No. 24-889

IN THE

Supreme Court of the United States

HIKMA PHARMACEUTICALS USA INC., ET AL.,
Petitioners,

v.

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

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

BRIEF OF NEW YORK INTELLECTUAL PROPERTY LAW ASSOCIATION AS AMICUS CURIAE IN SUPPORT OF NEITHER PARTY

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INTEREST OF AMICUS CURIAE[1]

The New York Intellectual Property Law Association ("NYIPLA") is a bar association of attorneys who practice in the area of patent, copyright, trademark and other intellectual property ("IP") law. It is one of the largest regional IP bar associations in the United States.

The NYIPLA's members include various attorneys specializing in patent law, including in-house counsel for businesses that own, enforce, and challenge patents, as well as attorneys in private practice who advise a wide array of clients on patent matters and procure issuance of patents through the U.S. Patent & Trademark Office. Members also advise on acquisitions and licensing transactions surrounding IP

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[1] No counsel for a party authored the brief in whole or in part. No party, counsel for a party, or any person other than amicus curiae and their counsel made a monetary contribution intended to fund the preparation or submission of the brief.

The arguments made in this brief were approved by an absolute majority of the officers and members of the NYIPLA's Board of Directors eligible to vote (excluding any officers or directors who did not vote for any reason, including recusal), but do not necessarily reflect the views of a majority of the members of the Association, or of the law or corporate firms with which those members are associated. After reasonable investigation, the NYIPLA believes that no officer or director or member of the Amicus Briefs Committee who voted in favor of filing this brief, nor any attorney associated with any such officer, director or committee member in any law or corporate firm, represents a party to this litigation. Some officers, directors, committee members or associated attorneys may represent entities, including other amici curiae, which have an interest in other matters that may be affected by the outcome of this litigation.

in technologies ranging from healthcare to electronics, from food to the gaming industry. NYIPLA's members represent inventors, entrepreneurs, businesses, universities, and industry and trade associations.

The NYIPLA's members and their clients have a strong interest in this case and regularly participate in patent litigation on behalf of both plaintiffs and defendants in the federal courts and counseling clients regarding intellectual property rights. Thus, NYIPLA brings the informed and balanced perspective of diverse stakeholders on patent issues. The NYIPLA hereby submits its amicus curiae brief in support of neither party.

INTRODUCTION AND SUMMARY OF ARGUMENT[2]

This case presents what should be a straightforward question: Does Plaintiff Amarin Pharma, Inc. plausibly allege that Defendant Hikma Pharmaceuticals USA, Inc. has "induce[d] infringement of a patent," under the provisions of 35 U.S.C. § 271(b). The standard for inducement is well-settled. *See generally Global-Tech Appliances, Inc. v. SEB S.A.*, 563 U.S. 754, 761 (2011). So is the civil pleading standard for bringing such an allegation. *See generally Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 556 (2007). The decision below cited both and questioned neither. Pet. App. 14a-16a.

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[2] We abbreviate Petition for Writ of Certiorari "Pet.," Petition Appendix "Pet. App.," Respondents Brief in Opposition "Amarin Br.," and Certiorari Reply Br. "Reply Br."

Yet both parties in this case have accused the other of seeking some modified pleading standard. Petitioner Hikma's core objection is that the Federal Circuit read Respondent Amarin's complaint too generously, adopting a "very permissive" standard. Pet. 6-8. Amarin, meanwhile, says that "[w]hat [Hikma] really want[s] is a *heightened* pleading standard" in patent litigation involving so-called skinny labels. Amarin Br. 23. Insofar as either party seeks any such standard, one way or the other, this Court should reject the invitation to modify the pleading standard surrounding challenges to skinny label claims. Nothing in this Court's case law or the governing statutory framework warrants a bespoke, technology-specific standard for evaluating an inducement claim. And indeed, there is good reason not to recognize one—reason grounded in statutory text, longstanding precedent, and legal policy.

