Syllabus

NOTE: Where it is feasible, a syllabus (headnote) will be released, as is being done in connection with this case, at the time the opinion is issued. The syllabus constitutes no part of the opinion of the Court but has been prepared by the Reporter of Decisions for the convenience of the reader. See *United States* v. *Detroit Timber & Lumber Co.,* 200 U. S. 321, 337.

SUPREME COURT OF THE UNITED STATES

Syllabus

HIKMA PHARMACEUTICALS USA INC. ET AL. *v.* AMARIN PHARMA, INC., ET AL.

CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE FEDERAL CIRCUIT

No. 24–889. Argued April 29, 2026—Decided June 4, 2026

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.

Syllabus

(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.

SUPREME COURT OF THE UNITED STATES

No. 24–889

HIKMA PHARMACEUTICALS USA INC., ET AL., PETITIONERS *v.* AMARIN PHARMA, INC., ET AL.

ON WRIT OF CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE FEDERAL CIRCUIT

[June 4, 2026]

JUSTICE JACKSON delivered the opinion of the Court.

Federal law allows pharmaceutical manufacturers to market generic versions of brand-name drugs, so long as they obtain approval from the Food and Drug Administration (FDA) and do not infringe on any patented uses. Because a generic drug is, by definition, "biologically equivalent to . . . the brand-name drug," *Caraco Pharmaceutical Laboratories, Ltd.* v. *Novo Nordisk A/S*, 566 U. S. 399, 405 (2012), many medical providers use brand-name and generic drugs interchangeably, regardless of whether the intended use is covered by a patent. Such substitution is allowed (and sometimes required) by state laws across the Nation, but generic manufacturers may be subject to liability under federal law if they "actively induc[e] infringement of [the brand manufacturer's] patent." 35 U. S. C. §271(b).

Respondent Amarin Pharma, Inc., the manufacturer of brand-name icosapent ethyl, brought an induced-infringement claim against petitioner Hikma Pharmaceuticals USA Inc., a manufacturer of generic icosapent ethyl. Amarin relied on a combination of Hikma's statements across its skinny label (an abbreviated label used for generic drugs),

its website, and its press releases to allege that Hikma took "active steps" to induce infringement of Amarin's patented uses. After the District Court dismissed the complaint for failure to state a claim, the Court of Appeals for the Federal Circuit reversed, finding it "at least plausible that a physician could read" the relevant statements "as an instruction or encouragement to" infringe. 104 F. 4th 1370, 1380 (2024).

That was error. The central question is whether Amarin plausibly alleged that Hikma actively encouraged infringing uses, not merely whether doctors could plausibly read the alleged statements as instructions to infringe. We therefore reverse the judgment of the Federal Circuit and remand the case for further proceedings.

I

A

The FDA must approve new and generic drugs before they go to market. See *Caraco*, 566 U. S., at 404–405. For approval to market a new drug, the manufacturer must submit a new drug application (NDA) with at least three types of supporting documents: (1) reports setting forth sufficient information to establish the drug's safety and efficacy for its intended uses; (2) "the labeling proposed to be used for such drug"; and (3) the relevant drug patents, whether they protect the drug itself or the manufacturer's exclusive rights over a particular "method of using such drug." 21 U. S. C. §§355(b)(1)(A)(i), (vi), (viii); see *Caraco*, 566 U. S., at 404–405.

Once the FDA has approved a new drug, federal law authorizes other manufacturers to seek approval for marketing generic versions. In particular, the Hatch-Waxman Amendments "allow a generic competitor to file an abbreviated new drug application (ANDA) piggy-backing on the brand's NDA." *Id.*, at 404–405 (citing §§355(j)(2)(A)(ii), (iv) (2012 ed.)). "[T]he typical ANDA shows that the generic

drug has the same active ingredients as, and is biologically equivalent to, the brand-name drug." *Id.*, at 405. The generic manufacturer can thereby "avoid the costly and time-consuming studies required for a pioneer drug." *Eli Lilly & Co.* v. *Medtronic, Inc.*, 496 U. S. 661, 676 (1990).

