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 THE LICENSING EXECUTIVES SOCIETY (U.S.A. AND CANADA), INC. AS *AMICUS CURIAE* IN SUPPORT OF NEITHER PARTY

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INTEREST OF *AMICUS CURIAE*[1]

The Licensing Executives Society (U.S.A. and Canada), Inc. (LES) is the global leader in the business applications of intellectual property (IP) rights and their management, and it is devoted to standards development, education, and certification. It is an independent, non-profit, professional society that promotes best practices in IP transactions, IP protection, and IP strategy. LES counts among its members lawyers as well as experts in the fields of IP strategy, business management, accounting, business development, supplier management, program management, sales, marketing, and IP valuation. Among these are representatives of innovation-oriented companies from all business sectors, government agencies, and university labs. LES is a community of approximately 2,000 IP management professionals and is part of a worldwide network (LES International or LESI) of about 8,000 IP management practitioners in 32 sister societies.

LES routinely files amicus briefs to offer practical, neutral perspectives on issues that affect licensing certainty, contracting practices, and reliance interests across industries. LES takes no position on the ultimate outcome of this case. Instead, LES participates as *amicus curiae* on behalf of neither party to bring to the Court's attention certain

[1] No counsel for any party has authored this brief in whole or in part, and no person other than the amici or their counsel have made any monetary contribution intended to fund the preparation or submission of this brief.

foreseeable practical effects of potential outcomes of this case upon the innovation ecosystem.

SUMMARY OF ARGUMENT

The outcome of this case will have significant practical implications for the American innovation ecosystem—in the pharmaceutical industry as well as all other industries that rely on patent protection to enable investment in innovative research and development. Inducement law and the pleading standards apply equally to all patent fields. Consequently, the clarification of relevant pleading standards in this case will affect patent owners' rights whenever induced infringement is alleged—not only in "skinny label" disputes.

When the rights granted under a U.S. patent become unpredictable, investment in innovation declines, which in turn reduces research and development. To avoid destabilizing patent rights, and the investments in innovation that they secure, the Court's clarification of the pleading requirements for induced infringement should provide a clear path for both innovators and implementers (*i.e.*, those implementing the innovations of others). Uncertainty will only stunt innovation and the public's access to it.

Additionally, because this case arises in the context of regulatory approval for generic drugs, the Court should reaffirm the clear legislative boundaries between patent liability and regulatory approval.

Under any outcome of this case, clear direction on the pleading requirements will avoid diminishing or destabilizing the innovation ecosystem.

ARGUMENT

I. BACKGROUND

A. Reliable Patent Rights are Essential for Robust Innovation and Investment

This case asks what must be pleaded for a plaintiff to make a plausible allegation of induced infringement, *i.e.*, that the defendant has been "encourag[ing], recommend[ing], or promot[ing] infringement." *Takeda Pharms. U.S.A., Inc. v. West-Ward Pharm. Corp.*, 785 F.3d 625, 631 (Fed. Cir. 2015). The Court will clarify what a patent owner must plead such that the case can proceed to an assessment of induced infringement on the evidence.

The Court's decision will have far-reaching implications for the American innovation ecosystem. Patent owners, licensees, investors, and implementers in all fields will all be affected, as will the public.

Our Constitution expressly gave Congress the power to grant inventors a limited exclusive right to their inventions. U.S. Const., Art. I, § 8, Cl. 8. A federal patent act was among the first laws passed by the first U.S. Congress. The inventor's exclusive right—the right to exclude others from practicing the invention—has been a central tenet of our patent system ever since. Inventors disclose their invention, and the manner of making and using it, to the public in exchange for a limited term of exclusivity. Our nation's patent laws (including this Court's decisions) transcend individual fields of endeavor and apply with equal force to all technological areas.

