

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

SUPPLEMENTAL BRIEF FOR RESPONDENTS

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CORPORATE DISCLOSURE STATEMENT

The statement in respondents' brief in opposition to certiorari remains accurate.

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The court of appeals' decision was a narrow, case-specific application of the settled legal standard for pleading induced patent infringement. That decision does not affect the section viii pathway for generic drugs under the Hatch-Waxman Act because Amarin pleaded in detail how petitioners intentionally encouraged infringing uses of Amarin's ground-breaking pharmaceutical product. The government's invitation brief *agrees* with the Federal Circuit that Congress imposed liability when a generic actively encourages patented uses of a branded drug, including through its advertising. OSG.Br.12, 14.

The government disagrees merely with the Federal Circuit's bottom-line conclusion that the particular constellation of facts pleaded in Amarin's operative complaint passed the plausibility threshold at the pleading stage. But that is just a request for fact-bound (purported) error correction. Indeed, the invitation brief undermines multi-

ple arguments for certiorari advanced by the petition: The government does not contest the brief in opposition’s showing that this case implicates no true conflict, and that the Federal Circuit identified the correct legal standard for induced infringement. The government’s question presented (Br.I)—“Whether respondents’ complaint plausibly alleged that petitioners had actively induced infringement”—confirms that this case comes to this Court with no meaningful *legal* dispute, just an application of established law.

The government also fails to identify any error—let alone a certworthy error—in the decision below. The government doesn’t contest the Federal Circuit’s finding that petitioners did not dispute at the pleading stage their specific intent to infringe. So the motion to dismiss came down to whether Amarin pleaded “‘active steps’” by petitioners to infringe, “includ[ing by] ‘advertising an infringing use.’” OSG.Br.14 (quoting *Metro-Goldwyn-Mayer Studios Inc. v. Grokster, Ltd.*, 545 U.S. 913, 936-937 (2005)). That is exactly what Amarin alleged in the complaint: Amarin pleaded how petitioners’ promotional materials—which included describing its generic product too broadly so as to encompass patented uses—encouraged prescription of its product for infringing uses. The government thinks it unlikely that petitioners’ website and press releases influenced prescription decisions. But whether petitioners succeeded in their (undisputed) specific intention to encourage infringement is a *fact* question currently subject to fact and expert discovery. Amarin pleaded how petitioners’ activities encouraged infringement, and those claims will be determined at trial.

The government’s brief recycles—often verbatim—the same policy concerns it offered unconvincingly three Terms ago in *Teva Pharmaceuticals USA, Inc. v. Glaxo-*

SmithKline LLC, 143 S.Ct. 2483 (2023) (No. 22-37). Those arguments have not aged well: Since this Court denied review in *Teva* despite the government’s recommendation, the government does not show that its predictions of an exodus from the section viii pathway have come to pass. And the government shortchanges the enormous benefits of recognizing patent protections for subsequent treatment indications for a drug, particularly given the immense investments often required to discover life-saving treatments. Hatch-Waxman created a careful balance, but the government skews it at the expense of the patients who will benefit from future new and improved therapies.

Last, the government’s brief confirms that this petition is a bad vehicle. The government’s question presented resolves disputed issues of fact. The brief introduces new arguments that petitioners never raised below and so the court of appeals never addressed. And even on the government’s framing, granting review would have virtually no practical application because Amarin would be entitled on remand to amend its complaint with the additional facts revealed in discovery that further support petitioners’ actions, intent, and liability.

The petition should be denied.

A. The government identifies no legal question or error warranting this Court’s review.

1. This Court does not grant certiorari “to review evidence and discuss specific facts.” *United States v. Johnston*, 268 U.S. 220, 227 (1925); see Sup. Ct. R. 10. Yet that is all the government asks this Court to do: to determine “whether [this] complaint plausibly alleged that petitioners had actively induced infringement.” OSG.Br.I. That is classic fact-bound error correction.

