

Alert | Intellectual Property Litigation

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The Skinny on the Supreme Court’s Decision in Patent Infringement Case *Hikma v. Amarin*

On June 4, 2026, the U.S. Supreme Court issued a **unanimous opinion** in *Hikma Pharmaceuticals USA Inc. v. Amarin Pharma, Inc.* Justice Jackson, writing for the Court, resolved a dispute over Hikma’s generic version of Amarin’s cardiovascular medication Vascepa®, holding that Amarin had not plausibly alleged induced infringement against Hikma. This decision clarifies what type of evidence brand manufacturers must present to pursue inducement claims based on a generic’s “skinny label.”

In its decision, the Supreme Court reversed a 2024 Federal Circuit decision, which held that Hikma’s marketing statements about its generic version of Vascepa® were sufficient to allow the induced infringement case to proceed past the pleadings stage. Specifically, the Court reasoned that the Federal Circuit incorrectly concluded that it was “at least plausible that a physician could read’ the relevant marketing materials ‘as an instruction or encouragement to’ infringe.” Instead, the Supreme Court held that the proper 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.” The Court concluded that whether implicit or explicit, the necessary inducement must be clear and affirmative to the relevant audience. Thus, the proper inquiry for induced infringement is whether the plaintiff plausibly alleges that the defendant actively encouraged infringing use, not whether third parties could interpret its statements that way.

The Court identified three categories of conduct that, as a matter of law, cannot support an inducement claim. First, statements that reflect adherence to the law and industry standards. For example, complying with the FDA’s “duty of sameness,” which requires a generic’s label to be identical to the brand’s except for the carved-out use, and truthfully describing a product as the “generic equivalent” of the branded drug, are insufficient. Second, omissions, inactions, or nonfeasance arising from a skinny label, including silence as to the patented indication, constitute insufficient grounds for an inducement claim. For example, a failure to affirmatively disclaim an infringing use is not an inducing act. Third, vague statements combined with speculation about how medical providers may act in response to those statements are inadequate to support an inducement claim. For example, generalized marketing language was not specific enough to substantiate an inducement claim. The Court also found that statements by a generic identifying its product as an AB-rated generic equivalent of the branded drug were vague and insufficient.

The Court did not eliminate the theory of induced infringement against generic manufacturers, and it took care to note that active inducement need not be express; implicit encouragement can suffice. But whether implicit or explicit, the inducement must be “clear” to the relevant audience and “affirmative.” The practical takeaway: brand manufacturers retain the ability to pursue induced infringement claims against generic competitors, but they must allege specific, affirmative conduct clearly designed to promote infringing use, not merely statements that a provider could construe that way.

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