No. 24-889

In the Supreme Court of the United States

HIKMA PHARMACEUTICALS USA INC. AND
HIKMA PHARMACEUTICALS PLC,
Petitioners,

v.

AMARIN PHARMA, INC., ET AL.,
Respondents.

On Writ of Certiorari to the
United States Court of Appeals for the Federal Circuit

BRIEF FOR RESPONDENTS

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QUESTION PRESENTED

Whether the court of appeals correctly found that, on the particular constellation of facts pleaded in respondents' complaint, respondents have plausibly alleged petitioners' active inducement to infringe patented uses of respondents' innovative pharmaceutical product.

PARTIES TO THE PROCEEDING

Petitioners in this Court, the defendants-appellees below, are Hikma Pharmaceuticals USA, Inc. and Hikma Pharmaceuticals PLC (HIK).

Respondents in this Court, the plaintiffs-appellants below, are Amarin Pharma, Inc., Amarin Pharmaceuticals Ireland Limited, and Mochida Pharmaceutical Co., Ltd.

CORPORATE DISCLOSURE STATEMENT

Both Amarin Pharma, Inc. and Amarin Pharmaceuticals Ireland Limited are wholly owned subsidiaries of Amarin Corporation plc (AMRN), a publicly held corporation. No other publicly held corporation owns 10% or more of the stock of Amarin Pharma, Inc. or Amarin Pharmaceutical Ireland Ltd.

Mochida Pharmaceutical Co., Ltd. (4534.T) is a Japanese company that is publicly traded on the Tokyo Stock Exchange. No publicly held corporation owns 10% or more of the stock of Mochida Pharmaceutical Co., Ltd., and it has no parent corporation.

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STATUTORY PROVISION INVOLVED

The Patent Act provides at 35 U.S.C. § 271, in relevant part:

> **(b)** Whoever actively induces infringement of a patent shall be liable as an infringer.

INTRODUCTION

Congress in the Hatch-Waxman Act adopted a careful compromise between expanding the availability of generic pharmaceuticals and preserving the intellectual-property rights necessary to encourage innovation. Yet to hear petitioners tell it, Congress's overriding purpose was to expand generic manufacturers' market access by all-but immunizing them against patent-infringement liability when using "skinny label" products.

That is not the law. For one thing, this case at bottom does not call for interpreting any statute or regulation governing the pharmaceutical industry. At issue is the induced-infringement statute protecting *all* patented inventions. Section 271(b) of the Patent Act establishes liability for "actively induc[ing] infringement of a patent"—whether the patent covers a pharmaceutical, a consumer product, an innovative computerized process, or anything else. Petitioners' arguments, if accepted, would dramatically dilute intellectual-property protection throughout the Nation by shielding intentional efforts to use crafty statements to encourage infringing copycat sales.

Petitioners' request for a sort of qualified immunity for generic drug manufacturers is flawed for another reason as well. As the United States recognizes (US.Br. 31-32), Congress deliberately maintained incentives for pioneer drug manufacturers like respondents to expend the enormous efforts and sums required to discover life-saving medical treatments—including discovering transformative new uses for existing drugs—by preserving patent protections for those innovations. The Hatch-Waxman Act's section viii pathway offers generic manufacturers like petitioners a lucrative bargain: generics, which did not invest the immense resources necessary to develop treatments, may market their drugs for unpat-

ented uses; but they must take care not to suggest—in advertising or elsewhere—that their products should be prescribed for any patented indication. See *Caraco Pharm. Laboratories, Ltd.* v. *Novo Nordisk A/S*, 566 U.S. 399, 415, 419 (2012). Petitioners broke that bargain. Unlike their generic competitors selling this same product, petitioners told the world that their drug can be prescribed for a therapeutic category that infringes respondents' patents.

Amarin Pharma's lifesaving medicine Vascepa® is a perfect example of why Congress incentivized and protected subsequent innovations. The Food & Drug Administration (FDA) originally approved Vascepa to treat severe hypertriglyceridemia (the "SH indication"). Amarin thereafter invested several years, and hundreds of millions of dollars, into extensive clinical trials to discover and demonstrate that Vascepa is also a revolutionary medicine for a different condition affecting far more patients: cardiovascular risks arising from hypertriglyceridemia (the "CV indication"). Doctors hailed Amarin's invention as a "game changer" for cardiovascular patients facing high risks of heart attack or stroke. Vascepa soon became synonymous in the market with its groundbreaking CV indication. By the time petitioners brought their generic product to market, they knew that Vascepa's patented CV indication accounted for the vast majority of prescriptions and Vascepa's commercial identity.

Because petitioners knew that Vascepa's overwhelming value was in the CV indication, they were not content to market their drug lawfully as only a treatment for severe hypertriglyceridemia. Instead, petitioners' website described their product as a treatment for "Hypertriglyceridemia," a category that unambiguously encompasses respondents' patented use. And petitioners rein-

forced their efforts to ensure their drug would be prescribed for all indications—including prescriptions that infringe respondents' patents—through additional statements in press releases and on its drug label. None of that was necessary to the Hatch-Waxman scheme. Nor was it lawful. This Court should not make new law to excuse petitioners' improper advertising, contrary to Congress's careful incentive structure for finding new treatments.

Petitioners' charge that respondents seek to stifle generic competition is baseless. There are seven other manufacturers in the same market selling the same generic drug using materially identical "skinny labels" as petitioners. But respondents have not sued any other manufacturer that confined its marketing to unpatented indications. Petitioners alone chose to publish statements that healthcare providers would interpret as encouraging prescriptions that infringe respondents' patents. The Patent Act makes petitioners liable for that encouragement, as the Federal Circuit correctly determined.

The court of appeals' judgment should be affirmed.

STATEMENT

A. Statutory and regulatory background

1. Drug approval

FDA must approve new and generic drugs before they may be marketed in interstate commerce. 21 U.S.C. § 355. To obtain approval for a new drug (or new use for a known drug), an applicant must file a New Drug Application (NDA) that, among other things, proposes a label and includes clinical data demonstrating safety and effectiveness for the intended use. 21 U.S.C. § 355(b)(1)(A)(i), (vi). That is a "long, comprehensive, and costly testing process." *FTC* v. *Actavis, Inc.*, 570 U.S. 136, 142 (2013). The NDA must include "full reports of investigations" into

safety and efficacy, a "full list of the articles used as components," and a "full description" of the drug's manufacturing, processing, and packaging. 21 U.S.C. § 355(b)(1); see 21 C.F.R. § 314.50(d)(1), (2), (5).

Before 1984, most drug applications required clinical trials, even if the active ingredient had been previously approved. See Weiswasser & Danzis, *The Hatch-Waxman Act: History, Structure, and Legacy*, 71 Antitrust L.J. 585, 587-589 (2003). Those requirements were inefficient and imposed barriers to entry of low-cost drugs to compete with medicines that were unpatented or whose patents would soon expire. *Ibid.* To balance incentivizing innovation with increasing generic competition, Congress passed what became known as the Hatch-Waxman Act. Pub. L. No. 98-417, 98 Stat. 1585 (1984).

Under Hatch-Waxman, a manufacturer may seek approval to market a generic version of an approved drug by filing an abbreviated new drug application (ANDA). 21 U.S.C. § 355(j). An ANDA need not provide independent safety or efficacy evidence; it need show only that the generic drug has the same active ingredient as, and is bioequivalent to, a reference listed drug. 21 U.S.C. § 355(j)(2)(A)(ii), (iv). That "allow[s] the generic to piggyback on the pioneer's approval efforts" and "avoid[] the 'costly and time-consuming studies' needed to obtain approval 'for a pioneer drug.'" *Actavis*, 570 U.S. at 142 (citation omitted).

Contrary to petitioners' view (Br. 7-8), Congress did not simply accept that "doctors and patients would inevitably infringe." Congress sought, instead, to protect intellectual-property rights. It made clear that "FDA cannot authorize a generic drug that would infringe a patent"—including patents claiming a listed drug or an approved "'indication'" or "method of using" the drug. *Caraco*, 566

U.S. at 405-406, 417 n.7; see 35 U.S.C. § 271(e)(4)(A) (requiring courts to block approval of infringing generics). As the government acknowledges (US.Br. 32), it is "important to the federal scheme that generic manufacturers not urge medical professionals to infringe brand-name manufacturers' method-of-use patents." That is because patents play a critical role in incentivizing drug developers to undertake extraordinarily expensive clinical trials, fund additional research, and discover new cures.

The Hatch-Waxman Act requires a brand-name drug manufacturer requesting approval for a new drug to identify each patent for which a claim of infringement could reasonably be asserted. 21 U.S.C. § 355(b)(1)(A)(viii), (c)(2). FDA publishes that patent information in a database known as the Orange Book. *Caraco*, 566 U.S. at 405-406; 21 U.S.C. § 355(c)(2). The Orange Book lists both patents relevant here. Pet.App. 3a.

ANDA filers must separately "assure" FDA through formal certification that their products "will not infringe" any patents listed in the Orange Book for the reference drug. *Actavis*, 570 U.S. at 143. For example, ANDA applicants may submit a "paragraph IV" certification that a listed patent "is invalid or will not be infringed by the manufacture, use, or sale of the new drug for which the [ANDA] is submitted." 21 U.S.C. § 355(j)(2)(A)(vii)(IV). Through the paragraph IV pathway, brand and generic manufacturers can "resolv[e]" patent disputes in pre-launch litigation. *Actavis*, 570 U.S. at 143; see 35 U.S.C. § 271(e)(2). Paragraph IV litigation ordinarily yields no prospect of damages. 21 U.S.C. § 355(j)(5)(B)(iii). But it carries a default automatic stay of FDA approval for up to 30 months while litigation proceeds, *ibid.*, which delays the generic manufacturer's market entry.

Generic applicants also have other options. If FDA has approved a reference drug for multiple indications but only some of them are patented, then a generic applicant can file a "section viii statement." In doing so, the applicant pledges to market its generic drug *only* for methods of use not covered by Orange Book patents. 21 U.S.C. § 355(j)(2)(A)(viii). If a generic manufacturer pursues that option, it must propose a "skinny label" for its product that carves out patented methods of use. *Caraco*, 566 U.S. at 406. Filing a section viii statement can avoid the possibility of pre-launch litigation and the automatic 30-month stay of approval under paragraph IV. The generic applicant thereby enjoys a lucrative opportunity—the right to sell the same product as the branded drug with only a tiny fraction of the pioneer's upfront investment—in exchange for promising not to market the generic product for any patented uses. And because FDA lacks "expertise" and "authority" to assess patent infringement, it accepts at face value the generic's representations that its carve-out label omits parts corresponding to any patented use and that the generic will not market carved-out methods. 68 Fed. Reg. 36,676, 36,683 (June 18, 2003).

