No. 24-889

IN THE

Supreme Court of the United States

HIKMA PHARMACEUTICALS USA INC.
AND HIKMA PHARMACEUTICALS PLC,

Petitioners,

v.

AMARIN PHARMA, INC., AMARIN PHARMACEUTICALS
IRELAND LTD., AND MOCHIDA PHARMACEUTICAL CO., LTD.,

Respondents.

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

BRIEF OF 76 SCHOLARS OF LAW, BUSINESS, ECONOMICS, AND MEDICINE AS *AMICI CURIAE* IN SUPPORT OF PETITIONERS

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INTEREST OF *AMICI CURIAE*

Amici curiae[1] are scholars of law, business, economics, and medicine, listed in Appendix A. Their interest is in the proper development of patent law in ways that best promote access to innovation and the public interest.

SUMMARY OF ARGUMENT

I. For a century and a half, the doctrine of inducement of patent infringement has required an act that is specific, unambiguous, and affirmative. Conduct that (1) does not specifically encourage infringement, (2) is ambiguous as to infringing or noninfringing behavior, or (3) is an omission has long been insufficient for patent inducement liability.

In this case, the Federal Circuit disregarded these principles. The court held that inducement liability could arise based on speculative inferences from general marketing statements and mandatory drug labeling text—statements that bore no specificity to the patented methods of use at issue. That holding followed the court's 2021 decision in *GlaxoSmithKline LLC v. Teva Pharmaceuticals USA*, which also expanded patent inducement beyond its historic bounds.

Such expansion is not just wrong on the law—it threatens the statutory scheme for generic drug competition, the innovation economy, the patent system's foundational principles, and patient health and welfare. This Court should return inducement law to its well-established roots.

[1]Pursuant to Rule 37.6, no counsel for a party authored this brief in whole or in part. No person or entity, other than *amici*, their members, or their counsel, made a monetary contribution to the preparation or submission of this brief.

II. Expanded inducement frustrates generic drug competition legislation. In 1984, Congress enacted a comprehensive scheme for generic drugs to obtain regulatory approval and reach the market. Of particular relevance here, when patents on a drug compound have expired but some methods of using the drug are patented, Congress created the "section viii carve-out" pathway for generic entry. Using this pathway, a generic drug manufacturer removes specific references to the patented uses from its official labeling, and the drug is approved for the unpatented uses.

The Federal Circuit's expansion of patent inducement contravenes this scheme. Congress created the section viii pathway against the backdrop of inducement law. Yet it provided no explicit guidance for dealing with potential inducement in the regulatory approval process. Nor did it provide mechanisms for resolving inducement disputes. Congress knew how to do these, and indeed offered detailed guidance and mechanisms for handling other patent issues relating to generic drugs. So the section viii pathway's simplicity demonstrates a congressional understanding that avoidance of patent inducement is a simple, clear, easily determined matter. That view is at odds with the fact-specific, indeterminate, inferential theories of inducement that the Federal Circuit embraced. A return to the longstanding conduct requirement of patent inducement best renders patent law consistent with that congressional understanding.

III. The expansion of patent inducement also harms competition and innovation. Under the Federal Circuit's decision, ordinary statements about product equivalence and comparative marketing could plausibly give rise to inducement liability. The resulting liability cloud over

truthful advertising stymies competition. Even more concerning, the Federal Circuit has now twice—in this case and *GlaxoSmithKline*—suggested that inducement liability can be premised on statements *required* by law, like mandatory drug labeling. This creates an impossible double-bind: the generic firm cannot comply with its regulatory obligations without the risk of inducing patent infringement.

These impairments to regulation and competition distort incentives to innovate. If even the most low-value patents can block competitors from advertising their products or complying with regulatory requirements, innovators will prefer to invest in those low-value patents instead of breakthrough innovation. That goes directly against the heart of the patent system—promoting innovation for the benefit of the public. Restoring the traditional requirements of patent inducement will avoid these incentive distortions.

IV. Concerns about an expanded patent inducement doctrine are not mere theory. The section viii carve-out was measurably effective at fostering generic competition and lower prices. The Federal Circuit's decisions, however, have already started to discourage use of this essential pathway. Exacerbated by the rapid growth in the number of patents on methods of drug use, the current state of the law is empirically problematic. Restoration of the inducement doctrine to its traditional bounds is necessary to maintain the benefits of generic competition for generations of patients to come.

ARGUMENT

I. Inducement of Patent Infringement Requires Specific, Unambiguous, and Affirmative Conduct

Under 35 U.S.C. § 271(b), "[w]hoever actively induces infringement of a patent shall be liable as an infringer." This requires (1) direct infringement, *Aro Mfg. Co. v. Convertible Top Replacement Co.*, 365 U.S. 336, 341 (1960), and (2) knowledge thereof, *see Glob.-Tech Appliances, Inc. v. SEB SA*, 563 U.S. 754, 766 (2011). But it also demands, through the phrase "actively induces," (3) *an act* that is specific, unambiguous, and affirmative with respect to the patented invention. *Id.* at 760; *accord Hewlett-Packard Co. v. Bausch & Lomb Inc.*, 909 F.2d 1464, 1469 (Fed. Cir. 1990) (same). *See generally* Mark A. Lemley, *Inducing Patent Infringement*, 39 U.C. Davis L. Rev. 225, 228–35 (2005).[2]

First, the act of inducement must be *specific*: intentionally and directly encouraging or causing infringing conduct, without need for "speculation." *A. Stucki Co. v. Worthington Indus., Inc.*, 849 F.2d 593, 597 (Fed. Cir. 1988); *see Warner-Lambert Co. v. Apotex Corp.*, 316 F.3d 1348, 1364 (Fed. Cir. 2003) ("[S]pecific intent and action to induce infringement must be proven . . . ."); *Vita-Mix Corp. v. Basic Holding, Inc.*, 581 F.3d 1317, 1329 n.2 (Fed. Cir. 2009) (instructions must "teach an infringing use," not merely "lead to infringing uses"); *DSU Med. Corp. v. JMS Co., Ltd.*, 471 F.3d 1293, 1306 (Fed. Cir.

