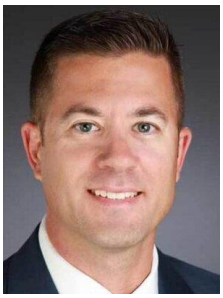
Upshot Of 'Skinny Label' Case May Go Beyond Pharma

By **Jason Shull** (February 3, 2026)



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On Jan. 16, the U.S. Supreme Court agreed to review Hikma Pharmaceuticals USA Inc. v. Amarin Pharma Inc., a case that sits at the intersection of patent law, U.S. Food and Drug Administration regulation, and generic drug competition. The court's decision to grant certiorari follows a 2024 ruling by the U.S. Court of Appeals for the Federal Circuit that revived Amarin's induced infringement claims and allowed the case to proceed past the pleading stage.

The U.S. Supreme Court's intervention has drawn immediate attention from pharmaceutical companies and their counsel because it raises a familiar but persistently unsettled question: When does otherwise lawful conduct by a generics manufacturer cross the line into induced patent infringement?

More specifically, the case asks whether the Hatch-Waxman Act's "skinny label" pathway retains practical meaning if generics manufacturers can face postlaunch inducement liability based not on their FDA-approved labels, but on surrounding marketing statements and communications.

Although the Supreme Court has yet to address the merits, the Federal Circuit's decision has already altered the risk calculus for practitioners advising both brand-name and generics companies. For many, Hikma v. Amarin is less about any single launch and more about whether compliance with FDA requirements remains a reliable way to manage patent risk in a heavily regulated industry.

This article explains why Hikma v. Amarin matters now, how it fits within existing inducement doctrine and what practitioners should be thinking about as the case proceeds.

Induced Infringement and the Centrality of Intent

Induced infringement under the Patent Act requires more than the sale of a product that might be used in an infringing manner. Liability turns on intent — specifically, whether the accused infringer knowingly took affirmative steps to encourage another party's direct infringement.

In Global-Tech Appliances Inc. v. SEB SA, decided in 2011, the Supreme Court held that induced infringement under Title 35 of the U.S. Code, Section 271(b), requires knowledge of the asserted patent and knowledge that the encouraged acts constitute infringement.

The court rejected a negligence standard, emphasizing that inducement is a culpability-based doctrine. Earlier, in Metro-Goldwyn-Mayer Studios Inc. v. Grokster Ltd., decided in 2005, the high court similarly explained that liability arises when a defendant distributes a product with the object of promoting its infringing use, as shown by clear expressions or other affirmative acts.

Together, these decisions underscore a consistent principle: Inducement liability is not based on foreseeability alone, nor does it arise from lawful conduct that merely facilitates infringement incidentally. Instead, it requires purposeful encouragement directed toward

infringing activity.

Skinny Labeling Under the Hatch-Waxman Act

The Hatch-Waxman Act overlays that inducement framework onto a detailed regulatory regime administered by the FDA. One of the act's most important mechanisms is the Section 8 carveout, which permits generics manufacturers to seek FDA approval for nonpatented uses of a drug while omitting patented indications from the product label.

Congress enacted this pathway to prevent method-of-use patents from blocking generics competition entirely when at least one lawful, noninfringing use exists. Off-label prescribing by physicians is lawful and common, and Congress was well aware of that reality when it designed the Hatch-Waxman Act framework.

For years, practitioners have advised that an FDA-approved skinny label substantially reduces — though does not eliminate — the risk of induced infringement. Courts often focused on the content of the label itself, distinguishing between label-based encouragement and separate conduct that affirmatively promoted patented uses. While not an absolute safe harbor, compliance with Section 8 was widely viewed as a meaningful risk-management tool.

The Federal Circuit's decision in Hikma v. Amarin tests the durability of that understanding.

The Federal Circuit's 2024 Decision

The dispute arose after Hikma launched a generic version of Amarin's Vascepa product with an FDA-approved skinny label that carved out Amarin's patented cardiovascular indication. Rather than bringing a traditional Hatch-Waxman Act artificial infringement action under Title 35 of the U.S. Code, Section 271(e)(2), Amarin sued Hikma for postlaunch induced infringement under Section 271(b).

In 2024, the Federal Circuit reversed the U.S. District Court for the District of New Jersey's dismissal of Amarin's complaint. Emphasizing the pleading posture of the case, the court held that Amarin had plausibly alleged inducement when Hikma's conduct was viewed collectively and in context.

