No. 24-889

In the Supreme Court of the United States

HIKMA PHARMACEUTICALS USA INC., ET AL.,
PETITIONERS

v.

AMARIN PHARMA, INC., ET AL.

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

BRIEF OF SANOFI AS *AMICUS CURIAE* IN SUPPORT OF RESPONDENTS

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INTEREST OF *AMICUS CURIAE*[1]

Sanofi is a global pioneer biopharmaceutical company at the forefront of researching, developing, and manufacturing lifesaving medications and vaccines. Its research-and-development pipeline currently includes 80 clinical-stage projects spanning five therapeutic areas—immunology, neurology, oncology, rare diseases, and vaccines. Several of these projects involve uncovering innovative new therapeutic indications for existing products.

[1] Pursuant to S. Ct. Rule 37.6, no counsel for any party authored this brief in whole or in part and no person or entity other than *amicus curiae* and its counsel made a monetary contribution to its preparation or submission.

Sanofi relies on the U.S. patent system to safeguard its groundbreaking scientific advancements. In particular, Sanofi depends on 35 U.S.C. 271(b) to preserve the balance Congress struck between permitting expedited market entry of generic drugs via a skinny label and protecting the valid patent rights of pioneer manufacturers. This balance—and the ability to police it—incentivizes companies like Sanofi to continue discovering and delivering innovative new treatments to millions of patients worldwide.

SUMMARY OF ARGUMENT

In enacting the Hatch-Waxman Amendments, Congress struck a balance between making generic medications widely available and promoting continued innovation by pioneer manufacturers through patent protection. Induced infringement actions are necessary to safeguard this balance against generic manufacturers who encourage infringement in a market primed to prefer generics, even for infringing uses. This Court should affirm. At the very least, this Court should account for the unique skinny-label context in assessing the plausibility analysis so as not to render induced infringement actions toothless.

1. Induced infringement actions play a critical role in effectuating Congress's statutory skinny-label scheme.

a. In enacting the Hatch-Waxman Amendments, Congress laid out a statutory framework that permits generic manufacturers to seek narrow market approval for generic versions of branded drugs for uses that are not protected by patent, provided that generic manufacturers "carve out" patented methods of use. In permitting skinny labels, Congress recognized the massive investments undertaken by pioneer manufacturers to research, develop, and obtain approval for new drugs and

new therapeutic uses, and sought to incentivize these continued discoveries by preserving patent protections.

Without the ability to enforce their patent rights through induced infringement actions, pioneers will be disincentivized from making the substantial investments required to bring new indications to market, and patients will be deprived of groundbreaking new treatments. As Congress recognized, unchecked generic substitution would thus come at a serious long-term cost to patient care.

2. Unique characteristics of the skinny-label scheme inform the plausibility of induced infringement allegations and make this case markedly different from this Court's recent aiding-and-abetting cases.

a. In ordinary aiding-and-abetting cases, the actor being held secondarily liable is typically less culpable than the primary wrongdoer. The inquiry then turns on the degree to which the remote actor decided to join in mind and hand with the primary wrongdoer to accomplish an unlawful end.

Induced infringement is very different. It is often the secondary offender—here, the generic manufacturer—who is most culpable and the primary infringer's intent is irrelevant. The focus, in turn, is on the inducer's active and deliberate efforts to cause a third party to infringe, without regard to whether the two parties were working together at all.

b. Factual market realities also distinguish skinny-label cases. The pharmaceutical market is primed to prefer generic substitution, even for patented off-label uses. Generic manufacturers also face powerful incentives to fill market demand for infringing uses, particularly where, as here, infringing uses are far more popular than non-patented uses. And generic manufacturers

typically do little to discourage this known risk of infringement. Instead, they often rely on a combination of express statements and subtle conduct to promote infringement in a highly receptive market. Together, these realities inform the plausibility of induced infringement allegations at the pleading stage.

