No. __-____

In the Supreme Court of the United States

HIKMA PHARMACEUTICALS USA INC. AND
HIKMA PHARMACEUTICALS PLC, PETITIONERS

v.

AMARIN PHARMA, INC., ET AL.

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

PETITION FOR A WRIT OF CERTIORARI

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QUESTIONS PRESENTED

Congress passed the Hatch-Waxman Act "[t]o facilitate the approval of generic drugs as soon as patents allow." *Caraco Pharm. Labs., Ltd.* v. *Novo Nordisk A/S*, 566 U.S. 399, 405 (2012). Recognizing that many drugs are approved for both patented and unpatented uses, Congress sought to ensure "that one patented use will not foreclose marketing a generic drug for other unpatented ones." *Id.* at 415. The statutory mechanism is a "skinny label": Generic drugmakers "carve out" patented uses from their labels, leaving only instructions to use generic drugs for their unpatented uses. See 21 U.S.C. § 355(j)(2)(A)(viii).

Congress designed this carve-out mechanism to encourage competition and to protect generic drugmakers from allegations that marketing a generic drug for an unpatented use "actively induces infringement." 35 U.S.C. § 271(b). After all, active inducement requires "clear expression or other affirmative steps taken to foster infringement"—there is no "liability when a defendant merely sells a commercial product suitable for some lawful use." *Metro-Goldwyn-Mayer Studios Inc.* v. *Grokster, Ltd.*, 545 U.S. 913, 936–937 & n.11 (2005).

The questions presented are:

1. When a generic drug label fully carves out a patented use, are allegations that the generic drugmaker calls its product a "generic version" and cites public information about the branded drug (e.g., sales) enough to plead induced infringement of the patented use?

2. Does a complaint state a claim for induced infringement of a patented method if it does not allege any instruction or other statement by the defendant that encourages, or even mentions, the patented use?

PARTIES TO THE PROCEEDING

Petitioners (defendants-appellees below) are Hikma Pharmaceuticals USA Inc. and Hikma Pharmaceuticals PLC (collectively, "Hikma").

Respondents (plaintiffs-appellants below) are Amarin Pharma, Inc., Amarin Pharmaceuticals Ireland Limited, and Mochida Pharmaceutical Co., Ltd. (collectively, "Amarin").

RULE 29.6 STATEMENT

Hikma Pharmaceuticals USA Inc. is an indirect, wholly owned subsidiary of Hikma Pharmaceuticals PLC, which is a publicly held corporation.

Hikma Pharmaceuticals PLC does not have a parent corporation, and no publicly held corporation owns 10% or more of its stock.

RELATED PROCEEDINGS

U.S. District Court for the District of Delaware:

Amarin Pharma, Inc. v. *Hikma Pharmaceuticals USA Inc.*, No. 20-cv-1630 (Oct. 13, 2022).

U.S. Court of Appeals for the Federal Circuit:

Amarin Pharma, Inc. v. *Hikma Pharmaceuticals USA Inc.*, No. 2023-1169 (June 25, 2024).

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INTRODUCTION

Under the Federal Circuit's decision in this case, accurately calling a generic drug the "generic version" of a branded drug and citing public information about the brand (e.g., annual sales) now exposes a generic drugmaker to potential damages for inducing infringement of patents on "*any* of the [brand's] approved uses"—even when, as here, the generic drug is labeled only for an *un*patented use. App. 19a, 17a. The decision effectively nullifies a statutory mechanism for expediting access to generic drugs and breaks sharply with precedent on inducement.

Forty years ago, Congress passed the Hatch-Waxman Act "to speed the introduction of low-cost generic drugs to market." *Caraco Pharm. Labs., Ltd.* v. *Novo Nordisk A/S*, 566 U.S. 399, 405 (2012). Among the Act's innovations is the "so-called section viii statement," which authorizes the Food and Drug Administration ("FDA") to approve generic versions of branded drugs when "the brand holds patents on only some approved methods of using the drug," provided that the "labeling for the generic drug [ ] 'carves out' from the brand's approved label the still-patented methods of use." *Id.* at 406 (citing 21 U.S.C. § 355(j)(2)(A)(viii)). The resulting carve-out, or "skinny label," App. 4a–5a, ensures "that one patented use will not foreclose marketing a generic drug for other unpatented ones," *Caraco*, 566 U.S. at 415.

The decision below changes all that. It is undisputed that petitioners ("Hikma") complied with section viii and fully carved out of their generic drug label the allegedly patented uses of respondents' ("Amarin") branded drug, Vascepa. App. 4a–5a, 17a. Amarin's patents require using the active ingredient, icosapent,

for "reducing risk of cardiovascular death" or (when taken with a second drug) "reducing occurrence of a cardiovascular event." App. 8a–9a. Amarin alleges these patents cover *one* of Vascepa's two approved uses: reducing cardiovascular ("CV") risk in specific populations. Hikma's generic product, however, is labeled only for the *other*, *off-patent* use: treating severe hypertriglyceridemia ("SH"). Nothing in Hikma's label or in any alleged statements about its generic product even *mentions* reducing CV risk.

The district court, therefore, dismissed Amarin's complaint alleging induced patent infringement for failure to state a claim under 35 U.S.C. § 271(b). App. 11a. But the Federal Circuit reversed. Despite *agreeing* that Hikma's skinny label fully carves out the patented uses of reducing CV risk, App. 17a, the decision holds that Amarin plausibly alleged induced infringement because Hikma called its product a "generic version" of Vascepa and quoted Vascepa's publicly available "sales figures," App. 18a–20a.

That result is extraordinary, and it effectively nullifies section viii of the Hatch-Waxman Act by allowing inducement claims against *every* generic drug with a skinny label. All generic drugs, by definition, are "generic versions" of branded drugs. And market-size discussions are inevitable in a for-profit industry. Under the ruling below, an earnings call with investors announcing a new "generic" product would invite a lawsuit for inducing infringement of *any* patent on *any* use of the branded drug, even if the generic label carves out all patented uses. As a practical matter, any branded pharmaceutical company can now point to some public statement by the generic-drug manufacturer to justify a post-launch suit alleging induced

infringement, even when the generic product is labeled only for unpatented uses—and that lawsuit could survive a motion to dismiss. This entirely defeats the point of section viii, which Congress enacted so that generics could *avoid* litigation and "quickly come to market." *Caraco*, 566 U.S. at 415.

But there is a more fundamental problem with the decision: It allows, for the first time, inducement claims against a defendant for marketing a product that undisputedly lacks *any* instruction to perform the patented use. That result conflicts with this Court's precedent and the Patent Act itself, which limits liability to "[w]hoever *actively* induces infringement." 35 U.S.C. § 271(b) (emphasis added). As this Court has recognized, the statutory language requires "the taking of affirmative steps to bring about" infringement. *Glob.-Tech Appliances, Inc.* v. *SEB S.A.*, 563 U.S. 754, 760 (2011). Absent "clear expression or other affirmative steps taken to foster infringement," there is no liability "when a defendant merely sells a commercial product suitable for some lawful use." *Metro-Goldwyn-Mayer Studios Inc.* v. *Grokster, Ltd.*, 545 U.S. 913, 936–937 (2005).

