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 *AMICUS CURIAE* AMERICAN INTELLECTUAL PROPERTY LAW ASSOCIATION IN SUPPORT OF AFFIRMANCE

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TABLE OF CONTENTS

INTEREST OF *AMICUS CURIAE*.....1

SUMMARY OF ARGUMENT.....2

ARGUMENT 4

I. With the enactment of § 271(b), Congress codified liability for those who induce others to infringe a patent.....4

II. The § 271(b) inducement inquiry requires a totality-of-circumstances analysis. 7

A. A wide range of conduct can satisfy the "affirmative steps" element of inducement.....7

B. The "affirmative steps" inquiry considers all facts and circumstances.....9

III. The Hatch-Waxman Act does not exempt "skinny label" entrants from liability for induced infringement.....13

IV. The Court should neither change the pleading standard nor adopt a categorical exemption from § 271(b) for section viii entrants.....16

A. The *Iqbal/Twombly* pleading standard provides appropriate flexibility for evaluating an inducement claim. 16

B. The Federal Circuit correctly applied the pleading standard to Amarin's inducement claim. 21

C. The Federal Circuit's decision does not "effectively nullify" the section viii regulatory pathway established by Congress. 23

D. Any categorical decision to exempt section viii entrants from induced infringement liability is for Congress, not the Court. 25

CONCLUSION 26

TABLE OF AUTHORITIES

Cases **Page(s)**

ArthroCare Corp. v. Smith & Nephew, Inc.,
406 F.3d 1365 (Fed. Cir. 2005) 9

Ashcroft v. Iqbal,
556 U.S. 662 (2009)..... 2-4, 16-18, 20

Astornet Techs. Inc. v. BAE Sys., Inc.,
802 F.3d 1271 (Fed. Cir. 2015) 7

Bell Atl. Corp. v. Twombly,
550 U.S. 544 (2007).....2-4, 16-18, 20, 23

In re Bill of Lading,
681 F.3d 1323 (Fed. Cir. 2012) 18

Caraco Pharm. Labs., Ltd. v. Novo Nordisk A/S,
566 U.S. 399 (2012).....14, 15

Carbice Corp. of Am. v. Am. Patents Dev. Corp.,
283 U.S. 27 (1931).....6

Cleveland Clinic Foundation v. True Health Diagnostics LLC,
859 F.3d 1352 (Fed. Cir. 2017) 19, 22, 23

Ericsson, Inc. v. D-Link Sys., Inc.,
773 F.3d 1201 (Fed. Cir. 2014) 9

Global-Tech Appliances, Inc. v. SEB S.A.,
563 U.S. 754 (2011) 7

Globus Med., Inc. v. Alphatec Spine, Inc.,
No. 25-cv-1522, 2025 U.S. Dist. LEXIS
253834 (S.D. Cal. Dec. 3, 2025) 19

Jazz Pharms., Inc. v. Avadel CNS Pharms., LLC,
136 F.4th 1075 (Fed. Cir. 2025) 14, 15

Lifetime Indus., Inc. v. Trim-Lok, Inc.,
869 F.3d 1372 (Fed. Cir. 2017) 18

Liquid Dynamics Corp. v. Vaughan Co., Inc.,
449 F.3d 1209 (Fed. Cir. 2006) 9

Mercoid Corp. v. Mid-Continent Investment Co.,
320 U.S. 661 (1944) 6

Mercoid Corp. v. Minneapolis-Honeywell Regulator Co.,
320 U.S. 680 (1944) 6

Metabolite Labs., Inc. v. Lab. Corp. of Am. Holdings,
370 F.3d 1354 (Fed. Cir. 2004) 8

Metro-Goldwyn-Mayer Studios Inc. v. Grokster, Ltd.,
545 U.S. 913 (2005) 8, 11, 12, 17

Morton Salt Co. v. G. S. Suppiger Co.,
314 U.S. 488 (1942) 6

Nalco Co. v. Chem-Mod, LLC,
883 F.3d 1337 (Fed. Cir. 2018) 18

Power Integrations, Inc. v. Fairchild Semiconductor Int'l, Inc.,
843 F.3d 1315 (Fed. Cir. 2016) 7, 10, 11, 17

Takeda Pharms. U.S.A., Inc. v. W.-Ward Pharm. Corp.,
785 F.3d 625 (Fed. Cir. 2015) 24

Thomson-Houston Elec. Co. v. Kelsey Elec. Ry. Specialty Co.,
75 F. 1005 (2d Cir. 1896) 8

Wallace v. Holmes,
29 F. Cas. 74 (C.C.D. Conn. 1871) 5

Westinghouse Elec. & Mfg. Co. v. Precise Mfg. Corp.,
11 F.2d 209 (2d Cir. 1926) 5, 8