Although a generic label *generally* must match the reference drug's label, FDA regulations provide that a generic manufacturer using the section viii pathway will omit "an indication or other aspect of labeling protected by patent." 21 C.F.R. § 314.94(a)(8)(iv); see 21 U.S.C. § 355(j)(2)(A)(v). That includes clinical-study data, *e.g.*, *H. Lundbeck A/S* v. *Lupin Ltd.*, 87 F.4th 1361, 1371 (Fed. Cir. 2023), and details about how the body reacts to a particular drug, *e.g.*, Letter from Director Gary J. Buehler, FDA Office of Generic Drugs, to Applicant King Pharm. Inc., at 3 (Mar. 1, 2004).[1]

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[1] https://perma.cc/BH3T-BZJR.

2. Patent infringement

The Patent Act imposes direct liability on anyone that "makes, uses, offers to sell," "sells" or "imports" any "patented invention" in or into the United States. 35 U.S.C. § 271(a). The statute also imposes secondary liability for "actively induc[ing] infringement of a patent." 35 U.S.C. § 271(b). Inducement requires direct infringement by a third party. *Limelight Networks, Inc.* v. *Akamai Techs., Inc.*, 572 U.S. 915, 920-921 (2014). It also requires "active steps … taken to encourage direct infringement." *Metro-Goldwyn-Mayer Studios, Inc.* v. *Grokster, Ltd.*, 545 U.S. 913, 935-936 (2005) (citation omitted) (discussing copyright and patent infringement). The defendant must "inten[d] to bring about" the induced acts, *Commil USA, LLC* v. *Cisco Sys., Inc.*, 575 U.S. 632, 642 (2015), and "know[] that the induced acts constitute patent infringement," *Global-Tech Appliances, Inc.* v. *SEB S.A.*, 563 U.S. 754, 766 (2011). But direct communication with the direct infringer is not required; "advertising an infringing use" has been a quintessential form of active encouragement to infringe since common law. *Grokster*, 545 U.S. at 936.

As this case comes to this Court, it does not raise questions about specific intent or direct infringement. Petitioners did not contest below that the complaint adequately pleaded their specific intent to induce infringement of respondents' patents, or that healthcare providers directly infringe by prescribing petitioners' product for patented CV uses. Pet.App. 15a. The question presented concerns only whether respondents plausibly pleaded petitioners' "active steps … taken to encourage direct infringement." *Grokster*, 545 U.S. at 936.

B. The present controversy

This case involves petitioners' marketing of generic icosapent ethyl—the active ingredient in Vascepa, a pharmaceutical product that Amarin developed and markets in the United States. S.App. 14a.[2] Amarin's patented indication for Vascepa was one of the most significant developments in cardiovascular (or "CV") event prevention in "nearly three decades." JA25. It has been shown to reduce the risk of major adverse cardiovascular events—*e.g.*, heart attacks, strokes, and death—by up to 30% in patients most vulnerable to those outcomes. JA26-27.

1. Vascepa is a prescription drug for treating diseases related to triglycerides. Triglycerides are a necessary fat that circulates in blood, but at elevated levels they can cause serious health problems. High triglyceride levels manifest as two conditions presenting distinct medical risks:

- "Hypertriglyceridemia" refers to a blood triglyceride level above the acceptable level of 150 mg/dL. JA4. The main concern with hypertriglyceridemia is elevated danger of adverse cardiovascular events like stroke or cardiac arrest. *Ibid.*
- "Severe hypertriglyceridemia" (or SH) refers to a blood triglyceride level above 500 mg/dL. JA16. The very high triglyceride levels in an SH population result in a meaningfully different medical concern: pancreatitis. *Ibid.*

Most patients with elevated triglycerides suffer from "hypertriglyceridemia," not "severe hypertriglyceridemia." S.App. 29a; see JA58.

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[2] "S.App." refers to the operative complaint provided in the supplemental appendix accompanying the brief in opposition to the petition for a writ of certiorari.

2. Vascepa today has two FDA-approved indications.

The original SH Indication. FDA first approved Vascepa in 2012 as a treatment for *severe* hypertriglyceridemia that does not raise bad cholesterol levels. Pet.App. 2a-3a; S.App. 6a. FDA approved Vascepa for the SH indication based on Amarin's clinical trial involving patients with severe hypertriglyceridemia. S.App. 6a.

The revolutionary CV Indication. After receiving approval for that small set of severe-hypertriglyceridemia patients, Amarin continued to investigate other medical applications for Vascepa, particularly for the millions of adults suffering from the more-common hypertriglyceridemia. Pet.App. 3a. Amarin's development efforts required major financial investment, diligence, and perseverance in the face of setbacks. Amarin began with an initial clinical trial investigating whether Vascepa could treat elevated triglyceride levels (200-500 mg/dL) and control bad cholesterol levels. S.App. 6a-7a. Then, believing its innovative method of treatment had even more potential benefit for additional patients, Amarin performed a second study called the REDUCE-IT trial. That study was an enormous undertaking. It involved monitoring more than 8,000 hypertriglyceridemia patients taking statins. S.App. 7a; JA196. It took more than five years. *Ibid.* And it cost Amarin more than $300 million.[3]

Amarin's investments in the REDUCE-IT trial led to a landmark discovery: Using Vascepa as an adjunct to statin therapy dramatically reduces the risk of catastrophic cardiovascular events like heart attacks and strokes in patients with hypertriglyceridemia. JA51; see S.App. 8a, 16a. Physicians hailed Amarin's CV indication

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[3] Amarin 2020 Form 10-K at 6, https://www.sec.gov/Archives/edgar/data/897448/000156459021008382/amrn-10k_20201231.htm.

as "one-of-a-kind," "historic," "phenomenal," "game-changing," and a "life-saving accomplishment" that could benefit "millions of high-risk patients." JA24-25, 29, 51. As one expert put it, "[n]othing this significant has happened in the world of cardiovascular prevention since the introduction of statins nearly three decades ago." JA25.

Because the CV indication is so impactful, it also benefits "the overall healthcare system." JA28. One economic study found that the costs of Vascepa are "offset by cost savings from reducing the occurrence of high-cost major adverse cardiovascular events." *Ibid.*

Amarin's work built on years of research by respondent Mochida. In the 1990s, Mochida sponsored the world's first large-scale randomized controlled cardiovascular-outcomes trial of its icosapent ethyl product. S.App. 9a-10a. That trial showed the beneficial effect of Mochida's icosapent ethyl product in certain statin-treated, hypercholesterolemic, Japanese patients. *Ibid.*

Based on Amarin's successful clinical efforts, FDA approved Vascepa for the CV indication. Because that indication was such a "major milestone in cardiovascular prevention," healthcare providers "rapidly associated" Vascepa with this second approved (and patented) CV use. S.App. 18a. By 2020, over 90% of Vascepa's sales were for the CV indication. JA58.

Amarin and Mochida sought and obtained patents to protect their innovations. Relevant here are U.S. Patent Nos. 9,700,537 and 10,568,861. S.App. 2a, 10a-12a. Respondents have pleaded that using icosapent ethyl according to the CV indication would directly infringe those patents. S.App. 19a, 27a, 46a, 48a. Petitioners have not challenged the sufficiency of that allegation.

3. Petitioners sell generic icosapent ethyl. They filed an ANDA when Vascepa's FDA approval was limited to the SH indication (for patients with *severe* hypertriglyceridemia). While that ANDA was pending, FDA approved Vascepa's new CV indication and respondents identified the relevant patents in the Orange Book. S.App. 19a-20a.

Rather than challenge respondents' patents through a paragraph IV certification, petitioners submitted a section viii statement seeking approval *only* for the less-common SH indication. S.App. 26a-29a. Yet petitioners revised their proposed label to generally mirror Vascepa's updated label, including changes resulting from Vascepa's new CV indication. FDA approved petitioners' proposed carve-out label in 2020. Pet.App. 4a-5a. Petitioners thus received approval to sell their generic product based on their promise, as required by law, that they would market their drug exclusively for the unpatented indication. S.App. 21a, 26a-29a.

Petitioners broke that promise. Even before receiving FDA's approval, petitioners began promoting their product in ways intended to capture *all* sales and uses of Vascepa. For example, even though petitioners' indication was only for patients with SH, Hikma's website marketed petitioners' generic for "Hypertriglyceridemia"—a broader term that includes not just the SH indication but also the much more common (and patented) CV indication with which Vascepa had since become synonymous. Pet.App. 7a; S.App. 33a-34a.

Petitioners also issued press releases, picked up by news agencies around the country, related to their ANDA approval and launch of their product. Pet.App. 5a-6a, 30a-33a; see JA1-2, 39-41, 42-44, 45-47. Petitioners publicized their drug as the "generic version" of Vascepa, Vascepa's "generic equivalent," or "generic Vascepa." Pet.App. 5a-

6a; see S.App. 30a-33a; JA1-2, 39-40, 42-43. Those statements were legally problematic for this section viii product because they capitalized on Vascepa's commercial identity, which had just recently become synonymous with the CV indication. Petitioners' statements thus increased the likelihood of infringement in this particular context—even though similar references to other generic medicines in other contexts likely would not raise similar concerns.

Petitioners also said that Vascepa is indicated only "in part" for severe hypertriglyceridemia. Pet.App. 5a-6a; see S.App. 30a, 32a; JA39-40, 42-43. Petitioners announced "FDA approval" for their generic without explaining that their approval was limited to Vascepa's far-less-common indication. Pet.App. 6a; JA1-2. They boasted about Vascepa's value in treating hypertriglyceridemia by touting Vascepa's *entire* domestic sales. Petitioners made those statements knowing that Vascepa's sales overwhelmingly reflected the patented CV indication for which they had neither sought nor obtained approval. Pet.App. 6a-7a; S.App. 30a, 32a; JA39-40, 42-43.