[2]For additional treatment of this statutory analysis, see Brief of a Professor of Patent Law as *Amicus Curiae* at 10–15, *Cox Commc'ns, Inc. v. Sony Music Ent.*, No. 24-171 (U.S. Sept. 4, 2025).

2006) (en banc) ("[I]nducement requires evidence of culpable conduct, directed to encouraging another's infringement . . . ."); *Tegal Corp. v. Tokyo Electron Co., Ltd.*, 248 F.3d 1376, 1379 (Fed. Cir. 2001) (act must "in fact cause[], or urge[], or aid[] another to infringe a patent").

Second, it must be *unambiguous*: not "vague" or amenable to multiple interpretations, some of which are connected with noninfringing conduct. *Takeda Pharms. U.S.A., Inc. v. W.-Ward Pharm. Corp.*, 785 F.3d 625, 632 (Fed. Cir. 2015); *C.R. Bard, Inc. v. Advanced Cardiovascular Sys.*, 911 F.2d 670, 675 (Fed. Cir. 1990) (no inducement where acts are "at best ambiguous"); *HZNP Meds. LLC v. Actavis Lab'ys UT, Inc.*, 940 F.3d 680, 702 (Fed. Cir. 2019) (no inducement where drug label notes possibility of performing a patented method but "does not require" those steps); *Eli Lilly & Co. v. Bd. of Regents*, 334 F.3d 1264, 1369 (Fed. Cir. 2003) (inducement may be found based on instructions that "are unambiguous on their face").

Third, it must be *affirmative*: an act of "commission," not omission. *Glob.-Tech*, 563 U.S. at 760 ("[I]nducement must involve the taking of affirmative steps . . . ."); *Beverly Hills Fan Co. v. Royal Sovereign Corp.*, 21 F.3d 1558, 1568 (Fed. Cir. 1994); *see also Tegal*, 248 F.3d at 1378.

This conduct requirement of induced infringement is the product of a century and a half of precedent of this Court and others. *See Wallace v. Holmes*, 29 F. Cas. 74, 80 (C.C.D. Conn. 1871) (requiring "actual concert with others"); *Motion Picture Pats. Co. v. Universal Film Mfg. Co.*, 243 U.S. 502, 516 (1917) (overruling *Henry v. A.B. Dick Co.*, 224 U.S. 1 (1912), which had approved of indirect patent liability despite ambiguity in the relevant act); *see also Carbice Corp. of Am. v. Am. Pats. Dev.*

Corp., 283 U.S. 27, 32 (1931) (explaining *Motion Picture Patents* as limiting contributory infringement); Giles S. Rich, *Infringement Under Section 271 of the Patent Act of 1952*, 21 Geo. Wash. L. Rev. 521, 542 (1953) (describing how § 271(b) arose out of these common-law precedents); P.J. Federico, *Commentary on the New Patent Act*, 75 J. Pat. & Trademark Off. Soc'y 161, 214 (1993) (same).

Moreover, the conduct requirement squares with copyright law, which requires "clear expression or other affirmative steps" to promote infringement. *See Metro-Goldwyn-Mayer Studios Inc. v. Grokster, Ltd.*, 545 U.S. 913, 937 (2005). And it is consistent with aiding and abetting under tort law, which requires "conscious, voluntary, and culpable participation in another's wrongdoing." *Twitter, Inc. v. Taamneh*, 143 S. Ct. 1206, 1223 (2023).

Here, the Federal Circuit has strayed from these core requirements of § 271(b). The court allowed for liability based on speculative inferences from truthful, and sometimes legally mandatory, statements about general features of a drug—statements that are neither specific nor unambiguous. Pet. App. 6–7a. And it allowed a generic company's non-removal of text from statutorily required drug labeling—an omission—to be a basis for inducement liability. *Id.* at 17a; *see also GlaxoSmithKline LLC v. Teva Pharms. USA*, 7 F.4th 1320, 1328–29 (Fed. Cir. 2021) (per curiam). These deviations from longstanding precedent require reversal and clarification from this Court.

II. The Conduct Requirement Promotes the Congressional Scheme for a Robust Generic Drug Market

Patent inducement's requirement of specific, unambiguous, and affirmative conduct is not only correct on

the law, but also critical to the proper functioning of the statutory scheme for generic drugs.

A. The Hatch–Waxman Act Is Intended to Facilitate Speedy Introduction of Generics

Four decades ago, Congress enacted the Drug Price Competition and Patent Term Restoration Act of 1984 ("Hatch–Waxman Act"), a carefully crafted statute fostering an equilibrium between brand-firm innovation and generic competition. Pub. L. No. 98-417, 98 Stat. 1585.

At the time that Congress took up the issue, the need for such an equilibrium was well-known. Evidence suggested a decline in regulatory approval of new drugs between the late 1950s and 1970s, particularly with respect to new compounds, dosage forms, and domestic research. *See* Maureen S. May et al., *New Drug Development During and After a Period of Regulatory Change*, 33 Clin. Pharm. Ther. 691, 691 (1983); John W. Egan et al., *Economics of the Pharmaceutical Industry* 105–06 (1982). According to the drug industry, one factor leading to this situation was the decline in the period between U.S. Food and Drug Administration ("FDA") approval and patent expiration, which had fallen from nearly 17 years in the early 1960s to under seven years by the early 1980s. James J. Wheaton, *Generic Competition and Pharmaceutical Innovation*, 35 Cath. U. L. Rev. 433, 451–52 (1986). *See generally* Michael A. Carrier, *Unsettling Drug Patent Settlements*, 108 Mich. L. Rev. 37, 43–44 (2009) [hereinafter Carrier, *Unsettling*].