The decision below contravenes these precedents. It is undisputed that Hikma's generic product is "suitable for some lawful use"—i.e., its sole approved use for treating SH. *Ibid.* And there is no alleged "clear expression or other affirmative steps [by Hikma] to foster infringement." *Ibid.* Instead, the inducement theory below speculates that physicians will infer they can use Hikma's "generic version" for all approved uses of Vascepa and then consult *Amarin's* Vascepa label—not Hikma's own label—to determine those uses. At best, this is a theory of *passive* inducement: There

is no plausible allegation that Hikma itself "actively" encourages *anyone* to practice the patented uses. See 35 U.S.C. § 271(b).

The Federal Circuit brushed aside this glaring defect in Amarin's complaint because the case is "at its most nascent stage: on a motion to dismiss," and thus lacks "the benefit of discovery." App. 14a. Citing pre-*Twombly* caselaw, the decision holds that courts may dismiss a claim "only if it is *certain* no relief could be granted under *any set of facts* that could be proven." App. 12a (quoting *Warden* v. *McLelland*, 288 F.3d 105, 110 (3d Cir. 2002)) (emphasis added). That holding contradicts this Court's decision in *Twombly*, which "retir[ed]" the same "no set of facts" standard as "best forgotten," and rejected the same reasoning that courts should wait for the "discovery process" to throw out defective claims. *Bell Atl. Corp*. v. *Twombly*, 550 U.S. 544, 563, 559 (2007). Under the outdated pleading standard below, "the threat of discovery expense will push cost-conscious defendants to settle even anemic cases," *id*. at 559—a concern that is especially vital in the generic drug industry.

Beyond reviving an abrogated pleading standard, the decision below categorically excludes inducement claims from dismissal: It holds that inducement is a pure "question of *fact*—not law—and is therefore *not proper for resolution on a motion to dismiss*." App. 18a–19a (emphasis added). That holding splits sharply with the Ninth Circuit's precedent in the analogous copyright context that "'[i]nducement' is a *legal* determination, and *dismissal may not be avoided* by characterizing a legal determination as a factual one." *Perfect 10, Inc.* v. *Visa Int'l Serv. Ass'n*, 494 F.3d 788, 802 (9th Cir. 2007) (emphasis added). The Ninth

Circuit thus requires courts to "determine whether the facts as pled constitute a 'clear expression' of a specific intent to foster infringement." *Ibid.* (dismissing inducement claim). The Ninth and Federal Circuits disagree fundamentally on whether inducement claims are subject to dismissal as a matter of law—a split that only this Court can resolve.

Notably, the only precedent the Federal Circuit cited for its holdings that a skinny-label generic may induce infringement and that inducement is a pure factual issue is its own controversial ruling in *GlaxoSmithKline LLC v. Teva Pharms. USA, Inc.*, 7 F.4th 1320 (Fed. Cir. 2021) ("*GSK*"). There, the Solicitor General urged this Court to grant certiorari because even "*potential* for inducement liability * * * may significantly deter use of the section viii pathway." Brief for the United States as Amicus Curiae, *Teva Pharms. USA, Inc.* v. *GlaxoSmithKline LLC*, 143 S. Ct. 2483 (2023) (No. 22-37), 2023 WL 2717391, at *22.

This case offers another chance to review the Federal Circuit's erosion of section viii and § 271(b)—with a much better vehicle than *GSK*, where the Federal Circuit credited alleged evidence that the generic drugmaker's "partial label instructed the method of use claimed." 7 F.4th at 1328. Here, it is undisputed that Hikma's label *is* "skinny enough." App. 13a, 17a. This case thus confirms what the dissent in *GSK* predicted: "a generic can be deemed liable for inducement for saying that its product is a 'generic version'"—"a drastic holding" that "makes little sense." 7 F.4th at 1353 (Prost, J., dissenting).

Commentators are raising alarms that this case is "a prototype for future litigation" that "may delay or

deter generics from entering the market,"[1] "diminish hope and add uncertainty to the statutory skinny label practices,"[2] "create[ ] uncertainty in the sale and marketing of generic drugs,"[3] and "embolden[ ]" branded drugmakers "to sue after [generic] launch based on theories of inducement where section viii carveouts were employed."[4] Because the decision "opens the door for post-launch lawsuits against generics that do have adequate carve-outs," this is one of the "biggest patent decisions of 2024."[5]

In short, the decision below is an imminent threat to generic competition, which is critically important to the U.S. healthcare system. And the "very permissive

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[1] S. Sean Tu & Charles Duan, *Pharmaceutical Patent Two-Step: The Adverse Advent of Amarin v. Hikma Type Litigation*, 12 NYU J. INTELL. PROP. & ENT. L. 1, 17–18 (2022).

[2] DUANE MORRIS LLP, *Federal Circuit Revives Induced Infringement Suit Against Generic Pharma When Its Skinny Label Is Skinny Enough* (July 15, 2024), https://www.duanemorris.com/alerts/federal_circuit_revives_induced_infringement_suit_against_generic_pharma_when_skinny_label_0724.html.

[3] Jeremiah Helm & Sean Murray, *The Fed. Circ. In June: More Liability For Generic-Drug Makers*, LAW360 (Aug. 2, 2024), https://www.law360.com/ip/articles/1863857/the-fed-circ-in-june-more-liability-for-generic-drug-makers.

[4] Christopher Bruno, *Is Pleading "Generic" Enough to Plead Inducement?*, IP UPDATE (July 11, 2024), https://www.ipupdate.com/2024/07/is-pleading-generic-enough-to-plead-inducement/.

[5] Ryan Davis, *The Biggest Patent Decisions of 2024*, LAW360 (Dec. 16, 2024), https://www.law360.com/trials/articles/2262517/.

pleading standard for induced infringement" that the decision creates will dramatically expand the risk of inducement liability, even "outside of just the pharmaceutical context." *Helm*, *supra* note 3.

The Court should grant certiorari.

OPINIONS BELOW

The decision below (App. 1a–22a) is reported at 104 F.4th 1370 (Fed. Cir. 2024). The order denying rehearing (App. 39a–41a) is unpublished. The district court's decision (App. 25a–38a) is reported at 578 F. Supp. 3d 642 (D. Del. 2022).

JURISDICTION

The district court had jurisdiction under 28 U.S.C. §§ 1331 and 1338(a). The Federal Circuit entered judgment on June 25, 2024, and denied rehearing on October 17, 2024. On January 3, 2025, the Chief Justice extended the time to file a petition for a writ of certiorari until February 14, 2025. This Court has jurisdiction under 28 U.S.C. § 1254(1).

STATUTORY PROVISIONS INVOLVED

This case involves the intersection of 35 U.S.C. § 271(b) and 21 U.S.C. § 355(j)(2)(A)(viii). The relevant statutory provisions are reproduced in the petition appendix, *infra*, at 42a–43a.

