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Legal Sidebar

Supreme Court Limits Patent Infringement Liability for "Skinny Label" Generic Drugs

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On June 4, 2026, the Supreme Court issued its decision in *Hikma Pharmaceuticals USA Inc. v. Amarin Pharma, Inc*., a closely watched patent-infringement case with significant consequences for the generic-drug industry. *Hikma v. Amarin* concerned what are sometimes called the "skinny label" provisions of the Hatch-Waxman Act of 1984, which created accelerated pathways for the approval of generic drugs by the U.S. Food and Drug Administration (FDA).

As relevant to *Hikma,* Hatch-Waxman contains special procedures (called the "skinny label" provisions or "carve-outs" pursuant to section viii statements) that allow for partial generic entry when some uses of a drug are covered by patents, but others uses are unpatented. Generic drugmakers using a skinny label can still be liable for patent infringement, however, if they take active steps to induce patent infringement—that is, to encourage others to use the drug in a way that is protected by patents. Recent decisions by the U.S. Court of Appeals for the Federal Circuit (Federal Circuit) on this issue had raised concerns from some stakeholders about whether the skinny-label pathway remained viable in light of litigation risks.

In a unanimous decision, the Supreme Court held that Amarin's complaint against Hikma, a generic drugmaker relying on a skinny label, failed to state a plausible claim for induced patent infringement. By establishing that certain statements and activities do not suffice as "affirmative steps to encourage infringement," the *Hikma* decision generally reduces liability risks for skinny-label generics.

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The Skinny-Label Provisions of Hatch-Waxman

New Drugs and Pharmaceutical Patents

New drugs must be approved by FDA before they can be marketed or sold in the United States, which is generally accomplished through a *new drug application* (NDA). To obtain FDA approval, NDA sponsors typically conduct clinical trials to demonstrate a drug's safety and effectiveness—a costly and time-consuming process. NDA sponsors must also submit proposed labeling for the drug for FDA's approval, including the approved indications for use of the drug (i.e., the diseases or conditions that the drug is approved to treat). Although FDA approves new drugs for specific indications, physicians may still prescribe an approved drug "off label" for other indications (i.e., to treat other diseases or conditions) that FDA has not reviewed for safety and effectiveness.

New drugs are often protected from generic competition by patents, which last for about 20 years. Drug manufacturers may patent a drug's active ingredient, formulations, methods of use (indications), and devices to administer a drug, among other things. A single drug may be protected by multiple patents that cover different inventions and expire at different times. If a patent is valid, no one else can lawfully make, use, sell, or import the patented invention in the United States without permission from the patent holder.

As part of an NDA, drugmakers must submit to FDA information on any patent that claims either the drug for which FDA approval is sought or a method of using that drug. For method-of-use patents, FDA regulations require the NDA sponsor to include a description of the patent and identify the sections of the proposed drug label that describe the method(s) of use claimed by the patent. The description provided by the NDA sponsor on method-of-use patents is known as a *use code.* If the drug is approved, FDA publishes the patent information and use codes (along with any updates) in an online database known as the "Orange Book." (For more information, see CRS In Focus IF12644, *Patent Listing in FDA's Orange Book*, by Kevin J. Hickey (2026).)

Generic Entry Under the Hatch-Waxman Act and "Skinny Labels"

To encourage market entry of generic drugs, Hatch-Waxman created a separate pathway for FDA approval through *abbreviated new drug applications* (ANDAs). ANDA filers need only show that their product is pharmaceutically equivalent and bioequivalent to an FDA-approved drug with the same active ingredient. Generic drug manufacturers therefore do not need to conduct their own clinical trials, and often sell the drug at lower prices. ANDA filers must also propose labeling for the generic drug, which generally must be the same as the referenced brand-name drug's labeling.

