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Supreme Court Hears Oral Argument in Hikma Pharmaceuticals USA, Inc.

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Today, the U.S. Supreme Court heard oral argument in *Hikma Pharmaceuticals USA Inc. v. Amarin Pharma, Inc.*, No. 24-889, a case that could reshape the landscape of pharmaceutical patent enforcement and generic drug competition. The case concerns the scope of induced infringement liability under 35 U.S.C. § 271(b) in the context of "skinny labels" — the mechanism by which generic drug manufacturers may carve out patented indications from their FDA-approved labeling and enter the market for unpatented uses under Section viii of the Hatch-Waxman Act. A decision is expected by the end of the Supreme Court's current term in June 2026. As we discussed in our earlier blog post on The Patent Playbook, this case squarely implicates the enforceability of method-of-use patents for later-developed drug indications, and the viability of the Section viii pathway for generic drug manufacturers.

Background

Amarin markets Vascepa® (icosapent ethyl), which has two FDA-approved indications: an earlier, now-unpatented indication for severe hypertriglyceridemia (the "SH indication"), and a later, patented indication for reducing cardiovascular risk in certain patients (the "CV indication"). The CV indication was approved in late 2019 following the REDUCE-IT clinical trial, a landmark study that physicians hailed as a "game changer" in cardiovascular prevention. Amarin holds two method-of-use patents covering the CV indication.

Hikma filed an Abbreviated New Drug Application ("ANDA") for a generic version of Vascepa and, rather than challenging Amarin's CV-indication patents, elected to file a Section viii statement seeking approval only for the unpatented SH indication. The FDA approved Hikma's ANDA — including its "skinny" label omitting the CV indication — in May 2020. Hikma launched its generic product in November 2020.

Shortly after launch, Amarin sued Hikma for induced infringement under § 271(b), alleging that Hikma's skinny label, press releases, and website — taken together — encouraged healthcare providers to prescribe Hikma's product for the patented CV indication. The district court dismissed the complaint, finding that Hikma's statements did not plausibly allege active inducement. The Federal Circuit reversed, holding that the "totality of the allegations" plausibly stated a claim for induced infringement.

Questions Presented

The Supreme Court granted certiorari on two questions:

When a generic drug label fully carves out a patented use, are allegations that the generic drugmaker calls its product a "generic version" and cites public information about the branded drug (e.g., sales) enough to plead induced infringement of the patented use?

Does a complaint state a claim for induced infringement of a patented method if it does not allege any instruction or other statement by the defendant that encourages, or even mentions, the patented use?

The Parties' Positions

Hikma's Position (Petitioners)

Hikma argues that the Federal Circuit's decision improperly expanded § 271(b) by allowing inducement liability to rest on "passive" conduct rather than the "active" inducement the statute requires. Hikma emphasizes several key points:

First, Section 271(b) requires "clear expression or other affirmative steps taken to foster infringement" — not mere vague product descriptions that encourage no action from direct infringers. Hikma contends that its skinny label is the only accused communication that instructs doctors and patients on how to use its product, and it is undisputed that the label alone does not induce infringement because it instructs only the non-infringing SH indication.

Second, Hikma argues that its pre-launch press releases — which described its product as a "generic version" or "generic equivalent" of Vascepa and cited Vascepa's overall sales figures — were directed to investors, not healthcare providers, and do not encourage any specific use, much less an infringing one. Hikma further notes that its November 2020 launch press release expressly stated that its "product is not approved for any other indication for the reference listed drug VASCEPA®."

Third, Hikma contends that its online product catalog, which listed the "Therapeutic Category" as "Hypertriglyceridemia," is directed to wholesalers and retailers — not physicians — and contains an express disclaimer that its product "is indicated for fewer than all approved indications of the Reference Listed Drug."

Finally, Hikma warns that affirming the Federal Circuit's decision would effectively nullify the Section viii pathway, deter generic entry, and "impose liability for mere passive inducement." Hikma notes that recent data suggest the Federal Circuit's decisions in this case and in *GlaxoSmithKline LLC v. Teva Pharmaceuticals USA, Inc.* have already had a chilling effect on Section viii filings.

Amarin's Position (Respondents)

Amarin contends that the Federal Circuit correctly applied established inducement principles and that its complaint plausibly alleges active inducement based on the totality of Hikma's conduct. Amarin frames the case not as a question of statutory interpretation, but as a straightforward application of settled patent law to well-pleaded facts.

Amarin emphasizes several key facts: By the time Hikma brought its generic to market, over 90% of Vascepa's sales were attributable to the patented CV indication, and Vascepa had become virtually synonymous with that indication among healthcare providers. Against that backdrop, Amarin alleges that Hikma engaged in a quintessential form of active encouragement — advertising its product as "generic Vascepa" without qualification, broadly marketing it for "Hypertriglyceridemia" (a category encompassing the patented CV use), and touting Vascepa's overall sales figures driven predominantly by the patented indication.

Amarin further argues that Hikma's label, while omitting the CV indication from its "Indications and Usage" section, retained information "acutely relevant" to physicians treating CV patients — including potential side effects for patients with cardiovascular disease, references to the REDUCE-IT trial, and statements that the medication is sometimes prescribed for uses other than the indicated purposes.

Critically, Amarin points out that seven other generic icosapent ethyl manufacturers sell materially identical products using the same skinny labels, yet Amarin has not sued any of them — because those manufacturers confined their marketing to unpatented indications. Amarin argues this demonstrates that the case is not about skinny labels at all, but about Hikma's additional conduct that crossed the line into active encouragement.