This Court should reinforce that there is no special or specific standard for inducement, no heightened or permissive pleading standard, and no prescriptive rules about what can or cannot be considered under either standard. There are just the broadly applicable *general standards*—the same inducement standard and the same pleading standard this Court has long embraced. To survive a motion to dismiss, a plaintiff must plausibly allege that the defendant took active steps to induce infringement of plaintiff's patents. This standard, which derives from the common law of aiding and abetting and adheres to *Twombly*, 550 U.S. 544, and *Ashcroft v. Iqbal*, 556 U.S. 662 (2009), has the benefit of providing uniformity and predictability across domains, unaffected by the tech-

nology at issue, while also being flexible enough to respond to differences across contexts and cases. These ordinary rules already provide patent owners and challengers with the stability they need, while allowing courts to adjudicate the varied and unpredictable fact patterns they confront. *Infra* § I. And in this ordinary patent infringement case, the Federal Circuit properly stated these rules. *Infra* § II.

ARGUMENT

I. This Court Should Preserve Ordinary Inducement And Pleading Standards.

A. Inducement is a flexible doctrine that broadly targets affirmative, culpable conduct without restricting the type of activities that can give rise to liability.

While knocking the Federal Circuit for (supposedly) adopting too "permissive" a standard for induced patent infringement (Pet. 6-7), Hikma at times appears to ask for a special standard of its own. According to the Petition, to state a claim of inducement against a generic-drug manufacturer with a skinny label, a plaintiff must plausibly plead that the defendant "instruct[ed]" a third party "to perform the patented use" in its product label. Pet. 3. Hikma disclaims any desire to "create[ ] [a] 'safe harbor,'" Reply Br. 12, but says that "[b]y omitting any instructions in the label that might otherwise encourage physicians to prescribe the drug for patented uses, the generic drugmaker avoids any potential claim for 'actively induc[ing]' infringement under § 271(b)," Pet. 11. According to Hikma, then, its statements outside

of the label—even if those statements encourage physicians to use its product for the patented use—simply do not count.

Amicus NYIPLA takes no position on the circumstances under which the user of a skinny label may be found to have induced infringement, nor whether Amarin successfully states a claim here. But any standard—at the pleading stage or otherwise—that purports to dictate the particular conduct that must be alleged to establish inducement, while excluding other types of conduct from consideration (here all statements outside of the label), marks a significant departure from the existing inducement standard. That standard, which derives from the common law, encompasses a broad range of culpable conduct, and has long been applied consistently and successfully across a variety of legal domains.

The patent infringement statute, 35 U.S.C. § 271, initially enacted in 1952, "was designed to 'codify in statutory form principles of contributory infringement' which had been [by that time] 'part of our law for about 80 years.'" *Global-Tech.*, 563 U.S. at 761 (citation omitted). This version of secondary liability "emerged from common law principles," and encompasses inducing another to infringe, as a form of "accomplice" (or aiding-and-abetting) liability. *Metro-Goldwyn-Mayer Studios Inc. v. Grokster, Ltd.*, 545 U.S. 913, 930 (2005); *Kalem Co. v. Harper Bros.*, 222 U.S. 55, 62 (1911). In this way, inducement liability is not unique to patent infringement. Indeed, this Court often cross-references cases and concepts from patent, copyright, and other legal contexts to set the contours

of secondary liability. *E.g.*, *Grokster*, 545 U.S. at 932; *Global-Tech*, 563 U.S. at 763.

Section 271(b), the provision at issue here, codifies the common law prohibition on inducement by providing that "[w]hoever actively induces infringement of a patent shall be liable as an infringer." 35 U.S.C. § 271(b). The term "induce" is broad—it means to "persuade or influence" someone or to "bring [something] about," *Merriam-Webster Dictionary* 374 (rev. ed. 2022)—and Congress has not seen fit to craft exceptions or corollaries. In this respect, this Court has made clear that "[t]he rule on inducement of infringement as developed in the early cases *is no different today*. Evidence of 'active steps ... taken to encourage direct infringement,' *such as* advertising an infringing use *or* instructing how to engage in an infringing use, show an affirmative intent that the product be used to infringe." *Grokster*, 545 U.S. at 936 (emphases added) (citation omitted) (adopting patent inducement rule in copyright context).

In recent cases applying aiding-and-abetting doctrine in other contexts, this Court has urged courts to avoid "inflexible codes." *Twitter, Inc. v. Taamneh*, 598 U.S. 471, 489, 497 (2023). "[I]ntentional participation [in another's wrong] can come in many forms, including abetting, inducing, encouraging, soliciting, or advising." *Id.* at 490. Courts must have the flexibility to view the nature and quantum of any alleged conduct in light of the degree of the defendant's "scienter," "moving back and forth between all these guideposts" as appropriate. *Id.* at 492. In short, a plaintiff must show that a defendant aided and abetted infringement through *some* knowing and culpable conduct;

the law does not require any *particular* act of encouragement or contribution. And indeed, any number of acts can constitute the requisite culpable conduct under the right set of circumstances.

