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

REPLY BRIEF FOR PETITIONERS

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INTRODUCTION

To state a claim for active inducement, Amarin needed plausible allegations that Hikma advertised or instructed an infringing use—expressly. There are no such allegations here. Instead, Amarin presses an unsupported theory of passive inducement, arguing that promotion to infringe can be inferred.

That position cannot be squared with the language of 35 U.S.C. § 271(b), which is short and simple: liability attaches only when one "actively induces infringement of a patent." This requires acts of "clear expression," *Metro-Goldwyn-Mayer Studios, Inc.* v. *Grokster, Ltd.*, 545 U.S. 913, 937 (2005)—that is, "express promotion [or] marketing" of infringement, *Cox Commc'ns, Inc.* v. *Sony Music Ent.*, 146 S. Ct. 959, 968 (2026).

Amarin urges the Court to find encouragement to infringe in statements that, on their face, do not satisfy the statute. Vague product descriptions like "generic version of Vascepa" (in pre-launch press releases touting litigation victories to investors) along with the phrase "Therapeutic Category: Hypertriglyceridemia" (in an online product catalog directed to wholesalers and retailers) do not actively induce any specific use, much less expressly promote using Hikma's generic product with a statin to reduce cardiovascular risk.

Like the court of appeals, Amarin misreads Rule 12(b)(6) precedent to allow speculative claims of induced infringement. Yet Amarin does not deny that Hikma's investor and customer communications have "obvious alternative explanation[s]," *Bell Atl. Corp.* v. *Twombly*, 550 U.S. 544, 567 (2007), and thus do not raise a "necessary implication" of liability, *id.* at 561 n.7. Even assuming Amarin's proposed inferences are

"consistent with" culpable conduct (which Hikma disputes), they are neither reasonable nor plausible under *Ashcroft* v. *Iqbal*, 556 U.S. 662, 681–682 (2009).

Amarin's inferred-inducement theme is belied by Hikma's press release at product launch. It specifies the product's sole, noninfringing indication and states that "Hikma's product is *not* approved for any other indication for the reference listed drug VASCEPA®." JA45–46 (emphasis added). That makes quick work of Amarin's assertion (at 14) that Hikma "communicated to healthcare providers that petitioners' generic should be used for the same indications as Vascepa." The record is clear that Hikma said the opposite.

Left with no plausible theory, Amarin turns to a speech-protective First Amendment case—ironically, in an effort to *restrict* Hikma's speech. See *NRA* v. *Vullo*, 602 U.S. 175, 181 (2024). But "courts should not create liability for inducement of non-infringing conduct where Congress has elected not to extend that concept." *Limelight Networks, Inc.* v. *Akamai Techs., Inc.*, 572 U.S. 915, 923 (2014). And the Court should take particular care in the Hatch-Waxman context to avoid "trenching on regular commerce," *Grokster*, 545 U.S. at 937, because even the specter of a damages award based on vague product descriptions would effectively shut down the section-viii pathway.

The remaining arguments by Amarin and its amici rely on strawman assertions and otherwise are meritless. Hikma is not asking for a safe harbor or qualified immunity. Hikma's merits brief directly addresses and is limited to the questions presented. And Amarin has no basis to revisit its waiver of a pleading amendment. The decision below should be reversed.

ARGUMENT

I. Section 271(b) requires plausible allegations that the defendant promoted specific acts sufficient to infringe.

Amarin's arguments, adopted by the Federal Circuit, turn on a misreading of the legal standards for assessing the sufficiency of claims for actively induced patent infringement. Both questions presented in Hikma's petition should be answered in the negative.

A. A plain statutory reading, confirmed by precedent, requires express promotion of infringing conduct.

As Hikma's brief shows (at 23–27), § 271(b) requires that (1) the defendant "actively induce[d]" a direct infringer to take specific action, and (2) that "induce[d] action suffices for infringement of a patent." Amarin's brief (at 31) does not dispute that "a defendant must induce performance of every step of the patented method." Instead, Amarin argues such inducement may be inferred at the pleading stage from vague product descriptions combined with knowledge that direct infringement is likely. Amarin is wrong.

1. Citing *Grokster*, Amarin emphasizes (at 21) that "'[a]ctive steps' can include not only 'instructing how to engage in an infringing use' but also '*advertising* an infringing use.'" This distinction is immaterial. To be sure, advertising can induce infringement, but only if it "advertis[es] *an infringing use*." *Grokster*, 545 U.S. at 936–937 (emphasis added). Regardless of whether the accused statement is characterized as "advertising an infringing use or instructing how to engage in an infringing use," there must be active encouragement of "an infringing use." *Id.* at 936.

