No. 24-889

In the Supreme Court of the United States

HIKMA PHARMACEUTICALS USA INC. AND
HIKMA PHARMACEUTICALS PLC, PETITIONERS

v.

AMARIN PHARMA, INC., ET AL.

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

REPLY TO BRIEF IN OPPOSITION

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RULE 29.6 STATEMENT

The corporate disclosure statement included in the petition remains accurate.

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The decision below urgently warrants review because it exposes every generic drugmaker marketing the "generic version" of a branded drug to potentially catastrophic damages, even if the generic omits all patented uses from its label. As the government and myriad commentators warn, Pet. 5–6, that will deter drugmakers from invoking Hatch-Waxman's skinny-label pathway, which Congress enacted so that low-cost generics could avoid litigation risk and "quickly come to market," *Caraco Pharm. Labs., Ltd.* v. *Novo Nordisk A/S*, 566 U.S. 399, 415 (2012).

Amarin's opposition rests on the false premise that the decision is "intensely fact-bound." Opp. 2. The facts deemed sufficient to plead inducement—calling a drug the "generic version" of another and citing market data, App. 19a—are ubiquitous. Whether such bare allegations suffice to plead induced infringement affects not just the pharmaceutical industry, but all competitive markets. Pet. 27–30; Scholars' Br. 13–18.

Unable to refute this, Amarin resorts to outright fabrication. Without any citation, Amarin falsely declares that Hikma "began marketing [its generic drug] broadly for both the unpatented *and patented uses*" and "*actively encouraged physicians* to prescribe Hikma's generic drug *so as to infringe Amarin's patents*." Opp. 2 (emphasis added). None of that is remotely true—or even alleged. Amarin's patents undisputedly require (i) administering icosapent for "reducing risk of cardiovascular death" or (ii) co-administering icosapent and another drug (a statin) for "reducing occurrence of a cardiovascular event." App. 8a–9a & n.5. No alleged statement by Hikma even mentions, much less encourages, either patented use.

When Amarin finally gets around to citing the record, it becomes clear that the only allegations here are the same that any branded drug company could level against any skinny-label generic, which have nothing to do with any patented use: Hikma (correctly) called its product "generic"; Hikma said Vascepa is indicated "in part" for off-patent use (as it must be, for a skinny label to be possible); and Hikma cited "domestic sales" (as competitors routinely do). Opp. 12. Amarin even relies on Hikma announcing it "received FDA approval," *ibid*., which is true of any legally marketed drug. Amarin's other allegations either concern the general population of "hypertriglyceridemia" patients—not the disputed claim steps—or rehash label-based theories that even the Federal Circuit rejected. Opp. 12–13; App. 16a–17a (summarizing Amarin's label-based allegations, then agreeing with Hikma they fail "as a matter of law").

As Amarin ultimately admits, "the only approved indication for Hikma's generic" is undisputedly off-patent—and, thus, "the thrust of the complaint is not that Hikma's label was 'not skinny enough.'" Opp. 27, 14. This case is about routine statements of therapeutic equivalence required for all generic drugs. See 21 U.S.C. § 355(j)(2)(A)(iv), (j)(4)(F). If this were enough to assert inducement, Hatch-Waxman's section viii would be a dead letter—as well as the Patent Act's requirement for "*actively* induc[ing]" all claimed method steps. 35 U.S.C. § 271(b) (emphasis added).

It is no answer that this case is at the pleadings stage. Opp. 2–3. That has never precluded this Court's review, and it misses the point. As the Solicitor General made clear in urging certiorari for the similar *GSK* case (which Amarin ignores), even "the

potential for inducement liability in these circumstances may significantly deter use of the section viii pathway even if such liability is rarely imposed." Brief for the United States as Amicus Curiae, *Teva Pharms. USA, Inc.* v. *GlaxoSmithKline LLC*, 143 S. Ct. 2483 (2023) (No. 22-37), 2023 WL 2717391, at *22. And "the threat of discovery expense will push cost-conscious defendants to settle even anemic cases." *Bell Atlantic Corp.* v. *Twombly*, 550 U.S. 544, 559 (2007). Given Hikma's "skinny enough" label, Opp. 14, this is an even better vehicle than *GSK* to prevent that result.

I. The decision below conflicts with precedent and urgently warrants this Court's review.

The Federal Circuit now allows inducement claims to proceed to discovery even if plaintiffs allege no affirmative steps that "actively" encourage infringement. The decision conflicts with the plain language of 35 U.S.C. § 271(b) and creates multiple conflicts meriting review.

A. By broadly exposing every skinny-label generic to potential inducement liability, the decision eviscerates the requirement for *active* inducement of *all* claim steps.

