

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 INTELLECTUAL PROPERTY
OWNERS ASSOCIATION AS *AMICUS CURIAE*
IN SUPPORT OF NEITHER PARTY**

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QUESTIONS PRESENTED

1. When a generic drug label fully carves out a patented use, are allegations that the generic drugmaker calls its product a “generic version” and cites public information about the branded drug (e.g., sales) enough to plead induced infringement of the patented use?

2. Does a complaint state a claim for induced infringement of a patented method if it does not allege any instruction or other statement by the defendant that encourages, or even mentions, the patented use?

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INTEREST OF *AMICUS CURIAE*

Amicus curiae Intellectual Property Owners Association (IPO)¹ represents many of the most innovative companies in the United States. IPO's nearly 200 corporate members develop, manufacture, and sell technology-based products in a wide range of industries. IPO is committed to serving the interests of all intellectual property owners in all industries and all fields of technology.²

IPO's corporate members invest tens of billions of dollars annually on research and development, as well as employ hundreds of thousands of scientists, engineers, and skilled professionals in the United States to develop, produce, and market innovative new products and services. To protect their inventions, IPO's members collectively hold tens of thousands of U.S. patents and account for a substantial portion of the patent applications filed every year at the United States Patent and Trademark Office. Based on their ownership of patents and their prominent positions in marketplaces involving technology, IPO's members appear frequently as parties in federal patent infringement litigation, both as plaintiffs protecting their intellectual property and defendants facing assertions of infringement.

¹ No counsel for any party authored this brief in whole or in part, and no person or entity other than *amicus curiae* made a monetary contribution to the preparation or submission of this brief.

² IPO procedures require approval of positions in briefs by a two-thirds majority of directors present and voting. The list of directors is attached to this brief.

This case presents a question of substantial practical importance to IPO: namely, what standard should be applied in assessing whether a complaint sufficiently pleads a claim for active inducement of patent infringement. IPO submits that all claims of patent infringement, regardless of the particular technology involved, should be assessed based on the totality of well-pled facts alleged in the complaint. IPO contends that this standard agrees with this Court's guidance in *Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009) and *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 556-557 (2007), and provides a fair balance between the interests of plaintiff patent owners and defendants accused of infringement.

SUMMARY OF THE ARGUMENT

IPO submits that the requirements for adequately pleading a claim for active inducement of infringement under 35 U.S.C. § 271(b) should be no different than the standards established by this Court in *Iqbal* and *Twombly*, which apply to all types of federal claims. *See Iqbal*, 556 U.S. at 684. No special, bright-line pleading rules should be implemented for cases involving U.S. Food and Drug Administration ("FDA") approved drugs or 21 U.S.C. § 355(j)(2)(A)(viii) ("Section viii") carveouts ("skinny labels") or, indeed, for any other specific technology. IPO submits that the U.S. Court of Appeals for the Federal Circuit applied this Court's pleading standards under *Iqbal* and *Twombly* to the particular fact pattern of this case. This approach is the legally appropriate framework for assessing the sufficiency of

a complaint alleging active inducement of infringement.³

Specifically, IPO contends that lower courts should review all well-pled facts in determining whether a claim for active induced infringement of a granted U.S. patent has been sufficiently pled under 35 U.S.C. § 271(b). In the context of a pharmaceutical patent, this would include all statements and information included in the FDA-approved drug label, as well as all statements made by the accused infringer in connection with the marketing of the alleged infringing drug product. Such an evaluation of the totality of the circumstances will turn on the particular facts plausibly pled in the complaint, as IPO contends it should.

In response to the first question presented in this case, IPO submits that the overall context of all well-pled factual allegations in a complaint should be taken into account in determining whether a complaint should be dismissed pursuant to Federal Rules of Civil Procedure 8(a) and 12(b)(6). Referring to the facts at issue in this case, a statement by Hikma that its drug is a "generic version" of Amarin's drug, Vascepa[®], standing entirely alone, may not be sufficient to state a claim for inducement. But if, for example, that statement were to follow another statement that Vascepa[®] has been approved for both the infringing cardiovascular (CV) use and the noninfringing severe hypertriglyceridemia (SH) use, the import of Hikma's statement that its drug is a "generic version" of Vascepa[®] changes and may now

³ IPO takes no position concerning any of the other issues, either factual or legal, presented by this matter.

encourage use of Hikma's drug for both noninfringing and infringing uses. The crucial point here is that context matters. Analyzing statements in isolation rather than in the total context of well-pled facts can lead to incorrect conclusions.