The Court's recent decision in *Cox* confirms that such active encouragement requires "express promotion [or] marketing" of an infringing use. 146 S. Ct. at 968 (quoting *Grokster*, 545 U.S. at 926). Stated differently, § 271(b) "requires that the party express 'an affirmative intent that the product be used to infringe.'" *Ibid.* (quoting *Grokster*, 545 U.S. at 936). As *Cox* and *Grokster* make clear, advertising or instructions do not actively induce infringement unless they expressly encourage conduct sufficient to infringe—precisely how Hikma construes the statute.

2. While Amarin purportedly relies on *Grokster*, it urges a broader theory of inferred inducement untethered to either the statutory language or precedent. As Amarin would have it (at 35): "A speaker need not be 'explicit' so long as the intended message is understood," and thus inducement can be found even where "the direct infringer must *infer* the speaker's instructions or encouragement" (cleaned up). It follows, under Amarin's view, that culpable, inducing conduct turns on how direct infringers will read accused statements. And, according to Amarin, physicians can infer encouragement from vague product descriptions that do not, on their face, advertise or instruct an infringing use. What matters, we are told (at 25, then 18), is that Hikma made its "statements knowing that Vascepa's commercial success and identity were driven primarily by its patented CV indication," and generic-substitution laws "should have heightened petitioners' caution in their statements."

Amarin's position contradicts both the statutory language and precedent. Section 271(b) proscribes only "actively" induced infringement. "The addition of the adverb 'actively'" is not surplusage—it "suggests

that the inducement must involve the taking of affirmative steps to bring about the desired result." *Glob.-Tech Appliances, Inc.* v. *SEB S.A.*, 563 U.S. 754, 760 (2011). Where, as here, the accused conduct involves statements allegedly made to direct infringers, active inducement requires "*express* promotion [or] marketing" of infringing conduct. *Cox*, 146 S. Ct. at 968 (emphasis added); see also *Grokster*, 545 U.S. at 936–937 (requiring "clear expression or other affirmative steps taken to foster infringement").

This Court has never adopted Amarin's expansive view of active inducement—for good reason. Infringement liability is not imposed indirectly absent "culpable expression and conduct." *Glob.-Tech*, 563 U.S. at 763. Instead of inferring inducement from vague product descriptions, precedent requires "evidence [that] goes beyond a product's characteristics or the knowledge that it may be put to infringing uses, and [instead] shows statements or actions directed to promoting infringement." *Grokster*, 545 U.S. at 935. Advertisements, instructions, and similar statements fall beyond the scope of § 271(b) when "[n]othing about [the accused] conduct is inherently culpable." *Cox*, 146 S. Ct. at 974 (Sotomayor, J., concurring).

Grokster never holds, as Amarin asserts (at 35), that "'suggestive[]' references can be actionable for inducing infringement." Amarin omits the next sentence: the defendants "communicated a *clear message* by responding affirmatively to requests for help in locating and playing copyrighted materials." *Grokster*, 545 U.S. at 938 (emphasis added); see also *id.* at 926 (relying on "evidence of express promotion [and] marketing"). *Cox* confirms that inducement "liability requires that the party express 'an affirmative intent

that the product be used to infringe.'" 146 S. Ct. at 968 (quoting *Grokster*, 545 U.S. at 936).

Until the decision below (Pet.App.19a–20a), defendants could not be held liable for inferred inducement based on vague product descriptions that would not necessarily lead to infringement. The Federal Circuit previously held that "vague * * * language cannot be combined with speculation about how physicians may act to find inducement." *Takeda Pharms. U.S.A., Inc.* v. *W.-Ward Pharm. Corp.*, 785 F.3d 625, 631–632 (Fed. Cir. 2015). The Federal Circuit got it right in *Takeda*. Contrary to Amarin's theory, echoed by its amici, "mere indifferent supposition or knowledge on the part of the seller that the buyer will use the product unlawfully is not enough to make the seller liable for the buyer's conduct," and liability cannot be imposed "merely based on a failure to take affirmative steps to prevent infringement." *Cox*, 146 S. Ct. at 968 (cleaned up). Holding otherwise would "create liability for inducement of non-infringing conduct where Congress has elected not to extend that concept," *Limelight*, 572 U.S. at 923, "trenching on regular commerce," *Grokster*, 545 U.S. at 937.

