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.

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

BRIEF FOR PETITIONERS

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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

This case is about the affirmative conduct a complaint must allege to state a plausible claim of "actively induce[d] infringement of a patent." 35 U.S.C. § 271(b). The legal standard for active inducement is especially important for the generic pharmaceutical industry because branded drugmakers often hold patents on "a particular method of using [a] drug." *Caraco Pharm. Labs., Ltd.* v. *Novo Nordisk A/S*, 566 U.S. 399, 405 (2012). Generic drugmakers are not held liable for directly infringing such patents because they do not treat patients, but they risk actively inducing doctors and patients to infringe depending on the instructions in their generic drug labels, which generally must match the labels for their branded counterparts.

"To facilitate the approval of generic drugs as soon as patents allow," *ibid.*, Congress passed the Drug Price Competition and Patent Term Restoration Act of 1984, commonly known as the Hatch-Waxman Act, which created regulatory pathways intended to resolve patent disputes before generic product launch, or to avoid litigation altogether. One of the Act's provisions, known in the pharmaceutical industry as "section viii," authorizes so-called skinny labels, which allow generic-drug manufacturers to carve out patented indications from their generic labels, leaving only unpatented indications that do not actively induce infringement. See 21 U.S.C. § 355(j)(2)(A)(viii).

When it passed section viii, Congress was aware of state laws allowing automatic substitution by pharmacists of generic-drug equivalents for branded counterparts, meaning that doctors and patients inevitably would use skinny-labeled generics for patented indications. *Infra* 7–8. Congress nonetheless contemplated

that generic manufacturers who choose the section viii pathway could avoid labeling that actively induces patent infringement. A skinny label that carves out the patented indication thus ensures "that one patented use will not foreclose marketing a generic drug for other unpatented ones." *Caraco*, 566 U.S. at 415.

This skinny-label solution works only if it remains an economically viable option to expedite generic-drug competition for unpatented uses. Until recently, the Federal Circuit understood this: The "market realities" of automatic substitution and resulting infringement by doctors and patients cannot suffice to plead active inducement by generic drugmakers that invoke the section viii pathway. *AstraZeneca Pharms. LP* v. *Apotex Corp.*, 669 F.3d 1370, 1380 (Fed. Cir. 2012). If merely alleging that a generic drug with a skinny label will inevitably be substituted for patented uses were enough to plead active inducement, 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*.

Following the Federal Circuit's decision in this case, however, it no longer makes economic sense for any generic drugmaker to invoke section viii. The court below interpreted § 271(b) to impose liability for the most routine and anodyne statements about skinny-labeled generics. In doing so, the court of appeals effectively read the word "actively" out of § 271(b), replacing it with the precise opposite word, "passively." Branded drugmakers now may threaten lost-profit damages for almost anything a generic drugmaker might say about generic drug products

brought to market under section viii—including (as here) statements to investors, and not even to doctors or patients. As a result, the Federal Circuit's holding risks shutting down the section viii pathway altogether.

The decision below should not stand. It spurns the statutory text and trammels Congress' settled purposes in enacting both the 1952 Patent Act and the 1984 Hatch-Waxman Act. Section 271(b) requires that (1) the defendant "actively induces" a direct infringer to take specific action, and (2) that action amounts to "infringement of a patent." A complaint assuredly fails to state a claim for actively induced infringement of a patented method under that straightforward test if it does not allege any instruction or other statement by the defendant that encourages, or even mentions, the patented use. Where, as here, a skinny label fully carves out all patented uses under section viii, allegations that the generic drugmaker simply calls its product a "generic version" of the branded drug and cites public information about the drug (for example, sales figures) are insufficient to state a claim under § 271(b).

Amarin's contrary positions are inconsistent with the plain text of the Patent Act and offend the Hatch-Waxman Act's well-recognized purposes. Allowing cases like this one to survive the pleadings stage—thus subjecting generic drugmakers to the burdensome costs of discovery and in terrorem threats of massive (and potentially trebled) lost-profits damages—would make the section viii pathway economically nonsensical, defeating Congress' intent to promote generic-drug competition. Reversal is in order.

OPINIONS BELOW

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

JURISDICTION

The district court, which dismissed the case with prejudice, JA64–65, 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. The Chief Justice extended the time to file a petition for a writ of certiorari until February 14, 2025. Hikma timely filed the petition, which the Court granted on January 16, 2026. This Court has jurisdiction under 28 U.S.C. § 1254(1).

STATUTORY PROVISIONS INVOLVED

The relevant statutory provisions are reproduced in the petition appendix at 42a–43a.

STATEMENT

A. Background

1. The Hatch-Waxman Act

a. A manufacturer seeking FDA approval to market a new drug must submit a new drug application (NDA) with "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 a] reference listed drug," 21 U.S.C. § 353d(a)(3), by filing an

abbreviated new drug application (ANDA). *Caraco*, 566 U.S. at 404–405.[1] 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 referenced 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)); see also 21 U.S.C. § 355(j)(2)(A)(iv), (j)(4)(F); 21 C.F.R. § 314.94(a)(7)(i). In general, "labeling proposed for the [generic version] is the same as the labeling approved for the [reference] listed drug." 21 U.S.C. § 355(j)(2)(A)(v).

"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." *Caraco*, 566 U.S. at 405. Some 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, and FDA lists those patents in "the Orange Book." *Id.* at 405–406.

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[1] All emphases are added unless stated otherwise.

b. An ANDA filer (i.e., generic-drug manufacturer) seeking to market a generic version of a reference listed drug with one or more unexpired patents in the Orange Book has two options as to each patent.

The first 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)).

The second option applies to Orange-Book patents that cover fewer than all FDA-approved methods of using a drug. 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 use a skinny label "that 'carves out' from the brand's approved label the still-patented methods of use." *Ibid.* Section viii thus represents an "exception to the usual rule that a generic drug must bear the same label as the brand-name product." *Ibid.*

By omitting instructions that might otherwise encourage patented uses, the generic drugmaker avoids a potential claim that its label "actively induces infringement" under § 271(b). Thus, an ANDA filed with a section viii statement and no paragraph IV

certification does not provoke Hatch-Waxman litigation or otherwise justify a 30-month stay of FDA approval. See 21 U.S.C. § 355(j)(5)(B)(iii). This process ensures that skinny-labeled generic drugs "can quickly come to market" inasmuch as "one patented use will not foreclose marketing a generic drug for other unpatented ones." *Caraco*, 566 U.S. at 415.

c. Congress adopted section viii and its skinny-label approach against the backdrop of state generic substitution laws, which "allow[] pharmacists to substitute generic drugs for brand name drugs under certain conditions." *Inwood Labs., Inc.* v. *Ives Labs., Inc.*, 456 U.S. 844, 847 & n.4 (1982). When Congress enacted the Hatch-Waxman Act in 1984, "all states had repealed their anti-substitution statutes in favor of drug product substitution." William Haddad, *The Drug Price Competition and Patent Term Restoration Act, 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.Cert.Br. 5–6 & nn.2–3 (collecting statutes).