While petitioners' label lists only the SH indication in its "Indications and Usage" section, Pet.App. 5a; JA114, it identifies information acutely relevant to patients eligible for the patented CV use. The label identifies potential side effects for people having cardiovascular disease or diabetes with a risk factor for cardiovascular disease. Pet.App. 5a; JA124-125. It also references Amarin's REDUCE-IT trial that established the CV indication. JA116.

4. Respondents filed suit against petitioners for inducing infringement of their CV-indication patents. S.App. 1a-62a. Respondents allege inducement not based solely on Hikma's label but rather on petitioners' full course of conduct, including their deliberate efforts to

market their product as "generic Vascepa" to steer sales away from Amarin's product and toward their own for a patented use. Pet.App. 7a-8a. The operative complaint details how petitioners intentionally induced infringement through their website and press releases. *Id.* at 9a. It alleges that petitioners—unlike any of the other FDA-approved manufacturers of generic icosapent ethyl—repeatedly communicated to healthcare providers that petitioners' generic should be used for the same indications as Vascepa—including the predominant and patented CV use. S.App. 31a-32a, 34a-38a; Pet.App. 9a.

Petitioners moved to dismiss, arguing that the complaint fails to allege active steps to induce infringement. The magistrate judge recommended denying that motion, but the district judge granted it. Pet.App. 10a-11a, 23a-24a. To facilitate an interlocutory appeal, the district court entered "final judgment" of dismissal under Federal Rule of Civil Procedure 54(b), which the court styled as a dismissal "with prejudice." JA63-65 (cleaned up).[4]

5. The Federal Circuit reversed, finding that the complaint plausibly alleges induced infringement. Pet. App. 1a-22a.

The court of appeals began "by noting what this case is not." Pet.App. 12a. This is "not a section viii case in which the patent owner's claims rest solely on allegations that the generic manufacturer's proposed label is 'not skinny enough.'" *Id.* at 13a. Instead, the court emphasized, the complaint presents "a run-of-the-mill" induced-infringement case grounded on "the *totality* of the allegations of inducement" as "a whole." *Ibid.*

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[4] The dismissal was interlocutory because other claims were pending against a defendant named Health Net, LLC. See JA63-64.

The court of appeals underscored that petitioners had conceded most of the elements of induced infringement: "[I]t is undisputed that Amarin's complaint sufficiently alleges (1) that health-care providers directly infringe the asserted patents by prescribing Hikma's generic icosapent ethyl product for the off-label CV indication, and (2) that Hikma had the requisite intent and knowledge to induce that infringement." Pet.App. 15a.

Then, "accepting all well-pleaded facts as true and drawing all reasonable inferences in Amarin's favor," the court of appeals held that the "complaint plausibly pleads" the remaining element of respondents' claim: that petitioners "'actively' induced healthcare providers' direct infringement." Pet.App. 13a, 15a-16a. The Federal Circuit identified several "active" steps that petitioners had plausibly taken based on their "label *in combination with* [their] public statements and marketing materials." *Id.* at 17a-18a. Among other things, physicians would plausibly understand petitioners' label to instruct infringing uses because it described "statin-treated patients with the same cardiovascular event history and lipid levels covered by" respondents' patents. *Id.* at 16a. The court of appeals also found it "plausible that a physician could read Hikma's press releases—touting sales figures attributable overwhelmingly to an infringing use, and calling Hikma's product the 'generic version' of a drug that is indicated 'in part' for the SH indication—as an instruction or encouragement to prescribe that drug for *any* of the approved uses" of icosapent ethyl. *Id.* at 19a-20a. And by broadly marketing their drug for "hypertriglyceridemia" (which includes the CV use), petitioners plausibly encouraged patented uses. *Ibid.*

The court of appeals found that petitioners are not entitled to dismissal because the well-pleaded allegations gave rise to a factual dispute: "what Hikma's label and public statements would communicate to patients and the marketplace," including prescribing physicians. Pet.App. 18a. And the court "reject[ed] Hikma's inflated characterizations" that denying their motion would "'effectively eviscerate section viii carve-outs.'" *Id.* at 21a (citation omitted). The court emphasized that generic manufacturers will "*not* be held liable for merely marketing and selling under a 'skinny' label omitting all patented indications, or for merely noting (without mentioning any infringing uses) that FDA had rated a product as therapeutically equivalent to a brand-name drug." *Ibid.* Nor would a generic be liable merely for referring to its product as a "generic version" of a name-brand drug. *Ibid.* Here, "Amarin has pleaded that Hikma did much more" to "induce[] infringement." *Ibid.*

The Federal Circuit denied rehearing. Pet.App. 41a.

6. The court of appeals issued its mandate in October 2024. Rather than move to stay the mandate, petitioners engaged in fact discovery. The parties have now exchanged millions of pages of documents and conducted more than a dozen depositions to date, including from "individuals acquainted with Hikma's pre-launch press releases and other promotional materials or sales forecasts associated with the launch of Hikma's product." D.Ct. Doc. 286 at 3. That fact discovery (stayed since the grant of certiorari) has revealed substantial additional evidence of petitioners' intentional induced infringement.

SUMMARY OF ARGUMENT

The court of appeals correctly determined that respondents plausibly alleged induced patent infringement.

A. Section 271(b) of the Patent Act creates liability for "actively induc[ing] infringement of a patent."

1. Respondents stated a plausible claim. Most elements of induced infringement are unchallenged: There is no dispute that the complaint sufficiently pleaded direct infringement when healthcare providers prescribed petitioners' product for respondents' patented treatment method. And petitioners have not contested (at this stage) that they "had the requisite intent and knowledge to induce." Pet.App. 15a. On the final element—that petitioners actively encouraged direct infringement—respondents alleged ample facts to make that claim plausible.

The complaint did not assert "passive" inducement. Petitioners engaged in a quintessential form of active encouragement: advertising. Petitioners' website and press releases, supported by their label, promoted a specific product (their generic drug) to a sophisticated audience (healthcare providers) for an overwhelmingly prevalent patented use (cardiovascular risk reduction).

With undisputed specific intent to infringe, petitioners crossed legal boundaries in their public communications. Their website wrongly advertised their product for the broader "Hypertriglyceridemia" therapeutic category, which healthcare providers would naturally understand to include Amarin's patented CV indication. Petitioners' press releases called their drug "generic Vascepa" without qualification and touted *all* of Vascepa's sales—which overwhelmingly derive from the patented use that physicians know best and prescribe most often. And petitioners' label contained unnecessary information that was relevant only to the predominant patented CV indication.

2. The counterarguments of petitioners and their amici, including the United States, lack merit. Petitioners misapply blackletter pleading standards by urging this Court to adopt the *defendants'* version of the alleged facts. They raise context-dependent factual disputes—such as whether their statements were "intended" for or "vague" to highly educated physicians who prescribe petitioners' drug—that cannot be resolved at the pleading stage. And they demand "particularized allegations" in patent cases, even though such a heightened pleading standard has no basis in any statute, rule, or precedent.

Petitioners' arguments distort patent law, too. They contend that courts cannot draw "inferences" about how a sophisticated doctor would understand petitioners' descriptions of their pharmaceutical product. But in patent law as in many other contexts, actionable statements may be implied or rely on predictable inferences. There is no "clear statement" or overt-ask requirement. Petitioners also insist that their encouragement did not necessarily account for *all* infringing activity. But just one instance of infringement establishes liability, for which damages "shall" be awarded. 35 U.S.C. § 284.

The government posits States' "generic-substitution" laws as an explanation for some (but not all) instances of direct infringement. Petitioners forfeited that argument, which respondents could and would have rebutted with additional factual allegations if petitioners had raised it below. Regardless, that assertion, even if accepted, *supports* the allegations of petitioners' intent and should have heightened petitioners' caution in their statements. Moreover, generic-substitution laws (even if applicable) could not explain *all* infringing sales, so the government's argument does not speak to whether respondents have stated a plausible claim at this stage.

B. Affirming the decision below would advance the policies underlying the Constitution, Patent Act, and Hatch-Waxman Act. Without meaningful intellectual-property protection, manufacturers would have few incentives to discover new uses for existing drugs. Drug development and clinical trials can cost billions of dollars and take decades. In enacting section viii, Congress affirmed that a generic manufacturer must pledge to forgo the market for a branded drug's patent-protected use.

Adopting petitioners' view would disturb Congress's carefully balanced incentive structure and risk stifling revolutionary and life-saving discoveries. And petitioners and their amici err in suggesting that affirming the decision below would nullify the skinny-label pathway or chill section viii filings. Their cited statistics refute that claim.

C. Because petitioners' merits arguments differ so meaningfully from those on which the petition was premised, this Court may wish to dismiss the writ of certiorari. The petition assured that this case required determining the legal standard for induced infringement; correcting "pre-*Twombly*" pleading standards; and deciding whether inducement is a question of law or fact. Petitioners have discarded those contentions and now openly seek (Br. 27-29) fact-bound error correction under a legal standard that they now agree with respondents is "not disputed."

Even if this Court concluded that the operative complaint did not meet the pleading threshold, respondents would be entitled to leave to amend. The Federal Rules direct courts to grant leave "freely." That principle applies with special force here because fact discovery has uncovered substantial evidence confirming petitioners' active inducement.

ARGUMENT

A. Respondents have stated a claim for induced patent infringement.

A complaint need only contain factual allegations that "state a claim to relief that is plausible on its face." *Bell Atlantic Corp.* v. *Twombly*, 550 U.S. 544, 570 (2007). Courts assume the truth of "well-pleaded factual allegations" and "reasonable inference[s]" therefrom. *NRA* v. *Vullo*, 602 U.S. 175, 181 (2024) (quoting *Ashcroft* v. *Iqbal*, 556 U.S. 662, 678-679 (2009)). Respondents' complaint exceeds that "relatively easy" standard. *Berk* v. *Choy*, 146 S. Ct. 546, 553 (2026).

