No. 24-889

In the Supreme Court of the United States

HIKMA PHARMACEUTICALS USA INC., ET AL.,
PETITIONERS

v.

AMARIN PHARMA, INC., ET AL.

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

BRIEF FOR THE UNITED STATES
AS AMICUS CURIAE SUPPORTING PETITIONERS

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QUESTION PRESENTED

The Hatch-Waxman Amendments to the Federal Food, Drug, and Cosmetic Act authorize the Food and Drug Administration (FDA) to approve generic drugs that have the same active ingredients as, and are therapeutically equivalent to, existing brand-name drugs. Brand-name drugs are frequently protected by patents, which may cover the drug itself and/or a particular method of using the drug.

Congress has created a mechanism to promote and expedite competition from otherwise-approvable generics in circumstances where some but not all approved methods of using a particular drug are patent-protected. A generic drugmaker may seek FDA approval for a non-patented use and sell its generic drug under "skinny" labeling that "carves out" patented uses but otherwise duplicates the brand's labeling.

Petitioners followed that approach here, carving out the patented use of respondents' drug from the labeling of their generic drug. Petitioners accurately described their drug as the generic version of respondents' and noted that respondents' drug is approved for additional uses. Petitioners also provided their investors with truthful information about the total sales of respondents' drug, including sales traceable to both the patented and non-patented uses. The question presented is as follows:

Whether respondents' complaint plausibly alleged that petitioners had actively induced infringement of respondents' patents claiming the carved-out uses.

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INTEREST OF THE UNITED STATES

This case concerns whether respondents have adequately alleged that the manufacturer of a generic drug unlawfully induced medical professionals to infringe method-of-use patents held by a brand-name drug manufacturer. The United States has substantial interests in encouraging manufacturers to bring lower-cost generic drugs quickly to market, and in lowering prescription-drug prices paid by federal programs such as Medicare, Medicaid, and the Veterans Health Administration. At the same time, the United States has a substantial interest in the patent protections available to drugmakers that identify new therapeutic uses for established products. At the invitation of the Court, the United States filed a brief as amicus curiae at the petition stage of this case.

INTRODUCTION

The Hatch-Waxman Amendments to the Federal Food, Drug, and Cosmetic Act reflect Congress's careful balance of competing policy objectives. On the one hand, Congress sought 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). In circumstances where some uses of a particular drug are patented but others are not, the "section viii" mechanism allows "a generic company to identify [the unpatented] uses, so that a product with a label matching them can quickly come to market." *Id.* at 415; see 21 U.S.C. 355(j)(2)(A)(viii). On the other hand, Congress sought to safeguard patent rights by (1) requiring generic manufacturers to use labeling "that 'carves out' from the brand's approved label the still-patented methods of use," *Caraco*, 566 U.S. at 406; and (2) leaving in place, and fully applicable to manufacturers of generic drugs, the preexisting statutory bars on both direct infringement of patents, see 35 U.S.C. 271(a), and active inducement of patent infringement, see 35 U.S.C. 271(b). While Congress presumably expected that some off-label uses of approved generic drugs would occur, Congress evidently viewed that prospect as an acceptable cost of expedited competition with respect to the lawful *unpatented* uses—so long as generic manufacturers do not actively *encourage* infringing uses.

The court of appeals in this case departed from that congressional balance by holding that respondents had adequately alleged active inducement of infringing conduct. None of petitioners' allegedly culpable statements expressly urged or encouraged third parties to infringe respondents' patents. Some of those statements—*e.g.*, petitioners' references to their own drug as a "generic

version" of respondents', and petitioners' use of "carved out" labeling approved by the Food and Drug Administration (FDA)—are integral to the Hatch-Waxman scheme. And none of the statements that petitioners are alleged to have made about their generic drug had any meaningful likelihood of causing infringing off-label uses, particularly given the critical role of state generic-substitution laws in governing the prescribing and dispensing practices of healthcare providers.

Because respondents' complaint does not plausibly allege active inducement of patent infringement, the court of appeals erred in allowing this suit to proceed. That erroneous decision may significantly deter generic manufacturers from using the section viii mechanism in the manner that Congress intended. Because the Federal Circuit erred in concluding that respondents have stated a claim of active inducement under 35 U.S.C. 271(b), this Court should reverse the court of appeals' judgment.

STATEMENT

A. Legal Background

1. The Federal Food, Drug, and Cosmetic Act (FDCA), 21 U.S.C. 301 *et seq.*, generally requires FDA approval before a new drug may be sold in the United States. 21 U.S.C. 355(a). One way to obtain such approval is to submit a new drug application (NDA) to FDA. See 21 U.S.C. 355(b) (2018 & Supp. III 2021). An NDA must contain scientific data and other information showing that the drug is safe and effective if used according to the labeling proposed in the application. 21 U.S.C. 355(b)(1)(A)(i) and

(vi) (Supp. III 2021); see 21 C.F.R. 201.57(c).[1] Establishing safety and efficacy can be expensive, and it can easily cost hundreds of millions of dollars to develop a new drug and obtain FDA approval via an NDA. See Aylin Sertkaya et al., *Costs of Drug Development and Research and Development Intensity in the US, 2000-2018*, at 7, JAMA Network Open (June 28, 2024), https://perma.cc/J7WY-N9JH.

Congress enacted the Drug Price Competition and Patent Term Restoration Act of 1984, Pub. L. No. 98-417, 98 Stat. 1585, known as the Hatch-Waxman Amendments, to facilitate competition by lower-cost "generic version[s]" of "brand-name drug[s]" that FDA has already found safe and effective, *Caraco Pharm. Labs., Ltd.* v. *Novo Nordisk A/S*, 566 U.S. 399, 404 (2012). Under those amendments, a would-be generic competitor may file an abbreviated new drug application (ANDA) that "piggyback[s]" in key respects on an approved NDA. *Id.* at 405. "Rather than providing 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." *Ibid.* (citing 21 U.S.C. 355(j)(2)(A)(ii) and (iv)). Subject to specified exceptions, the labeling proposed for the generic drug must be "the same as the labeling approved" by FDA for the brand-name drug. 21 U.S.C. 355(j)(2)(A)(v).

