No. 24-889

IN THE

Supreme Court of the United States

HIKMA PHARMACEUTICALS USA INC. AND
HIKMA PHARMACEUTICALS PLC,

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 AMICI CURIAE PATENT LAW PROFESSORS PAUL R. GUGLIUZZA AND JACOB S. SHERKOW IN SUPPORT OF NEITHER PARTY

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INTEREST OF AMICI CURIAE

Paul R. Gugliuzza is the Thomas W. Gregory Professor of Law at the University of Texas at Austin School of Law. Jacob S. Sherkow is the Richard W. and Marie L. Corman Professor of Law at the University of Illinois College of Law.[1] Amici teach and research patent law, including patent litigation under the Hatch-Waxman Act. Their scholarship includes two recent articles examining the intersection of drug labels, the Hatch-Waxman Act, and induced patent infringement. *See* Jacob S. Sherkow & Paul R. Gugliuzza, *Infringement by Drug Label*, 78 Stan. L. Rev. 131 (2026); Paul R. Gugliuzza & Jacob S. Sherkow, *Drug Labels as Evidence of Patent Infringement — A Troubling Legal Trend*, 394 NEJM 630 (2026) [hereinafter Gugliuzza & Sherkow, *Trend*].

Amici have no personal interest in this case. Their sole interest is in the orderly development of induced infringement doctrine in a way that is faithful both to longstanding patent law and to Congress's policy choices in the Hatch-Waxman Act.

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[1] No counsel for a party authored this brief in whole or in part, and no party or counsel for a party made a monetary contribution intended to fund its preparation or submission. No person other than the *amici* or their counsel made a monetary contribution to the preparation or submission of this brief. Amici's affiliations are provided for identification purposes only; they are participating in their individual capacity and not on behalf of their institutions.

INTRODUCTION AND SUMMARY OF ARGUMENT

The decision below is the latest in a line of Federal Circuit pharmaceutical cases that have turned decades of patent inducement jurisprudence on its head. Across *GlaxoSmithKline LLC v. Teva Pharmaceuticals USA, Inc.*, *United Therapeutics Corp. v. Liquidia Technologies, Inc.*, *Vanda Pharmaceuticals Inc. v. West-Ward Pharmaceuticals International Ltd.*, and now this case, the Federal Circuit has improperly relied on Food and Drug Administration (FDA)-regulated drug labeling to expand inducement liability beyond its proper boundaries.

By allowing inducement to rest on a bare textual reading of a drug label combined with anodyne public statements about generic equivalence, the Federal Circuit has embraced a theory of liability that amici have called "infringement by label." Sherkow & Gugliuzza, *supra*, at 131. Infringement by label departs from the common and statutory law of inducement and patent infringement. Instead of asking whether a generic company has intentionally encouraged and caused infringement, the Federal Circuit has imposed liability simply because a generic's label could be read to "contain" a patented method of use and the generic holds itself out as, well, a generic.

Applying common law infringement principles, this Court has long held that patent inducement liability exists only when a party actively encourages, recommends, or promotes infringement by taking affirmative acts with the intent to cause direct infringement by another. Nothing in the 1952 Patent Act or the Hatch-Waxman Act changes these core principles.

The Federal Circuit's recent decisions, by contrast, improperly base inducement liability on FDA-mandated drug labels and unremarkable statements about generic equivalence.

Generics do not write their drugs' labels; FDA law generally requires them to copy that of the reference brand drug. Even brand drug labels are produced under intense agency scrutiny and constraints of federal law. Sherkow & Gugliuzza, *supra*, at 135, 141. And physicians rarely rely on these labels for prescribing decisions. The Federal Circuit's approach to inducement is inconsistent with this Court's command that inducement demands "purposeful, culpable expression and conduct" demonstrated through clear acts taken to foster infringement. *Cf. Metro-Goldwyn-Mayer Studios Inc. v. Grokster, Ltd.*, 545 U.S. 913, 937 (2005).

