No. 24-889

IN THE

Supreme Court of the United States

HIKMA PHARMACEUTICALS USA INC. AND HIKMA PHARMACEUTICALS PLC,

Petitioners,

v.

AMARIN PHARMA, INC., ET AL.,

Respondents.

On Writ of Certiorari to the United States Court of Appeals for the Federal Circuit

BRIEF OF *AMICUS CURIAE* FORMER CONGRESSMAN HENRY A. WAXMAN IN SUPPORT OF PETITIONERS

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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 House Energy and Commerce 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 Hikma Pharmaceuticals, USA Inc. and Hikma Pharmaceuticals Inc. (Hikma) because he believes both that the Federal Circuit's decision in this case is flatly inconsistent with the language of the Act and congressional intent, and that unless 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.

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[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 contributed money to fund the brief. Sup. Ct. R. 37.6.

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

INTRODUCTION AND SUMMARY OF 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).

One of the main purposes of the Hatch-Waxman Amendments was to increase competition among prescription drugs by facilitating the approval of generic copies of brand name drugs. *See* H.R. Rep. No. 98-857, pt. II, at 8-9 (Aug. 1, 1984); *see also Mead Johnson Pharmaceutical Group* v. *Bowen*, 838 F.2d 1332, 1333 (D.C. Cir. 1988). Congress did so by eliminating the requirement that generic manufacturers conduct expensive clinical trials demonstrating a drug's safety and efficacy. Congress also created a mechanism for ensuring to the extent possible that the brand's patents do not block generic drugs from getting on the market any longer than the life of the patent.

Relevant here, Congress recognized that a drug product could have more than one indication or use, and that the generic may choose not to sell its drug for all uses, and in particular may desire to exclude any

uses still covered by a patent. To advance its goal of getting generic drugs on the market as soon as possible, Hatch-Waxman explicitly allows an abbreviated new drug application (ANDA) applicant to exclude a particular use for a multiple-use product where the excluded use is still protected by a patent or other exclusivity. In this case, the generic applicant files what is called a "section viii statement," named after the section in the statute that created it, 21 U.S.C. § 355(j)(2)(A)(viii), and "carves out" the protected use, excluding it from the generic label. For this to be an option, there must be at least one use for which a patent or regulatory exclusivity is not preventing approval of the generic and the exclusion of the protected use must not make the ANDA product less safe than the reference listed drug (RLD). *See*, Guidance for Industry, *180 Day Exclusivity: Questions and Answers* at 2 (Jan. 2017) [available at https://www.fda.gov/media/102650/download.] (last visited Feb. 23, 2026).

This is a particularly important provision because in some cases the brand can get a patent for a new use (or multiple patents for multiple new uses) years after its product has been approved, as occurred in this case. Without the section viii procedure, brands could effectively extend their patent protection and block the marketing of a generic for many years by getting approval of one or more patents for a new use or multiple patents for multiple new uses, as patents on the drug's use or uses expire.

Congress anticipated this exact situation when it enacted Hatch-Waxman. As this Court has 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." *Caraco Pharm. Labs., Ltd.* v. *Novo Nordisk A/S*, 566 U.S. 399, 415 (2012) (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 .

The Federal Circuit's decision in this case would completely undermine the section viii pathway and seriously undercut the availability of generic drugs by allowing brand companies to sue for induced patent infringement regarding a patented use of a drug that the generic company has carved out from its label merely because the generic manufacturer has matched the brand's label except for the carved-out indication, has identified its product a "generic version" and has cited public information about the branded drug's sales.

ARGUMENT

For decades, the Hatch-Waxman Act has been instrumental in maintaining the availability of less expensive but equally safe and effective generic medicines. In 2024 generic drugs comprised 90% of prescriptions filled nationally, saving $447 billion, including $142 billion in Medicare savings and $62.1 billion in Medicaid savings.[3] The Federal Circuit's

[3] Association for Accessible Medicines, *2025 U.S. Generic and Biosimilars Medicines Savings Report*, at 10 (Sept. 2025) [available at https://accessiblemeds.org/wp-

decision in an earlier case, *GlaxoSmithKline LLC* v. *Teva Pharm. USA, Inc.*, 7 F.4th 1320 (Fed. Cir. 2021), had already threatened to destroy the hard-fought compromise at the heart of the Act by effectively eliminating the section viii pathway. This decision if upheld would put a nail in the coffin for this important generic pathway to market.

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 Federal Circuit's 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

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content/uploads/2025/09/AAM-2025-Generic-Biosimilar-Medicines-Savings-Report-WEB.pdf.] (last visited Feb. 23, 2026).

