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U.S. Supreme Court Reinstates Skinny Labeling Induced Infringement Standard

On June 4, 2026, Justice Ketanji Brown Jackson representing a unanimous U.S. Supreme Court issued an opinion on the "skinny labeling" case *Hikma v. Amarin*, dismissing in Hikma's favor and remanding for further proceedings. As we have previously blogged, the Court decided to hear the case to determine:

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?

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?

The Court stated that it wanted to reverse the trend in *GSK v. Teva* that it is "at least plausible that a physician could read" the relevant statements "as an instruction or encouragement" for inducted infringement. Instead, the Court said the "key question is whether a defendant actively encouraged infringement through its statements, not merely how others may understand those statements."

As a reminder, Amarin's Vascepa (icosapent ethyl) is approved for treating severe hypertriglyceridemia (SH indication) and cardiovascular risk reduction (CV indication). Hikma's carveout omitted the CV indication but also including related "labeling":

- A press release that described Hikma's product as the "generic version" of Amarin's drug without specifying that Hikma's product was approved for fewer

indications than Amarin's.
- A press release that gave information about Amarin's total sales for its drug, not sales tied to certain indications.
- Website materials that noted therapeutic equivalence to Amarin's product for a "therapeutic category" that was broader than Hikma's approved indication.

Looking at all of the arguments made by Amarin for alleged induced infringement, the Court found for dismissal for failure to meet the plausibility standard articulated in *Twombly* and *Iqbal*, i.e., Amarin failed to allege "more than a possibility" that Hikma actively induced infringement of Amarin's CV-indication patents. Specifically, the Court concluded:

- Hikma's statements that its product was "generic Vascepta" or the "'generic equivalent' of Vacepta" is "normal industry practice" to "truthfully describe" a generic drug as equivalent to the brand-name competitor.
- While "some medical providers could read between the lines and draw improper conclusions from the skinny labeling's omission of the CV Limitation of Use and press release's failure to "mention[n] that [Hikma's] approved use was limited to the far-lesser-known SH indication", such actions are not affirmative "statements of actions" necessary to support induced infringement.
- "Vague" statements "combined with speculation about how [medical providers] may act" in response to statements that copied the reference product's potential side effects for people with cardiovascular diseases and note that the product is sometimes prescribed for uses other than those indicated does not constitute plausible steps to induce infringement.
- Hikma's statements on its website that the therapeutic category for its drug is hypertriglyceridemia" (a broad category) and that its product is "AB" rated (commonly understood to mean a product is equivalent to the brand-name drug "under the conditions specified in the generic's label" that excludes unapproved, patented methods of use, is not plausible "to stimulate others to commit" infringement.
- Sales figures in Hikma's press releases for Amarin are "the vaguest of 'vague' statements" to create a plausible scenario of active inducement that would require prescribers to read the press releases intended for investors, understand the quotes sales figures are attributed to both the SH and CV indications, and

draw a subtle encouragement to prescribe the drug to patients already receiving statins.

Takeaways

The U.S. Supreme Court appears to not only have reversed the trend in *GSK v. Teva* for patent-holder plaintiffs to argue successfully that extraneous statements made outside of FDA-approved skinny labeling to carve out patented methods of use may plausibly induce infringement but also raised the bar for induced infringement generally. While pleading a case for induced infringement remains a fact-intensive inquiry, to survive a motion to dismiss, such complaint now must identify active steps taken by the alleged infringer to deliberately encourage such infringement beyond assembling a set of vague factual statements that could possibly be connected to induce infringement.

This blog was drafted by Brian Malkin, a Spencer Fane attorney on the FDA Pharmaceutical and Biologics Market Team. For more information, visit spencerfane.com.

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