1. Amarin concedes this Court's precedents and § 271(b) require "'active' inducement" by "clear expression or other affirmative steps." Opp. 21–22. For method patents, that requires actively "inducing performance of all the claimed steps." Opp. 22. Here the claimed steps *require*, among other things, reducing risk of cardiovascular ("CV") death or co-administering a statin to reduce CV events. App. 8a–9a & n.5. Amarin alleges no "clear expression or other affirmative steps" by Hikma that actively induce others to perform

such steps. Hikma's alleged conduct is no different than any skinny-label generic's.

First, Hikma called its product a "generic version" or "generic equivalent" of Vascepa. Opp. 12, 22; App. 18a. That cannot actively induce infringement of specific treatment steps, or else calling *any* drug "generic" would induce infringement of every patented method for using the generic drug's branded equivalent. Amarin does not dispute that this Court, Congress, FDA, and the pharmaceutical industry routinely call generic drugs "generic versions." Pet. 27–29. That cannot be what Congress meant by "actively induc[ing] infringement." 35 U.S.C. § 271(b). As the *GSK* dissent foresaw, "a generic can be deemed liable for inducement for saying that its product is a 'generic version'"—"a drastic holding" that "makes little sense." *GlaxoSmithKline LLC* v. *Teva Pharms. USA, Inc.*, 7 F.4th 1320, 1353 (Fed. Cir. 2021) (Prost, J., dissenting).

Second, Hikma correctly stated Vascepa is indicated "in part" for the *noninfringing* severe hypertriglyceridemia ("SH") indication. Opp. 12, 22; App. 18a. Again, that cannot actively induce method steps for reducing CV-death risk or (with a statin) CV events. Amarin admits the SH indication is "off-patent," Opp. 22, and the branded equivalent for *every* skinny-label generic is indicated "in part" for the generic's approved indication. That is the premise of a carve-out.

Third, Hikma quoted Vascepa's "sales figures." Opp. 22; App. 18a. But those are *numbers*. The statement that, "[a]ccording to IQVIA, US sales of Vascepa® were approximately $919 million in the 12 months ending February 2020," App. 32a, says nothing about patented uses—and it is not materially different from financial reporting in any industry.

Fourth, Hikma's website included the word "[h]ypertriglyceridemia," Opp. 12, 22, coupled with "an express disclaimer that Hikma's product is FDA-approved for fewer than all uses of Vascepa," App. 20a n.6. The accurate statement that Hikma's product falls under the general category for treating "hypertriglyceridemia," especially combined with the disclaimer, cannot actively encourage the specific, patented treatment steps for reducing CV-death risk or (with a statin) CV events. Although one asserted patent includes a triglyceride limitation, App. 8a, "the patent is not infringed unless *all* the steps are carried out," *Limelight Networks, Inc.* v. *Akamai Techs., Inc.*, 572 U.S. 915, 921 (2014) (emphasis added).[1] Until now, reciting a general category that could include both patented and unpatented uses was not enough to induce infringement. See *Grunenthal GmbH* v. *Alkem Labs. Ltd.*, 919 F.3d 1333, 1339 (Fed. Cir. 2019) (no inducement by generic labeled for "severe chronic pain," which covered both patented "polyneuropathic pain" relief and off-patent pain relief, because it did "not specifically encourage" the patented use).[2]

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[1] Amarin conflates triglycerides with CV risk, Opp. 4, but it admits "lowered triglycerides" do not "prove[] a reduction in cardiovascular risk," Opp. 6, and "other omega-3 based therapies[] lowered triglyceride levels in this patient population but did not show an actual reduction in cardiovascular risk," S.App. 7a.

[2] Amarin incorrectly states "[t]he court of appeals reasoned that * * * portions of [Hikma's] label" induced infringement. Opp. 14 (citing App. 16a). The decision summarizes *Amarin's* label-based allegations before *rejecting* them,

2. That the decision quotes the general standard for "clear expression or other affirmative steps," Opp. 22, does not preclude review. By holding that "generic version" and sales figures suffice to plead inducement—without any alleged instruction to perform the patented steps—the Federal Circuit eviscerated the statutory requirement for "actively induc[ing] infringement." 35 U.S.C. § 271(b). This is not mere "disagreement with the application of settled law to specific facts." Opp. 16. The same facts apply to any patented method and any generic drug.

Amarin's opposition confirms that its inducement theory is *passive*—not active, as § 271(b) demands. Amarin denies physicians must "research Amarin's brand-name label" to infringe, but only because it assumes Vascepa's CV indication is already "known" to them. Opp. 24, 33. Any such knowledge does not result from *Hikma*'s actions; it results from *Amarin* promoting its own product. If accepted, Amarin's theory would eliminate the need for active inducement in every case. Nothing would stop any patentee from alleging its patented method is so "common" that it needs no instruction. Opp. 24–25.

