No. 24-889

Supreme Court of the United States

HIKMA PHARMACEUTICALS USA INC., ET AL.,
PETITIONERS

v.

AMARIN PHARMA, INC., ET AL.

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

BRIEF OF SHASHANK UPADHYE, AS AMICUS CURIAE IN SUPPORT OF PETITIONERS

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INTEREST OF AMICUS CURIAE[1]

Amicus curiae submits this brief to address an important and recurring question of federal civil procedure: how courts should apply *Twombly* and *Iqbal* to scienter-based liability when the alleged wrongful conduct consists of activity affirmatively authorized by statute.

Amicus is an attorney and scholar who has practiced extensively in pharmaceutical patent and regulatory law under the Hatch-Waxman Act. He has served as chief intellectual property and FDA counsel for pharmaceutical companies, where he was responsible for advising on labeling, regulatory strategy, patent litigation, and compliance matters. He has also practiced in private law firms representing pharmaceutical clients in patent and regulatory disputes. In addition, amicus has written and published extensively on the intersection of pharmaceutical patent law, FDA regulation, and inducement doctrine.

Through both in-house and private practice experience, amicus has observed firsthand the practical and legal significance of inducement allegations premised on lawful Section viii "skinny label" conduct. 21 U.S.C. §355(j)(2)(A)(viii). The pleading standard governing such claims has substantial implications for statutory balance, litigation costs, and the coherence of inducement

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[1] Under this Court's Rule 37.6, amicus states that no counsel for a party authored this brief in whole or in part, that no such counsel or party made a monetary contribution intended to fund the brief's preparation or submission, and that no person other than amicus and its counsel made such a monetary contribution.

doctrine.

Amicus submits this brief to assist the Court in addressing the doctrinal and institutional dimensions of the pleading question presented. Amicus takes no position on the ultimate commercial dispute between the parties.

INTRODUCTION & SUMMARY OF THE ARGUMENT

Induced infringement under 35 U.S.C. §271(b) is not negligence. It is not strict liability. And it is not mere foreseeability. It is a doctrine of purposeful encouragement; liability for intentionally persuading another to engage in unlawful conduct. This Court has repeatedly emphasized that inducement requires specific intent. See *Global-Tech Appliances, Inc. v. SEB S.A.*, 563 U.S. 754, 766 (2011); *Commil USA, LLC v. Cisco Sys., Inc.*, 575 U.S. 632, 642 (2015). And in *Metro-Goldwyn-Mayer Studios Inc. v. Grokster, Ltd.*, 545 U.S. 913, 937 (2005), the Court made clear that inducement requires "purposeful, culpable expression and conduct" directed toward fostering infringement.

This case presents a distinct procedural question: what level of factual specificity is required at the pleading stage when inducement is alleged based on conduct that Congress has affirmatively authorized.

A Section viii Statement under the Hatch-Waxman Act permits a generic manufacturer to seek approval to market a drug for non-patented uses by carving out patented indications from its label. That pathway reflects an express Congressional judgment. Federal Circuit precedent has long recognized that lawful, FDA-approved conduct cannot alone establish

inducement. A skinny label, generic designation, or therapeutic equivalence rating, each contemplated or required by statute and regulation, does not itself demonstrate specific intent to cause infringement.

When lawful conduct cannot supply inducement, plaintiffs must rely on "other factors" to establish the requisite intent. But when intent is the sole element transforming statutorily authorized conduct into alleged wrongdoing, the pleading burden carries unusual institutional significance. Conclusory allegations that lawful labeling or regulatory communications somehow "encouraged" infringement cannot suffice.

This Court's decisions in *Twombly* and *Iqbal* provides the governing framework. *Bell Atlantic Corp. v. Twombly*, 550 U.S. 544 (2007); *Ashcroft v. Iqbal*, 556 U.S. 662 (2009). Those cases did not amend Fed. R. Civ. P. Rule 9(b), but they clarified that Rule 8 does not unlock the doors of discovery for a plaintiff armed with nothing more than conclusions. Plausibility is context-specific. Where the gravamen of liability is specific intent, where the alleged wrongful acts consist of communicative conduct, and where the underlying conduct is otherwise lawful, courts may require particularized factual allegations rendering that intent plausible.

That conclusion follows naturally from *Grokster*. There, inducement liability arose not from neutral instructions or product descriptions, but from an integrated course of conduct designed to foster infringement. The defendants marketed directly to infringing users, provided technical assistance to ensure infringement continued, expressed internally a desire to promote unlawful use, and structured their

enterprise around infringement. The "instructions" in *Grokster* were part of a coordinated master plan to facilitate and encourage infringement.

Transposing *Grokster's* terminology into the Hatch-Waxman context without its demanding factual foundation risks distorting inducement doctrine. If inducement may be inferred from lawful, FDA-approved labeling plus conclusory assertions of intent, then specific intent collapses into foreseeability. That would erode this Court's precedents and undermine the balance Congress struck in Section viii.