Patent valuation—including the value of enforcement rights—determines the rational amount of investment in a technology to be patented. Pharmaceuticals and medical devices, for example, require substantial investment in up-front research and development—often billions of dollars. Michael Schlander, et al., *How Much Does It Cost to Research and Develop a New Drug? A Systematic Review and Assessment*, 39 PharmacoEconomics 1243 (August 2021) (pre-launch capitalized costs ranging from $161 million to $4.5 billion in USD as of 2019). The risk and uncertainty inherent in medical research demands that commercialization of successful products must not only cover the costs of researching and developing that product, but must also fund research and development of new, undiscovered therapeutics. *E.g.*, Congressional Budget Office, *Research and Development in the Pharmaceutical Industry* (April 2021)[2] (On average, pharmaceutical companies spent about *one-quarter of their revenues* (net of expenses and buyer rebates) on R&D expenses in 2019[.]" (emphasis added). Many of these products never reach the market. *E.g.*, Chi Heem Wong, et al., *Estimation of clinical trial success rates and related parameters*, 20 Biostatistics 273 (April 2019) (probabilities of success in clinical trials ranging from 3.4% for oncology drugs to 33.4% for infectious disease vaccines).

These high costs of development are only justified by the return on investment—much of which is generated during (and as a result of) patent exclusivity. And these returns support continued or increased investment in new pharmaceutical

[2] https://www.cbo.gov/publication/57126

interventions, whether in the form of new drugs, improved formulations, or new medical uses for known drugs, all of which might lay undiscovered without robust investment in research. *E.g.*, Dominik Jurek, *Patents, innovation, and market entry*, 10 J. Open Innovation: Tech., Market, and Complexity, Article 100246 (2024) ("Patents are positively related to entry and job creation *through the exploration of new technologies*." (emphasis added)).

Entry of follow-on or generic products—whether in the pharmaceutical industry or other markets—provides consumers with additional options. Generic drug products, for example, come to market free of the burden of research and development costs required of market-leading products. They can offer substantially the same product at lower cost to consumers. *E.g.*, Negar Tavasoli Hozouri, et al., *Estimating Cost Savings from New Generic Drug Approvals in 2023* (November 2025)[3] (estimating $18.6 billion in savings during the twelve months following generic-drug approvals in 2023). Although this improves consumer welfare in the short run, when follow-on products invade the field of an inventor's exclusive right, they reduce sales made by the patent owner (or its licensee) of patented products, or of products having uses that are not yet off-patent, thereby reducing returns as well as the incentives for innovators to discover and develop new products and new uses.

[3] https://www.fda.gov/media/189635/download?attachment

B. Induced Infringement's Role in Enforcing Patent Rights

Induced infringement, 35 U.S.C. § 271(b), is cognizable against those who "encourage, recommend, or promote infringement" by others, causing infringement, and with the intent of causing it. *Takeda*, 785 F.3d at 631 (infringement, as well as "'specific intent and action to induce infringement must be proven.'" (quoting *Warner-Lambert Co. v. Apotex Corp.*, 316 F.3d 1348, 1364 (Fed. Cir. 2003)). Whether and how these legal elements are met is generally a question of fact. The Court has recognized the value of "the inducement rule," and applied it to copyright law as well. *Metro-Goldwyn-Mayer Studios, Inc. v. Grokster, Ltd.*, 545 U.S. 913, 936—37 (2005) ("one who distributes a device with the object of promoting its use to infringe copyright, as shown by clear expression or other affirmative steps taken to foster infringement, is liable for the resulting acts of infringement by third parties."). This theory of vicarious liability has long been recognized at common law, and in statute. 35 U.S.C. § 271(b); *see Grokster,* 545 U.S. at 942 (Ginsburg, J., concurring).

Induced infringement is an important tool for the patent owner (or its licensee) in enforcing its rights. This is especially so where the patent claims a method and direct infringement occurs only separately or individually within a large population. In those situations, "it may be impossible to enforce rights in the [patented method] effectively against all direct infringers, the only practical alternative being to go against the distributor[.]" *Grokster*, 545 U.S. at 929–30 (citation omitted).

Although inducement does not occur in every infringement scenario, it remains an important remedy—and, in some cases, the only practical one.

II. Clear, Flexible Pleading Requirements Promote Stable Patent Rights

As already discussed, a patent's value is determined by its predictability, which depends in part on its enforceability. The pleading requirements' application in this case will set the "floor" for asserting cognizable claims of induced infringement. Wherever the Court sets the "floor," its decision will bear on the value of patent rights by setting the minimum requirements for cognizable claims of induced infringement. And because patent rights must be reliable and predictable if they are to drive investment in innovation, pleading requirements must be clear and sufficiently flexible to ensure the ongoing stability of the American innovation ecosystem.