ARGUMENT

I. Policing The Line Between Valid Generic Promotion and Induced Infringement Is Critical To Maintaining The Balance Congress Struck In The Hatch-Waxman Amendments

In the Hatch-Waxman Amendments, Congress struck a careful balance between "two competing policy interests: (1) inducing pioneering research and development of new drugs and (2) enabling competitors to bring low-cost, generic copies of those drugs to market." *Andrx Pharms., Inc.* v. *Biovail Corp.*, 276 F.3d 1368, 1371 (Fed. Cir. 2002). On the generic side, the scheme creates a narrow exception for generic manufacturers to "piggyback[]"[2] off the "safety and efficacy studies previously submitted by the pioneer manufacturer," *ibid.*, "avoid[ing] the costly and time-consuming studies" shouldered by pioneer drug manufacturers, *Eli Lilly & Co.* v. *Medtronic, Inc.*, 496 U.S. 661, 676 (1990). This helps "make available more low cost generic drugs" for non-patented uses, reducing medical costs for patients. H.R. Rep. No. 98-857(1), at 14 (1984).

On the other side of the balance, Congress maintained critical patent protections for pioneer manufacturers who develop new therapeutic uses of a drug—in order to preserve the incentive to develop those uses and

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[2] *Caraco Pharm. Lab'ys, Ltd.* v. *Novo Nordisk A/S*, 566 U.S. 399, 405 (2012).

bring them to market. See H.R. Rep. No. 98-857(1), at 17 (1984) ("Patents are designed to promote innovation by providing the right to exclude others from making, using, or selling an invention. They enable innovators to obtain greater profits than could have been obtained if direct competition existed. These profits act as incentives for innovative activities.").

The balance reflects the high "ratio of inventor cost to imitator cost[]" in the pharmaceutical market. Dan L. Burk & Mark A. Lemley, *Policy Levers in Patent Law*, 89 Va. L. Rev. 1575, 1616-17 (2003). Costs for research, development, and approval of innovative new uses for existing drugs are immense. A recent study found that investments associated with developing supplemental indications ranged from $149.3 million to $905.3 million.[3] By comparison, "[t]he time and cost required to develop a generic small-molecule drug is far lower than the time required to bring an innovator drug to market; the generic can take less than two years' time and about $2 million." Rachel E. Sachs, *The Uneasy Case for Patent Law*, 117 Mich. L. Rev. 499, 506 (2018). Against this backdrop, "patents serve as a powerful motivator enabling private inventors to recoup their investments in the development of new technologies by excluding others from copying those technologies for a period of time." *Id.* at 505.

Thus, to maintain that balance, it is vital to police the line between (1) valid generic promotion of the approved on-label use and (2) improper generic inducement of the

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[3] See Kerstin N. Vokinger, Gellért Perényi & Olivier J. Wouters, *Investments in Research and Development for Supplemental Drug Indications—Implications for Drug Price Negotiations*, 4 JAMA Health F., Sept. 1, 2023, at e232798 (analyzing four drugs for which data are publicly available).

patented off-label use. Generic manufacturers can legitimately market their drugs for the approved on-label use. But they cannot actively induce the still-patented off-label use, because that would subvert Congress's scheme and powerfully undercut the incentive to develop those innovations in the first place.

Without the ability to reap the benefit of their investment, pioneers will curtail or stop investing in testing known drugs for different therapeutic uses or patient subgroups. In turn, patients will be deprived of significant and potentially lifesaving medical advancements. Indeed, many critical medical improvements come from the discovery of supplemental indications for already-existing molecules that reduce mortality, treat different diseases, work in a new population, or increase the effectiveness of the treatment.

For example, Coreg® (carvedilol), which was initially indicated for hypertension, was later discovered to treat congestive heart failure and reduce cardiovascular mortality after myocardial infarction with left-ventricular dysfunction.[4] The later indication was a lifesaving post-market innovation. But without meaningful inducement liability, such innovations may go undiscovered and patient care would suffer as a result.

At bottom, the scheme "will not work … if the holder of the patent pertaining to the pioneer drug is disabled from establishing in court that there has been an act of infringement" by a generic manufacturer. *Eli Lilly & Co.*, 496 U.S. at 678. In fact, because the FDA does not independently assess patent scope when reviewing a

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[4] Robert R. Ruffolo Jr. & Gloria Z. Feuerstein, *Pharmacology of Carvedilol: Rationale for Use in Hypertension, Coronary Artery Disease, and Congestive Heart Failure*, 11 Cardiovascular Drugs & Therapy (Supp. 1) 247 (1997).

generic's proposed skinny label, infringement actions may be the only mechanism for pioneer manufacturers to challenge skinny labels after they hit the market. See *Caraco Pharm. Lab'ys*, 566 U.S. at 406-07. Without such liability, generic manufacturers would be free to induce substitution for patented off-label uses, thereby undercutting or nullifying the incentive to innovate—and thus upsetting the balance Congress struck.