In its first Question Presented, Petitioner appears to be advocating for several "bright-line" rules, i.e., that statements by a generic drugmaker calling its product a "generic version" and statements citing public information about the branded drug (e.g., sales), cannot, as a matter of law, constitute evidence of active inducement of patent infringement. IPO submits that the imposition of any special, bright-line pleading rules is inconsistent with this Court's precedent and does not find support in either the Federal Food, Drug, and Cosmetic Act ("FFDCA") or the Patent Act of 1952. The practical effect of these bright-line tests advocated for by Petitioner would permit generic drugmakers to game the carefully balanced system set up by Congress, allowing generic drugmakers to receive FDA approval based on a Section viii carveout while, at the same time, promoting potentially infringing, off-label uses.

As to the second Question Presented, IPO sees it as a tautology. If the totality of well-pled facts in the Complaint does not "encourage" the patented use, then, by definition, there is no inducement. IPO agrees with that proposition, but it merely begs the question. As an example from the facts in this case, Amarin's Complaint quotes statements by Hikma that its drug treats "hypertriglyceridemia," which is alleged to be broad enough to cover both infringing and noninfringing uses. Accepted as true, as is

required at the pleadings stage, this is an example of a well-pled fact that should be considered as part of the totality of circumstances in assessing Hikma's motion to dismiss, even in the absence of any explicit mention of the patented CV indication.

ARGUMENT

I. THE FEDERAL CIRCUIT APPLIED THE CORRECT PLEADING STANDARD.

The District Court granted Hikma's motion to dismiss the Complaint for failing to state a cause of action for active inducement. In an opinion authored by Judge Lourie and joined by Chief Judge Moore and Judge Albright (sitting by designation from the Western District of Texas), the Federal Circuit panel reversed the District Court's dismissal, holding that Amarin's Complaint sufficiently alleges active inducement of the CV treatment claims such that the case can proceed to discovery.

We therefore focus narrowly on the question whether Amarin's complaint plausibly pleads that Hikma 'actively' induced healthcare providers' direct infringement, i.e., that Hikma 'encourage[d], recommend[ed], or promote[d] infringement.' . . . Accepting all well pleaded facts as true and drawing all reasonable inferences in Amarin's favor, we conclude that it does.

....
Though the merits of Amarin's allegations have not yet been tested or proven, we cannot say at this stage that those allegations are not at least plausible.

Amarin Pharma, Inc. v. Hikma Pharms. USA Inc.,
104 F.4th 1370, 1379-1381 (Fed. Cir. 2024).

The analytical framework used by the Federal Circuit comports with the requirements of *Iqbal* and *Twombly* by identifying the narrow question of whether the complaint plausibly pleaded that Hikma actively induced infringement. Under this standard, the Complaint does not need to prove the case at the outset but rather need only plead “enough facts to state a claim to relief that is plausible on its face.” *Twombly* 550 U.S. at 570. This threshold standard is the benchmark “in all civil actions and proceedings in United States district courts,” including those for patent infringement. *Iqbal*, 556 U.S. at 684.

Under *Iqbal* and *Twombly*, pleading sufficiency is a “context-specific task that requires the reviewing court to draw on its judicial experience and common sense.” *Id.* at 679. The line between legal competition and inducement of infringement is often a fine one in the realm of Section viii carveout drug products and induced infringement. The Federal Circuit appropriately drew upon its comprehensive experience and expertise in this realm to determine the plausibility of the pleaded facts, not their probability. Uniformity in federal pleadings is the rule, not the exception. Neither Congress nor this Court has established a heightened bar for induced infringement claims involving “skinny labels.” Thus, the plausibility standard under *Iqbal* and *Twombly* should apply.

II. THERE IS NO STATUTORY BASIS FOR SPECIAL PLEADING STANDARDS FOR SECTION VIII CARVEOUTS AGAINST INDUCED INFRINGEMENT CLAIMS.

There is no statutory or precedential basis for creating a special pleading standard for Section viii carveouts, or any other specific technology.⁴ Thus, IPO contends that the requirements for adequately pleading a claim for active inducement of infringement under § 271(b) should be no different than the standards set by the Supreme Court in *Iqbal* and *Twombly*.