By endorsing Amarin's passive inducement theory, the decision not only departs from this Court's precedent demanding "active steps," *Metro-Goldwyn-Mayer Studios Inc.* v. *Grokster, Ltd.*, 545 U.S. 913, 936–937 (2005), but also departs from the Federal Circuit's own precedent that "vague" language "cannot be combined with speculation about how physicians may act to find

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"agree[ing] with the district court (and Hikma) that the label does not, as a matter of law, recommend, encourage, or promote an infringing use." App. 17a (cleaned up).

inducement," *Takeda Pharms. U.S.A., Inc.* v. *W.-Ward Pharm. Corp.*, 785 F.3d 625, 632 (Fed. Cir. 2015).

This case is unlike *Grokster*, where "[i]t was enough for a defendant to promote a device's use to infringe copyright generally, without any reference to specific copyrighted works." Opp. 23. Amarin cites no alleged promotion by Hikma "to infringe [patents] generally," *ibid.*, and it ignores that a method "patent is not infringed unless all [claim] steps are carried out," *Limelight*, 572 U.S. at 921. This may not require "*recit*[*ing*] all the claim limitations" verbatim, Opp. 23, but it requires *actively inducing* each step. The Federal Circuit found plausible inducement without *any* alleged instruction that promotes Hikma's generic product for reducing CV-death risk or for co-administration with a statin to reduce CV events—breaking sharply with precedent.

B. The decision flouts this Court's pleading standard, deterring generic competition.

Amarin admits the decision "quote[s] the pre-*Twombly* no-set-of-facts standard," Opp. 20, which this Court rejected. *Twombly*, 550 U.S. at 562–563; App. 12a. Amarin brushes aside this undisputable conflict because the decision uses the word "plausibility." Opp. 20. The problem is the decision never identifies *any* instruction—plausible or not—to perform the patented steps. The decision deems it sufficient that Amarin presented a "theory" for how doctors might interpret "generic version" and "sales figures" based on allegedly preexisting knowledge of the patented uses. App. 17a–18a. And the decision invokes a need for "discovery," both "fact discovery and expert testimony," to explore whether inducement exists. App. 14a, 19a.

Twombly rejected identical logic that "revealing the theory of the claim will suffice" and that "the prospect of unearthing direct evidence * * * preclude[s] dismissal." 550 U.S. at 561–562. "It is no answer" that a claim can "be weeded out early in the discovery process"—"the threat of discovery expense will push cost-conscious defendants to settle even anemic cases." *Id.* at 559. Amarin is thus wrong to call the decision's reliance on the pre-*Twombly* standard "fact-bound" error. Opp. 20. As in *Twombly*, 550 U.S. at 559, "the potentially enormous expense of discovery" will have far-reaching effects—deterring generic market entry.

C. The decision creates a circuit split and aggravates uncertainty over whether inducement is a legal or factual question.

1. Amarin does not dispute the importance of maintaining uniform pleading standards for inducement across patent and copyright law. Pet. 25–26. The Federal Circuit's holding cannot be reconciled with the Ninth Circuit's opposite approach: The decision below holds inducement is a "question of *fact*—not law—and is therefore *not proper for resolution on a motion to dismiss*." App. 18a–19a (emphasis added). In contrast, the Ninth Circuit holds "'[i]nducement' is a *legal* determination, and *dismissal may not be avoided* by characterizing a legal determination as a factual one." *Perfect 10, Inc.* v. *Visa Int'l Serv. Ass'n*, 494 F.3d 788, 802 (9th Cir. 2007) (emphasis added).

Amarin invokes an older case where the Federal Circuit dismissed inducement claims, Opp. 17–18, but that only confirms the departure from precedent. Amarin also cites this Court's holding that *direct* infringement "is a question of fact," *Markman* v. *Westview Instruments, Inc.*, 517 U.S. 370, 384 (1996), but it admits

this case is not about direct infringement, Opp. 11, which is a strict-liability tort. By contrast, inducement is a form of "secondary liability"—a limited exception to "the law's reluctance to find liability when a defendant merely sells a commercial product suitable for some lawful use." *Grokster*, 545 U.S at 934, 936. Only "clear expression or other affirmative steps taken to foster infringement" render a defendant "liable for the resulting acts of infringement by third parties." *Id*. at 937. That is a legal inquiry distinct from the underlying factual question of direct infringement.