Statutes

21 U.S.C. § 355(b)(1)(A)(viii) 14

§ 355(j) 14

§ 355(j)(2)(A)(vii)(IV) 14, 21

§ 355(j)(2)(A)(viii) ..2-4, 15, 16, 20, 21, 23-25

35 U.S.C. § 271 8

§ 271(b) 2-4, 7, 8, 11, 16, 20, 23, 24

§ 271(c) 4, 7

§ 271(e)(1) 23

§ 271(e)(2)(A) 14, 15

§ 271(f)(1) 9

Drug Price Competition and Patent Term Restoration Act of 1984 ("Hatch-Waxman Act"), Pub. L. No. 98-417, 98 Stat. 1585 ..... 2, 4, 13-16, 20, 24

Federal Food, Drug, and Cosmetic Act ("FDCA"), 21 U.S.C. § 301 *et seq.*, ... 13

Legislative Materials

H. R. Rep. No. 82-1923 (1952) 7

Skinny Labels, Big Savings Act, H.R. 6485, 119th Cong. (2025). 25

Skinny Labels, Big Savings Act, S. 43, 119th Cong. (2025). 25

Other Authorities

21 C.F.R. § 314.53(c)(2)(ii)(P)(3) 14, 15

68 Fed. Reg. 36,676 (June 18, 2003) 15

Charles W. Adams, *A Brief History of Indirect Liability for Patent Infringement,* 22 Santa Clara High Tech. L.J. 369 (2005) 5, 6, 8

Mark A. Lemley, *Inducing Patent Infringement,* 39 U.C. Davis L. Rev. 225 (2005) 5, 12, 13

Giles S. Rich, *Infringement under Section 271 of the Patent Act of 1952,* 35 J. Pat. Off. Soc'y 476 (1953) 5, 6

INTEREST OF *AMICUS CURIAE*

The American Intellectual Property Law Association ("AIPLA") is a national bar association representing the interests of approximately 6,500 members engaged in private and corporate practice, government service, and academia. AIPLA's members represent a diverse spectrum of individuals, companies, and institutions involved directly or indirectly in the practice of patent, trade secret, trademark, and copyright law, as well as other fields of law relating to intellectual property. Our members represent both owners and users of intellectual property.[1]

AIPLA's mission includes providing courts with objective analyses to promote an intellectual property system that stimulates and rewards invention, creativity, and investment while accommodating the public's interest in healthy competition, reasonable costs, and basic fairness. AIPLA has no stake in either of the parties to this litigation or in the result of this case. AIPLA's only interest is in seeking correct and consistent interpretation of the law as it relates to intellectual property issues.

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

SUMMARY OF ARGUMENT

This case presents the question of what a patentee must plead to state a claim for induced infringement by a generic manufacturer with a skinny label. Under this Court's decisions in *Iqbal* and *Twombly,* a complaint must plead facts that allow the court to draw the reasonable inference that the defendant is liable for the alleged inducement.

35 U.S.C. § 271(b) conditions liability on "actively" inducing infringement by another, meaning that inducement requires the taking of affirmative steps to promote infringement of a patent. A wide range of conduct can satisfy this requirement, including advertising an infringing use and providing instructions for infringement, as well as distributing promotional materials and publishing technical literature that encourage direct infringement. The inquiry into whether particular conduct constitutes an active step (or steps) to encourage infringement is necessarily context-specific and fact-intensive. It further requires courts to evaluate the totality of a defendant's conduct rather than examining each act in isolation. Acts that might appear insignificant or benign individually may, when considered together, demonstrate a coordinated effort to encourage infringement.

Congress enacted § 271(b) to ensure robust protection for patent holders against indirect infringers who facilitated and profited from the infringement of their patents. Section 271(b) provides protection against induced infringement regardless of technology field. And while the Hatch-Waxman Act created the section viii pathway permitting generic

manufacturers to omit patented methods of use from their labels, it did not create an exemption to § 271(b) for "skinny label" manufacturers that would exempt them from liability for induced infringement or otherwise disturb that doctrine. FDA's approval of a skinny label is not a determination of non-infringement. Section 271(b) remains fully applicable to the section viii entrant who risks liability if it engages in conduct encouraging use beyond its approved label where such use is covered by another's patent.

There is no basis for this Court to read special protections into inducement law for section viii entrants as Hikma proposes. Section 271(b) is not only industry-agnostic, but also flexible. Adopting a categorical rule that excludes certain public statements made on a generic drug company's website, such as in press releases, from qualifying as evidence of inducement would fracture the uniformity of inducement law, create a technology-specific safe harbor that Congress has not authorized, and invite other industries to seek similar exemptions from liability under § 271(b).

The Federal Circuit correctly declined to adopt a categorical rule excluding certain types of evidence from the inducement inquiry at the pleading stage.[2]

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[2] AIPLA takes no position on the ultimate question of liability in this case. AIPLA's interest is solely in urging this Court to apply the *Iqbal/Twombly* pleading standard and inducement law uniformly, evaluating the allegations under the established totality-of-circumstances framework without creating industry-specific categorical exclusions.

The court applied the *Iqbal/Twombly* standard to evaluate the sufficiency of Amarin's amended complaint. It accepted the well-pleaded facts as true, drew all reasonable inferences in favor of Amarin, and found that Amarin plausibly pled that Hikma's label and public statements, taken together, actively induced healthcare providers' direct infringement.

