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

BRIEF FOR THE UNITED STATES AS AMICUS CURIAE

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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 pathway 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 label 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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This brief is submitted in response to the Court's order inviting the Solicitor General to express the views of the United States. In the view of the United States, the petition for a writ of certiorari should be granted.

STATEMENT

A. Legal Background

1. The Federal Food, Drug, and Cosmetic Act (FDCA), 21 U.S.C. 301 *et seq.*, generally requires approval by the Food and Drug Administration (FDA) 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 "piggy-back[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 ap-

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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.

proved "method of using" it (including an "'indication,'" 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 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 it contends 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. Assuming 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 litigation 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 obtain judicial resolution of the patent dispute before marketing its product, eliminating the risk of patent damages.

Second, a generic manufacturer may seek 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 typically entails.

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 basis. This combination strategy may narrow the scope of patent litigation and speed the 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 (Mar. 27, 2025), https://www.fda.gov/drugs/development-approval-process-drugs/orange-book-preface. Therapeutic-equivalence evaluations are published in the Orange Book, where generics

that FDA considers to be therapeutically equivalent to their brand-name counterparts are assigned a code beginning with "A," such as "AB." *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 remaining 16 States generally man-

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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); Del. Code § 2549(a), repealed by 85 Del. Laws c. 49 (June 30, 2025) (reenacting provisions of Del. Code § 2549 at 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

date 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 indicating 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).

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 contain the information about a patient's diagnosis and treatment

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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 2025 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).

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").

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

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[4] Several States allow doctors to include indication information 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).

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.* Use of icosapent ethyl for the CV Indication is claimed by two listed method-of-use patents held by Amarin. *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. 4, *supra*. Hikma also 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" label. Pet. App. 5a. Unlike Vascepa's labeling, the labeling for Hikma's generic "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 C.A. App. 635, 642-645 (Vascepa), with *id.* at 694, 702 (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. 4-5, *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, see C.A. App. 613, 709, 712—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. The press releases also stated that Vascepa was approved only "in part" for the SH Indication. *Id.* at 709, 712. The website identified Hikma's generic drug's rating as "AB" and its "Therapeutic Category" as "Hypertriglyceridemia." *Id.* at 820; see p. 8, *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 descrip-

tion of its product as a generic equivalent of Vascepa could not plausibly be understood as active inducement of infringement. *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 citation 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 plausi-

ble" 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 product is the 'generic version' of a brand-name drug," or on the bare fact that a generic manufacturer "note[s] (without mentioning any infringing uses) that FDA ha[s] rated a product as therapeutically equivalent to a brand-name drug." Pet. App. 21a. 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.

DISCUSSION

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, 405-406 (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 pathway 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 invoke the section viii pathway 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 remain fully applicable to the marketing, sale, and use of generic drugs.

The decision below subverts Congress's balance between competing interests by subjecting Hikma to a substantial threat of infringement liability for statements that either (a) are integral to the section viii pathway or (b) have no meaningful likelihood of increasing the prevalence of infringing off-label uses. The contents

of Hikma's "skinny label" are 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 a healthcare professional 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 liability. Uncertainty about the section viii pathway 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 grant the petition for a writ of certiorari and reverse the judgment of the court of appeals.

A. The Federal Circuit's Decision Is Incorrect

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).

1. The Patent Act provides: "Whoever actively induces infringement of a patent shall be liable as an infringer." 35 U.S.C. 271(b). The statute'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). "[M]ere 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. *Id.* 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).

To survive a motion to dismiss in this case, 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 could lead a healthcare provider—presumably a doctor or pharmacist—to prescribe or dispense Hikma's drug to reduce a patient's cardiovascular risk. But the complaint contains only a conclusory statement in that regard, asserting 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). Absent more detailed factual allegations connecting Hikma's statements to direct infringement by a third party, the complaint's conclusory allegation is "not entitled to be assumed true." *Iqbal*, 556 U.S. at 681.

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 therefore

should be alert to the possibility that even subtle efforts to encourage infringing uses of a specific drug could prove efficacious. Under established pleading standards, however, Amarin was still required to offer particularized allegations establishing a plausible causal link between Amarin's statements and subsequent infringing uses of its generic drug. In assessing the plausibility of such allegations, moreover, courts should take account of the evidently undisputed facts that dispensing decisions are usually made by pharmacists who do not know why a particular drug is being prescribed (because doctors do not tell them), and whose choice of drug may be compelled or constrained by state law. See pp. 5-7, *supra*.