1. The complaint plausibly alleges that petitioners took active steps to encourage infringement.

a. Section 271(b) imposes liability on anyone who "actively induces infringement of a patent." A plaintiff must show, by either direct or circumstantial evidence, (1) underlying direct infringement by one or more third parties, *Limelight Networks, Inc.* v. *Akamai Techs., Inc.*, 572 U.S. 915, 920-921 (2014); (2) the inducing party's specific intent to infringe, *Global-Tech Appliances, Inc.* v. *SEB S.A.*, 563 U.S. 754, 761 n.2, 766 (2011); and (3) "active steps … taken to encourage direct infringement," *Metro-Goldwyn-Mayer Studios, Inc.* v. *Grokster, Ltd.*, 545 U.S. 913, 936 (2005) (citation omitted). The settled rule since common law has been that "one who distributes [something] with the object of promoting its use to infringe …, as shown by clear expression or other affirmative steps taken to foster infringement, is liable for the resulting acts of infringement by third parties." *Id.* at 936-937 (citing several cases). A "single instance" of induced infringement sustains a claim for liability. *American Wood-Paper Co.* v. *Fibre Disintegrating Co.*, 90 U.S. 566, 600 (1874). The existence and scope of inducement "is a question of

fact." *Markman* v. *Westview Instruments, Inc.*, 517 U.S. 370, 384 (1996) (citation omitted).

Because petitioners have not disputed that respondents plausibly pleaded the first two elements of the claim—direct infringement and specific intent—this case concerns petitioners' active steps to encourage direct infringement. Pet.App. 15a. "[A]ctive steps" can include not only "instructing how to engage in an infringing use" but also "*advertising* an infringing use." *Grokster*, 545 U.S. at 936-937 (emphasis added). "The classic instance of inducement is by advertisement or solicitation that broadcasts a message designed to stimulate others to commit violations." *Id.* at 937. As the government recognizes (US.Br. 14), respondents need allege only a "plausible chain of events through which statements" made by petitioners could lead a healthcare provider—presumably a doctor or pharmacist—"to prescribe or dispense Hikma's drug to reduce [a] patient['s] cardiovascular risk."

b. Respondents have plausibly alleged that petitioners took active steps that at least one healthcare provider would have understood as encouragement to infringe by prescribing Hikma's generic product to a patient for the CV indication. Petitioners "advertis[ed]" a specific well-known infringing use for a specific product to a specific, highly educated and astute infringing audience. *Grokster*, 545 U.S. at 936-937.

It is more than plausible that prescribing healthcare providers would be interested in petitioners' generic drug precisely because of its potential for the broader (and patented) CV use, rather than the rarer SH use. JA58. Inducement is a "context"-driven analysis. *Grokster*, 545 U.S. at 940. Respondents allege that the relevant context here was the approval of Amarin's "game-chang[ing]" CV indication in 2019 that marked a "major milestone in car-

diovascular prevention." S.App. 8a, 18a. That context established an inextricable connection in the marketplace between Vascepa and its primary, patented CV indication. *Id.* at 30a, 32a. Petitioners "aim[ed] to satisfy a known source of demand" for that CV use. *Grokster*, 545 U.S. at 939; JA29-30. Amid the interest and acclaim surrounding Vascepa and Amarin's innovation, petitioners had every reason to make public statements "designed" to convey to physicians that the generic version could and should be prescribed for all the same uses as Vascepa. *Grokster*, 545 U.S. at 937-938.

That is just what petitioners did. Their website—unlike that of competing FDA-approved generic icosapent ethyl products—advertised their generic product as suited for "Hypertriglyceridemia" and AB-rated for that use. JA195; S.App. 30a, 33a-34a.[5] That statement was inaccurate. It "d[id] not match and [was] broader than" the Hikma product's narrow approval, and it undisputedly encompassed an infringing use. S.App. 33a-34a. It is certainly plausible that, to the medical audience used to reading technical language on pharmaceutical websites, petitioners' classification conveyed that their drug "offer[ed] the same … ability" as Vascepa "to the same people" who prescribed Vascepa to treat their CV patients. *Grokster*, 545 U.S. at 938; see Dennis Crouch, *The Tinderbox: Market Structure, Skinny Labels, and Induced Patent Infringement* at 8, Research Paper No. 2026-30, SSRN (Mar. 16, 2026) ("conduct takes on different significance depending on the market in which it occurs"). That is especially so because "doctors consider" generic manu-

[5] AB-rated "means the generic product is therapeutically equivalent to the brand product *under the conditions specified in the generic's label*." *GlaxoSmithKline LLC* v. *Teva Pharms. USA, Inc.*, 7 F.4th 1320, 1335 (Fed. Cir. 2021) (emphasis added).

facturers' public statements on websites and press releases to "'know when drugs are going generic'" and understand how those generics "should [be] prescribe[d]." *GlaxoSmithKline LLC* v. *Teva Pharms. USA, Inc.*, 7 F.4th 1320, 1336 (Fed. Cir. 2021) (recounting cardiovascular physician's trial testimony); see Pet.App. 19a-20a.[6]

Petitioners further encouraged infringement by issuing press releases trumpeting their drug as "generic Vascepa" and the "generic equivalent" of Vascepa without qualification. Pet.App. 5a-6a; S.App. 30a-33a. Those were headlines intended to capture the attention of a broad audience—not merely details buried in an investor report. In May 2020, petitioners broadcast approval of "generic Vascepa®" without mentioning that their approved use was limited to the far-lesser-known SH indication. JA1-2. Petitioners promoted that approval as "an important milestone towards bringing this product to market"—a reference that medical providers plausibly would have understood to invoke Amarin's recent medical breakthrough with Vascepa. *Ibid.* In another press release, petitioners announced they were "working closely" with FDA to obtain approval of their "generic version of Vascepa®." JA39-40. They again touted that the generic drug would provide "patients and healthcare providers" access to this "important medicine." *Ibid.* Petitioners named Vascepa and alluded to its well-known primary use, explaining that Vascepa was indicated only "in part" for the SH indication. JA40. And petitioners explained that "US sales of Vascepa® were approximately $919 mil-

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[6] Hikma later changed its website to specify "severe hypertriglyceridemia." D.Ct. Doc. 283-15 at 65:22-66:5. The current version omits the reference to being "AB" rated for "Hypertriglyceridemia" and inserts the text "Reference Name VASCEPA®." https://www.hikma.com/en-us/products/.

lion in the 12 months" prior—again, not limited to the unpatented use. *Ibid.*

A few months later, petitioners advertised "FDA approval for the product" and the imminent "launch" of "generic Vascepa®." JA42 (September 2020). Once more, petitioners "suggestively" referenced Vascepa's broader uses and across-the-board sales. See *Grokster*, 545 U.S. at 938. Petitioners again emphasized access to "healthcare providers," JA42, which plausibly signaled to prescribers how they might use petitioners' generic product.

When petitioners launched their generic drug in November 2020, they doubled down. Even though FDA's approval was limited to the indication accounting for a tiny (and lesser-known) fraction of prescriptions and actual use, petitioners boasted that they had "accelerated" their launch "to quickly provide patients with access to this important medicine." JA45. Petitioners further announced plans to "work[] to scale up manufacturing and increase availability as soon as possible." *Ibid.* Petitioners again stressed the launch's relevance to "healthcare providers" and Hikma's efforts to "put better health, within reach, every day for millions of people." *Ibid.* This time petitioners noted the approved SH indication, and finally mentioned that the generic drug was "*not* approved for any other indication for the reference listed drug." JA46 (emphasis added). But petitioners—unlike other manufacturers of generic icosapent ethyl—declined to specifically explain that their product was not approved for Amarin's predominant and patented CV use. Compare JA49, with Press Release, Dr. Reddy's Labs., *Dr. Reddy's Laboratories announces the launch of Icosapent Ethyl Capsules* (June 22, 2021).[7]

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[7] https://myday-portauth.mydrreddys.com/media/998767/press-release-icosapent-ethyl.pdf.

Respondents adequately allege that at least some healthcare providers would have understood the totality of petitioners' active public statements as encouragement to prescribe petitioners' product for infringing uses. See *NRA*, 602 U.S. at 195 (courts consider communications "against the backdrop of other allegations in the complaint"); *Grokster*, 545 U.S. at 933 (considering fact that "90% of works available" on product's download network were copyrighted). Petitioners made those statements knowing that Vascepa's commercial success and identity were driven primarily by its patented CV indication. S.App. 7a, 18a; JA58. That indication was a "game changer," S.App. 8a, and to physicians the CV use was all but synonymous with Vascepa. Doctors knew of Vascepa's highly publicized clinical breakthrough from the REDUCE-IT trial, and of the "milestone" approval. Hikma itself argued in prior litigation, based on the REDUCE-IT trial and related materials, that the SH limitation was not commercially successful and the "vast majority" of prescriptions were for the CV indication. *Id.* at 29a-30a. The timing mattered too: Petitioners issued their statements throughout 2020, shortly after Vascepa had been approved for the CV indication in 2019 and was receiving widespread acclaim. *Id.* at 31a-33a. And petitioners continued to maintain those press releases on Hikma's website, though they eventually scrubbed a few from one launch page. *Ibid.*

Petitioners' labeling reinforced their efforts to encourage use of their product for the CV indication. While the label omitted the CV indication from the "indications and usage" section, compare JA114 (petitioners' drug) with JA78 (Vascepa), petitioners left in place multiple statements primarily relevant to physicians treating statin-taking CV patients. S.App. 27a-29a, 34a-38a. For example, petitioners retained details on the drug's interactions with

statins and the selection of treatment groups in clinical studies with relevant triglyceride levels and CV risk, and they noted that the medication is sometimes prescribed for uses other than the indicated purposes. *Ibid.* At a previous trial, petitioners' expert opined that some of that language "specifically tells" patients that physicians may prescribe the medication for off-label use, *id.* at 36a-37a—precisely what a section viii statement must forswear. Petitioners also omitted from their label a "limitation of use" previously included when the drug was approved only for the SH indication that would have made clear FDA had not evaluated the effects of Hikma's generic product on cardiovascular risk or approved it for that use. *Id.* at 28a-29a.

None of that was "integral" to the Hatch-Waxman scheme. Contra US.Br. 20, 30. Petitioners were free to propose a label omitting information about unapproved uses or that included the limitation of use. See 21 U.S.C. § 355(j)(2)(A)(v); 21 C.F.R. § 314.94(a)(8)(iv).

