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 REGENERON PHARMACEUTICALS, INC. AS AMICUS CURIAE IN SUPPORT OF RESPONDENTS

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INTEREST OF AMICUS CURIAE[1]

Regeneron Pharmaceuticals, Inc. is a leading biotechnology company that invents, develops, and commercializes life-transforming medicines for people with serious diseases. It regularly seeks and receives patent protection for its scientific advancements. Regeneron regularly acts as plaintiff and defendant in patent cases. It has a strong interest in having clear, predictable, and uniform pleading standards.[2]

Regeneron believes (i) that the pleading standards of *Twombly* and *Iqbal* work well for patent cases, and (ii) that the Court should not change those clear and uniform rules to create industry-or-technology-specific pleading rules.

SUMMARY OF ARGUMENT

As the law currently stands, a plaintiff can satisfy the pleading standard for induced infringement by pleading facts that plausibly show that all of the elements of induced infringement are satisfied.

In evaluating whether a plaintiff has met that burden, a court will look at *all* the alleged facts. No

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

[2] Regeneron takes no position on respondents' pleading. Regeneron's view is that the Federal Circuit applied the law correctly and that the Court should not impose any technology-specific pleading rules and that courts should instead consider all factual allegations in evaluating a motion to dismiss.

facts are excluded from the analysis, and no specific facts or words need be recited.

The position urged by petitioners would change this *status quo*. Under the petitioners' approach, *some* facts (e.g., "general" marketing statements) would not be considered in determining whether a defendant either *intended* to cause or *actually* did cause infringement. More specifically, statements outside the product label would be excluded from the analysis, along with any alleged facts about the *context—i.e.* how the defendant's marketing statements were understood by the people to whom they were directed.

At the same time, petitioners' position would *require* a plaintiff to plead certain "magic words"—namely it would require a plaintiff to allege that the defendant expressly called for a specific, patented use of its product.

Regeneron urges the Court to refrain from either (i) excluding certain kinds of factual allegations from the analysis or (ii) requiring a plaintiff to plead that a defendant has expressly mentioned the patented use. Instead, the Court should use this case to reaffirm the basic standard of *Twombly* and *Iqbal*—that the only question at the motion to dismiss stage is whether the *totality* of the facts alleged give rise to a *plausible* showing that the elements of the asserted claim are met.

This framework is important. Among other things, it provides a clear, neutral standard and the flexibility that lower courts need to adequately address both technological evolution and the messy fact

patterns that arise in the real world. Moving away from this standard and towards a rule-based system with specialized requirements and exceptions for certain technologies would undermine the neutrality and the flexibility of the current system.

It would also encourage gamesmanship. Imagine, for example, if the Court were to adopt petitioners' position that a defendant *cannot* be sued for inducing infringement based on marketing statements. As the Court knows, inducement requires a defendant to both (i) *actually* cause a third party to infringe and (ii) *intend* to cause that third party to infringe. Should it really be the case that a defendant that both *intends* to and *succeeds* in causing infringement gets a pass because the mechanism through which it acted was a marketing statement? Petitioners apparently think so. Regeneron does not.

ARGUMENT

I. *Twombly* And *Iqbal* Supply A Neutral, Workable Pleading Standard.

This Court's decisions in *Twombly* and *Iqbal* together enunciate the standard for evaluating a motion to dismiss in civil litigation, regardless of the area of law or claims asserted. In *Twombly*, the Court established the "plausibility standard" governing motions to dismiss under Federal Rule of Civil Procedure 12(b)(6). *Bell Atlantic Corp. v. Twombly*, 550 U.S. 544, 560 (2007). Applying that standard, a court assesses whether a complaint survives a motion to dismiss by reviewing whether "*all* the allegations in the complaint," if taken as true, are sufficient "to raise a right

to relief above the speculative level," i.e., to establish "plausible grounds" for relief, excluding only bare "'legal conclusion[s] couched as … factual allegation[s].'" *Id.* at 555-56 (emphasis added). This standard reflects Federal Rule of Civil Procedure 8(a)'s requirement that a complaint include "'a short and plain statement of the claim showing that the pleader is entitled to relief.'" *Id.* at 555.