In resolving this case, the Court should reaffirm that inducement requires evidence of voluntary, targeted efforts that influence prescribing behavior—not a textual exegesis of isolated phrases from mandatory labels and innocuous statements about "generic equivalence."

ARGUMENT

I. Inducing Infringement Under § 271(b) Requires Encouraging, Recommending, or Promoting Infringement.

Section 271(b) of the 1952 Patent Act imposes liability on those who "actively induce[] infringement of a patent." 35 U.S.C. § 271(b). That section, along with § 271(c), was "designed to 'codify in statutory form principles of contributory infringement'" that had been "part of our law for about 80 years." *Global-Tech*

Appliances, Inc. v. SEB S.A., 563 U.S. 754, 761 (2011) (quoting *Aro Mfg. Co. v. Convertible Top Replacement Co* (*Aro II*)., 377 U.S. 476, 485–86 n.6 (1964) (quoting H.R. Rep. No. 82-1923, at 9 (1952))).

As this Court has recognized in the context of copyright infringement, indirect infringement is based on "doctrines of secondary liability [that] emerged from common law principles and are well established in the law." *Grokster*, 545 U.S. at 930 (citing *Sony Corp. v. Universal City Studios, Inc.*, 464 U.S. 417, 486 (1984) (Blackmun, J., dissenting)). Therefore "[o]ne infringes contributorily by intentionally inducing or encouraging direct infringement." *Id.* (citing *Gershwin Pub. Corp. v. Columbia Artists Mgmt., Inc.*, 443 F. 2d 1159, 1162 (2d Cir. 1971)).

As with other forms of secondary liability, indirect patent infringement liability arose to ensure patent law could efficiently hold culpable actors liable even when they do not themselves directly practice the invention. *See* Mark A. Lemley, *Inducing Patent Infringement*, 39 U.C. Davis L. Rev. 225, 227–28 (2005). Before enactment of the 1952 Patent Act, indirect infringement consisted of contributory infringement—the aiding and abetting of direct infringement—with inducement treated as evidence of the intent required for such liability. *Glob.-Tech*, 563 U.S. at 764; Lemley, *supra*, at 227. While courts were comfortable assuming intent when the indirect infringer sold products useful only for infringing acts, they required affirmative acts demonstrating infringement when products could be used for noninfringing purposes. *See* Lemley, *supra*, at 227.

When indirect infringement was codified in § 271(c) and § 271(b), the basic distinction was

between liability for contributory infringement and liability for inducing infringement. While contributory infringement requires the sale of products "especially made or especially adapted for use in an infringement," 35 U.S.C. § 271(c), inducing infringement requires "'other acts' that direct, facilitate, or abet infringement." Lemley, *supra*, 227 (2005).

The rule of inducement "as developed in the early cases is no different today." *Grokster,* 545 U.S. at 936. Inducement "must involve the taking of affirmative steps to bring about the desired result," *Glob.-Tech*, 563 U.S. at 760, and requires proof that the defendant "actively and *knowingly* aid[ed] and abett[ed] another's direct infringement." *DSU Med. Corp. v. JMS Co.*, 471 F.3d 1293, 1305 (Fed. Cir. 2006) (citing *Water Techs. Corp. v. Calco, Ltd,*, 850 F.2d 660, 668 (Fed. Cir. 1988)). Furthermore, those acts must "encourage, recommend, or promote infringement." *Takeda Pharms. USA, Inc. v. West-Ward Pharm. Corp.*, 785 F.3d 625, 631 (Fed. Cir. 2015).

Reflecting inducement's common law origins, this Court has applied the same principles to patent, copyright, and trademark law. *See, e.g.*, *Grokster,* 545 U.S. at 936 (citing *Sony*, 464 U.S. at 417) (adopting patent law's inducement rule as "a sensible one for copyright"); *Glob.-Tech*, 563 U.S. at 763 (citing *Grokster,* 545 U.S. at 913); *see also Inwood Labs., Inc. v. Ives Labs., Inc.*, 456 U.S. 844, 854 (1982) ("[I]f a manufacturer or distributor intentionally induces another to infringe a trademark . . . [it] is contributorily responsible.") (citing *William R. Warner & Co. v. Eli Lilly & Co.*, 265 U.S. 526 (1924)).