Contrary to the arguments of Hikma and its amici, this Court's affirmance will not "effectively nullify" the section viii pathway for generic approval. Section viii applicants are free to market their products in a manner consistent with (but not broader than) their approved use, as Congress contemplated in the Hatch-Waxman Act. Whether more incentives are needed to increase the viability of section viii "skinny labels"—either now or in the future—is a policy decision for Congress, not the courts.

ARGUMENT

I. With the enactment of § 271(b), Congress codified liability for those who induce others to infringe a patent.

Congress codified the doctrine of indirect infringement in the Patent Act of 1952, recognizing two forms of liability. Section 271(b) addresses inducement; it provides that "[w]hoever actively induces infringement of a patent shall be liable as an infringer." Section 271(c) prohibits contributory infringement—that is, the sale of components of a patented product that constitute a material part of the invention and are known to be especially made for use in the infringement. 35 U.S.C. § 271(c).

Although the statutory provisions for indirect infringement were not enacted until 1952, the underlying doctrine originates from the common law of torts which has "long punished not only tortfeasors but also those who aid and abet the commission of a tort". Mark A. Lemley, *Inducing Patent Infringement*, 39 U.C. Davis L. Rev. 225, 227 (2005). The earliest patent cases addressing conduct now recognized as inducement treated such conduct not as a separate offense, but as evidence supporting the then-requisite intent element for contributory infringement. *Id.* Where a defendant sold a component that had no use outside the patented invention, courts readily inferred intent to cause infringement. *See Wallace v. Holmes*, 29 F. Cas. 74, 79-80 (C.C.D. Conn. 1871); *see also* Giles S. Rich, *Infringement Under Section 271 of the Patent Act of 1952*, 35 J. Pat. Off. Soc'y 476, 482 (1953); Charles W. Adams, *A Brief History of Indirect Liability for Patent Infringement*, 22 Santa Clara High Tech. L.J. 369, 371-72 (2005). The analysis was more complex when a defendant sold a product capable of both infringing and non-infringing uses. *See* Lemley, *supra*, at 227. In such circumstances, courts sought evidence of intent to promote infringement, for example, by advertising the product for use in a patented combination or teaching the direct infringer how to infringe. *See, e.g., Westinghouse Elec. & Mfg. Co. v. Precise Mfg. Corp.,* 11 F.2d 209, 210-12 (2d Cir. 1926); Adams, *supra*, at 375.

By the mid-twentieth century, some patentees had exploited that contributory infringement doctrine to extend their patent monopolies beyond the scope of their inventions through tying arrangements that

required purchasers of patented products to also buy unpatented goods.[3] By 1944, this Court's *Mercoid* decisions dramatically expanded the patent misuse doctrine, holding that any attempt to control the market for unpatented goods constituted misuse—even if those goods had no use outside the patented invention. *Mercoid Corp. v. Mid-Continent Investment Co.,* 320 U.S. 661 (1944); *Mercoid Corp. v. Minneapolis-Honeywell Regulator Co.,* 320 U.S. 680 (1944); *see also* Adams, *supra*, at 382-84. The Court acknowledged that its ruling would "limit substantially the doctrine of contributory infringement," but declined to specify "[w]hat residuum may be left." *Mercoid,* 320 U.S. at 669. This cryptic pronouncement led to confusion for practitioners and the lower courts.

Congress recognized that the judicial expansion of the patent misuse doctrine had swung the pendulum too far away from protecting legitimate patent rights, effectively eviscerating liability for indirect infringement and leaving patentees without meaningful recourse against parties who facilitated and profited from the infringement of their patents. *See* Rich, *supra*, at 485-89. Concerned that this near

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[3] If a purchaser bought unpatented goods from a competitor, the purchaser's use of the patented device became unauthorized, which in turn exposed the competing supplier to liability for contributory infringement. Adams, *supra*, at 376-84. In response, this Court developed the defense of patent misuse to bar patentees from leveraging their patents to monopolize unpatented materials. *See Carbice Corp. of Am. v. Am. Patents Dev. Corp.,* 283 U.S. 27 (1931); *Morton Salt Co. v. G. S. Suppiger Co.,* 314 U.S. 488 (1942).

elimination of contributory infringement liability had critically weakened patent rights, Congress acted to restore the balance by "codify[ing] . . . principles of contributory infringement" that had developed over the preceding eight decades through its enactment of § 271(b) and (c). *See* H. R. Rep. No. 82-1923, at 9 (1952).

