Supreme Court Clarifies Induced Infringement Standard for Generic Drugs in Patent Disputes

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***Hikma Pharmaceuticals USA Inc. v. Amarin Pharma, Inc.*, 608 U.S. ___ (June 4, 2026)**

In *Hikma Pharmaceuticals USA v. Amarin Pharma, Inc.*, the U.S. Supreme Court held that generic drug manufacturer Hikma Pharmaceuticals did not actively induce infringement of Amarin Pharma's cardiovascular-indication patents. In doing so, the court clarified the standard governing induced infringement claims brought by brand-name drug manufacturers against generic manufacturers under 35 U.S.C. Section 271(b) in the context of "skinny label" generics.

Background

Amarin Pharma developed Vascepa, a drug with the active ingredient icosapent ethyl, initially approved by the U.S. Food and Drug Administration (FDA) in 2012 for treating severe hypertriglyceridemia (the "SH indication"). In 2019, the FDA approved a second, commercially significant use: reducing cardiovascular risk in hypertriglyceridemia patients who already take statins (the "CV indication"). Amarin obtained method-of-use patents covering this second indication.

Hikma, a generic manufacturer, pursued FDA approval of a generic version of icosapent ethyl through the so-called "skinny label" pathway under Section viii of the Hatch-Waxman Amendments. Section vii permits a generic manufacturer to seek approval for a generic drug that is biologically equivalent to a brand-name drug, but only for a particular non-patented use. Hikma sought approval *only* for the SH indication, carving out the still-patented CV indication. The FDA approved Hikma's abbreviated new drug application (ANDA) in 2020.

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A generic manufacturer that obtains skinny label approval cannot promote the still-patented use. But medical professionals can prescribe the generic drug for that patented use, and a generic manufacturer can be liable for patent infringement if they step over the line and induce that infringement. Amarin sued Hikma for actively inducing infringement of its patent for icosapent ethyl's use for the CV indication, pointing to a constellation of statements: Hikma's skinny label, an accompanying patient information leaflet, its website, and pre-launch press releases that described the product as the "generic equivalent" of Vascepa and cited sales figures encompassing both the SH and CV indications. The district court dismissed the complaint, but the U.S. Court of Appeals for the Federal Circuit reversed. In a unanimous opinion by Justice Jackson, the Supreme Court reversed the Federal Circuit's ruling and remanded for further proceedings.

Supreme Court's Opinion

There are three elements of an induced-infringement claim under Section 271(b): (1) direct infringement by a third party; (2) knowledge by the inducer that the induced acts constitute patent infringement; and (3) "active steps" by the inducer to encourage that direct infringement. The Supreme Court's analysis centered on the third "active steps" requirement. Drawing on *Metro-Goldwyn-Mayer Studios Inc. v. Grokster, Ltd.*, 545 U.S. 913 (2005), and *Global-Tech Appliances, Inc. v. SEB S.A.*, 563 U.S. 754 (2011), the Supreme Court reaffirmed that liability under Section 271(b) demands "purposeful, culpable expression and conduct" — that is, taking "affirmative," not passive, "steps to bring about the desired result" of infringement.

The Supreme Court rejected the "recent approach" of the Federal Circuit: whether the defendant made statements that could be read by medical providers as instructions to infringe, rather than whether Hikma had actively encouraged infringement through its statements. A defendant's liability turns on the nature of its own conduct — not on how a third party might conceivably interpret neutral or ambiguous communications.

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Applying this standard, the Supreme Court found Amarin's allegations wanting on three grounds. First, several of Hikma's statements had an obvious alternative explanation — compliance with law or standard industry practice. Federal statute required Hikma's label to mirror Amarin's (with limited exceptions), and describing a product as a "generic equivalent" is conventional commercial practice, not affirmative promotion of inducement. Second, the court rejected reliance on omissions or inactions — such as the label's failure to include a cardiovascular limitation-of-use statement, or press releases that did not highlight the narrower approved use. Consistent with the Supreme Court's recent decision in *Twitter, Inc. v. Taamneh (2023)*, the court held that active inducement cannot be premised on "mere omissions, inactions, or nonfeasance." Third, Hikma's remaining statements — a leaflet warning about cardiovascular side effects, a broad therapeutic category description on its website, and investor-facing press release sales figures — were too vague and speculative to constitute affirmative encouragement of infringement.

Key Takeaways

- ***Hikma* is a significant victory for generic manufacturers.** The ruling reinforces that the "skinny label" framework depends on maintaining a meaningful distinction between passive market participation and active encouragement of infringement.
- **Brand-name pharmaceutical companies seeking to bring induced infringement claims will need to identify concrete, affirmative steps** — not merely ambiguous statements or regulation-mandated content — to survive early motion practice.
- **The active steps inquiry is defendant-focused, not audience-focused.** The Supreme Court firmly rejected the Federal Circuit's tendency to frame the analysis around how a physician could plausibly interpret a defendant's statements.
- **Conduct compelled by statute or standard industry practice — such as label sameness requirements and the conventional use of "generic equivalent" language —**

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cannot form the basis of an inducement claim. This holding limits the utility of attacks premised on mandatory labeling content and ordinary commercial communications.

- **Omissions are not "active steps."** A generic manufacturer's failure to emphasize the limited scope of its approved indication — whether on the label, in press releases, or elsewhere — does not constitute active inducement.
- **Vague statements plus speculation will not suffice at the pleading stage.** Broad categorical descriptions, general therapeutic equivalence designations, and investor-oriented financial disclosures do not plausibly constitute affirmative encouragement of patent infringement.
- **The Federal Circuit's trend line is corrected.** The Supreme Court explicitly noted that the Federal Circuit had been "increasingly" focusing its inducement analysis on how medical providers could read a defendant's statements. By rejecting that trend, the Supreme Court has reset the circuit's analytical framework and will likely require revisiting prior Federal Circuit precedents that allowed induced infringement claims to proceed on similar allegations.

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