one or more of an ACE inhibitor, a diuretic, and digoxin to decrease mortality caused by CHF" for more than six months. *Id.* at 1323, 1324. Because Teva carved the patented indication out of its label, per the FDA's instructions (and GlaxoSmithKline's), the Majority decision primarily relies on the testimony of a single expert witness who "walked through [Teva's label] and found piecemeal language that he could say 'met' or 'mentioned' each claim limitation in isolation" to show infringement. *Id.* at 1357 (Prost, J., dissenting).

The Majority specifically identifies testimony that one of the skinny label's approved indications (the "post-MI LVD" indication)—which Teva was required to include because it was not protected by a patent—reduced mortality in patients "with or without symptomatic heart failure" whose hearts struggle to pump blood after a heart attack. *Id.* at 1328 (citations omitted). Additionally, the label referenced a

clinical trial of that non-patented method of treatment,[7] which involved "treatment for longer than six months" and some patients who had "background treatment of ACE inhibitors and diuretics." *Id.* at 1328–29. In other words, the basis for finding induced infringement was that Teva's label—which relied on GlaxoSmithKline's representations regarding carve-outs related to the patented indication—included GlaxoSmithKline's language for a non-patented indication that, like the patented indication, could be read to refer to heart failure and referenced a study that included patients also being treated for more than six months, some on drugs involved in the patented indication.

Although the Majority maintains its decision is a "narrow, case-specific review of substantial evidence [that] does not upset the careful balance struck by the Hatch-Waxman Act regarding section viii carve-outs," *id.* at 1326, the impact of the decision is unfortunately not so limited. As Judge Prost noted in dissent, "the background facts here will seemingly persist in most skinny-label cases." *Id.* at 1360. Generic drugs are required to demonstrate "bioequivalence" and be "compar[ed] to a brand drug." *Id.* Yet in his testimony, GlaxoSmithKline's expert (and perhaps the jury) relied on Teva's catalogue's statement that its generic drug is bioequivalent to GlaxoSmithKline's product as evidence of infringement. J.A.

[7] Because GlaxoSmithKline included the study on its label, tied to one of the non-patented indications, Teva was required also to include it on its skinny label. *See Caraco*, 566 U.S. at 406.

10,634–36. Other background facts that persist in most or all skinny label cases include: "duplication of a brand's label (at least in part); reliance on a brand's clinical-trial data; references to a drug's therapeutic class; cursory press releases announcing a generic's regulatory approval; doctors' assumptions about what going generic means; pharmacies' generic substitution; [and] a generic's knowledge that some sales may occur from off-label, infringing uses." *GlaxoSmithKline*, 7 F.4th at 1360 (Prost, J., dissenting).

The Majority decision incentivizes brand companies to develop labels with an eye toward future infringement actions, wait for years to sue—as happened here—then hire experts willing to cherry-pick parts of skinny labels to show infringement. A brand company thus "would be able to maintain its exclusivity merely by regularly filing a new patent application claiming a narrow method of use not covered by its" original patent and use 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." *Warner-Lambert*, 316 F.3d at 1359. Such fears are 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;[8]

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

GlaxoSmithKline waited seven years to file its infringement suit and sought nearly $750 million in damages, *GlaxoSmithKline LLC v. Teva Pharm. USA, Inc.*, 976 F.3d 1347, 1350, 1363 (Fed. Cir. 2020); and numerous lawsuits have already been filed following the Majority's 2020 decision.[9]

The Majority decision thus threatens to decimate the compromise at the heart of the Hatch-Waxman Act, which in turn threatens to undermine the generic pharmaceutical industry. Generic drugs saved the United States "nearly $2.4 trillion" over the past ten years,[10] but the Majority decision "leav[es] [generics] in the dark about what might expose them to liability," *GlaxoSmithKline*, 7 F.4th at 1343 (Prost, J., dissenting), requiring them to take into account the risk of multi-million-dollar lawsuits years down the line and thus discouraging them from putting generic drugs into the marketplace in the first place. This is exactly the opposite outcome that Congress intended with the Hatch-Waxman Act.

[9] Ian Lopez, *Teva Drug-Label Case Spurs Fresh Litigation as Judges Weigh Redo*, Bloomberg Law (Mar. 8, 2021), https://news.bloomberglaw.com/health-law-and-business/teva-drug-label-case-spurs-fresh-litigation-as-judges-weigh-redo.

[10] *The U.S. Generic & Biosimilar Medicines Savings Report*, Ass'n for Accessible Meds., 8 (2021), https://accessiblemeds.org/sites/default/files/2021-10/AAM-2021-US-Generic-Biosimilar-Medicines-Savings-Report-web.pdf.

CONCLUSION

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

Dated: October 27, 2021

Respectfully submitted,

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CERTIFICATE OF SERVICE

I, William B. Schultz, hereby certify that on October 27th, 2021, I caused to be served electronically the foregoing corrected 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 corrected 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 2,599 words.

Date: October 27, 2021

/s/ William B. Schultz
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