Statutory interpretation supports that lower courts should evaluate the totality of the circumstances pled in a complaint when deciding whether it states a plausible claim for induced infringement by a Section viii drug product. That a generic drug applicant has been approved for a skinny label based on a Section viii carveout should not be the end of the inquiry. The portion of the FDA statute creating skinny labels, 21 U.S.C. § 355(j)(2)(a)(viii), does not include provisions relating to inducement of patent infringement and indeed never refers to 35

⁴ In the same way, IPO believes that there is no need to alter the standards for proving induced or contributory patent infringement under 35 U.S.C. §§ 271 (b) and (c) as set forth in the previous decisions of this Court, such as *Glob.-Tech Appliances, Inc. v. SEB S.A.*, 563 U.S. 754, 766 (2011) (holding that induced infringement under 35 U.S.C. § 271(b) requires knowledge that the induced acts constitute patent infringement and such knowledge can be satisfied by willful blindness) and *Limelight Networks, Inc. v. Akamai Techs., Inc.*, 572 U.S. 915, 921-923 (2014) (holding that liability for induced infringement must be predicated on a finding of direct infringement under 35 U.S.C. § 271).

U.S.C. § 271. In similar fashion, the Patent Act of 1952 does not create any special requirements, pleadings or otherwise, for a claim of active inducement involving a Section viii carveout.

A generic drug applicant's approval for a "skinny label" via a Section viii carveout is a regulatory milestone, not a legal immunity. When dealing with Section viii carveout drug products, the FDA does not itself evaluate induced infringement by the generic drug product. *See, e.g., Caraco Pharm. Labs., Ltd. v. Novo Nordisk A/S*, 566 U.S. 399, 406-407 (2012) (describing that the FDA will not approve a Section viii carveout label if it overlaps with the brand's patent use code, but the FDA "does not independently assess the patent's scope or otherwise look behind the description authored by the brand."). It follows that the reach of 21 U.S.C. § 355(j)(2)(a)(viii) should not extend beyond FDA approval and should not interfere with well-settled patent infringement statutes or this Court's precedents regarding those statutes.

In implementing Section viii carveout protections, Congress could have made clear that obtaining a "skinny label" insulated a generic drug filer from all claims of inducing patent infringement of the indications that were carved out. Primarily, Congress could have added this "safe harbor" language to the Federal Food, Drug, and Cosmetic Act (FFDCA). It did not. Similarly, Congress could have added language to this effect to the Patent Act of 1952. It did not. Finally, if Congress had intended to implement special rules for pleading induced infringement claims by a Section viii generic drugmaker, it would have made those rules explicit in

either of the relevant statutes. It did not. Absent that direction, it is not the role of federal courts to create such immunity on their own.

III. THIS COURT HAS CONSISTENTLY CAUTIONED AGAINST APPLYING SPECIAL, RIGID STANDARDS IN PATENT CASES.

Petitioner argues for the creation of categorical, “bright-line” tests for assessing the sufficiency of pleading inducement in Section viii carveout drug product cases, i.e., that statements by a generic drugmaker calling its product a “generic version” and statements citing public information about the branded drug (e.g., sales), cannot, as a matter of law, constitute evidence of active inducement of patent infringement. IPO submits that such rigid tests are inappropriate at the pleading stage and run counter to this Court’s longstanding jurisprudence.

This Court has repeatedly overturned patent-specific, formalistic tests, favoring instead flexible standards that account for the nuances of each case. Over the past two decades, this Court has struck down several patent specific, rigid tests implemented by the Federal Circuit in the context of infringement, validity, and remedy. *See, e.g., KSR Int’l Co. v. Teleflex Inc.*, 550 U.S. 398, 415 (2007) (holding that the Federal Circuit’s rigid, mandatory application of the “teaching, suggestion, or motivation” (TSM) test was improper where obviousness determinations require a “expansive and flexible approach”); *eBay Inc. v. MercExchange, L.L.C.*, 547 U.S. 388, 391-392 (2006) (overturning the Federal Circuit’s “general rule . . . that a permanent injunction will issue once infringement and validity have been adjudged” and

holding that courts must apply the four-factor equitable test); and *Festo Corp. v. Shoketsu Kinzoku Kogyo Kabushiki Co.*, 535 U.S. 722, 737-738 (2002) (holding prosecution history estoppel is not a “complete bar” to the doctrine of equivalents, but instead creates a rebuttable presumption of surrendered equivalents). Additionally, in *FTC v. Actavis, Inc.*, this Court rejected a rigid immunity for pharmaceutical patent settlements. This Court held that patent-related agreements must be subject to the same “rule of reason” analysis in antitrust claims, similar to any other commercial contract. 570 U.S. 136, 158-160 (2013). By refusing to grant an “exceptional” shield to patent-related transactions, the Court emphasized that patent law does not operate in a vacuum, insulated from general legal principles. *See id.*