At the same time, Congress recognized an urgent need to ensure the provision of "low-cost, generic drugs for millions of Americans." 130 Cong. Rec. 24427 (1984)

(statement of Rep. Henry Waxman). Generic competition would save consumers, as well as the federal and state governments, millions of dollars each year. And it would "do more to contain the cost of elderly care than perhaps anything else this Congress has passed." *Id.* (statement of Rep. Waxman). *See generally* Carrier, *Unsettling*, *supra*, at 42.

The major hold-up for generic entry was that the costs of FDA approval were often prohibitive for generic drug manufacturers, especially those anticipating vigorous competition. *See Eli Lilly & Co. v. Medtronic, Inc.*, 496 U.S. 661, 676 (1990). And the drafters of the Hatch–Waxman Act lamented the "practical extension" of the patentee's "monopoly position" beyond the ordinary patent term. H.R. Rep. No. 98-857, pt. 2, at 4 (1984).

The Hatch–Waxman Act's drafters, in particular Representative Waxman, repeatedly underscored the "fundamental balance of the bill" between the rights of patent owners and the interests of generic competitors. 130 Cong. Rec. 24425; *see also* H.R. Rep. No. 98-857, *supra*, pt. 1, at 28 (describing bill as "fairly balanced"); *id.* pt. 2, at 30 (asserting that the bill will "balance the need to stimulate innovation against the goal of furthering the public interest"). In that spirit of compromise, the Hatch–Waxman Act offered benefits to both patent-holding brand manufacturers and generic firms.

For patent holders, the statute first allowed for the extension of the patent term for key drug patents to compensate partially for time in FDA review. 35 U.S.C. § 156(c), (g)(6). Second, it provided for FDA market exclusivity periods not based on patents, for example on a drug with a new active ingredient. Federal Food, Drug, and Cosmetics Act (FFDCA) § 505(j)(5)(F)(ii), 21

U.S.C. § 355. Third, it granted to brand manufacturers an automatic 30-month stay of FDA approval of any generic equivalent during the pendency of certain patent litigation—effectively an automatic preliminary injunction against generic competitors without the ordinary equitable safeguards such as likelihood of success and irreparable harm. FFDCA § 505(j)(5)(B)(iii).

For generic firms, the centerpiece of the legislation was an expedited pathway for the approval of generic drugs. *See id.* § 505(j). Rather than needing to present a full application with efficacy and safety evidence, a generic manufacturer under the Hatch–Waxman Act could file an Abbreviated New Drug Application ("ANDA") based on a showing of bioequivalence between the generic and a previously approved drug. *See* FFDCA § 505(j)(2)(iv). The Hatch–Waxman Act also allowed generics a limited exception to patent infringement to facilitate bioequivalency testing. 35 U.S.C. § 271(e)(1).

As a further dimension of the legislative compromise, the Hatch–Waxman Act added a key limitation on the expedited ANDA pathway. Most brand-name drugs are patented, and there are often multiple patents on one drug—up to 17 per drug by one measure.[3] If a drug manufacturer notifies the FDA about patents associated with its product, FFDCA § 505(b)(1)(A)(viii), then the Hatch–Waxman Act prohibits the agency from approving generics of that drug unless the generic manufacturer can overcome each of the patents. FFDCA § 505(j)(5)(B). The generic firm has two options for doing so.

[3]Caroline Horrow et al., *Patent Portfolios Protecting 10 Top-Selling Prescription Drugs*, 2024 JAMA Internal Med. 810 (17 patents, figures from small-molecule setting); *see also* Theodore W. Teng et al., *Tertiary Patents on Drugs Approved by the FDA*, 2026 JAMA Health F. 1, 4 (7 patents).

The first option is a "paragraph IV" certification, which allows a generic to certify that the patent "is invalid or will not be infringed." *Id.* § 505(j)(2)(A)(vii)(IV). The mere filing of a paragraph IV certification is treated as an artificial act of infringement, which allows the brand firm to immediately file suit even before the generic enters the market. 35 U.S.C. § 271(e)(2).

Although generics often use the paragraph IV route, it has major disadvantages. *See generally* Michael A. Carrier, *Skinny Labels' Importance for Drug Competition*, Wis. L. Rev. Forward (forthcoming 2026) [hereinafter Carrier, *Importance*], *available online*.[4] Most notably, it tends to be lengthy and costly. A survey of patent lawyers reveals that for pharmaceutical litigation with more than $25 million at risk, the average litigation costs are $6.2 million. Am. Intell. Prop. L. Ass'n, *Report of the Economic Survey* I-158 (2023). Plus, as noted above, the brand firm, merely by *filing* a lawsuit, automatically obtains an effective preliminary injunction in the form of a 30-month stay of generic approval. FFDCA § 505(j)(5)(B)(iii).[5]

B. The Section viii "Skinny Labeling" Pathway is Critical to Effective Generic Entry

The alternative to paragraph IV litigation is called the "carve-out," the "skinny label," or by reference to the relevant part of the statute, section viii. *Id.* § 505(j)(2)(A)(viii).

[4] Locations of authorities available online are shown in the Table of Authorities.

[5] Additionally, the first generic to file an ANDA with a paragraph IV certification receives a 180-day period of marketing exclusivity. FFDCA § 505(j)(5)(B)(iv).