II. The § 271(b) inducement inquiry requires a totality-of-circumstances analysis.

A. A wide range of conduct can satisfy the "affirmative steps" element of inducement.

Section 271(b) expressly requires that a defendant "actively" induce infringement in order to be liable for another's direct infringement of a patent. This Court has observed that the addition of the adverb "actively" to the text of § 271(b) "suggests that [] inducement must involve the taking of affirmative steps to bring about the desired result." *Global-Tech Appliances, Inc. v. SEB S.A.*, 563 U.S. 754, 760 (2011). The Federal Circuit has long taken a consistent approach: "[t]o prove inducement of infringement, the patentee must []show that the accused inducer took an affirmative act to encourage infringement with the knowledge that the induced acts constitute patent infringement." *Power Integrations, Inc. v. Fairchild Semiconductor Int'l, Inc.,* 843 F.3d 1315, 1332 (Fed. Cir. 2016) (quoting *Astornet Techs. Inc. v. BAE Sys., Inc.*, 802 F.3d 1271, 1279 (Fed. Cir. 2015)).

The affirmative steps requirement ensures that inducement liability attaches only to those who take deliberate action to encourage infringement. Advertising an infringing use or providing

instructions for infringement are classic examples of conduct long recognized as probative of the affirmative encouragement required for inducement. *See, e.g., Westinghouse,* 11 F.2d at 210*; Thomson-Houston Elec. Co. v. Kelsey Elec. Ry. Specialty Co.,* 75 F. 1005, 1007–08 (2d Cir. 1896). This Court's 2005 decision in *Grokster* recognized that principle in the copyright context, pointing to "advertising an infringing use or instructing how to engage in an infringing use" as "[e]vidence of active steps taken to encourage direct infringement." *Metro-Goldwyn-Mayer Studios Inc. v. Grokster, Ltd.,* 545 U.S. 913, 936 (2005).

While traditional advertising and instructions are illustrative of the conduct that can satisfy the affirmative steps requirement, they are not the only conduct that can do so. As Judge Giles S. Rich wisely foresaw at the time of § 271(b)'s enactment, "[a]n infinite variety of promotional activities calculated to result in infringement to a greater or less degree, can be envisaged." Rich, *supra*, at 497.[4] Courts applying the inducement doctrine have accordingly found a wide range of conduct probative of affirmative encouragement.

For example, in *Metabolite Labs., Inc. v. Lab. Corp. of Am. Holdings*, 370 F.3d 1354, 1365 (Fed. Cir. 2004), the Federal Circuit upheld an inducement verdict where the defendant published educational

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[4] Judge Rich played an important role on the committee of the Patent Law Association of New York that initially drafted the bill that became 35 U.S.C. § 271. Adams, *supra*, at 384.

articles and a directory of the laboratory tests it offered to the physicians who ordered such tests, which together specifically promoted the infringing use of the patented method by instructing physicians on how to interpret the test results. In *ArthroCare Corp. v. Smith & Nephew, Inc.*, 406 F.3d 1365, 1377 (Fed. Cir. 2005), the court affirmed inducement based on sales literature and instruction manuals that directed surgeons to use the accused surgical probes in the precise manner covered by the patented method.

As yet another example, in *Ericsson, Inc. v. D-Link Sys., Inc.*, 773 F.3d 1201, 1220, 1222 (Fed. Cir. 2014), the court affirmed the jury's finding of induced infringement where the defendants advertised their products' compliance with a WiFi standard that practiced the patented methods, thereby encouraging customers to use the products in an infringing manner. And in *Liquid Dynamics Corp. v. Vaughan Co., Inc.*, 449 F.3d 1209, 1223 (Fed. Cir. 2006), the court affirmed the jury's finding of induced infringement under 35 U.S.C. § 271(f)(1). The court held that there was circumstantial evidence of inducement where the defendant distributed an engineering manual to its customers that was replete with examples of tank installations similar to the patented design, supporting the inference that the defendant intended its buyers to install systems that practice the patented invention outside the U.S.

B. The "affirmative steps" inquiry considers all facts and circumstances.

Whether a given act promotes an infringing use cannot be resolved in the abstract. The inquiry is

inherently fact-bound, requiring careful examination of the context surrounding the alleged inducing conduct. Courts must therefore evaluate each case on its own facts, assessing the nature, content, and likely effect of the defendant's affirmative actions and communications in light of the surrounding circumstances.

The Federal Circuit has consistently held that inducement must be evaluated based on the totality of a defendant's conduct, not by examining each act in isolation, including in the oft-cited *Power Integrations,* 843 F.3d 1315. In that case, Power Integrations accused Fairchild of inducing third parties to import controller chips into the United States that practiced Power Integrations' patents. In evaluating whether substantial evidence could support an inducement verdict, the court considered multiple affirmative acts by Fairchild: (1) designing its controller chips to meet U.S. energy standards; (2) competing for business it knew was directed to the U.S.; (3) providing demonstration boards containing the infringing controller chips to customers in the U.S.; (4) maintaining a website that enabled customers to locate a U.S.-based distributor that sold Fairchild's infringing controller chips; (5) maintaining a technical support center in the U.S. that provided support for the infringing chips to customers in the U.S.; and (6) having standard terms and conditions that indemnified customers against claims for infringement of U.S. patents. *Id.* at 1333-34.

The *Power Integrations* court explained that "[w]hile each piece of evidence may not individually be sufficient to establish [the defendant's] liability…the

evidence as a whole provided the jury substantial evidence upon which to find inducement." *Id.* at 1334. This holistic approach recognizes that context matters—acts that might appear benign in isolation may, when considered together, demonstrate a coordinated effort to encourage infringement.