As *Cox* confirms, Amarin and its amici also cannot rely solely on Hikma's "intent and knowledge," combined with a purported failure to mitigate the risk of infringement. Resp.Br.17. Section 271(b) requires both culpable conduct and intent, and "[t]he intent required for [indirect] liability can be shown only if the party" engaged in culpable conduct—that is, "induced

the infringement." *Cox*, 146 S. Ct. at 967.[1] While intent can turn on circumstantial evidence, the inducing conduct itself cannot be inferred from vague product descriptions falling short of "express promotion [or] marketing" of infringing acts. *Id.* at 968.

B. Inducement cannot plausibly be inferred at the pleading stage unless express statements necessarily promote infringement.

Amarin does not dispute the relevant Rule 12(b)(6) standard. See Resp.Br.30–32. But like the court below, which cites pre-*Twombly* precedent (Pet.App.12a), Amarin misstates the Court's plausibility requirement—ignoring that allegations merely "consistent with" liability are not plausible. *Iqbal*, 556 U.S. at 681–682. Under the correct standard, courts may not infer inducement from express statements unless they necessarily promote infringement.

1. Notably, Amarin does not dispute that, under regional circuit law, the accused Hikma statements attached to the complaint control. Alleged characterizations that diverge from the undisputed statements are conclusory and carry no weight. See Pet.Br.31–32

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[1] As Amarin agrees (at 8, 20), it needed to plead separately that Hikma (1) actively encouraged acts that infringe, and (2) was specifically aware those encouraged acts would practice known Amarin patents. The second prong converts general intent to induce particular *conduct* into specific intent to induce *infringement*. This appeal focuses on whether Amarin plausibly pleaded prong one; if not, prong two becomes moot. While Amarin argues (at 35) that specific intent is "undisputed," this is true only in the sense that Hikma has not made an alternative, prong-two pleading challenge.

(citing *ALA, Inc.* v. *CCAIR, Inc.*, 29 F.3d 855, 859 n.8 (3d Cir. 1994)).

Likewise, Amarin does not dispute that "[t]hreadbare recitals of the elements of a cause of action, supported by mere conclusory statements, do not suffice." *Iqbal*, 556 U.S. at 678. A claim is plausible only "when the plaintiff pleads factual content that allows the court to draw the *reasonable inference* that the defendant is liable for the misconduct alleged." *Ibid.* (emphasis added).

2. Amarin, like the court below (Pet.App.19a), misstates this Court's "reasonable inference" standard as allowing courts to read infringing instructions into undisputed statements containing only vague product descriptions. But a "reasonable inference" requires pleading "more than a sheer possibility that a defendant has acted unlawfully." *Iqbal*, 556 U.S. at 678. Where a pleaded claim is "merely consistent with a defendant's liability, it stops short of the line between possibility and plausibility of entitlement to relief." *Ibid.* (cleaned up). Even where "allegations are consistent with" an unlawful purpose, "given more likely explanations, they do not plausibly establish this purpose." *Id.* at 681.

Put simply, unlawful conduct cannot reasonably or plausibly be inferred unless the "necessary implication" of well-pleaded facts supports liability. See *Twombly*, 550 U.S. at 561 n.7. Where, as here, a substantial noninfringing use exists, actively induced infringement cannot plausibly be inferred from anodyne statements that fall short of expressly advertising or instructing an infringing use. This conclusion follows from *Iqbal*'s industry-agnostic Rule 12(b)(6) standard: "[W]here the well-pleaded facts do not permit the court

to infer more than the mere possibility of misconduct, the complaint has alleged—but it has not 'show[n]'—'that the pleader is entitled to relief.'" 556 U.S. at 679 (quoting Fed. R. Civ. P. 8(a)(2)); cf. *Vita-Mix Corp.* v. *Basic Holding, Inc.*, 581 F.3d 1317, 1329 (Fed. Cir. 2009) ("Especially where a product has substantial non-infringing uses, intent to induce infringement cannot be inferred even when the defendant has actual knowledge that some users of its product may be infringing the patent."); *Takeda*, 785 F.3d at 632 (vague statements would not "necessarily lead doctors" to infringe).

Allegations of actively induced infringement based on vague product descriptions and knowledge of direct infringement due to generic-substitution laws—despite obvious, alternative explanations—do not plausibly state a claim. This is true even if one potential explanation for the accused statements is consistent with liability. An "obvious alternative explanation" for the accused statements—i.e., lawful, commercial communications to investors and wholesaler/retailer customers unrelated to infringement—suffices to render inferences of unlawful conduct implausible as a matter of law. See *Iqbal*, 556 U.S. at 681–682; U.S.Br.28–30.