2. In concluding that Amarin had adequately alleged active inducement of infringing uses, the Federal Circuit relied on three categories of statements made by Hikma. Both individually and taken together, 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. The section viii pathway 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. 2-4, *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 label as evidence of culpable inducement would be at odds with section viii's basic design. A particular carved-out

label does not reflect a generic manufacturer's unencumbered choice. Rather, it 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. And before FDA approves an ANDA, the agency reviews the generic manufacturer's proposed skinny label to verify that the labeling omits the uses that the patentholder has described as claimed by its patents. See *Caraco*, 566 U.S. at 405-407. At least absent exceptional circumstances, treating the generic manufacturer's compliance with those requirements as evidence of culpable encouragement to infringe would substantially deter generic manufacturers from invoking the section viii pathway, thus defeating Congress's intent.

Second, and for similar reasons, the 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. See Pet. App. 18a-21a. Without mentioning the patented CV Indication, those statements simply communicated that Hikma's product meets the statutory and regulatory requirements for approval under an ANDA—including therapeutic equivalence to Vascepa—and described the unpatented indication for which Vascepa 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 for the unpatented indications. To the extent such statements reach individuals 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 generic 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 was on the market (and in some cases before FDA had approved the generic).

Potential Hikma investors do not make prescribing or dispensing decisions, but they 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 treating them as an intentional inducement to

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, as described above (see pp. 5-7, *supra*). At a minimum, further factual allegations would be needed to plead a 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 could plausibly be expected to occur.

Like its 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," C.A. App. 820, but even the non-infringing SH Indication treats that condition, see pp. 7-8, *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 making substitution decisions 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 intentional encouragement of infringing uses, while identifying no factual allegations in the complaint suggesting a causal link between these statements and any subsequent prescribing or dispensing decisions.

B. The Question Presented Warrants Review In This Case

1. The section viii pathway 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 Approvals 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 pathway permit-

ted 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. To be sure, the availability of method-of-use patents provides an important incentive for continued research to study additional therapeutic uses of established drugs. Direct infringement of method-of-use patents would doubtless 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 successfully challenged. The whole point of the section viii pathway, however, is to reject that all-or-nothing approach. 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 direct patent infringement is an acceptable price for expediting generic competition with respect to non-infringing uses.

In creating the section viii pathway, Congress balanced competing objectives by (a) allowing a generic drug to enter the market even while one or more patents claiming methods of using the relevant chemical compound remain in effect; (b) carving out still-patented methods of use to ensure that the generic label itself does not encourage infringement; and (c) leaving in place, and fully applicable to generic drugs, the Patent Act provisions that prohibit both direct infringement of method-of-use patents and active inducement of such infringement. To achieve that balance, generic manu-

facturers must be able to take the steps necessary to bring lower-cost generic drugs to market, such as using carved-out labels, 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 take steps to affirmatively encourage patent infringement. But absent any allegation that Hikma's statements were directed to and intended to induce infringement by the people who make prescribing and dispensing decisions—other than through the sorts of communications that are integral to the Hatch-Waxman scheme, see pp. 15-17, *supra*—the Federal Circuit's decision does not meaningfully enforce those limits.

2. To be sure, the decision below holds only that Amarin's complaint can withstand a motion to dismiss. Even without this Court's intervention, Hikma might ultimately prevail at summary judgment or trial. But the Federal Circuit's decision creates a substantial disincentive to invoke the section viii pathway, 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. de-

nied, 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. 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 pathway.

3. This case is an appropriate vehicle to decide the question presented. The parties' dispute arises out of a motion to dismiss a narrow and uncomplicated pleading. And despite Amarin's efforts to portray that dispute as "fact-bound," see Br. in Opp. 27-28, the relevant circumstances alleged in the complaint—a skinny label that discusses the generic's use in a patient population that may overlap with the carved-out indication; a description of the generic product as the brand-name drug's "equivalent"; and the provision of accurate sales figures to investors—are likely to be present in most instances where generic manufacturers invoke the section viii pathway.

The fact that Hikma is not presently contesting its general knowledge and intent that direct infringement would occur, see Pet. App. 15a, should not impede this Court's review of the active-inducement question. 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 allegations that Hikma af-

firmatively promoted off-label uses of its generic drug with specific, culpable intent to encourage infringement. See Pet. C.A. Br. 24-26.

Finally, it would be imprudent to wait for another case to resolve the important issues presented here. Many cases of this kind settle, due to the extreme pressures on generic manufacturers to avoid the costs of litigation and potentially high damages. And the lenient pleading standard applied by the court below may cause fewer generic manufacturers to invoke the section viii pathway, further reducing the likelihood that a better alternative vehicle will arise. This Court's intervention is accordingly warranted now.

CONCLUSION

The petition for a writ of certiorari should be granted.

Respectfully submitted.

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