II. The Plausibility Analysis For Skinny-Label Induced Infringement Must Be Sensitive To Context

When courts are considering the plausibility of allegations of induced infringement in this context, they can and should assess several unique features of the skinny-label marketplace. Those features bear on the plausibility analysis and make this case meaningfully different from this Court's recent cases involving allegations that a business aided and abetted the third-party wrongdoing of some of its customers. See *Smith & Wesson Brands, Inc.* v. *Estados Unidos Mexicanos*, 605 U.S. 280 (2025); *Twitter* v. *Taamneh*, 598 U.S. 471 (2023).

A. Induced Infringement Is Fundamentally Different From This Court's Recent Aiding-And-Abetting Cases

At the outset, secondary liability principles for induced patent infringement are meaningfully different from the Court's recent cases addressing aiding-and-abetting claims at the pleading stage.

In the typical aiding-and-abetting context, the greatest degree of culpability traditionally rests with the primary offender. To avoid ensnaring innocent third parties in liability for acts to which they are strangers, a court's inquiry focuses on the conscious choice to participate in the primary actor's unlawful conduct. Courts accordingly assess whether the allegations plead

"conscious … and culpable participation in another's wrongdoing." *Smith & Wesson*, 605 U.S. at 291; see *Cox Commc'ns, Inc.* v. *Sony Music Ent.*, No. 24-171, slip op. at 7 (U.S. Mar. 25, 2026) (Sotomayor, J., concurring) ("[A]iding-and-abetting liability requires proof that the defendant aided another with the intent of helping that other person succeed in committing wrongful conduct."). Alleging that kind of conscious, voluntary, and culpable participation in third-party wrongdoing is often difficult, as this Court has held. See *Smith & Wesson*, 605 U.S. at 291; *Taamneh*, 598 U.S. at 506.

Induced patent infringement is fundamentally different: It is often the secondary offender who is most culpable. "[P]atent courts have long recognized that focusing only on the party who actually practices the invention will sometimes let off the hook the party who most deserves to be held liable"—*i.e.*, the secondary offender. Mark A. Lemley, *Inducing Patent Infringement*, 39 U.C. Davis L. Rev. 225, 226 (2005); see also Lynda J. Oswald, *The Intent Element of "Inducement to Infringe" Under Patent Law: Reflections on* Grokster, 13 Mich. Telecomm. & Tech. L. Rev. 225, 227 (2006) ("Over a century ago, the courts recognized that extending liability only to the direct infringer might well enable others whose culpability in the infringing activities is even greater to escape liability."). This is especially true in the pharmaceutical industry, where "a patent on a new use for an existing drug is directly infringed by each individual patient taking the drug for the new use, or perhaps by the doctors who prescribe it. But it is impractical to sue them." Lemley, 39 U.C. Davis L. Rev. at 228.

This notion is enshrined in the Patent Act itself. Direct infringement is a strict liability offense. See 35 U.S.C. 271(a). The infringer is liable "regardless of

whether the defendant was aware of the patent at the time he or she was infringing it, or whether the defendant had any intent to infringe." Oswald, 13 Mich. Telecomm. & Tech. L. Rev. at 229.

Induced infringement, by contrast, includes an express *mens rea* element, which "requires that the party express 'an affirmative intent that the product be used to infringe.'" *Cox*, slip op. at 8 (quoting *Metro-Goldwyn-Mayer Studios Inc.* v. *Grokster, Ltd.*, 545 U.S. 913, 936 (2005)); see also *GlaxoSmithKline LLC* v. *Teva Pharms. USA, Inc.*, 7 F.4th 1320, 1327 (Fed. Cir. 2021) (induced infringement claim "requires establishing 'that the defendant possessed *specific intent* to encourage another's infringement'" (quoting *DSU Med. Corp.* v. *JMS Co.*, 471 F.3d 1293, 1306 (Fed. Cir. 2006) (emphasis added))); see 35 U.S.C. 271(b).

Thus, in skinny-label inducement cases, the question is not whether a generic manufacturer "joined both mind and hand" with any primary wrongdoer. *Smith & Wesson*, 605 U.S. at 293. Rather, the question is whether the generic manufacturer, acting with specific intent and knowledge of the patent, actively induced third parties to infringe. See *GlaxoSmithKline*, 7 F.4th at 1327. Unlike in this Court's recent aiding-and-abetting cases, the inducer and primary infringer could be complete strangers to one another. They need not participate in any shared enterprise; indeed, the direct infringer could be entirely unaware that he or she was induced to infringe and entirely unaware of the patent.