Those few pages of history reflect volumes of logic. The existing inducement standard is flexible enough to account for differences in circumstances, as it well should be. Activity that might actively encourage infringement in one domain might not rise to the level of encouragement in another. Liability can depend on background norms and industry conventions, the particularities of technology or configurations between parties, shared understandings and expectations, and many other particular vagaries of the case at hand. Thus, for decades, courts have stuck with a commonsense, common law standard, without the need to ratchet the standard up or down to account for differences in factual circumstances, technological subject matter, or even the area of law (e.g., patent versus copyright).

The conventional, adaptable standard for inducement is just as appropriate in the context presented here. Today's skinny label entrants and brand-name innovators operate in a dynamic landscape where online communications, marketing strategies, and digital outreach all play a role in shaping physicians' prescribing behavior, and are constantly changing. It is therefore essential that courts resist the temptation to freeze fact patterns into rigid rules for future disputes.

More broadly, adopting any special rule for inducement in this context would threaten the stability

of the law that patent owners and competitors have come to rely upon. As noted, the inducement standard is not particular to disputes between generics and brand-name companies. It is not even particular to patent law. It is a cross-cutting principle that comes from the common law of accomplice liability and applies to a variety of intellectual property—and indeed, many other—claims. To create special rules for certain categories of cases would fracture the unified framework and undermine the predictability that fuels long-term investment, not just in pharmaceutical breakthroughs, but in all areas of emerging technologies.

B. This Court has consistently rejected bespoke pleading standards as unwarranted and unwise.

Turning to the standards applicable to pleading one's case for inducement, it is similarly unwise to create a bespoke pleading-stage standard unique to a specific industry, technology, or fact pattern. This Court has already recognized that "the precise requirements of a prima facie case can vary depending on the context and were 'never intended to be rigid, mechanized, or ritualistic,'" *Swierkiewicz v. Sorema N. A.*, 534 U.S. 506, 512 (2002) (discussing the standard for employment discrimination) (citation omitted); under this generally flexible standard, this Court should resist any urge to impose a specialized pleading requirement that restricts "the ordinary rules for assessing the sufficiency of a complaint." *Id.* at 511.

The Court has declined such invitations repeatedly. For example, it has "consistently rejected … efforts … to require [at the pleading stage] more information for certain kinds of claims." *Berk v. Choy*, 607 U.S. ___, 2026 WL 135974, at *4 (Jan. 20, 2026) (citing cases). "Rule 8(a)'s simplified pleading standard applies to all civil actions, with limited exceptions," like when a rule or statute specifically raises the threshold. *Swierkiewicz*, 534 U.S. at 513; *see, e.g.*, Fed. R. Civ. P. 9(b) (requiring greater particularity in allegations of fraud or mistake); *Chadbourne & Parke LLP v. Troice*, 571 U.S. 377, 383, 390 (2014) (explaining that Securities Litigation Uniform Standards Act and Private Securities Litigation Reform Act impose heightened pleading standards).

One must recognize that "Congress, as creator of federal statutory claims, has power to prescribe what must be pleaded to state the claim, just as it has power to determine what must be proved to prevail on the merits." *Tellabs, Inc. v. Makor Issues & Rts., Ltd.*, 551 U.S. 308, 327 (2007). Yet, under § 271(b), Congress did not impose any heightened pleading standard. In this situation, the regular pleading rules apply.

As well, in the case of skinny label products, there is no "special problem" for a bespoke pleading standard to solve. In fact, the particular case in front of this Court is quite routine. The product at issue is already on the market, with actual sales and marketing activities having taken place, all as alleged in the complaint. Neither party appears to question that the complaint adequately alleges both direct infringement by physicians and Hikma's scienter for purposes

of an inducement claim. The only issue is whether, in this mix of facts and circumstances, the complaint has also plausibly alleged active steps to induce infringement—which, as explained above, is a question bound up with the nature of the industry, relationships between Hikma and physicians, and degree of Hikma's scienter.