Inducement, though not a species of fraud, shares important structural features with fraud-based liability. Both doctrines impose liability for communicative conduct undertaken with specific intent to cause unlawful action by another. Both depend on inferred mental states. Both require a causal link between words and unlawful acts. And both, if loosely pleaded, expose defendants to intrusive discovery and substantial settlement pressure before intent is meaningfully tested. Courts have long exercised caution in such settings.

Requiring particularized factual allegations in this narrow context does not expand Rule 9(b) or create a new categorical pleading rule. It reflects a principled application of Rule 8 as interpreted in *Twombly* and *Iqbal*. Where Congress has declared the underlying conduct lawful, and where liability depends entirely on proving purposeful encouragement beyond that conduct, plausibility demands concrete factual content, not inference built upon inference.

Allowing threadbare inducement allegations to proceed would carry significant institutional costs.

Hatch-Waxman litigation often entails expansive discovery into regulatory strategy, marketing practices, and internal deliberations. Permitting conclusory allegations of intent to unlock that discovery risks creating precisely the in terrorem pressure that *Twombly* sought to prevent. It also risks chilling statutorily authorized generic entry by converting lawful conduct into litigation leverage.

This Court need not adopt a formal Rule 9(b) mandate to address these concerns. It need only clarify that when an inducement claim rests primarily on legal conduct Congress has authorized, the complaint must plead with particularity the objective facts that render specific intent plausible by identifying the acts of encouragement, the audience targeted, the connection to the claimed method, and a plausible causal pathway to infringement.

Such a requirement preserves the integrity of inducement doctrine, respects the Federal Rules, and protects the careful balance Congress enacted in the Hatch-Waxman framework. It ensures that inducement remains what this Court has said it is: liability for purposeful, culpable encouragement, not a vehicle for imposing discovery burdens based on lawful conduct and speculative inference.

ARGUMENT

I. Inducement Requires Purposeful, Culpable Encouragement

Induced infringement under 35 U.S.C. §271(b) is a doctrine of specific intent. It does not impose liability for negligence, strict liability, or mere foreseeability. This Court has made clear that inducement requires knowledge of the underlying patent and purposeful

encouragement of infringement. See, *Global-Tech Appliances, Inc. v. SEB S.A.*, 563 U.S. 754, 766 (2011); *Commil USA, LLC v. Cisco Sys., Inc.*, 575 U.S. 632, 642 (2015).

In *Grokster,* the Court explained that inducement requires "purposeful, culpable expression and conduct" directed toward fostering infringement. *Metro-Goldwyn-Mayer Studios Inc. v. Grokster, Ltd.*, 545 U.S. 913, 937 (2005).

The defendants in *Grokster* built and marketed a file-sharing system whose principal object was the unauthorized distribution of copyrighted works. The system was designed to attract users displaced from Napster. Internal communications expressed a desire to capture infringing traffic. When users encountered obstacles, the defendants provided technical assistance to facilitate continued infringement. They advertised copyrighted music categories, knowing those works were protected. They took no meaningful steps to mitigate infringement. Their revenue model depended on infringing activity. In short, the "instructions" in *Grokster* were not neutral product descriptions; they were part of an integrated strategy to foster copyright violations.

Inducement liability did not arise from stray language or passive knowledge. It arose from conduct whose object was infringement. The "instructions" were not incidental. They were part of a master plan. *Grokster* did not impose liability for neutral instructions or passive knowledge.

Grokster thus establishes a critical principle: inducement requires affirmative, culpable conduct. The presence of language capable of being used in an

infringing manner does not, without more, establish specific intent.

II. Section viii Establishes a Baseline of Lawful Conduct That Cannot Alone Support Inducement

A Section viii Statement under the Hatch-Waxman Act permits a generic manufacturer to seek approval for non-patented uses by carving out patented indications from its label. Such conduct is expressly authorized by Congress and approved by the FDA.

Federal Circuit precedent confirms that inducement cannot be premised solely on lawful conduct. In *Warner-Lambert Co. v. Apotex Corp.*, the court held that lawful marketing and regulatory compliance, even with knowledge that downstream infringement may occur, do not alone establish inducement. *Warner-Lambert Co. v. Apotex Corp.*, 316 F.3d 1348, 1364 (Fed. Cir. 2003).

Likewise, in *Amarin v. Hikma*, the Federal Circuit rejected the notion that inducement may be inferred merely from the existence of a skinny label, generic designation, or therapeutic equivalence rating. *Amarin Pharma, Inc. v. Hikma Pharms. USA Inc.*, 104 F.4th 1370, 1380-81 (Fed. Cir. 2024), cert. granted sub nom. *Hikma Pharms. v. Amarin Pharma, Inc.*, No. 24-889, 2026 WL 120677 (U.S. Jan. 16, 2026).

Each of these features is mandated or contemplated by the Hatch-Waxman framework. Treating them as evidence of inducement would effectively nullify the Section viii pathway.