At the time of section viii's adoption, it was thus widely understood that doctors and patients necessarily would infringe method-of-treatment patents despite the use of skinny labels. As former Congressman Henry A. Waxman explained in a later-filed brief to the Federal Circuit, "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"; yet, Congress "intended that, without more, a generic would not be liable for infringement if a physician prescribes generic drugs for patented off-label uses." *GlaxoSmithKline LLC* v. *Teva Pharms.*

USA, Inc., No. 18-1976 (Fed. Cir. Oct. 27, 2021), Amici Curiae Br. in Support of Pet. for Reh'g En Banc, Dkt. 226, at 5 (citation omitted).

Congress adopted section viii nevertheless. In section viii, Congress allowed generic drugs to reach the market—with no prior notice to brands—using a skinny label, to ensure doctors and patients had access to unpatented drugs for unpatented indications, even though doctors and patients would inevitably infringe by also practicing carved-out, patented indications. The House Report explained that, under section viii, "if [a] listed drug has been approved for hypertension and angina pectoris, and if the indication for hypertension is protected by patent, then [an] applicant could seek approval for only the angina pectoris indication." H.R. Rep. No. 98-857, at 21 (1984).

2. Amarin's icosapent ethyl drug product branded as Vascepa

In 2012, FDA approved Amarin's NDA to market Vascepa, which contains the active ingredient icosapent ethyl. BIO.App.6a, ¶¶ 28, 30. The approval followed the completion of a study demonstrating that icosapent ethyl reduces triglycerides in patients with severe hypertriglyceridemia, a condition characterized by very high levels of triglycerides (fats) in the blood. BIO.App.6a, ¶ 30. Vascepa was thus initially approved and indicated solely for use to reduce triglyceride levels in adult patients with severe hypertriglyceridemia. *Ibid.*; BIO.App.13a–14a, ¶ 56. This is the "SH indication." As Amarin acknowledges, "the primary concern for patients with *severe* hypertriglyceridemia" is pancreatitis, which is general inflammation of the pancreas. BIO.6.

In late 2019, FDA approved a second Vascepa indication for use "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" and certain risk factors for cardiovascular disease. BIO.App.8a, ¶ 34; BIO.App.13a–14a, ¶ 56. This is the "CV indication."

The parties agree the SH and CV indications are distinct. For one, Amarin acknowledges the SH indication is now "off-patent." BIO.22. As Amarin also acknowledges, "FDA was not convinced" that clinical data demonstrating icosapent ethyl reduces triglycerides "proved a reduction in cardiovascular risk." BIO.6; see also BIO.App.7a, ¶ 32 (explaining FDA determined "lowered triglyceride levels * * * did not show an actual reduction in cardiovascular risk").

3. Hikma's ANDA for a generic version of Vascepa

In 2016, Hikma filed an ANDA seeking approval for a generic icosapent ethyl product. That ANDA included paragraph IV certifications challenging Amarin's then-existing patents tied to Vascepa's sole FDA-approved indication at the time—the SH indication. Pet.App.4a, n.4. Amarin sued Hikma on those patents. Hikma prevailed, invalidating all asserted SH patents as obvious. *Ibid.*; see also *Amarin Pharma, Inc.* v. *Hikma Pharm. USA*, 449 F. Supp. 3d 967 (D. Nev. 2020), *aff'd*, 819 F. App'x 932 (Fed. Cir. 2020).

FDA approved the CV indication in 2019, shortly before trial on the patents for the SH indication. BIO.App.8a, ¶ 34. Per FDA regulations, Amarin listed patents associated with the CV indication in the

Orange Book. BIO.App.19a–20a, ¶¶ 70–78. Hikma's ANDA thus had to address the CV indication before FDA could approve that ANDA.

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

Hikma's section viii statement and proposal to carve out the CV indication were consistent with the use codes Amarin provided FDA for each of its Orange Book-listed, CV-indication patents. See *Caraco*, 566 U.S. at 407 ("whether section viii is available to a generic manufacturer depends on how the brand describes its patent"); BIO.App.26a, ¶ 97 (FDA's "role with respect to patents [i]s 'ministerial'"). FDA approved Hikma's skinny-label generic product in May 2020. BIO.App.27a, ¶ 105.

In November 2020, shortly after the Federal Circuit summarily affirmed the invalidity judgment for the SH-indication patents, Hikma launched its generic icosapent product with the CV indication carved out of its label. Pet.App.7a. Hikma's label has remained materially the same ever since. See BIO.App.27a, ¶ 106.

B. Procedural background

1. The operative complaint

Within a month of Hikma's product launch, Amarin sued again, this time asserting claims for actively induced infringement of patents that allegedly cover the CV indication under § 271(b). See BIO.App.1a–62a.

Amarin seeks "damages, including lost profits." BIO.App.47a, ¶ 170; BIO.App.51a, ¶ 186. Amarin also seeks a finding that Hikma's alleged infringement was willful, BIO.App.59a, which allows courts to "increase the damages up to three times the amount found or assessed," 35 U.S.C. § 284. See *Halo Elecs., Inc.* v. *Pulse Elecs., Inc.*, 579 U.S. 93, 103–104 (2016).

Amarin currently asserts two patents allegedly related to the CV indication.[2] The first, the '537 patent, claims a specific method of treatment, including using icosapent ethyl with a second agent (a recited statin) for "reducing occurrence of a cardiovascular event" in certain patients. Pet.App.8a; BIO.App.10a–11a, ¶ 45; JA76. The second, the '861 patent, claims a different method of treatment for a different patient population that requires using icosapent ethyl for "reducing risk of cardiovascular *death* in a subject with established cardiovascular disease." Pet.App.9a; BIO.App.12a–13a, ¶ 53; JA180. Vascepa is not indicated to reduce the risk of cardiovascular death. See BIO.App.13a–14a, ¶ 56 (CV indication covers Vascepa's use "as an adjunct to maximally tolerated statin therapy to reduce the risk of myocardial infarction, stroke, coronary revascularization, and unstable angina requiring hospitalization," with no mention of cardiovascular death).

Amarin's induced-infringement allegations, summarized below, rely on a combination of Hikma communications contained in its FDA-approved skinny label, in pre-launch press releases to investors announcing litigation victories, and on its website. Amarin

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[2] The parties stipulated to dismissal of Amarin's claim as to a third asserted patent. Pet.App.3a–4a n.3.

alleges that doctors and patients may infer from the combination of these communications that they may use Hikma's product for both Vascepa indications.

a. Amarin does not allege—and no lower court has found—that Hikma's label, standing alone, induces infringement. See Pet.App.17a, 21a. Amarin's complaint instead relies on four features of the label, in combination with Hikma's other public statements.

It relies, first, on the absence of a "CV Limitation of Use" that was in the original Vascepa label, before FDA approved the CV indication. See BIO.App.27a–29a, ¶¶ 107–108. That limitation stated that "[t]he effect of VASCEPA on cardiovascular mortality and morbidity in patients with severe hypertriglyceridemia has not been determined." BIO.App.14a–16a, ¶ 60. Amarin alleges "Hikma intentionally amended the *proposed* labeling for its icosapent ethyl capsules to remove the CV Limitation of Use." BIO.App.28a–29a, ¶ 108. The complaint asserts that the absence of this language in Hikma's label leads "healthcare providers and patients [to] believe that Hikma's generic icosapent ethyl capsules could be and should be used * * * to reduce the risk of CV events." *Ibid.*

At the same time, Amarin acknowledges that Hikma never distributed its product with the CV Limitation of Use, against which the absence of the limitation might be compared. Hikma only "removed" the CV Limitation of Use from a *draft* label submitted to FDA that was never public. See BIO.App.27a–29a, ¶¶ 104–108; Pet.App.31a n.1. And Hikma removed the limitation only because the generic product label must be the "same" as the branded drug's label, 21 U.S.C. § 355(j)(2)(A)(v), and Vascepa's label no longer has that CV Limitation of Use. While section viii allows

generic labeling to omit information on patented methods, thus making the label "skinny," it does not provide a mechanism for generics to add disclaimer language; Amarin does not allege otherwise. See generally *PLIVA, Inc.* v. *Mensing*, 564 U.S. 604, 614–615 (2011) (explaining how generic drug labels generally must be the same as branded drug labels).