This option exists because, as this Court has explained, "a single drug may have multiple methods of use, only one or some of which a patent covers." *Caraco Pharm. Lab'ys, Ltd. v. Novo Nordisk A/S*, 566 U.S. 399, 414 (2012). But method-of-use patents can be applied for—and thus expire—years (or even *decades*) after the drug compound itself is off-patent and legitimately open to generic competition. If the Hatch–Waxman Act precluded the FDA from approving a generic drug on account of method-of-use patents, then generic competition could be delayed indefinitely.

Section viii deals specifically with method-of-use patents and overcomes this hurdle by permitting a generic firm to seek approval for only unpatented uses. The firm carves out the patented uses from its labeling to produce a skinny label, and includes in its ANDA "a statement that the method of use patent does not claim" the uses for which approval is sought. FFDCA § 505(j)(2)(A)(viii). Through this procedure, the Hatch–Waxman Act "authorize[s] the FDA to approve the marketing of a generic drug for particular unpatented uses; and section viii provides the mechanism for a generic company to identify those uses, so that a product with a label matching them can quickly come to market." *Caraco*, 566 U.S. at 415. In other words, section viii ensures "that one patented use will not foreclose marketing a generic drug for other unpatented ones." *Id.*

While a generic firm could theoretically use a paragraph IV certification for a method-of-use patent, section viii provides unique advantages. *See* Carrier, *Importance*, *supra*. Because a section viii statement does not require the same notification to patent holders as does a paragraph IV certification, litigation is "not usually trig-

ger[ed]." Shashank Upadhye, *Generic Pharmaceutical Patent and FDA Law* § 26:11 (2024).

In addition, drug applications based on a section viii statement are not subject to the 30-month stay, ensuring faster FDA final approval so generics can more quickly enter the market. *See* FFDCA § 505(j)(5)(B)(iii). With paragraph IV litigation, the generic must wait during the 30-month stay, paying the costs of litigation all the while, before getting final FDA approval to enter the market. Even after that, to market its less expensive drug, the generic often must launch "at risk" because the patent litigation typically extends beyond the 30-month stay. Launching at risk exposes the generic to potentially substantial lost-profit damages since the brand product sells at a much higher price than the generic. *Teva Pharms. USA, Inc. v. Sebelius*, 595 F.3d 1303, 1305 (D.C. Cir. 2010); *see* Peter Loftus, *Pfizer, Takeda to Get $2.15 Billion Settlement*, Wall St. J., June 12, 2013.

The advantages of the section viii carve-out over paragraph IV litigation are compounded by the fact that method-of-use patents, the focus of skinny labels, are especially questionable as to validity. *See infra* pp. 26–27. There are multiple reasons why patents are often overturned in court, including limited time for examination, incentives to grant patents, and the ex parte nature of the patent acquisition process. *See, e.g.*, Nat'l Rsch. Council, *A Patent System for the 21st Century* 47–48 (2004), *available online*. But to the extent that such patents are granted and are associated with drug products—the FDA exercises only a "ministerial" role over those associations, *Caraco*, 566 U.S. at 407—generic competitors must deal with these questionable patents,

either through the simplicity of a section viii carve-out or in costly paragraph IV litigation.

For these reasons, courts have recognized that section viii is "an attractive route for generic manufacturers," *Purepac Pharm. Co. v. Thompson*, 354 F.3d 877, 880 (D.C. Cir. 2004), and a pathway with "a diminished set of . . . risks," *TorPharm, Inc. v. Thompson*, 260 F. Supp. 2d 69, 73–74 (D.D.C. 2003). The skinny labeling pathway provides certainty, efficiency, cost savings, and simplicity for both generic firms applying for approval and the FDA reviewing ANDAs. And it does this without harming innovation, as brand manufacturers can still patent new methods of use and compel generics to carve out those uses. It is a central part of the design of the Hatch–Waxman Act.

C. The Conduct Requirement Avoids Circumvention of the Statutory Design

Twice now, the Federal Circuit has allowed generic firms to be haled into an induced infringement lawsuit based, at least in part, on the very actions those generics took to comply with the section viii carve-out pathway. *See* Pet. App. 17a; *see also GlaxoSmithKline*, 7 F.4th at 1328–29. Doing so depended on an expansionist view of inducement that ensnared acts that were not specific, unambiguous, or affirmative. The text and structure of the Hatch–Waxman Act carve-out, however, show that the Federal Circuit's expansion of inducement under § 271(b) is in error.

As an initial matter, section viii is closely tied to inducement. No other form of liability under § 271 could logically attach to a generic firm based on a method-of-use patent covering an otherwise off-patent drug. A generic

firm cannot directly infringe under § 271(a) because a mere seller of a drug performs no methods of using it. Contributory infringement under § 271(c) is avoided because an off-patent drug has "substantial noninfringing uses," namely those first identified when the drug was discovered.[6] Importation and exportation under § 271(f)–(g) are presumably not at issue, and § 271(e) applies only to Paragraph IV certifications, not section viii. *Warner-Lambert*, 316 F.3d at 1362. Inducement under § 271(b) is all that is left.

Given that the drafters of the Hatch–Waxman Act were keenly aware of patent law, the section viii carve-out undoubtedly reflects how Congress understood inducement under § 271(b). The legislature's understanding conflicts with that of the Federal Circuit in at least two ways.

First, the statutory text suggests that carve-outs should be simple. Section viii says nothing about how to carve out a method of use from generic labeling. *See* FFDCA § 505(j)(2)(A)(viii). Indeed, the generic's labeling must be "the same" as the brand-name product's except for deviations irrelevant to patents. *See id.* § 505(j)(2)(A)(v). If § 271(b) required detailed labeling revisions to avoid even speculative inferences of inducement, then generic companies would need guidance on permissible labeling revisions, and the FDA would need authorization to accept them. The lack of guidance and authorization shows that the carved-out text must be so obviously removable that the resulting labeling remains

[6]Patent law's utility requirement ensures that, at the time the first patent application covering a drug is filed, at least one use of the drug is known. *Janssen Pharmaceutica NV v. Teva Pharms. USA, Inc.*, 583 F.3d 1317, 1324 (Fed. Cir. 2009) (discussing *Brenner v. Manson*, 383 U.S. 519, 534–35 (1966)).