Petitioners' statements are materially similar to the kinds of "inducing message[s]" that this Court has held would support a plausible claim. See *Grokster*, 545 U.S. at 937-940 (applying similar principles under the Copyright Act). In *Grokster*, this Court recognized that "[t]he classic instance of inducement is by advertisement or solicitation that broadcasts a message designed to stimulate others to commit violations." *Id.* at 937; see *id.* at 935. The defendants there were distributors of file-sharing software that made advertisements available to users of "Napster"—a "notorious file-sharing service"—that "readily" could "have been understood in the Napster market" as "offer[ing] software to perform the same services." *Id.* at 937-938. The defendants also invited users to download the defendants' programs and "suggestively named" their

product to underscore its similarities with known infringing uses. *Ibid.* This Court further emphasized the well-established principles "at common law" that a defendant could be secondarily liable for patent infringement by "advertis[ing]" a product's "most conspicuous use." *Id.* at 935 (quoting *Henry* v. *A.B. Dick Co.*, 224 U.S. 1, 48-49 (1912)); accord *Kalem Co.* v. *Harper Bros.*, 222 U.S. 55, 62-63 (1911) (cited approvingly in *Grokster*); *Thomson-Houston Elec. Co.* v. *Kelsey Elec. Ry. Specialty Co.*, 75 F. 1005, 1008 (2d Cir. 1896) (same).

Here too it is plausible that prescribing physicians consulted Hikma's website and other public statements about petitioners' generic drug—just as physicians have done in other cases. See *GlaxoSmithKline*, 7 F.4th at 1336-1337. Those doctors (and respondents' patented use) are a "known source of demand" for—and the most conspicuous driver of petitioners' revenue from—this icosapent ethyl product. *Grokster*, 545 U.S. at 939-940. And the patented CV indication is far-and-away the "'most conspicuous use.'" *Id.* at 935.

As the decision below correctly recognized, respondents' allegations, coupled with petitioners' undisputed specific intent, amply "allo[w] the court to draw the reasonable inference that the defendant[s] [are] liable for the misconduct alleged." *Iqbal*, 556 U.S. at 678.

2. The counterarguments offered by petitioners and the United States lack merit.

a. Petitioners' arguments rest on misapplying the pleading standard in multiple respects.

Petitioners' defenses share a fundamental defect: they assume the defendants' version of facts and draw inferences against the plaintiffs. That is not how to properly assess a pleading. *NRA*, 602 U.S. at 194-195; *Iqbal*, 556 U.S. at 678-679; *Twombly*, 550 U.S. at 570.

1. Petitioners first dispute (Br. 32-33, 35, 37) whether their public statements were "active steps" to induce infringement.

Petitioners argue that they "intended" the press releases and website for investors, wholesalers, and pharmacies. That argument contradicts the well-pleaded allegations. Petitioners' statements were not only public, but intentionally "communicate[d] to … healthcare providers and patients." S.App. 31a, 33a; see *id.* at 34a-38a. Petitioners conceded below that those public statements reflected their "requisite intent" to induce direct infringement by "healthcare providers." Pet.App. 15a.[8]

Even if petitioners "directed" some of their words to "potential investors," US.Br. 28, respondents plausibly allege (S.App. 31a-34a, 37a) that physicians in fact consult those types of statements when assessing a generic drug's availability and uses, see *GlaxoSmithKline*, 7 F.4th at 1336-1337. Indeed, FDA commonly issues letters to drug manufacturers warning that investor-facing press releases and websites may mislead the "general public," *e.g.*, FDA Div. of Pharm. Quality Operations, *Warning Letter to Honest Globe, Inc.* (Mar. 15, 2021),[9] and can constitute unlawful "advertising or promotion" of a drug, *e.g.*, FDA, *Warning Letter to MaxLife Technologies Inc.* (Feb. 20,

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[8] The government errs in suggesting (US.Br. 23, 25) that petitioners issued their public statements without the "'object of promoting'" infringing results, or that Hikma's specific intent was limited to "want[ing] its product to be used as widely as possible." The Federal Circuit found it "undisputed" that petitioners "had the requisite intent and knowledge to induce [direct] infringement." Pet.App. 15a. In making that finding, the court explicitly referenced petitioners' "'press releases.'" *Ibid.*

[9] https://www.fda.gov/inspections-compliance-enforcement-and-criminal-investigations/warning-letters/honest-globe-inc-597177-03152021.

2026);[10] FDA Office of Prescription Drug Promotion, *Letter to PharmaTher Inc.* (Sept. 30, 2025).[11] Petitioners cannot evade liability for their public statements that plausibly "advertis[ed] an infringing use" simply by arguing that their advertising was intended *primarily* for investors rather than doctors. *Grokster*, 545 U.S. at 935-936.

Similarly mistaken is petitioners' contention (Br. 32-37) that their public statements must be construed literally and in their favor. For example, petitioners insist (Br. 32-35) that they did not encourage infringement because only the skinny label "instructs doctors and patients on how to use Hikma's generic," whereas petitioners' website makes "no mention of Vascepa, SH use, CV use, or statins" and the press releases "contain no information on how to use" the drug. That assertion is not fully accurate: petitioners' product listing now lists "Vascepa" as a reference drug. See p. 23 n.6, *supra*. Regardless, this Court recently explained why a similar argument fails at the pleading stage: petitioners "could only reach th[eir asserted] conclusion by taking the allegations in isolation and failing to draw reasonable inferences in [respondents'] favor in violation of this Court's precedents." *NRA*, 602 U.S. at 194-195. Petitioners' blinkered approach to the pleadings is especially inapt because inducement can involve either instructions *or* "advertising." *Grokster*, 545 U.S. at 935-936. Physicians, moreover, look to sources beyond the label when deciding what uses to prescribe. *GlaxoSmithKline*, 7 F.4th at 1336 (recounting physician's testimony about "the impact of the press releases on doctors," and that "doctors consider press releases so they

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[10] https://www.fda.gov/inspections-compliance-enforcement-and-criminal-investigations/warning-letters/maxlife-technologies-inc-dba-maxlife-721453-02202026.

[11] https://www.fda.gov/media/189734/download?attachment.

'know when drugs are going generic'"); see S.App. 31a-34a, 37a.

Petitioners again seek to predetermine fact questions by declaring (Br. 36-38) that any reference to Vascepa's sales information and therapeutic category "does not encourage" anything, that petitioners' website merely "informs … customers that [their] product is available for purchase," or that their statements were "vague." What matters at the pleading stage is whether petitioners' "communications" could be "*reasonably* understood" to encourage infringement. *NRA*, 602 U.S. at 193 (emphasis added). Precisely because statements need not be "explicit" to support a plausible inference, *ibid.*, disputes over how particular statements "should be understood" cannot typically be resolved on a motion to dismiss, *id.* at 195; see *GlaxoSmithKline*, 7 F.4th at 1336-1337.

Cardiovascular physicians are sophisticated actors who would understand that petitioners' public statements encouraged the patented CV indication because (1) petitioners affirmatively identified their generic product for the broader "Hypertriglyceridemia" category; (2) Vascepa was the only possible reference drug; and (3) Vascepa has only two approved uses, with prescriptions predominated by the exceedingly well-known and patented CV use. See pp. 10-12, *supra.* That highly trained audience would plausibly understand that this meant petitioners' generic could be used broadly to treat the therapeutic category "Hypertriglyceridemia," which includes the predominant CV indication. See *Grokster*, 545 U.S. at 939.

2. Petitioners next mischaracterize (Br. 27-28, 38-41) respondents' complaint as relying on a theory of "passive" inducement. That ignores the factual allegations, the impact of petitioners' public statements on an expert audience, and petitioners' undisputed mental state. There

is nothing "passive" about publicly touting $919 million in sales, the vast bulk of which petitioners knew were tied to a patented use, while simultaneously and intentionally advertising a generic as "equivalent" for a broad therapeutic category that encompasses that very use. Inducement does not require overt instructions to infringe; it requires affirmative steps to foster infringement. *Grokster*, 545 U.S. at 936-937.

Petitioners further contend (Br. 29) that a defendant must induce performance of every step of the patented method. But petitioners' statements achieved just that. Vascepa has only two known uses. The CV indication necessarily practices even the most specific claims of respondents' patents because it describes patients already on statin therapy—an allegation that petitioners do not (and cannot) dispute. See pp. 10-12, 15, *supra*; Pet.App. 8a-9a, 15a. That use of Vascepa is well-known to healthcare providers. S.App. 18a; JA58. "Against this backdrop," *NRA*, 602 U.S. at 192, physicians would plausibly "understand[]" petitioners' communications, *Grokster*, 545 U.S. at 938, as encouraging them to prescribe what petitioners called "generic Vascepa" for Vascepa's overwhelmingly prevalent and effective indication.[12]

3. Straying even further from bedrock pleading standards, petitioners demand that this Court credit their post-hoc explanations for their statements. For example, petitioners contend that some of their communications

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[12] Despite implying (Br. 23-28) that inducement requires specifically instructing each limitation of a patent claim, petitioners eventually renounce that argument (Br. 29). For good reason: Nothing in Section 271(b) or this Court's precedents suggests that actionable advertisement or encouragement must recite patent steps. In *Grokster*, this Court did not even require inducing statements to describe the protected work. 545 U.S. at 937-938.

have "logical explanations," were "anodyne," or had a "disclaimer" consistent with their factual defense. Pet.Br. 35-37; see U.S. Br. 20, 30. Those arguments repeat the errors this Court recently rejected in *NRA*: Even if discovery "might show … that certain actions should be understood differently," "[a]t this stage … the Court must assume the well-pleaded factual allegations in the complaint are true." 602 U.S. at 195. Whether doctors would have noticed petitioners' website "disclaimer"—buried in tiny font that appears to flout FDA's placement and legibility guidelines—is a fact issue that cannot be resolved in petitioners' favor on the pleadings. Pet.App. 18a-19a; see FDA, *Guidance for Industry Presenting Risk Information in Prescription Drug and Medical Device Promotion* (May 2009).[13] The relevant question is whether petitioners' statements have a plausible *unlawful* explanation. *NRA*, 602 U.S. at 195. They do.

