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Hikma v. Amarin: Supreme Court Unanimously Rejects Induced Infringement Claims in Generic "Skinny Label" Case

On June 4, 2026, the Supreme Court ruled unanimously in *Hikma Pharmaceuticals USA Inc., et al. v. Amarin Pharma, Inc., et al.* that a generic company's "skinny label" combined with certain alleged public statements were not sufficient to state a claim for induced infringement. The decision was written by Justice Jackson. All nine justices joined it, with no separate concurrences.

The case concerns Amarin's brand drug Vascepa® (icosapent ethyl), which was originally approved to reduce triglyceride levels in adults with severe hypertriglyceridemia (the "SH indication") and later approved to reduce cardiovascular risk (the "CV indication"). Amarin has patents directed only to the CV indication, as its SH patents were invalidated through prior litigation. Hikma, a generic drug manufacturer, obtained FDA approval of a generic version of Vascepa® for treating only the unpatented SH indication. Hikma "carved out" the patented CV indication by removing this indication from its label. Not long after Hikma began marketing its generic drug, however, Amarin filed suit in the District of Delaware for induced infringement, pointing to (1) statements and omissions in Hikma's "skinny label;" and (2) various public statements made by Hikma. These included statements that (i) touted the Hikma product as a "generic equivalent" to Vascepa®, and (ii) referred to the brand's sales figures, which were largely attributable to the off-label (but patented) CV indication.

Hikma moved to dismiss the case for failure to state a claim, arguing that none of these statements constituted "active steps" to encourage infringement, one of the required elements of induced infringement. The District Court granted the motion to dismiss, but the Federal Circuit subsequently reversed. The Federal Circuit found that, at the pleadings stage, and based on the totality of the allegations, it was "at least plausible that a physician could read" the alleged statements across Hikma's skinny label, press releases, and marketing materials together "as an instruction or encouragement to infringe." Thus, the Federal Circuit held that Amarin's allegations were sufficient to survive a motion to dismiss.

In its 9-0 decision, the Supreme Court reversed the Federal Circuit, holding that Amarin failed to allege "more than a sheer possibility that Hikma actively induced infringement of Amarin's CV-indication patents." Specifically, the Court found that Amarin did not plausibly allege that Hikma took "active steps" to encourage direct infringement.

First, the Supreme Court held that Hikma's public statements fell short of active steps to encourage infringement because there was "an obvious alternative explanation" for them – namely, compliance with the law or standard industry practice. For example, the Court explained that Hikma's description of its product as "generic Vascepa" was standard industry practice for how generics described their drugs as being equivalent to the brand.

Second, mere omissions such as Hikma's omission of the CV Limitation of Use in its label, or Hikma's failure to state in its press releases that its approved use was limited to the SH indication, are insufficient to allege active inducement. Notably, Hikma's label matched Amarin's (which also did not include the CV Limitation of Use).

Third, and as emphasized by the Court, "vague" language by the defendant – combined with speculation on how others may understand that language – is not enough for induced infringement. For example, Amarin's speculation that a physician *might* see the sales figures attributable to both the SH and CV indications in Hikma's press release, and in turn *might* perform an infringing

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method of treating the SH indication, requires a chain of events that may be "possible" but, without more, is not "plausible." This, according to the Court, is not sufficient for induced infringement.

Notably, in a footnote, the Supreme Court also expressly rejected the recent "trend" of the Federal Circuit in focusing on "whether the relevant statements could be read by medical providers as instructions to infringe." Instead, the Supreme Court emphasized that "the key question is whether a defendant actively encouraged infringement through its statements, not merely how others may understand those statements."

This case highlights the importance of ensuring at every stage of the case, from pleadings through trial, that a party's evidence of induced infringement is sufficient both to demonstrate direct infringement and an infringer's "specific intent" and also to satisfy the "active steps" prong of the inducement standard. This is particularly true where a patent owner is facing a generic company's "skinny label," which carves out the patented indication. Otherwise, disciplined defendants may avoid induced infringement by simply restricting public statements to, e.g., "standard industry practice."

While the Supreme Court's decision may be seen as a "win" for generic drug manufacturers, the Court rejected the argument that active inducement must be "express." Rather, the Court reinforced that "[a] defendant can achieve active inducement through implicit encouragement" so long as it is "clear to the relevant audience" and "affirmative." Patent owners should thus consider early, comprehensive investigations of a potential infringer's public statements and activities, including actions that may implicitly – if not expressly – encourage infringement, in order to build their case and protect against early dismissals. Additionally, brand companies should carefully consider how updates to drug labels may impact patent strategy (and vice versa), particularly in circumstances where there is a high risk that a generic can obtain a skinny label because the operative patents are limited by indication, and where the unpatented "off-label" use may be the predominant commercial driver.

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