No. 2023-1169

United States Court of Appeals for the Federal Circuit

AMARIN PHARMA, INC., AMARIN PHARMACEUTICALS IRELAND LIMITED, MOCHIDA PHARMACEUTICAL CO., LTD.,
Plaintiffs-Appellants

v.

HIKMA PHARMACEUTICALS USA INC., HIKMA PHARMACEUTICALS PLC,
Defendants-Appellees

HEALTH NET LLC,
Defendant

APPEAL FROM THE UNITED STATES DISTRICT COURT FOR THE DISTRICT OF DELAWARE,
CASE NO. 1:20-CV-01630-RGA-JLH, JUDGE RICHARD G. ANDREWS

BRIEF FOR THE ASSOCIATION FOR ACCESSIBLE MEDICINES AS *AMICUS CURIAE* IN SUPPORT OF DEFENDANT-APPELLEES AND AFFIRMANCE

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June 7, 2023

CERTIFICATE OF INTEREST

Counsel for *Amicus Curiae* Association for Accessible Medicines certifies the following:

1. **Represented Entities.** Fed. Cir. R. 47.4(a)(1). Provide the full names of all entities represented by undersigned counsel in this case:

   Association for Accessible Medicines.

2. **Real Party in Interest.** Fed. Cir. R. 47.4(a)(2). Provide the full names of all parties in interest for the entities. Do not list the real parties if they are the same as the entities:

   N/A

3. **Parent Corporations and Stockholders.** Fed. Cir. R. 47.4(a)(3). Provide the full names of all parent corporations for entities and all publicly held companies that own 10% or more stock in the entities:

   N/A

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).

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5. **Related Cases.** Provide the 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. Do not include the originating case number(s) for this case. Fed. Cir. R. 47.4(a)(5). See also Fed. Cir. R. 47.5(b):

   N/A

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).

N/A

June 7, 2023

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INTEREST OF *AMICUS CURIAE*[1]

The Association for Accessible Medicines ("AAM") is a nonprofit, voluntary association representing manufacturers and distributors of generic and biosimilar medicines and bulk active pharmaceutical chemicals, as well as suppliers of other goods and services to the generic pharmaceutical industry. AAM's members provide patients with access to safe and effective generic and biosimilar medicines at affordable prices. AAM's core mission is to improve the lives of patients by providing timely access to safe, effective, and affordable prescription medicines. Generic drugs constitute 90% of all prescriptions dispensed in the United States, yet account for only 22% of total drug spending.

AAM regularly participates in litigation as *amicus curiae*, including in several cases concerning induced infringement arising from a "section viii carve-out," or the omission of patent protected conditions of use from generic product labeling. AAM has a particular interest in this case, as its members frequently are involved in such pharmaceutical patent litigation. Both the carve-out and the stringent statutory requirements to demonstrate induced infringement ensure patients' access to low-cost medicines. Thus, AAM's members have a significant interest in ensuring the

[1] No counsel for any party authored this brief in any part, and no party, counsel, or person other than Amicus, its members, and its counsel contributed money to fund the preparation and submission of this brief. *See* Fed. R. App. P. 29(a)(4)(E). This brief is filed with the consent of all parties.

continued utility of such statutory-enabled labeling carve-outs intended to facilitate expedited access to lower-cost medicines.

INTRODUCTION

Congress clearly and expressly provides generic drug manufacturers with the opportunity to market generic medicines that omit patented uses from their labeling—called, after the provision enabling it, the "section viii carve-out." 21 U.S.C. § 355(j)(2)(A)(viii). But that statutory pathway is at risk of demise from brand sponsors' claims of induced infringement. This appeal threatens to be the final nail in the carve-out's coffin if the decision below is reversed.

Amarin Pharma, Inc. et al. ("Amarin") alleges induced infringement against Hikma Pharmaceuticals et al. ("Hikma") in this case based on a carved-out label and innocuous statements of generic equivalence. Far from an overt demonstration of intent to induce infringement, the evidence Amarin cites cannot serve as the basis to find induced infringement without gutting the section viii carve-out provision. With a pleading standard so low, this Court would open the flood gates to relentless—and often baseless—induced infringement actions against *any* generic with a section viii carve-out. Reviving this case by finding for Amarin thus threatens the existence of this statutory-created marketing pathway designed to facilitate access to much-needed affordable medicines. This could not be what Congress intended.