III. Once Lawful Conduct Is Removed, The "Other Factors" Must Supply Specific Intent

Because lawful Section viii conduct cannot itself establish inducement, any viable claim must rely on "other factors" to demonstrate specific intent. Those factors must supply the element that transforms otherwise lawful activity into alleged wrongdoing.

When intent is the sole element performing that transformation, then pleading discipline becomes essential. Without particularized factual allegations demonstrating purposeful encouragement, conclusory assertions that lawful communications 'encouraged' infringement risk collapsing specific intent into mere foreseeability.

IV. *Twombly* and *Iqbal* Permit Heightened Specificity in This Narrow Context

This Court need not expand Rule 9(b) to address the issue presented. Rule 9(b) formally governs fraud and mistake. But *Twombly* and *Iqbal* make clear that plausibility under Rule 8 is context-specific. See, *Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009); *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 555 (2007).

Under Rule 8 as interpreted in *Twombly* and *Iqbal*, plausibility depends on context. Where liability turns entirely on specific intent, where the underlying conduct is otherwise lawful, and where discovery costs are substantial, courts may require particularized factual allegations sufficient to render that intent plausible. That approach does not amend Rule 9(b) or create a new categorical exception. It reflects the proper application of Rule 8's plausibility standard in a scienter-based context. This is not a case-specific

pleading rule, but a straightforward application of *Twombly* and *Iqbal* to a context in which intent is the sole transforming element.

Inducement, though not a species of fraud, shares structural features with other doctrines grounded in culpable persuasion. Both fraud and inducement impose liability for communicative conduct undertaken with specific intent to cause unlawful action by another. Both hinge on state of mind. Both require a causal nexus between the defendant's communication and the resulting unlawful act, reliance in fraud, infringement in inducement. Neither permits liability based on negligence or mere foreseeability.

In Section viii cases, the alleged inducement often consists entirely of speech: labeling language; regulatory descriptions; or public statements. When liability depends on inferred intent manifested through such communicative conduct, courts have long required concrete factual allegations demonstrating purposeful wrongdoing rather than allowing conclusory assertions of intent to unlock discovery.

The Federal Circuit has imposed comparable rigor in inequitable conduct cases, recognizing that loose allegations of scienter distort patent litigation. See, *Exergen Corp. v. Wal-Mart Stores, Inc.*, 575 F.3d 1312, 1327 (Fed. Cir. 2009). The same concern arises here. Requiring particularized factual allegations in this narrow context does not transform Rule 9(b) into a new mandate. It ensures that scienter-based liability remains tethered to plausible, objective facts commensurate with the seriousness of the charge.

Amicus does not contend that Rule 9(b) categorically governs §271(b). Rather, context-sensitive plausibility under Rule 8 may require particularized factual allegations where specific intent is the gravamen of liability.

V. Institutional Consequences of Permitting Conclusory Inducement Pleading

Allowing threadbare inducement allegations to survive under a minimal pleading standard would carry significant institutional consequences. Hatch-Waxman litigation entails expansive discovery into regulatory strategy, marketing practices, and internal communications.

In these skinny-label cases: (i) the alleged inducement is often neutral, FDA-required labeling; (ii) Congress expressly authorized the Section viii conduct; (iii) the product has lawful uses; and (iv) the alleged "instruction" is often regulatory boilerplate.

Permitting conclusory allegations of intent to unlock that discovery risks creating in terrorem settlement pressure, distorting the statutory balance Congress enacted, and chilling lawful, FDA-approved communications. See, *Bell Atl. Corp.*, 550 U.S. at 557-58.

If inducement can be inferred from lawful labeling plus speculative assertions of intent, specific intent collapses into foreseeability. That result would erode this Court's inducement jurisprudence and undermine the integrity of Section viii.

VI. The Narrow Procedural Rule

The Court need not impose a categorical Rule 9(b) requirement. It need only clarify that when an

inducement claim rests primarily on legal conduct Congress has authorized, the complaint must plead with particularity the objective facts rendering specific intent plausible. Requiring heightened pleading in this narrow context preserves the Hatch-Waxman balance, protects lawful generic entry, and ensures that inducement liability is imposed only where intent, not inference, supports it.

Even under ordinary plausibility principles, inducement requires factual allegations of purposeful encouragement; where lawful Section viii conduct is at issue, plausibility requires particularized factual support. Nothing in this standard prevents inducement claims where concrete facts plausibly show purposeful encouragement beyond lawful regulatory conduct.

Such allegations should identify the specific inducing statements, the audience targeted, how the statements map onto claim limitations, and a plausible causal pathway to infringement. This heightened specificity preserves inducement's doctrinal roots in culpable encouragement while respecting both the Federal Rules and the Hatch-Waxman framework.

CONCLUSION

For the foregoing reasons, the Court should clarify that when an inducement claim rests primarily on conduct Congress has affirmatively authorized, Rule 8 requires particularized factual allegations rendering specific intent plausible, and the judgment of the court of appeals should be reversed.

Respectfully submitted,

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