Amarin relies, second, on a warning in the patient information leaflet under the heading: "What are the *possible side effects* of icosapent ethyl?" BIO.App.36a, ¶ 131; JA124–125. One of the "possible side effects" identified is "[h]eart rhythm problems which can be *serious and cause hospitalization * * * especially in people who have heart (cardiovascular) disease* or diabetes with a risk factor for heart (cardiovascular) disease." *Ibid.* This warning to patients with "cardiovascular[] disease" about "serious" side effects is the only instance in which the label uses the term "cardiovascular." Amarin asserts that this warning against using Hikma's product in patients with CV risk "encourages, promotes, and instructs treating patients" with "established cardiovascular disease." BIO.App.36a, ¶ 131.

Amarin relies, third, on language in Hikma's patient information leaflet concerning "[g]eneral information" about icosapent ethyl, stating that "[m]edicines are sometimes prescribed for purposes other than those listed in a Patient Information leaflet." BIO.App.36a–37a, ¶ 132; JA125.

Amarin relies, fourth, on other elements of Hikma's label, including baseline characteristics of patients in a clinical study and some statin usage. See, e.g., BIO.App.35a–36a, ¶ 130; BIO.App.37a–38a, ¶ 134 (citing JA122). The only clinical study described in Hikma's label, however, is the clinical study for

"Severe Hypertriglyceridemia." JA122. Cf. JA85 (current Vascepa label that describes an additional clinical study for "Prevention of Cardiovascular Events" in "statin-treated adult patients," which does not appear in Hikma's label).

b. The operative complaint alleges that the combination of Hikma's label with other public statements induces infringement. These other statements include Hikma's pre-launch press releases from March and September 2020. See BIO.App.30a–31a, ¶¶ 112 (citing JA39–41), 118 (citing JA42–44).

The March 2020 press release addresses Hikma's trial victory in the earlier litigation regarding Amarin's SH-indication patents and is titled: "Hikma confirms favourable ruling in generic Vascepa® patent suit." JA39. Below are the relevant statements, with the allegedly inducing statements italicized:

> Hikma * * * today confirms that the United States District Court for the District of Nevada has ruled that *Hikma's generic version of Amarin Corporation's Vascepa*® (icosapent ethyl) 1 gm capsules does not infringe six United States Patents, as asserted by Amarin, because the asserted claims of these patents were held to be invalid.
>
> Hikma is working closely with the U.S. Food and Drug Administration (FDA) to gain approval for its Abbreviated New Drug Application (ANDA) for *its generic version of Vascepa*®. * * *
>
> Vascepa® is a prescription medicine that is indicated, *in part*, as an adjunct to diet to

> reduce triglyceride levels in adult patients with severe (≥500 mg/dL) hypertriglyceridemia.
>
> *According to IQVIA, US sales of Vascepa® were approximately $919 million in the 12 months ending February 2020.*

JA39–40. This pre-launch press release includes no labeling information for Hikma's anticipated product, mentions only Vascepa's unpatented SH indication, and is directed to investors. It includes Hikma's stock information and invites enquiries to the following email address: uk-investors@hikma.uk.com. JA40.

The September 2020 press release, which also predates Hikma's product launch, is similarly titled: "Hikma receives favourable court ruling for its generic Vascepa®." JA42. Below are the relevant statements, with the allegedly inducing statements italicized:

> Hikma * * * announces that the US Court of Appeals for the Federal Circuit today upheld a ruling by the US District Court for the District of Nevada finding that *Hikma's generic version of Vascepa®* (icosapent ethyl) 1gm does not infringe any valid claim of six key Amarin-owned patents. Hikma received FDA approval for the product in May 2020 and is working towards a launch.
>
> Vascepa® is a prescription medicine that is indicated, *in part*, as an adjunct to diet to reduce triglyceride levels in adult patients with severe (≥500 mg/dL) hypertriglyceridemia. *According to IQVIA, US sales of Vascepa® were approximately $1.1 billion in the 12 months ending July 2020.*

JA42–43.

Like the March 2020 press release, the only Vascepa indication mentioned in the September 2020 press release is Vascepa's unpatented SH indication. *Ibid*. Neither press release uses the term "cardiovascular," discusses statin use, or contains any use instructions for Hikma's anticipated generic product.

Amarin alleges that these press releases induce infringement because they "do[] not state that Hikma's 'generic version' of VASCEPA® should not be used for the CV Indication" and report annual "sales for all uses of Vascepa®, including the CV Indication." BIO.App.30a–31a, ¶¶ 113–114; BIO.App.32a, ¶¶ 120–121. The operative complaint asserts, without further elaboration, that each pre-launch press release "communicates to and instructs healthcare providers and patients that Hikma's 'generic version' of VASCEPA® should be used for all the same indications as VASCEPA®, including to reduce the risk of CV events." BIO.App.31a, ¶ 115; BIO.App.32a, ¶ 122. The press releases themselves, however, are attached as exhibits to Amarin's complaint. JA39–44.

Amarin also attached Hikma's November 2020 press release announcing its generic-product launch. See JA45–50. That press release, copied below in relevant part, includes labeling information for Hikma's generic icosapent product, says the product is indicated for the SH Indication, and states that the product is "not approved for any other indication for the reference listed drug VASCEPA®":

> Hikma's FDA-approved Icosapent Ethyl Capsule product is indicated for the following indication: as an adjunct to diet to reduce

> triglyceride levels in adult patients with severe (≥500 mg/dL) hypertriglyceridemia. *Hikma's product is not approved for any other indication for the reference listed drug VASCEPA®.*

JA45–46.

The complaint acknowledges that Hikma removed the March and September 2020 press releases from the "Newsroom" webpage on its website in mid-October 2020, before launching its generic product in November 2020. BIO.App.31a, ¶ 117; BIO.App.32a–33a, ¶ 124. Thus, only Hikma's November 2020 press release, which Amarin does not allege induces infringement, remained on Hikma's "Newsroom" webpage when its generic product became available to doctors and patients.

c. Amarin alleges finally that a Hikma webpage described Hikma's generic product as therapeutically equivalent (i.e., AB rated) to VASCEPA® for treating "hypertriglyceridemia." See BIO.App.26a, ¶ 98; BIO.App.30a, ¶ 111; JA195. This webpage, which does not mention Vascepa or statins, includes a disclaimer similar to the one in Hikma's November 2020 press release: "Hikma's generic version is indicated for fewer than all approved indications of the Reference Listed Drug." JA195; Pet.App.7a.