The decision below was sound. The District Court's determination that "Amarin's complaint has failed to plead inducement based on Hikma's label or public statements," *Amarin Pharma v. Hikma Pharms.*, 578 F. Supp. 3d 642, 648 (D. Del. 2022), properly preserves the burden for brand sponsors to show actual *active inducement* in order to maintain induced infringement cases predicated on section viii carve-outs. Simply put, Amarin did not provide a plausible basis to allege induced infringement. This is because the omission of a condition of use in labeling, combined with statements of generic equivalence, simply cannot be enough to support induced infringement. If merely stating that a product is a "generic equivalent" is sufficient to maintain an induced infringement claim, any section viii carve-out could be subject to litigation. Entertaining such a claim threatens to write the section viii carve-out right out of the Drug Price Competition and Patent Term Restoration Act of 1984 (the "Hatch-Waxman Act"), Pub. L. No. 98-417, 98 Stat. 1585, and forces generics to undertake costly and unnecessary litigation in direct contravention of the intent of the carve-out. This Court should therefore affirm and maintain the longstanding carve-out provision.

ARGUMENT

The section viii carve-out is a mechanism by which a generic sponsor may omit a patent-protected method of use from generic drug labeling. Integral to the delicate balance between access and innovation, Congress established the carve-out

in the Hatch-Waxman Act to facilitate approval and marketing of generic products where "the brand's patent on the drug compound has expired and the brand holds patents on only *some* approved methods of using the drug." *Caraco Pharm. Labs., Ltd. v. Novo Nordisk A/S*, 566 U.S. 399, 406 (2012) (emphasis added). The carve-out allows the U.S. Food and Drug Administration ("FDA") to approve a generic drug omitting a method of use "which does not claim a use for which the applicant is seeking" while preserving patent protections for unexpired listed patents. 21 U.S.C. § 355(j)(2)(A)(viii); 21 C.F.R. § 314.94(a)(8)(iv). In turn, the carve-out "allows the generic company to place its drug on the market (assuming the ANDA meets other requirements), but only for a subset of approved uses—*i.e.*, those not covered by the brand's patents." *Caraco*, 566 U.S. at 406. "The statutory scheme, in other words, contemplates that one patented use will not foreclose marketing a generic drug for other unpatented ones." *Id.* at 415.

In approving a generic that omits from labeling an approved use claimed by a patent, FDA allows patients to access more affordable versions of medicines for unprotected uses expeditiously. Indeed, rather than wait for expiration or litigation of unrelated patents and any related statutory stay, "FDA may approve a section viii application immediately, making it an attractive route for generic manufacturers . . . ." *Purepac Pharm. Co. v. Thompson*, 238 F. Supp. 2d 191, 195 (D.D.C. 2002). It

is similarly critical for patients, as it allows expedited access to more affordable versions of branded products for the unpatented uses.

For nearly 40 years, section viii carve-outs have allowed the U.S. healthcare system to save billions of dollars by providing access to unpatented drug compounds for unpatented uses. FDA has estimated that "[g]eneric drugs approved between 2018 and 2020 are estimated to have saved consumers more than $50 billion in the first 12 months of generic sales," and the approval of the first generic version of a brand-name drug, often a generic with a carved-out condition of use, has reduced prices by more than 75 percent. Brief for United States at 20, *Teva Pharm. USA, Inc. v. GSK LLC*, No. 22-37 (Fed. Cir. Mar. 29, 2023) (citing Ryan Conrad et al., FDA, *Estimating Cost Savings from New Generic Drug Approvals in 2018, 2019, and 2020*, at 3-4 (2022)). "According to one recent study, the section viii pathway permitted generic drugs to be approved for sale an average of three years before the relevant method-of-use patents expired." *Id.* at 20 (citing Bryan S. Walsh et al., *Frequency of First Generic Drug Approvals With 21 'Skinny Labels' in the United States*, 181 JAMA Internal Med. 995, 995-997 (2021)).