This plausibility standard is not unique to the pharmaceutical context. The Court has repeatedly found complaints deficient in other contexts on analogous grounds. See, *e.g.*, *Twombly*, 550 U.S. at 567–569 (antitrust conspiracy implausible due to "an obvious alternative explanation"); *Iqbal*, 556 U.S. at 681–682 (claim based on action merely "consistent with" discrimination but more likely explained by a "nondiscriminatory intent" implausible); *Twitter, Inc.* v. *Taamneh*, 598 U.S. 471, 502–503 (2023) (refusing, in

the motion-to-dismiss context, to "hold any sort of communication provider liable for any sort of wrongdoing merely for knowing that the wrongdoers were using its services and failing to stop them"); *Smith & Wesson Brands* v. *Mexico*, 605 U.S. 280, 292 (2025) ("[A]n ordinary merchant does not become liable for all criminal misuses of his goods, even if he knows * * * misuse will occur," but "only if, beyond providing the good on the open market, he takes steps to promote the resulting crime and make it his own.") (cleaned up).

3. Amarin's key case, *NRA*, does not alter this pleading standard. *NRA* addresses a materially different claim arising under the First Amendment, which requires "a plaintiff [ ] plausibly [to] allege conduct that, viewed in context, could be reasonably understood to convey a threat of adverse government action in order to punish or suppress the plaintiff's speech." *NRA*, 602 U.S. at 191. That is, express threats are not required—they can be inferred if "reasonably understood" as such by the recipient of the accused communication. *Ibid.* That standard has nothing to do with the Rule 12(b)(6) context; it is simply the substantive standard for protecting speech against government coercion under the First Amendment. *Ibid.* (citing *Bantam Books, Inc.* v. *Sullivan*, 372 U.S. 58, 67–68 (1963) (applying same "reasonably understood" standard)).

In contrast, a claim to restrict speech under § 271(b) requires "express promotion [or] marketing," *Cox*, 146 S. Ct. at 968—that is, "clear expression or other affirmative steps taken to foster infringement," *Grokster*, 545 U.S. at 936–937. This is because the relevant statute proscribes only "actively induced infringement." 35 U.S.C. § 271(b). Other commercial speech remains lawful. In short, Amarin cites no case

altering the *Twombly*/*Iqbal* plausibility standard discussed above. Cf. *Berk* v. *Choy*, 146 S. Ct. 546, 553 (2026) (addressing only whether an expert affidavit was required).

II. Amarin fails to state a plausible claim for actively induced patent infringement.

The undisputed, accused statements attached to the complaint—viewed individually or collectively—do not plausibly meet the § 271(b) and pleading standards discussed above. See JA39–44, JA114–127, JA195.

A. Amarin does not argue that Hikma's label suffices to induce infringement.

Amarin does not dispute that Hikma's label is, as the Federal Circuit put it, "skinny enough." Pet.App.13a. Amarin concedes (at 13) that its theory of inducement is "not based solely on Hikma's label," because Hikma's label admittedly "lists only the [non-infringing] SH indication in its 'Indications and Usage section.'" In fact, this was the sole FDA-approved Vascepa indication when Hikma filed its ANDA. Compare BIO.App.14a ¶ 59, with *id.* at 26a ¶ 99.

While Amarin still points to labeling statements to support its claims, those statements tell cardiovascular patients *not* to use Hikma's product: "The label identifies potential side effects for people having cardiovascular disease or diabetes with a risk factor for cardiovascular disease." Resp.Br.13 (citing JA124–125); see also JA116 ("Icosapent ethyl is associated with an increased risk of atrial fibrillation or atrial flutter requiring hospitalization."). This represents the opposite of instructing Amarin's patented uses to reduce cardiovascular risk.

Moreover, a failure to discourage infringement through a "limitation of use" or otherwise is not, as a matter of law, an advertisement or instruction to infringe. See *Cox*, 146 S. Ct. at 968 (citing *Grokster*, 545 U.S. at 939 n.12). And Amarin mistakenly argues (at 13), citing JA116, that Hikma's labeling "references Amarin's REDUCE-IT." It does not.

