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Justices To Clarify What's Fair Game With 'Skinny Labels'

By **Ryan Davis**

Law360 (January 20, 2026, 9:13 PM EST) -- A new U.S. Supreme Court patent case that will require the justices to spell out what generic-drug makers can say when marketing drugs with so-called skinny labels will shape whether and how those companies use the tactic of carving out patented uses from labels, attorneys say.

The high court agreed on Friday to hear Hikma Pharmaceuticals Inc.'s appeal of a decision that revived an induced infringement suit over its generic version of Amarin Pharma Inc.'s blockbuster heart drug Vascepa.

On what are known as skinny labels, makers of generic drugs legally carve out uses for a medication that are patented by the brand-name company and only seek U.S. Food and Drug Administration approval for unpatented uses.

Amarin's Vascepa is approved for two uses — one that is protected by patents and another that is not. Hikma's label does not mention the patented uses, but Amarin alleged that Hikma's marketing materials induced doctors to prescribe the generic for protected uses.

While a lower court dismissed Amarin's patent suit, the Federal Circuit **reversed in 2024**. It found that Amarin had plausibly alleged induced infringement by pointing to how Hikma promoted its version as a full generic of Vascepa and cited Amarin sales data that included patent-protected uses.

The decision from the Supreme Court will likely provide some clear guidance on whether such statements in marketing generic drugs that use skinny labels can give rise to a patent case, said Jeremiah Helm of Knobbe Martens.

The case provides a good vehicle for the court to issue "a pretty definitive statement allowing, or not, the type of advertising that Hikma was doing for their generic," he said.

If the Federal Circuit's decision is affirmed, generics makers could be "very, very limited" in what they are allowed to say when promoting products that have skinny labels, Helm said, but in the event of a reversal, "you might expect to see more expansive statements" in marketing.

Comments like those made by Hikma describing a product that uses a skinny label as a generic of the branded version are fairly standard, said Taylor Weilnau of McDonnell Boehnen Hulbert & Berghoff LLP. A decision upholding the Federal Circuit therefore could "allow for more patent holders to assert

induced infringement, based on what could be considered a normal course of conduct for generic manufacturers," she said.

A reversal decision, meanwhile, would likely result in the Supreme Court further defining "what is sufficient conduct to allege induced infringement," which would provide generics makers with "greater guidance and guardrails" that could help them avoid patent infringement claims, she said.

That would raise the bar for branded drug companies by requiring them to do more to show that a generics company engaged in affirmative conduct to induce infringement, "but I don't think it completely shuts them out," Weilnau said.

In its Supreme Court petition, Hikma argued that the Federal Circuit's ruling means that "no skinny label is safe" because branded drugmakers will always be able to find ways to argue that a generics company's marketing materials induce doctors to prescribe them for infringing uses.

Irena Royzman of Orrick Herrington & Sutcliffe LLP, who represents branded drug companies, said "all of these 'sky is falling, skinny labeling is dead' type of concerns really have no basis in fact and reality. These cases are rare."

She said not every generic-drug maker that uses a skinny label gets sued, and patent cases are brought when there is other evidence of infringement. Hikma appears to be arguing that if a skinny label doesn't mention the patented use, the generics maker should be off the hook, but courts should be able to look at evidence like marketing materials, Royzman said.

Branded-drug companies spend a lot of time and money developing new uses for drugs and obtaining patents on them, and "if they are infringed and generics and biosimilar makers just get a pass, that's really unhelpful and that's a serious disincentive for innovation," she said.

She noted that the Hikma case is still at the pleading stage and that Amarin still had to prove its case, "but not to investigate the facts, that seems wrong to me."

In contrast, Laura Lydigsen of Crowell & Moring LLP, who represents generics makers, said it appears that the Federal Circuit has allowed induced infringement cases involving skinny labels to survive motions to dismiss based on "very slender facts," such as describing the product as a generic version of the brand, which is "a hard statement, historically, for generic companies to avoid."

"It seemed like the exception was starting to swallow the rule here," she said.

Lydigsen said she's hopeful that the justices will dial back those holdings, because "I feel like the pendulum has swung too far in favor of allowing these suits with the Hikma case, and I'm optimistic that we'll reach a better balance."

Similarly, Michael Carrier, a professor at Rutgers Law School, said Congress permitted generic drugs to use skinny labels carving out patented uses in the 1984 Hatch-Waxman Act, and the Federal Circuit has "expanded liability far beyond what it was intended to be."

The appeals court has "made it really difficult for generics to use the skinny label pathway when they do no more than what was anticipated under Hatch-Waxman," he said.

Carrier added that since branded drugs cost more than generics, an infringement finding requiring a generics maker to compensate a patent owner for lost profits could mean that the generic "will face liability even higher than the profits they make."

He said he hopes the Supreme Court will reverse, because otherwise, the risk of liability could mean that "generic manufacturers will abandon this essential pathway, and consumers will pay more as a result."

Hikma's petition has the support of the Trump administration, which argued last month that the lower court ruling could deter companies from using skinny labels, "thereby threatening the availability of lower-cost generic drugs."

The system of letting companies carve out patented uses "cannot function as Congress intended if a generic manufacturer's anodyne descriptions of its product create a serious risk of massive patent liability," the government said.

Helm of Knobbe Martens said in patent law, policy arguments like the administration's focus on lowering drug prices are generally viewed as secondary by courts, "but in this case, the statutory framework is set up to lower drug prices" by promoting generic competition.

"So I think it will be something on the justices' mind at the very least, because they need to determine whether the type of permissive pleading applied by the Federal Circuit in their decision undermines the congressional intent in allowing the skinny label in the first place," he said.

The case is Hikma Pharmaceuticals USA Inc. et al. v. Amarin Pharma Inc. et al., case number 24-889, in the Supreme Court of the United States.

--Editing by Emily Kokoll and Marygrace Anderson.