The government does not endorse petitioners' arguments claiming a conflict or that the court of appeals misunderstood applicable law. Instead, the invitation brief shows that Amarin, the Federal Circuit, and the United States all agree on the relevant standard: While the patent laws do not “foreclose” marketing a generic drug limited to “unpatented” methods, they do prohibit “encouraging infringing uses.” OSG.Br.12 (quoting *Caraco Pharm. Lab'ys, Ltd. v. Novo Nordisk A/S*, 566 U.S. 399, 415 (2012)); accord Pet.App.13a-16a; Opp.8-9, 20-21. It's common ground that “culpable ‘active steps to encourage infringement include advertising an infringing use or instructing how to engage in an infringing use.’” OSG.Br.14 (quoting *Grokster*, 545 U.S. at 936-937); accord Pet.App. 15a-21a; Opp.21-22. It's also settled that alleging a “plausible chain of events through which statements made by Hikma could lead a healthcare provider—presumably a doctor or pharmacist—to prescribe or dispense Hikma's drug to reduce a patient's cardiovascular risk” was all that was required of Amarin at this threshold stage. OSG.Br. 14. That is what the Federal Circuit found to be plausible here, based on the “totality” of Amarin's case-specific allegations. Pet.App.12a-13a. This is thus “an intensely fact-specific case in which the court below unquestionably applied the correct rule of law and did not unquestionably err—precisely the type of case in which [this Court is] most inclined to deny certiorari.” *Kyles v. Whitley*, 514 U.S. 419, 460 (1995) (Scalia, J., dissenting).

The government cautions (Br.12) that liability should not attach to a generic manufacturer's statements that are “integral to the section viii pathway.” But as the government acknowledges (Br.11), the Federal Circuit did *not* hold that a generic's mere statement of biological equivalence would meet the pleading burden. Pet.App. 21a. The complaint instead alleged multiple public state-

ments by petitioners that the government concedes (Br.17) were “not necessary to the operation of the Hatch-Waxman scheme.”

The government doubts (Br.17-19) Amarin’s allegations that those statements influenced doctors and pharmacists. But whether petitioners’ identified statements succeeded in their intended goal to increase the prevalence of infringing uses is a question of fact to be developed—and currently being developed—in fact and expert discovery. At this stage, Amarin’s well-pleaded allegations about those influences must be “assume[d]” true, and its legal theory need only be *plausible*. *Ashcroft v. Iqbal*, 556 U.S. 662, 679 (2009). Besides, any question about the “prevalence” of infringing uses, OSG.Br.12, pertains only to damages, not liability: A “single instance” of infringement suffices to state a claim for liability. *American Wood-Paper Co. v. Fibre Disintegrating*, 90 U.S. 566, 600 (1874).

2. The government’s additional criticisms of Amarin’s pleading lack merit.

The government badly errs in arguing (Br.14) that the complaint “contains only a conclusory statement” that petitioners encouraged infringement. That overlooks Amarin’s detailed allegations. For example, petitioners chose to use their website to go well beyond the scope of their approval or the section viii pathway by advertising to buyers that their drug fell within the broad “hypertriglyceridemia” therapeutic category—a category that encompassed Amarin’s patents—rather than the “severe hypertriglyceridemia” patient category for which petitioners’ generic was approved. Opp.12-13; S.App.29a-38a. The government recognizes (Br.18) that petitioners mounted a “broad” marketing campaign that encompassed “both infringing and non-infringing uses.” That is just what the

law forbids: A generic may “market a drug for *only* unpatented methods of use.” *Caraco*, 566 U.S. at 419 (emphasis added); see OSG.Br.12. Moreover, the government’s fact argument necessarily assumes without support that providers would view severe hypertriglyceridemia as a subset of hypertriglyceridemia rather than a distinct therapeutic category.

The government also fails to construe petitioners’ alleged statements in the light most favorable to Amarin, as *Iqbal* requires. The government minimizes (Br.17-19) petitioners’ press releases as “orthogonal” and “anodyne” because they were purportedly directed at “investors” rather than healthcare providers. But the press releases expressly reference “healthcare providers” and emphasize petitioners’ efforts to “quickly provide patients with access” to their generic drug. C.A.App. 613, 709-710, 712-713, 715-717. The government also misapprehends the relevant timeline. It contends (Br.17) that petitioners issued their press releases before marketing their drug, when in fact the press releases *were* part of their marketing scheme: Petitioners issued one release on the cusp of FDA approval, two more upon approval, and another right after product launch. Pet. App.5a-7a.

The government likewise disregards (Br.16-19) the content and context of petitioners’ statements. The May 22, 2020 press release, for instance, announced FDA approval of a “generic equivalent to Vascepa.” S.App.4a; see C.A.App.613. But the press release did not identify any limitations on use, nor state that FDA’s approval was limited to “AB-equivalence”—meaning equivalent only when used *for an approved use*. Pet.App.18a. Petitioners’ September 3, 2020 press release (which announced victory in earlier litigation) similarly omitted any mention of limitations on the use of their generic. S.App.31a-32a.

