Good News for Generics: SCOTUS Unanimously Holds Amarin Failed to Prove Hikma's Skinny Label Induced Infringement

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Generic drug makers can temporarily breathe a sigh of relief after the U.S. Supreme Court's unanimous decision in *Hikma v. Amarin*[1]. The Court held that Amarin did not sufficiently plead that Hikma's sale of a generic version of Amarin's Vascepa (icosapent ethyl) with a skinny label[2] that carved out Amarin's patented indication constituted inducement to infringe. However, the case has been remanded for further proceedings.

In this case, Amarin held patents on the use of Vascepa for severe hypertriglyceridemia (SH) as well as for a cardiovascular (CV) indication, and had sued Hikma after Hikma filed an abbreviated new drug application with a Paragraph IV certification alleging the SH indication patents were invalid. The district court invalidated the SH indication patents, and Hikma then sought approval of a skinny label for the SH indication, which was approved by the FDA.

Amarin then filed suit in the District of Delaware, alleging that Hikma's skinny label, along with statements on its website and in press releases, constituted "active steps" to encourage direct infringement. While the district court dismissed the complaint for failure to state a claim, the Federal Circuit reversed, finding it "plausible" that a prescribing physician could construe the statements as encouragement to infringe the CV indication patents that were still in force.

The "statements" that Amarin referenced included: (1) Hikma's skinny label failed to include the CV limitation of use and referenced a clinical study where patients were taking statins (the patented CV indication method of use involved patients taking Vascepa with statins); (2) the patient information leaflet warned against possible side effects for people with heart, or CV, disease; and (3) Hikma's website referred to its AB rating (indicating equivalence to Vascepa) and listed "[h]ypertriglyceridemia" as the drug's therapeutic category, a category that includes, but is broader than, SH.

The Court held that Amarin alleged no more than a "sheer possibility" that Hikma actively induced infringement of the Amarin CV indication patents. The Court noted that by law Hikma's label must be identical to Amarin's except for the carved-out use and that it is normal industry practice to describe a generic drug as an equivalent to the branded drug. Amarin's speculation on how a physician might "read between the lines" and be encouraged to prescribe the product for a use other than one enumerated on the skinny label did not demonstrate that Hikma took "active steps" to induce infringement. As such, the Court held that "without more, it is not a 'plausible' scenario of active inducement giving rise to liability under §271(b)."

It remains to be seen whether the Court's holding that, to find induced infringement, a defendant must take "affirmative steps to encourage infringement" will find broader application beyond the skinny label and the pharmaceutical industry.

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[1] *Hikma Pharms. USA Inc. v. Amarin Pharma, Inc.,* 608 U.S. ___ (2026).

[2] The Hatch-Waxman Act allows a generic company to file an Abbreviated New Drug Application (ANDA) that may include a Section viii statement that they are only seeking approval for unpatented indications. A "skinny label," which matches the branded drug label but excludes indications which are still under patent, allows the generic company to bring its generic drug to market faster without infringing the brand's method-of-use patents that are still in force.

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