B. Amarin did not plausibly allege that Hikma's online product catalog actively induced infringement.

Amarin primarily relies instead on Hikma's online product catalog. But, at worst, the accused webpage identifies the "Therapeutic Category" for Hikma's icosapent ethyl product as "Hypertriglyceridemia," which simply means high triglycerides. JA195. This is not an advertisement or instruction for any specific use, much less an infringing one. By analogy, calling a product a "cancer drug" does not promote a specific method of treating a specific cancer—it simply describes a vague therapeutic category.

While Amarin argues (at 3) that this webpage "unambiguously encompasses respondents' patented use," that is quite an overstatement for several reasons.

First, the accused webpage mentions neither patented use. Those uses cover either "reducing occurrence of a cardiovascular event in a hypercholesterolemia patient," JA76, or "reducing risk of cardiovascular death in a subject with established cardiovascular disease," JA180. Because these patent-claim preambles are limiting (see Pet.App.9a n.5), induced infringement requires promotion to administer Hikma's product with "the intentional purpose" of practicing the claimed method. *Jansen* v. *Rexall Sundown, Inc.*, 342

F.3d 1329, 1333 (Fed. Cir. 2003). There is no such promotion.

Second, the accused webpage never mentions "Vascepa" or its CV indication. Critically, Amarin concedes (at 33) that inducement can be avoided by calling the product "'generic icosapent ethyl' without invoking Amarin's well-known brand." Yet, this is precisely how Hikma described its product on the webpage. See JA195 (referring to "Icosapent Ethyl Capsules" without invoking "Vascepa"). Indeed, the only product-use instruction tied to that webpage is in Hikma's non-infringing product label, available via the "Product Insert" link at the bottom of the webpage. *Ibid.* As Amarin admits (at 22 n.5), reference to the "AB" rating on the webpage confirms that Hikma's drug is "therapeutically equivalent for only the labeled [SH] indication." See Pet.App.18a.

The vague reference to "Hypertriglyceridemia" is not plausibly referring to Amarin's CV indication, which is not directed to lowering triglycerides. The only FDA-approved Vascepa indication for treating hypertriglyceridemia ("to reduce TG levels") is the non-infringing indication to treat severe hypertriglyceridemia. JA79. FDA approved Vascepa's CV indication only "to reduce the risk of" specific cardiovascular events, an entirely different use. *Ibid.* Having high triglycerides is just one marker (in addition to having established cardiovascular disease or diabetes mellitus combined with two or more additional risk factors) for the patient population covered by the CV indication. *Ibid.*; see also BIO.App.7a ¶ 32 (explaining FDA determined "lowered triglyceride levels * * * did not show an actual reduction in cardiovascular risk").

Third, the webpage never mentions, much less actively encourages, concurrent statin use—which the CV indication requires (JA79). Amarin ignores this point entirely.

Fourth, the accused webpage contains an express disclaimer, saying "Hikma's generic version is indicated for fewer than all approved indications of the Reference Listed Drug." JA195. This extra step by Hikma to mitigate any infringement dispels any notion that the webpage actively advertises or instructs doctors and patients to use its product for the CV indication. See *Cox*, 146 S. Ct. at 968.

Finally, while Amarin repeatedly characterizes the accused online product catalog as an advertisement, the complaint does not allege that either doctors or patients purchase products from Hikma (they do not) or otherwise have a plausible motive to browse Hikma's online product catalog.

These undisputed, pleaded facts confirm that the accused webpage comes nowhere close to promoting an infringing use. It certainly is not plausible to infer culpable conduct in view of an "obvious alternative explanation." *Iqbal*, 556 U.S. at 681–682. The most natural reading of this webpage lawfully informs potential Hikma customers that generic icosapent ethyl is available for purchase according to its FDA-approved—and non-infringing—indication. Any contrary reading is not plausible.[2]

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[2] Although outside the record, Amarin says (at 23 n.6) that Hikma changed the therapeutic category on the webpage to "*severe* hypertriglyceridemia." If anything, this would further mitigate the risk of infringement, not induce it.

C. Amarin did not plausibly allege that Hikma's press releases actively induced infringement.

1. The two accused *pre-launch* press releases addressing litigation victories also do not plausibly advertise or instruct infringing use. In fact, they do not advertise or instruct any use for Hikma's product.

To be clear, the complaint alleges that only two Hikma press releases from March and September 2000 (JA39–44) induce infringement. BIO.App.31a–32a, 34a. Amarin eschews the subject matter of these press releases—they merely announce Hikma's trial and appellate litigation victories, respectively, in an earlier case invalidating Amarin's patents on the SH indication. JA39–44. Neither press release discusses any use for Hikma's product, much less an infringing one.