Amarin alleges, in substance, that "hypertriglyceridemia" is a broader concept than "severe hypertriglyceridemia." BIO.App.33a–34a, ¶ 126. But the complaint does not allege that merely treating "hypertriglyceridemia" reduces the risk of a cardiovascular event or cardiovascular death as required by the asserted patent claims. See BIO.App.7a, ¶ 32

(acknowledging other drugs "lowered triglyceride levels in this patient population but did not show an actual reduction in cardiovascular risk").

2. The district court's decision

The district court granted Hikma's motion to dismiss for failure to state a claim under Federal Rule of Civil Procedure 12(b)(6). Pet.App.11a, 25a–35a.

The court began by accepting any non-conclusory, factual allegations as true under this Court's pleading standard in *Bell Atlantic Corp.* v. *Twombly*, 550 U.S. 544, 555–556 (2007), and *Ashcroft* v. *Iqbal*, 556 U.S. 662, 678 (2009). Pet.App.27a. It then addressed Amarin's factual allegations summarized above.

First, the court found that Hikma's "label does not instruct CV risk reduction," as required by Amarin's patents. Pet.App.32a. As the court explained, the "warning as to side effects * * * * is hardly instruction or encouragement." Pet.App.31a.

The court then found "that the lack of a CV limitation on Hikma's label does not plausibly teach CV risk reduction." Pet.App.32a. It cited Federal Circuit precedent "reject[ing] the argument that generic labels must contain a 'clear statement' discouraging use of the patented indication." *Ibid.* (quoting *Takeda Pharms. U.S.A., Inc.* v. *W.-Ward Pharm. Corp.*, 785 F.3d 625, 632 n.4 (Fed. Cir. 2015)); see also *Twitter, Inc.* v. *Taamneh*, 598 U.S. 471, 489 (2023) (reinstating dismissal of complaint—"our legal system generally does not impose liability for mere omissions, inactions, or nonfeasance").

Turning to the press releases, the court found that statements referring to Hikma's "icosapent ethyl as the 'generic equivalent' of Vascepa do[ ] not expose

Hikma to liability" because they too fail to instruct CV-risk reduction. Pet.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.*

Finally, applying the Rule 12(b)(6) standard, 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. Pet.App.32a–33a. But the 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. 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." Pet.App.35a; see also Pet.App.34a (quoting *GlaxoSmithKline LLC* v. *Teva Pharms. USA, Inc.*, 7 F.4th 1320, 1335 n.7 (Fed. Cir. 2021) ("*GSK*") ("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.").

The court thus granted Hikma's motion to dismiss. Pet.App.23a–24a. Amarin failed to seek timely leave to amend its complaint further, so the final judgment under Rule 54(b) dismissed Amarin's operative complaint "WITH PREJUDICE." JA64.

3. The court of appeals' decision

The Federal Circuit reversed. It agreed that Hikma's label, standing alone, "does not, as a matter of law, recommend, encourage, or promote an infringing use." Pet.App.17a (cleaned up). As the decision

notes, "even Amarin seems to agree that the label alone does not instruct infringement." Pet.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." Pet.App.19a (emphasis in original).

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." Pet.App.19a–20a n.6. But see JA195 (the actual disclaimer does not mention "Vascepa" but refers to "the Reference Listed Drug").

The Federal Circuit did not identify any alleged statement by Hikma that mentions, much less encourages, administering icosapent ethyl for "reducing risk of cardiovascular death" or "reducing occurrence of a cardiovascular event" when taken with a statin, as Amarin's patents require. Pet.App.8a–9a. Nor did the Federal Circuit point to any alleged statement by Hikma instructing doctors and patients that they should use its generic product as they use Vascepa for its CV indication (no such statement exists). Yet the Federal Circuit held that it could not dismiss Amarin's complaint without "the benefit of discovery" and that induced infringement is "not proper for resolution on a motion to dismiss." Pet.App.14a, 18a–19a.

SUMMARY OF THE ARGUMENT

I. Congress limited liability for induced patent infringement to one who "actively induces infringement of a patent." 35 U.S.C. § 271(b). The plain language requires (1) an "active[]" step that "induce[d]" (i.e., encouraged) a direct infringer to take specific action; and (2) that induced action must suffice for "infringement of a patent," including each limitation of a patent claim. Absent both requirements, there is no active inducement under the statute, and mere inferences or assumptions about how third parties might react to vague communications that lack any instruction or encouragement to infringe cannot trigger liability.

II.A. These requirements apply with equal force on a motion to dismiss. Applying this Court's pleading standard under *Iqbal* and *Twombly*, "[t]hreadbare recitals of the elements of a cause of action, supported by mere conclusory statements, do not suffice." *Iqbal*, 556 U.S. at 678. Thus, a plaintiff cannot avoid a motion to dismiss merely by *asserting* that a defendant's statements actively induce infringement. Rather, the complaint must allege "enough facts to state a claim to relief that is plausible on its face," *Twombly*, 550 U.S. at 570, without contradicting or misstating documents attached to the complaint that are "a part of the pleading for all purposes," Fed. R. Civ. P. 10(c).

B. Amarin's complaint fails to state a plausible claim for actively induced infringement. The only accused Hikma communication that encourages any specific action by doctors and patients is Hikma's skinny label, yet it is undisputed that the label alone does not induce infringement. Pet.App.17a, 21a. The only action it induces is unpatented: Amarin does not allege that the asserted patents cover the label's sole

indication to treat SH. See BIO.22; BIO.App.21a, ¶ 82. Hikma's pre-launch press releases and website are even further afield. Their accurate statements describing Hikma's anticipated product as a "generic version" or "generic equivalent" that falls within the "therapeutic category" of "[h]ypertriglyceridemia" do not encourage specific action by anyone, let alone by doctors or patients. The complaint fails to state a claim for this reason alone.

C. An independent reason for dismissal is that any allegedly induced conduct is insufficient for "infringement of a patent," as § 271(b) requires. Hikma's accused statements never mention Vascepa's allegedly patented CV indication, which requires co-administering icosapent ethyl with a statin—a second agent that Hikma does not distribute and its press releases and website never mention. Nor do Hikma's accused statements say anything about reducing the risk of CV events or CV death, as the patent claims require. Because there is no plausible allegation that Hikma's statements actively induce specific conduct that satisfies all claim steps for any asserted claim, Amarin fails to plead actively induced infringement.

D. Instead of pleading *actively* induced infringement, as the statute requires, Amarin's theory at best is a theory of *passive* inducement, which is not actionable. Amarin relies not on the actual content of Hikma's statements, but on alleged inferences and assumptions a third party might draw upon receiving them. Thus, Amarin and the Federal Circuit purport to "read" instructions that Hikma never made into anodyne statements of generic equivalence—effectively misattributing a physician's intervening reliance on their own knowledge and independent

judgment to Hikma. See Pet.App.19a. This passive-inducement theory is untethered from the Patent Act and, if accepted, would render § 271(b) and Rule 12(b)(6) meaningless: Patentees could always allege that third parties will interpret statements as instructions to infringe—even when those statements facially lack instructions at all. This Court should reject Amarin's passive-inducement theory and reverse.