The Court's application of the pleading requirements must be clear, regardless of the substantive outcome. The general pleading standards apply: to survive a motion to dismiss, a complaint must "contain sufficient factual matter, accepted as true, to 'state a claim to relief that is plausible on its face.'" *Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009) (quoting *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 570 (2007)). The pleadings are only disputed as to whether Petitioner "actively" induced infringement. Pet. App.14a–15a (opinion below, noting no dispute as to either Petitioner's intent or that infringement would result from off-label prescriptions for the CV indication). The pleading requirements are disputed in several ways, including (1) whether the facts

pleaded render the legal conclusions plausible, Pet. Br. 32–35; (2) whether induced infringement requires express inducement of each discrete method patent step, Pet. Br. 35–37; and (3) whether Respondent pleaded conduct amounting to "active" inducement, Pet. Br. 38–41. The Court's application of the pleading standards to those questions must be clear for patent rights to be reliably enforced—and thus, for patent rights to remain durable and predictable.

Finally, there is no dispute that inducement of infringement harms patentees and their licensees. If the pleading standards become insurmountable, claims for induced infringement will become foreclosed as a practical matter. Thus, the pleading standards must remain sufficiently flexible for these rights to be meaningfully enforced.

For example, if the Court evaluates the sufficiency of the factual pleadings in supporting inducement as a legal conclusion,[4] *see Iqbal*, 556 U.S. at 679–80 (describing the same two-step approach to evaluating the sufficiency of a complaint), it should explain either (a) why the facts pleaded *are* sufficient, in affirming the decision below, or (b) why "the plaintiffs . . . have not nudged their claims across the line from conceivable to plausible," *Twombly*, 550 U.S. at 570—and what factual pleadings *would be* sufficient to render the claims plausible—in reversing. Regardless of which issue the Court deems dispositive, clear directions on the pleading standards should follow.

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[4] This is simply an example; *amicus* does not advocate for or against any particular outcome, including this one.

The Federal Rules impose no heightened pleading standard here. The pleadings are only disputed as to whether it has been sufficiently alleged that Petitioner "actively" induced infringement. Pet. App.15a. The only claims where "circumstances" must be "state[d] with particularity," Fed. R. Civ. P. 9(b), are "fraud or mistake[.]" Neither are at issue here. Thus, there is no basis for imposing a heightened pleading standard to the disputed elements of the claim. *Leatherman v. Tarrant Cnty. Narcotics Intel. & Coordination Unit*, 507 U.S. 163, 168 (1993) (declining to Rule 9(b)'s heightened standard to matters other than fraud and mistake, citing the interpretive canon "*[e]xpressio unius est exclusio alterius*.").

Indeed, neither party has argued that a heightened pleading standard might apply. But if the Court does impose a heightened standard, it should clarify the basis for and application of that deviation from the baseline requirement that a claim must set forth "'a short and plain statement of the claim[.]'" *Twombly*, 550 U.S. at 555 (quoting Fed. R. Civ. P. 8(a)(2)). A clear, thorough explanation of the pleading standards is necessary for those standards to be applied consistently—that is, consistent with the Court's decision *and* consistent with other lower-court decisions that will follow.

The outcome of this case will have far-reaching implications—for the future of innovation and for the public.

If the Court affirms, permitting enforcement of claims of induced infringement as presented here, patent rights will be seen as more reliable and predictable and, thus, stronger. This will lead to

increased investment in innovation, including the discovery of new drugs and new treatments.

Conversely, if the Court reverses and curtails enforcement of induced infringement claims such as are made here, entry of follow-on (generic) products during the patent term—in pharmaceutical markets and others—will be more likely to occur. And it bears repeating that the outcome of this case will have implications for patent law generally and thus will reach far beyond the pharmaceutical sector. As noted above, the pleading requirements for induced infringement will apply equally to all patents and all industries, from microchips to baseball mitts.

