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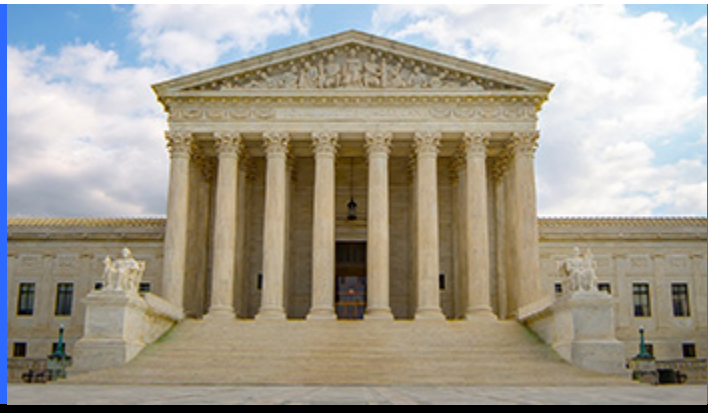

Appellate and Constitutional Law Update June 4, 2026

Supreme Court Reinforces Pleading Standards For Active Inducement Of Patent Infringement

***Hikma Pharmaceuticals USA Inc. v. Amarin Pharma, Inc.*, No. 24-889** –
Decided June 4, 2026

The Supreme Court unanimously held today that a pharmaceutical company failed to plausibly allege that a generic manufacturer had actively induced patent infringement, rejecting the argument that active inducement may be shown based on neutral statements that may be understood as instructions to infringe.

"[T]he key question is whether a defendant actively encouraged infringement through its statements, not merely how others may understand those statements."

JUSTICE JACKSON, WRITING FOR THE COURT

Background:

Patents often protect some but not all of a drug's uses rather than the entire drug. Under the Hatch-Waxman Act, generic drug manufacturers may obtain approval to sell such drugs only for their unpatented uses (in what is often called "skinny" labeling). The generic manufacturers are

not liable if third parties use their generic drugs off-label for patented indications unless the manufacturers "actively induc[e]" the third parties to do so. 35 U.S.C. § 271(b).

Amarin Pharma holds patents that protect some uses of icosapent ethyl, which Amarin sells under the brand name Vascepa. Generic manufacturer Hikma Pharmaceuticals obtained approval to sell icosapent ethyl for unpatented uses under a "skinny" label. Amarin sued, claiming that Hikma had actively induced third parties to infringe Amarin's patents by prescribing Hikma's generic version of icosapent ethyl for patented uses. The district court granted Hikma's motion to dismiss, ruling that Amarin had not plausibly alleged that Hikma actively encouraged third parties to infringe Amarin's patents. But the Federal Circuit reversed, emphasizing that Hikma's skinny label did not expressly disclaim using the drug for patented uses; that Hikma publicly described its drug as "generic Vascepa"; and that Hikma's marketing materials touted the total sales of Vascepa, the vast majority of which derive from patented uses.

The Supreme Court granted certiorari to resolve whether a plaintiff can plausibly plead active inducement of patent infringement where a drugmaker "calls its product a 'generic version'" and "cites public information about the branded drug" but does not expressly "encourag[e], or even mentio[n], the patented use."

Issue:

Whether a company plausibly alleges that a generic drug manufacturer actively induced patent infringement without expressly mentioning or encouraging the patented use.

Court's Holding:

Generally no: Although active inducement may be implicit as well as explicit, a party claiming active inducement must plausibly allege that the defendant took clear, affirmative steps to encourage infringement, not merely that the defendant's statements plausibly could be understood that way.

What It Means:

- The Court's opinion emphasizes that active inducement of patent infringement, at the motion-to-dismiss stage, requires allegations that the defendant took affirmative steps to encourage others to infringe the patent.
- Although the Court cautioned that active inducement need not be express, "the necessary inducement must be 'clear' to the relevant audience and 'affirmative.'" Knowledge that others will employ a product for infringing uses, omissions or inaction, and suggestive statements that are merely consistent with inducing infringement do not suffice.
- In directing dismissal of the complaint, the Court underscored that the "well-established federal pleading standards" from *Bell Atlantic Corp. v. Twombly*, 550 U.S. 544 (2007), and *Ashcroft v. Iqbal*, 556 U.S. 662 (2009), were enough to resolve the case. The Court's opinion provides a helpful datapoint for litigation on Rule 12(b)(6) motions to dismiss, illustrating how *Twombly* and *Iqbal* should be applied and reinforcing that allegations must nudge the complaint across the line from possible to plausible.
- The Court also reiterated recent decisions, including *Twitter, Inc. v. Taamneh*, 598 U.S. 471 (2023), in which it has cautioned that ordinary business activities should not lightly give rise to legal liability. Here, for instance, the Court emphasized that patent law should

avoid "trenching on regular commerce" and afford generic manufacturers "breathing room" when they comply with skinny-labeling laws and undertake "'ordinary acts incident to product distribution.'"

- The Court's opinion illustrates that, both in active-inducement patent-infringement cases and more broadly, motion-to-dismiss analysis is highly fact-specific and requires close attention to all the allegations and the broader context.

The Court's opinion is available here.

Gibson Dunn's lawyers are available to assist in addressing any questions you may have regarding developments at the Supreme Court. Please feel free to contact the following practice group leaders:

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