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 consumers 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 manufacturers 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, pt. I at 14-15 (June 21, 1984). The Act also established a regulatory scheme where there is 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.

In this case, Amarin's product Vascepa® initially was approved and indicated to reduce triglyceride levels in adult patients with severe hypertriglyceridemia. Appellee's Pet. Resp. App.13a–14a, ¶ 56. This is the SH indication. Hikma filed its ANDA and obtained approval of the SH indication. Appellee's Pet. Resp. App. 21a, ¶ 82. Amarin then received approval for a new indication for cardiovascular

risk (the CV indication), which was protected by a patent. Appellee's Pet. Resp. App. 16a, ¶ 62. Importantly, Congress had 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*, 566 U.S. at 406 (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 405–06.

Congress thus 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." *Caraco*, 566 U.S. at 415 (emphasis added); *see also Takeda*, 785 F.3d at 630; *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 a generic would not be liable for infringement simply because a physician prescribes generic drugs or a pharmacy substitutes generic drugs for patented off-label uses.

B. The Federal Circuit's Decision Is Inconsistent with the Statute and Will Have Major, Adverse Implications.

The Federal Circuit's 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. As recognized by the dissent in *GlaxoSmithKline LLC*,

"it's unclear what [Hikma] even did wrong—or, put another way, what another generic in its shoes should do differently." 7 F.4th at 1360 (Prost, J., dissenting).

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);[4] FDA Amendment to NDA requirements, 68 Fed. Reg. 36676, 36682 (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 Federal Circuit's decision destroys the carefully constructed roadmap.

[4] 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).

1. The Federal Circuit's Reliance on Language in the Label, Hikma's Website and Press Releases was Misplaced.

The Federal Circuit relied, in part, on language included, or not included, in Hikma's label as evidence of induced infringement. Pet. App. 16a-18a. What the Federal Circuit failed to recognize, however, is that the content of the label is determined by FDA pursuant to statutory and regulatory requirements. 21 U.S.C. § 355(j)(2)(A)(v); 21 C.F.R. § 314.94(a)(8)(iv). The manufacture has no real say. Yet the Federal Circuit bought into Amarin's allegations regarding the clinical studies section of the label, which describes statin-treated patients with the same cardiovascular event history and lipid levels covered by the asserted patents. Pet. App. 16a. But this is information that is and always has been in the brand label (even before the brand added the new patented CV indication). JA 88, JA 98 and JA 109-110. Hikma is required to mirror the brand label (minus the carved out patented indication, which it did not include).

The Federal Circuit also pointed to the elimination of the CV limitation of use and Hikma's inclusion of a warning of potential side effects for patients with cardiovascular disease as communicating to physicians that Hikma's generic product could be used for the off-label CV indication and thus serving as evidence of induced infringement. Pet. App. 16a-18a But again, Hikma was required to eliminate the CV limitation of use language and include the warning of potential side effects in order to mirror Amarin's label, as was required by law. Even though the Federal

Circuit expressed doubt that the label alone would be sufficient to allege induced infringement, it believed that the label together Hikma's "public statements and marketing materials" "plausibly state a claim for induced infringement." Pet. App. 17a-18a.

Specifically, the Federal Circuit referred to Hikma's website which promotes its product as AB-rated in the therapeutic category "Hypertriglyceridemia" which the Court believed was broad enough to encompass both infringing and non-infringing uses. Pet. App. 18a. But as the district court found this alleged overlap "does not rise to the level of encouraging, recommending, or promoting taking Hikma's generic for the reduction of CV risk." Pet. App. 33a. And as the district court further explained, "Hikma has not pointed to Vascepa's patented uses in describing [Hikma's product] as Vascepa's generic equivalent." Pet. App. 35a; *see also* Pet. App. 34a (quoting *Glaxo-SmithKline*, 7 F.4th at 1335 n.7 ("We do not hold that an AB rating in a true section viii carve-out (one in which a label was produced that had no infringing indications) would be evidence of inducement."). What Hikma was doing was referring to its product as a "generic version" or "generic equivalent" of Vascepa® for its SH indication, and this indication falls within the "hypertriglyceridemia" therapeutic category.

The Federal Circuit further pointed to two press releases in which Hikma called its product a "generic version of Vascepa®" or the "generic equivalent to Vascepa®" and which touted sales figures that were largely attributable to the off-label use. Pet. App. 18a. But again, these statements are simply communications that the drug is therapeutically

equivalent to the brand with respect to its approved indications – a statement that all generics routinely have made since the enactment of Hatch-Waxman.