STATEMENT

A. Congress enacts § 271(b), limiting inducement liability to one who "actively induces infringement of a patent."

Although direct patent infringement is a strict-liability tort, Congress limited liability for inducing another's infringement to "[w]hoever actively induces

infringement of a patent…." 35 U.S.C. § 271(b). "The term 'induce' means '[t]o lead on; to influence; to prevail on; to move by persuasion or influence,'" whereas "'actively' suggests that the inducement must involve the taking of affirmative steps to bring about the desired result." *Glob.-Tech*, 563 U.S. at 760 (alteration in original) (quoting WEBSTER'S NEW INT'L DICTIONARY 1269, 27 (2d ed. 1945)).

Added by the 1952 Patent Act, § 271(b) codifies an inducement standard that governs both patent and copyright law, and which originates in aiding-and-abetting liability at common law. See *id.* at 764; *Grokster*, 545 U.S. at 935–936 & nn.10–11. In both patent and copyright cases, inducement requires "active steps taken to encourage direct infringement, such as advertising an infringing use or instructing how to engage in an infringing use"—i.e., "clear expression or other affirmative steps taken to foster infringement." *Grokster*, 545 U.S. at 936–937 (cleaned up).

Only "a showing that infringement was encouraged overcomes the law's reluctance to find liability when a defendant merely sells a commercial product suitable for some lawful use." *Id.* at 936. In contrast, "mere knowledge of infringing potential or of actual infringing uses would not be enough [ ] to subject a distributor to liability." *Id.* at 937. "The inducement rule, instead, premises liability on purposeful, culpable expression and conduct, and thus does nothing to compromise legitimate commerce or discourage innovation having a lawful promise." *Ibid.*

B. Congress enacts the Hatch-Waxman Act, including section viii, allowing generic drugs to avoid any potential inducement liability by "carving out" patented uses.

The Hatch-Waxman Act—formally, the Drug Price Competition and Patent Term Restoration Act of 1984—provides the regulatory foundation for today's generic drug industry. See 98 Stat. 1585.

1. A manufacturer seeking FDA approval to market a new drug must submit a new drug application ("NDA"), which includes "scientific data showing that the drug is safe and effective, and proposed labeling describing the uses for which the drug may be marketed." *Caraco*, 566 U.S. at 404 (citing 21 U.S.C. § 355(b)(1), (d)). After FDA approves an NDA, other companies can seek approval for a generic version of the drug by filing an abbreviated new drug application ("ANDA") that refers to the NDA. *Id*. at 404–405. Instead of recreating "independent evidence of safety and efficacy, the typical ANDA shows that the generic drug has the same active ingredients as, and is biologically equivalent to, the brand-name drug"—an expedited process "designed to speed the introduction of low-cost generic drugs to market." *Id*. at 405 (citing 21 U.S.C. §§ 355(j)(2)(A)(ii), (iv)).

"Because the FDA cannot authorize a generic drug that would infringe a patent, the timing of an ANDA's approval depends on the scope and duration of the patents covering the brand-name drug," which "come in different varieties." *Ibid*. Some patents cover "the drug compound itself." *Ibid*. Others cover only "a particular method of using the drug." *Ibid*. Importantly, "FDA may approve a brand-name drug for multiple methods of use—either to treat different conditions or

to treat the same condition in different ways"—and, oftentimes, "the brand holds patents on only some approved methods of using the drug." *Id.* at 404, 406. "To facilitate the approval of generic drugs as soon as patents allow," the brand must publicly identify any patents that allegedly cover the drug or its approved methods of use, which FDA lists in "the Orange Book." *Id.* at 405–406.

2. An ANDA filer (i.e., generic company) seeking to market a generic version of a drug with unexpired patents in the Orange Book has two options.

One option is to file a "paragraph IV certification" that the listed patent is invalid or not infringed by the proposed generic drug. *Id.* at 407 (citing 21 U.S.C. § 355(j)(2)(A)(vii)(IV)). "Filing a paragraph IV certification means provoking litigation" because it "gives the brand an immediate right to sue." *Ibid.* (citing 35 U.S.C. § 271(e)(2)(A)). "Assuming the brand does so, the FDA generally may not approve the ANDA until 30 months pass or the court finds the patent invalid or not infringed," which may "keep the generic drug off the market for a lengthy period." *Id.* at 407–408 (citing 21 U.S.C. § 355(j)(5)(B)(iii)).

For Orange-Book patents that cover fewer than all approved uses of a drug, ANDA filers have another option. To avoid the burdens and delays of patent litigation, the ANDA filer may submit a section viii statement, which "asserts that the generic manufacturer will market the drug for one or more methods of use not covered by the brand's patents." *Id.* at 406 (citing 21 U.S.C. § 355(j)(2)(A)(viii)).

Under section viii, an ANDA filer can market its generic drug with a skinny label "that 'carves out' from

the brand's approved label the still-patented methods of use." *Ibid.* By omitting any instructions in the label that might otherwise encourage physicians to prescribe the drug for patented uses, the generic drugmaker avoids any potential claim for "actively induc[ing]" infringement under § 271(b). This ensures that generic drugs "can quickly come to market"—and avoid litigation altogether—because "one patented use will not foreclose marketing a generic drug for other unpatented ones." *Id.* at 415.

C. Hikma follows the section viii pathway and fully carves out the sole patented use.

This case is Amarin's second attempt to block competition by Hikma to Amarin's brand-name Vascepa, which contains icosapent—a purified omega-3 fatty acid found naturally in fish oil. App. 2a.

1. In 2012, FDA originally approved Vascepa for a single use: treating SH, which is characterized by a blood triglyceride level of at least 500 mg/dL. App. 2a–3a. In 2016, Hikma filed an ANDA for generic icosapent with paragraph IV certifications challenging Amarin's then-existing patents on using icosapent to treat SH. App. 4a n.4. Amarin sued Hikma on those patents, but Hikma prevailed, invalidating the SH patents as obvious under 35 U.S.C. § 103. *Ibid.*

In 2019, while that first lawsuit was pending, FDA approved a second indication for Vascepa to reduce certain types of CV risk in certain patients. App. 3a. Specifically, Vascepa was approved "as an adjunct to maximally tolerated statin therapy to reduce the risk of myocardial infarction, stroke, coronary revascularization, and unstable angina requiring hospitalization in adult patients with elevated triglyceride (TG) levels

(≥150 mg/dL) and established cardiovascular disease or diabetes mellitus and 2 or more additional risk factors for cardiovascular disease." C.A. App. 636.

Amarin obtained patents, including the two asserted here, claiming icosapent's use for "reducing risk of cardiovascular death" or (when combined with a second drug, a statin) "reducing occurrence of a cardiovascular event" in patient populations with triglycerides of at least 150 mg/dL. App. 8a–9a. Amarin alleges both patents cover Vascepa's CV indication, even though Vascepa is *not* approved for "reducing risk of cardiovascular death." See App. 9a; C.A. App. 636.