Petitioners also assert (Br. 35-36, 41, 43) that their references to "generic Vascepa" and "AB-rat[ing]" were "accurate[]" and "consistent with Hatch-Waxman's statutory scheme." But their communications were *not* all accurate: Petitioners' icosapent product is not a full "generic equivalent" or "generic Vascepa" because FDA evaluated and approved it *only* for the labeled SH indication; FDA did not evaluate its therapeutic equivalence for the CV use. See pp. 12, 22, *supra*; 21 C.F.R. § 314.3(b) (limiting therapeutic equivalence to "the conditions specified in the labeling"). "AB-rating means the generic product is therapeutically equivalent to the brand product" *only* "under the conditions specified in the generic's label." *GlaxoSmithKline*, 7 F.4th at 1335. The two products are not legally equivalent either: FDA approved petitioners' drug only for SH, and using petitioners' product for the CV

[13] https://www.fda.gov/media/76269/download.

indication infringes. Even the government agrees (US.Br. 28) that some of Hikma's statements were "not necessary to the operation of the Hatch-Waxman scheme."

Petitioners cannot defend their press releases (Br. 36) based on a purported "'industry practice'" of referring to a branded drug's "'generic versions.'" Referencing "generic Vascepa" *in the section viii context* is not like referencing "generic Tylenol" or other unpatented products. The whole point of the section viii compromise is to enable a generic manufacturer to market its drug for only *some* of the branded product's uses, but not for others. In exchange, the generic may promptly enter the market by avoiding pre-launch litigation and an automatic stay. Petitioners could easily and accurately call their product "generic icosapent ethyl" without invoking Amarin's well-known brand, just as Vascepa's other generic competitors do. Respondents are not aware of any other manufacturer of a generic icosapent product claiming to sell "generic Vascepa." See pp. 13-14, 24, *supra*.

4. Because petitioners cannot overcome the complaint under settled pleading rules, they resort to a heightened standard that has no application here.

Petitioners contend that induced-infringement plaintiffs must plead "'particularized allegations'" of a chain of events explaining how the defendant caused direct infringement. Pet.Br. 27, 39-41; see US.Br. 15, 23, 29. The Patent Act says no such thing. 35 U.S.C. § 271(b). When Congress imposes a "particularity" requirement, it does so expressly. *E.g.*, 15 U.S.C. § 78u-4(b); *Chadbourne & Parke LLP* v. *Troice*, 571 U.S. 377, 383 (2014). Likewise the Federal Rules of Civil Procedure do not single out patent-inducement claims for "special treatment" beyond Rule 8's "'short and plain statement'" requirement. *Berk*, 146 S. Ct. at 553. The rules "impose a particularity re-

quirement" only in "specific instances," such as "'averments of fraud or mistake.'" *Leatherman* v. *Tarrant County Narcotics Intel. & Coordination Unit*, 507 U.S. 163, 168 (1993) (quoting Fed. R. Civ. P. 9(b)).

This Court has "consistently rejected such efforts" to "require more information" in pleadings or "added specificity" not expressly demanded by statute or rule. *Berk*, 146 S. Ct. at 553; see, *e.g.*, *Leatherman*, 507 U.S. 163 (Section 1983); *Swierkiewicz* v. *Sorema N.A.*, 534 U.S. 506 (2002); *Jones* v. *Bock*, 549 U.S. 199 (2007). It should reject petitioners' effort here too.

Nor is there merit to the government's arguments (US.Br. 15, 17, 20-22, 28-30) that a complaint must establish a "meaningful likelihood" of causing infringement, or that courts should decide which facts are "likely," "unlikely," "necessarily," or "usually" true on a motion to dismiss. The standard is *plausibility*. A complaint "may proceed even if it strikes a savvy judge that actual proof of the facts alleged is improbable." *Berk*, 146 S. Ct. at 553 (quoting *Twombly*, 550 U.S. at 556); see also *Iqbal*, 556 U.S. at 678.

Petitioners (Br. 30-31) and the government (US.Br. 24) argue that respondents' allegations resemble those rejected in *Twombly* and *Iqbal*. Those cases involved very different pleading problems absent here: Both complaints failed to identify any conduct that had actually occurred with an actionable mental state. The core allegations in *Twombly* comprised a mere "conclusion" that an unlawful (but "unidentified") agreement existed. 550 U.S. at 555-557. And *Iqbal* involved the plaintiffs' bare assertion that the government harbored discriminatory intent. 556 U.S. at 669, 681. In each case, the plaintiffs urged the Court to infer misconduct from generalized background patterns. Here, by sharp contrast, respondents do not simply allege

that some unspecified inducing act occurred based on broad market trends. The complaint identifies discrete statements to a specific audience for a particular purpose with an (undisputed) mental state giving rise to liability.

Petitioners' position is profoundly mistaken precisely because this case involves the pleading standard governing almost all civil actions in federal court—not just patent cases. As multiple neutral amici emphasize (IPO. Br. 7-10; NYIPLA.Br. 4-10; LES.Br. 7-10), there is no special pleading standard for induced patent infringement under the Hatch-Waxman Act. Petitioners' theory thus threatens to undermine the flexible and fact-intensive approach to pleading that the law requires.

b. Petitioners misstate settled patent law.

Adopting petitioners' and the government's arguments would distort patent law in at least two ways: they would (1) foreclose induced infringement claims unless the defendant used explicit, smoking-gun language; and (2) demand that inducement be the primary or exclusive cause of direct infringement. Neither proposition has any basis in law or logic.

1. Petitioners contend (Br. 38) that courts should reject inducement claims whenever the direct infringer must "*infer*[]" the speaker's instructions or encouragement. That makes no sense, particularly because petitioners' specific intent behind their statements is undisputed. Pet.App. 15a. A speaker need not be "explicit" so long as the intended message is understood. *NRA*, 602 U.S. at 193. That is how people communicate.

This Court has held that "suggestive[]" references can be actionable for inducing infringement. *Grokster*, 545 U.S. at 938. That unremarkable principle is not unique to patent cases. Multiple other areas of law recognize that statements need not be express to convey meaning or give

rise to liability. A statement can plausibly be "seen as a threat or an inducement" in violation of the First Amendment even when it is *not* "'explicit.'" *NRA*, 602 U.S. at 177, 193; see *Elonis* v. *United States*, 575 U.S. 723, 740 (2015) (criminal liability may attach based on "purpose" or "knowledge that [a] communication will be viewed as a threat"). An "implied statement" can be a tortious misrepresentation when paired with an omission that would have "rebut[ted] the recipient's predictable inference." *Omnicare, Inc.* v. *Laborers Dist. Council Constr. Indus. Pension Fund*, 575 U.S. 175, 191 (2015). And a statement "imply[ing] a false assertion of fact" can defame. *Milkovich* v. *Lorain Journal Co.*, 497 U.S. 1, 3-4, 18-19 (1990). This Court should decline petitioners' invitation to devise a unique clear-statement rule for induced infringement that would weaken the property rights of every patent holder in the country.

The government wrongly asserts (US.Br. 22) that "active" steps to induce require "an explicit instruction or exhortation." In fact, instructions are not required at all. "'[A]ctive'" inducement can include "advertising an infringing use" or "broadcast[ing] a message designed to stimulate others to commit violations." *Grokster*, 545 U.S. at 936-937. The inducing acts in *Grokster* included general and "suggestive[]" advertisements about software, even though the software itself was not inherently infringing and its intended use was implied. *Id.* at 937-938; see *NRA*, 602 U.S. at 193. That is what petitioners plausibly achieved with their statements here.

2. Petitioners argue (Br. 41) that the presence of other possible causes of direct infringement (like "independent judgment") renders inducement implausible. The government likewise implies (US.Br. 24-25) that actions cannot induce infringement if the direct infringement "of-

ten" has other potential contributing causes, or if active encouragement does not "increase the frequency" of direct infringement. But those arguments all confirm petitioners' knowledge of the likelihood of direct infringement in this context, and the corresponding need for caution not to induce that infringement. These arguments, moreover, implicate the potential *breadth* of petitioners' encouragement—not its existence. To plead liability, respondents need not allege that petitioners' inducement caused *all* instances of direct infringement. For centuries, this Court has correctly recognized that a "single instance" suffices. *American Wood-Paper*, 90 U.S. at 600.

c. Petitioners may not invoke new, forfeited arguments.

In this Court petitioners embrace (Br. 40-41) the government's new theory (US.Br. 25, 29, 33) that States' generic-substitution laws might explain some (but not all) instances of direct infringement. By their telling, an unknown number of pharmacies could have automatically substituted generics and therefore may have been unmoved by petitioners' encouragement.

This Court need not even consider that theory because petitioners did not fairly raise it. This is a "court of review, not of first view," *Cutter* v. *Wilkinson*, 544 U.S. 709, 718 n.7 (2005), that typically "will not entertain arguments not made below," *OBB Personenverkehr AG* v. *Sachs*, 577 U.S. 27, 38 (2015); see *City & County of San Francisco* v. *Sheehan*, 575 U.S. 600, 609 (2015). Because the government first unveiled its generic-substitution argument at the certiorari stage, respondents had no opportunity to allege the additional facts they could and would use to show that generic-substitution laws did not preclude significant infringement. This Court should not hold respondents' *fact pleading* deficient based on an argument

introduced by an amicus at the eleventh hour. See, *e.g.*, *FTC* v. *Phoebe Putney Health Sys., Inc.*, 568 U.S. 216, 226 n.4 (2013) (declining to "consider" an amicus argument "not raised by the parties or passed on by the lower courts"). Rather, it should be "up to the lower courts to decide whether to consider the Government's proposals." *Dewberry Grp., Inc.* v. *Dewberry Eng'rs Inc.*, 604 U.S. 321, 330 (2025).

Regardless, generic-substitution laws (even if applicable) could not explain *all* infringing sales, so the government's argument does not speak to whether any act of induced infringement plausibly occurred. Substitution is neither universal nor automatic. In certain cases, a patient will be dispensed a generic only if a physician says so. See, *e.g.*, Amirala S. Pasha, *Generic Substitution Laws and Combination Products*, 78 Food & Drug L.J. 215, 221 (2023). Some States, like Oklahoma, make it unlawful to substitute a generic without authority of the physician or purchaser. Okla. Stat. tit. 59, § 353.24(B)(4). Still other States, like Florida, permit substitution only for drugs on particular formularies. Fla. Stat. § 465.025(2)(b), (5); see Jesse C. Vivian, *Generic-Substitution Laws*, 33 U.S. Pharmacist 30, 30-34 (2008).

