Articles + Publications | July 15, 2026

The Supreme Court Raises the Bar for Skinny Label Inducement Claims

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KEY POINTS

- In *Hikma Pharmaceuticals USA Inc. v. Amarin Pharma, Inc.*, the Supreme Court held that to plausibly allege induced infringement in the skinny label context, a brand manufacturer must allege that the generic drug manufacturer actively encouraged infringement — not merely that health care providers could have plausibly interpreted the generic's statements as encouraging infringing use.
- The Court repudiated a line of Federal Circuit cases permitting inducement claims to proceed based on how health care providers could plausibly interpret labeling, marketing materials, or other communications as instructions to practice a patented method of use.
- The decision is expected to prompt branded manufacturers to focus future complaints on portions of the FDA-approved label that can show active inducement in addition to conduct outside the regulatory framework, such as sales and marketing activities that could be viewed as actively encouraging use of a generic for a patented indication.
- The Court left open what types of communications would constitute active inducement, noting that implicit encouragement may suffice where it is directed toward promoting infringement, stopping short of creating a safe harbor for generic manufacturers in the skinny label context.

On June 4, the Supreme Court addressed a question that has been the subject of much discussion among Hatch-Waxman practitioners for several years: what is required, at the pleading stage, for a brand to allege induced infringement against a generic manufacturer?

The answer: the brand must plausibly allege that the generic drug manufacturer *actively encouraged* infringement.

As described in our prior articles on induced infringement and skinny labeling, the core issue has revolved around what pleadings are necessary to plausibly allege induced infringement in the context of a carve-out prescribed by 21 U.S.C. 355(j)(2)(A)(viii) ("skinny label" or Section viii carve-out) in order to survive a motion to dismiss. "Skinny labeling" is a mechanism that allows generic manufacturers to remove or "carve out" patented indications from their labels, such that the generic company does not need to make a Paragraph IV certification as to patents on the carved-out indication. In this manner, the generic can argue it does not induce infringement of method-of-use patents covering the carved-out indication. Nonetheless, many branded manufacturers may still allege that the generic manufacturer has induced infringement by encouraging physicians and patients to use the drug for those carved-out, patented indications.

With this latest ruling, the Supreme Court has refocused the analysis, shifting away from whether doctors *could* plausibly interpret the alleged statements as encouraging infringing uses, toward whether the generic manufacturer designed its statements to *actively encourage* such uses.

BACKGROUND

Method-of-use patents typically cover methods of treating patients, and because generic manufacturers do not treat patients themselves, carve-outs often become the focal point of induced infringement disputes. When a generic carves out a patented indication from its label, it may still receive an AB rating from the Food and Drug Administration (FDA) upon a showing of bioequivalence, meaning pharmacists can substitute the generic for the brand at the pharmacy level unless the prescription is marked "Dispensed As Written." Because prescriptions do not identify the condition being treated, that substitution can occur for any indication, including a patented one the generic omitted from its label. A generic does not directly infringe simply because its product is prescribed for an indication covered by a method of treating patent; liability attaches only if the generic induces infringement of the claimed method, *i.e.*, actively took steps to encourage physicians to prescribe for the carved-out use.

In *Hikma Pharmaceuticals USA Inc. v. Amarin Pharma, Inc.*, a brand manufacturer alleged induced infringement related to use of a skinny label for a generic version of its drug, Vascepa®. The Vascepa® product label had two indications, treatment of severe hypertriglyceridemia and reduction of cardiovascular risk in patients with hypertriglyceridemia. The generic had previously prevailed on invalidity of patents covering the first indication and was therefore authorized to market for that use. When the brand obtained patent protection for the cardiovascular risk indication, the generic responded by carving that indication out of its label while continuing to market the product as bioequivalent to the brand product, setting up the central inducement question in this case.

The branded manufacturer claimed that the generic's labeling, combined with its marketing and press release statements, including those highlighting bioequivalence and substitutability of the products, constituted induced infringement.