This longstanding approach to inducement under § 271(b) is consistent with this Court's unanimous 2005 decision in *Grokster*. Although *Grokster* arose in the copyright context, this Court expressly grounded its inducement analysis in patent law. *Grokster*, 545 U.S. at 936-37. It held that "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." *Id.* at 919. The conduct that the Court relied on to support liability in *Grokster* was informed by the circumstances surrounding the alleged inducement, most notably the shutdown of Napster, an earlier peer-to-peer file sharing service that had facilitated massive copyright infringement by enabling users to share copyrighted music files freely over the internet. The affirmative steps identified in *Grokster* included the naming of defendants' systems as "Swaptor" and "OpenNap"—wordplays on "Napster" and file swapping, which the Court found to be evidence of affirmative encouragement to former Napster users to infringe on the new systems. *Id.* at 937-38. The Court also pointed to Grokster's distribution of a newsletter containing links to articles promoting its software's ability to access popular copyrighted music, and defendants' affirmative responses to user requests for

help locating and playing copyrighted materials. *Id.* at 924-27, 937-38.

In addition to the advertising and instructing conduct detailed above, the Court stated that the record was "replete with other evidence that [defendants]…acted with a purpose to cause copyright violations by use of software suitable for illegal use." *Id.* at 938. For example, the Court relied on the fact that defendant "StreamCast's internal documents made constant reference to Napster," revealing a deliberate strategy to capture the market of former Napster users. *Id.* at 939. The Court also found it significant that neither defendant attempted to develop filtering tools or other mechanisms to diminish infringing activity. *Id.* And the Court noted that defendants' advertising-based revenue model depended on high-volume infringing use, confirming that the "commercial sense of their enterprise turns on high-volume use, which the record shows is infringing." *Id.* at 940. The Court emphasized that this business-model evidence "alone would not justify an inference of unlawful intent, but viewed in the context of the entire record its import is clear." *Id.* at 939-40. Thus, the Court's analysis of liability turned on a holistic assessment of evidence of intent, including defendants' outward-facing affirmative steps to promote infringement and other evidence of intent revealed through discovery.[5]

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[5] Professor Lemley has posited that rather than creating "a single category of forbidden acts or a proper level of intent" the elements should be understood to "interact": "[t]he more significant the defendant's conduct, the less intent should be

This totality-of-circumstances approach makes eminent sense: an accused inducer may engage in numerous acts and communications, including over a period of time. Those acts and communications must be considered as a whole to determine whether the accused party was knowingly and actively encouraging conduct that practices the patented use.

III. The Hatch-Waxman Act does not exempt "skinny label" entrants from liability for induced infringement.

Hikma argues that when a generic drug label fully carves out a patented use, allegations that the generic drug maker calls its product a "generic version" and cites public information about the branded drug (e.g., sales) cannot be enough to plead induced infringement of the patented use as a matter of law. Pet. Br. at 29. However, in creating the regulatory pathway for generic drugs, the Drug Price Competition and Patent Term Restoration Act of 1984, Pub. L. No. 98-417, 98 Stat. 1585 (the "Hatch-Waxman Act") left unchanged the law of inducement and the courts' role in adjudicating patent rights.

The Hatch-Waxman Act amended both the Federal Food, Drug, and Cosmetic Act ("FDCA"), 21 U.S.C. § 301 *et seq.*, and the Patent Act to balance

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required for liability," and conversely, "[t]he clearer the defendant's intent to facilitate patent infringement, the less direct his contribution need be." Lemley, *supra*, at 242-44. At the same time, the law correctly maintains minimum thresholds for each element: the defendant must take some affirmative act, and must possess some level of intent.

facilitating generic drug entry and ensuring that the Patent Act continues to incentivize the innovation of new medicines. It created the Abbreviated New Drug Application ("ANDA") pathway for the approval of generic drugs, through which a "bioequivalent" drug can rely upon the safety and efficacy data of an approved drug. *See* Pub. L. No. 98-417 § 101, codified at 21 U.S.C. § 355(j). As part of this regulatory framework, FDA maintains an official register called the Orange Book that lists approved drugs, the regulatory exclusivities to which they may be entitled, and any patents covering those drugs.[6]

If the Orange Book includes unexpired patents for the approved drug, a generic manufacturer has two options. One option is a paragraph IV certification, where the ANDA applicant certifies that its marketing of the generic product will not infringe the listed patent or that the patent is invalid. 21 U.S.C. § 355(j)(2)(A)(vii)(IV). The Hatch-Waxman Act's amendments to the Patent Act make the filing of a paragraph IV certification an act of "artificial" infringement under § 271(e)(2)(A), establishing a specific litigation process for the branded manufacturer to pursue patent infringement claims prior to the generic's approval. *See Jazz Pharms., Inc.*