Given the enormous cost savings associated with generic drugs, effectively losing accelerated access to generics through the section viii carve-out pathway would be devastating for patients. But that is exactly what is likely to happen should this Court reinstate Amarin's induced infringement suit against Hikma. Permitting

litigation to go forward based on FDA-compliant carved-out labeling and Hikma's vague and innocuous statements about "generic equivalen[ce]"—an accurate and factual statement reflecting precisely what FDA itself has determined, *see* FDA, Approved Drug Products with Therapeutic Equivalence Evaluations, at viii (43rd. ed. 2023) ("FDA believes that products classified as therapeutically equivalent can be substituted with the full expectation that the substituted product can be expected to have the same clinical effect and safety profile as the prescribed product when administered to patients under the conditions specified in the labeling")—would encourage the filing of induced infringement lawsuits for *any* section viii carve-out; and the mere threat of such litigation would deter ANDA filers from using the section viii carve-out—a key feature of the Hatch-Waxman Act from the moment it was passed some 40 years ago.

To be clear, it is not just the possibility of damages for induced infringement that would serve as a deterrent to use of the section viii carve-out; if the bar to inducement infringement litigation is as low as approval based on a section viii carve-out and a few innocuous statements about generic equivalence—which "simply reflect the truism that a generic drug is required to be therapeutically equivalent to its brand-name reference drug if used as directed on the labeling," Brief for United States, at 2 n.2, *Teva Pharm. USA, Inc. v. GSK LLC*—the threat of costly and resource-intensive litigation would loom large over any putative skinny label,

regardless of the likelihood of success of that litigation. Indeed, it is "the *potential* for inducement liability in these circumstances" that "may significantly deter use of the section viii pathway, *even if such liability is rarely imposed*." *Id.* (emphasis added).

Put frankly, if any section viii carve-out was subject to induced infringement litigation—as will be the case if Amarin's complaint is revived—section viii carve-outs would fail to avoid infringement litigation, which is their sole purpose. All generics facing unexpired patents will either need to wait until those patents expire or engage in costly, time-consuming litigation—again, even if the remaining listed method-of-use patents do not cover the relevant condition of use—and the section viii carve-out would be rendered meaningless. Meanwhile, absent the skinny-label pathway, brands will continue to obtain method-of-use patents that effectively block generics even for unpatented uses and enjoy an unwarranted extension of their monopolies. All the while, patients will be deprived of lower-priced, non-infringing products, which is certainly not what Congress intended when it adopted the section viii carve-out "to speed the introduction of low-cost generic drugs to market." *Caraco*, 566 U.S. at 405.

"Uncertainty about the section viii pathway is likely to deter generic manufacturers from invoking that mechanism, thereby threatening the availability of lower-cost generic drugs, in contravention of the statutory design." Brief for

United States at 13, *Teva Pharm. USA, Inc. v. GSK LLC*. Indeed, "if playing by the skinny-label rules doesn't give generics some security from label-based liability, there is a significant risk that generics simply won't play." *Id.* (internal citations omitted). If this Court finds that Amarin has stated a claim for inducement based on omitted label language and "generic equivalence" claims, this is exactly what will happen. This Court can prevent that by affirming the district court's decision below.

CONCLUSION

For the foregoing reasons, the district court's decision should be affirmed.

Respectfully submitted,

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June 7, 2023

CERTIFICATE OF SERVICE

I certify that true and correct copies of the foregoing *Brief for Association for Accessible Medicines as Amicus Curiae* was caused to be served on June 7, 2023, on all counsel of record by the CM/ECF system.

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CERTIFICATE OF COMPLIANCE
WITH TYPE-VOLUME LIMITATION, TYPEFACE
REQUIREMENTS, AND TYPE STYLE REQUIREMENTS

1. This brief complies with the type-volume limitation of Federal Rule of Appellate Procedure 32(a)(7)(B) because it contains 1726 words, excluding the parts of the brief exempted by Federal Rule of Appellate Procedure 32(a)(7)(B)(iii) and Federal Circuit Rule 32(b).

2. This brief complies with the typeface requirements of Federal Rule of Appellate Procedure 32(a)(5) and the type style requirements of Federal Rule of Appellate Procedure 32(a)(6) because this brief has been prepared in 14-point Times New Roman, a proportionally spaced typeface, using Microsoft Word for Microsoft 365 (2022).

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