Nor does inducement change based on the industry in which the patent arises or the presence of

overlapping regulatory schemes. *See Glob.-Tech*, 563 U.S. at 762–64 (consumer appliances) (deriving the inducement knowledge standard from *Aro II*, 377 U.S. 476 (automobile parts), and *Henry v. A. B. Dick Co.*, 224 U.S. 1 (1912) (office equipment)); *Commil USA, LLC v. Cisco Sys., Inc.*, 575 U.S. 632 (2015) (telecommunications) (reaffirming inducement framework from *Glob.-Tech,* 563 U.S. 754, and *Aro II*, 377 U.S. 476).

II. Hatch-Waxman Does Not Alter the Requirements for Induced Infringement Liability Under § 271(b).

Just as inducement principles are the same across various forms of intellectual property and among different industries, those principles remain unaltered in cases involving generic drugs. Decades ago, Congress enacted the Drug Price Competition and Patent Term Restoration Act of 1984 ("Hatch-Waxman Act"), Pub. L. No. 98-417, 98 Stat. 1585, which established a litigation framework that allows generic drugs to enter the market as soon as patent protection for a brand-name drug ends. 35 U.S.C. § 271(e); 21 U.S.C. § 355(j). In order to achieve that goal, the Act created "an 'artificial' act of infringement that creates case-or-controversy jurisdiction" enabling early judicial resolution of patent disputes between brand name and generic drug companies. *Warner-Lambert Co. v. Apotex Corp.*, 316 F.3d 1348, 1365 (Fed. Cir. 2003).

However, "once jurisdiction is established . . . the substantive determination whether actual infringement or inducement will take place is determined by traditional patent infringement analysis[.]" *Id.* This is confirmed by the Act's own legislative history: "The

provisions of [the Hatch Waxman Act] relating to the litigation of disputes involving patent . . . infringement are not intended to modify existing patent law with respect to the burden of proof and the nature of the proof to be considered by the courts in determining whether a patent is . . . infringed." H.R. Rep. No. 98-857, pt. 1, at 27–28 (1984).

Therefore, whether a claim is made under 35 U.S.C. § 271(b), which codified the common law standard for inducing patent infringement, or § 271(e)(2), under the Hatch-Waxman Act, the inquiry about inducement is the same. *See Allergan v. Alcon Labs., Inc.,* 324 F.3d. 1322, 1337 (Fed. Cir. 2003) (Schall, J., concurring) (noting that a cause of action exists for "induced infringement under section 271(e)(2)" because otherwise "the owner of a method of use patent . . . will bring a section 271(b) induced infringement action, after the ANDA has been approved[.]").

When resolving other infringement questions arising under the Hatch-Waxman Act, this Court has adhered to ordinary infringement principles rather than inventing a pharmaceutical-specific doctrine. In *Eli Lilly & Co. v. Medtronic, Inc.*, 496 U.S. 661 (1990), the Court described § 271(e)(2)'s submission-based trigger as a "highly artificial act of infringement," created solely to permit premarket adjudication. *Id.* at 678. But the Court did not alter what counts as infringement. To the contrary, it analyzed liability by reference to the traditional categories in § 271(a) of making, using, and selling—confirming that Hatch-Waxman changes when suit may be brought, not what must be proved. *Id.* at 670–71, 678.

Likewise, in *Merck KGaA v. Integra Lifesciences I, Ltd.*, 545 U.S. 193, 201 (2005), the Court, relying on the Hatch-Waxman Act's text and structure, treated § 271(e)(1) as a safe harbor from liability, not as a re-definition of substantive patent rights. In doing so, the Court rejected arguments that the safe harbor provision should be narrowly construed. The Court left the underlying standards of infringement untouched. *Id.* at 201–02.

