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Supreme Court Reverses Federal Circuit in *Hikma Pharmaceuticals USA Inc. v. Amarin Pharma, Inc.*: A Unanimous Decision for "Skinny Labels" and Generic Drug Competition

June 4, 2026

Today, the U.S. Supreme Court issued its decision in *Hikma Pharmaceuticals USA Inc. v. Amarin Pharma, Inc.*, No. 24-889, unanimously reversing the Federal Circuit and holding that Amarin failed to state a claim "more than a sheer possibility" for active inducement of patent infringement under 35 U.S.C. § 271(b) to allow the case to move forward. Writing for the Court, Justice Jackson held that Amarin's allegations—drawn from Hikma's "skinny" label, patient information leaflet, website, and press releases—did not plausibly allege the "active steps" that § 271(b) requires.

As we previewed in our earlier posts on The Patent Playbook when the Court granted certiorari and following oral argument, the case asked the Court to draw the line between lawful generic competition and active inducement of infringement in the "skinny label" context. While the result today favors the generic manufacturer on the facts pleaded, the Court was careful to preserve inducement liability as a meaningful protection for innovators—expressly confirming that implicit encouragement can give rise to liability and that method-of-use patents on later-developed indications remain fully enforceable.

The Question Presented

The Supreme Court granted certiorari to decide whether Hikma's various statements — across its skinny label, patient information leaflet, website, and press releases — when considered in their totality, were sufficient to state a plausible claim for induced infringement of Amarin's patented cardiovascular indication under the familiar *Twombly/Iqbal* pleading standard.

Background

Amarin markets Vascepa® (icosapent ethyl), which has two FDA-approved indications: an earlier indication for severe hypertriglyceridemia (the "SH indication"), approved in 2012, and a later, patented indication for reducing cardiovascular risk in certain hypertriglyceridemia patients who already take statins (the "CV indication"), approved in 2019. Amarin holds two method-of-use patents covering the CV indication.

Hikma, a generic drug manufacturer, filed an Abbreviated New Drug Application ("ANDA") for generic icosapent ethyl. After a district court invalidated Amarin's SH-indication patents, Hikma supplemented its application with a Section viii statement seeking approval of a skinny label that included only the unpatented SH indication and carved out the patented CV indication. In 2020, the FDA approved Hikma's ANDA with the skinny label and assigned an "AB" rating indicating therapeutic equivalence to Vascepa when used according to Hikma's labeling.

Shortly after Hikma launched its generic product, Amarin filed suit in the District of Delaware, alleging that the totality of Hikma's statements across its skinny label, patient information leaflet, website, and press releases actively induced healthcare providers to prescribe Hikma's product for the patented CV indication. The District Court granted Hikma's motion to dismiss for failure to state a claim. The Federal Circuit reversed, finding it "at least plausible that a physician could read" the relevant statements "as an instruction or encouragement to" infringe.

The Court's Decision

The Supreme Court reversed the Federal Circuit in a unanimous decision. The Court held that Amarin failed to state a claim for active inducement in violation of § 271(b). The Court framed the "central question" as whether Amarin plausibly alleged that Hikma *actively encouraged* infringing use — not merely whether doctors *could plausibly read* the alleged statements as instructions to infringe. The Court expressly rejected the Federal Circuit's recent trend of focusing on how medical providers might understand a generic manufacturer's statements, rather than whether the manufacturer affirmatively designed those statements to encourage infringement.

Applying this framework, the Court found each category of Hikma's statements insufficient. First, several statements had an "obvious alternative explanation": compliance with the law or standard industry practice. Hikma's label retained clinical study information because, by statute, its label must mirror Amarin's except for the carved-out use; and describing a product as "generic Vascepa" reflects "normal industry practice." The Court stated it would "decline to put generic manufacturers between a rock and a hard place by turning adherence to the law and industry standards into building blocks for illegal conduct." Second, the Court held that Amarin could not rely on "mere omissions, inactions, or nonfeasance" — such as the skinny label's omission of the CV Limitation of Use — to allege active inducement. Third, the Court found Hikma's remaining statements — including the patient leaflet's side-effect warnings, the website's broad therapeutic category description, and investor-directed press releases citing Vascepa's sales figures — too vague to constitute active inducement.

The Court also clarified that while inducement need not be "express," whether implicit or explicit, it must be "clear" to the relevant audience and "affirmative."

Consequences for the Industry

The Court's unanimous decision offers significant guidance for both generic and brand-name pharmaceutical manufacturers.

For generic manufacturers, the decision provides reassurance that the Section viii skinny-label pathway remains a viable mechanism for entering the market without exposure to inducement liability. Generic manufacturers can market their products with greater confidence that certain practices — describing a product as "generic" to the brand, using broad therapeutic categories, citing publicly available sales figures to investors, and complying with statutory labeling requirements — will not alone give rise to induced infringement claims. Importantly, however, the Court did not hold that such statements are categorically off-limits as evidence: where a generic pairs otherwise-routine language with affirmative messaging that encourages the patented use, those same communications may form part of a viable inducement theory.

For brand-name innovators, the Court likewise provided guidance for pleading induced infringement. The Court took care to preserve the inducement remedy: it expressly rejected Hikma's argument that inducement must be "express," confirmed that *implicit* encouragement can give rise to liability, and reaffirmed that method-of-use patents on later-developed indications remain fully enforceable. The decision channels that enforcement toward affirmative, purposeful encouragement of the patented use, rather than the foreseeable behavior of sophisticated prescribers, but it leaves brand companies a clear and viable path: where a generic's communications—express or implicit—actively steer prescribers toward the patented indication, an inducement claim remains available.

Brand companies evaluating method-of-use enforcement strategies, and generics designing skinny-label launch communications, should both calibrate to this clarified standard.

We will continue to monitor how the lower courts apply the Court's "active steps" framework in future skinny-label disputes.

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