Brand-name drugs are often protected by multiple patents that claim the listed "drug" itself and/or an approved "method of using" it (including an "'indication,'"

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[1] The FDCA uses the term "label" for material printed on a drug's immediate container, and the broader term "labeling" for any printed material accompanying a drug. See 21 U.S.C. 321(k) and (m). The courts below sometimes used the term "label" to refer to labeling. *E.g.*, Pet. App. 4a-5a.

which "refers generally to what a drug does," *e.g.*, "treat diabetes"). *Caraco*, 566 U.S. at 405-406, 417 n.7. Accordingly, the requirements that generic drugs have the same active ingredients as and be therapeutically equivalent to their predecessors have led to frequent disputes over whether the brand-name manufacturers' patents are valid and (if so) whether sale or use of the generic will infringe them. The Hatch-Waxman Amendments establish mechanisms to quickly identify and resolve those disputes so that competition can begin "as soon as patents allow." *Id.* at 405.

At the outset, a brand-name manufacturer must submit to FDA information about each patent that allegedly claims its drug or a relevant method of using the drug. 21 U.S.C. 355(b)(1)(A)(viii) and (c)(2) (Supp. III 2021). FDA then lists information about those patents in a published compendium known as the Orange Book. See *Caraco*, 566 U.S. at 405-406; 21 U.S.C. 355(c)(2) (Supp. III 2021).

An ANDA applicant, in turn, generally must address the listed patents for the brand-name drug. If the applicant does not wish to delay marketing its generic drug until the relevant patents expire, see 21 U.S.C. 355(j)(2)(A)(vii)(III), it has two options.

First, the applicant may certify its belief that the relevant patents are invalid or would not be infringed by sale of the generic drug. 21 U.S.C. 355(j)(2)(A)(vii)(IV). Such a "paragraph IV certification" is deemed an act of patent infringement and may trigger litigation to determine the disputed patents' validity and scope. *Caraco*, 566 U.S. at 407; see 35 U.S.C. 271(e)(2)(A) and (5). By then filing a timely patent-infringement suit, the brand-name manufacturer can generally obtain a 30-month stay of approval of the generic drug (unless the patent litiga-

tion is resolved in the generic's favor before then). 21 U.S.C. 355(j)(5)(B)(iii). This option allows the generic manufacturer to provoke a lawsuit—which the brand-name manufacturer has an incentive to bring in order to obtain the 30-month stay—and thus obtain judicial resolution of the patent dispute before marketing its product, eliminating the risk of patent-infringement damages. The generic manufacturer is also entitled, even if the brand-name manufacturer does not sue, to file its own suit seeking a declaratory judgment that the patent is invalid or would not be infringed. 21 U.S.C. 355(j)(5)(C).

Second, a generic manufacturer may submit a statement indicating that it seeks FDA approval to market its drug only for uses that are *not* claimed by the brand-name manufacturer's listed method-of-use patents. 21 U.S.C. 355(j)(2)(A)(viii). Such a "section viii statement" is "typically used when the brand's patent on the drug compound has expired and the brand holds patents on only some approved methods of using the drug." *Caraco*, 566 U.S. at 406. An ANDA applicant that submits a section viii statement proposes "labeling for the generic drug that 'carves out' from the brand's approved label the still-patented methods of use." *Ibid.*; see 21 C.F.R. 314.94(a)(8)(iv) and (12)(iii)(A). By marketing a generic drug only for unpatented uses under a carved-out or "skinny" label, the generic manufacturer can potentially launch its product without the 30-month wait that a paragraph IV certification and subsequent lawsuit typically entail.

A generic manufacturer may also employ a combination of paragraph IV certifications and section viii statements, because the choice is made on a patent-by-patent (or claim-by-claim) basis. This combination strategy

may narrow the scope of patent litigation and speed the generic's path to market.

When FDA approves a generic drug, that approval reflects that the generic drug has been evaluated as therapeutically equivalent to its brand-name predecessor. FDA, *Orange Book Preface* § 1.7 (Jan. 15, 2026), https://www.fda.gov/drugs/development-approval-process-drugs/orange-book-preface. Therapeutic-equivalence evaluations are published in the Orange Book, where generic drugs that FDA considers to be therapeutically equivalent to their brand-name counterparts are assigned a code beginning with "A," such as "AB." *Ibid.* Such a rating indicates that the generic contains the same active ingredients as the brand-name drug; that the two are identical in certain other respects; and that "data and information [have been] submitted demonstrating [biological equivalence]." *Ibid.*

2. Once one or more approved generics have joined a brand-name drug on the market, the FDCA does not address which product is dispensed for a given prescription. Rather, every State either allows or requires pharmacists to fill a prescription for a brand-name drug by dispensing an available therapeutically equivalent generic—for example, by filling a prescription for "Crestor" with generic rosuvastatin. Thirty-four States and the District of Columbia generally permit pharmacists to substitute a therapeutically equivalent generic (at least when substitution will save the patient money). See, *e.g.*, Tex. Occ. Code § 562.008(b); Ark. Code § 17-92-503(a)(1)(A).[2] The

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[2] See also Ala. Code § 34-23-8(a)(1); Alaska Stat. § 08.80.295(a); Ariz. Rev. Stat. § 32-1963.01(A); Cal. Bus. & Prof. Code § 4073(a); Colo. Rev. Stat. § 12-280-125(1)(a); Conn. Gen. Stat. § 20-619(b); 24 Del. Code § 2549(a), repealed by 85 Del. Laws c. 49 (June 30, 2025)

remaining 16 States generally mandate such substitution when it will save the patient money. See, *e.g.*, Fla. Stat. § 465.025(2).[3]

In both permissive- and mandatory-substitution States, doctors may prevent generic substitution by expressly directing that a prescription identifying the brand-name drug must be dispensed exactly as written. *E.g.*, Tex. Occ. Code § 562.008(a); N.Y. Educ. Law §§ 6810(6)(a), 6816-a(1)(a). Most States also give patients an opportunity to refuse substitution at the pharmacy. *E.g.*, Tex. Occ. Code § 562.009; 35 Pa. Cons. Stat. § 960.3(b).

