

Strategic Perspectives

“Skinny labeling” case gives Supreme Court another shot at clarifying secondary IP infringement standards

By [Thomas Long, J.D.](#)

The Supreme Court is soon to hear arguments in a case could have significant impacts on the availability and cost of generic versions of prescription drugs. Oral argument in *Hikma Pharmaceuticals USA Inc. v. Amarin Pharma, Inc.* (No. 24-889) is scheduled for April 29. It is a pharmaceutical patent infringement case involving Hatch-Waxman Act rules for “carving out” patented uses of a drug from a generic drug label (known as “skinny labeling”), and it raises questions as to how much generic drugmakers can rely on their compliance with those rules. The case also comes hot on the heels of a decision in which the Court took a restrictive view of secondary infringement liability under the Copyright Act.

Hikma’s generic drug. At the center of the case is a generic version of a branded drug marketed by Amarin (Vascepa) with an active ingredient initially indicated for treatment of severely high triglycerides but later patented for use in reduction of cardiovascular disease risk. Hikma obtained Food and Drug Administration approval for the non-patented triglyceride indication and carved out (that is, omitted) the patented cardiovascular indication from the label, pursuant to [21 U.S.C. § 355\(j\)\(2\)\(A\)\(viii\)](#), a portion of the provision relating to abbreviated applications for new drugs that is commonly referred to as “section viii.” Section viii states that an applicant for a new generic drug that has

uses covered by a patent does not infringe that patent if the applicant carves out the patented uses from its labeling.

“The Federal Circuit’s holding risks shutting down the [skinny labeling] pathway altogether.”

Infringement dispute. Although Hikma followed the section viii carve-out rules for its generic drug by only indicating unpatented uses for treatment of high triglycerides, Amarin accused it of infringing its patent on use of the drug for prevention of cardiovascular problems. The issue was whether Hikma could be liable for “actively inducing” doctors to infringe Amarin’s patent in violation of [35 U.S.C. § 271\(b\)](#).

Federal Circuit decision. In a June 2024 [decision](#) (104 F.4th 1370), the Federal Circuit said “yes,” reasoning that Amarin plausibly alleged that Hikma had engaged in conduct that could show specific intent to induce infringement, despite the label carveout. These included distributing promotional materials that referenced the brand-name drug’s commercial profile, referred to Amarin’s drug by name, and called Hikma’s product a generic version of it. The Federal Circuit

reversed a district court’s 2022 [dismissal](#) of the case. In the district court’s view, Hikma did not engage in active inducement because its FDA-approved labeling did not instruct or encourage the patented use.

Questions presented. Hikma [petitioned](#) for review to the Supreme Court, arguing that the Federal Circuit’s holding will gut the carve-out mechanism of the Hatch-Waxman Act and hinder the introduction of lower-cost generic drugs, chilling competition. The U.S. government filed an amicus brief in which it agreed with Hikma and urged the Court to require active encouragement or instruction to infringe for inducement liability to attach.

The Court granted certiorari on January 16, 2026, with respect to the following questions:

1. 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?
2. 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?

Hikma’s argument. According to Hikma, the “skinny-label solution works only if it remains an economically viable option to expedite generic-drug competition for unpatented uses.” Hikma argues that the section viii the skinny labeling rules would, in practice, be destroyed or impaired if it is enough to plead inducement merely by alleging that a generic drug with a skinny label will inevitably be substituted for patented uses. Under the Federal Circuit’s decision, they assert, it no longer makes economic sense for generic drugmakers to invoke them.

“The court below interpreted § 271(b) to impose liability for the most routine and anodyne statements about skinny-labeled generics,” the brief states. “In doing so, the court of appeals effectively read the word ‘actively’ out of § 271(b), replacing it with the precise opposite word, ‘passively.’” Under the Federal Circuit’s holding, Hikma contends, makers of brand-name drugs can “threaten lost-profit damages for almost anything a generic drugmaker might say about generic drug products brought to market under section viii—including (as here) statements to investors, and not even to doctors or patients.” According to Hikma, “The Federal Circuit’s holding risks shutting down the section viii pathway altogether.” Hikma urges the Supreme Court to reverse the decision.

Amarin’s argument. In its [brief](#), Amarin reframes the question presented: “Whether the court of appeals correctly found that, on the particular constellation of facts pleaded in respondents’ complaint, respondents have plausibly alleged petitioners’ active inducement to infringe patented uses of respondents’ innovative pharmaceutical product.”

According to Amarin, there was no dispute that its complaint sufficiently pleaded direct infringement by healthcare providers who prescribed Hikma’s generic product

for Amarin’s patented treatment method. Amarin also asserts that, at this stage, Hikma has not contested that it had the intent to induce infringement. Amarin rejects Hikma’s characterization of the alleged conduct as “passive,” contending that Hikma “engaged in a quintessential form of active encouragement: advertising.” Amarin’s brief notes that Hikma’s website and press releases promoted its generic drug to doctors (a sophisticated audience) “for an overwhelmingly prevalent patented use (cardiovascular risk reduction).” These public communications “crossed legal boundaries,” Amarin asserts. Its brief argues that in Hikma’s advertising of its generic product for the “hypertriglyceridemia” therapeutic category (which Amarin asserts was an overbroad categorization), Hikma put forth communications that “healthcare providers would naturally understand to include Amarin’s patented CV indication.” In addition, press releases allegedly called Hikma’s drug “generic Vascepa” without qualification, and the generic’s label allegedly “contained unnecessary information that was relevant only to the predominant patented CV indication.”