2. There is "no statutory requirement or instruction from th[is] Court indicating that the determination of all elements of inducement are actually questions of fact." Garrett T. Potter, *Beefing Up Skinny Labels: Induced Infringement as a Question of Law*, 97 NOTRE DAME L. REV. 1707, 1711 (2022). Amarin dismisses this commentary as "one student note," Opp. 18 n.6, but it ignores more recent commentary (published after the petition) confirming that the decision below raises the same uncertainty:

> [D]ecisions like *GSK* and *Amarin*, which purport to hinge on factual questions, could just as easily be understood as hinging on questions about inducement *law*. * * * In *Amarin*: is a warning about the patented use, coupled again with statements about 'equivalence' and knowledge of prescribing practices, *legally* sufficient to state a claim of inducement? These assessments of legal sufficiency sound much more like issues of law than fact.

Jacob S. Sherkow & Paul R. Gugliuzza, *Infringement by Drug Label*, 78 STAN. L. REV. —, 48 (2026) (rev. May 20, 2025), https://papers.ssrn.com/sol3/papers.cfm?

abstract_id=5145419. These scholars propose treating inducement "as ultimately a legal question that can be based on underlying factfinding." *Ibid.* Amarin disagrees, but that is a merits-stage dispute. Either way, this Court's guidance is needed.

3. Amarin's efforts to distinguish *Perfect 10* confirm that the conflict is real—and the law-or-fact divide affects the outcome. Contra Opp. 18. As Amarin acknowledges, the Ninth Circuit dismissed inducement claims because the plaintiff "alleged no 'affirmative steps taken to foster infringement'" and "asserted merely that the defendants marketed their credit cards *generally* but provided no allegations that the defendants affirmatively promoted the infringing products." Opp. 19 (citing *Perfect 10*, 494 F.3d at 800–801). So too here: Amarin asserts Hikma *generally* marketed its "generic version," but it provides no allegation that Hikma affirmatively promoted the infringing methods—reducing risk of CV death and co-administering a statin to reduce CV events.

Under the Ninth Circuit's standard, Amarin's complaint is deficient: While courts "must take as true the allegations" of factual statements, "'[i]nducement' is a legal determination," and courts "must determine whether the facts as pled constitute a 'clear expression' of a specific intent to foster infringement." *Perfect 10*, 494 F.3d at 802. The Federal Circuit rejected this exact approach—urged by Hikma below, contra Opp. 18—that "the factual contents of Hikma's label and public statements are undisputed, such that we can resolve this case as a matter of law," App. 19a.

Amarin falsely declares without citation that "Hikma is alleged to have courted prescribers of the CV indication to use their generic rather than

Amarin's product." Opp. 19. But there is no allegation that Hikma—a generic drug manufacturer—"courted" anyone. This case is about vague statements in press releases that are not directed to doctors and do not describe any treatment steps. That would never pass muster in the Ninth Circuit; in the Federal Circuit, it does. The split is undeniable.

II. This case is an excellent vehicle to address the critically important questions presented.

Amarin raises no real vehicular obstacle. Its refrain that this case is "about the *pleadings*," Opp. 25, supports review. The pleadings-stage posture is ideal for considering the *legal* sufficiency of inducement allegations—not post-trial disputes over facts—and this Court commonly reviews cases in the same posture. See, *e.g.*, *Twitter, Inc.* v. *Taamneh*, 598 U.S. 471, 482 (2023) (reinstating district court's dismissal of aiding-and-abetting allegations that court of appeals had reversed); *Twombly*, 550 U.S. at 552–553.

It is no answer that Amarin must still prove liability and remedies. Opp. 31. This is a test case; the industry is watching. See Pet. 5–7. If lawsuits like these survive the pleadings, the harm will already be done: The risks and costs of litigating will chill generic competition. Pet. 31–34. As the Solicitor General warned (and Amarin ignores), even "the *potential* for inducement liability * * * may significantly deter use of the section viii pathway." *Teva*, 2023 WL 2717391, at *22.

These are not "concerns [ ] properly addressed by Congress." Opp. 25. Congress has already spoken—requiring "active" inducement in § 271(b) and enacting section viii to ensure "patented use[s] will not foreclose marketing a generic drug for other unpatented ones."

Caraco, 566 U.S. at 415. Enforcing these statutory mandates creates no "safe harbor" for drugmakers that illegally promote unapproved, infringing method steps. Opp. 26. Amarin pleads no such misconduct. Absent this Court's review, accurately calling a drug "generic" and citing public market data will suffice to plead inducement of any patented method—opening floodgates to post-launch litigation and rendering both § 271(b) and section viii meaningless. As in *Caraco*, this Court need not wait for widespread abuse of a Federal Circuit ruling that misinterprets the Hatch-Waxman Act; the Court should grant review now.

CONCLUSION

The petition should be granted. Alternatively, the Court should call for the views of the Solicitor General.

Respectfully submitted.

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