(reenacting provisions of 24 Del. Code § 2549 at 24 Del. Code. § 2550 effective June 30, 2026); D.C. Code § 48-803.02(a)(1); Ga. Code Ann. § 26-4-81(a); Idaho Code § 54-1733B(1); 225 Ill. Comp. Stat. Ann. § 85/25; Ind. Code §§ 16-42-22-5, 16-42-22-6, 16-42-22-8; Kan. Stat. Ann. § 65-1637(g)(1); La. Rev. Stat. § 37:1241(A)(17); Md. Code Ann., Health Occ. § 12-504(d)(1); Mich. Comp. Laws Ann. § 333.17755(1); Miss. Code § 73-21-117(1); Mo. Ann. Stat. § 338.056(1); Mont. Code Ann. § 37-7-505(1); Neb. Rev. Stat. Ann. §§ 38-2818.03, 38-28111(1); N.H. Rev. Stat. Ann. § 146-B:2(I); N.M. Stat. Ann. § 26-3-3(B); N.C. Gen. Stat. § 90-85.28(a); N.D. Cent. Code § 19-02.1-14.1(3); Ohio Rev. Code § 4729.38(B); Okla. Stat. tit. 59, § 353.24(B)(4); Or. Rev. Stat. § 689.515(2); S.C. Code Ann. § 39-24-30(a); S.D. Codified Laws § 36-11-46.1; Utah Code Ann. § 58-17b-605(2)(a); Va. Code Ann. § 54.1-3408.03(A); Wyo. Stat. Ann. § 33-24-148. Iowa law does not specifically address generic substitution, but it broadly authorizes licensed pharmacists to dispense prescription drugs consistent with "the appropriate standard of care." Iowa Code §§ 155A.2B, 155A.8(2). All citations to state statutes are dated 2026 unless otherwise specified.

[3] See also Haw. Rev. Stat. § 328-92(a); Ky. Rev. Stat. Ann. § 217.822(1); Me. Stat. tit. 32, § 13781; Mass. Gen. Laws ch. 112, § 12D; Minn. Stat. § 151.21(3); Nev. Stat. § 639.2583(1)(a); N.J. Stat. Ann. § 24:6E-7; N.Y. Educ. Law § 6816-a(1); 35 Pa. Cons. Stat. § 960.3(a); R.I. Gen. Laws § 5-19.1-19; Tenn. Code Ann. § 53-10-205(a); Vt. Stat. Ann. tit. 18, § 4605(a)(1); Wash. Rev. Code § 69.41.130; W. Va. Code § 30-5-12b(b); Wis. Stat. Ann. § 450.13(1s).

The FDCA does not prohibit doctors or pharmacists from prescribing or dispensing a drug "off-label"—*i.e.*, for uses other than those for which FDA has determined that the drug is safe and effective if used as instructed on the drug's labeling. See FDA, *Understanding Unapproved Use of Approved Drugs "Off Label"* (Feb. 5, 2018), https://www.fda.gov/patients/learn-about-expanded-access-and-other-treatment-options/understanding-unapproved-use-approved-drugs-label. And no State's law makes substitution depend on whether a generic drug is labeled for the use for which a drug is being prescribed. Indeed, no State even requires that prescriptions for non-controlled substances must contain the information about a patient's diagnosis and treatment that would enable pharmacists to make that determination. As relevant here, state laws typically require only that such prescriptions identify the drug being prescribed and provide basic directions for use (*e.g.*, "take once daily with food"). See, *e.g.*, Ariz. Rev. Stat. § 32-1968(C).[4] Accordingly, only a small percentage of prescriptions include information about the use for which the drug is prescribed. See Alejandra Salazar et al., *How Often Do Prescribers Include Indications in Drug Orders? Analysis of 4 Million Outpatient Prescriptions*, 76 Am. J. Health-System Pharm. 970, 973 (2019) (finding that "more than 92% of prescriptions in a large database * * * did not include indications").

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[4] Several States allow doctors to include indication information on a prescription or require them to include that information if a patient so requests. See Cal. Bus. & Prof. Code § 4040(a)(1); Colo. Rev. Stat. § 12-280-103(31)(a); 225 Ill. Comp. Stat. Ann. 85/3(e); Nev. Stat. § 639.2352; Okla. Stat. tit. 59, § 353.20.1(B); 22 Tex. Admin. Code § 291.34(b)(7)(A)(vii); W. Va. Code R. § 15-1-18.1.4.d; Wis. Stat. Ann. § 450.11(4m).

B. Facts

Respondents (collectively, "Amarin") market icosapent ethyl under the brand name Vascepa. Pet. App. 2a. Vascepa is used to treat patients with two conditions involving excessive levels of triglycerides, a type of fat that circulates in the blood. "'Hypertriglyceridemia' refers to having a blood triglyceride level above the acceptable level of 150 mg/dL," and "'[*s*]*evere* hypertriglyceridemia' (or SH) refers to having a blood triglyceride level above 500 mg/dL." Br. in Opp. 4 (emphasis added; citations omitted).

FDA has approved Vascepa for two indications addressing these two health conditions. Pet. App. 2a-3a. In 2012, FDA approved Vascepa for treatment of severe hypertriglyceridemia (the "SH Indication"). *Id.* at 2a. Amarin later conducted additional clinical trials, which showed that Vascepa reduced cardiovascular risk in certain patients. *Id.* at 3a. Based on those data, in 2019 the agency approved Vascepa for use to "reduce cardiovascular risk" in "patients having blood triglyceride levels of at least 150 mg/dL" (the "CV Indication")—*i.e.*, patients with hypertriglyceridemia, not limited to those with severe hypertriglyceridemia. *Ibid.* Amarin holds two listed method-of-use patents that claim use of icosapent ethyl for the CV Indication. *Ibid.*

In 2016, petitioners (collectively, "Hikma") submitted an ANDA for generic icosapent ethyl. Pet. App. 4a. After FDA approved Vascepa for the CV Indication in 2019, Hikma amended its ANDA to include section viii statements as to Amarin's method-of-use patents. Hikma thus "sought the FDA's approval of a 'skinny label' for its generic product that would include only the SH indication," not the patented CV Indication. *Id.* at 4a-5a; see p. 6, *supra*. Apart from the carve-out of the CV In-

dication, Hikma sought to conform its proposed labeling to Amarin's. Pet. App. 5a.

In May 2020 FDA approved Hikma's ANDA, including its carved-out or "skinny" labeling. Pet. App. 5a. Unlike Vascepa's labeling, the labeling for Hikma's generic drug "does not provide an implied or express instruction to prescribe the drug for the CV indication" and omits clinical evidence showing effectiveness for that use. *Id.* at 16a; compare J.A. 78, 85-88 (Vascepa), with J.A. 114, 122 (Hikma). FDA has assigned Hikma's generic an "AB" rating, indicating that it is therapeutically equivalent to Vascepa when used according to its labeling. FDA, *Orange Book: Product Details for ANDA 209457*, https://www.accessdata.fda.gov/scripts/cder/ob/results_product.cfm?Appl_Type=A&Appl_No=209457#39458; see pp. 6-7, *supra*.