In *Iqbal*, the Court emphasized that *Twombly* provided "the pleading standard for 'all civil actions.'" *Ashcroft v. Iqbal*, 556 U.S. 662, 684 (2009). In other words, aside from a few special pleading provisions specifically enumerated in the Federal Rules, *see infra* 7-8, the *Twombly/Iqbal* standard "controls in every case, regardless of its size, complexity, or the number of parties that may be involved." 5 *Wright & Miller's Federal Practice & Procedure* § 1221 (4th ed.)

Twombly, *Iqbal*, and the Federal Rules of Civil Procedure provide a uniform civil-pleading standard for good reason. This approach supplies a flexible standard that keeps the Federal Court system open without constant Congressional intervention. Put differently, both the *kinds* of problems and the *fact patterns* that the Federal Courts must address change over time. Nothing in the pleading standard permits a court to ignore the factual allegations in determining whether a plaintiff has established "plausible grounds" for relief. *Twombly*, 550 U.S. at 556. To the contrary, *Iqbal*, just like *Twombly*, makes clear that a court may only disregard improper legal conclusions. 556 U.S. at 678. "When there are well-pleaded factual allegations, a court should assume their veracity and

then determine whether they plausibly give rise to an entitlement to relief." *Id.* at 679.

In this case the Federal Circuit *did* look at all the facts and analyzed whether (taken together) they stated a plausible claim—exactly as *Twombly and Iqbal* require. *See, e.g.*, Pet. App. 13a-15a, 18a-19a, 21a-22a.

For example, the court observed that the patent owner's claims did not "rest *solely* on allegations that the generic manufacturer's proposed label is 'not skinny enough,' such that the label alone induces infringement." Pet. App. 13a; *see also* Pet. App. 17a. Rather, because the "alleged infringement" here was "based on the generic manufacturer's skinny label *as well as* its public statements and marketing of its already-approved generic product," Pet. App. 13a, the court assessed the respondents' factual allegations regarding "Hikma's public statements and marketing materials," Pet. App. 17a-18a. In doing so, the court deemed it "at least plausible that a physician could read" some of these public statements as encouraging doctors to prescribe Hikma's product for *all* approved uses, including off-label, patent-protected uses. Pet. App. 18a-19a.

In sum, consistent with the *Twombly/Iqbal* standard, the Federal Circuit emphasized that its conclusion was based on its assessment of the totality of the factual allegations in the complaint. *See* Pet. App. 17a-18a. The Federal Circuit therefore used the correct standard. *See* Pet. App. 14a (reciting *Twombly* plausibility standard).

II. Petitioners' Arguments Would Undermine *Twombly* And *Iqbal* By Creating Heightened Pleading Rules For Certain Induced-Infringement Claims.

Section 271(b) of the Patent Act provides that "[w]hoever actively induces infringement of a patent shall be liable as an infringer." 35 U.S.C. § 271(b). To state a claim for induced infringement, a plaintiff must allege that (i) direct infringement occurred, and (ii) the defendant both intended to and *did* something to induce that infringement. *See Limelight Networks, Inc. v. Akamai Techs., Inc.*, 572 U.S. 915, 922 (2014); *MGM Studios Inc. v. Grokster, Ltd.*, 545 U.S. 913, 936-37 (2005). Thus, under *Twombly* and *Iqbal*, a plaintiff must allege facts which, taken together, create a plausible showing that someone infringed, and that the defendant actively encouraged that infringement.

In this case, the plaintiff made that showing by relying (in part) on statements the defendant allegedly made in its marketing materials. While none of these statements explicitly mentioned the patented use, the complaint alleged that they were both intended to encourage and did *in fact* encourage doctors to prescribe the defendant's drug for the patented methods of treatment. *See, e.g.*, BIO App. 29a-34a, 37a-38a. And the Federal Circuit agreed that, in context, it was plausible that they did.

According to petitioners, however, the Court should not accept this perfectly ordinary line of inference. Instead, petitioners apparently believe there should be special rules that require a plaintiff to

allege that the defendant explicitly "mention[ed]" the patented indications or provided "instructions" for someone to practice them. Petrs' Br. 22.