The government itself concedes that not every State requires substitution, and that all States preserve physicians' authority to override default generic-substitution rules by "directing that a prescription" be "dispensed exactly as written." US.Br. 7-9. If it is plausible that at least one act of direct infringement was influenced by petitioners' actions, then even under the government's framing the complaint states a claim for relief.

B. Affirming the decision below would advance the policies underlying the Constitution, the Patent Act, and the Hatch-Waxman Act.

The decision below vindicates the Framers' purpose to "promote the Progress of Science," U.S. Const. art. I, § 8, cl. 8, and the careful balance that Congress struck across multiple statutes.

1. Holding generic manufacturers liable for their induced infringement is essential to a properly functioning section viii pathway. Congress deliberately permitted generics pursuing that pathway to market "only" "*unpatented* methods of use." *Caraco*, 566 U.S. at 419 (emphasis added); see *id.* at 415. As the government acknowledges, Congress "determin[ed]" that "some measure" of patent infringement would be "acceptable" only "so long as generic manufacturers do not encourage infringing uses of their drugs." US.Br. 32. It is therefore "important to the federal scheme that generic manufacturers not urge medical professionals to infringe." *Ibid.* That is precisely what respondents plausibly allege here.

Congress's approach makes good sense. There are minimal incentives to discover new uses for a drug after the first FDA-approved use. Drug development and clinical trials can cost billions. See Joseph A. DiMasi, *Innovation in the Pharmaceutical Industry: New Estimates of R&D Costs*, 47 J. Health Econ. 20, 20 (2016) (estimating "a total pre-approval cost estimate of $2558 million (2013 dollars)"). Amarin's and Mochida's life-saving breakthroughs followed years of research and multiple clinical trials. S.App. 6a-9a; JA29. The REDUCE-IT trial alone required more than $300 million and exceeded five years of study involving 8,179 patients across 11 countries. See pp. 10-11, *supra*. Yet many new-use investments may prove unrecoverable because "[p]atent protection on

drugs typically begins and ends too early to permit firms to capture the full value of subsequently developed information about drug effects." Rebecca S. Eisenberg, *The Problem of New Uses*, 2 Yale J. Health Pol'y L. & Ethics 717, 720 (2005). As the government emphasizes (US.Br. 31), "the availability of method-of-use patents"—and the ability to sue for induced infringement—"provide[ ] an important incentive for continued research to identify additional therapeutic uses of established drugs." That is especially true when, as here, continued research identifies a far more impactful and life-saving treatment than the initially approved use.

2. Petitioners' various policy arguments lack merit.

Petitioners contend that the Federal Circuit "nullif[ied]" or "'vitiate[d]' section viii" and the skinny-label process. Pet.Br. 41-46; see US.Br. 31-33; Waxman.Br. 13-16. That is irreconcilable with the decision below. The court was unequivocal: "[T]his is *not* a section viii case" where the plaintiff contends merely that a generic label "is 'not skinny enough.'" Pet.App. 13a (emphasis added). Respondents instead pleaded "much more": "the allegations of the complaint transform this case from a pre-approval, label-only induced infringement claim to one where the alleged infringement is based on the generic manufacturers' skinny label *as well as* its public statements and marketing of its already-approved generic product." *Ibid.* (emphasis added).

Petitioners (Br. 12-13) and their amici (AAM.Br. 12; Waxman.Br. 9-10; Public.Citizen.Br. 10-11) incorrectly contend that generic manufacturers lack control over the content of their label carve-outs. FDA regulations recognize that generic labels properly omit *any* "aspect of labeling" implicating a patent, including "indication[s]." 21 C.F.R. § 314.94(a)(8)(iv); see *H. Lundbeck A/S* v. *Lupin*

Ltd., 87 F.4th 1361, 1371 (Fed. Cir. 2023) (omitting clinical data); Buehler Letter, *supra*, at 3 (granting proposal to omit patented method of use). And they may seek "to force" FDA to "correct[]" its "inaccurate[] descri[ptions]" of "the brand's patent." *Caraco*, 566 U.S. at 404.

Every other generic icosapent ethyl drug remains on the market with the same label—and respondents have not sued them. Pet.Br. 13 n.6.[14] Those generics have been careful in accurately describing their products as generic "Icosapent Ethyl" and noting repeatedly—and upfront—that they are not approved for Amarin's CV indication. See *ibid.*; pp. 13-14, 33, *supra*. Petitioners cite no support or law or logic for their premise that a section viii carve-out should provide a safe harbor protecting a generic that *also* markets its drug for the carved-out use. Although section viii carve-outs may allow generics to avoid pre-launch litigation under 35 U.S.C. § 271(e)(2)(A), they do not shield against conventional inducement allegations under Section 271(b)—particularly when those allegations include the generic's intentional promotion of patented uses.

Petitioners and their amici seriously err in stating that a "recent study confirms that the decision below" and the Federal Circuit's 2021 decision in *GlaxoSmithKline*, 7 F.4th 1320, "have had a chilling effect on section viii filings." Pet.Br. 45-46; see 76.Scholars.Br. 27; US.Br. 31. Instead, that study shows that the rate of section viii filings by eligible generics has remained the same: Both before and after *GlaxoSmithKline*, 43% of all generic

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[14] FDA maintains a database of approved brand and generic drugs, https://www.accessdata.fda.gov/scripts/cder/daf/index.cfm, and the National Institutes of Health maintains a database of labels, https://dailymed.nlm.nih.gov/dailymed/index.cfm. As of March 2026, ten other ANDAs are approved for icosapent ethyl.

drugs eligible for section viii pursued that path. Therese J. Ziaks, *Frequency of First Generic Drugs Approved Through "Skinny Labeling," 2021 to 2023*, 31 J. Managed Care & Specialty Pharm. 343, 343 (2025); see Bryan S. Walsh, *Frequency of First Generic Drug Approvals with "Skinny Labels" in the United States*, 181 J. Am. Med. Ass'n Int'l Med. 995, 995 (2021).

Petitioners (Br. 46) and their amici (76.Scholars.Br. 27) assert that the number of section viii approvals "fell" to 20% in 2023. That is misleading. In 2023, only five new generics were susceptible to skinny labeling. Ziaks, *supra*, at 347. For context: FDA approves around 1,000 generics a year. See, *e.g.*, FDA, *Office of Generic Drugs 2023 Annual Report* 6 (Feb. 2024).[15] It approves around 100 *first* generics a year. *Ibid.* Of those, only around 10 are susceptible to skinny labeling. Ziaks, *supra*, at 346. Because so few new generics are even eligible for skinny labeling, the number that pursue skinny labeling changes year-to-year, even as the overall fraction remains stable over time. Before *GlaxoSmithKline*, the percent was 26% (2015) and 25% (2017). Walsh, *supra*, at 996. A similar number in 2023 thus shows no chilling effect.

The same data undermine petitioners' other policy arguments. For example, the section viii pathway has little effect on the availability of new generic drugs on the market. From 2021 to 2023, FDA approved new generics of 290 drugs; of those, only 21 were even eligible for skinny labeling under section viii—seven drugs a year. Ziaks, *supra*, at 345-346.[16] The cited data also show no

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[15] https://www.fda.gov/media/176440/download?attachment.

[16] Amici imply (76.Scholars.Br. 27) that skinny labels play an outsize role in public access to generic medications by claiming that "the number of drugs approved using the skinny-label pathway was

meaningful difference between skinny-label and non-skinny-label generics in time to market entry after initial brand approval (~10 years). *Id.* at 345. Permitting respondents to litigate their claims against the sole bad actor among a half-dozen makers of generic icosapent ethyl will have no effect on section viii filings—or on the public's access to generic drugs.

Petitioners (Br. 42-43) and their amici (AAM.Br. 18-19; Public.Citizen.Br. 11-17; 76.Scholars.Br. 16-19) insist that the decision below imperils the ability of generics and others to make equivalence statements or call their products a "generic version." But other generic manufacturers with identical products using the same carve-out label have shown that they know how to issue tailored press releases and marketing statements that avoid the encouragement that petitioners employed here. Respondents did not argue, and the Federal Circuit expressly did not hold, that merely saying "generic version" triggers a claim for induced infringement. Pet.App. 21a. Instead, the court relied on a constellation of well-pleaded facts: website marketing for "Hypertriglyceridemia," not SH; press releases referring to generic equivalence in various ways; advertising that the equivalent drug has multiple indications; and touting sales figures for the more-common patented use—all in the context of a drug for which the only approved additional use was the game-changing, famous, patented one. *Ibid.*; see *id.* at 8a, 18a-20a.

Petitioners assert (Br. 45-46) that "the decision below will delay generic market entry and increase drug prices." That is unsupported and illogical. Any deterrence is an

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roughly 40 to 50%" before *GlaxoSmithKline*. But it is *not* true that 40-50% of *all* generic drugs used the skinny-label pathway. Rather, 43% of first generic approvals *susceptible to skinny labeling* did so. Ziaks, *supra*, at 346. That equals five or fewer drugs a year.

economic consideration that depends on liability and the remedy under the facts of a particular case. The decision below addressed neither. The economic policy underlying the federal drug and patent laws, moreover, is "for Congress, not the courts." *Georgia* v. *Public.Resource.Org, Inc.*, 590 U.S. 255, 272 (2020) (citation omitted). And respondents are not seeking to block generic entry; they brought suit against the *only* manufacturer that actively and intentionally encouraged infringing uses. Respondents must still prove their lost profits when they prevail on the merits.

Petitioners (Br. 45-46) and amici (US.Br. 30-32; Waxman.Br. 4-5) further observe that generic drugs generally save patients or the government money. That has no bearing here. Again, this suit will not affect the several other manufacturers that sell generic icosapent ethyl for unpatented uses without actively encouraging infringement. Nor is there any hint that Amarin's price was high or unfair. Five years after generics entered the market, Amarin still accounts for "greater than 50% of [icosapent ethyl] prescriptions" throughout the nation because of its competitive pricing. See, *e.g.*, Amarin, *Preliminary 2025 Financial Highlights* 1 (Jan. 8, 2026).[17]

Petitioners portray (Br. 44) the decision below as having "ma[de] skinny labels *riskier* than paragraph IV certifications." Not at all. In fact, petitioners' view presents an irrational asymmetry: Generics that file paragraph IV certifications face pre-launch patent litigation and a 30-month stay of FDA approval. 21 U.S.C. § 355(j)(5)(B)(iii). But under petitioners' view, a generic that files a section viii statement—and thus avoids pre-launch litigation—could market patented uses with near impunity, so long as

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[17] https://investors.amarincorp.com/node/25161/pdf.

they did not *expressly* instruct how to infringe a patent. Petitioners' approach eliminates any need for the paragraph IV process for a second-approved use.

