High Court's Hikma Decision Reshapes 'Skinny Label' Suits

By **Paul Ainsworth, William Milliken and Harrison Adams** (June 9, 2026)

Paul Ainsworth

William Milliken

Harrison Adams

On June 4, the U.S. Supreme Court **issued** its decision in Hikma Pharmaceuticals USA Inc. v. Amarin Pharma Inc., marking a significant victory for generic drug manufacturers.

The decision is especially important because induced-infringement claims have become a key vehicle for patent holders seeking to challenge generic launches through skinny label carveouts.

The court reinforced the viability of skinny label carveouts by demanding a rigorous standard for pleading induced infringement and clarifying what counts as active steps to induce infringement. However, the opinion leaves important questions about the doctrine's outer limits open for interpretation.

Background

Amarin sells Vascepa, which the U.S. Food and Drug Administration first approved in 2012 to treat patients with severe hypertriglyceridemia.

In 2019, the FDA approved Vascepa for a second use: to reduce cardiovascular risk in certain patients already taking statins. After the 2019 approval, Amarin obtained method-of-use patents covering that cardiovascular indication.

Hikma, which had already filed an abbreviated new drug application, or ANDA, for its generic version of Vascepa, amended its application to pursue a skinny label carveout under Title 21 of the U.S. Code, Section 355(j)(2)(A)(viii), commonly referred to as a Section viii carveout. The amended ANDA removed language about the cardiovascular indication and sought approval only for the unpatented severe-hypertriglyceridemia indication.

The FDA approved Hikma's generic icosapent ethyl with that carveout, and assigned it an AB rating, deeming the generic therapeutically equivalent to Vascepa.

Amarin sued Hikma, alleging induced infringement of the cardiovascular-use patents based on the totality of Hikma's actions. These actions included Hikma's skinny label, patient leaflet, website and press releases.

According to Amarin, Hikma's label language and omissions, equivalence statements, website descriptions and references to sales figures tied to Vascepa collectively encouraged infringement.

The U.S. District Court for the District of Delaware dismissed the complaint under Rule 12(b)(6), but the U.S. Court of Appeals for the Federal Circuit reversed, holding that it was at least plausible Hikma induced infringement. The Supreme Court granted certiorari.

The case asks whether a generic manufacturer can face inducement liability based not on an express instruction to practice the patented use, but on the combined effect of labeling language, statements asserting the equivalence of the generic to the branded drug, and other launch-related commercial statements.

Decision

In a unanimous decision, the Supreme Court reversed the Federal Circuit's ruling and held that Amarin failed to state a claim upon which relief could be granted. In its opinion, the Supreme Court emphasized that induced infringement requires the defendant to take active steps to encourage direct infringement. Those active steps need not be express; however, they must be clear and affirmative.

The court also narrowed the Federal Circuit's recent approach to induced infringement cases. It pushed back on the Federal Circuit's reasoning in GSK v. Teva in 2021, which focused heavily on whether prescribing physicians could understand a manufacturer's statements as encouraging the patented use.

Instead, the court clarified that the relevant question is whether a defendant "actively encouraged infringement through its statements, not merely how others may understand those statements."

The court also declined to place generic manufacturers "between a rock and a hard place" by treating lawful, industry-standard conduct as a basis for liability.

The opinion will likely give rise to further litigation on at least two related questions: (1)

whether allegedly inducing statements are sufficiently clear and affirmative to count as active encouragement, and (2) whether allegedly inducing statements can be explained as regulatory compliance or ordinary industry practice.

Consequences of the Decision

The court's decision may shift future induced infringement disputes to center on whether particular statements are sufficiently active to warrant liability.

Here, the court's discussion of its 2005 decision in MGM Studios Inc. v. Grokster Ltd. will be instructive as it drew a sharp distinction between statements designed to stimulate infringement and statements that merely could stimulate infringement.

The court rejected the Federal Circuit's focus on whether physicians could read a generic's statements as infringing instructions, instead requiring clear and affirmative encouragement.