A drug manufacturer intending to market a generic version of a brand-name drug must typically either wait for the patents listed in the Orange Book to expire or challenge the validity or applicability of the patents. Under Hatch-Waxman, ANDA filers must make a certification for each patent in the Orange Book for the drug at issue. For example, ANDA filers may certify that there are no patents listed for the drug or that all the listed patents have expired. In that case, FDA may approve the ANDA whenever its review is complete. ANDA filers may also make a paragraph IV certification that challenges a listed patent as either invalid or not infringed by the ANDA filer, which often leads to patent litigation in federal court.

For method-of-use patents, Hatch-Waxman provides an additional certification option called a section viii statement (after the relevant subsection of the *U.S. Code*). Section viii statements are typically used when some approved methods of using the drug are still patented, but other uses are not. By using a section viii statement, an ANDA filer certifies that the patent does not cover the uses of the drug for which the ANDA

filer seeks approval. In other words, the ANDA filer agrees to seek FDA approval only for the approved uses of the drug that are not patented.

The ANDA filer must submit proposed labeling along with a section viii statement. That labeling should omit the parts of the brand-name drug's labeling that correspond to the still-patented uses identified by the NDA holder. For this reason, generics relying on section viii statements are said to "carve out" the patented uses. The result is a "skinny label" for the generic version that lacks the still-patented uses.

"Skinny Labels" and Induced Patent Infringement

Because the brand-name drug is still protected by one or more patents, doctors who prescribe or patients who use a skinny-label generic for patented off-label uses may infringe the brand-name drug's patents. Section 271(b) of the Patent Act holds liable anyone who "actively induces infringement of a patent." Case law interpreting this provision has found three required elements for inducement liability. First, there must be an act of direct patent infringement by another person. Second, the defendant must take "active steps" to encourage that direct infringement. Finally, the defendant must have knowledge of the patent and that "the induced acts constitute patent infringement." Thus, if a generic manufacturer knowingly takes active steps to encourage the "carved out" patented uses—and doctors or patients subsequently use the drug in an infringing manner—then the manufacturer may be liable for inducing infringement.

Recent judicial decisions on patent infringement liability for skinny-label drugmakers created concern by some stakeholders about whether the skinny-label provisions remain effective in facilitating partial generic competition. For example, in *GlaxoSmithKline LLC v. Teva Pharmaceuticals USA* (*GSK v. Teva*), the Federal Circuit affirmed a jury verdict finding a generic manufacturer liable for inducement even though the manufacturer carved out the label portions identified by the brand's use codes, and did not directly tell doctors to prescribe the generic for patented uses. The majority in *GSK v. Teva* held that a jury could reasonably find that Teva actively induced patent infringement based on the generic's skinny label (which included an infringing indication that was not identified by the use code), as well as press releases that promoted the generic as a "generic equivalent" or "generic version" of the brand-name drug.

Hikma v. Amarin

Factual Background

Amarin developed the drug Vascepa and obtained approval from FDA in 2012 for the use of Vascepa to treat severe hypertriglyceridemia (the "SH indication"). In 2016, Hikma filed an ANDA with a paragraph IV certification, seeking to market generic Vascepa; in separate litigation, Hikma succeeded in invalidating Amarin's patents on the SH indication.

In 2019, while Hikma's ANDA was still pending at FDA, Amarin obtained FDA approval of Vascepa for a more common use: to reduce cardiovascular risk in patients with hypertriglyceridemia who already take statins (the "CV indication"). Amarin also secured two patents on methods of use corresponding to the CV indication. Hikma then amended its ANDA with a section viii statement for the CV-indication patents; in effect, Hikma sought FDA approval for a generic version of Vascepa only for the unpatented SH indication. In 2020, FDA approved Hikma's ANDA with a skinny label that omitted the CV indication, and Hikma began selling its generic drug to the public.

Shortly thereafter, Amarin sued Hikma for patent infringement, alleging that Hikma actively induced doctors to prescribe (and patients to use) the generic for the CV indication. Amarin's allegations relied on several pieces of evidence, including that Hikma's label did not disclaim the CV use, a patient information leaflet mentioned side effects for "people who have heart (cardiovascular) disease," Hikma

publicly described its drug as "generic Vascepa" or the "generic equivalent" of Vascepa, and Hikma press releases cited Vascepa sales figures attributable to both the SH and CV indications.