And in *Caraco Pharmaceutical Laboratories, Ltd. v. Novo Nordisk A/S*, 566 U.S. 399, 403 (2012)—a case about a particular provision of the Hatch-Waxman Act regarding "use codes"—this Court, again, did not alter any substantive requirements of the law of infringement, treating the Hatch-Waxman Act simply as procedural scaffolding to facilitate generic entry. *Id.* at 404.

None of these decisions—nor any others from this Court—suggest that the doctrine of patent inducement should be treated differently under the Hatch-Waxman Act. Inducement liability under § 271(b) thus continues to require proof that the alleged inducer had knowledge of the patent, intended that the induced acts constitute infringement, and engaged in affirmative acts that caused direct infringement. *Glob.-Tech*, 563 U.S. at 766; *Commil*, 575 U.S. at 642; *Takeda*, 785 F.3d at 631.

III. The Federal Circuit's Labeling-Based Theory of Inducement Improperly Expands § 271(b) Beyond Its Statutory Limits.

Despite widespread acknowledgment that the Hatch-Waxman Act does not change the standard for inducement, a line of Federal Circuit cases has made

up a special rule about inducement in generic drug patent cases: "infringement by label." This theory predicates inducement liability on a generic drug's label text alongside common-place statements about "generic equivalence." Sherkow & Gugliuzza, *supra*, at 134. That approach is wrong under the common law, distorts patent inducement doctrine, misunderstands the FDA's labeling framework, and thwarts the Hatch-Waxman Act.

A. The Federal Circuit's decision continues the trend of imposing inducement liability for regulated statements by generic drug companies.

In this case, the Federal Circuit reversed the district court's holding that Amarin had not adequately pleaded the facts necessary to find Hikma induced infringement by marketing a generic version of Amarin's brand name drug, Vascepa. *Amarin Pharma, Inc. v. Hikma Pharms. USA Inc.*, 104 F.4th 1370, 1380 (Fed. Cir. 2024). The Federal Circuit ruled that, notwithstanding Hikma's use of a skinny label to carve out the indication claimed in Amarin's patents, Amarin adequately alleged inducement based on "Hikma's press releases, website, and product label evidence." *Id.* at 1375. The Federal Circuit ruled that those statements could plausibly induce physicians to prescribe the medication for a patented use. *Id.* at 1380.

The Federal Circuit's reasoning in this case follows from that court's earlier decision in *GlaxoSmithKline LLC v. Teva Pharmaceuticals USA, Inc.* (*GSK*), 7 F.4th 1320 (Fed. Cir. 2021) in which it ruled that the generic's carved-out label "intentionally encouraged" infringement. *Id.* at 1338. In that case, Teva

launched a generic version of GlaxoSmithKline's Coreg with a section viii carve-out omitting the patented congestive heart failure (CHF) indication and retaining only unpatented indications. *Id.* at 1323–24. Even though the purpose of the CHF carve-out was to *avoid* having physicians practice an infringing use, the Federal Circuit concluded that the remaining indications fell "within the definition of congestive heart failure." *Id.* at 1330. Combined with Teva's statements that its generic product was a "therapeutic equivalent"—a term of art under FDA law—the court concluded that Teva had encouraged substitution for all the drug's uses. *Id.* at 1335.

In dissent, Judge Prost pointed out that Teva complied with the Hatch-Waxman Act by removing the patented use, that unrebutted evidence showed physicians rarely rely on labels, and that it makes little sense to infer culpable intent from describing a drug as "equivalent" in a system that requires generics to be equivalent. *Id.* at 1360–61. In a subsequent dissent from the denial of rehearing en banc in that case, Judge Prost further cautioned that, under the court's view of inducement, "no skinny-label generic is safe." *GlaxoSmithKline LLC v. Teva Pharms. USA, Inc.*, 25 F.4th 949, 955 (Fed. Cir. 2022) (Prost, J., dissenting).