C. Proceedings Below

1. Shortly after Hikma began marketing its generic drug, Amarin filed suit in the District of Delaware, alleging that Hikma had actively induced others to infringe Amarin's method-of-use patents. Pet. App. 7a-8a; see 35 U.S.C. 271(b) ("Whoever actively induces infringement of a patent shall be liable as an infringer."). Amarin's operative complaint does not allege that Hikma's carved-out labeling, standing alone, encouraged doctors or pharmacists to prescribe or dispense the generic drug for the CV Indication. See Pet. App. 17a-18a. Rather, Amarin alleges that the "totality" of statements in Hikma's labeling, press releases, and website encouraged that infringing use. Br. in Opp. App. 34a (¶ 128); see *id.* at 34a, 37a (¶¶ 127, 133). The relevant press releases—which Hikma issued before it began to market the drug—directed inquiries to Hikma's investor- and public-relations teams rather

than to its sales and marketing personnel. See J.A. 2, 39-40, 42-43. The press releases described Hikma's product as a generic version of Vascepa, and in some instances they provided information about Vascepa's total sales without distinguishing between Vascepa's two indications. *Ibid.* The press releases also stated that Vascepa was approved only "in part" for the SH Indication. J.A. 40, 42. The website identified Hikma's generic drug's rating as "AB" and its "Therapeutic Category" as "Hypertriglyceridemia." J.A. 195; see p. 10, *supra*.

Hikma moved to dismiss Amarin's complaint for failure to state a claim, arguing that Amarin had not plausibly alleged that Hikma took active steps to encourage infringement of Amarin's method-of-use patents. Pet. App. 9a. The district court granted the motion. *Id.* at 23a-38a. The court determined that Hikma's description of its product as a generic equivalent of Vascepa could not plausibly be understood as active inducement to infringe. *Id.* at 32a-35a. It also concluded that Hikma's "citation of Vascepa's sales figures" was potentially relevant to "Hikma's intent to induce" infringement, but that the citation itself was not "an inducing act." *Id.* at 33a. And the court determined that Amarin had not plausibly alleged active inducement based on Hikma's description of its generic drug as being in a "therapeutic category"—"'hypertriglyceridemia'"—that includes both infringing and non-infringing uses. *Id.* at 33a-35a. The court concluded that this broad description did not "specifically encourage[]" infringement. *Id.* at 35a (citation omitted).

2. The Federal Circuit reversed. Pet. App. 1a-22a. The court of appeals concluded that "the totality of the allegations" in Amarin's complaint "plausibly states a claim for induced infringement." *Id.* at 21a. The court

treated as undisputed for purposes of the appeal that (1) third parties had used Hikma's product to reduce cardiovascular risk, thereby infringing Amarin's patents; and (2) Hikma knew and intended that such infringement would occur. *Id.* at 15a. The court therefore focused on whether Amarin had plausibly alleged "that Hikma 'actively' induced" others' "direct infringement, *i.e.*, that Hikma 'encouraged, recommended, or promoted infringement.'" *Id.* at 15a-16a (brackets and citations omitted).

The court of appeals concluded that, taken together, Amarin's allegations about Hikma's carved-out labeling, public statements, and marketing materials plausibly supported an inference that Hikma had actively induced infringement of Amarin's method-of-use patents. Pet. App. 16a-21a. The court deemed it "at least plausible" that a doctor could discern "encouragement to prescribe [Hikma's] drug for *any* of [Vascepa's] approved uses" from statements in Hikma's press releases "touting [Vascepa's] sales figures attributable largely to" the CV Indication, and "calling Hikma's product the 'generic version' of a drug [Vascepa] that is indicated 'in part' for the SH indication"—"particularly where" Hikma's carved-out labeling "suggests that the drug may be effective for an overlapping patient population" that encompasses both infringing and non-infringing uses. *Id.* at 19a. The court likewise deemed it plausible that doctors could understand Hikma's website "marketing its drug in the broad therapeutic category of 'Hypertriglyceridemia'" as "encouraging prescribing the drug for an off-label use." *Ibid.*

The Federal Circuit cautioned that it was not permitting claims of active inducement to go forward based on a "mere statement that a generic manufacturer's prod-

uct is the 'generic version' of a brand-name drug," or on the bare fact that a generic manufacturer "not[es] (without mentioning any infringing uses) that FDA ha[s] rated a product as therapeutically equivalent to a brand-name drug." Pet. App. 21a (citation omitted). To the extent questions remained as to what message Hikma's statements had "communicate[d] to physicians and the marketplace," the Federal Circuit left those questions to be resolved after discovery. *Id.* at 18a-19a.

3. The Federal Circuit denied Hikma's petition for rehearing en banc. Pet. App. 39a-41a.

SUMMARY OF ARGUMENT

Pleading a claim of active inducement to infringe a patent requires, at minimum, factual allegations that plausibly explain how the defendant's statements or actions—beyond the bare sale of a product that may be put to infringing use—actively encouraged and caused direct infringement by a third party. Amarin's complaint includes no such allegations.

A. Although the Hatch-Waxman Amendments provide important context for assessing Amarin's inducement claims, the Amendments do not contain their own inducement provision. Rather, Amarin seeks to hold Hikma liable under the generally applicable Patent Act rule that "[w]hoever actively induces infringement of a patent shall be liable as an infringer." 35 U.S.C. 271(b); see Br. in Opp. App. 45a, 48a, 49a, 51a, 54a, 56a. Amarin's complaint does not plausibly allege that Hikma actively induced infringement of Amarin's patents.

Inducement liability under Section 271(b) is premised on "the taking [by the defendant] of affirmative steps to bring about the desired result." *Global-Tech Appliances, Inc.* v. *SEB S.A.*, 563 U.S. 754, 760 (2011). Establishing such liability 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." *Metro-Goldwyn-Mayer Studios Inc.* v. *Grokster, Ltd.*, 545 U.S. 913, 935 (2005); see *ibid.* ("The classic case of * * * unlawful purpose occurs when one induces commission of infringement by another."). To satisfy that standard at the pleading stage, Amarin's complaint at minimum needed to include factual allegations describing a plausible chain of events by which Hikma's statements caused healthcare providers to prescribe or dispense Hikma's generic drug to reduce cardiovascular risk.

Amarin's complaint contains no such factual allegations. It relies instead on the conclusory assertion that any healthcare provider who encounters Hikma's statements will inevitably infringe Amarin's patents. That is not enough to state a plausible claim. Amarin does not identify any plausible reason to believe that healthcare providers would have seen most of Hikma's allegedly problematic statements. Nor does it plausibly explain how those statements would have influenced providers' behavior or played any causal role in infringement of Amarin's method-of-use patents. Any inference that Hikma's statements would have had that forbidden effect is especially unlikely given the prevalence of state laws that encourage or mandate generic substitution regardless of the indication for which a particular drug is prescribed.