"the same," at least with respect to the unpatented methods of use.

Second, section viii's simplicity suggests that Congress viewed avoidance of inducement liability as so straightforward that an agency without patent expertise, like the FDA, could administer it. As this Court has observed, the basic premise of the Hatch–Waxman Act is that "the FDA cannot authorize a generic drug that would infringe a patent." *Caraco*, 566 U.S. at 405. If inducement were as expansive as the Federal Circuit deemed it to be, then Congress would have devised some mechanism to determine whether labeling induces infringement—litigation procedures like paragraph IV, perhaps, or at least a protest opportunity for the patent holder. Section viii has no such mechanism. Congress therefore must have found that determining whether a label induces infringement requires no speculation, patent expertise, or detailed fact-finding—the opposite of how the Federal Circuit has characterized inducement. *See GlaxoSmithKline*, 7 F.4th at 1330–31.

Patent inducement's historic requirement of specific, unambiguous, and affirmative conduct is consistent with these consequences of the statutory text. Specific and unambiguous language of inducement is easy enough to identify that the FDA, even in its traditional ministerial role, can do it. Such language can be excised from the labeling without intricate or detailed edits, allowing the remainder of the label to remain "the same."

That makes the historic requirement consistent with the statute's motivating principle—congressional intent to facilitate generic entry. Federal Circuit Judge Prost has explained, "if playing by the skinny-label rules doesn't give generics some security from label-based li-

ability," they "simply won't play" because "[t]he risk is too great." *GlaxoSmithKline LLC v. Teva Pharms. USA* ("*GlaxoSmithKline II*"), 25 F.4th 949, 955 (Fed. Cir. 2022) (per curiam) (Prost, J., dissenting from denial of petition for rehearing en banc). The historic requirement gives generics that certainty and security, and thus effectuates the legislative scheme.

III. The Conduct Requirement Promotes Innovation and the Purposes of the Patent Act

The Federal Circuit's failure to adhere to the specific, unambiguous, and affirmative conduct requirement frustrates not only the Hatch–Waxman Act, but also the patent system as a whole. It allows a method-of-use patent to distort legitimate competition, misaligns incentives for innovation, and potentially allows patent protection to run indefinitely rather than for a limited term.

A. An Expanded Inducement Doctrine Interferes with Competition and Regulatory Compliance

The expansion of patent inducement opens the door to anticompetitive behavior and regulatory manipulation. To see why, consider the four acts upon which the Federal Circuit relied in this case to infer possible inducement: (1) the text of the generic drug label, (2) descriptions of the generic drug as "AB-rated," (3) statements that the generic was a "generic version," and (4) investor press releases reciting the total sales of the brand-name drug. Pet. App. 16–18a.

Many of these actions are standard tropes of comparative marketing. Generic cereals, sodas, car parts,

and other products regularly compare themselves to "the leading brand" and may even reference the leading brand's sales. Charles Duan, *The Importance of Being Equivalent*, 17 Am. U. Intell. Prop. Brief (forthcoming 2026) [hereinafter Duan, *Equivalent*] (manuscript at sec. I.A), *available online*. Computer products advertise compatibility with information technologies like Wi-Fi or USB—a claim that the product is "equivalent" to other compatible systems. *Id.*; *see* Dylan Niederland, *The Software Inducement Paradox*, 75 Am. U. L. Rev. 307 (2025).

In all these fields, truthful advertising enables fair competition. Equivalence statements allow new entrants to attract customers away from incumbents. *See Warner Lambert Co. v. McCrory's Corp.*, 718 F. Supp. 389, 399–400 (D.N.J. 1989) (observing ubiquity of "compare and save" advertisements for generic products); Duan, *Equivalent*, *supra*, sec. I.B. They are also a commonplace of discourse, both in the industry and outside. The words "generic version," which the Federal Circuit would proscribe as inducement, are how doctors, pharmacists, patients, and even Congress and this Court describe generic drugs. 21 U.S.C. § 353d(a)(3); *Caraco*, 566 U.S. at 415. If § 271(b) could ensnare truthful statements of comparative advertising, it would impede legitimate competition, boosting dominant firms for no good reason.

Due to conflicts with regulatory requirements, inducement based on the drug label and AB-rating statements is even more pernicious. A generic drug may be approved only if the generic's labeling is "the same as the labeling approved for" the brand equivalent. *See* FFDCA § 505(j)(2)(A)(v); *accord* 21 C.F.R. § 314.127(a)(7). And the "AB" rating is an assigned FDA determination based on the generic's therapeutic equivalence. *See* Food &

Drug Admin., *Approved Drug Products with Therapeutic Equivalence Evaluations* xiii–xiv (45th ed. 2025). If statements in drug labeling or a government-issued rating can induce infringement, then the generic company is thrust into an impossible double-bind of being required by regulation to violate a patent—what one might call "mandatory infringement." *See generally* Charles Duan, *Mandatory Infringement*, 75 Fla. L. Rev. 219 (2023) [hereinafter Duan, *Mandatory Infringement*].

The copyright case of *SmithKline Beecham Consumer Healthcare, LP v. Watson Pharmaceuticals, Inc.* illustrates this double-bind. A generic manufacturer sought to market an off-patent nicotine chewing gum. 211 F.3d 21, 23 (2d Cir. 2000). Complying with the Hatch–Waxman Act's same-labeling requirement, the generic used the same labeling as the brand-name gum, and the brand-name manufacturer sued for copyright infringement. *SmithKline*, 211 F.3d at 23–24. When the generic tried to rewrite its labeling, the FDA refused it, requiring the generic "to copy verbatim substantially all of the text." *See id.* at 24. The district court asked the FDA to "revisit" its refusal, but the agency responded, correctly under the law, that the agency had no authority to consider copyright issues in its approval of labeling. *See id.*; FFDCA § 505(j)(4)(G) (prohibiting FDA from approving an ANDA absent same-labeling).