Amarin further ignores that both accused press releases predate Hikma's product launch by months. And, as Amarin alleges, both press releases were taken down from the "Newsroom" page of Hikma's website before product launch, meaning they were accessible only if one conducted a targeted website search. BIO.App.31a ¶ 117; BIO.App.32a–33a ¶ 124. Amarin alleges no reason why anyone would do so.

Amarin's gripe with these archived press releases is that they use the phrase "generic version of Vascepa" and cite sales data covering the entire market. But Amarin concedes (at 43) that using the term "generic version" is not enough to induce infringement. And Amarin does not dispute that it used the same phrase—"generic version of Vascepa"—in its own public communication attached to the complaint. JA58. Amarin also makes no serious argument that reciting

sales data advertises or instructs an infringing use. It most certainly does not, and Amarin ignores the "obvious alternative explanation" that sales figures are directed to investors—not to doctors or patients. See *Iqbal*, 556 U.S. at 681–682; U.S.Br.28–29.

Instead, Amarin argues, and convinced the Federal Circuit, that doctors could "read" these press releases as implicitly encouraging them to use Hikma's product just as they use Vascepa, including for its CV indication. Pet.App.19a. The press releases obviously say no such thing.

Promotion that induces infringement cannot plausibly be read into these pre-launch, litigation-related press releases, particularly because they do not even discuss how to use Hikma's product. The vaguely worded phrase "generic version of Vascepa" merely informs investors about the reference-listed drug and, theoretically, could refer to the generic version as labeled (1) solely for the SH indication, (2) solely for the CV indication, or (3) for both indications. The press releases reveal what is by far the most likely interpretation: option (1). This is because the press releases mention only Vascepa's non-infringing SH indication. JA39–44. This "obvious alternative explanation," *Iqbal*, 556 U.S. at 681–682, renders inferences of inducement implausible.

To the extent Amarin is now arguing, for the first time, that any reference to "Vascepa" induces infringement because the CV indication is its predominant use, that argument is not supported by allegations in the complaint, was not raised below, and has thus been waived. Regardless, Amarin's argument requires implausible inferences due to an obvious, alternative

explanation—namely, Vascepa's original, FDA-approved, non-infringing use to treat SH.

2. To be sure, the complaint references two other press releases, one from May 2020 (JA1–2, announcing FDA approval) and a second from November 2020 (JA45–50, announcing the generic-product launch). But the complaint does not allege that either one induces infringement. Instead, both press releases are mentioned solely in the background of the complaint describing the parties. See BIO.App.4a ¶¶ 12–13. Amarin cannot amend its pleading through briefing and, thus, cannot rely on either of these press releases to support its inducement allegations.

Regardless, the May 2020 press release, like the ones discussed above, neither expressly nor implicitly promotes using Hikma's anticipated product for the CV indication or a patented use. JA1–2. Nor is that the plausible implication given that only the non-infringing SH indication is mentioned.

As for the November 2020 press release, it actively *dis*courages infringement. This press release, issued before Amarin filed its complaint, is the only one of the four press releases discussed above readily available on Hikma's website at the time it launched its generic icosapent ethyl product. And it expressly informs the public that Hikma's product is approved solely for the non-infringing SH indication, and for no other Vascepa indication: "Hikma's product is not approved for any other indication for the reference listed drug VASCEPA®." JA45–46. Under no stretch of the imagination does this press release actively induce infringement, likely explaining why Amarin did not make that allegation in its complaint.

Yet, for the first time in its brief (at 24), Amarin now tries to characterize this November 2020 press release as "doubl[ing] down" on inducement. Amarin concedes that "petitioners noted the approved SH indication" and further "mentioned that the generic drug was 'not approved for any other indication for the reference listed drug.'" *Ibid.* Despite this express mitigation step at product launch, Amarin mangles the § 271(b) standard beyond recognition, protesting that Hikma "declined to specifically explain that their product was not approved for Amarin's predominant and patented CV use." *Ibid.*

Amarin's argument goes beyond nitpicking Hikma's disclaimer—it is illogical and, worse, "turns the legal test on its head." *Takeda*, 785 F.3d at 632 n.4. Amarin "needs to show that Hikma took affirmative steps to induce, not affirmative steps to make sure others avoid infringement." *Ibid.* Liability cannot be imposed "merely based on a failure to take affirmative steps to prevent infringement, if the device otherwise was capable of substantial noninfringing uses." *Grokster*, 545 U.S. at 939 n.12.