But the FDA cannot authorize a generic drug that would infringe a patent. So, while the FDA does not control the approval of drug patents, it keeps track of them in a volume called Approved Drug Products With Therapeutic Equivalence Evaluations, or more memorably, the Orange Book. A manufacturer seeking to market a generic version of a drug that appears in the Orange Book has two options. The first is to file a "paragraph IV certification," which states that a patent "is invalid or will not be infringed by the manufacture, use, or sale of the [generic] drug." §355(j)(2)(A)(vii)(IV). Such filing is an act of infringement under patent law, and it gives the brand-name manufacturer the right to file a lawsuit against the generic manufacturer to determine the validity and scope of the patent. *Caraco*, 566 U. S., at 407 (citing 35 U. S. C. §271(e)(2)(A) (2012 ed.)). The generic manufacturer that chooses this approach wagers that it will eventually be able to "market its drug for all approved uses," not just the unpatented ones. *Caraco*, 566 U. S., at 408.

The second option is to submit a "section viii statement," and assert "that the generic manufacturer will market the drug for one or more methods of use not covered by the brand's patents." *Id.*, at 406; see 21 U. S. C. §355(j)(2)(A)(viii). This less confrontational path may be available if, for example, "the brand's patent on the drug compound has expired and the brand holds patents on only some approved methods of using the drug." *Caraco*, 566 U. S., at 406. A manufacturer that selects the section viii option must file with its ANDA a proposed "skinny label" that "'carves out' from the brand's approved label the still-patented methods of use." *Ibid.*; see 21 CFR

§314.94(a)(8)(iv) (2025). In other words, the skinny label may not give instructions for uses that would infringe the patented methods of use.

These provisions do not foreclose the possibility that an approved ANDA may still interfere with a patented method of use. Because a generic drug is, by definition, "biologically equivalent to . . . the brand-name drug," *Caraco*, 566 U. S., at 405, medical professionals routinely prescribe (and pharmacists routinely dispense) the former interchangeably with the latter, including for patented methods of use, see *Inwood Laboratories, Inc.* v. *Ives Laboratories, Inc.*, 456 U. S. 844, 847, n. 4 (1982). They do so with the blessing of their States' generic substitution laws, which, depending on the State, permit or require providing the cheaper generic version to patients. See, *e.g.*, Tex. Occ. Code Ann. §562.008(b) (West 2018) (permitting); Fla. Stat. §465.025(2) (2025) (requiring).

Given that all 50 States and the District of Columbia have such laws, see Brief for United States as *Amicus Curiae* 7–8 (collecting statutes), generic manufacturers surely know (and perhaps even expect) that their products will be put to infringing use. But "mere knowledge of infringing potential or of actual infringing uses [is] not . . . enough . . . to subject a distributor to liability." *Metro-Goldwyn-Mayer Studios Inc.* v. *Grokster, Ltd.*, 545 U. S. 913, 937 (2005); see also *Cox Communications, Inc.* v. *Sony Music Entertainment*, 607 U. S. ___, ___ (2026) (slip op., at 8). Still, a generic manufacturer can cross the line into liability if it "actively induces infringement of [the brand manufacturer's] patent." 35 U. S. C. §271(b).

A trio of our patent cases illuminates the required elements of an induced-infringement claim. First, there must be direct infringement by a third party. *Limelight Networks, Inc.* v. *Akamai Technologies, Inc.*, 572 U. S. 915, 920–921 (2014). Second, the inducer must know that "the induced acts constitute patent infringement." *Global-Tech*

Appliances, Inc. v. *SEB S. A.*, 563 U. S. 754, 766 (2011). Third, and most relevant here, the inducer must take "active steps . . . to encourage direct infringement." *Grokster*, 545 U. S., at 936 (internal quotation marks omitted).

B

Amarin developed a drug called Vascepa, which contains the active ingredient icosapent ethyl. See 104 F. 4th, at 1372. "In 2012, the [FDA] approved Vascepa for the treatment of severe hypertriglyceridemia ('the SH indication')," a condition characterized by very high blood triglyceride levels. *Ibid.* Vascepa's label disclosed that its effect "on cardiovascular mortality and morbidity in patients with severe hypertriglyceridemia has not been determined" (the "CV Limitation of Use") because Vascepa was not yet approved for other uses. *Ibid.* (internal quotation marks omitted). In the meantime, Amarin continued its research into Vascepa's potential cardiovascular uses.