Moreover, the two press releases upon which the Federal Circuit relied were published on news websites for investors – they were not directed at prescribing health care professionals. In fact, the press releases were issued to announce Hikma's victory in earlier litigation on the patents covering the original indication and they preceded approval and launch of Hikma's product. JA 39 and JA 42. And importantly, they no longer appeared on Hikma's website when the product was launched. This type of press release is a common practice and is how companies get investors to consider providing capital to invest in their drugs. It was odd for the Federal Circuit to conclude that press releases directed at investors announcing a victory in an earlier patent challenge that were issued before Hikma's product was approved and launched support an argument that Hikma was encouraging health care providers to prescribe its drug for an off-label use.

2. The Fact that Hikma's Generic Can and May Be Prescribed or Dispensed for an Off-label Use is Not a Sufficient Basis to Allege Infringement.

As noted above, there is no evidence that Hikma encouraged off-label prescribing of its generic. The reality is, however, that Hikma's generic drug may be prescribed by a health care practitioner for an off-label use or substituted by a pharmacist when dispensing. Off-label prescribing is a common practice – well

known to FDA and to Congress at the time it created the section viii pathway. Likewise state substitution laws (which permit or require the substitution of a lower cost generic) [5] were around long before Hatch-Waxman was passed. In fact, by the time Hatch-Waxman was passed all states already had generic substitution laws in place.[6] In fact, when pharmacists are filling prescriptions, they are unlikely to know why the physician has prescribed the drug because physicians need not and generally do not include such information on the prescription. In 1984, these practices and substitution laws were publicly known when Congress developed the section viii pathway. Allowing off-label prescribing or generic substitution to provide evidence of induced infringement would nullify section viii and be flatly inconsistent with clear Congressional intent and the statute.

3. The Federal Circuit's Decision has Major Adverse Implications.

The dissent in the Federal Circuit's earlier *GlaxoSmithKline* decision regarding this issue noted

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[5] Mengde Liu & Lu Yao, *The effect of USA state generic substitution laws on the generic utilization and market competition*, Pharmacoeconomics and Policy 1 (2025) 33–41 [available at https://www.sciencedirect.com/science/article/pii/S2950266725000023.] (last visited Feb. 23, 2026).

[6] William Haddad, *The Drug Price Competition and Patent Term Restoration Act of 1984, Generic Drug Laws: A Decade of Trial—A Prescription for Progress*, 509, 510 (Theodore Goldberg et al. eds., U.S. Dep't of Health & Human Servs. 1986); *see also* U.S. Amicus Br. (in support of petitioners) 5–6 & nn.2–3 (collecting statutes).

that that decision had effectively rescinded 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," *GlaxoSmithKline*, 7 F.4th at 1342, 1357 (Prost, J., dissenting). Although the Majority in that case maintained that its decision was 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 outcome in this case demonstrates that the Federal Circuit's position is unfortunately not so limited. As Judge Prost predicted, "the background facts [t]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, as Judge Prost noted, 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. Other background facts that persist in most or all skinny label cases include:

> [D]uplication 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).

To add insult to injury, the Federal Circuit provides no direction for how to avoid infringement when using a skinny label. If the Federal Circuit's decision is left standing, generic companies, who are generally less financially secure, may choose not to market generic drugs with a skinny label because without clear guidance they would fear the cost of prolonged litigation and potential massive damages. Thus, generic competition for drugs that have patents on some, but not all uses will at best be delayed and at worst never come to fruition.

At bottom, the Federal Circuit's decision incentivizes brand companies to develop labels with an eye toward future infringement actions. 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 if the patent is approved 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 an average of 71 patents granted per drug.[7]

The Federal Circuit's decision thus threatens to decimate the compromise at the heart of the Hatch-

[7] *Overpatented, Overpriced: How Excessive Pharmaceutical Patenting Is Extending Monopolies and Driving up Drug Prices*, I-MAK at 6 (2018), [available at https://www.i-mak.org/wp-content/uploads/2018/08/I-MAK-Overpatented-Overpriced-Report.pdf.] (last visited Feb. 23, 2026)

Waxman Act, which in turn threatens to undermine the generic pharmaceutical industry. Generic and biosimilar drugs saved the United States "nearly $3.4 trillion" over the past ten years,[8] but the Federal Circuit's decision here leaves generic drug companies in the dark about what might expose them to liability, requires them to take into account the risk of multi-million-dollar lawsuits years down the line, and thus discourages 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.

CONCLUSION

For the foregoing reasons, Amicus Curiae Former Congressman Henry A. Waxman urges this court to reverse the Federal Circuit's decision and order reinstatement of the district court's order dismissing Amarin's claims with prejudice.

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[8] *See 2025 U.S. Generic and Biosimilars Medicines Savings Report*, supra n.3, at 14.

Dated: February 25, 2026

Respectfully submitted,

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