Amarin takes the position that affirming the Federal Circuit would advance the policies of the Hatch-Waxman Act, as well as the Patent Act and the Constitution. “Without meaningful intellectual-property protection, manufacturers would have few incentives to discover new uses for existing drugs,” Amarin argues, adding that “adopting petitioners’ view would disturb Congress’s carefully balanced incentive structure and risk stifling revolutionary and life-saving discoveries.”

Hikma’s reply. In its [reply brief](#), Hikma reiterates its contention that Amarin alleged only passive behavior on Hikma’s part. Hikma points out that its product-launch press release “specifies the product’s sole, noninfringing indication

and states that ‘Hikma’s product is not approved for any other indication for the reference listed drug VASCEPA®.’”

“Adopting petitioners’ view would disturb Congress’s carefully balanced incentive structure and risk stifling revolutionary and life-saving discoveries.”

Hikma argues that Section 271(b) requires plausible allegations that the defendant promoted specific acts sufficient to infringe, which Amarin failed to plead. According to Hikma, Amarin has taken the incorrect position that inducement can be inferred at the pleadings stage “from vague product descriptions combined with knowledge that direct infringement is likely.”

Inducement liability: *Grokster* and *Cox*.

Both parties disagree about the relevance of a copyright decision by the Supreme Court—*Metro-Goldwyn-Mayer Studios Inc. v. Grokster, Ltd.*, 545 U.S. 913, 930 (2005)—which involved a determination that the promotion and marketing of file-sharing software as a tool to infringe copyrights could give rise to inducement liability. Amarin contends that *Grokster* supports its position that Hikma’s advertising could infringe under Section 271(b). Hikma counters that advertising is inducement to infringe only if it actively encourages an infringing use. Hikma also refers to the Supreme Court’s March 25 [decision](#) in *Cox Communications, Inc. v. Sony Music Entertainment*, No. 24-171, in which the Court (quoting *Grokster*) said that active encouragement requires “express

promotion [or] marketing” of an infringing use. Hikma also contends that the holding in *Cox* makes it clear that Hikma’s “intent and knowledge,” combined with a purported failure to mitigate the risk of infringement, is not enough for infringement liability.

Views of amici curiae. The United States filed an amicus brief supporting Hikma, and several IP industry organizations and pharmaceutical companies also filed briefs taking varying positions. The United States [contends](#) that Amarin’s complaint did not plausibly allege that Hikma actively induced infringement. According to the government, Amarin’s complaint “relies on the conclusory assertion that any healthcare provider who encounters Hikma’s statements will inevitably infringe Amarin’s patents. That is not enough to state a plausible claim.” According to the government, the Federal Circuit erroneously interpreted Hikma’s promotional statements and “erred in inferring culpability from a Hikma website that described its generic as a therapy for ‘hypertriglyceridemia’—a term that encompasses both infringing and non-infringing uses.” In the government’s view, the Federal Circuit’s holding “threatens to undermine the broader Hatch-Waxman scheme.”

The American Intellectual Property Law Association (AIPLA) takes a contrary position in its [brief](#) supporting affirmance of the Federal Circuit’s decision. According to AIPLA, the Section 271(b) analysis requires examination of the “totality of circumstances,” with a wide range of conduct being sufficient to satisfy the “affirmative steps” component of inducement. AIPLA argues that the skinny labeling rules of section viii do not exempt generic drugmakers from inducement liability, and the Federal Circuit correctly applied traditional pleading principles in determining that Amarin’s allegations plausibly stated a claim for induced infringement.

The Intellectual Property Owners Organization (IPO) filed a [brief](#) in support of neither party, taking the view that the *Iqbal* and *Twombly* pleading standards for federal claims should apply to claims under Section 271(b), and there should be no bright-line test based on section viii carveouts. IPO argues that the Federal Circuit took the correct approach in assessing Amarin’s complaint.

Biopharmaceutical companies AbbVie Inc. and Bristol-Myers Squibb Company filed a [brief](#) in support of Amarin. They rephrase the question before the Court as “whether a manufacturer should be held

liable for induced patent infringement when it continues to supply and profit from end users’ pervasive and systematic infringing uses, while knowing that its profit is predominantly generated from such infringing uses, but taking no steps to try to mitigate or prevent such infringement.” Although this resembles the question addressed in a copyright context in *Cox*, the companies contend that Amarin’s allegations that Hikma failed to take meaningful steps to prevent direct infringement by third parties were “sufficient to state a plausible claim for active inducement at the pleading stage under 35 U.S.C. § 271(b).”

How the Court might see it. This is the second case of the current Supreme Court term that addresses secondary liability for direct IP infringement by others. In *Cox*, the Court appeared to sharply limit the circumstances under which contributory copyright infringement can be found. The Court might extend this reasoning to liability for inducing patent infringement. However, even if it does hold that inducement liability requires active encouragement or other intentional acts, it could agree with the Federal Circuit that Amarin plausibly alleged conduct that violated Section 271(b). The oral argument session should shed light on the Justices’ views.