III. Proper enforcement of the Rule 12(b)(6) pleading requirements is necessary to reconcile § 271(b) and Hatch-Waxman's section viii. As this Court recognized in *Twombly*: "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 through 'careful case management.'" 550 U.S. at 559. Allowing cases like this one to survive the pleadings stage would eviscerate section viii, which was designed to expedite generic-drug competition *without litigation*. Absent reversal, the Federal Circuit's passive-inducement theory will swallow section viii's carve-out provision, smothering generic competition and raising drug prices—all contrary to congressional intent.

Because Amarin's operative complaint fails to state a plausible claim for relief, the Federal Circuit's decision should be reversed, and the district court's dismissal with prejudice should be reinstated.

ARGUMENT

I. Indirect liability for inducement under § 271(b) requires *active* inducement.

A. The Patent Act imposes direct-infringement liability when a party "without authority makes, uses, offers to sell, or sells any patented invention, within the United States or imports into the United States

any patented invention during the term of the patent therefor." 35 U.S.C. § 271(a). Although direct patent infringement is a strict-liability tort, Congress raised the bar when imposing *indirect* liability for inducing another's infringement: "Whoever *actively* induces infringement of a patent shall be liable as an infringer." *Id*. § 271(b).[3] Thus, the statute imposes no liability absent allegations that the defendant:

> (1) "*actively* induce[d]" a direct infringer to take specific action, and
>
> (2) that "induce[d]" action suffices for "infringement of a patent." *Ibid*.

First, "actively induces" is unambiguous: "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 Appliances, Inc.* v. *SEB S.A.*, 563 U.S. 754, 760 (2011) (alteration in original) (quoting WEBSTER'S NEW INT'L DICTIONARY 1269, 27 (2d ed. 1945)). Active inducement thus requires "clear expression or other affirmative steps taken to foster infringement." *Metro-Goldwyn-Mayer Studios Inc.* v. *Grokster, Ltd.*, 545 U.S. 913, 936–937 (2005). Both *Global-Tech* and *Grokster* recognized that active inducement derives in part from aiding-and-abetting liability, which requires deliberate action to promote another's misconduct. Cf. *Smith & Wesson Brands* v. *Estados Unidos Mexicanos*, 605 U.S. 280, 291 (2025) (reinstating dismissal—"Federal aiding-and-abetting law

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[3] The statute also requires specific intent, knowledge that the induced acts constitute infringement, and direct infringement. See *Global-Tech*, 563 U.S. at 766.

reflects a centuries-old view of culpability: that a person may be responsible for a crime he has not personally carried out if he deliberately helps another to complete its commission.") (cleaned up); *id.* at 292 ("[A]n ordinary merchant does not become liable for all criminal misuses of his goods, even if he knows * * * misuse will occur," but "only if, beyond providing the good on the open market, he takes steps to 'promote' the resulting crime and 'make it his own.'") (cleaned up).

Second, the statute requires the induced conduct to suffice for "infringement of a patent." In both patent and copyright cases, this Court has required "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); see also *id.* at 935 (requiring "statements or actions directed to promoting infringement"); *Glob.-Tech*, 563 U.S. at 766 ("[I]nduced infringement under § 271(b) requires knowledge that *the induced acts constitute patent infringement*."). Thus, "it is necessary for the plaintiff" both to allege and to show, among other things, that "the induced acts were infringing." *Commil USA, LLC* v. *Cisco Sys., Inc.*, 575 U.S. 632, 637 (2015).

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." *Grokster*, 545 U.S. at 936. "[M]ere knowledge of infringing potential or of actual infringing uses would not be enough [ ] to subject a distributor to liability." *Id.* at 937. Nor does active inducement result from "failure to take affirmative steps to prevent infringement," if the defendant merely

distributed a product that "otherwise was capable of substantial noninfringing uses." *Id.* at 939 n.12; see also *id.* at 940 n.13 ("Inducement liability" applies "where evidence shows that the distributor intended and *encouraged the product to be used to infringe*.").

"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." *Id.* at 937. The law requires "evidence [that] goes beyond a product's characteristics or the knowledge that it may be put to infringing uses, and shows statements or actions directed to promoting infringement." *Id.* at 935. In short, "the *inducer must persuade another to engage in conduct that* the inducer knows *is infringement*." *Glob.-Tech*, 563 U.S. at 761.

B. 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.* (quotation omitted). "[A] patentee's rights extend only to the claimed combination of elements, and no further." *Ibid.*

This principle is critical in inducement cases to avoid "depriv[ing] § 271(b) of ascertainable standards." *Id.* at 922. "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?" *Ibid.* A claim for inducement thus lies against only a

defendant that actively induces another to perform "all the steps" of the patented method. *Id.* at 921. This legal standard is not disputed. BIO.22 ("Petitioners also assert that there is no induced infringement of a method patent unless a third party is induced to perform all the steps. But that is neither disputed nor contrary to the decision below.") (citation omitted); see also U.S.Cert.Br.15 ("Amarin was * * * required to offer particularized allegations establishing a plausible causal link between [Hikma]'s statements and subsequent infringing uses of its generic drug.").

C. The statutory standard requiring "*actively* induce[d] infringement" thus forecloses liability for mere passive or inferred inducement. This is where the Federal Circuit went astray.

Mere inferences or assumptions on the part of a direct infringer, or speculation as to how the infringer may respond to the communication, do not state a claim for actively induced infringement. "[C]ourts should not create liability for inducement of non-infringing conduct where Congress has elected not to extend that concept." *Limelight*, 572 U.S. at 923. Imposing liability for conduct that falls short of actively encouraging "infringement of a patent" would be "trenching on regular commerce" and "ordinary acts incident to product distribution." *Grokster*, 545 U.S. at 937; see also *Smith & Wesson*, 605 U.S. at 292 ("[R]outine and general activity that happens on occasion to assist in a crime—in essence, 'incidentally'—is unlikely to count as aiding and abetting.").

A communication encouraging only four of five steps required by a method patent, for example, would not constitute "actively induce[d] infringement." A complaint cannot plead otherwise by alleging that the

direct infringer could infer the missing fifth step from vague statements or omissions falling short of "clear expression" or from "mere knowledge of infringing potential or of actual infringing uses." *Grokster*, 545 U.S. at 937. Unless the complaint properly pleads a communication that "*actively* induces" conduct *sufficient* for "infringement of a patent," 35 U.S.C. § 271(b), the complaint fails to allege the requisite "purposeful, culpable expression and conduct" needed for induced-infringement liability, *Grokster*, 545 U.S. at 937.

The legal standard under § 271(b) thus imposes no liability for *actively* induced patent infringement if the alleged communication:

- is not received by the direct infringer,
- is received but does not encourage specific action (e.g., the communication merely describes a patented method or encourages only vague action),
- encourages specific action that, if taken, would not satisfy all limitations of a patent claim, or
- does not actually influence the direct infringer's actions.

See, e.g., *Takeda*, 785 F.3d at 631 ("merely describing an infringing mode is not the same as recommending, encouraging, or promoting an infringing use"); *id.* at 632 ("vague" language "cannot be combined with speculation about how [others] may act to find inducement"); *HZNP Medicines LLC* v. *Actavis Labs. UT, Inc.*, 940 F.3d 680, 702 (Fed. Cir. 2019) ("Merely describing the infringing use, or knowing of the possibility of infringement, will not suffice; specific intent and action to induce infringement must be shown."). Cf.