Hikma is a generic drug manufacturer. In 2016, Hikma submitted an ANDA for approval of its generic icosapent ethyl. Hikma opted to file a paragraph IV certification, asserting that Amarin's method-of-use patents for the SH indication was invalid. *Ibid.*, n. 4. Amarin sued Hikma, and a district court invalidated Amarin's SH-indication method-of-use patents. *Ibid.*

But that decision did not spell doom for Amarin. In 2019, before the invalidation of Amarin's SH-indication patents, and while Hikma's ANDA remained pending, the FDA approved Vascepa for a second, much more common use: as a treatment to reduce cardiovascular risk in hypertriglyceridemia patients who already take statins (the "CV indication"). *Id.*, at 1372. Amarin removed the CV Limitation of Use from Vascepa's label and obtained two method-of-use patents for the CV indication. *Ibid.*

Hikma responded to these new developments by supplementing its pending ANDA with a section viii statement.

Hikma now sought approval of a skinny label that included only the SH indication (no longer protected by a method-of-use patent). *Id.*, at 1373. To ensure that its labeling otherwise mirrored Vascepa's, see 21 U. S. C. §355(j)(2)(A)(v) (requiring generic labeling to be the "same" as the brand-name labeling with a few exceptions), Hikma also removed the CV Limitation of Use from its proposed label. In 2020, the FDA approved Hikma's ANDA with the skinny label, and assigned Hikma's generic drug an "AB" rating, indicating that it is therapeutically equivalent to Vascepa when used according to its labeling. 104 F. 4th, at 1373–1374.

Soon after Hikma began marketing its generic drug, Amarin filed suit in the District of Delaware, alleging that Hikma had actively induced others to infringe Amarin's patent for the CV-indication method of use. Amarin alleged that the totality of Hikma's statements across several documents encouraged infringing uses. 578 F. Supp. 3d 642, 645–647 (2022). First, the label omitted the CV Limitation of Use and retained information about a clinical study in which some of the patients were taking statins.[1] Second, the patient information leaflet that accompanied the label warned against possible side effects for "people who have heart (cardiovascular) disease"—the target population for Vascepa's patented CV-indication method of use—and noted that "[m]edicines are sometimes prescribed for purposes other than those listed in a Patient Information leaflet." 2 App. 124–125. Third, Hikma's website described its generic drug as "AB" rated, and listed the drug's therapeutic category as "[h]ypertriglyceridemia," a category that includes but is broader than SH. *Id.*, at 195. Finally, prior to the launch of its generic drug, Hikma issued a series of press releases describing the product as "'generic Vascepa'

[1] Recall that the CV-indication method of use that Amarin successfully patented was the concurrent taking of Vascepa with statins. See *supra*, at 5.

without mentioning that th[e] approved use was limited to the far-lesser-known SH indication," and touting Vascepa's U. S. sales figures attributable to both the SH and CV indications. Brief for Respondents 23–24. In response to Amarin's complaint, Hikma filed a motion to dismiss under Federal Rule of Civil Procedure 12(b)(6), for failure to state a claim for induced infringement.

The District Court granted Hikma's motion to dismiss, explaining that none of Hikma's statements constituted active steps to encourage infringing Amarin's method-of-use patents for the CV indication. 578 F. Supp. 3d, at 645–648. The Federal Circuit reversed. It held (as all agree here) that Hikma's label, standing alone, does not induce infringement. See 104 F. 4th, at 1379; Brief for Respondents 40–41. But the court found it "at least plausible that a physician could read" the label, website, and press releases "as an instruction or encouragement to prescribe [Hikma's generic] for any of the approved uses of icosapent ethyl." 104 F. 4th, at 1378–1380 (emphasis deleted).

We granted certiorari, 607 U. S. 1147 (2026), to decide whether Hikma's various statements, when considered in their totality, boost Amarin's lawsuit over the Rule 12(b)(6) hurdle. For the reasons that follow, we hold that they do not.

II

Our well-established federal pleading standards are not up for debate in this case. In order to proceed to discovery, a plaintiff must "state a claim to relief that is plausible on its face." *Bell Atlantic Corp.* v. *Twombly*, 550 U. S. 544, 570 (2007). That plausibility standard "asks for more than a sheer possibility that a defendant has acted unlawfully." *Ashcroft* v. *Iqbal*, 556 U. S. 662, 678 (2009). If the complaint "pleads facts that are merely consistent with a defendant's liability, it stops short of the line between possibility and plausibility of entitlement to relief." *Ibid.* (internal

quotation marks omitted). Instead, to nudge a claim "across the line from conceivable to plausible," a plaintiff must plead facts that, if true, "allo[w] the court to draw the reasonable inference that the defendant is liable for the misconduct alleged," *id.*, at 678, 680 (internal quotation marks omitted), and to rule out "obvious alternative explanation[s]" for the defendant's conduct, *Twombly*, 550 U. S., at 567.