Unlike for the earlier SH patents, Hikma did not file paragraph IV certifications challenging Amarin's CV patents. Instead, Hikma filed a section viii statement "seeking FDA approval only for uses not covered by Amarin's newly listed CV indication patents." App. 4a. Hikma therefore sought FDA "approval of a 'skinny label' for its generic product that would include only the SH indication and not the CV indication," which FDA approved. App. 4a–5a.

2. In 2020, with the SH patents invalidated and the CV indication fully carved out, Hikma finally launched its generic icosapent product. App. 7a. Within a month, however, Amarin sued Hikma again, this time for allegedly inducing infringement of the CV patents and seeking "damages, including lost profits." C.A. App. 545, 546, 548.

Amarin's complaint admits that Hikma's product "is not FDA-approved for the CV Indication" and approved for "only the [SH] Indication." C.A. App. 521–522. Nevertheless, Amarin alleges that statements in three pre-launch press releases and Hikma's website

induce infringement of the CV patents.[6] App. 5a–7a; C.A. App. 709–713, 613, 820. The press releases are not directed to physicians but instead report on Hikma's litigation victories involving Amarin's SH patents (C.A. App. 709, 712) and the regulatory approval of Hikma's generic product (C.A. App. 613). These press releases refer to Hikma's product as a "generic version" of Vascepa. *Ibid.* Two press releases quote Vascepa's annual sales. *Ibid.* A fourth press release announcing Hikma's launch, however, quotes the SH indication and warns that "Hikma's product is not approved for any other indication for the reference listed drug VASCEPA®." App. 7a; C.A. App. 715–717.

Hikma's website states that Hikma's generic icosapent product is in the "Therapeutic Category: Hypertriglyceridemia" and "AB" rated (i.e., therapeutically equivalent to a branded drug). App. 7a. The website does not mention Vascepa, and it explicitly warns that Hikma's generic icosapent product "is indicated for fewer than all approved indications of the Reference Listed Drug." *Ibid.*; C.A. App. 820.

None of Hikma's alleged statements mention Vascepa's CV indication or CV risk, let alone using icosapent (with or without a statin) to reduce CV risk.

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[6] Amarin's complaint also alleged that Hikma's skinny label induced infringement of the CV patents, but both the district court and the Federal Circuit rejected that theory. App. 17a, 31a–32a. Tellingly, Amarin has not asserted its CV patents against any other drugmaker with a generic icosapent product (which all have the same skinny label), confirming that Amarin's lawsuit here depends on statements outside of the label.

Indeed, the statements do not even mention the term "cardiovascular," or make any reference to statins.

D. The district court dismisses Amarin's suit for failure to state a claim.

The district court granted Hikma's motion to dismiss Amarin's complaint for failure to state a claim. App. 11a, 25a–35a.

Applying this Court's pleading standard in *Twombly* and *Iqbal*, App. 28a, the district court found that Hikma's "label does not instruct CV risk reduction," as required by Amarin's patents, App. 32a. Turning to the press releases, the court found that statements in "Hikma's advertising of icosapent ethyl as the 'generic equivalent' of Vascepa do[ ] not expose Hikma to liability" because they too fail to instruct CV-risk reduction. App. 33a. The court found that, at most, statements about Vascepa's sales "might be relevant to intent," but "[i]ntent alone is not enough; Amarin must plead an inducing act." *Ibid.*

For purposes of Hikma's motion, the court accepted Amarin's theory that the reference to "Hypertriglyceridemia" on Hikma's website is broader than SH and overlaps with the patient population for the CV indication. App. 32a–33a. But the court found that this alleged overlap "does not rise to the level of encouraging, recommending, or promoting taking Hikma's generic for the reduction of CV risk." App. 33a. The court explained that, both in Hikma's press releases and website, "Hikma has not pointed to Vascepa's patented uses in describing [Hikma's product] as Vascepa's generic equivalent." App. 35a.

E. The Federal Circuit resurrects Amarin's suit—despite agreeing that Hikma fully carved out Amarin's patented use.

The Federal Circuit reversed. It began by holding that appellate courts "may affirm [a dismissal] only if it is certain no relief could be granted under any set of facts that could be proven." App. 12a. Even under this permissive standard, the Federal Circuit agreed that Hikma's "label does not, as a matter of law, recommend, encourage, or promote an infringing use." App. 17a (cleaned up). As the decision notes, "even Amarin seems to agree that the label alone does not instruct infringement." App. 21a.

Nevertheless, the Federal Circuit found "it at least plausible that a physician could read Hikma's press releases—touting sales figures attributable largely to an infringing use, and calling Hikma's product the 'generic version' of a drug that is indicated 'in part' for the SH indication—as an instruction or encouragement to prescribe that drug for *any* of the approved uses of icosapent ethyl, particularly where the label suggests that the drug may be effective for an overlapping patient population." App. 19a.

The Federal Circuit also relied on the word "Hypertriglyceridemia" on Hikma's website to find plausible induced infringement of Amarin's asserted CV patents, despite the website's "express disclaimer that Hikma's product is FDA-approved for fewer than all uses of Vascepa." App. 19a–20a & n.6.

The Federal Circuit did not identify a single alleged statement by Hikma that even mentions, much less encourages, administering icosapent for "reducing risk of cardiovascular death" or "reducing occurrence of a

cardiovascular event" when taken with a statin, as Amarin's patents require. App. 8a–9a. Yet the Federal Circuit held that it could not dismiss Amarin's complaint without "the benefit of discovery" because, in its view, induced infringement is purely a "question of fact" that is "not proper for resolution on a motion to dismiss." App. 14a, 18a–19a.

REASONS FOR GRANTING THE PETITION

Under the decision below, a defendant that distributes a product with noninfringing instructions may face liability for induced infringement merely for marketing its product as the "generic version" of a branded product with patented uses and citing publicly available information about the brand—even if the defendant never *mentions* the patented uses, let alone instructs anyone to practice them.

The decision creates a new, "very permissive pleading standard for induced infringement" (Helm, *supra* note 3), which conflicts with multiple lines of precedent (*infra*, Part I) and effectively nullifies section viii of the Hatch-Waxman Act—a result that will deter generic competition and raise drug prices, contrary to congressional intent (*infra*, Part II).

I. The decision below warrants review because it creates a "very permissive pleading standard for induced infringement" that conflicts with multiple lines of precedent.

The Federal Circuit's decision here creates three related conflicts, and each warrants this Court's review. *First*, in holding that vague marketing statements about a competitor's product can induce infringement of specific method steps, the decision conflicts with precedent on 35 U.S.C. § 271(b), which

limits liability to "active[ ]" inducement. *Infra*, Part A. *Second*, in precluding dismissal so long as "any set of facts" could reveal inducement with "the benefit of discovery," App. 12a, 14a, the decision conflicts with precedent requiring the complaint *itself* to recite sufficient allegations to state a claim for relief. *Infra*, Part B. *Third*, in categorically holding that inducement is a "question of fact * * * not proper for resolution on a motion to dismiss," App. 18a–19a, the decision creates a circuit split with the Ninth Circuit, which holds exactly the opposite. *Infra*, Part C.