As *SmithKline* recognized, the situation produced "a conflict between two statutes"—copyright law prohibits what regulation requires. 211 F.3d at 28. Left unresolved, this conflict would mean that a generic firm "cannot realistically use the ANDA process to sell its generic" products. *Id.* By the same token, if the required labeling or regulatory designations of generic drugs could give rise

to patent inducement, then generic drugs could not be realistically marketed without an ongoing threat of liability. *See* Duan, *Mandatory Infringement*, *supra*, at 238–40.[7]

The section viii carve-out does offer a limited degree of flexibility from the same-labeling requirement, authorizing generics to carve out patented methods of use. *See* FFDCA § 505(j)(2)(A)(viii); 21 C.F.R. § 314.127(a)(7). But that minimal flexibility provides little help in this setting. Consistent with its statutory duties, the FDA will only allow patent-accommodating deviations from the same-label requirement if those deviations "do not render the proposed drug product less safe or effective." 21 C.F.R. § 314.127(a)(7); *see* Ctr. for Drug Evaluation & Rsch., FDA, *ANDA Submissions—Refuse-to-Receive Standards* 12 (2d rev. Dec. 2016), *available online* (disallowing "differences in . . . labeling . . . that may be associated with safe/effective use of the drug product").

At odds with this mandate, the Federal Circuit has been willing to find plausible inducement allegations based on labeling text in, among other places, the "Clinical Study" and "Dosage and Administration" sections of a drug label. *GlaxoSmithKline*, 7 F.4th at 1329. These are sections where the FDA would likely refuse revisions. *See* 21 C.F.R. § 201.57(c)(15) (Clinical Studies section describes "how to use the drug safely and effectively"). Minor flexibility under section viii cannot resolve the conflict between the Hatch–Waxman Act and the Federal Circuit's expansive theories of inducement.

[7]The court in *SmithKline* resolved the problem by inserting an implicit exception into the Copyright Act. There is no need to do the same here because the statutory conflict disappears under a proper construction of inducement.

B. Such Interference Distorts Incentives for Innovation, Contrary to Patent Law and Policy

It is problematic enough that the Federal Circuit's expansion of inducement creates a statutory conflict. But the problems run deeper, as this conflict undermines the reason for the very existence of the patent system.

Patents are granted "to promote the progress of science and useful arts." U.S. Const. art. I, § 8, cl. 8. As a form of temporary exclusivity over an invention, a patent offers incentives to invent, to disclose inventions, and to commercialize them. *See, e.g.*, *Bonito Boats, Inc. v. Thunder Craft Boats, Inc.*, 489 U.S. 141, 150–51 (1989). But these incentives must be calibrated—the patent's private value to the inventor ought generally to correlate with the patented technology's public value. Too little reward and inventors may opt out of inventing; too much reward and inventors may focus on rent-seeking rather than research. *See id.* at 146–47. As a result, there is a "paramount interest in seeing that patent monopolies are kept within their legitimate scope." *Medtronic, Inc. v. Mirowski Family Ventures, LLC*, 571 U.S. 191, 203 (2014) (quoting *Precision Instrument Mfg. Co. v. Auto. Maint. Mach. Co.*, 324 U.S. 806, 816 (1945)).

This calibration ought to happen naturally through the "market-set reward" nature of patents. *See* Daniel J. Hemel & Lisa Larrimore Ouellette, *Innovation Policy Pluralism*, 128 Yale L.J. 544, 553–54 (2019). A patent's exclusivity over an invention has value only to "the extent to which consumers prefer it over alternatives and prior technology." Fed. Trade Comm'n, *The Evolving IP Marketplace* 138 (2011). In an ideal world, marginal improvements would command little or no price increase, while

substantial improvements would lead to larger returns to the patent holder. As a result, "a well-functioning market incentivizes inventors to pursue those inventions that are more likely to be valued by consumers." *Id.* at 140 (citing Roger D. Blair & Thomas F. Cotter, *Intellectual Property: Economic and Legal Dimensions of Rights and Remedies* 16–17 (2005)).

But where market competition is distorted, for example by an overbroad patent inducement doctrine, the incentive structure of patents is also upended. *See generally* Duan, *Mandatory Infringement*, *supra*, at 256–58; Bernard Chao, *Horizontal Innovation and Interface Patents*, 2016 Wis. L. Rev. 287, 295–307. This is because the market-distortive effects described above do not depend on the value of the patent causing the distortion.

Consider again the four types of non-specific statements about product equivalence and regulatory compliance discussed above. *See supra* p. 16. *Any method-of-use patent* on the relevant drug could rope a generic firm into protracted inducement litigation based on those statements, regardless of whether that patent helps five million patients or five. *See* Duan, *Mandatory Infringement*, *supra*, at 257. A rational drug developer, looking to exploit method-of-use patents to stymie generic competition, would rationally pursue the cheapest, least innovative methods of use to do so.

This upside-down incentives phenomenon can occur in many industries, such as pharmaceuticals, agriculture, and communication technologies. *See* Charles Duan, *Licensing Patents, but Not by Choice*, 18 Landslide 7, 8–10 (Sept.–Oct. 2025), *available online*. But it is especially acute for methods of drug uses. New drug development is expensive in part because of the extensive clinical trial

data that the drug developer must generate. Once that data is generated, though, it is merely a matter of statistical analysis to find another correlation or patient subpopulation that reacts differently to the drug, which can be patented as a method of use. *See* Jin Park et al., *Overlapping Method of Use Patents to Prevent Generic Entry*, 53 J.L. Med. & Ethics 577, 578–79 (2025) (reviewing method-of-use patent portfolios of this type).[8] Indeed, nothing stops a drug patent holder from "discovering" a new method of use every twenty years, thereby generating generic-blocking patents theoretically forever. *See* Duan, *Equivalent*, *supra*, sec. III.B.