Smith & Wesson, 605 U.S. at 292 ("aiding and abetting is most commonly a rule of secondary liability for *specific* wrongful acts") (quotations omitted; emphasis in original). The types of communications listed above, without more, do not "*actively* induce[] infringement of a patent." 35 U.S.C. § 271(b).

To be clear, Hikma is *not* arguing that the statute requires an inducer to instruct each step of an asserted method patent explicitly. But the statute requires encouraging conduct that, if followed, would meet each claim limitation, as there is no induced infringement of a method patent unless a third party is induced to perform all the steps. *Limelight*, 572 U.S. at 921. Again, Amarin conceded that this standard is not disputed. BIO.22.

II. Amarin's complaint fails to state a plausible claim for active inducement.

When a generic drug label fully carves out a patented use, allegations that the generic drugmaker calls its product a "generic version" and cites public information about the branded drug (e.g., sales) are not enough to plead induced infringement of the patented use. These and similar statements, which do not encourage or even mention the patented use, do not state a plausible claim that a defendant "actively induce[d]" a direct infringer to take any action, much less action sufficient for "infringement of a patent."

To state a claim that Hikma "actively induce[d] infringement of a patent," 35 U.S.C. § 271(b), Amarin thus needed—but failed—to plead enough non-conclusory, factual allegations to make it plausible that: (1) Hikma encouraged specific action; and (2) the encouraged action suffices to satisfy all patent-claim

limitations. The district court properly dismissed the complaint under Rule 12(b)(6), and the Federal Circuit legally erred when holding otherwise.

A. Rule 12(b)(6) requires dismissing a complaint that does not contain sufficient factual allegations to state a plausible claim.

1. Under Rule 12(b)(6) of the Federal Rules of Civil Procedure, courts must dismiss a complaint that does not satisfy this Court's "two-pronged approach" under *Iqbal* and *Twombly*. *Iqbal*, 556 U.S. at 679.

First, courts should "begin by identifying pleadings that, because they are no more than conclusions, are not entitled to the assumption of truth." *Ibid.* "Threadbare recitals of the elements of a cause of action, supported by mere conclusory statements, do not suffice." *Id.* at 678. In *Twombly*, for example, the Court gave no weight to "the plaintiff's assertion of an unlawful agreement" or its "allegation of a conspiracy," which was merely a "legal conclusion." *Iqbal*, 556 U.S. at 680 (quoting *Twombly*, 550 U.S. at 555). In *Iqbal* too, allegations that government officials discriminated in imposing "harsh conditions of confinement 'as a matter of policy'" were "conclusory and not entitled to be assumed true." *Id.* at 680. The Court did "not reject these bald allegations on the ground that they are unrealistic or nonsensical," or otherwise "fanciful," but simply due to their "conclusory nature." *Id.* at 681.

Second, "[w]hen there are well-pleaded factual allegations, a court should assume their veracity and then determine whether they plausibly give rise to an entitlement to relief." *Id.* at 679. This is "a context-specific task that requires the reviewing court to draw on its judicial experience and common sense." *Ibid.*

Put simply, plaintiffs must allege "enough facts to state a claim to relief that is plausible on its face." *Twombly*, 550 U.S. at 570. "A claim has facial plausibility when the plaintiff pleads factual content that allows the court to draw the reasonable inference that the defendant is liable for the misconduct alleged." *Iqbal*, 556 U.S. at 678. "Where a complaint pleads facts that are merely consistent with a defendant's liability, it stops short of the line between possibility and plausibility of entitlement to relief." *Ibid.* (cleaned up).

Thus, while "the well-pleaded, nonconclusory factual allegation of parallel behavior" in *Twombly* "was consistent with an unlawful agreement, the Court nevertheless concluded that it did not plausibly suggest an illicit accord because it was not only compatible with, but indeed was more likely explained by, lawful, unchoreographed free-market behavior." *Id.* at 680. Similarly, allegations in *Iqbal* that officials "arrested and detained thousands of Arab Muslim men" were "consistent with" discrimination but more likely explained by a "nondiscriminatory intent to detain aliens who were illegally present in the United States and who had potential connections to those who committed terrorist acts." *Id.* at 682. The Court has recently applied the same standard to dismiss aiding-and-abetting claims at the pleadings stage. See *Twitter*, 598 U.S. at 506; *Smith & Wesson*, 605 U.S. at 296–299.

2. Two important corollaries to the *Iqbal-Twombly* framework are relevant.

First, "courts must consider the complaint in its entirety," including "documents incorporated into the complaint by reference." *Tellabs, Inc.* v. *Makor Issues & Rights, Ltd.*, 551 U.S. 308, 322 (2007). "A copy of a written instrument that is an exhibit to a pleading is

a part of the pleading for all purposes." Fed. R. Civ. P. 10(c). Undisputed regional circuit law (Amarin filed in Delaware) holds that "[w]here there is a disparity between a written instrument annexed to a pleading and an allegation in the pleading based thereon, the written instrument will control." *ALA, Inc.* v. *CCAIR, Inc.*, 29 F.3d 855, 859 n.8 (3d Cir. 1994).

Second, 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." *Iqbal*, 556 U.S. at 678. "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 through 'careful case management.'" *Twombly*, 550 U.S. at 559. As explained below in section III, enforcing Rule 12(b)(6) to dismiss deficient inducement claims is necessary to reconcile § 271(b) and Hatch-Waxman's section viii.

B. Hikma's skinny label encourages only noninfringing use, and its other statements do not "actively induce[]" specific conduct.

Applying the *Iqbal-Twombly* pleading standard, Amarin's operative complaint fails to state a plausible claim that Hikma actively induced infringement. Dismissal is required because Hikma's skinny label encourages only noninfringing use, and its other statements do not "actively induce" specific conduct.

1. Hikma's label is the only accused communication that instructs doctors and patients on how to use Hikma's generic icosapent product; yet, it admittedly does not suffice to induce infringement. Pet.App.17a,

21a. Hikma's FDA-approved skinny label undisputedly carves out the allegedly patented CV indication and, instead, is indicated for only the non-infringing SH indication. Pet.App.5a, 28a. As Amarin's complaint admits, "[t]he Hikma Defendants' generic version of VASCEPA® was FDA approved *for only the Severe Hypertriglyceridemia Indication, and not for the CV Indication*." BIO.App.21a, ¶ 82.

The Federal Circuit thus "agree[d] with the district court (and Hikma) that the label does not, as a matter of law, recommend, encourage, or promote an infringing use," Pet.App.17a (cleaned up), and "even Amarin seems to agree that the label alone does not instruct infringement," Pet.App.21a. There is no serious dispute Hikma's label is "skinny enough." Pet.App.13a.

The only time the label uses the term "cardiovascular" is in a warning *against* using Hikma's product "in people who have heart (cardiovascular) disease" because it could cause "serious" side effects requiring "hospitalization." JA124–125. As the district court aptly put it: "This is hardly instruction or encouragement." Pet.App.31a; see also U.S.Cert.Br.15 ("Treating a generic manufacturer's approved skinny label as evidence of culpable inducement would be at odds with section viii's basic design.").

2. Hikma's pre-launch press releases and website do not actively lead on, influence, persuade, recommend, encourage, promote, or otherwise instruct doctors and patients to bring about any desired result. Thus, they cannot support a claim for "*active*[] induce[ment]" as a matter of law.