B. In concluding that Amarin had adequately alleged active inducement of infringing uses, the Federal Circuit relied on three categories of statements made by Hikma. Those statements are insufficient to create a plausible inference of culpable active inducement.

First, Hikma's skinny labeling cannot properly be viewed as evidence of culpable encouragement to infringe. Doing so would contravene the basic design of section viii, under which generic drugs may be approved and sold for unpatented uses even while valid patents still claim some of the approved uses of the brand-name drug. The point of the section viii carve-out mechanism is to ensure that the generic's label does not reference, and thus potentially encourage, still-patented uses of the relevant drug. The text of a generic's carved-out labeling, moreover, is driven by statutory and regulatory requirements rather than by a generic manufacturer's independent choices. At least absent exceptional circumstances, treating the generic manufacturer's compliance with those requirements as evidence of culpable encouragement to infringe would be illogical and would significantly deter generic manufacturers from invoking the section viii mechanism that Congress provided.

Second, the Federal Circuit erred in treating Hikma's description of its own product as a "generic equivalent" or "generic version" of Amarin's drug Vascepa, and Hikma's description of Vascepa as approved "in part" for an unpatented indication, as potentially culpable efforts to encourage infringement of Amarin's method-of-use patents. These statements accurately communicated that Hikma's product met the statutory and regulatory requirements for generic-drug approval as a therapeutic equivalent to Amarin's drug, and they described the unpatented indication for which Amarin's drug is approved. Like the labeling itself, that sort of statement is essential to the Hatch-Waxman scheme: Medical professionals must know which generic products are therapeutically equivalent to which brand-

name drugs in order to determine whether the generics may be substituted safely and effectively.

Third, Hikma's other disputed public statements do not lend plausibility to Amarin's claim that Hikma took active steps to induce infringement. The Federal Circuit relied in part on sales figures contained in press releases that predated the launch of Hikma's generic and were directed on their face to investors rather than to medical professionals. Potential Hikma investors do not make medical decisions, but they would likely want to know the potential market for Hikma's generic drug, which will ultimately include lawful on-label use of Hikma's drug for the CV Indication once Amarin's method-of-use patents expire. At least in the absence of specific factual allegations suggesting such a practice, there is no reason to believe that any healthcare provider would have made prescribing or dispensing decisions based on sales figures cited in outdated press releases. Treating these press releases as attempts to influence the decisions of medical providers therefore would be implausible, and it would needlessly impede the intended operation of the Hatch-Waxman scheme. The Federal Circuit also erred in inferring culpability from a Hikma website that described its generic as a therapy for "hypertriglyceridemia"—a term that encompasses both infringing and non-infringing uses.

C. The decision below threatens to undermine the broader Hatch-Waxman scheme. Section viii plays a key role in that scheme by allowing FDA to approve the sale of generic drugs even while some uses of the relevant chemical compound remain patented. Section viii thereby encourages the introduction of low-cost drugs for American consumers and helps avoid exploitative and anticompetitive practices by brand-name manufac-

turers. The Federal Circuit's decision creates a significant disincentive for generic manufacturers to use the section viii mechanism, especially given the threat of massive patent-infringement damages under Federal Circuit precedent. This Court should reverse the decision below and restore the proper functioning of the balanced scheme created by the Hatch-Waxman Amendments.

ARGUMENT

AMARIN'S COMPLAINT DOES NOT PLAUSIBLY ALLEGE THAT HIKMA ACTIVELY INDUCED INFRINGEMENT

The Hatch-Waxman Amendments reflect Congress's effort to "speed the introduction of low-cost generic drugs," *Caraco Pharm. Labs., Ltd.* v. *Novo Nordisk A/S*, 566 U.S. 399, 405 (2012), while "guard[ing] against infringement of [brand-name] patents," *Eli Lilly & Co.* v. *Medtronic, Inc.*, 496 U.S. 661, 676-677 (1990). In striking that balance between competing objectives, Congress determined that patents covering only some approved methods of using a drug should "not foreclose marketing a generic drug for other unpatented ones." *Caraco*, 566 U.S. at 415. The section viii mechanism reflects and reinforces the Hatch-Waxman scheme's larger goals by allowing generics labeled only for non-infringing uses to "quickly come to market," *ibid.*, so that a patent on one method of using a drug does not create a de facto monopoly on the drug itself.

Congress presumably understood that, if generic manufacturers can market drugs approved for unpatented methods of use while other uses of those drugs remain patented, some off-label uses will occur. Congress evidently viewed that prospect as an acceptable cost of expedited competition with respect to lawful *unpatented* uses. Congress attempted, however, to prevent generic

manufacturers who use section viii from *encouraging* infringing uses. By prohibiting labeling that suggests that a generic drug is approved for still-patented methods of use, section viii itself precludes one obvious way that generic manufacturers might encourage infringement. More generally, the Patent Act provisions that govern both direct infringement and active inducement, see 35 U.S.C. 271(a) and (b), remain fully applicable to the marketing, sale, and use of generic drugs.

To be sure, allowing generic entry while method-of-use patents remain in force may entail meaningful costs. Even when a particular drug is no longer patented, the prospect of obtaining method-of-use patents may encourage valuable innovation by creating a financial incentive for brand-name manufacturers to identify new therapeutic benefits of their existing products. Widespread infringement of such method-of-use patents may reduce that incentive to innovate by reducing the perceived value of those patents.

Section viii makes clear, however, that Congress preferred to accept that risk rather than to delay generic entry until all method-of-use patents for a given drug have expired. Under the basic bargain struck in section viii and in the Hatch-Waxman Amendments more generally, a generic manufacturer may market its product with skinny labeling so long as it does not actively encourage healthcare professionals to infringe the patents that still protect the carved-out uses. That approach is consistent with the rules that generally govern inducement liability in the intellectual-property context, under which vendors may sell goods or services that are capable of both infringing and non-infringing uses so long as they do not actively encourage infringement.

The decision below subverts Congress's balance between competing interests by subjecting Hikma to a substantial threat of infringement liability for statements that (a) are integral to the Hatch-Waxman scheme, including the section viii mechanism; and/or (b) have no meaningful likelihood of causing infringing off-label uses. The content of Hikma's "skinny label" is largely dictated by the Hatch-Waxman Amendments, and Hikma's description of its drug as the "generic equivalent" of Vascepa is central to the Hatch-Waxman scheme. And while the Federal Circuit identified a handful of other statements to investors that accurately described the generic drug and its brand-name counterpart, the complaint in this case did not describe any plausible sequence of events by which those statements could have led healthcare professionals to engage in direct infringement.