In sum, clear and flexible pleading requirements are possible under any outcome of this case but are not necessary to any. And clear, flexible pleading requirements are imperative to avoid destabilizing patent rights. Therefore, while *amicus* LES does not file in support of either party on the facts presented, LES nonetheless urges the Court to resolve the case by holding for clear and flexible pleading requirements.

III. FDA Approval Concerns Equivalence—Not Patent Law

In addition to the broad issues of pleading discussed above, this case concerns induced infringement by generic drugs approved by the U.S. Food and Drug Administration (FDA). Under the Hatch-Waxman Act, the FDA has responsibility for evaluating proposed generic drugs and their equivalence to already-approved ("listed") drugs. 21 U.S.C. § 355(j)(4) (mandating approval unless certain standards are not met). However, regulatory approval

of drugs does not confer any patent rights or licenses. The Hatch-Waxman Act confers on the FDA no authority with respect to any substantive issue of patent law—and certainly no authority to condone induced infringement.

The FDA maintains the "Orange Book" compilation of patents that cover listed drugs. But entries in the Orange Book are self-submitted by patentees. 21 C.F.R. § 314.53 (submission of patent information). As the FDA itself states, its "patent listing role is ministerial." U.S. Food & Drug Administration, Frequently Asked Questions on Patents and Exclusivity, No. 18.[5] Indeed, scholars have lamented that "FDA has long sought to minimize its responsibility to administer the [Hatch-Waxman Act's] patent provisions[.]" Rebecca S. Eisenberg & Daniel A. Crane, *Patent Punting: How FDA and Antitrust Courts Undermine the Hatch-Waxman Act to Avoid Dealing with Patents*, 21 Mich. Telecomms. & Tech. L. Rev. 197, 199-200. Although the FDA provides some generic drugs with 180-day marketing exclusivity if the generic's sponsor successfully challenges patents listed in the Orange Book, the FDA does not decide those patent disputes—federal courts do. 21 U.S.C. § 355(j)(5)(B)(iv).

Because the FDA has no authority to decide substantive issues of patent law, its approval of a generic drug application and associated labelling *cannot* insulate the generic manufacturer from patent liability. And although the FDA's Office of

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[5] https://www.fda.gov/drugs/development-approval-process-drugs/frequently-asked-questions-patents-and-exclusivity#whenshould

Prescription Drug Promotion oversees and regulates advertising of prescription drugs, neither of the parties has suggested that office reviews statements for compliance with induced infringement laws—nor has the Executive Branch, which filed separate briefs here.

Bearing all that in mind, there is no basis to assert that FDA approval might insulate products or advertising statements from patent-law liability. Courts may consider a broad range of facts in evaluating whether induced infringement has been pleaded, but regulatory approval is not among them. Generic drug manufacturers must comply with our patent laws, just as they must comply with our national tax code and securities laws. FDA review is equally orthogonal to all. The FDA's conclusion that a generic drug is equivalent to a listed drug does not immunize the manufacturer from patent liability. The balance struck by the Hatch-Waxman Act concerns the earlier regulatory approval of generic drugs—not their liability (or lack thereof) under federal patent laws.

Just as the Court's decision in this case should be clear on the pleading issues presented, it should likewise clearly reaffirm that FDA approval is wholly irrelevant to the issue of patent infringement, regardless whether that infringement is direct or indirect (*e.g.*, inducement of infringement). To the extent that the Court's analysis relies on FDA approval in determining the success or failure of the complaint in alleging induced infringement, the Court must be clear about the import of FDA approval, as well as the authority for considering FDA approval in evaluating the sufficiency of a pleading for induced

infringement. That clarity is necessary to provide sufficient guidance to lower courts and to avoid uncertainty for patent holders and generic manufacturers.

IV. CONCLUSION

The outcome of this case will affect patentees' rights against alleged infringers, which, in turn, will affect patent values and investment in the innovation ecosystem. Regardless of the outcome, reliability and predictability of patent rights require clear direction on how the pleading standards apply to induced infringement. And because this case arises in the context of FDA approvals, clarity is also needed regarding any perceived overlap between those approvals and pleading claims for induced infringement. Under any outcome, the Court's decision can bring greater clarity to patent law and enhance innovation.

Respectfully submitted,

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