This case is no different. Just as this Court has found in other patent cases, the sufficiency of a complaint alleging induced infringement of a Section viii carveout cannot be immune from general legal principles. Thus, whether a Complaint states an actionable claim of induced infringement by a Section viii drug product should be no different and should be analyzed based on the totality of the well-pled facts. In the context of generic drugmakers, determining whether a claim for active inducement has been sufficiently pled should include all statements and information included in the drug label and statements made by the accused infringer in marketing and promotional efforts. Such an evaluation of the totality of the circumstances will turn on the particular facts plausibly pled in the complaint, as it should.

IV. THE PLAUSIBILITY PLEADING STANDARD PRESERVES THE STATUTORY BALANCE BETWEEN GENERIC COMPETITION AND INNOVATION.

The FDCA and Patent Act of 1952, as enacted by Congress, reflect a delicate public policy balance: to facilitate the entry of generic drugs into the marketplace for patient access with the need to encourage continued innovation by branded drugmakers. The existing statutory framework allows a generic drugmaker to carve out patented indications and receive FDA approval for limited indications. A heightened, rigid pleading standard for Section viii carveout drug products would upset this equilibrium, creating an extra-statutory immunity for generic manufacturers. A generic drugmaker who holds a skinny label cannot promote uses of its drug outside of its skinny label. If the generic drugmaker abides by this restriction, IPO agrees that there should be no viable claim for active induced infringement of the carved out, patented indication.

This balance is upset, however, when the generic drugmaker promotes its generic drug for indications beyond its skinny label. It is often monetarily advantageous for generic drugmakers to blur this line and promote uses beyond its limited label, including patented indication(s). Why? Because, as in this matter, the off-label uses often form a substantial portion (or the majority) of the sales of its drug. While such off-label promotion may make sense from a sales perspective, it should subject the generic drugmaker to potential infringement liability. IPO contends that whenever a generic drugmaker crosses the line and encourages the use of its drug for patented

indications, by any means, a valid claim for induced infringement of the patented indication should be allowed to proceed through the discovery process. The plausibility pleading standard serves as the appropriate gatekeeper in these instances. This standard ensures that when a plaintiff provides well-pleaded factual allegations of such plausible promotion, the claim may proceed to discovery to determine the true extent of any inducement.

There are good policy reasons supporting this approach with respect to skinny labels. The patent system is designed to encourage innovation. Incentivizing new uses for existing drugs should be encouraged to help maintain a healthy pipeline of new treatment regimens for patients and physicians. However, if regulatory carveouts are transformed into a shield against induced infringement liability, pharmaceutical innovators will have little incentive to look for, let alone conduct the necessary clinical trials to identify new diseases and conditions that can be safely and efficaciously treated with existing drugs. This would potentially allow generic drugmakers to receive FDA approval for an unpatented indication while simultaneously giving generic drugmakers a free pass to promote its use for the patented indication. Of course, to the extent that an approved FDA label is truly “skinny” and the generic manufacturer does not otherwise encourage infringement of a carved-out indication, it remains clear that an infringement suit against the generic drugmaker for inducement cannot stand.

CONCLUSION

The Federal Circuit's application of the pleading standards dictated by *Iqbal* and *Twombly* does not threaten the Section viii carveout system, it upholds its integrity. Without specific Congressional or precedential direction, IPO respectfully submits that rigid, bright-line tests are inappropriate for assessing the sufficiency of pleadings for active inducement of patent infringement made against all classes of accused infringers, including generic drugmakers. Instead, pleadings should be judged based on the totality of well-pled facts, accepted as true, in accordance with *Iqbal*, *Twombly*, and the Federal Rules of Civil Procedure.

Respectfully submitted,

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