Notwithstanding Judge Prost's critique, the flawed reasoning in *GSK* has been replicated in other Federal Circuit decisions. In *Vanda Pharmaceuticals v. West-Ward Pharmaceuticals International Ltd.*, 887 F.3d 1117, 1130–31 (Fed. Cir. 2018), the Federal Circuit affirmed an inducement finding based on an FDA-required warning in a generic's label, one which the generic had no authority to alter or modify, and

which was copied directly from the brand's label. And in *United Therapeutics Corporation v. Liquidia Technologies*, 74 F.4th 1360, 1370 (Fed. Cir. 2023), the court sustained inducement liability because following the label's instructions *could hypothetically* infringe, even absent evidence that physicians read the label or that the label influenced any physician's prescribing decisions.

B. Labeling reflects regulatory compliance rather than affirmative encouragement.

The Federal Circuit's infringement-by-label case law, including the decision below, allows inducement liability to rest on cobbled-together snippets of label text and anodyne equivalence statements. It also fails to account for how drug labels are developed and regulated. FDA regulations require every prescription drug, made by either a brand or generic company, to include a document describing indications, dosing, contraindications, clinical trial results, and safety measures, known as the drug's package insert. Gugliuzza & Sherkow, *Trend*, *supra*, at 630. This insert is not unilaterally prepared by the drug company or the FDA. Rather, it is the result of negotiations between the companies and the federal government. Sherkow & Gugliuzza, *supra*, at 135, 140.

Practically, this means that drug companies cannot include in their labeling *any* information that has not been approved by the FDA, down to such minutiae as comma placement. *Id.* at 141. FDA drug labeling is not a marketing document, but a legally mandated regulatory instrument. *See* 21 U.S.C. § 355(j)(2)(A)(v). It reflects what a drug company *must* say, not what it

wishes to promote. Sherkow & Gugliuzza, *supra*, at 188.

FDA regulations are even more restrictive for *generic* drug labels which must, absent specific and narrow exceptions, copy the brand drug's label. As Judge Prost explained in her *GSK* dissent, the statutory design of the Hatch-Waxman Act makes it untenable to infer culpable intent from what the law mandates. 7 F.4th at 1357 (Prost, J., dissenting). Physicians understand that a generic is, by definition, therapeutically equivalent to its brand counterpart, and generics are required to communicate that equivalence to participate in the regime Congress created. *See id.* at 1360 (Prost, J., dissenting) ("Given that the Hatch-Waxman Act's framework requires ANDA generics to be the same as a brand drug, and that doctors understand what being a generic means, [inducement] seems a dubious proposition.").

This Court has recognized the same reality, explaining that generic companies operate under an ongoing federal "duty of 'sameness.'" *PLIVA, Inc. v. Mensing*, 564 U.S. 604, 616 (2011). Accordingly, the "sameness" of these labels reflects federal law; something physicians and other market participants readily understand when they encounter a generic equivalent.

"Skinny labels," which omit patented indications while retaining unpatented ones, similarly reflect regulatory compliance rather than volitional advocacy to promote direct infringement. *See* § 355(j)(2)(A)(viii). As Judge Prost explained in her *GSK* dissent, a skinny label that omits the patented indication demonstrates that the generic "very much intended *not* to encourage infringement." 7 F.4th at 1350 (Prost, J., dissenting).

Inferring inducement from a label that has "intentionally omitted everything that the brand said covers that method" is inconsistent with the requirement of purposeful encouragement to establish inducement. *Id*.

The Federal Circuit's embrace of "infringement by label" converts 35 U.S.C. § 271(b)'s narrow, intent-based doctrine into a form of strict liability triggered by paperwork rather than actual persuasion.

C. Labeling cannot be inducement without evidence of causation.

The Federal Circuit's recent cases have not fully articulated how drug labels and equivalence statements affect physician behavior. Instead, the court's approach makes all information provided by a generic potentially inducing, creating a regime of text-based liability that is untethered from both causation and intent.

