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Supreme Court Hands Generics a Unanimous Win on Skinny Labels in Hikma v. Amarin

A unanimous Supreme Court reversed the Federal Circuit and held that Amarin did not plausibly allege that Hikma's skinny label and marketing actively induced infringement of Vascepa's cardiovascular-use patents — a decisive win for the generic industry that affirms skinny labeling as a shield against method-of-use liability.

Key Takeaways

- **A decisive win for the generic industry.** On June 4, 2026, a unanimous Court — in an opinion by Justice Jackson — reversed the Federal Circuit and held that Amarin failed to state a claim for active inducement under 35 U.S.C. §271(b). The decision affirms skinny labeling and will generally shield generic companies that properly carve out a patented indication from induced-infringement liability.
- **The Court ruled unanimously and just five weeks after argument** — a strong signal that the entire bench agreed with the position urged by Hikma and the generic-drug industry.
- **Inducement requires affirmative steps, not passive ones.** In a notable footnote, the Court rejected the recent trend of focusing on how medical providers might read a statement rather than on whether the defendant actively encouraged infringement. This is a fundamental difference from direct infringement, where the patent owner does not have to demonstrate active encouragement to succeed.
- **The door is not shut entirely.** Active encouragement can be explicit or implicit, but it must be "clear" and "affirmative." A brand company patent holder that can plausibly allege affirmative steps may still bring an inducement claim — but for the generic industry, the decision is a clear endorsement of the continued use of skinny labeling.

The Supreme Court Rejects a Broad Theory of Skinny-Label Inducement

As we reported when the Federal Circuit revived this suit in 2024, when the Supreme Court granted certiorari in January 2026, and in our read of April's oral argument, the case turns on a strategy generics have relied on for decades. Vascepa is approved both for severe hypertriglyceridemia (the off-patent "SH" indication) and, since 2019, for cardiovascular risk reduction in statin patients (the patented "CV" indication). Hikma used

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a section viii "skinny label" to carve out the patented CV use and market only for SH. Amarin nonetheless sued, arguing that the totality of Hikma's label, patient leaflet, website, and press releases actively induced infringement for the patented CV use.

The District of Delaware dismissed the complaint, but the Federal Circuit reversed, finding it "at least plausible that a physician could read" Hikma's statements "as an instruction or encouragement" to infringe. The Supreme Court held flatly: "that was error."

Inducement under §271(b) requires direct infringement, knowledge and — the only element in dispute — "active steps…to encourage direct infringement." Those steps must be *affirmative*, "purposeful, culpable expression and conduct," not "ordinary acts incident to product distribution." As we anticipated after April's argument, the Court declined to craft a new pharmaceutical inducement standard and instead applied the familiar *Twombly* / *Iqbal* pleading principles the Justices had pressed on both sides. On those terms, Amarin's allegations — "whether viewed together or separately" — came up short for three reasons:

- **Compliance with the law is not a building block for liability.** Hikma's label omitted the CV indication of use but otherwise tracked Amarin's label because the statutory "duty of sameness" required it, and calling the product "generic Vascepa" is "normal industry practice." The Court "decline[d] to put generic manufacturers between a rock and a hard place by turning adherence to the law and industry standards into building blocks for illegal conduct."
- **Omissions are not active inducement.** A skinny label's *silence* about the carved-out use — or a press release's failure to flag that the generic is approved only for the lesser-known SH indication — is "mere omission" that cannot establish affirmative encouragement.
- **Vague statements plus speculation are not enough.** The patient leaflet's cardiovascular side-effect warning and off-label disclaimer were "implausibly roundabout ways to induce"; the website's "hypertriglyceridemia" category and "AB" rating were no more an instruction to infringe than calling a leukemia drug a "cancer drug"; and the sales figures in Hikma's investor press releases were "the vaguest of" the statements alleged. That a provider *might* draw encouragement from them was "possible" but not "plausible."

What the Decision Means for Generic and Brand Manufacturers

For generic manufacturers, the decision restores the section viii carve-out as a workable pathway and pulls the Federal Circuit back from a line of cases that had made the skinny label feel newly fragile. By grounding liability in the generic's affirmative conduct rather than a hypothetical physician's reading, the Court reset the bar a brand company patent holder must clear and gave properly carved-out products meaningfully more "breathing room."

It is not, however, a green light to market loosely. The Court was clear that inducement need not be *express* — implicit encouragement still counts — but whether implicit or explicit, the encouragement must be "clear" and "affirmative." The holding rests on the pleadings, not on a categorical rule that skinny labels are immune. Brand company patent holders retain a path, but they must allege affirmative steps "designed" to drive the patented use, not merely statements a physician could construe that way.

What Generic and Brand Manufacturers Should Watch After *Amarin v. Hikma*

- **The remand.** The case returns to the Federal Circuit and the District of Delaware; watch whether Amarin seeks leave to amend and whether any repleading can clear

the higher “affirmative encouragement” bar.

- **Federal Circuit recalibration.** The Court’s rejection of *GSK v. Teva’s* physician-interpretation reasoning will ripple through pending and future induced-infringement disputes.
- **Brand company enforcement strategy.** Brand companies will likely pivot from label-and-marketing-totality theories toward pleading specific, affirmative steps — or toward earlier discovery — to satisfy the standard the Court set.

For more information about the Supreme Court’s decision and its implications for generic drug manufacturers, brand companies and Section viii carve-out strategies, please contact the eAlert authors or your preferred Polsinelli attorney.