The press releases merely announce litigation victories to investors and contain no information on how

to use Hikma's generic product, which was not yet even on the market. Compare BIO.App.34a, ¶¶ 127–128 (relying on press releases in March and September 2020), with BIO.App.4a, ¶ 13 (Hikma launched its generic product in November 2020). Hikma did not provide such usage information until its (unaccused) November 2020 press release, which recites the sole indication in Hikma's labeling (for treating SH) and says: "Hikma's product is not approved for any other indication for the referenced listed drug VASCEPA®." JA45–46; see also U.S.Cert.Br.16 ("[T]he Federal Circuit erred in treating Hikma's description of its own product as a 'generic equivalent' or 'generic version' of Vascepa, and Hikma's description of Vascepa as approved 'in part' for the SH Indication, as suggesting culpable intent to encourage infringement.") (citing Pet.App.18a–21a).

To be sure, Amarin's operative complaint includes conclusory assertions that Hikma's pre-launch press releases "communicate[] to and instruct[] healthcare providers and patients" to use its generic product for both Vascepa indications. BIO.App.31a–32a, ¶¶ 115, 122. But those assertions carry no weight under this Court's *Iqbal-Twombly* pleading standard because they are "conclusory and not entitled to be assumed true." *Iqbal*, 556 U.S. at 681. Moreover, the accused communications—which do not contain the alleged instructions—are attached as exhibits to Amarin's complaint and thus are part of the pleadings. See Fed. R. Civ. P. 10(c). Where, as here, "there is a disparity between a written instrument annexed to a pleading and an allegation in the pleading based thereon, *the written instrument will control*." *ALA*, 29 F.3d at 859 n.8.

The accused statements from Hikma's website—i.e., that Hikma's product falls under the therapeutic category "[h]ypertriglyceridemia" and is "AB" rated—also do not encourage specific action directed to doctors and patients for using Hikma's product. The only potential instruction on the website is to "[b]rowse our products." JA195. The website makes no mention of Vascepa, SH use, CV use, or statins. And, like the November 2020 press release, it contains "an express disclaimer" (Pet.App.20a n.6): "Hikma's generic version is indicated for fewer than all approved indications of the Reference Listed Drug." JA195; see also U.S.Cert.Br.18 ("the website's statement does not urge a 'necessarily infringing' use") (quoting *Grokster*, 545 U.S. at 931).

An accused statement cannot actively encourage a patented method-of-use without encouraging *use*. The accused press releases and website are legally irrelevant because they do not actively induce potential direct infringers to *use* Hikma's product. The Federal Circuit's judgment should be reversed on this basis alone.

C. Hikma's accused statements, alone or together, do not encourage action sufficient for "infringement of a patent."

In addition to these fatal pleading deficiencies, the accused statements in Hikma's labeling, pre-launch press releases, and website—alone or in combination—certainly do not encourage conduct sufficient to constitute "infringement of a patent." 35 U.S.C. § 271(b).

1. Attempting to allege otherwise, Amarin points to statements in Hikma's pre-launch press releases

referring to its product as a "generic version" or "generic equivalent" of Vascepa that is "indicated, in part," for the unpatented SH indication. BIO.App.30a, ¶¶ 111–112; BIO.App.31a–32a, ¶¶ 118–119. As the government explains, these are all "anodyne statements with logical explanations." U.S.Cert.Br.19.

According to Hatch-Waxman and FDA regulations, Hikma's product is a "generic version" and a "generic equivalent" of Vascepa even though it has a skinny label. See *supra* 4–7. It is "normal industry practice" that generic drugmakers "truthfully describe generic [drugs] as 'equivalent' or 'comparable' to [their branded counterparts]." *Inwood Labs.*, 456 U.S. at 847–848. Amarin itself publicly referred to "generic versions of VASCEPA."[4] See JA58 (Amarin letter to insurance payors: "Amarin is aware that Hikma Pharmaceuticals has launched a *generic version of VASCEPA*® (icosapent ethyl) 1-gram capsules.").

Amarin alleges that these press releases cite Vascepa's annual sales, including sales tied to the CV indication. BIO.App.30a, ¶ 113; BIO.App.32a, ¶ 120. While such data may be relevant to investors deciding whether to invest in Hikma, Vascepa sales figures do not plausibly convey information relevant to doctors or patients on how Hikma's product should be *used*.

Again, these press releases do not encourage any action, much less action sufficient to infringe the specific methods of treatment claimed by the two asserted patents. The press releases do not mention CV use or

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[4] https://www.amarincorp.com/news-and-media/amarin-comments-ruling-vascepar-anda-litigation (Amarin March 30, 2020, press release stating Amarin seeks to "prevent launch of *generic versions of VASCEPA*").

otherwise encourage using Hikma's then-forthcoming product for off-label use, much less a patented one. The only use mentioned is the unpatented SH use on Hikma's label. Statins are not mentioned at all.

2. Amarin unduly relies on Hikma's website, which is plainly directed to customers who purchase generic products—i.e., "wholesalers, hospitals, and retail pharmacies," not doctors or patients. See *Inwood Labs.*, 456 U.S. at 847–848. The website merely informs such customers that Hikma's product is available for purchase. Amarin does not allege that Hikma sells its products to doctors or patients (Hikma does not). Nor does Amarin allege that Hikma's customers administer its product to patients (they do not).

Like the press releases, the website does not encourage (and there would be no reason to encourage) any use of the product, much less encourage action by doctors or patients to use the product for unlabeled indications with a statin. Describing the "therapeutic category" does not encourage any patented CV method, especially given the undisputed disclaimer that "Hikma's generic version is indicated for fewer than all approved indications of the Reference Listed Drug"—with no mention of Vascepa. JA195. And, to the extent a reader had questions about how to use Hikma's product, there is a link to Hikma's "Package Insert," which is the non-infringing skinny label. *Ibid.*

Amarin cannot cobble together disparate documents intended for different audiences—i.e., Hikma's label, pre-launch press releases, and website—to infer instructions that the documents never actually make. Alone or together, the accused communications do not (1) "actively induce[]" specific action (2) sufficient for "infringement of a patent." 35 U.S.C. § 271(b).

D. The Federal Circuit's decision, if allowed to stand, would impose liability for mere passive inducement.

1. Ultimately, Amarin's complaint fails to state a claim because it relies on alleged instructions or encouragement *inferred* from vague and innocuous statements describing Hikma's product instead of "actively induce[d]" conduct under § 271(b). That is *passive*—not active—inducement. The Federal Circuit legally erred in holding such allegations sufficient:

> [W]e find 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.

Pet.App.19a. The court doubled down on this passive-inducement theory when referring to Hikma's website:

> Further, it is at least plausible that *a physician may recognize that*, by marketing its drug in the broad therapeutic category of 'Hypertriglyceridemia' on its website, *Hikma was encouraging prescribing the drug for an off-label use.*

Ibid.

The Federal Circuit thus allowed Amarin's complaint to survive based on *inferred* instructions that Hikma never made—as confirmed by the undisputed, accused communications attached to Amarin's operative complaint. Even worse, the court of appeals

essentially slammed the door on Rule 12(b)(6) challenges in the section viii context, holding that whether conclusory allegations like those at issue here support a claim for induced infringement is "not proper for resolution on a motion to dismiss." Pet.App.14a, 18a–19a.