The pleading burden is accordingly different. In particular, when knowledge and specific intent are adequately alleged, as here, the focus is on whether the plaintiff has plausibly alleged active steps that encouraged third-party infringement. See *Cox*, slip op. at 7 ("A

provider induces infringement if it actively encourages infringement through specific acts."); *Grokster*, 545 U.S. at 936 (requiring "evidence of 'active steps … taken to encourage direct infringement'").

B. Market Realities Of The Skinny-Label Context Help Plausibly Support Inducement

The market structure of the generic pharmaceutical industry provides important context that courts must consider when assessing the plausibility of allegations of induced infringement in the skinny-label context. See *Grokster*, 545 U.S. at 939-40 (identifying features probative of induced infringement). In this context, the market is primed to respond to inducement, because of the strong market incentives to engage in generic substitution, and even subtle affirmative steps can be sufficient to actively induce. To be clear, marketing skinny label drugs that properly carve out patented uses—without more—does not show inducement. But the quantum of active inducement courts require at the pleading stage should take into account the structural incentives inviting induced infringement.

1. The Pharmaceutical Market Is Primed To Respond To Skinny-Label Off-Label Promotion

Market participants—including doctors, patients, pharmacists, and insurers—have strong incentives to respond to promotion of patented uses in the skinny-label context. As a result, it takes little for generic manufacturers to actively induce downstream actors to prescribe generics for patented off-label uses.

Patients often seek lower-cost, generic versions of branded medications.[5] About 91% of all prescriptions in the United States are filled as generics.[6] And patients generally have little awareness or concern for whether generic medications are being used for on-label or off-label use. In the skinny-label context, patient demand for generics therefore drives substitution for both on- and off-label uses. For example, just one year after a generic version of the cancer drug imatinib hit the market, more than 88% of patients with gastrointestinal stromal tumors—a supplemental indication—received a generic version of imatinib, even though that indication was off-label and patented.[7]

Doctors, in turn, face pressure from their patients to prescribe lower-cost generic options. And doctors are generally not restricted from prescribing drugs for off-label uses—and sometimes may even do so unknowingly.[8] This means that, as a practical matter, doctors

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[5] The FDA estimates that generics are sold at an 80 to 85% discount, largely owing to the streamlined approval process. See *Generic Drugs: Questions & Answers*, U.S. Food & Drug Admin. (Mar. 16, 2021), https://www.fda.gov/drugs/frequently-asked-questions-popular-topics/generic-drugs-questions-answers.

[6] Off. of Generic Drugs, Ctr. for Drug Evaluation & Rsch., U.S. Food & Drug Admin., *Office of Generic Drugs 2022 Annual Report* (Jan. 2023), https://www.fda.gov/media/165435/download.

[7] Brian S. Walsh et al., *Indication-Specific Generic Uptake of Imatinib Demonstrates the Impact of Skinny Labeling*, 40 J. Clinical Oncology 1102 (2022).

[8] Electronic health records (EHR) and e-prescribing systems generally do not have capabilities to distinguish between indications. So, when a generic is in the system as interchangeable, but the system doesn't specify which indications the product is approved for, a prescriber may unknowingly select the less expensive generic drug for a patented indication.

have significant incentives to prescribe skinny-label generics for patented uses.

Insurance companies similarly make it easy for generic manufacturers to prompt infringement. For example, insurance companies may put generic alternatives on cheaper co-pay tiers, require preauthorization for branded drugs, or mandate step therapy—directing patients to use generic alternatives and covering the branded version only if the generic is ineffective.[9]

For their part, pharmacies often (and are sometimes required to) dispense generics and do so without regard for whether the generic is dispensed for a patented use.[10] Indeed, pharmacies may be entirely unaware of the intended use of a particular prescription.

Putting these structural features together, the skinny-label market effectively sits on a hair-pin trigger. Because the skinny-label landscape is tilted to favor infringement at every step, it does not take much for generic manufacturers to cross the line to induce infringement.