Petitioners are also incorrect about the relative risks of each pathway. In a paragraph IV action, a patentee may recover damages if the generic launches while the litigation is ongoing. 35 U.S.C. § 271(e)(4)(C). By the same token, lawsuits concerning skinny labels might not involve damages if no infringing sales are proven, *e.g.*, *TecSec, Inc.* v. *Adobe Inc.*, 978 F.3d 1278, 1291-1292 (Fed. Cir. 2020), or if the parties seek declaratory relief before or shortly after product launch, *e.g.*, *AstraZeneca LP* v. *Apotex, Inc.*, 633 F.3d 1042, 1047 (Fed. Cir. 2010). Injunctive relief, moreover, is automatic and lasts up to 30 months under paragraph IV, 35 U.S.C. § 271(e)(4)(A), while skinny-label litigation requires the plaintiff to satisfy the traditional four-factor test for injunctions, *eBay Inc.* v. *MercExchange, L.L.C.*, 547 U.S. 388, 390 (2006). And there is no real risk for generics that (unlike petitioners) do not intentionally and actively advertise patented uses of their drug.

The government incorrectly perceives (US.Br. 32-33) a "disincentive to use of the section viii mechanism" because, in its view, Federal Circuit precedent "could be read" to require petitioners to "pay damages for *all* infringing uses of its drug, including uses that [petitioners] played no causal role in inducing." The government gives no example of such an award. Nor does it dispute that the Federal Circuit has "adopted a more measured approach," US.Br. 33, by making plain that lost-profits awards are governed by "proper causation standards," *Brumfield* v. *IBG LLC*, 97 F.4th 854, 876 (2024). That forecloses the result the government fears.

Petitioners (Br. 7-8) and amici (US.Br. 28; Waxman.Br. 13) likewise overstate the significance of Congress's legislating against the backdrop of States' generic-substitution laws. States enacted generic-substitution laws to address a different issue: In the 1950s, many States imposed *anti*-substitution laws to counter an "epidemic" in which poor-quality knockoff products were substituted for brand drugs. Bureau of Consumer Protection, FTC, *Drug Product Selection: Staff Report to the Federal Trade Commission* 143-145 (1979); Pasha, *supra*, at 220-221. Over the next two decades, FDA began modernizing the drug-approval pathway by requiring, for example, proof of efficacy and bioavailability for all drugs. *Abigail Alliance for Better Access to Developmental Drugs* v. *von Eschenbach*, 495 F.3d 695, 725 (D.C. Cir. 2007) (Rogers, J., dissenting) (discussing history); *Drug Product Selection*, *supra*, at 111-112, 124-125. With "strict controls" in place, counterfeiting "virtually disappeared," and States repealed their outdated anti-substitution measures. See *Drug Product Selection*, *supra*, at 151-153. But their focus was not to encourage unpatented uses; it was to permit medical professionals to exercise their judgment where doing so could save patients money and posed no risk. *Id.* at 153. Petitioners' active advertisements plausibly induce infringement *precisely because* physicians have authority to decide whether to prescribe a generic.

Finally, amici predict that the decision below will lead to "forever" patent terms, 76.Scholars.Br. 22, whereby patent holders "'regularly fil[e] a new patent application claiming a narrow method of use not covered by its' original patent," Waxman.Br. 15 (citation omitted). Not even close. Amici suppose that an innovator could start with a broad indication and then, after one patent's term, continually pursue more-obscure, narrower indications to patent and iteratively add to its label. But the facts alleged

here are the opposite: Amarin's first indication was narrower, and the second was a more prevalent, broader use. It is the still-patented use for which Vascepa is most famous and was hailed as a "game changer." Nor does the Federal Circuit's reasoning raise the risk of forever-patenting—especially because (as amici indicate) token new uses have minimal medical significance and are unlikely to justify the steep price of the additional research necessary to receive FDA approval for new indications.

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At bottom, petitioners seek a safe harbor for generics choosing a carve-out label under section viii. But Congress knew how to draft a safe harbor. It provided one in 35 U.S.C. § 271(e)(1) for certain regulatory approval-related use of patents. See *Merck KGaA* v. *Integra Lifesciences I, Ltd.*, 545 U.S. 193, 202, 206 (2005). Congress did not extend that protection to circumstances after approval, nor did it provide a safe harbor for section viii carve-outs—let alone immunity for promoting patented uses.

C. The Court may wish to dismiss the writ of certiorari based on petitioners' shifting arguments, and in any event respondents would be entitled to amend the complaint.

1. The weakness of petitioners' argument is underscored by the extent to which they have abandoned the positions they staked at the certiorari stage. The central premises of petitioners' request for this Court's discretionary review were that this dispute involved far more than "application of settled law to specific facts," Pet. Reply 1, 16, that the decision below rested on "the pre-*Twombly*" pleading standard, *id.* at 8; see Pet. 21-23, and that this case turned on "whether inducement is a question of law or fact," Pet.Reply 8-9; see Pet. 26. Those arguments are nowhere to be found in petitioners' merits

brief. In fact, petitioners now admit (Pet.Br. 27-29) what respondents argued in the brief in opposition (at 22): the applicable legal standard applied by the Federal Circuit in this case is "not disputed." And petitioners make no mention of "pre-*Twombly*" pleading standards or any law-versus-fact distinction.

In recent similar circumstances where petitioners in this Court have argued one thing to secure review and something else at the merits stage, this Court has dismissed the writs of certiorari as improvidently granted. See, *e.g.*, *Facebook, Inc.* v. *Amalgamated Bank*, 604 U.S. 4 (2024) (per curiam); *NVIDIA Corp.* v. *E. Ohman J:or Fonder AB*, 604 U.S. 20 (2024) (per curiam). The same result may be warranted here.

2. Finally, even if this Court disagreed with the court of appeals about the metes and bounds of induced infringement and concluded that the operative complaint does not state a claim, it should vacate the judgment below with instructions that respondents be granted leave to amend the complaint. Petitioners' argument that they are entitled to end this case altogether—despite respondents' successful appeal and the substantial additional evidence of wrongdoing that respondents have since uncovered through discovery—is meritless.

Courts "should freely give leave" to amend "when justice so requires." Fed. R. Civ. P. 15(a)(2). That Rule reflects the "'principle that the purpose of pleading is to facilitate a proper decision on the merits.'" *Foman* v. *Davis*, 371 U.S. 178, 182 (1962). "If the underlying facts or circumstances relied upon by a plaintiff may be a proper subject of relief, he ought to be afforded an opportunity to test his claim on the merits." *Ibid.* Denying leave to amend a potentially viable claim requires a "justifying reason," such as "undue delay, bad faith[,] or dilatory motive." *Ibid.*

The strong policy favoring amendment applies with special force here, particularly considering the evidence respondents have obtained in discovery. As the government recognizes (US.Br. 17, 24, 29), additional "factual allegations" of petitioners' conduct—and its effect on direct infringers—could further support a plausible claim of induced infringement. Even petitioners acknowledge that "more" factual allegations, coupled with "[t]he types of communications" petitioners admittedly made, might suffice to show that they "'actively induce[d] infringement.'" Pet.Br. 29 (cleaned up).

Respondents have uncovered precisely those kinds of facts: Since the Federal Circuit issued its mandate in October 2024, the parties have taken more than a dozen depositions and engaged in voluminous written and document discovery. That new evidence includes petitioners' additional marketing materials and strategy, their pre- and post-launch communications, and the effect of their marketing and other communications. Those facts further confirm petitioners' intentional acts to induce infringement. Cf. *Twombly*, 550 U.S. at 556 (allegations need only "raise a reasonable expectation that discovery will reveal evidence" satisfying the claim).

Petitioners nonetheless demand (Br. 23, 46) dismissal "with prejudice" simply because the district court entered a form of judgment using that language. But petitioners offer no argument or authority for their extraordinary request. Nor could they: The trial court entered "final" judgment solely to facilitate appellate jurisdiction under Federal Rule of Civil Procedure 54(b). JA63-65. It never concluded or indicated that amendment would be futile. Pet.App. 23a n.1. Respondents successfully appealed the district court's "with prejudice" judgment and—without any motion by petitioners to stay the mandate—took sig-

nificant discovery that further reveals petitioners' illegal inducement. Given that material evolution in the case's procedural history, Hikma would not be entitled to automatic reinstatement of the district-court order even if this Court vacated the Federal Circuit's judgment.

Petitioners' arguments once again conflict with the premise of their petition: that the court of appeals applied the wrong "legal" test for pleading and proving inducement claims. When this Court announces or refines a legal test—or when it concludes that the court of appeals misconstrued a statute—its practice is to remand for further proceedings, not to end the litigation. See, *e.g.*, *Rodriguez* v. *FDIC*, 589 U.S. 132, 138-139 (2020); *Pacific Bell Tel. Co.* v. *linkLine Commc'ns, Inc.*, 555 U.S. 438, 455-457 (2009); *Iqbal*, 556 U.S. at 687. That has been true in multiple cases having the *same procedural posture* as this one, where the district court purported to dismiss the complaint "with prejudice" and the court of appeals reversed. See, *e.g.*, *Facebook, Inc.* v. *Duguid*, 592 U.S. 395, 409 (2021); *Comcast Corp.* v. *National Ass'n of African American-Owned Media*, 589 U.S. 327, 331, 341 (2020); *Spokeo, Inc.* v. *Robins*, 578 U.S. 330, 343 (2016); *Tellabs, Inc.* v. *Makor Issues & Rts., Ltd.*, 551 U.S. 308, 308, 329 (2007); *Dura Pharms., Inc.* v. *Broudo*, 544 U.S. 336, 348 (2005).

There is no sound reason to foreclose respondents from amending their complaint to plead the additional incriminating facts petitioners have disclosed in discovery.

CONCLUSION

The judgment of the court of appeals should be affirmed.

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