Section viii cannot function as Congress intended if a generic manufacturer's anodyne descriptions of its product create a serious risk of massive patent-infringement liability. Uncertainty about section viii will deter generic manufacturers from invoking that mechanism, thereby threatening the availability of lower-cost generic drugs, in contravention of the statutory design. This Court should reverse the judgment of the court of appeals.

A. Amarin's Allegations Do Not Make Out A Plausible Claim Of Active Inducement To Infringe

Amarin's allegations do not support a plausible inference that Hikma actively encouraged infringement of Amarin's patents. See generally *Ashcroft* v. *Iqbal*, 556 U.S. 662 (2009).

Although the Hatch-Waxman Amendments provide important context for assessing Amarin's inducement claims, those claims arise under the Patent Act's gener-

ally applicable inducement provision, 35 U.S.C. 271(b). See Br. in Opp. App. 45a, 48a, 49a, 51a, 54a, 56a. That provision states: "Whoever actively induces infringement of a patent shall be liable as an infringer." 35 U.S.C. 271(b). Section 271(b)'s use of "the adverb 'actively' suggests that the inducement must involve the taking of affirmative steps to bring about the desired result." *Global-Tech Appliances, Inc.* v. *SEB S.A.*, 563 U.S. 754, 760 (2011). And inducement liability is premised on "culpable expression and conduct." *Metro-Goldwyn-Mayer Studios Inc.* v. *Grokster, Ltd.*, 545 U.S. 913, 936-937 (2005) (drawing on patent law to adopt a liability rule for inducing copyright infringement).

The Hatch-Waxman Amendments (and section viii in particular) allow generic manufacturers to sell their products when (a) the drug itself is no longer patented and (b) some but not all FDA-approved uses of the drug are still covered by method-of-use patents. See *Caraco*, 566 U.S. at 406. In allowing the sale of generic drugs that are capable of both infringing and non-infringing uses, section viii is consistent with the rules that generally govern inducement liability in the intellectual-property context. See *Sony Corp.* v. *Universal City Studios, Inc.*, 464 U.S. 417, 441 (1984) ("Unless a commodity has no use except through practice of the patented method, the patentee has no right to claim that its distribution constitutes contributory infringement.") (citation and internal quotation marks omitted). As a general rule, "mere knowledge of infringing potential or of actual infringing use[]," or suggestions to purchase a product for broad categories of uses that are not "necessarily infringing," do not suffice to establish inducement liability. *Grokster*, 545 U.S. at 931, 937. Rather, 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. Examples of such culpable "'active steps'" include "advertising an infringing use or instructing how to engage in an infringing use." *Id.* at 936 (citation omitted).

Read literally, none of Hikma's statements can plausibly be viewed as an explicit instruction or exhortation to use Hikma's generic drug for the CV indication. To be sure, doctors and pharmacists are sophisticated actors who possess a base of relevant knowledge that most laypeople lack. In determining whether a brand-name manufacturer has alleged active inducement with sufficient plausibility, courts should keep in mind the sophistication of an alleged statement's intended audience.

In assessing the plausibility of such allegations, however, courts should also consider the likelihood (or unlikelihood) that potential direct infringers will become aware of, and will be influenced by, particular statements that are alleged to induce infringement. Here, it appears to be undisputed that dispensing decisions are usually made by pharmacists who do not know why a particular drug is being prescribed (because prescriptions typically do not specify), and whose choice between a brand-name drug and its generic equivalent may be compelled or constrained by state law. See pp. 7-9, *supra*; see also Br. in Opp. App. 34a-35a (¶ 129) (acknowledging that some States have policies that "encourage or require" generic substitution "regardless of whether the generic drug label includes all the indications in the branded drug labeling"). And some of Hikma's statements were directed to potential investors rather than to the healthcare professionals who are the potential direct infringers here. The ultimate question is whether Amarin's allegations, considered in

light of undisputed market realities and with all reasonable inferences drawn in Amarin's favor, make it plausible that Hikma crossed the line between merely "'expect[ing]'" infringement and culpably "promoting" infringing uses. *Grokster*, 545 U.S. at 935 (citation omitted).

To survive a motion to dismiss under these established pleading standards, Amarin needed to plausibly allege that Hikma took active steps to induce infringement of Amarin's patents. In particular, Amarin needed to identify some plausible chain of events through which statements made by Hikma led healthcare providers—presumably doctors or pharmacists—to prescribe or dispense Hikma's drug to reduce patients' cardiovascular risk. Without (at minimum) particularized allegations making it plausible that these statements actually "foster[ed]" infringing uses of Hikma's product, there is no basis to infer that the statements *caused* infringement to occur, or that Hikma made them with the "object of promoting" that unlawful result rather than merely "incident" to "legitimate commerce" in an FDA-approved generic drug. *Grokster*, 545 U.S. at 936-937.

Amarin's complaint contains no such allegations. It relies instead on the conclusory assertion that "a healthcare provider with knowledge" of Vascepa's approvals and Hikma's statements "will inevitably" infringe Amarin's patents. Br. in Opp. App. 37a (¶ 133). To state a claim against Hikma under Section 271(b), however, Amarin must plausibly allege not only that Hikma's generic drug has been used to infringe Amarin's patents, but also that Hikma's statements encouraged and caused that infringement. Under established and widespread prescribing and dispensing practices, a doctor seeking to treat cardiovascular risk could write

a prescription for "Vascepa," which might then be filled with Hikma's generic drug by a pharmacist who does not know the purpose for which the drug will be used. These market realities may make it inevitable that some degree of direct infringement will occur. But Amarin's complaint identifies no basis for inferring that Hikma's allegedly inducing statements will increase the frequency of such infringement, or that Hikma made the statements for the purpose of producing that result.

Absent factual allegations that plausibly connect Hikma's statements to direct infringement by a third party, the complaint's conclusory allegations that those statements "instruct, promote, and encourage" infringement, Br. in Opp. App. 34a (¶ 128), and that healthcare professionals "will inevitably" infringe as a result, *id.* at 37a (¶ 133), are "not entitled to be assumed true." *Iqbal*, 556 U.S. at 681. These sorts of conclusory allegations resemble the "bare assertion of conspiracy" held to be inadequate to plead an antitrust claim in *Bell Atlantic Corp.* v. *Twombly*, 550 U.S. 544, 556 (2007). If anything, the grounds for inferring a connection between Hikma's statements and any infringing conduct are weaker here than in *Twombly*. There, this Court explained that while "parallel conduct" by interdependent businesses could provide circumstantial evidence of an agreement, such conduct was "just as much in line with a wide swath of rational and competitive business strategy unilaterally prompted by common perceptions of the market." *Id.* at 554. Here, the off-label dispensing of generic drugs that is routine and even required in some States does not provide even circumstantial evidence of an additional push by Hikma to induce healthcare providers to engage in infringing activity.

