Now & Next
Intellectual Property Alert

June 4, 2026

Supreme Court tightens active steps requirement for skinny-label inducement claims

By Seth D. Levy and Ryan Dean

Supreme Court clarifies induced infringement standard, ruling that Amarin didn't plausibly show Hikma's skinny label encouraged infringement.

What's the impact?

- Pleading-stage focus shifts back to the defendant's conduct: The question is whether the defendant actively encouraged infringement, and not merely whether physicians could plausibly interpret neutral statements as encouragement.
- Regulatory compliance and ordinary equivalence messaging are poor inducement building blocks: FDA-driven "duty of sameness" labeling and routine descriptions like "generic equivalent" and "AB rated" often have "obvious alternative explanations" consistent with lawful conduct.
- Omissions and vague statements are not enough: Inducement cannot rest on "mere omissions, inactions, or nonfeasance," or on vague language plus an attenuated chain of inferences about how others might act.
- But liability remains possible: The decision does not create a Hatch-

Waxman safe harbor; clear, affirmative promotion of a patented use can still support inducement claims.

On June 4, 2026, in *Hikma Pharmaceuticals USA Inc. v. Amarin Pharma, Inc.*, 608 U.S. ___ (2026), the United States Supreme Court unanimously reversed the Federal Circuit's decision allowing Amarin's induced-infringement claim to proceed past a motion to dismiss. Justice Jackson delivered the opinion for the Court.

Background

Amarin markets Vascepa (icosapent ethyl), which has two FDA-approved indications: (1) treatment of severe hypertriglyceridemia (the "SH Indication"), and (2) reduction of cardiovascular risk in certain patients taking statins (the "CV Indication"). Amarin obtained method-of-use patents covering the CV Indication. Hikma submitted an ANDA for generic icosapent ethyl and ultimately pursued FDA approval via a Hatch-Waxman "section viii" statement with a skinny label that carved out the patented CV Indication. The FDA approved Hikma's ANDA and assigned an AB rating.

Amarin sued Hikma in the District of Delaware, alleging Hikma actively induced infringement of Amarin's CV Indication patents based on the "totality" of Hikma's communications, including the skinny label, patient leaflet, website statements (including AB rating and therapeutic category), and pre-launch press releases referencing Vascepa and sales figures. The district court dismissed under Rule 12(b)(6), but the Federal Circuit reversed, holding it was "at least plausible" that a physician could read Hikma's statements as encouraging infringing use.

The Court's opinion

In its opinion, the Court reiterated three elements of inducement under § 271(b): (1) direct infringement by a third party; (2) knowledge that the induced acts constitute infringement; and (3) "active steps to encourage" infringement. The dispute centered on the third element—the governing standard in induced infringement liability. Relying on *Grokster*, *Global-Tech*, and the Court's recent secondary-liability analysis in *Cox Communications v. Sony Music Entertainment*, the Court emphasized that "active steps" require "purposeful, culpable expression and conduct," and exclude "ordinary acts incident to product distribution."

Relying on this standard, the Court rejected the Federal Circuit's "could read it as encouragement" approach. According to the Court, the "central question" is whether the complaint plausibly alleged that Hikma actively encouraged infringement. The Federal Circuit had held it was "at least plausible" that a physician could read Hikma's label, website, and press statements as encouraging infringing use. The Supreme Court disagreed, emphasizing that the plausibility inquiry turns on whether the complaint alleges affirmative, culpable "active steps" by the defendant to bring about infringement, and not on speculation about how third parties might interpret statements that are facially consistent with lawful, noninfringing conduct. Furthermore, and consistent with *Twombly* and *Iqbal*, allegations that are merely consistent with liability (and fail to rule out "obvious alternative explanations"), and that fail to allege "more than a sheer possibility," do not cross the plausibility threshold.

Applying this standard here, the Court reversed and remanded, holding that Amarin did not plausibly allege active inducement. According to the Court, Amarin's allegations failed for several reasons:

OBVIOUS LAWFUL EXPLANATIONS

Much of what Amarin pointed to in the label was dictated by the Hatch-Waxman "duty of sameness," which generally requires a generic label to match the brand label except for carved-out patented uses. Likewise, describing a product as a "generic equivalent" to a brand drug is ordinary industry practice. The Court declined to treat compliance with law and standard practice as evidence of culpable inducement.

NO INDUCEMENT BY OMISSION

Amarin also relied on what Hikma allegedly did not say, for example, not highlighting that approval was limited to the SH Indication or not including a cardiovascular limitation of use that had appeared on an earlier version of Vascepa's label. Citing *Taamneh*, the Court held inducement must be grounded in affirmative statements or actions, not "mere omissions, inactions, or nonfeasance."

VAGUE STATEMENTS AND SPECULATIVE CAUSAL CHAINS ARE INSUFFICIENT

The patient leaflet warnings and general disclaimers, the website's therapeutic category and AB rating (particularly where the website clarified the generic had fewer indications), and investor-oriented sales figures required too attenuated a chain of inferences to plausibly constitute purposeful steps "designed to stimulate" infringement.

Key takeaways

FOR GENERIC MANUFACTURERS AND OTHER ANDA FILERS

- Section viii remains viable at the pleadings stage: The Court's analysis gives defendants stronger Rule 12 arguments where the alleged "inducement" is largely FDA-driven labeling content plus routine equivalence messaging.
- Avoid affirmative patented-use promotion: The opinion leaves room for inducement liability where a generic's communications clearly encourage the patented use (for example, expressly touting the patented indication or echoing brand marketing about that indication).
- Be deliberate with external communications: Website descriptors, therapeutic categories, and AB-rating language should be accurate and should not be paired with messaging that could be read as promoting the carved-out use. Where appropriate, consider clear, accurate statements about the limited indicated use, while recognizing the Court did not impose any affirmative "duty to disclaim."

FOR BRAND MANUFACTURERS AND PATENT OWNERS

- There is a higher hurdle for "passive" inducement theories: Complaints premised on omissions, regulatory compliance, or "physicians could infer X" theories face a more difficult plausibility showing.
- Focus on affirmative promotion tied to the patented method: Inducement claims are most likely to survive when they identify specific communications or conduct plausibly aimed at encouraging the patented use and link that conduct to infringement without an attenuated inferential chain.

FOR THE BROADER PATENT AND HEALTHCARE MARKETS

- This case reinforces the active/passive line: The Court reiterated that inducement targets purposeful, culpable encouragement, and not mere foreseeability that a dual-use product will sometimes be used in infringing ways.

For guidance navigating induced infringement, skinny-label strategies, and evolving Hatch-Waxman risks, Nixon Peabody's intellectual property lawyers offer practical, business-focused counsel. We help clients align regulatory pathways with strong, defensible patent strategies in a rapidly shifting landscape. For more information on the content of this alert, please contact your Nixon Peabody attorney or:

Seth D. Levy
213.629.6161
slevy@nixonpeabody.com

Ryan Dean
617.345.1197
rdean@nixonpeabody.com

NIXON PEABODY