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How Skinny is Skinny Enough? Takeaways from the SCOTUS Oral Argument in the Amarin/Hikma Case

Key Takeaways

- **The U.S. Supreme Court did not seem inclined to create a new rule for induced infringement for pharmaceuticals.** Although it's always difficult to predict the outcome based on oral argument, the questions from the Justices (and the responses from the parties) suggested that a new standard for induced infringement is unlikely to be adopted.
- **SCOTUS appears interested in ruling on the merits.** The questioning relating to inducement standards suggests that SCOTUS may be interested in weighing in on the patent merits surrounding skinny labeling. That being said, given that the case was decided on a motion to dismiss, at least one or two questions suggested that it's possible that SCOTUS will punt on the issue and instead focus on the plausibility standard for pleadings.
- **All eyes will be on the lookout for an opinion by the end of June.**

We finally got our first glimpse into the U.S. Supreme Court's thinking during oral argument in the highly-anticipated case involving skinny labeling and induced infringement in the pharmaceutical industry. After granting Hikma's *cert.* petition on Jan. 16, 2026, the entire biopharmaceutical industry has been focused on whether the Supreme Court will create a bright-line rule to shield generic and biosimilar companies from being held liable for induced infringement when they utilize skinny labeling, even if marketing materials identify the follow-on product as a "generic version" of the innovator product and/or reference total brand company sales that include sales for an indication that is omitted from the follow-on product label.

Skinny Labeling and Induced Infringement: Background of Amarin v. Hikma

Generic and biosimilar companies have for decades used skinny labeling to avoid liability for induced infringement of method-of-use patents. In the case at issue, Hikma had obtained a dismissal of Amarin's induced infringement complaint in the U.S. District Court for the District of Delaware, based on Hikma's skinny label that included the hypertriglyceridemia indication, but carved out the patented cardiovascular risk reduction

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(CV) indication.

But the Federal Circuit reversed, focusing on (1) Hikma's public statements that it was selling a "generic version" of the branded product without specifying which indication Hikma was seeking; (2) Hikma referencing total brand sales, which included both the hypertriglyceridemia and CV indication; and (3) Hikma marketing its drug in the therapeutic category of "hypertriglyceridemia" on its website. The Federal Circuit found that the combination of these statements were sufficient to state a claim and survive a motion to dismiss.

Inside the Oral Argument: Justices Probe the Limits of Skinny Labeling

During the approximately one hour of oral argument, the Justices actively questioned the lawyers on both sides of the case, including the Solicitor General, who argued in favor of Hikma's position. Notable exchanges from the oral argument include:

- Justices Gorsuch and Kavanaugh expressed interest on the impact of the Federal Circuit's decision on the generic pharmaceutical market and cost of drugs. One of them even cited the amicus brief from Henry Waxman — yes, the Waxman responsible for the Hatch-Waxman Act — which suggested that affirming the Federal Circuit decision would "gut" the Hatch-Waxman balance.
- Justice Alito asked if just saying "generic Vascepa" was enough, but counsel for Amarin said that one statement would not be enough and focused instead on the context and totality of Hikma's statements.
- Justice Coney Barrett asked whether this case is really just about the plausibility standards set out in the *Twombly* and *Iqbal* cases. She and at least one other Justice questioned why *cert.* was even granted in the case.
- Some members of the Court were interested in whether SCOTUS needed to adopt a new rule for inducement of infringement in pharmaceutical cases, while one Justice expressed skepticism about adopting a new rule based on policy grounds. The parties and the Solicitor General appeared to generally agree that a new rule was not required for pharmaceutical cases.
- The Solicitor General seemed to go a step beyond *Hikma* in arguing that a generic company's label should not be relevant at all in evaluating an induced infringement claim, given that the label is required by FDA. Justice Jackson appeared to be somewhat receptive to the limitations placed on generic drug manufacturers by FDA regulatory requirements.

Although it's always difficult to predict how SCOTUS will come out on an issue, the decision is certain to be significant for the drugs and biologics industries and may have spillover effects into induced infringement cases in other industries. The decision may also provide guidance as to what information a generic drug manufacturer may include in a press release announcing the approval of its product. Stay tuned!