Instead, petitioners touted Vascepa’s “approximately \$1.1 billion” in yearly U.S. sales, the bulk of which—as petitioners indisputably knew—related to the infringing CV risk-reduction indication. *Ibid.* It is eminently plausible that healthcare providers would have known that the most common use of Vascepa was for the widely publicized *infringing* CV risk-reduction indication that is close to synonymous with Vascepa. *Id.* at 34a-37a.

As the government recognizes (Br.14-15), healthcare providers’ “sophisticat[ion]” and “base of relevant knowledge” suggest that “even subtle efforts to encourage infringing uses of a specific drug could prove efficacious.” Factual discovery in other cases has shown that providers “consider” and are “encourage[d]” by generics’ “press releases.” *E.g., GlaxoSmithKline LLC v. Teva Pharms. USA, Inc.*, 7 F.4th 1320, 1336-1337 (Fed. Cir. 2021), cert. denied, 143 S.Ct. 2483 (2023). It is plausible that the same is true here.

The government asserts (Br.15-16) that an FDA-approved carveout label itself will not encourage infringement “absent exceptional circumstances.” But that question is not implicated here. The Federal Circuit made clear that its decision did *not* rest on petitioners’ label; it turned instead on the “totality” of Amarin’s allegations, including petitioners’ numerous and unnecessary public statements marketing its generic drug for an infringing use. Pet.App.12a-13a. Amarin has thus plausibly alleged the “exceptional circumstances” that the government contemplates.

No case holds that FDA approval for a label establishes virtually per se immunity against patent-infringement liability. FDA disclaims patent expertise, performs no patent analysis, and makes clear that it is the *generic applicant’s* responsibility to ensure that a carveout is

adequate. See, *e.g.*, 68 Fed. Reg. 36,676, 36,683 (2003); S.App.26a. Petitioners’ particular label here, moreover, provided detailed, medically oriented language that Amarin plausibly showed would communicate to sophisticated healthcare providers that the generic drug should be used for the infringing (and far more prevalent) use. What providers understood from that language—and whether it “encourage[d]” them to infringe, OSG.Br.12—are fact questions for a later stage, Opp.12-13, 17-18.

Last, the government suggests (Br.18, 22) that some (not all) infringing conduct may be explained by States’ mandatory-substitution laws, rather than petitioners’ encouragement. But petitioners never raised that argument below, perhaps because it implicates other fact questions of actual causation and damages that cannot be determined on the pleadings. As the government concedes (Br.6), state law preserves healthcare providers’ discretion to specify a brand or generic. That confirms that this argument pertains only to the ultimate measure of Amarin’s damages to be determined at trial, not whether Amarin has plausibly stated a claim for infringement—including whether Amarin is entitled to its requested injunctive relief. S.App.59a.

B. The government’s retreaded policy arguments remain unpersuasive.

Regarding purported certworthiness, the government repeats the very same policy arguments from its invitation brief unsuccessfully urging review in *Teva Pharmaceuticals*. U.S. Br., 143 S.Ct. 2483 (No. 22-37). Those contentions are even less persuasive here.

The government reiterates (Br.12-13, 19-20) that the section viii pathway plays an important role in expediting approval of certain generic drugs, and it claims once again that this decision (like *Teva*) “subverts” Congress’s plan.

Cf. *Teva* U.S. Br.17, 20-21. But Congress permitted generics to market “only” “unpatented methods of use.” *Caraco*, 566 U.S. at 419 (emphasis added); see *id.* at 415. The government itself says that Congress “determin[ed]” that “some measure of direct patent infringement” would be acceptable only “so long as generic manufacturers do not encourage infringing uses of their drugs.” OSG.Br.20 (emphasis added); see OSG.Br.12 (similar). Because the court of appeals found that Amarin plausibly alleged that petitioners intentionally encouraged a patented method of use, the decision below is perfectly consistent with Congress’s balance.

The government speculates (Br.21-23) that the decision below will disincentivize the section viii pathway. But the court of appeals was faithful to this Court’s decision in *Caraco*, 566 U.S. 399, which has been on the books since 2012. The government ventured the exact same predictions in *Teva*, see U.S. Br.21, yet it identifies no evidence from the last several years that FDA has seen meaningfully fewer applications. Nor does the government address Congress’s countervailing policy interests in preserving patent protections, including the imperative need to incentivize companies to commit the millions—often billions—of dollars required to discover and develop new lifesaving treatments for an existing drug. Opp.26. As the government acknowledges (Br.21), moreover, “[e]ven without this Court’s intervention, [petitioners] might ultimately prevail at summary judgment or trial.”

The government also renews (Br.15-16) its earlier argument that a generic lacks control over its carveout label. Cf. *Teva* U.S. Br.14-15. That contention has even less force here because the decision below, unlike in *Teva*, does not turn solely on the content of petitioners’ label. Pet.App.16a-21a.