A. The decision conflicts with precedent interpreting § 271(b), which requires *active* inducement of all method steps.

1. Neither Congress nor this Court has ever recognized a cause of action for passive inducement. Instead, Congress conditioned liability on "*actively* induc[ing]" infringement. 35 U.S.C. § 271(b) (emphasis added). This statutory language requires "affirmative steps to bring about the desired result" of infringement by "lead[ing] on," "influenc[ing]," "prevail[ing] on," or "mov[ing] by persuasion or influence" a third party to infringe. *Glob.-Tech Appliances*, 563 U.S. at 760. Thus, defendants cannot be liable for inducement without taking "active steps [ ] to encourage direct infringement, such as advertising an infringing use or instructing how to engage in an infringing use," "as shown by clear expression or other affirmative steps." *Grokster*, 545 U.S. at 936–937 (cleaned up).

Importantly, "[a] method patent claims a number of steps; under this Court's case law, the patent is not infringed unless all the steps are carried out." *Limelight Networks, Inc.* v. *Akamai Techs., Inc.*, 572 U.S. 915, 921 (2014). "This principle follows ineluctably

from what a patent is: the conferral of rights in a particular claimed set of elements," each of which "'is deemed material to defining the scope of the patented invention.'" *Ibid.* (quoting *Warner-Jenkinson Co.* v. *Hilton Davis Chem. Co.*, 520 U.S. 17, 29 (1997)). "[A] patentee's rights extend only to the claimed combination of elements, and no further." *Ibid.*

That principle is critical in inducement cases to avoid "depriv[ing] § 271(b) of ascertainable standards. If a defendant can be held liable under § 271(b) for inducing conduct that does not constitute infringement, then how can a court assess when a patent holder's rights have been invaded?" *Id.* at 922. A claim for inducement thus lies only against a defendant that actively induces another to perform "all the steps" of the patented method. *Id.* at 921.

2. The decision below cannot be reconciled with these precedents. The patents here recite specific methods of administering icosapent to patients for "reducing risk of cardiovascular death" or (when taken with a statin) "reducing occurrence of a cardiovascular event." App. 8a–9a. It is undisputed that these patented steps are "limiting, such that infringement of the claims *requires* use of icosapent ethyl to reduce cardiovascular risk." App. 9a n.5. Yet neither the decision below nor Amarin's complaint identifies *any* alleged statement by Hikma that actively induces—i.e., "encourage[s]" "by clear expression or other affirmative steps," *Grokster*, 545 U.S. at 936–937—using icosapent to reduce CV risk, much less with a statin. Amarin pleaded no such statement by Hikma, whose generic product is undisputedly labeled *only* for the *noninfringing* use of treating SH. App. 17a.

Nevertheless, the decision below holds that vague statements in Hikma's pre-launch press releases calling its product a "generic version" and quoting "sales figures" plausibly amount to "an instruction or encouragement to prescribe [Hikma]'s drug for *any* of the approved uses of icosapent," App. 19a—including the CV use that appears only in Amarin's Vascepa label—even though "Hikma's approved label refers only to the SH indication," App. 5a.

At most, this is a theory of *passive* inducement. It requires speculating that physicians will: (1) read Hikma's pre-launch press releases (which are not directed to physicians but instead report on litigation and regulatory developments); (2) infer that they can use Hikma's "generic version" for all approved uses of Vascepa (including uses that Hikma does not promote); (3) consult *Amarin's* Vascepa label—instead of Hikma's label—to determine those uses; and (4) prescribe Hikma's generic product for Vascepa's CV use, which is never mentioned in Hikma's label or in any of Hikma's statements outside the label.

This expansive theory of liability is unprecedented. Until now, it was settled that "[p]ublication of information about a patented product is not itself inducement." Mark A. Lemley, *Inducing Patent Infringement*, 39 U.C. DAVIS L. REV. 225, 231 (2005). The Federal Circuit previously held that "vague" statements "cannot be combined with speculation about how physicians may act to find inducement." *Takeda Pharms. U.S.A., Inc.* v. *W.-Ward Pharm. Corp.*, 785 F.3d 625, 632 (Fed. Cir. 2015). Yet the decision below *depends upon* speculation that third parties will independently research the uses of a competitor's product, based on external sources of knowledge that Hikma does not

control. This cannot be what Congress meant by "actively induc[ing] infringement of a patent." 35 U.S.C. § 271(b).

Notably, the holding below is "not limited" to generic drugs; it expands potential inducement "outside of just the pharmaceutical context." Helm, *supra* note 3. Now, for example, merely calling a computer product "compatible" with a patented system, or comparing a product to "the leading brand," may invite a lawsuit for induced patent infringement. Even "citing sales data related to a patented method might be enough." *Ibid.* There are no "ascertainable standards" to limit the reasoning in the decision below, *Limelight*, 572 U.S. at 922, which will create uncertainty and risk across all industries.

3. Equally disturbing are the decision's repeated admonishments that Hikma should have done more to *discourage* infringement. The decision acknowledges that Hikma's "website includes an express disclaimer that Hikma's product is FDA-approved for fewer than all uses of Vascepa" and "clearly labels the drug as AB-rated, indicating generic equivalence for only labeled uses." App. 19a–20a & n.6. Yet the decision criticizes Hikma for including these disclaimers only on its website "and nowhere else," *ibid.*, warning that greater "clarity and consistency" in public statements "may be essential in *avoiding* liability for induced infringement," App. 22a (emphasis added).

This flips the burden of proof—and the meaning of "inducement"—on its head. As *Grokster* makes clear, "a *failure* to take affirmative steps to *prevent* infringement" is *not* inducement. 545 U.S. at 939 n.12 (emphasis added). "[O]ur legal system generally does not impose liability for mere omissions, inactions, or

nonfeasance," and all forms of aiding-and-abetting liability (inducement is one) require "culpable *participation* in another's wrongdoing"—not inaction. *Twitter, Inc.* v. *Taamneh*, 598 U.S. 471, 489, 493 (2023) (emphasis added); see also *Takeda*, 785 F.3d at 632 n.4 (recognizing that inducement requires "affirmative steps to induce, not affirmative steps to make sure others avoid infringement").

Making matters worse, the Federal Circuit here "provided little guidance" on what defendants can do "to help avoid inducement, and generally left that question unresolved," which "creates uncertainty." Helm, *supra* note 3. This Court's review is needed to clarify the standard for inducement and dispel the confusion that the decision below creates.

B. The decision conflicts with this Court's pleading standard.

Beyond conflicting with the substantive law of inducement, the decision below conflicts with this Court's precedent in *Twombly* and *Ashcroft* v. *Iqbal*, 556 U.S. 662 (2009), which govern the allegations a complaint must recite to avoid dismissal.