But Amarin cannot avoid Rule 12(b)(6) by speculating about how a direct infringer "could read" statements accurately describing Hikma's product that, objectively, do not encourage any action, much less action sufficient to infringe. If this were enough, plaintiffs could allege inducement in any case simply by asserting that third parties would infer instructions that defendants never made. Neither Congress nor this Court has ever adopted such a cause of action for induced infringement caused by intervening inferences and conduct by third parties, and doing so would contradict the plain statutory language imposing inducement liability only on one who "*actively* induces infringement of a patent." 35 U.S.C. § 271(b).

2. Instead of alleging any communication that actively induces conduct sufficient to infringe, Amarin's complaint requires the reader to suspend logic and assume the following events:

(a) after Hikma launched its product, doctors and patients ignored Hikma's press release at the time of launch expressly disclaiming indications other than the unpatented SH indication and, instead, searched for archived copies of Hikma's *pre*-launch press releases announcing litigation victories;[5]

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[5] The operative complaint alleges that these materials had been removed from Hikma's "Newsroom" webpage by the

(b) these doctors and patients would have seen references in the pre-launch press releases only to the SH indication but nonetheless believed that Hikma was encouraging use of its product for other, unmentioned indications;

(c) these same doctors and patients would have inferred from vague statements referring to Hikma's product as a "generic version" or "generic equivalent" of Vascepa, Vascepa sales data, and/or the fact that Hikma's website refers to its icosapent product as falling under the "[h]ypertriglyceridemia" therapeutic category, that Hikma was instructing to use its product with a second drug—a statin—for *all* Vascepa indications (even though Hikma never said any of this or encouraged using its product with a statin);

(d) these doctors and patients would either know about the Vascepa CV indication, or look it up;

(e) optionally, these doctors and patients would then look to Hikma's FDA-approved skinny label, but would disregard the indication solely for the unpatented SH indication—instead, these doctors and patients would focus on the warning about administering Hikma's product to CV patients and read that warning as encouraging use of Hikma's product, off-label, with a statin, to reduce CV risks or death (even though the label never says any of this); and then

(f) patients would be induced from the combination of all these assumptions and inferences from Hikma's pre-launch press releases, its website, and portions of

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time of Hikma's product launch, but they allegedly were still available online at specific URLs. BIO.App.31a, ¶ 117; BIO.App.32a–33a, ¶ 124.

its product label—instead of relying on the independent judgment of their doctors, or automatic substitution by the pharmacy—to use Hikma's product off label with a statin for Vascepa's CV indication.

These allegations are not plausible. See U.S.Cert. Br.18. To say Amarin's inducement theory is far-fetched would be an understatement. At most, Hikma accurately referred to its anticipated icosapent product as a "generic version" or "generic equivalent" of Vascepa for its SH indication, and this indication falls within the "hypertriglyceridemia" therapeutic category. These statements do not encourage any doctors or patients to take any action, much less action sufficient to meet all limitations of an asserted patent claim.

As discussed, "courts should not create liability for inducement of non-infringing conduct where Congress has elected not to extend that concept." *Limelight*, 572 U.S. at 923. The Federal Circuit's decision to recognize a cause of action based on communications that facially fall short of encouraging patent infringement improperly proscribes legitimate commercial speech. Reversal is needed to avoid "trenching on regular commerce" and chilling "ordinary acts incident to product distribution." *Grokster*, 545 U.S. at 937.

III. Allowing a complaint like Amarin's to proceed would effectively nullify section viii.

The Federal Circuit's expansion of induced-infringement liability to encompass a theory of passive inducement is especially egregious in the context of the Hatch-Waxman Act. No skinny label would be safe from a post-launch suit if the decision below were affirmed. The Federal Circuit converted what Congress

intended to be risk-free generic-product launches to *at-risk* product launches—creating extreme financial disincentives to invoke the section viii process. The interplay between § 271(b) and Hatch-Waxman's section viii requires enforcing Rule 12(b)(6)'s gatekeeping function to dismiss Amarin's complaint.

A. The Federal Circuit doubled down on its controversial decision in *GSK*, 7 F.4th 1320, when it allowed this case to survive the pleadings—driving a final nail into the section viii coffin. Under the Federal Circuit's logic, a branded drugmaker can plead induced infringement despite a skinny label based on mere speculation that doctors could "read" instructions that induce infringement into statements that merely describe Hikma's product accurately as a generic version or equivalent of Vascepa. Pet.App.19a. 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). This Court 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."). 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"). 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." *Abbreviated New Drug Application (ANDA)*, FDA, https://www.fda.gov/drugs/types-applications/abbreviated-new-drug-application-anda.

Congress could not have intended for generics to be held liable for inducing patent infringement, despite a section viii carve-out, merely for characterizing a product as a "generic version" consistent with Hatch-Waxman's statutory scheme.

B. It is no answer that Vascepa's sales figures are "largely attributable to the off-label CV indication." Pet.App.18a. 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. And the informed investor community understands "market realities"—"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*, 669 F.3d at 1380. If that were enough to plead inducement, 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.*

Enforcing § 271(b)'s "requirement of inducing acts is particularly important in the Hatch-Waxman Act context" because the Act "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; see also *supra* 7–8. Instead

of requiring "inducing acts," however, the decision below finds plausible inducement based on accurately reporting sales figures that allegedly include "off-label infringing uses." *Takeda*, 785 F.3d at 631. 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.

C. 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, *Caraco*, 566 U.S. at 407, so 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) (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.*

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." *Blonder-Tongue Labs., Inc.* v. *Univ. of Ill. Found.*, 402 U.S. 313, 334,

338 (1971). Seven years ago, "the average cost to defend an infringement lawsuit in the United States [wa]s 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. 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, 18 (2022). As in *Twombly*, "the potentially enormous expense of discovery" often "will push cost-conscious defendants to settle even anemic cases." 550 U.S. at 559.

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

Section viii plays a critical role in achieving these cost savings. Historically, nearly half of all generics for drugs with multiple approved uses launched with skinny labels, providing low-cost alternatives years before patents on carved-out uses expired. Tu & Duan, *supra*, 12 NYU J. INTELL. PROP. & ENT. L. at 15; 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). In a five-year period, 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." U.S. Dep't of

Health & Human Servs., *Comprehensive Plan for Addressing High Drug Prices* 21 (Sept. 2021).

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." *Ibid.* A recent study confirms that the decisions below and in *GSK* have had a chilling effect on section viii filings. While "approximately half" of all drugs eligible for labeling carve-outs had a generic launch with skinny labeling in 2021 and 2022, "[i]n 2023, only one-fifth (20%) of susceptible brand-name drugs had [ ] skinny label generic prescriptions, which may be a signal of a diminished use of the pathway." Therese J. Ziaks et al., *Frequency of First Generic Drugs Approved Through "Skinny Labeling," 2021 to 2023*, 31 J. MANAG. CARE SPEC. PHARM. 343, 346 (2025).

As the government predicted, "the lenient pleading standard applied by the court below may cause fewer generic manufacturers to invoke the section viii pathway." U.S.Cert.Br.23. Enforcing Rule 12(b)(6) for deficient claims under § 271(b) can prevent that result and restore Congress' intent in enacting section viii.

CONCLUSION

The court of appeals' judgment should be reversed, and the district court's order dismissing Amarin's claims with prejudice should be reinstated.

Respectfully submitted.

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