On that question, there is an enormous gulf between requiring a plaintiff to plead that the defendant specifically instructed the performance of the patented use in the label (as Hikma advocates) and allowing a claim to proceed whenever the defendant refers to its skinny-labeled product as a generic (as Hikma incorrectly accuses the Federal Circuit of holding). Neither extreme suggests such a rule. Further, none but the most stylized and bare-bones complaints will present so simple a question anyway.

In this case, as in most cases, the lower court was tasked with evaluating all facts and circumstances to determine whether any acts alleged nudged the plaintiff's allegations of induced infringement from the merely conceivable to the plausible. Every day judges apply *Iqbal* and *Twombly* to assess the sufficiency of all kinds of issues like this. They do so for claims that rely on flexible, common-law-like standards (like inducement), and they do so where parties may also be subject to specialized statutory mechanisms governing particular types of conduct (like skinny labeling). And here specifically, for over forty years, induced infringement cases involving skinny labels have proceeded under the ordinary pleading rules, without causing the disruption Hikma and the Solicitor General fear.

Swinging too far in either direction—too rigid or too lax a standard—would instead unsettle the "balance" Congress struck in the Hatch-Waxman Act "'between … (1) inducing pioneering research and development of new drugs and (2) enabling competitors to bring low-cost, generic copies of those drugs to market.'" *Caraco Pharm. Lab'ys, Ltd. v. Forest Lab'ys, Inc.*, 527 F.3d 1278, 1282 (Fed. Cir. 2008) (citation omitted). A flexible standard that can apply across a range of circumstances—as the existing standard does—would ensure that balance.

II. The Federal Circuit Below Correctly Articulated The Ordinary Inducement Pleading Standard.

The Federal Circuit announced the correct, "run-of-the-mill" standard for pleading inducement, Pet. App.13a; it did not introduce a novel "permissive" approach. *Contra* Pet. 6-7.

For starters, the Federal Circuit explained that, to state a claim for induced infringement, "a patent owner must plausibly allege facts establishing that there has been direct infringement by a third party and that the alleged infringer affirmatively induced that infringement with knowledge that the induced acts constituted patent infringement." Pet. App. 14a-15a; Pet. App. 15a-16a (assessing whether the complaint "plausibly pleads that Hikma 'actively' induced healthcare providers' direct infringement, *i.e.*, that Hikma 'encourage[d], recommend[ed], or promote[d] infringement.'" (quoting *Takeda Pharms. U.S.A., Inc. v. W.-Ward Pharm. Corp.*, 785 F.3d 625, 631 (Fed. Cir.

2015))). In assessing that, the Federal Circuit recognized that it must look to "the allegations of inducement as a whole, not piece-meal." Pet. App. 13a. And so it considered, among other things, allegations about Hikma's marketing statements and strategy. Pet. App. 19a. The court expressly did *not* hold that "a mere statement that [the product] is the 'generic version' of a brand-name drug is enough to be liable for induced infringement." Pet. App. 21a. This flexible, totality of the circumstances approach is just what this Court requires in an inducement case. *See Grokster*, 545 U.S. at 930; *supra* § I.A.

Next, the court applied the correct and generally applicable pleading standard: The Federal Circuit considered "whether the totality of the allegations, taken as true, plausibly plead that Hikma induced infringement." Pet. App. 13a (emphasis omitted). Noting that this "run-of-the-mill induced infringement case" reached the court "at its most nascent stage," that is, a Rule 12(b)(6) motion to dismiss, the court explained that it was "tasked with reviewing *allegations*, not findings, for *plausibility*, not probability." Pet. App. 14a (second emphasis added) (citing *Twombly*, 550 U.S. at 556).

After "[a]ccepting all well-pleaded facts as true and drawing all reasonable inferences in Amarin's favor," the court held that the complaint did plausibly plead induced infringement. Pet. App. 16a. Amicus NYIPLA does not take a position as to whether the Federal Circuit was ultimately correct in this conclusion—that is a fact-bound question this Court can resolve for itself (or let stand, if it chooses). What

matters is that this Court preserve the ordinary, effective, and legally sound standard that has served so many so well for so long.

CONCLUSION

For all these reasons, NYIPLA respectfully urges the Court to reaffirm that courts must apply the generally applicable substantive and pleading standards to all claims of inducement, irrespective of subject matter. The totality of facts and their context must be considered.

Respectfully submitted,

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