1. *Twombly* reached this Court in the same posture as this case: The district court dismissed the complaint for failure to state a claim (there, for antitrust conspiracy), but the court of appeals reversed, holding "a court would have to conclude that there is no set of facts that would permit a plaintiff to demonstrate" its entitlement to relief. 550 U.S. at 553. The court of appeals relied on *Conley* v. *Gibson*, which articulated the same "no set of facts" test. 355 U.S. 41, 45–46 (1957). That test effectively led the court of appeals in *Twombly* to deem "the prospect of unearthing direct evidence of

conspiracy sufficient to preclude dismissal, even though the complaint does not set forth a single fact in a context that suggests an agreement." *Twombly*, 550 U.S. at 561–562.

This Court reversed, announcing that *Conley*'s "no set of facts" standard "has earned its retirement" and is "best forgotten." *Id*. at 562–563. Two years later, in *Iqbal*, the Court confirmed that "*Twombly* retired the *Conley* no-set-of-facts test" and that *Twombly*'s holding was not limited to antitrust cases but "expounded the pleading standard for '*all* civil actions.'" *Iqbal*, 556 U.S. at 670, 684 (emphasis added).

"To survive a motion to dismiss [under the now-governing standard], a complaint must contain sufficient factual matter, accepted as true, to 'state a claim to relief that is plausible on its face.'" *Id*. at 678 (quoting *Twombly*, 550 U.S. at 570). The "sheer possibility" that discovery might uncover wrongdoing is not enough; the complaint *itself* must allege sufficient "factual content that allows the court to draw the reasonable inference that the defendant is liable for the misconduct alleged." *Id*. at 678. Recently, this Court applied the same plausibility standard in dismissing aiding-and-abetting claims where the complaint failed to recite sufficient allegations to conclude that the defendants "culpably participated in the tort at issue." *Twitter*, 598 U.S. at 506.

2. The decision below contradicts these precedents. Most glaringly, the decision recites pre-*Twombly* caselaw to hold that "[w]e may affirm [a dismissal] only if it is *certain* no relief could be granted *under any set of facts that could be proven*." App. 12a (quoting *Warden*, 288 F.3d at 110) (emphasis added). This is the same "no-set-of-facts test" that *Twombly* "retired,"

Iqbal, 556 U.S. at 670, which "left open the possibility that a plaintiff might later establish some 'set of [undisclosed] facts' to support recovery," *Twombly*, 550 U.S. at 561 (alteration in original) (quoting *Conley*, 355 U.S. at 45–46).

As in *Twombly*, the complaint here "does not set forth a single fact," *id.* at 561–562, suggesting that Hikma actively encourages the patented uses, which *require* reducing CV risk, App. 9a n.5. Again, it is undisputed that none of Hikma's alleged statements even *mention* CV risk. Nor does the complaint allege that a single physician has even read Hikma's press releases or website, much less been induced by those materials to infringe Amarin's patents.

Despite this fatal flaw in Amarin's complaint, the decision below invokes the "benefit of discovery," including both "fact discovery and expert testimony," because it could *possibly* lead to evidence of inducement. App. 14a, 19a. This Court rejected identical logic in *Iqbal* and *Twombly*: A complaint that facially lacks sufficient allegations to state a claim for relief "does not unlock the doors of discovery." *Iqbal*, 556 U.S. at 678–679. "It is no answer to say that a claim just shy of a plausible entitlement to relief can, if groundless, be weeded out early in the discovery process," or at summary judgment. *Twombly*, 550 U.S. at 559. If that were enough, "the threat of discovery expense w[ould] push cost-conscious defendants to settle even anemic cases." *Ibid.* The result here will be even more drastic—"the potentially enormous expense of discovery," *ibid.*, may deter generics from entering the market at all, *infra*, Part II.

C. The decision creates a circuit split over whether inducement can be decided on the pleadings as a matter of law.

Apart from conflicting with this Court's precedent, the Federal Circuit's decision here conflicts with the Ninth Circuit's approach to inducement claims in the analogous context of copyright law, creating a circuit split that only this Court can reconcile.

1. In *Perfect 10*, the Ninth Circuit recognized that this Court has "applied the patent law concept of 'inducement'" to claims for contributory copyright infringement and that inducement (in either context) requires "'clear expression or other affirmative steps taken to foster infringement.'" 494 F.3d at 800 (quoting *Grokster*, 545 U.S. at 936–937). The Ninth Circuit then dismissed a complaint that alleged induced copyright infringement for failure to state a claim because, as here, the complaint "point[ed] to no 'clear expression' or 'affirmative acts' with any specific intent to foster infringement." *Id.* at 801.

As the Ninth Circuit explained, upholding an inducement complaint that alleges "no facts suggesting that Defendants *promoted* their [product] *as a means to infringe* * * * would render the concept of 'inducement' virtually meaningless." *Id.* at 800–801 (emphasis added). Because the plaintiff had "not alleged any 'specific acts' intended to encourage or induce infringement," the Ninth Circuit affirmed the dismissal for failure to state a claim. *Id.* at 802.

Importantly, the Ninth Circuit held that it "need not * * * take as true that Defendants 'induce' consumers" to infringe because "'[*i*]*nducement' is a legal determination*, and dismissal may not be avoided by

characterizing a legal determination as a factual one." *Ibid.* (emphasis added). After all, courts "are not bound to accept as true a legal conclusion couched as a factual allegation." *Iqbal*, 556 U.S. at 678 (citation omitted). In the Ninth Circuit, therefore, courts considering motions to dismiss induced copyright infringement claims "must determine whether the facts as pled constitute a 'clear expression' of a specific intent to foster infringement" as a matter of law. *Perfect 10*, 494 F.3d at 802.

2. The decision below reaches exactly the opposite result. It rejects Hikma's "argu[ment] that the factual contents of Hikma's label and public statements are undisputed, such that [the court] can resolve this case as a matter of law." App. 19a. Instead, the decision holds that whether an undisputed statement induces infringement "is a *question of fact—not law*—and is therefore *not proper for resolution on a motion to dismiss*." *Ibid.* (emphasis added). The only citation supporting this holding is the Federal Circuit's own decision in *GSK*, which reversed a district judge (now-Federal Circuit Judge Stark) for treating the "fact question" of inducement "as though it were a legal one," App. 19a—a result that would be entirely proper under Ninth Circuit law.

There is no principled reason for this divergent approach. In *Grokster*, this Court adopted the *same* "inducement rule" for copyrights that Congress codified for patents, 545 U.S. at 936 & n.11, reaffirming "the historic kinship between patent law and copyright law," *Sony Corp. of Am.* v. *Universal City Studios, Inc.*, 464 U.S. 417, 439 (1984). Now, however, the same district courts in the Ninth Circuit will arbitrarily apply different pleading standards depending on whether a

plaintiff alleges induced infringement of a patent (controlled by Federal Circuit law) or copyright (controlled by regional circuit law).