C. The government’s brief confirms that the petition presents a poor vehicle.

The government’s brief does nothing to fix the petition’s multiple vehicle defects. Opp.22-23. If anything, it compounds them.

For one, the government’s articulation of the question presented depends on resolving disputed facts: that petitioners accurately described their drug as a generic; that they adequately carved out the patented use from their label; and that they directed their communications solely to investors. Even under the government’s fact-bound framing, then, this case is an unsuitable vehicle to review a motion-to-dismiss ruling.

The government also introduces two new arguments that petitioners either forfeited or waived. Such late-breaking arguments by an amicus curiae offer no sound basis for granting interlocutory review. First, the government asserts (Br.15) that courts should consider whether prescribing pharmacists “know why a particular drug is being prescribed” or are “compelled or constrained by state law” to select certain products. But the court of appeals had no occasion to consider those contentions because petitioners did not raise them. See C.A.App.945-967. As a “court of review, not of first view,” *Cutter v. Wilkinson*, 544 U.S. 709, 718 n.7 (2005), this Court “does not ordinarily decide questions that were not passed on below,” *City & County of San Francisco v. Sheehan*, 575 U.S. 600, 609 (2015).

Second, the government fights the uncontested record by questioning (Br.14, 22-23) whether Amarin adequately alleged petitioners’ “specific, culpable intent.” That challenge is unpersuasive: The government cites (Br.23) the pages of Hikma’s appellate brief that recited the legal standard but challenged only the element of “active steps

to encourage” infringement. Petrs.C.A.Br.24-26. The Federal Circuit thus found it “*undisputed* that Amarin’s complaint sufficiently alleges ... that Hikma had the requisite intent and knowledge to induce th[e] infringement,” and the court proceeded on that basis. Pet.App.15a (emphasis added). Tellingly, petitioners did not seek review of that finding. Opp.22-23.

Similarly misplaced is the government’s expression (Br.21-22) of “uncertainty as to the calculation of potential damages” because, in its view, *Teva*’s discussion of lost-profits awards “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 Federal Circuit has already foreclosed the result the government fears. *Brumfield v. IBG LLC*, 97 F.4th 854, 876 (2024) (“An award of lost profits generally depends on showing the existence and magnitude of profits lost to the patentee on sales the patentee did not make, or made at lower prices, as a result, *under proper causation standards*, of the infringement.” (emphasis added)).

The government nonetheless recommends review on the theory (Br.22) that allegations like Amarin’s will appear in “most” section viii cases. Not at all. Other generics can and do avoid describing their drugs’ equivalence more broadly than their approvals; avoid citing sales from patented uses; and avoid featuring their drugs on websites in ways that encroach on patent claims. Nor will a patented use always be the one that is overwhelmingly familiar to healthcare providers and that drives nearly all sales. Opp.28-31.

The government likewise errs in contending (Br.23) that it would be “imprudent” to wait for a case with developed facts because “[m]any cases of this kind settle.” Most civil cases of *all* kinds settle. But pharmaceutical patent

cases settle less often—and are tried more often—than non-pharmaceutical patent cases. See, *e.g.*, Lex Machina, Patent Litigation Report 2023, at 17 (2023) (observing that “only 33% of ANDA cases resolved with a likely settlement compared to 79% of non-ANDA cases”); John D. Garretson, *Litigating Patent Cases: Industry-Specific Developments, Issues, and Strategies*, Aspatore, 2013 WL 574399, at *5 (Jan. 2013) (“pharmaceutical patent cases are much less likely to settle”). The parties here have litigated this case for months since the Federal Circuit reversed the district court’s order dismissing the complaint.

Finally, granting interlocutory review of the particular allegations in this operative complaint would have minimal impact—if any at all. As explained above (at 3-5), the government raises case-specific issues that would not govern future cases. Indeed, a decision by this Court may not “make any difference even to the[] litigants” in *this* case. *Ticor Title Ins. Co. v. Brown*, 511 U.S. 117, 122 (1994); see *The Monrosa v. Carbon Black Export, Inc.*, 359 U.S. 180, 184 (1959). Even under the government’s fact-bound framing, the appropriate disposition would be a remand with leave for Amarin to amend the Complaint. Fed. R. Civ. P. 15(a)(2). Amarin would then replead its claims by adding the substantial evidence—derived from ongoing documentary and deposition discovery—that has since confirmed each element of petitioners’ intentional induced infringement and identified additional acts of induced infringement.

CONCLUSION

The petition should be denied.

Respectfully submitted,

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