Contrary to Amarin's contention (Supp. Br. 10-11), the fact that Hikma is not presently contesting its general knowledge and intent that direct infringement would occur, see Pet. App. 15a, does not strengthen Amarin's allegations of active inducement. As a practical matter, every generic manufacturer will subjectively want its product to be used as widely as possible and will know that generic-substitution laws often lead to infringing off-label uses. And while Hikma has not disputed that those circumstances are present here, it has contested Amarin's assertion that the statements alleged in the complaint plausibly suggest "culpable conduct, directed to encouraging" direct infringement. Pet. C.A. Br. 24 (quoting *DSU Med. Corp.* v. *JMS Co.*, 471 F.3d 1293, 1306 (Fed. Cir. 2006) (en banc)) (emphasis omitted); see *id.* at 39-40 (explaining that alleged inducer's knowledge of direct infringer's conduct is insufficient to establish inducement liability, and that "Amarin has not plausibly alleged that Hikma took 'active steps' to encourage infringement") (citation omitted). Hikma's subjective expectations or "knowledge that it[s drug] may be put to infringing uses" does not control the determination whether Amarin has plausibly alleged "statements or actions directed to promoting infringement." *Grokster*, 545 U.S. at 935.

B. The Statements On Which The Federal Circuit Relied Provide No Basis For Liability

In concluding that Amarin had adequately alleged active inducement of infringing uses, the Federal Circuit relied on three categories of statements made by Hikma. Read literally, none of those statements encourages any healthcare provider to infringe Amarin's method-of-use patents. Both individually and taken to-

gether, those statements are insufficient to create a plausible inference of culpable active inducement.

First, Hikma's skinny labeling cannot properly be treated as evidence of culpable encouragement to infringe. Section viii is designed to enable generic versions of a brand-name drug to be marketed where the drug itself is not patented and only some of its FDA-approved uses are claimed by method-of-use patents. See 21 U.S.C. 355(j)(2)(A)(viii); pp. 4-7, *supra*. By authorizing FDA to approve an ANDA in those circumstances, Congress necessarily contemplated and intended that "one patented use will not foreclose marketing a generic drug for other unpatented ones." *Caraco,* 566 U.S. at 415.

Treating a generic manufacturer's approved skinny labeling as evidence of culpable inducement would be at odds with section viii's basic design. The content of carved-out labeling is driven by statutory and regulatory requirements that allow only narrow exceptions to the general statutory command that generic labeling must be the same as the brand's labeling. See 21 U.S.C. 355(j)(2)(A)(v); 21 C.F.R. 314.94(a)(8)(iv). Before FDA approves an ANDA, the agency reviews the generic manufacturer's proposed skinny labeling to verify (i) that the labeling omits the uses that the brand-name manufacturer has described as claimed by its patents, see *Caraco*, 566 U.S. at 405-407; (ii) that those omissions do not "render the proposed [generic] drug product less safe or effective than the [brand] drug for all remaining, nonprotected * * * use[s]," see 21 C.F.R. 314.127(a)(7); and (iii) that the carved-out labeling remains the same as the brand's with respect to the remaining methods of use, see *ibid.*

The point of the skinny-label mechanism is to make unlawful inducement *less* likely, by ensuring that the generic's label does not reference (and thus potentially encourage) still-patented uses of the drug. And because the content of the skinny label is largely dictated by statute and regulations, use of the label says little about the generic manufacturer's culpability. At least absent exceptional circumstances, treating the generic manufacturer's compliance with those requirements as evidence of culpable encouragement to infringe therefore would be illogical and would significantly deter generic manufacturers from using section viii, thus defeating the statutory scheme.

Second, and for similar reasons, the Federal Circuit erred in concluding that 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, could plausibly be viewed as culpable attempts to encourage infringement. See Pet. App. 18a-21a. Those statements did not mention the patented CV Indication, let alone encourage healthcare professionals to prescribe or dispense Hikma's generic drug for that purpose. Rather, they communicated that Hikma's product meets the statutory and regulatory requirements (including therapeutic equivalence to Vascepa) for approval under an ANDA, and they described the unpatented indication for which Vascepa is approved.

Like the labeling itself, that sort of statement is essential to the Hatch-Waxman scheme, since medical professionals must know which generic products are therapeutically equivalent to which brand-name drugs in order to determine whether the generics may be substituted safely and effectively. To the extent such statements reach indi-

viduals who make prescribing and dispensing decisions, they serve Hatch-Waxman's purpose of encouraging substitution of cheaper generics for unpatented indications. And to the extent particular statements do not reach such individuals, those statements cannot induce infringement of the patented methods of use.

Third and finally, Hikma's other disputed public statements—which were not directed to medical professionals—do not lend plausibility to Amarin's claim that Hikma took active steps to induce infringement. To be sure, unlike the labeling and generic-equivalent statements discussed above, Hikma's citation in press releases of Vascepa's total sales figures is not necessary to the operation of the Hatch-Waxman scheme. But that is largely because those press releases are orthogonal to the processes by which generic drugs are approved, labeled, prescribed, and dispensed. They relate instead to the commercial processes by which generic manufacturers seek to attract the investors needed to develop and market their drugs. On their face, Hikma's press releases were directed to investors rather than to medical professionals, and they were issued before Hikma's generic drug was on the market (and in some instances before FDA had approved the generic).

Because potential Hikma investors do not make prescribing or dispensing decisions, those statements directed to them cannot plausibly be viewed as attempts to induce infringement. But potential investors would likely want to know the potential market for Hikma's generic drug. And that potential market will ultimately include use of Hikma's drug for the CV Indication, since generic icosapent ethyl may lawfully be promoted for that indication—indeed, its labeling *must* be updated to include that indication—once Amarin's method-of-use

patents expire. Chilling such investor communications, by implausibly construing them as actively encouraging infringement by medical providers, would needlessly impede the intended operation of the Hatch-Waxman scheme.