Consistent with this theory, firms are taking increased advantage of method-of-use patents today. *See* S. Sean Tu & Ameet Sarpatwari, *A "Method of Use" to Prevent Generic and Biosimilar Entry*, 388 New Eng. J. Med. 483, 485 & fig. (2023). Indeed, many of the method-of-use patents held by the respondents are simple variations on a theme, covering methods of using icosapent ethyl on different patient populations based on cholesterol levels.[9] *See generally* S. Sean Tu & Charles Duan, *Pharmaceutical Patent Two-Step: The Adverse Advent of Amarin v. Hikma Type Litigation*, 12 N.Y.U. J. Intell. Prop. & Ent. L. 1, 14 (2022).

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[8]This is sometimes called "*in silico*" or "computational drug repurposing." *See, e.g.*, Ziaurrehman Tanoli et al., *Computational Drug Repurposing*, 24 Nature Revs. Drug Discovery 521 (2025). FDA approval of a drug's new use may require clinical trials or other studies, but those are not required for patenting the new use.

[9]*See, e.g.*, U.S. Patent No. 9,700,537 cl. 1 (issued July 11, 2017) (claiming treatment of patients with triglycerides of at least 150mg/dl); U.S. Patent No. 8,399,446 cl. 1 (issued Mar. 19, 2013) (500 to 1500mg/dl); U.S. Patent No. 12,171,738 cl. 1 (issued Dec. 24, 2024) (200 to 500mg/dl).

The infamous patent on the use of the drug BiDil on African-American patients also fits this cheap-innovation pattern precisely. *See* Jonathan Kahn, *Race in a Bottle: The Story of BiDil and Racialized Medicine in a Post-Genomic Age* 48–49 (2013). Knowing that its general patent on BiDil would expire soon, the developer of the drug hastily reexamined its existing clinical trial data to find a race-based statistical correlation—apparently, one that was "weak at best." *Id.* at 59. The developer then obtained a method-of-use patent on the correlation, delaying generic competition for thirteen additional years. *See id.* at 49.

To be sure, new uses of known drugs can be valuable, and inventors of new uses arguably face some difficulties exploiting their patents. This is a consequence of complex interactions among doctors' prescription practices, pharmacy substitution laws, and a lack of policies regarding off-label uses. *See* David A. Simon, *Off-Label Innovations*, 56 Ga. L. Rev. 701, 730–33 (2022).

As the Solicitor General observed, these difficulties were a trade-off that Congress "presumably understood." Br. United States as Am. Cur. 12, Dec. 5, 2025. Furthermore, the proper solution to any such difficulties is specific policy targeted to this particular interaction. *See, e.g.*, Simon, *supra*, at 749–50. It is not to foreclose the market for generics by expanding the scope of inducement liability to sweep in ordinary and mandatory acts of drug marketing. Swinging the pendulum so far in the direction of expanded liability would encourage the development of only the cheapest methods of use. Such a result would be at cross-purposes with the patent system.

C. The Conduct Requirement Avoids These Innovation and Competition Distortions

Avoiding these systemic harms to competition, regulation, and innovation is a simple matter of returning to the standard that the Federal Circuit abandoned: the long-standing requirement of a specific, unambiguous, and affirmative act.

Under that standard, generalized comparative advertising or statements of product equivalence generally do not induce infringement, as long as the advertising or statements do not identify the specific patented method of use. In particular, assuming that the product in question has noninfringing uses, any such nonspecific marketing claim would be ambiguous at best.

Applied to the marketing statements in the present case, for example, the description of generic icosapent ethyl as a "generic version" and "AB rated" are not specific to any particular use of the drug, and they are ambiguous insofar as icosapent ethyl has noninfringing uses. Similarly, the press releases describing brand-name sales of Vascepa do not specifically encourage any particular use, and are ambiguous in that the sales numbers cover multiple uses of Vascepa. Interpreted this way, § 271(b) would "avoid imposing liability on those who participate in the stream of lawful commerce merely because their products can be misused." Lemley, *supra*, at 228.

The specific, unambiguous, and affirmative act requirement also resolves the conflict with the Hatch–Waxman Act. If a generic drug's labeling specifically and unambiguously encourages a patented use of a drug, then that text would likely induce infringement. *See Eli Lilly & Co. v. Teva Parenteral Meds., Inc.*, 845 F.3d 1357, 1369 (Fed. Cir. 2017). But labeling that generally char-

acterizes the safety, dosage, or clinical trial characteristics of a drug would likely be nonspecific and ambiguous with respect to a patented use. *See, e.g.*, *Takeda*, 785 F.3d at 631–32. It would not induce infringement and thus would avoid any need for labeling modifications that would subvert the FDA's safety and efficacy mandate. A generic firm's declining to speculate about how doctors interpret ambiguous labeling text also would not induce infringement because the omission would not be affirmative. *Cf. Worthington Indus.*, 849 F.2d at 597 (no inducement where "no document exists which states" inducement-relevant conduct).

Accordingly, the historic rule that inducement of infringement requires a specific, unambiguous, and affirmative act preserves competitive markets while also avoiding unnecessary conflicts with the regulatory system.

IV. Empirical Studies Show the Conduct Requirement's Importance to Patients and Public Health

The harms of expanding patent inducement liability are not mere theory, but borne out through numerous empirical studies.