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[6] The Orange Book lists the patent number, expiration date, and, for method-of-use patents, a short description known as a "use code" for each patent that the unlicensed manufacture, sale, or use of a listed drug could reasonably infringe. This information is provided to FDA by branded manufacturers as part of the new drug approval process. 21 U.S.C. § 355(b)(1)(A)(viii); 21 C.F.R. § 314.53(c)(2)(ii)(P)(3); *Caraco Pharm. Labs., Ltd. v. Novo Nordisk A/S*, 566 U.S. 399, 405 (2012).

v. Avadel CNS Pharms., LLC, 136 F.4th 1075, 1086 (Fed. Cir. 2025). This procedure reflects "[a] fundamental assumption" about the Hatch-Waxman Act: "that the courts are the appropriate mechanism for the resolution of disputes about the scope and validity of patents." 68 Fed. Reg. 36,676, 36,683 (June 18, 2003).

Alternatively, where there are method-of-use patents listed, the generic manufacturer may make a section viii statement to certify that it is not seeking approval for any patented method of use. *See* 21 U.S.C. § 355(j)(2)(A)(viii); *Caraco*, 566 U.S. at 406. If approved, the generic manufacturer may market its drug "only for a subset of approved uses—*i.e.,* those not covered by the brand's patents." *Id.* FDA does not make a determination as to whether the proposed skinny label infringes the unexpired method-of-use claims. It considers only whether the contents of that label overlap with the listed method-of-use patent's use code—a short description of the claimed use which is submitted by the branded manufacturer. 21 C.F.R. § 314.53(c)(2)(ii)(P)(3); *Caraco*, 566 U.S. at 406-407. FDA "does not independently assess the patent's scope or otherwise look behind the description authored by the brand" because "it lacks 'both [the] expertise and [the] authority' to review patent claims." *Caraco*, 566 U.S. at 406-407 (quoting 68 Fed. Reg. at 36,683).

In addition to the creation of an artificial act of infringement to allow for pre-launch patent litigation in § 271(e)(2)(A), the Hatch-Waxman Act amended other provisions of the Patent Act. For example, it created a "safe harbor" exemption from patent

infringement for activities reasonably related to developing and submitting information to FDA. Pub. L. No. 98-417 § 202. However, the Hatch-Waxman Act did not amend the induced infringement provision codified by the 1952 Patent Act. Section 271(b) remains fully applicable. Accordingly, a section viii entrant risks liability for inducing infringement if it engages in conduct encouraging the use of the reference-listed drug's patented methods.

IV. The Court should neither change the pleading standard nor adopt a categorical exemption from § 271(b) for section viii entrants.

Hikma asks this Court to adopt a categorical rule excluding certain types of statements, such as references to its product as a "generic version" of the branded drug and public information about the drug (including sales information), from qualifying as evidence of inducement when the accused inducer is a section viii entrant. *See* Pet. Br. at 3. This Court should reject that invitation. A rigid rule that categorically excludes particular types of evidence of section viii entrants' actions would fracture the uniformity of inducement law and create technology-specific safe harbors that Congress has not authorized and that the inducement doctrine does not recognize.

A. The *Iqbal/Twombly* pleading standard provides appropriate flexibility for evaluating an inducement claim.

This Court and the Federal Circuit have consistently held that the inducement inquiry is contextual and fact-intensive, requiring courts to evaluate the totality of a defendant's conduct and

other evidence of intent. *See Grokster,* 545 U.S. at 937-40; *Power Integrations,* 843 F.3d at 1334. Accordingly, the line between actionable encouragement and lawful commercial activity is often difficult to draw without a developed factual record, including the full context within which the alleged conduct has occurred.

The conventional *Iqbal/Twombly* pleading standard provides the appropriate threshold for making the determination of whether an inducement claim may proceed past the pleading stage and into discovery. *See Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009); *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 570 (2007). A complaint satisfies this standard when it pleads enough "factual content that allows the court to draw the reasonable inference that the defendant is liable for the misconduct alleged" but not when it offers only "[t]hreadbare recitals of the elements of a cause of action, supported by mere conclusory statements." *Iqbal*, 556 U.S. at 678 (citing *Twombly*, 550 U.S. at 555-56). In short, the complaint must "state a claim to relief that is plausible on its face." *Twombly*, 550 U.S. at 570. Critically, this plausibility standard must not be conflated with the ultimate standard for liability. The plausibility inquiry "is not akin to a 'probability requirement,'" *Iqbal*, 556 U.S. at 678 (quoting *Twombly*, 550 U.S. at 556); rather, "a well-pleaded complaint may proceed even if it strikes a savvy judge that actual proof of those facts is improbable." *Twombly*, 550 U.S. at 556. The question is simply whether the complaint pleads enough facts to raise a reasonable expectation that discovery will reveal evidence of the misconduct alleged. *Id.*