Amarin also disputes claims that the Federal Circuit's decision would chill generic entry, arguing that data show Section viii filing rates have remained stable over time.

The United States' Position

The United States filed an amicus brief supporting Hikma, arguing that the Federal Circuit's decision should be reversed because Amarin's complaint does not plausibly allege active inducement. While recognizing the importance of both generic drug competition and patent protection, the government argued that the Hatch-Waxman framework reflects Congress's careful balancing of these interests, and that the decision below upsets that balance.

The government's brief made three principal arguments. First, Hikma's skinny labeling cannot properly be treated as evidence of culpable encouragement to infringe because the content of carved-out labeling is driven by statutory and regulatory requirements — not by a generic manufacturer's independent choices. Second, Hikma's descriptions of its product as a "generic equivalent" or "generic version" of Vascepa, and its use of the therapeutic category "Hypertriglyceridemia," are "anodyne statements with logical explanations" integral to the Hatch-Waxman scheme. Third, the government emphasized that Amarin's complaint fails to identify any plausible chain of events by which Hikma's statements could have led healthcare providers to prescribe or dispense the generic drug for the CV indication, particularly given the critical role of state generic-substitution laws — which operate to encourage or mandate generic substitution without regard to the indication for which a drug is prescribed.

The government also warned that the Federal Circuit's decision creates a significant disincentive for generic manufacturers to invoke the Section viii mechanism, threatening the availability of lower-cost generic drugs and undermining the broader Hatch-Waxman scheme. Notably, the government cautioned that Federal Circuit precedent on damages could compound this chilling effect, potentially requiring a generic manufacturer to pay damages for all infringing uses of its drug — even those its statements played no causal role in inducing.

Today's Oral Argument

During today's oral argument, the justices' questions probed at the heart of this case: how to draw the line between lawful generic competition and actively inducing infringement. Several justices queried whether the answer to that question lies not in rules unique to the pharmaceutical or "skinny" label context, but in the ordinary application of the *Twombly/Iqbal* plausibility standard. Justice Sotomayor, for instance, asked whether it was necessary for the Court to adopt "special rules" for this context. The advocates for Hikma, Amarin, and the United States uniformly agreed that no new legal framework is required to decide the case. The advocates sharply disagreed, however, about where the existing standard leads on the facts of this case. Charles Klein, Hikma's counsel, argued that Hikma's statements were "anodyne" and had "obvious alternative explanations" entirely consistent with non-infringement that prevented Amarin's complaint from satisfying the plausibility standard. Michael Huston countered, however, that Hikma's intent to induce infringement was undisputed, and thus the only question is whether Hikma took "active steps" to encourage infringement. He argued it did by uniquely marketing its product for "Hypertriglyceridemia" (a category he argued encompassed the patented CV indication), touting Vascepa's sales figures driven overwhelmingly by that indication, and calling itself "generic Vascepa" in a market where Vascepa had become synonymous with the patented cardiovascular use. Both sides agreed that the generic manufacturer's skinny label alone would not suffice to plead induced infringement but disagreed on whether the label should be given any weight at all.

Justices also questioned both sides on the potential consequences of a decision. Although querying the weight it is owed, Justice Kavanaugh invoked former Congressman Waxman's amicus brief cautioning that the Federal Circuit's decision "threatens to decimate the compromise at the heart of [the] Hatch-Waxman Act," noting that generics have saved people $3.4 trillion. Huston disputed that prediction, pointing to the seven other generic icosapent ethyl manufacturers on the market that Amarin has not sued and arguing that "generics have a ready roadmap to avoid induced infringement" — "all they have to do is accurately describe the limited purpose for which their drug is approved." Huston also warned that if the Court were to hold that Amarin's allegations "do not even state a claim for relief," it would become "much harder to plead induced patent infringement" and it would become "economically irrational" for branded manufacturers to invest in discovering new uses for existing drugs. Several justices also probed the practical posture of a reversal, with Klein observing in rebuttal that, given the procedural history below, "the only thing left would be a Rule 60 motion" — suggesting that a reversal here may effectively end the case rather than simply resetting the pleadings.

Potential Consequences

The Court's decision could have significant ramifications for the pharmaceutical industry regardless of which way it rules.

If the Court reverses (ruling for Hikma), the decision would reinforce the viability of the Section viii skinny-label pathway and provide generic manufacturers greater certainty that they can market their products without the threat of inducement liability based on routine promotional language and product descriptions. This could accelerate generic drug entry and reduce drug costs, particularly for drugs with multiple approved indications. At the same time, a reversal could make it significantly more difficult for brand-name manufacturers to enforce method-of-use patents against skinny-label generics that engage in marketing beyond their labels but stop short of explicitly promoting patented uses. Branded companies and innovators may argue that such a ruling would erode the value of later-developed indications — which often represent enormous additional investment — and discourage follow-on innovation.

If the Court affirms (ruling for Amarin), the decision would preserve the Federal Circuit's framework permitting inducement claims to proceed past the pleading stage based on the "totality of the allegations," including marketing materials, press releases, and label features beyond the carved-out indication. For brand-name pharmaceutical companies, this would provide reassurance that method-of-use patents retain meaningful enforceability against generics that engage in conduct arguably encouraging use for patented indications. An affirmance, however, could deter generic manufacturers from invoking the Section viii mechanism, particularly given the specter of massive lost-profits damages awards.

We will continue to monitor this case and will provide an update when the Court issues its decision.

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