This conflict requires the Court's guidance. As commentators observe, there is "no statutory requirement or instruction from the Supreme Court indicating that the determination of all elements of inducement are actually questions of fact." Garrett T. Potter, *Beefing Up Skinny Labels: Induced Infringement as a Question of Law*, 97 NOTRE DAME L. REV. 1707, 1711 (2022). History suggests, however, that inducement is at least partly a *legal* issue: "There is no suggestion that juries had the responsibility during the 18th century of analyzing inducement of infringement, and the first example of any indirect infringement was assessed unilaterally by the judge, not a jury." *Id.* at 1730 (citing *Wallace* v. *Holmes*, 29 F. Cas. 74, 79–80 (D. Conn. 1871)).

Given the uncertainty and split in authority over whether inducement is a question of law or fact, and whether courts may dismiss inducement claims on the pleadings, this Court should grant review.

II. Review is urgently needed because the decision below effectively nullifies labeling carveouts under section viii, threatening severe harm to generic-drug competition.

The questions presented are exceptionally important and warrant immediate review because the decision below effectively vitiates section viii—a critical statutory mechanism for expediting access to low-cost, generic versions of branded drugs.

Although generics can still seek FDA approval for skinny labels carving out patented uses, it no longer

makes sense to do so because the brand can sue anyway—including for patented uses the skinny label undisputedly omits. Indeed, the facts deemed sufficient to state a claim for inducement here exist in *every* skinny-label case. *Infra*, Part A. The decision thus defeats section viii's core purpose: ensuring that patents on carved-out uses do not "delay or block approval of a generic drug that infringes no patent." *Caraco*, 566 U.S. at 424. Absent review, the decision will deter drugmakers from invoking section viii, delaying access to generic drugs until *all* patents covering *all* approved uses expire, which will drive up healthcare costs significantly. *Infra*, Part B.

A. The allegations deemed sufficient to plead induced infringement here apply to *every* generic drug with a skinny label.

Under the decision below, no skinny label is safe. Brands will always find ways to allege induced infringement of uses that a skinny label carves out.

1. Consider the phrases "generic version" and "generic equivalent," which the decision repeatedly relies on to find plausible inducement of uses that Hikma undisputedly carved out of its label. App. 5a–7a, 18a–20a. As the dissent in *GSK* recognized: "Essentially *all* ANDA generics are the 'generic version' or 'generic equivalent' of a brand drug; the law requires them to be." *GSK*, 7 F.4th at 1353 (Prost, J., dissenting) (citing 21 U.S.C. § 355(j)(2)(A)(iv), (j)(4)(F) (requiring ANDA applicants to establish "bioequivalence") and 21 C.F.R. § 314.94(a)(7)(i)).

Congress itself refers to generic drugs as the "'*generic version*' * * * [of a] reference listed drug." 21 U.S.C. § 353d(a)(3) (emphasis added). This Court has

used the same phrase when interpreting section viii. See *Caraco*, 566 U.S. at 415 ("Caraco wishes to market a *generic version* of repaglinide for two (and only two) uses.") (emphasis added). So has the Department of Health and Human Services, which includes FDA. See 42 C.F.R. § 423.132(a) (referring to the "lowest priced *generic version* of [a] covered [Medicare] Part D drug") (emphasis added). As FDA explains, the Hatch-Waxman Act allows it "to approve applications to market *generic versions of brand-name drugs* without repeating costly and duplicative clinical trials to establish safety and efficacy."[7]

If accurately calling a generic drug a "generic version" or "generic equivalent" were enough to induce infringement, every generic drug with a skinny label would induce infringement of every patent on its branded equivalent—rendering section viii useless. As commentary on the decision below warns, Hikma's statement that its product is "a generic equivalent of Vascepa * * * * accurately reflects [its] FDA approval," yet the decision "suggests that such accurate statements regarding regulatory approval may constitute inducement." Helm, *supra* note 3. It is "highly unlikely that Congress intended to make generics liable for simply stating what the law requires." *GSK*, 7 F.4th at 1353 (Prost, J., dissenting). Nor is it plausible that Congress intended for generics to be held liable for inducing patent infringement, despite a section viii carve-out, merely for characterizing a product as a

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[7] *Abbreviated New Drug Application (ANDA)*, FDA, https://www.fda.gov/drugs/types-applications/abbreviated-new-drug-application-anda (emphasis added).

"generic version" consistent with the Hatch-Waxman Act's statutory scheme.

2. To be sure, the decision adds that "Hikma did much more than call its product a 'generic version.'" App. 21a. But the "much more" here amounts to "touting sales figures" for the branded drug—without even *mentioning*, much less encouraging, its patented uses. App. 19a–20a. Again, patentees can allege similar facts in nearly every skinny-label case. Market size is a basic consideration for any competitive product launch, and the pharmaceutical industry is no exception. Under the panel's logic, a generic company's CEO announcing a new "generic" product and estimating the market size for the relevant drug compound to shareholders on an earnings call would invite a lawsuit for induced infringement.

It is no answer that the "touted sales figures for Vascepa" are "largely attributable to the off-label CV indication." App. 18a–19a. Sales of a branded drug will *always* include uses that are "off-label" for a skinny-label generic; by definition, the skinny label does not include all uses of the branded drug.

Likewise, every skinny-label generic can be accused of competing for the brand's sales, including carved-out uses, due to "market realities" of generic substitution—i.e., brands can always allege that "even if a generic drug is formally approved only for unpatented uses, pharmacists and doctors will nonetheless substitute the generic for all indications once it becomes available." *AstraZeneca Pharms. LP* v. *Apotex Corp.*, 669 F.3d 1370, 1380 (Fed. Cir. 2012). If this were enough to induce infringement, it "would, in practice, vitiate" section viii and "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," "contrary to the statutory scheme." *Ibid.*

That is why the "requirement of inducing acts is particularly important in the Hatch-Waxman Act context"—"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*." *Takeda*, 785 F.3d at 631 (emphasis added). Instead of requiring "inducing acts," however, the decision below finds plausible inducement based on accurately reporting publicly available sales figures that allegedly include "off-label infringing uses." *Ibid.* Because patentees can always allege that a skinny-label generic will effectively compete for sales attributable to off-label uses, the decision below will, "in practice, vitiate" section viii. *AstraZeneca*, 669 F.3d at 1380.

B. The decision below will deter generics from using labeling carve-outs, which will delay market entry and raise drug prices.

Left undisturbed, the decision will "delay or deter generics from entering the market." Tu, *supra* note 1, at 18. Indeed, there will be no incentive for generic drugmakers to use section viii at all.

1. Recall, Congress created section viii as an alternative to paragraph IV certifications, which "provok[e] litigation" that "is likely to keep the generic drug off the market for a lengthy period." *Caraco*, 566 U.S. at 407–408. The "hazard of sparking costly litigation," in turn, can deter generic drugmakers from challenging unexpired patents on branded drugs. *Teva Pharms. USA, Inc.* v. *Sebelius*, 595 F.3d 1303, 1305 (D.C. Cir.

2010). By enacting section viii, Congress allowed generic drugmakers to *avoid* the costs and risks of paragraph IV litigation with a skinny label, which ensures that "one patented use will not foreclose marketing a generic drug for other unpatented ones." *Caraco*, 566 U.S. at 415.