Applied to induced infringement, the *Iqbal/Twombly* framework requires facts plausibly showing that the accused infringer "specifically intended [another party] to infringe [the patent] and knew that the [other party]'s acts constituted infringement." *Lifetime Indus., Inc. v. Trim-Lok, Inc.*, 869 F.3d 1372, 1379 (Fed. Cir. 2017) (quoting *In re Bill of Lading*, 681 F.3d 1323, 1339 (Fed. Cir. 2012)). Where concrete allegations support the required inferences, courts have denied motions to dismiss. For example, where the plaintiff alleged that the defendants advertised their products' ability to perform functions closely mirroring the steps of the patented method (and did so after receiving cease-and-desist letters making them aware of the patent), the Federal Circuit reversed the dismissal of inducement claims. *In re Bill of Lading*, 681 F.3d at 1341. Likewise, in *Lifetime Industries*, the court found inducement adequately pled where the plaintiff alleged that former employees with knowledge of the patent had joined the defendant shortly before the allegedly infringing conduct, and the defendant thereafter directed the installation of an identical product to perform the patented method. 869 F.3d at 1379–80. And in *Nalco Co. v. Chem-Mod, LLC*, 883 F.3d 1337, 1355–56 (Fed. Cir. 2018), the court reversed dismissal of inducement claims where it was pled that the defendants provided instructions, support, and technical assistance to downstream customers with knowledge of the patent and specific intent to induce practice of the patented method.

The *Iqbal/Twombly* standard thus permits plaintiffs who allege specific affirmative acts, knowledge, and intent to proceed to discovery, where

the factual record may be developed to support the allegations, while screening out complaints resting on bare awareness and speculation. For example, where the patentee alleged that a diagnostic laboratory's test reports would lead physicians to administer a lipid-lowering treatment covered by the patent, the complaint was properly dismissed because it alleged "no facts that suggest any connection between [the defendant] and doctors that may prescribe lipid lowering drugs," and thus the patentee fell "short of showing 'specific intent and action' on behalf of [the defendant-laboratory] to induce infringement." *Cleveland Clinic Foundation v. True Health Diagnostics LLC*, 859 F.3d 1352, 1364 (Fed. Cir. 2017). Similarly, the court dismissed induced infringement claims where the complaint recited that the defendant published surgical techniques, conducted training courses, and engaged in marketing activities—but failed to identify the specific content of those materials or explain how they encouraged infringement. *Globus Med., Inc. v. Alphatec Spine, Inc.*, No. 25-cv-1522, 2025 U.S. Dist. LEXIS 253834, *9-10 (S.D. Cal. Dec. 3, 2025).

Hikma argues that "Amarin cannot cobble together disparate documents intended for different audiences—i.e. Hikma's label, pre-launch press releases, and website—to infer instructions that the documents never actually make." Pet. Br. at 37. This reductive approach flies in the face of the totality-of-circumstances analysis that considers the context of the alleged affirmative acts including any norms, practices, and terms of art familiar to alleged direct infringers. It would also require courts to make fact-intensive determinations at the pleading stage about

the intent and effect of communications to an alleged direct infringer.

Nothing in the Patent Act, the Hatch-Waxman Act, or this Court's precedent supports the proposition that plaintiffs alleging inducement in pharmaceutical cases must surmount a higher hurdle for pleading an inducement claim under § 271(b) than patent plaintiffs in any other inducement case. Yet if this Court were to adopt Hikma's proposed categorical rule and hold that press releases, equivalence statements, or reference to a branded drug's total sales figures are categorically irrelevant to a section viii inducement claim, branded pharmaceutical litigants would face a more demanding set of pleading standards than litigants in other technology sectors.

Hikma's proposed rule about section viii inducement cases would also invite requests for courts to create policy-driven exemptions from inducement liability in other sectors to purportedly advance policy goals over § 271(b)'s express statutory prohibition. This could result in a judicially created patchwork of industry-specific safe harbors that would incentivize gamesmanship; parties could then carefully craft their communications to encourage infringing acts through exempted communications, thereby exploiting those safe harbors.

The *Iqbal/Twombly* pleading standard provides appropriate flexibility for evaluating an inducement claim. The need for flexibility, rather than categorical exclusions, is underscored by the reality that the channels through which companies communicate with customers, end users, and the public are continually evolving. Product instructions, specifications, and

labeling are no longer confined to physical packaging; they are published on company websites, where potential users routinely consult them. Press releases and other communications detailing new products circulate instantly online. A wide range of promotional content reaches professionals and consumers through various social media platforms. A categorical rule that treats only certain types of statements as relevant would inevitably fail to account for the diverse and evolving ways in which companies may signal to potential direct infringers that a product is suitable for patented uses. The inducement inquiry must remain flexible enough to encompass the full spectrum of modern communications and promotional activity through which encouragement to infringe may be conveyed.

B. The Federal Circuit correctly applied the pleading standard to Amarin's inducement claim.

This case is a standard induced infringement case directed to a product that is being promoted and marketed. As the Federal Circuit noted, it is not a paragraph IV litigation triggered by an artificial act of infringement. Nor is it a section viii case in which the patent owner's inducement claim rests solely on allegations that the proposed label is not "skinny enough" such that the label alone induces infringement. App. at 12a-13a. Rather, Amarin's inducement claim is based "on the label ***in combination*** with Hikma's public statements and marketing materials" including those that describe its product as the "generic equivalent" of Amarin's Vascepa and within the "therapeutic category" of

"hypertriglyceridemia," a category that includes patented and non-patented indications. App. 17a-18a (emphasis added). The Federal Circuit properly considered the product label as part of its totality-of-circumstances analysis because the label provides necessary context for understanding a manufacturer's public statements and marketing materials.