Amarin's "doubled down" argument extends the "heads I win, tails you lose" logic that pervades its brief. We are told "generic icosapent ethyl" is fine when other generics say it (at 33), but not when Hikma does (see JA195). We are told generics must add disclaimers (at 24), but Hikma's are too generalized or too small (at 32). We are told "AB-rated" refers only to the indication on the generic skinny label (at 22 n.5, Pet.App.20a–21a), but when coming from Hikma, this implies "infringing use" (at 22, 32). There is no rhyme or reason to Amarin's distinctions. Amarin's arguments thus provide a cautionary tale. If the Court

were to affirm, companies would abuse § 271(b) by arguing that any statement—or any omission—suffices to state an inducement claim that requires "the benefit of discovery" and is "not proper for resolution on a motion to dismiss." Pet.App.14a, 18a–19a. That is not, and certainly should not be, the law.

III. Allowing Amarin's complaint to proceed would effectively nullify section viii.

This appeal emphasizes why properly enforcing Rule 12(b)(6) in the Hatch-Waxman section-viii context is so important. Where, as here, a skinny label completely carves out an infringing use, the generic-drug manufacturer does not induce infringement by making vague statements like its product is a "generic version of a branded drug." Apart from the implausibility of such allegations, holding otherwise would render the section-viii pathway meaningless and economically irrational.

As former Congressman Waxman explained in his amicus brief (at 3), section viii "is a particularly important provision" of Hatch-Waxman because it prevents brands from "effectively extend[ing] their patent protection and block[ing] the marketing of a generic for many years by getting approval of one or more patents for a new use * * * as patents on the drug's use or uses expire." See also U.S.Br.31 ("Section viii reflects Congress's judgment that a patent on one use of a drug should not create a de facto monopoly on the drug itself."). Because of the section-viii pathway, "hundreds of generic drugs" have entered "the market sooner, with billions of dollars in savings." AAM.Br.3; see also Public.Citizen.Br.24–25 (in a study between 2015 and 2019, "for drugs whose brand-name manufacturers ha[d] outstanding patents covering only

some of multiple approved uses for the drugs * * * 43% of the generic versions approved" by the FDA "used skinny labels").

The decision below would undermine this important purpose of section viii. Finding plausible inducement based on inferences and speculation from vague product descriptions that encourage no action from direct infringers would unduly muzzle generic-drug manufacturers from selling their skinny-labeled products for unpatented uses and "thus discourage[] them from putting generic drugs into the marketplace in the first place"—the "opposite outcome that Congress intended." Waxman.Br.16. Likewise, imposing a "gotcha" rule that would subject generic-drug manufacturers to liability absent a specifically worded disclaimer to mitigate infringement is not supported by either the statute or precedent. Indeed, "Congress created the section viii pathway against the backdrop of inducement law," Scholars.Br.2, yet did not enact a special rule requiring generic drugmakers to take "affirmative steps to prevent infringement," *Cox*, 146 S. Ct. at 968 (cleaned up).

To be clear, and contrary to strawman arguments by Amarin and its amici, Hikma is not seeking a safe harbor. See Pet.Reply.12. Instead, the problem is that, under "the low bar set by the Federal Circuit," essentially "every skinny label launch could give rise to allegations" of induced infringement. See AAM.Br.25. Absent reversal, branded drug companies would have the green light to sue generic-drug manufacturers selling section-viii products for induced infringement based on the flimsiest of allegations. That result is wrong and requires correction.

Nor, as discussed, is Hikma seeking a special rule for skinny labeling. Indeed, Amarin seeks a new rule, contrary to statute and precedent, that would give it and similarly situated companies an opportunity to abuse § 271(b) by discouraging section-viii carveouts. The Court's admonishment in *Twombly* rings true here: "It is no answer to say that a claim just shy of a plausible entitlement to relief can, if groundless, be weeded out early in the discovery process through 'careful case management.'" 550 U.S. at 559. Many, if not most, generic-drug manufacturers will forgo the section-viii pathway if invoking it could result in an induced-infringement lawsuit and a lost-profits damages claim based solely on vague product descriptions. Even if they might ultimately prevail, the litigation costs alone would deter generic competition if such lawsuits survived pleading challenges.