It is a matter of common sense and ordinary communication that exhorting someone to do something *general* can, in context, encourage them to do something specific. For instance, if a company that sells nails says that its product can be used in place of screws, it is plausible that the company both intends to encourage and actively did encourage carpenters to use its nails to secure boards to a deck, even if it did not call out that specific use. The Court's caselaw on induced infringement accordingly has long recognized that broad messaging may, in context, impermissibly channel users towards specific infringing uses. *See, e.g.*, *Glob.-Tech Appliances, Inc. v. SEB S.A.*, 563 U.S. 754, 758-59 (2011). There is no reason to create a technology-specific exception to that principle.

To be sure, there are "limited exceptions" where the Federal Rules of Civil Procedure call for a heightened pleading standard. *Swierkiewicz v. Sorema N.A.*, 534 U.S. 506, 513 (2002). For instance, Federal Rule of Civil Procedure 9(b) creates a heightened pleading standard for fraud claims, requiring greater "particularity" in alleging the "circumstances constituting fraud."

But no such rule applies to this case. And heightened pleading rules may be prescribed only by amending the Federal Rules, not by judicial fiat. Accordingly, the Court has "consistently rejected" lower court efforts "[t]o protect defendants from th[e] burden" of discovery by "tr[ying] to require more

information for certain kinds of claims" at the pleading stage. *See Berk v. Choy*, 607 U.S. __, 2026 WL 135974, at *4 (Jan. 20, 2026).

Because the FRCP do not impose a heightened pleading standard on inducement claims, the inquiry should be the one this Court articulated in *Twombly* and *Iqbal*—whether the facts, taken together, plausibly allege the required claim elements. The Court should not adopt a special rule *specific to this context* or more generally that categorically disregards certain facts and inferences (e.g., that a general exhortation encourages specific conduct) or that requires a particular fact to be plead (e.g., that a defendant expressly called out a patented use in its communications).

III. Adopting Special Pleading Rules Would Be Inconsistent With Patent Protections.

Creating a technology-specific pleading rule would also be contrary to the technology-neutral structure of the Patent Act and the United States' international commitments. Patent law in the United States has long "accord[ed] the same treatment to all forms of invention." *Eolas Techs. Inc. v. Microsoft Corp.*, 399 F.3d 1325, 1339 (Fed. Cir. 2005). The Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS) likewise requires signatories to commit to making "patents … available and patent rights enjoyable without discrimination as to the place of invention[] [and] the field of technology." TRIPS Agreement, Part II, Section 5 (1994).

Commentators have explained that technology-neutral rules allow the patent system to adapt to new technologies without constant statutory revision and preserve coherence across fields. *See* Mark D. Janis, Comment, *Equilibrium in a Technology-Specific Patent System*, 54 Case W. L. Rev. 743, 744 (2004), https://perma.cc/UL33-TDN9. "[A] regime of near-infinite specificity" presents courts with "an insurmountable number of boundaries to police" while litigants face overwhelming uncertainty. *Id.* at 746.

A heightened pleading rule crafted for a subset of induced-infringement cases would undermine that neutrality. It would cause arguments over whether other industries warrant similar treatment. And it would incentivize ancillary litigation about how to categorize the subject matter in question, with litigants fighting to get into the technology-specific regime that appears most favorable to their position. *See id.* at 745.

Most troublingly, petitioners' rule would also risk under-protecting entire classes of inventions in fields where inducement is the only viable theory of enforcement. If a complaint must allege that the accused inducer specifically directed users to practice the patented method, inducement claims become enforceable only against defendants who are candid enough to put the infringing instructions in writing. That turns the current *standard* into a *rule* that could be avoided through gamesmanship.

Indeed, were petitioners' pleading standard adopted, a defendant could avoid inducing infringement by couching its instructions in general

language, perhaps accompanied by a wink and a nudge. That would work, because (again, under petitioners' position) courts would not be allowed to consider the wink or the nudge, as they would no longer look at the totality of the factual allegations.

CONCLUSION

Regeneron urges the Court to affirm that the ordinary pleading rules apply to induced-infringement claims and to decline any invitation to adopt technology-specific pleading rules.

Respectfully submitted,

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