The Federal Circuit relied on allegations that included Hikma's public statements describing its product as a generic equivalent, references to Vascepa's sales figures, and other launch-related communications.

Although the court stressed that it was not deciding liability, it concluded that these allegations could support an inference of intent sufficient to survive a motion to dismiss.

Notably, the court rejected the notion that compliance with FDA labeling requirements categorically forecloses inducement liability. Instead, it framed the inquiry as whether the defendant's overall conduct — including marketing and public communications — affirmatively encouraged infringement.

From Label-Based to Conduct-Based Inducement

One reason the Federal Circuit's decision has drawn such scrutiny is that it appears to shift the inducement analysis away from the FDA-approved label and toward the totality of a generics manufacturer's commercial behavior.

Earlier skinny-label cases often centered on whether the label itself instructed physicians to perform a patented method. In Hikma, by contrast, the label carved out the patented indication, yet the court allowed inducement claims to proceed based on surrounding conduct. For practitioners, this raises the question of whether skinny labeling remains a meaningful limitation on inducement liability, or whether it now represents only one factor among many.

Why the Supreme Court Granted Review

The Supreme Court's decision to grant certiorari suggests broader institutional concern. The U.S. urged the high court to take the case, arguing that the Federal Circuit's approach threatens to dilute inducement doctrine and undermine the Hatch-Waxman Act framework Congress created.

According to the government, FDA regulations require generics manufacturers to demonstrate therapeutic equivalence, and state drug-substitution laws depend on those representations. Treating such statements as evidence of inducement, the government argued, risks placing generics manufacturers in an untenable position — complying with regulatory requirements on the one hand while incurring patent liability on the other.

The certiorari grant signals that the court may be interested not only in pharmaceutical economics, but also in how inducement doctrine should operate in regulated industries where lawful downstream use is foreseeable and often unavoidable.

Counseling Generics Manufacturers After Hikma

For lawyers advising generic-drug makers, the Federal Circuit's decision complicates a familiar counseling framework. Statements describing a product as therapeutically equivalent, references to the branded drug's market success, and other routine communications may now carry increased litigation risk — even when the product's label fully complies with FDA requirements.

Practitioners may increasingly recommend more conservative approaches to public-facing communications, sales training and investor disclosures, not because those activities violate FDA rules, but because they may be cited as circumstantial evidence of intent to induce infringement.

The decision also elevates the importance of prelaunch planning and documentation. Clear internal records reflecting an intent to market only approved, nonpatented uses may play a greater role in defending against inducement claims at early stages of litigation.

Implications for Brand-Name Companies

For brand-side counsel, Hikma v. Amarin offers a potential enforcement pathway beyond traditional label-focused theories. By framing inducement claims around postapproval conduct, brand-name companies may seek to extend the practical reach of method-of-use patents.

At the same time, overly expansive inducement theories risk eroding the balance Congress struck in the Hatch-Waxman Act. Courts may be wary of interpretations that effectively penalize generics manufacturers for engaging in truthful, regulated conduct that accompanies nearly every generic launch.

What Hikma Does — and Does Not — Decide

It is equally important to recognize what Hikma v. Amarin does not resolve. The Federal Circuit did not hold that skinny labeling is unlawful, nor did it create per se inducement liability for generic equivalence statements. The decision addressed only whether Amarin's allegations were sufficient to proceed beyond the pleading stage.

The Supreme Court's review likewise need not dismantle the Section 8 pathway to have significant impact. Even a narrow ruling clarifying how intent may be inferred could recalibrate how courts evaluate inducement claims in regulated markets.

Broader Implications Beyond Pharmaceuticals

Although the case arises in the pharmaceutical context, the Supreme Court's reasoning could influence inducement doctrine in other regulated industries where products have substantial lawful uses. Medical devices, diagnostics and other FDA-regulated products present similar tensions between regulatory compliance and patent enforcement.

Conclusion

The Supreme Court's decision to hear Hikma v. Amarin ensures that skinny labeling and induced infringement will remain at the forefront of pharmaceutical patent law in 2026. Even before a merits ruling, the Federal Circuit's 2024 decision has prompted closer scrutiny of conduct that many generics manufacturers have long considered routine.

For practitioners, the lesson is not simply to predict how the Supreme Court will rule, but to recognize that FDA compliance and patent risk can no longer be evaluated in isolation. As the boundaries of inducement continue to evolve, effective counseling will require an integrated assessment of regulatory obligations, commercial strategy and litigation exposure.

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