The amicus brief filed by the Academic Medical Centers, ostensibly supporting Amarin, underscores (at 12) why the Federal Circuit's loose interpretation of § 271(b) in the Rule 12(b)(6) context would spur lawsuits that, under real-world standards, are not needed to prevent induced infringement. Branded pharmaceutical companies do not face any real risk of induced infringement by companies that market generic counterparts, because generic-drug manufacturers do *not* promote their products to doctors and patients: "The real-world dynamics of the generic drug market are clear—*there is no consumer advertising or promotion of the* [*generic*] *drug to physicians or patients*. There is no role of the consumer or physician in the selection of which generic drug will be dispensed by the pharmacy for administration to the patient." Acad.Med. Ctrs.Br.12 (emphasis added). Thus, "[t]he typical acts of inducement for a consumer product, such as

advertising or instructions to consumers, are not relevant in this market." *Ibid.*

As a practical matter, therefore, a company marketing a skinny-labeled generic drug is highly unlikely to induce infringement. Putting aside the litigation risk, there is nothing to gain. The notion that vague statements in press releases or product catalogs are designed to drive doctors to prescribe generics off label for infringing uses ignores market realities. Any such direct infringement would be driven by factors beyond a generic-drug manufacturer's control—such as generic-substitution laws, pharmacy benefit managers (PBMs), or formulary placement.

The decision below thus allows for contrived claims under § 271(b) designed to deter generic-drug competition, not to prevent induced infringement. Such lawsuits do not serve the policies and compromises underlying Hatch-Waxman. While Amarin and some of its amici may believe that Hatch-Waxman's section-viii process leads to direct infringement, Congress considered and rejected those arguments as part of the Hatch-Waxman compromise. See Waxman.Br.6–8; Pet.Br.7–8.

IV. Amarin's other arguments are misguided.

The Court can easily discard Amarin's remaining arguments.

First, Amarin argues that Hikma is presenting arguments forfeited below. Not so. All arguments presented in Hikma's brief and this reply were preserved, and all track the questions presented accepted for review. Section 271(b) requires express conduct sufficient to cause infringement, meaning that no liability attaches unless the indirect infringer communicated to

a direct infringer an express advertisement or instruction to infringe. Regardless of whether generic-substitution laws bar Amarin from proving causation, these laws do not lessen Amarin's burden to plead actively induced infringement. Again, mere "knowledge of infringement and insufficient action to prevent it" is not enough to state a claim. *Cox*, 146 S. Ct. at 969.

Second, Amarin has no basis to seek dismissal of Hikma's petition. The Court granted review to resolve two questions, both of which are addressed directly in the introduction and argument sections of Hikma's merits brief. For example, there can be no denying that Hikma challenges the Federal Circuit's application of the Rule 12(b)(6) standard and argues that the complaint should be dismissed as a matter of law. Compare Resp.Br.47–48 with Pet.Br.29–41. Amarin's criticism that Hikma does not address a circuit split at the merits stage is equally misplaced. Now that certiorari has been granted, the Court reviews the questions presented de novo, regardless of a circuit split.

Finally, the Court should reject Amarin's untimely request for leave to amend its operative complaint. The district court already gave Amarin an opportunity to amend its complaint a second time under Federal Rule of Civil Procedure 15. Pet.App.23a n.1. Amarin not only neglected to file an amended pleading by the court's deadline, it expressly waived its right to amend, representing: "Plaintiffs will not be seeking leave to amend its claims against Hikma." D.Ct. Doc. 123-1 at 4. Amarin also stipulated to a dismissal with prejudice without objection. See D.Ct. Doc. 106 at 2 ("Plaintiffs and Hikma respectfully request that * * * the Court enter final judgment in the form attached to this stipulation to dismiss Plaintiffs' claims against

Hikma with prejudice[.]"); D.Ct. Doc. 106-1 at 2 (proposed final judgment filed by Amarin requesting its claims be "DISMISSED WITH PREJUDICE"). Amarin cites no authority that would allow it to rescind that waiver.

Instead, Amarin improperly suggests (at 16, 19) that evidence outside the record supports a pleading amendment. This argument is both improper and baseless. Despite stressing (at 37) that "a single instance" of infringement suffices, Amarin failed to allege (or identify in discovery) a single direct infringer who even saw the accused press releases or webpage. See D.Ct. Doc. 221 (magistrate judge noting Amarin's "fail[ure] to identify specific health care providers and/or instances of direct infringement").

If the Court reverses the decision below, this will require a new Federal Circuit mandate affirming the district court's dismissal with prejudice. Then, the strict requirements of Rule 60, not Rule 15, would govern any effort by Amarin to reopen this case.

CONCLUSION

The court of appeals' judgment should be reversed, and the district court's order dismissing Amarin's claims with prejudice should be reinstated.

Respectfully submitted.

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