2. Generic Manufacturers Often Aim To Satisfy Known Demand For Patented Uses

In a market already primed to prefer substitution, one important factor to consider in assessing plausibility is whether the generic manufacturer takes active steps "to satisfy a known source of demand … for … infringement." *Grokster*, 545 U.S. at 939. In *Grokster*, for

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[9] Ctrs. for Medicare & Medicaid Servs., *Tips for Understanding Your Drug Coverage & Prescriptions* (Nov. 2023), https://www.cms.gov/files/document/understanding-drug-coverage-and-prescriptions.pdf.

[10] Richard G. Frank, Thomas G. McGuire & Ian Nason, *The Evolution of Supply and Demand in Markets for Generic Drugs*, 99 Milbank Q. 828, 832 (2021).

example, the defendants knew that infringing uses constituted about 90% of the total uses of their platform, and only a small fraction of the uses (about 10%) were non-infringing. See *id.* at 933. This Court found it probative that the defendants engaged in "efforts to supply services" for both lawful and unlawful users, in an effort to fully satisfy demand for both. *Id.* at 939.

This same factor can weigh heavily in the skinny-label context. For example, as in *Grokster*, in this case there is nearly a 10:1 ratio of infringing to non-infringing use: By 2020, respondents' patented CV indication accounted for approximately 90% of Vascepa sales. See Resp. Br. at 11. Recognizing this massively disproportionate demand for the patented use, petitioners promoted the generic broadly for *both* the patented and non-patented uses by marketing the generic for "Hypertriglyceridemia," *id.* at 12, touting Vascepa's total domestic sales data, *id.* at 13, and referring to their product as the generic equivalent of Vascepa, *id.* at 13-14. Where a defendant "not only expected but invoked by advertisement" the infringing use of its product, it is secondarily liable for that infringement. *Kalem Co.* v. *Harper Bros.*, 222 U.S. 55, 63 (1911); cf. *Cox*, slip op. at 9 (no inducement where plaintiff "provided no 'evidence of express promotion, marketing, and intent to promote' infringement" (quoting *Grokster*, 545 U.S. at 926)).

Indeed, generic manufacturers like petitioners face significant financial incentives to profit from sales for all potential uses, particularly where, as here, demand for the patented off-label use drives sales. See Resp. Br. at 27. These allegations powerfully support a deliberate effort to satisfy the *entire* market for Vascepa, not just the legitimate portion of the market.

And this case is not a one-off. Methotrexate was initially approved to treat a variety of malignancies, but later approved to treat rheumatoid arthritis.[11] It is now the standard of care for the treatment of rheumatoid arthritis, the supplemental indication.[12] Lyrica (pregabalin) was primarily indicated to treat partial onset seizures, but later indicated to treat neuropathic pain and fibromyalgia, a blockbuster use.[13]

This market reality also sharply distinguishes *Cox*, which involved a business that "provided Internet access, which is used for many purposes other than copyright infringement." *Cox*, slip op. at 9. And it also further distinguishes *Taamneh* and *Smith & Wesson*, where the defendants' products and services (social media platforms and firearms) were overwhelmingly used for lawful purposes and the businesses were not meaningfully incentivized to promote the unlawful uses.

In this context, however, when doctors and patients have strong incentives to respond to promotion of low-cost generics for a patented use, and when the off-label, patented use can open up a larger portion of the market, generic manufacturers are strongly incentivized to satisfy—and often do aim to satisfy—demand for infringing uses. See *Henry* v. *A.B. Dick Co.*, 224 U.S. 1, 48 (1912) (intent and purpose to promote infringement "may … be

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[11] Michael E. Weinblatt, *Methotrexate: Who Would Have Predicted Its Importance in Rheumatoid Arthritis?*, 20 Arthritis Rsch. & Therapy, art. no. 103 (2018), https://pmc.ncbi.nlm.nih.gov/articles/PMC5977479/.

[12] *Ibid.*

[13] Christopher W. Goodman & Allan S. Brett, *Gabapentin and Pregabalin for Pain — Is Increased Prescribing a Cause for Concern?*, 377 New Eng. J. Med. 411 (2017), https://www.nejm.org/doi/full/10.1056/NEJMp1704633.

inferred" where a product's "most conspicuous use is one which will co-operate in an infringement when sale to such user is invoked by advertisement"), overruled on other grounds, *Motion Picture Pats. Co.* v. *Universal Film Mfg. Co.*, 243 U.S. 502 (1917).