The court also rejected Hikma's argument that inducement must be express, explaining that implicit encouragement can suffice so long as it is clear and affirmative.

The court's decision narrows the type of statements that may qualify as inducing infringement. For example, generic drug manufacturers are free to describe their product as equivalent to a patent holder's product, even where the generic product is approved for only a subset of the branded product's indications.

Generic drug manufacturers are also less restricted in general commercial statements they might make relating to the launch of a new generic product. Now, to show liability for induced infringement for patented uses outside of an approved skinny label, a patent holder will need to show that a generic company made statements that are sufficiently targeted, concrete and prescriptive to show they were designed to bring about the infringing use.

This may make induced infringement claims rare where a generic drug manufacturer is marketing based on a skinny label given the highly regulated nature of pharmaceutical marketing. In the long run, that likely means more skinny label generics and thus lower drug prices, but also reduced incentives for patent holders to invest in research and development on follow-on indications.

Although the Hikma case involved a Section viii carveout, the reasoning is not limited to skinny label cases. The court's emphasis on clear and affirmative encouragement applies equally to cases where a generic does not carve out the patented use, and instead markets with a fully overlapping label.

In those noncarveout scenarios, plaintiffs usually rely more on the label itself as the basis for inducement. But Hikma suggests that even in noncarveout cases, plaintiff must do more than point to statements on the label that could suggest an infringing use. Rather, they must show that such statements were sufficiently clear and affirmative that they were designed to stimulate infringement.

In particular, infringement theories that are predicated upon portions of the label outside of the indications and usage section may now be more open to challenge. Future litigation will likely revolve around whether challenged statements reflect regulatory obligations or ordinary market practice rather than an effort to promote the patented use.

The court repeatedly emphasized that several of Hikma's alleged inducing statements had an obvious alternative explanation. That explanation, the court said, was compliance with the federal duty of sameness or ordinary industry practice. The court cautioned against turning "adherence to the law and industry standards into building blocks for illegal conduct."

Generics will likely cite that language to argue that FDA-required labeling and customary launch materials should not create inducement liability for foreseeable downstream infringement.

From the generic's perspective, such a rule reflects the congressional intent behind Section viii: Ensure that generics are permitted to market their drugs for nonpatented indications even where that availability ends up resulting in some infringing uses, so long as the generic does not expressly encourage infringement.

From a patent holder's perspective, however, this framing could function as a powerful pleading-stage shield even in cases where actual encouragement to infringe is present. It could let defendants characterize key language on their drug label as legally required or industry-standard in order to avoid potential infringement.

Importantly, the court stopped short of saying that a skinny label or related promotional materials can never matter. On the contrary, it only said that Hikma's skinny label "does not

come close" to inducing infringement under these facts.

That formulation is likely to invite future litigation on what truly counts as compliance rationale. This is especially true where a patent holder may argue that the generic's presentation, emphases or surrounding communications go beyond what the FDA requires.

Conclusion

While this decision reflects a win for generic drug manufacturers, it is not the end of induced-infringement disputes in the skinny label context.

Instead, the court has redrawn the terrain on which those disputes will be fought. The court held that liability must rest on clear, affirmative conduct designed to encourage infringement. It also warned against treating compliance with the law or ordinary industry practice as the basis for liability.

Together, those principles make it harder for patent holders to survive a motion to dismiss based on standard launch materials alone. For that reason, the court's decision is best understood not as the end of skinny label inducement claims, but as a decision that narrows and refocuses them.

The opinion stops short of creating categorical immunity for generics, leaving open future fights over when a generic's statements go beyond regulatory compliance and qualify as active inducement.

Paul A. Ainsworth is a director in the trial and appellate practice group at Sterne Kessler Goldstein & Fox PLLC.

William H. Milliken is a director in the trial and appellate practice group and a co-chair of the appellate practice at the firm.

Harrison J. Adams is an associate at the firm.

affiliates. This article is for general information purposes and is not intended to be and should not be taken as legal advice.