The district court granted Hikma's motion to dismiss the case, finding that neither the label nor Hikma's public statements amounted to "recommending, encouraging, or promoting" an infringing use. On appeal, the Federal Circuit reversed. In its view, Amarin's complaint stated a plausible claim of inducement because a physician could read Hikma's press releases in combination with its label "as an instruction or encouragement to prescribe that drug for *any* of the approved uses," including the CV indication.

The Supreme Court's Decision

The Supreme Court reversed the Federal Circuit in a unanimous opinion written by Justice Ketanji Brown Jackson. Justice Jackson's opinion emphasized that, to sustain inducement liability, a complaint must plausibly allege "affirmative" actions or statements by the defendant that are "*designed*" to encourage infringement, as opposed to statements that merely "*could* stimulate" infringing conduct. In emphasizing that the defendant must "actively encourage[] infringement," the Court explicitly rejected the "recent approach" of the Federal Circuit in cases such as *GSK v. Teva*. In the Court's view, the proper focus is the defendant's affirmative actions and intent, "not merely how others may understand" the defendant's actions and statements.

Under this standard, the Court concluded that none of Hikma's alleged actions and statements were "affirmative steps to encourage infringement." First, the allegations relating to Hikma's label were not *active* steps because "by statute, Hikma's label must be identical to Amarin's except for the carved-out use." As to Hikma's press releases—which described its product as the "generic equivalent" of Vascepa—the Court held that such "truthful[]" descriptions followed "standard industry practice" and were not designed to encourage infringement. Amarin's remaining allegations—such as failing to disclaim the CV indication or citing Vascepa's total sales in a press release—were either "mere omissions" or "vague statements" that fell short of active steps to induce infringement. The Court's opinion emphasized that the Patent Act requires *active*, "not passive," inducement. Amarin was therefore required to allege direct and affirmative steps encouraging the patented use, and not merely speculative or "implausibly roundabout" causal theories of how Hikma's statements might lead doctors and patients to infringe.

Considerations for Congress

The Court's opinion in *Hikma v. Amarin* is widely understood as providing more certainty and lowering litigation risk for generic drugmakers seeking to use skinny labels. While the holding does not remove all risk of inducement liability, stakeholders have described the decision as providing more "breathing room" for generic drugmakers to make general statements about their products—and to use the skinny label required by FDA—without risking patent infringement liability. This reduced risk could lead to greater use of skinny labels, and thus earlier generic entry and lower drug prices. On the other hand, the decision may also reduce incentives for brand name drugmakers to research and develop new indications for existing drugs (as Amarin did for Vascepa's CV indication).

The standards for patent infringement liability, whether for direct infringement or indirect theories such as inducement, are set by Congress in the Patent Act. Thus, to the extent that Congress disagreed with the holding of *Hikma v. Amarin*, it could clarify the appropriate standards by amending the relevant statute (35 U.S.C. § 271). For example, a bill introduced prior to the *Hikma* decision—the Skinny Labels, Big Savings Act (H.R. 6485 and S. 43 in the 119th Congress)—would create a statutory safe harbor from patent infringement liability for generic and biosimilar manufacturers. With respect to skinny-label generics, the bill provides that marketing that generic drug with FDA-approved labeling, or describing the product as a "generic" or "therapeutically equivalent" to the brand-name drug, would not be treated as

acts of patent infringement. Like the holding in *Hikma*, the bill generally rejects the Federal Circuit's approach in decisions like *GSK v. Teva*, although the bill's protections are broader and more categorical.

The impact of *Hikma v. Amarin* is not limited to the pharmaceutical context. The case can be viewed as part of a trend of recent Supreme Court decisions generally making it more difficult for plaintiffs to hold defendants secondarily liable (i.e., legally responsible for another's actions), such as the Court's recent copyright decision in *Cox v. Sony*. At a minimum, the *Hikma* decision raises the burdens of pleading inducement in patent cases involving technologies outside of the pharmaceutical context; it may have implications for analogous areas of law (such as trademark cases) as well.

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