3. Generic Manufacturers Often Encourage Both Infringing and Non-Infringing Uses In An Undifferentiated Way

A generic manufacturer's choice to encourage all use of its product without differentiation is another probative factor. In *Grokster*, for example, the defendants were aware that a significant number of users used their platforms for unlawful purposes. Still, the defendants did not "develop filtering tools or other mechanisms to diminish the infringing activity." *Grokster*, 545 U.S. at 939. While the absence of filtering tools was not alone sufficient to establish secondary liability, it was a factor. See *ibid.*

So too here. In many skinny-label cases, the manufacturer will actively promote the product in an undifferentiated way that reaches both lawful and infringing uses, while knowing that the primary demand is for a patented off-label use and that its promotion will encourage *both* uses.

This case is a prime example. Petitioners marketed their generic for "Hypertriglyceridemia," which encompassed *both* the SH indication and the patented CV indication—knowing full well that the patented indication was the source of the vast majority of product demand. See Resp. Br. at 12; see also *Henry*, 224 U.S. at 48. That undifferentiated promotion without disclaimer is much unlike the allegations in *Cox*. There, infringement constituted an insubstantial use of Cox's product; still, Cox "repeatedly *discouraged* copyright infringement by

sending warnings, suspending services, and terminating accounts." *Cox*, slip op. at 9 (emphasis added). Petitioners' choice to promote both uses of their drug equally without differentiation or disclaimer, by contrast, is a factor that supports the plausibility of allegations of active inducement of the infringing use.

4. Generic Manufacturers Commonly Rely On Subtle Conduct To Encourage Infringement

A generic manufacturer can actively induce infringement through express statements promoting the infringing use. But generic manufacturers often induce through more subtle communication or without communication at all—with "other affirmative steps" that "foster infringement … by third parties." *Grokster,* 545 U.S. at 937. Against an already-receptive market, nuanced conduct that promotes an infringing use is another factor that is probative of inducement.

There are a wide variety of ways in which generic manufacturers can subtly induce infringement, including through conduct that appears superficially benign:

First, generic manufacturers may target off-label prescribers for promotional activities that are ostensibly neutral. For example, using claims data for branded drugs, generic manufacturers can identify and prioritize particular high-prescribing physicians and disproportionately target them with marketing efforts. In this way, even by using the same neutral marketing materials across physicians that refrain from expressly promoting the patented off-label use, manufacturers can still actively encourage off-label use by targeting particular physicians. For example, even if a drug is indicated on label only for ages 18 and up, generic manufacturers may still target pediatricians to discuss the drug, thereby impliedly encouraging off-label use.

Second, generic manufacturers may circulate to healthcare providers a published research article or drug reference listing that highlights the patented indication. These publications do not involve express statements by the generic manufacturer itself. But generic manufacturers can use these communications to prompt providers to reach out to the generic manufacturers' medical affairs teams with questions, including about patented uses, which the medical affairs teams answer in detail.

Third, generic manufacturers can request that prescription drug plans replace or de-prioritize branded drugs in favor of generic alternatives. While this may appear on the surface as ordinary price competition, such replacement can have the practical effect of encouraging substitution for *all* uses in order to foster use of the generic for a patented indication.

Fourth, generic manufacturers may sponsor speaker bureaus—educational events attended by healthcare professionals to learn about conditions, treatments, and products—and offer materials or presentations that may in context be understood to convey that a generic product can be used for patented indications.

The case law bears out that promotion may occur subtly through statements and conduct. For example, in *AlexSam, Inc.* v. *Aetna, Inc.*, the Federal Circuit held that the plaintiff plausibly alleged intent to induce infringement from allegations that the defendant continued to "provid[e] and support[]" its products and "instruct[ed] its customers on how to use them in an infringing manner, at least through information available on Defendant's website including information brochures, promotional material, and contact information." 119 F.4th 27, 46 (Fed. Cir. 2024).

At bottom, skinny-label inducement does not occur in a vacuum, but rather within the context of highly specialized interactions in an industry that is primed to respond to promotion of generic substitution. Within this context, while generic manufacturers can certainly lawfully promote their products exclusively for the on-label use, it takes little to cross the line into induced infringement. Indeed, the types of behaviors that can actively encourage that substitution are often less overt than in many more typical contexts. See, *e.g.*, *GlaxoSmithKline*, 7 F.4th at 1338.

CONCLUSION

This Court should affirm. At a minimum, in assessing plausibility, the Court should recognize the importance of policing induced infringement in the skinny-label context and the market dynamics that often make allegations of active inducement plausible.

Respectfully submitted.

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