An extreme example is *Sanofi v. Watson Laboratories Inc.*, 875 F.3d 636 (Fed. Cir. 2017), in which a clinical trial describing the patented use was mentioned in the Indications and Usage section of the package insert, with the summary statistics of that trial in the separate Clinical Trials section. The Federal Circuit did not ask whether physicians would have examined the Indications and Usage section, turned to the Clinical Trials section, and, based on that information, prescribe the drug for the patented use. Instead, the court found it sufficient that the patented method of use was *in* the label, skipping any causal analysis. *Id*. at 645–46.

Focusing on a label's text, rather than its effect, rests on the assumption that physicians review and

adhere to every section of a package insert. Sherkow & Gugliuzza, *supra*, at 142. However, both empirical data and clinical experience indicate that physicians rarely consult labels when making treatment decisions.

Instead, physicians prescribe medications guided by clinical judgment, peer-reviewed literature, and established professional guidelines—not regulatory disclosures. As noted by Judge Prost in her *GSK* dissent, "every expert cardiologist at trial said he *didn't even read* the label to make prescribing decisions." 7 F.4th at 1342 (Prost, J., dissenting); *see also* Sherkow & Gugliuzza, *supra*, at 180–82 (describing the prevalence of off-label prescribing); David A. Simon, *Off-Label Inducement*, 111 Iowa L. Rev. (forthcoming 2026) (manuscript at 7–9), https://dx.doi.org/10.2139/ssrn.5533301 (same). The American Medical Association ("AMA") confirms this clinical reality, stating that official labeling "should not be regarded as the sole standard of acceptable or accepted medical practice," nor should it serve as a "substitute for clinical judgment or experience." *Am. Med. Ass'n*, Prescription Product Labeling H-115.994 (2025), https://perma.cc/7QN8-V2N8. Rather, the AMA clarifies that FDA-approved statements merely "establish the parameters governing advertising or promotion." *Id.*

The AMA's statements demonstrate that physicians view the label as a regulatory boundary for drug companies, not a directive for patient care. The FDA has also stated that it views the package insert as "informational only" in relation to its role in medical practice and that unlabeled uses may be "appropriate and rational in certain circumstances." U.S. Food & Drug

Admin., *Use of Approved Drugs for Unlabeled Indications*, 12 FDA Drug Bull. 4, 5 (Apr. 1982). If physicians neither read nor rely on the label, then the label cannot be said to "induce" anything.

IV. This Court Should Reaffirm Existing Inducement Law.

The Federal Circuit's recent decisions have created a system in which generic companies that adhere to FDA requirements may still face liability if any portion of their products' labeling, such as warnings or descriptions of clinical trials, could be interpreted as referencing a patented method of use. In resolving this case, the Court should reaffirm that inducement requires active, volitional conduct that encourages, recommends, or promotes infringement and that *actually* influences physicians' prescribing behavior. Moreover, the Court should make clear that FDA-mandated labeling, coupled with rote statements about generic equivalence, are not, alone, sufficient to establish inducement.

A. "Skinny labels" and other labeling should not, alone, create liability for inducement.

If complying with FDA-mandated labeling requirements can trigger inducement liability, market entry by generics becomes legally precarious and economically untenable, particularly for drugs with multiple indications. Faced with legal uncertainty, generic companies may forgo or delay entry, resulting in prolonged high prices and restricted patient access. This outcome subverts the purpose of the Hatch-Waxman Act: to encourage the development of new drugs and

lower the costs of generic entry. Sherkow & Gugliuzza, *supra*, at 145; *see also Caraco,* 566 U.S. at 405 ("As we have previously recognized, this process is designed to speed the introduction of low-cost generic drugs to market."). A "skinny label" carve-out should be strong evidence that the generic lacks the intent to encourage infringement—though that inference can of course be countered with evidence of a generic's promotional conduct and other real-world evidence of inducement. Sherkow & Gugliuzza, *supra*, at 188.