In order for Hikma's press releases to induce infringement, a prescriber or pharmacist would need to (1) have read an outdated investor press release, (2) know of the relative contributions to sales made by each of Vascepa's two indications, (3) construe the bare inclusion of total Vascepa sales in Hikma's estimate of market size as encouragement to prescribe or dispense Hikma's drug to reduce cardiovascular risk, and (4) act to prescribe or dispense Hikma's drug based upon that encouragement rather than based upon other reasons, such as the constraints imposed by state generic-substitution laws, see pp. 7-9, *supra*. At a minimum, further factual allegations would be needed to plead a plausible causal connection between the press releases and any ultimate acts of direct infringement. But Amarin's complaint offered no subsidiary allegations suggesting that this sequence of events can plausibly be thought to have occurred. See *Iqbal*, 556 U.S. at 679 (holding that a complaint does not state a claim for relief "where the well-pleaded facts do not permit the court to infer more than the mere possibility of misconduct").

Like Hikma's press releases, the relevant page on Hikma's website does not mention cardiovascular risk at all. The website describes icosapent ethyl as a therapy for "Hypertriglyceridemia," J.A. 195, but even the non-infringing SH Indication treats that condition, see p. 10, *supra*. Accordingly, the website's statement does not urge a "necessarily infringing" use, *Grokster*, 545 U.S. at 931, but rather amounts at most to marketing a

lawful product in terms broad enough to encompass both infringing and non-infringing uses. Even apart from the unlikelihood that individuals who prescribe and dispense drugs would consult the website, the statement does not raise a plausible inference of culpable inducement to infringe.

The nature of the statements on which the Federal Circuit relied highlights the unduly lenient standard it applied in assessing Amarin's complaint. For example, the court faulted Hikma for noting that Vascepa was approved only "in part" for the indication for which Hikma's drug was approved. Pet. App. 19a. But if Hikma had *omitted* that qualifier, it could equally have been faulted for failing to provide sufficient notice that Hikma's product is not labeled for all the same indications as Vascepa. At every turn, the Federal Circuit relied on anodyne statements with logical explanations having nothing to do with active encouragement of infringing uses, see *Grokster*, 545 U.S. at 937 (emphasizing that "ordinary acts incident to product distribution" do not "support liability in themselves"), without identifying any factual allegations in the complaint suggesting a causal link between these statements and any subsequent prescribing or dispensing decisions.

C. The Federal Circuit's Decision Undermines The Broader Hatch-Waxman Scheme

1. The section viii mechanism is an integral component of a complex statutory scheme designed to encourage market entry by generic-drug manufacturers "as soon as patents allow." *Caraco*, 566 U.S. at 405. Generic drugs approved between 2018 and 2020 are estimated to have saved consumers more than $50 billion in the first 12 months of generic sales. Ryan Conrad et al., FDA, *Estimating Cost Savings from New Generic Drug Ap-*

provals in 2018, 2019, and 2020, at 3 (2022). In many instances, FDA approval of the first generic version of a brand-name drug reduced the price of the drug by more than 75%. *Id.* at 4. Such "first generic" approvals often involve carved-out labeling. See, *e.g.*, Bryan S. Walsh et al., *Frequency of First Generic Drug Approvals With 'Skinny Labels' in the United States*, 181 JAMA Internal Med. 995, 995-997 (July 2021). According to one recent study, the section viii mechanism has allowed generic drugs to be approved for sale an average of three years before the relevant method-of-use patents expired. See *id.* at 995.

Section viii reflects Congress's judgment that a patent on one use of a drug should not create a de facto monopoly on the drug itself. That policy judgment does not reflect special solicitude for manufacturers of generic drugs. Rather, it is consistent with the general rule that sales of a product with both infringing and non-infringing uses will not subject the seller to inducement liability unless the seller actively encourages infringing conduct. See, *e.g.*, *Sony*, 464 U.S. at 441 ("[I]n contributory infringement cases arising under the patent laws the Court has always recognized the critical importance of not allowing the patentee to extend his monopoly beyond the limits of his specific grant.").

To be sure, the availability of method-of-use patents provides an important incentive for continued research to identify additional therapeutic uses of established drugs. Direct infringement of method-of-use patents would be reduced, and those patents would become more valuable (and accordingly would provide a greater incentive for such research), if generic equivalents could not be marketed *at all* until every method-of-use patent on the relevant drug has expired or been success-

fully challenged. The whole point of section viii, however, is to reject that all-or-nothing approach, which had previously enabled "anticompetitive practices" by brand-name manufacturers "to prevent or delay the marketing of generic drugs." *Caraco*, 566 U.S. at 408. And the Hatch-Waxman Amendments' skinny-label mechanism represents an evident congressional determination that, so long as generic manufacturers do not encourage infringing uses of their drugs, some measure of dispensing for such uses is an acceptable price for expediting generic competition with respect to non-infringing uses.

To achieve the balance that Congress struck in enacting section viii, generic manufacturers must be able to take the steps necessary to bring lower-cost generic drugs to market, such as using carved-out labeling, describing their drugs as the generic version of the corresponding brand-name drugs, and providing basic information to investors. It is equally important to the federal scheme that generic manufacturers not urge medical professionals to infringe brand-name manufacturers' method-of-use patents. But absent any allegation that Hikma's statements encouraged the people who make prescribing and dispensing decisions to use Hikma's drug for the CV Indication, the Federal Circuit's decision does not meaningfully enforce those limits.

2. The Federal Circuit's decision creates a substantial disincentive to use of the section viii mechanism, both by increasing the likelihood of ultimate damages liability and by allowing conclusory allegations to subject generic manufacturers to the burdens of litigation.

That disincentive is exacerbated by the approach the Federal Circuit has taken to the calculation of damages when generic manufacturers are found liable for inducing infringement of method-of-use patents. Federal Circuit

precedent suggests that a prevailing brand-name plaintiff in such a case may recover lost profits calculated as if the brand-name manufacturer would (but for the inducement) have captured "every infringing sale" of the defendant's generic drug for the patented use. *GlaxoSmithKline LLC* v. *Teva Pharms. USA, Inc.*, 7 F.4th 1320, 1340-1341 (Fed. Cir. 2021) (per curiam), cert. denied, 143 S. Ct. 2483 (2023). That analysis could be read to mean that, if Hikma's statements on its website and to investors are found to have caused some small number of doctors or pharmacists to engage in infringing off-label uses of Hikma's generic drug, Hikma can be made to pay damages for *all* infringing uses of its drug, including uses that the statements played no causal role in inducing. See *id.* at 1341 (rejecting argument that automatic generic substitution by pharmacies would break chain of causation for damages purposes). To be sure, Amarin asserts that a later Federal Circuit decision has adopted a more measured approach. See Supp. Br. 11. But at a minimum, uncertainty as to the calculation of potential damages increases the disincentive that the decision below creates for generic manufacturers to invoke the section viii mechanism.

CONCLUSION

The judgment of the court of appeals should be reversed.

Respectfully submitted.

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