The district court originally dismissed the induced infringement allegations. However, the U.S. Court of Appeals for the Federal Circuit reversed the ruling, suggesting that at the motion to dismiss stage, the generic's labeling taken in combination with the public statements at least plausibly supported the branded manufacturer's claim.

THE SUPREME COURT'S DECISION

The Supreme Court disagreed with the Federal Circuit, reversing and remanding the case to district court. The Supreme Court situated its analysis in the background of the Hatch-Waxman Act and its goal of facilitating market entry for generic drugs that are bioequivalent to branded products, so long as they do not infringe a patent. The Supreme Court recognized that a generic drug may be used for an infringing purpose even when it is labeled only for a noninfringing indication. However, that fact alone is not sufficient to establish induced infringement; there must be active inducement of direct infringement.

According to the Court, the relevant inquiry is not whether health care providers could plausibly read a generic's statements as encouraging infringement, but whether the generic company itself took active steps to encourage infringement. The Court explained that allegations consistent with obvious alternative explanations — such as regulatory compliance or ordinary commercial practice — are insufficient to plausibly establish inducement. The

Court reasoned that the inducement allegations in the complaint must be designed to encourage infringement, not merely possibly encourage infringement.

Perhaps the most consequential aspect of the decision was the Court's express repudiation of a line of Federal Circuit cases that permitted inducement claims to proceed where a health care provider could plausibly interpret labeling, marketing materials, or other communications as instructions to practice a patented method of use.

KEY TAKEAWAYS AND OPEN QUESTIONS

The Court's decision is likely to reshape how both branded and generic pharmaceutical manufacturers litigate induced infringement claims in cases where skinny labeling is present.

1. What Does This Mean for Brands and Generics at the Pleading Stage? The Court emphasized that liability cannot rest solely on speculation regarding how third parties may understand otherwise lawful statements.

As a result, brands can no longer rely merely on allegations that physicians, pharmacists, or other health care providers might *infer* an infringing use from a generic manufacturer's communications.

For generic manufacturers, the decision provides greater certainty that mere participation in the Hatch-Waxman framework (and compliance with FDA labeling requirements) will not, standing alone, give rise to induced infringement liability. The Court reasoned that conduct consistent with regulatory requirements or ordinary commercial practices alone does not plausibly establish inducement. Going forward, generic manufacturers who have opted to adopt a "skinny label" likely will rely on the ruling to challenge inducement claims at the pleading stage.

2. How Will This Shape Branded and Generic Strategy Going Forward? For brand drug products that have multiple indications and method-of-treatment patents on less than all the indications, this decision may encourage greater use of Section viii carve-outs.

Prior to the ruling, generic manufacturers faced uncertainty regarding whether identifying their product as bioequivalent to or a generic of a brand product, alone or with other routine promotional statements could expose them to inducement claims notwithstanding an FDA-approved carve-out. The Court's decision now reduces that uncertainty.

Branded pharmaceutical companies alleging inducement will need to identify facts in their complaints plausibly showing the generic manufacturer took affirmative steps to actively encourage the patented use, conduct that goes beyond the ordinary marketing of a bioequivalent drug under a Section viii carve-out.

As a practical matter, future complaints may focus less on the contents of FDA approved labels and more on conduct outside the regulatory framework, such as sales activities, marketing activities, or other communications that could be viewed as actively encouraging use of the generic product for the patented indication. Brands could also opt to file separate New Drug Applications (NDA) for each new indication, instead of selling all of the indications under the same NDA, thereby obviating the carve-out procedure. Brands could also pursue different patenting strategies for their method-of-use patents, such as on dosing regimens or safety considerations that cannot be carved out of labels.

3. What Did the Court Leave Unresolved? While the Court's decision provides some clarity on the types of allegations that will not support an inducing infringement claim in the context of a skinny label, it stopped short of creating a safe harbor for generic manufacturers or foreclosing inducement claims in the skinny label context altogether. Indeed, the Court asserted that inducement does not need to be express; implicit encouragement may suffice where it is directed toward promoting infringement. Thus, while clarifying some aspects of inducing infringement in the skinny labeling context, the opinion leaves open what kinds of communications would be considered sufficient to constitute active inducement.

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