HIKMA PHARMACEUTICALS USA INC. v. AMARIN PHARMA, INC.

608 U.S. 1370 (2026)

Case No. No. 24–889

Decided June 4, 2026

HEADNOTE/SYLLABUS:

(NOTE: This headnote/syllabus constitutes no part of the opinion of the Supreme Court but has been prepared by the Court's Reporter of Decisions for the convenience of readers.)

Once the Food and Drug Administration (FDA) has approved a new drug, federal law authorizes other manufacturers to seek approval for marketing generic versions so long as they do not infringe on any patented uses. All 50 states and the District of Columbia permit (or require) medical providers to substitute the brand-name drug with the cheaper generic version. Still, generic manufacturers may be subject to liability under federal law if they actively induce infringement of the brand manufacturer's patent. See 35 U. S. C. §271(b).

Amarin Pharma, Inc. developed Vascepa, a drug containing the active ingredient icosapent ethyl. In 2012, the FDA approved Vascepa for the treatment of severe hypertriglyceridemia (the "SH indication"). In 2019, the FDA approved Vascepa for a second, more common use: reducing cardiovascular risk in hypertriglyceridemia patients who already take statins (the "CV indication"). Amarin obtained two method-of-use patents for this indication.

Hikma Pharmaceuticals USA Inc., a generic drug manufacturer, submitted an abbreviated new drug application for generic icosapent ethyl in 2016. It initially filed a paragraph IV certification, see 21 U. S. C. §355(j)(2)(A)(vii)(IV), asserting that Amarin's SH-indication patents were invalid. After a district court invalidated Amarin's SH-indication patents, Hikma supplemented its application with a section viii statement, see §355(j)(2)(A)(viii), seeking approval of a skinny label that included only the SH indication and carved out Vascepa's still-patented CV-indication method of use. In 2020, the FDA approved Hikma's application with the skinny label and assigned an "AB" rating indicating therapeutic equivalence to Vascepa when used according to its labeling.

Amarin filed suit in the District of Delaware, alleging that Hikma actively induced others to infringe Amarin's CV-indication patents based on the totality of Hikma's statements across the skinny label, the patient information leaflet, Hikma's website, and its press releases. The District Court granted Hikma's motion to dismiss for failure to state a claim,

explaining that none of these statements constituted active steps to encourage infringement. The Federal Circuit reversed, finding it at least plausible that a physician could read the relevant statements as an instruction or encouragement to infringe.

Held: Amarin has failed to state a claim for active inducement in violation of §271(b), so its complaint cannot withstand Hikma's motion to dismiss. The central question is whether Amarin plausibly alleged that Hikma actively encouraged infringing use, not merely whether doctors could plausibly read the alleged statements as instructions to infringe. Pp. 7–14.

(a) A claim for active inducement of infringement under §271(b) requires three elements: direct infringement by a third party, *Limelight Networks, Inc.* v. *Akamai Technologies, Inc.*, 572 U. S. 915, 920–921; knowledge that "the induced acts constitute patent infringement," *Global-Tech Appliances, Inc.* v. *SEB S. A.*, 563 U. S. 754, 766; and "active steps . . . to encourage direct infringement," *Metro Goldwyn Mayer Studios Inc.* v. *Grokster, Ltd.*, 545 U. S. 913, 936 (internal quotation marks omitted). Pp. 4–5.

(b) This case concerns the third element—"active steps." Active steps involve "purposeful, culpable expression and conduct," *Grokster*, 545 U. S., at 937, *i.e.*, "affirmative," as opposed to passive, actions "to bring about the desired result" of patent infringement, *Global-Tech.*, 563 U. S., at 760. We have defined "active steps" to exclude "ordinary acts incident to product distribution," *Grokster*, 545 U. S., at 937; those are insufficient to support liability. Pp. 8–9.

(c) Given these standards, Amarin misses the mark in arguing that it need not do more than "allege . . . a plausible chain of events through which statements made by [Hikma] could lead a healthcare provider . . . to prescribe or dispense Hikma's drug to reduce a patient's cardiovascular risk." Brief for Respondents 21 (alterations and internal quotation marks omitted). Allegations of "active steps" cannot be based only on "vague" language "combined with speculation about how [others] may act." *Takeda Pharmaceuticals U. S. A., Inc.* v. *West-Ward Pharmaceutical Corp.*, 785 F. 3d 625, 632. Pp. 8–10.

(d) Applying these standards, Amarin fails to allege "more than a sheer possibility" that Hikma actively induced infringement. *Ashcroft* v. *Iqbal*, 556 U. S. 662, 678. Pp. 10–14.

(1) Several of Hikma's statements have an "obvious alternative explanation": compliance with the law or standard industry practice. *Bell Atlantic Corp.* v. *Twombly*, 550 U. S. 544, 567. Hikma's label retained information about a clinical study, but that is because by statute Hikma's label must be identical to Amarin's except for the carved-out use, 21 U. S. C. §355(j)(2)(A)(v). Further, describing a drug as the " 'generic equivalent' " to the brand-

name comparator is "normal industry practice." *Inwood Laboratories, Inc.* v. *Ives Laboratories, Inc.*, 456 U. S. 844, 847–848. Pp. 10–11.

(2) Because the court looks for *affirmative* statements or actions to induce liability, Amarin may not rely on "mere omissions, inactions, or nonfeasance"—such as the skinny label's omission of the CV Limitation of Use or the press releases' failure to "mentio[n] that [Hikma's] approved use was limited to the far-lesser-known SH indication," Brief for Respondents 23, 26—to plausibly allege active inducement, *Twitter, Inc*. v. *Taamneh*, 598 U. S. 471, 489. Pp. 11–12.

(3) Hikma's remaining statements are too vague to support inducement liability. The patient information leaflet's warning about side effects for people with cardiovascular disease and its disclaimer that medicines are sometimes prescribed for other purposes are implausibly roundabout ways to induce medical providers to infringe. The website's description of the therapeutic category as "hypertriglyceridemia" and the indication that the drug is "AB" rated do not plausibly constitute statements designed "to stimulate others to commit" infringement, *Grokster*, 545 U. S., at 937, especially where the website clarifies that Hikma's generic is indicated for fewer than all approved indications of Vascepa. Finally, the sales figures in Hikma's press releases—the vaguest of the statements alleged—require a "possib[le]" but not " 'plausible' " chain of events to occur for a medical provider to draw encouragement to infringe. *Iqbal*, 556 U. S., at 678. Pp. 12–14.

104 F. 4th 1370, reversed and remanded.

Jackson, J., delivered the opinion for a unanimous Court.