Absurdly, the decision below makes skinny labels *riskier* than paragraph IV certifications. At least with a paragraph IV certification, the generic drugmaker is unlikely to pay damages: Any litigation begins before FDA can approve the generic drug, *id.* at 407, and "[m]onetary damages are permitted only if there has been 'commercial manufacture, use, or sale,'" *Eli Lilly & Co.* v. *Medtronic, Inc.*, 496 U.S. 661, 678 (1990) (quoting 35 U.S.C. § 271(e)(4)(C)). As a result, it "is usually true of a paragraph IV litigation" that there is "no claim for damages." *F.T.C.* v. *Actavis, Inc.*, 570 U.S. 136, 152 (2013).

In contrast, the decision below allows brands to assert patents against skinny-label generics *after* launch—when the generic can be on the hook for the brand's lost profits. In *GSK*, for example, a jury awarded more than $234 million in lost profits. 7 F.4th at 1340–1341. As the dissent foresaw, "generics simply won't play" with section viii if complying with it can lead to massive damages. *GlaxoSmithKline LLC* v. *Teva Pharms. USA, Inc.*, 25 F.4th 949, 955 (Fed. Cir. 2022) ("*GSK Rehearing*") (Prost, J., dissenting). "The risk is too great. Generics sell their products for considerably less than brands, so a jury's award of lost profits to the brand can dwarf whatever profits a generic could make." *Ibid.*

"It seems implausible that Congress, when enacting the skinny-label provisions against the backdrop of

the inducement statute, intended to put generics in this position." *Ibid.* Yet that is the practical result of the Federal Circuit's decisions in *GSK* and below, which will *deter*, rather than encourage, drugmakers from seeking approval for unpatented uses until all patents on a branded drug have expired.

2. Beyond the risk of damages, the cost of litigation alone will deter generic drugmakers from invoking section viii. This Court has long recognized that "patent litigation is a very costly process," and "prospective defendants will often decide that paying royalties under a license or other settlement is preferable to the costly burden of challenging the patent." *Blonder-Tongue Labs., Inc.* v. *Univ. of Ill. Found.*, 402 U.S. 313, 334, 338 (1971). By one estimate, "the average cost to defend an infringement lawsuit in the United States is roughly $3.5 million." Gregory Day & Steven Udick, *Patent Law and the Emigration of Innovation*, 94 WASH. L. REV. 119, 125 (2019). Thus, even unsuccessful "lawsuits increase the potential costs for competitors to enter the market or delay the entry of" generic drugs. Tu, *supra* note 1, at 18. Again, this Court raised a similar concern in *Twombly* that "the potentially enormous expense of discovery" often "will push cost-conscious defendants to settle even anemic cases." 550 U.S. at 559.[8]

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[8] This case is a prime example of that risk. In addition to suing Hikma, Amarin sued a health insurer (Health Net LLC) for providing coverage and reimbursement for prescriptions filled with Hikma's generic product. App. 35a. The insurer has since settled. App. 2a n.2. Although Hikma continues to litigate this case on remand, Amarin is

As the federal government has recently warned, generic drugmakers "face difficult economic conditions that stem from low and/or unpredictable sales volumes, prices, and profit margins for many generic drugs."[9] Adding litigation costs *and* the risk of lost-profits damages will "deter potential market entrants."[10] That is why the Solicitor General in *GSK* warned that even "*potential* for inducement liability in these circumstances may significantly deter use of the section viii pathway, even if such liability is rarely imposed." *Teva*, 2023 WL 2717391, at *22.

3. By deterring generic companies from using section viii, the decision below will delay generic market entry and increase drug prices, defeating Congress's intent "to speed the introduction of low-cost generic drugs to market." *Caraco*, 566 U.S. at 405.

"The cost of pharmaceuticals has a massive influence on the healthcare system." Potter, *supra*, at 1707. The U.S. pharmaceutical industry accounts for nearly a trillion dollars in annual revenue, *ibid*., and generic

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aggressively pursuing costly discovery—even on its label-based inducement theory that the Federal Circuit rejected (see App. 17a–18a)—in a clear attempt to force Hikma off the market.

[9] U.S. Dept. Health & Human Services, *Policy Considerations to Prevent Drug Shortages and Mitigate Supply Chain Vulnerabilities in the United States* 3 (2024), https://aspe.hhs.gov/sites/default/files/documents/3a9df8acf50e7fda2e443f025d51d038/HHS-White-Paper-Preventing-Shortages-Supply-Chain-Vulnerabilities.pdf.

[10] *Ibid*.

drugs have saved patients and payors an estimated $2.9 trillion in the last decade alone.[11]

Section viii plays a critical role in achieving these savings. Nearly half of all generics for drugs with multiple approved uses launch with skinny labels, providing low-cost alternatives years before patents on carved-out uses expire. Tu, *supra* note 1, at 15.[12] In a five-year period, for example, skinny labels saved Medicare an estimated $1.5 billion. *Ibid.* The federal government has echoed that skinny labeling is a "critical practice[ ]" that "may result in decreased costs to patients and to the federal government, including reducing spending on Medicare and Medicaid."[13] As the decision below illustrates, however, "[r]ecent litigation * * * may discourage the use of carve-outs and thus delay the approval of some generic drugs," threatening these important cost-savings.[14]

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In passing the Hatch-Waxman Act, "Congress sought to get generic drugs into the hands of patients

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[11] Ass'n for Accessible Meds., 2023 *The U.S. Generic & Biosimilar Medicines Savings Report* 7 (Sept. 2023), https://accessiblemeds.org/sites/default/files/2023-09/AAM-2023-Generic-Biosimilar-Medicines-Savings-Report-web.pdf.

[12] See also Bryan S. Walsh et al., *Frequency of First Generic Drug Approvals With "Skinny Labels" in the United States*, 181 J. AM. MED. ASS'N INTERNAL MED. 995 (2021).

[13] U.S. Dep't of Health & Human Servs., *Comprehensive Plan for Addressing High Drug Prices* 21 (Sept. 2021), https://aspe.hhs.gov/sites/default/files/2021-09/Drug_Pricing_Plan_9-9-2021.pdf.

[14] *Ibid.*

at reasonable prices—fast." *In re Barr Labs., Inc.*, 930 F.2d 72, 76 (D.C. Cir. 1991). The decision below derails that objective. It transforms section viii from a virtual guarantee against patent-infringement liability to an invitation for exorbitant damages claims. Even with long odds of ultimate success, patentees will reflexively file suit if they can dodge motions to dismiss with vague and practically unavoidable statements that their generic competitors sell "generic versions" competing for the branded drug's sales. Without this Court's review, patients, doctors, and payors (including the government) will pay the price.

CONCLUSION

For the foregoing reasons, the petition for certiorari should be granted. At a minimum, given the importance of the question presented to the U.S. healthcare system and the federal government's support for certiorari in *GSK*, the Court should call for the views of the Solicitor General.

Respectfully submitted.

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