While the court noted that, in isolation, the statements on Hikma's label may not, as a matter of law, actively induce infringement, it reasoned that "many of the allegations depend on what Hikma's label and public statements would communicate to physicians and the marketplace." *Id.* at 18a-19a. The court emphasized that this "is a question of fact—not law—and is therefore not proper for resolution on a motion to dismiss." *Id.* On such a motion, Amarin's allegations regarding what those statements communicate, and reasonable inferences supported by those allegations, must be accepted as true. *Id.* The Federal Circuit correctly concluded that, when considered as a whole, Amarin's allegations "at least plausibly state a claim for induced infringement." *Id.* at 18a.

This case is readily distinguishable from the Federal Circuit's decision in *Cleveland Clinic*, 859 F.3d 1352. That case involved a method of treatment claim directed to administering a lipid-lowering agent to a patient based on elevated levels of myeloperoxidase (MPO) mass and/or activity. The Federal Circuit affirmed the grant of a motion to dismiss where the only alleged affirmative act to induce physicians to infringe the method claim was defendant's provision of MPO mass and/or activity

test results to physicians. It was undisputed that the accused inducer did not sell or prescribe lipid-lowering agents to patients, and plaintiff alleged no facts suggesting any communication or connection between the accused inducer and physicians other than the provision of the test results. *Id.* at 1364.

To be clear, as this Court has stated, plausibility is not probability. *See Twombly*, 550 U.S. at 556 ("Asking for plausible grounds…does not impose a probability requirement at the pleading stage; it simply calls for enough fact to raise a reasonable expectation that discovery will reveal evidence of illegal agreement."). Amarin may not ultimately prevail at trial, or even survive summary judgment based on the record evidence developed in discovery, but its claim is adequately pled under the law and should move forward.

C. The Federal Circuit's decision does not "effectively nullify" the section viii regulatory pathway established by Congress.

Assertions that the Federal Circuit's decision will eviscerate the section viii pathway for generic drug entry are unfounded. Pet. Br. at 41. Congress's creation of the section viii pathway eliminated a regulatory hurdle for a generic drug product, but that pathway is not and has never been entirely free from the risk of inducement liability.

The constraints of § 271(b) remain in place and apply to section viii entrants. When Congress wants to do so, it knows how to establish an exemption to infringement—as the § 271(e)(1) safe harbor provision

in the Hatch-Waxman Act evidences. It did not create any exemption to the induced infringement doctrine for section viii entrants.

At the same time, § 271(b) does not impose liability merely because a manufacturer markets a product under a skinny label. Section viii entrants who exercise care in marketing their products in a manner consistent with their approved indications and who do not take affirmative steps to encourage patented uses remain free from inducement liability.

The Federal Circuit's decision in this case does not "force" generic drug companies to take affirmative steps to avoid liability for inducement, but they could choose to do so. Historically, companies across sectors seeking to minimize the risk of induced infringement claims may decide to include statements in their press releases, instruction manuals, or statements on their websites that their product is not intended for certain uses. However, the choice not to do so does not render them per se liable for inducing infringement of patented uses of their product. *See Takeda Pharms. U.S.A., Inc. v. W.-Ward Pharm. Corp.*, 785 F.3d 625, 632 n.4 (Fed. Cir. 2015). Rather, the pleading standard will continue to protect section viii entrants against unfounded claims by screening out baseless complaints while permitting plaintiffs who allege specific affirmative acts, knowledge, and intent to proceed to discovery.

D. Any categorical decision to exempt section viii entrants from induced infringement liability is for Congress, not the Court.

While Congress may have understood that off-label infringing uses would result from skinny label approvals, *see* Pet. Br. at 43, it nevertheless made the policy determination to create the section viii pathway to enable access to generic drugs for unpatented uses without delay. But Congress did not authorize section viii entrants to engage in inducing conduct, nor did it create a per se exemption from induced infringement liability for those entrants. Rather, it left in place the law of inducement codified in the 1952 Patent Act so that section viii entrants do not encourage off-label infringing uses that undercut patent rights. The Court should respect Congress's policy choice.

If significant adverse impacts on section viii generic manufacturers materialize from the application of existing inducement law, it is for Congress—not this Court—to address those consequences. Indeed, companion bills proposing certain exemptions from induced infringement liability for section viii entrants have already been introduced. Skinny Labels, Big Savings Act, S. 43 & H.R. 6485, 119th Cong. (2025). The creation of exemptions from infringement is fundamentally a policy choice for Congress.

CONCLUSION

For the foregoing reasons, the decision of the court of appeals should be affirmed.

Respectfully submitted,

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