Grounding the inducement inquiry in the regulatory and commercial reality of the pharmaceutical market would also resolve a procedural quandary plaguing these cases. Namely, the Federal Circuit has treated the interpretation of mandatory label text as presenting a question of fact to be decided by a jury and entitled to deference on review. *E.g.*, *GSK*, 7 F.4th at 1330 ("[T]he district court erred by treating this fact question—whether the post-MI LVD indication [in the generic label] instructs a physician to prescribe carvedilol for a [patented] use—as though it were a legal one for it to decide *de novo*."). By focusing on a generic company's actual promotional activity, courts can avoid resting the factual determination of inducement on the interpretation of legally mandated label text. Sherkow & Gugliuzza, *supra*, at 188.

And when a patent owner cannot point to real-world conduct encouraging an infringing use (independent of the FDA-mandated label) there should be no plausible claim of inducement as a matter of law. Disposing of deficient claims early would avoid years of costly litigation. *Cf. Corcept Therapeutics, Inc. v. Teva Pharms. USA, Inc.*, 709 F. Supp. 3d 138, 142 (D.N.J. 2023) ("The [c]ourt denied the parties' cross-

motions for summary judgment, observing that it was critical to hear 'expert testimony regarding [the generic] label's dosing regimens[.]'"), *aff'd per curiam*, No. 2024-1346, 2026 WL 468866 (Fed. Cir. Feb. 19, 2026); *see also* Paul R. Gugliuzza & Jacob S. Sherkow, Corcept v. Teva *Oral Argument: Infringement by Drug Label, Again*, Patently-O (July 8, 2025), https://perma.cc/4YXX-CRYN ("Teva wasn't really able to dispute that the patented method is *in* its label—albeit in a section discussing safety and warnings—even if no doctor in the real world would ever practice the patented method.").

Conversely, in cases where there are plausible allegations and genuine, disputed evidence of inducement beyond the mere wording of a label, both brands and generics would retain their right to have those factual disputes resolved at trial. A clear distinction between regulatory disclosures that, on their own, cannot establish a claim of inducement, and active affirmative promotion of infringement, which can, would ensure that § 271(b) remains a tool for penalizing culpable conduct rather than a mechanism for imposing (or threatening to impose) significant litigation costs. Sherkow & Gugliuzza, *supra*, at 188–89.

B. The plain text of § 271(b) requires a causal connection between communication and infringement.

Section 271(b) targets conduct that persuades others to infringe; this Court has repeatedly emphasized that inducement requires "affirmative steps." *Glob.-Tech*, 563 U.S. at 760. Rather than relying on labeling or marketing statements about generic equivalence, courts should ask concrete, behavioral

questions: Did physicians read the challenged statements? And were they induced to act in accordance with them? Those questions cannot be answered by parsing language in the abstract. It requires evidence of real-world *effect*. Brand companies should be required to provide evidence of a demonstrated connection between what the generic communicated and how physicians *actually behaved*. Sherkow & Gugliuzza, *supra*, at 187.

Inducement turns on actual influence, not on conjecture about what someone might have inferred from regulatory language. Applied in the pharmaceutical context, that principle yields a straightforward rule. Liability must rest on communications or conduct that shapes prescribing behavior—targeted promotional efforts such as sales calls, marketing materials directed toward healthcare providers, "Dear Doctor" letters, advertising, or direct communications with healthcare decisionmakers—not the mere existence of FDA-mandated label text or unremarkable statements about generic equivalence. Sherkow & Gugliuzza, *supra*, at 188.

A recent nonprecedential Federal Circuit decision reflects a more appropriate approach to claims of infringement by label. In *Corcept*, 2026 WL 468866, at *3, the Federal Circuit made clear that "outside-the-label evidence" that physicians had not and were not likely to practice the patented methods could defeat a claim of inducement, regardless of what the label said.

CONCLUSION

Expanding indirect infringement liability to encompass passive labeling, regulatory compliance, and

unheeded information—as the Federal Circuit has done in *GSK*, the decision below, and several other recent opinions—untethers inducement doctrine from its common-law roots, converting a narrow secondary-liability rule into a sweeping form of strict liability. However the Court resolves this case, it should reject the Federal Circuit's embrace of infringement by label and reaffirm the settled rule that inducement requires active encouragement, direction, or promotion of infringing conduct that causes direct infringement.

Respectfully submitted,

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