Skinny labeling has resulted in proven benefits for access to medicines and competitive drug pricing. One study identified 15 brand-name drugs for which the first generic competition between 2015 and 2019 occurred via a skinny-label entrant and found that skinny labels resulted in generic entry a median of 2.5 years earlier. Alexander C. Egilman et al., *Estimated Medicare Part D Savings from Generic Drugs with a Skinny Label*, 177 Annals Internal Med. 833 (2024). Competition from these 15 drugs alone saved the Medicare Part D $14.6 billion

from 2015 to 2021 and increased use of the drugs, which "suggest[ed] improved patient access." *Id.* at 835.[10]

Over the last few decades, though, brand-name manufacturers have increasingly been building up stockpiles of method-of-use patents on their drugs. *See* Doni Bloomfield et al., *Prescription Drug Method-of-Use Patent Protection, 1991–2018*, 41 J. Gen. Internal Med. 261, 261–62 (2026); *see also* Tu & Sarpatwari, *supra* (finding sixfold increase in registration of "use codes," which correlate with method-of-use patents).

For example, in 2012, the FDA originally approved Amarin's Vascepa for severe hypertriglyceridemia, which is characterized by triglyceride levels of at least 500 milligrams per deciliter. This indication is now unpatented. *See* Tu & Duan, *supra*, at 21–22. But in 2019, Amarin received FDA approval for Vascepa to treat cardiovascular risk in patients with triglyceride levels of at least 150 milligrams per deciliter, with patent protection lasting until 2033. As of 2024, respondents' product Vascepa was associated with 67 patents with expiration dates ranging from May 31, 2027 to June 28, 2033. *Id.* at 19–20.

Perhaps connected to the problems of incentives for low-value innovation described above, the evidence also suggests that method-of-use patents are often of questionable validity. One study found that the Federal Circuit upheld method-of-use patents only 29% of the time

[10]Medicare Part D provides prescription drug coverage. 42 U.S.C. ch. 7, subch. XVIII, pt. D. For similar findings for biologics in the context of Medicare, see Alexander C. Egilman et al., *Frequency of Approval and Marketing of Biosimilars with a Skinny Label and Associated Medicare Savings*, 183 JAMA Internal Med. 82 (2023) (finding $1.5 billion in savings and 2.5 years of earlier entry on five biologics between 2015 and 2020).

(as compared to 75% for active ingredient patents). Errol B. Taylor & Fredrick M. Zullow, *Focusing Only on Active Ingredient Patents Ignores Case Law Success Rates*, Pharm. L. & Indus. Rep. (BNA), Oct. 28, 2011.

Similarly, another study found that while patents covering a drug's active ingredient are almost always (92%) upheld in court, those involving secondary patents covering "ancillary aspects of drug innovation" are upheld in only 32% of the cases. C. Scott Hemphill & Bhaven Sampat, *Drug Patents at the Supreme Court*, 339 Science 1386, 1386–87 (2013).[11]

Growing stockpiles of method-of-use patents and an expanded inducement doctrine appear to have led to declining use of the skinny-label pathway. Between 2015 and 2022, the number of drugs approved using the skinny-label pathway was roughly 40 to 50%. *See* Bryan S. Walsh et al., *Frequency of First Generic Drug Approvals with "Skinny Labels" in the United States*, 181 JAMA Internal Med. 995 (2021) (2015–2019 period); Therese J. Ziaks et al., *Frequency of First Generic Drugs Approved Through "Skinny Labeling," 2021 to 2023*, 31 J. Managed Care & Specialty Pharmacy 343 (2025) (2021–2022 period).

In 2023, however, the number of drugs using the pathway fell to 20%, likely due to the Federal Circuit's first expansion of inducement, *GlaxoSmithKline*, two years earlier. *See* Ziaks et al., *supra*, at 346–47. This appears to confirm Judge Prost's prediction that generics "simply won't play" absent certainty from the skinny-labeling

[11] For oft-cited general studies, see John R. Allison & Mark A. Lemley, *Empirical Evidence on the Validity of Litigated Patents*, 26 AIPLA Q.J. 185, 194, 205 (1998) (courts invalidated 46% of patents); Kimberly A. Moore, *Judges, Juries, and Patent Cases—An Empirical Peek Inside the Black Box*, 99 Mich. L. Rev. 365, 384–85 (2000) (alleged infringers prevailed in 42% of patent cases).

pathway. *GlaxoSmithKline II*, 25 F.4th at 955 (in dissent).

These concerns led the FDA to include in its 2024 legislative proposals a safe harbor for skinny labeling. Justification of Estimates for Appropriations Committees 38–39 (Food & Drug Admin. 2024), *available online*. In particular, the agency asked Congress to "exclud[e] such labeling from the evidence that can be used to support a claim of patent infringement" and "clarify[] that statements regarding therapeutic equivalence cannot be used as evidence to support an infringement claim." *Id.* at 39. The FDA was "concerned" that the *GlaxoSmithKline* decision "imperils an important statutory marketing pathway that allows earlier generic drug market entry for conditions of use of a drug not protected by a patent." Justification of Estimates for Appropriations Committees, *supra*, at 39. And it worried that "[w]ithout this change, . . . [the] decision could significantly impact the timely availability of generic drugs." *Id.*

Congress designed the section viii pathway to enable the speedy introduction of generic drugs in settings where patents cover some but not all uses of those drugs. *See Caraco*, 566 U.S. at 414–15. The evidence shows that it has worked—up until the Federal Circuit expanded the patent inducement doctrine to reach beyond its proper bounds. Restoring the requirement of a specific, unambiguous, and affirmative act would return inducement doctrine to its common law roots while having measurable impacts on the health and welfare of all Americans.

CONCLUSION

For the foregoing reasons, the decision of the Court of Appeals should be reversed.

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