June 5, 2026

Supreme Court Rules In Favor of "Skinny Label" Generic Manufacturer

By Josh Wesneski and Rachael Jones

Yesterday, the Supreme Court issued a unanimous opinion in *Hikma v. Amarin*, ruling in favor of the manufacturer of a generic drug in a patent suit about "skinny label" marketing. The decision is narrow, but clarifies the requirements to state a claim against a generic manufacturer for inducing patent infringement. In particular, marketing the FDA-approved "skinny label" alone, coupled with describing the drug as a generic version of the brand-name pharmaceutical, is insufficient to trigger liability.

Amarin makes Vascepa, the brand name for a drug (icosapent ethyl) that is FDA-approved for two uses. The first use (severe hypertriglyceridemia) is now unpatented but relatively rare. The newer use (reducing cardiovascular risk) is still patented and far more common. Hikma, a generic manufacturer, received FDA approval to sell a generic version of Vascepa with a so-called "skinny label"—*i.e.*, a label that authorizes marketing for the unpatented use, but that carves out the newer and still-patented use.

Amarin sued Hikma, arguing that Hikma's marketing encouraged doctors to prescribe its generic drug for the patented use, thus inducing infringement. Amarin alleged that Hikma described its drug as "generic Vascepa," omitted a disclaimer on its label about the patented use, and made other statements that could be understood to cover both the patented and unpatented use. The district court granted Hikma's motion to dismiss, finding the allegations insufficient. But the Federal Circuit reversed, finding it "at least plausible that a physician could read" Hikma's statements "as an instruction or encouragement to prescribe" Hikma's generic drug for the patented use.

The Supreme Court reversed and remanded, rejecting the Federal Circuit's rule. The Court held that "[t]he central question is whether Amarin plausibly alleged that Hikma actively encouraged infringing uses, not merely whether doctors could plausibly read the alleged statements as instructions to infringe."

Turning to the allegations in Amarin's complaint, the Court found them insufficient. First, the Court reasoned, several of Hikma's statements have "obvious alternative explanation[s]." Hikma's skinny label mirrored Amarin's label because the FDA requires that, and the Court found that drug manufacturers routinely refer to their products as "generic" versions of name-brand drugs.

Second, the Court concluded that allegations of "omissions, inactions, or nonfeasance" are insufficient to allege active inducement. Hikma's failure to specifically disclaim the patented use in each and every communication thus did not constitute affirmative statements or actions.

Third, the Court rejected Amarin's reliance on otherwise "vague" statements that could be read to cover both uses, coupled with "speculation about how [medical providers] may act" in response to those statements.

The opinion trains a court's focus on the generic manufacturer's active inducement, making clear that it is insufficient that doctors could potentially understand the manufacturer's statements to cover both uses. And by ruling in favor of the generic manufacturer on a set of specific alleged facts, the decision clarifies the standard courts should apply to determine when conduct rises to the level of inducement.

Still, the decision is narrow. The Court rejected Hikma's position that active inducement must be express; instead, implicit encouragement is sufficient, so long as it is clear to the relevant audience and affirmative. The precise boundaries of that standard are certain to be litigated in the lower courts. Because the Court's analysis is largely limited to this one complaint, those questions will remain open. Indeed, Amarin may potentially be able to replead on remand.

Finally, *Hikma* is the latest in a series of cases from the Supreme Court in which it has rejected claims of secondary liability, often at the pleading stage. The Court now has four recent decisions—*Twitter v. Taamneh*, *Smith & Wesson v. Estados Unidos Mexicanos*, *Cox v. Sony*, and *Hikma*—rejecting claims seeking to hold upstream business entities liable for misuse of their products or services by others. *Hikma* thus fits neatly into that broader trend.

Weil's SCOTUS Term in Review is published by the Appeals and Strategic Counseling practice of Weil, Gotshal & Manges LLP, 767 Fifth Avenue, New York, NY 10153, +1 212 310 8000, www.weil.com.

If you have questions concerning the contents of this issue, or would like more information about Weil's Appeals and Strategic Counseling practice, please speak to your regular contact at Weil, or to the editors or practice group members listed below:

Practice Co-Heads:

Robert B. Niles-Weed
Appeals and Strategic Counseling
New York
+1 212 310 8651
robert.niles-weed@weil.com

Zack Tripp
Appeals and Strategic Counseling
Washington, D.C.
+1 202 682 7220
zack.tripp@weil.com

Authors:

Josh Wesneski
Appeals and Strategic Counseling
Washington, D.C.
+1 202 682 7248
joshua.wesneski@weil.com

Rachael Jones
Appeals and Strategic Counseling
Washington, D.C.
+1 202 682 7084
rachael.jones@weil.com