This case requires us to apply these familiar pleading standards to the third element of an induced-infringement claim: that the inducer took "active steps . . . to encourage direct infringement." *Grokster*, 545 U. S., at 936 (internal quotation marks omitted).[2] Our case law defining "active steps" thus governs the boundaries of a plausible induced-infringement claim. Most fundamentally, "inducement must involve the taking of affirmative," as opposed to passive, "steps to bring about the desired result" of patent infringement. *Global-Tech.*, 563 U. S., at 760; see also *Grokster*, 545 U. S., at 935 (requiring "statements or actions directed to promoting infringement"); *Cox Communications*, 607 U. S., at ___ (slip op., at 9) (citing lack of "evidence of express promotion [or] marketing" as a reason for no liability (internal quotation marks omitted)). To avoid "trenching on regular commerce," "ordinary acts incident to product distribution" are insufficient to support liability. *Grokster*, 545 U. S., at 937.

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

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[2] Hikma does not dispute before us that Amarin plausibly pleaded the other two elements of induced infringement: direct infringement and specific intent. See 104 F. 4th 1320, 1378 (CA Fed. 2024).

quotation marks omitted).[3] Amarin relies primarily on two cases to press its point. First, it points to our holding in *National Rifle Association of America* v. *Vullo*, 602 U. S. 175 (2024), that, "[t]o state a claim that the government violated the First Amendment through coercion of a third party, a plaintiff must plausibly allege conduct that, viewed in context, could be *reasonably understood* to convey a threat of adverse government action," *id.*, at 191 (emphasis added). Importing this First Amendment standard into the induced-infringement context, however, would water down the statute's express requirement of "activ[e] induce[ment]." 35 U. S. C. §271(b).

Amarin's second (and more germane) case is *Grokster*, where we described "[t]he classic instance of inducement" as an "advertisement or solicitation that broadcasts a message designed to stimulate others to commit violations." 545 U. S., at 937; see Brief for Respondents 21. But statements *designed* to stimulate others form a narrower category than statements that *could* stimulate others. And in *Grokster*, the defendants' statements fit into that narrower class: Grokster, a distributor of free file-sharing software, "sent users a newsletter promoting its ability to provide particular, popular copyrighted materials." 545 U. S., at 926. StreamCast, another such distributor, "beamed onto the computer screens of users of Napster," another

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[3] To Amarin's credit, this argument reflects the recent approach of the Federal Circuit, which has increasingly trained its focus on whether the relevant statements could be read by medical providers as instructions to infringe. See, *e.g.*, *GlaxoSmithKline LLC* v. *Teva Pharmaceuticals USA, Inc.*, 7 F. 4th 1320, 1336–1337 (2021). The decision below appears to follow this trend line. See 104 F. 4th, at 1378–1380 (resting reversal on the conclusion that it is "at least plausible that a physician could read" the relevant statements "as an instruction or encouragement" to infringe). We reject that trend today, and hereby emphasize that the key question is whether a defendant actively encouraged infringement through its statements, not merely how others may understand those statements.

notorious file-sharing service, "ads urging the adoption of its OpenNap program, which was designed, as its name implied, to invite the custom of patrons of Napster." *Id.*, at 937. "And both companies communicated a clear message by responding affirmatively to requests for help in locating and playing copyrighted materials." *Id.*, at 938. We held that such overt efforts to "entic[e] or persuad[e] another" to engage in copyright infringement "overc[ame] the law's reluctance to find liability when a defendant merely sells a commercial product suitable for some lawful use." *Id.*, at 935–936.

All in all, inducement 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 (CA Fed. 2015); see also *Grokster*, 545 U. S., at 937 (requiring "purposeful, culpable expression and conduct"). That said, Hikma overshoots by urging that active inducement must be "express." See Reply Brief 22–23. A defendant can achieve active inducement through implicit encouragement, as StreamCast did through the "suggestiv[e]" name of its "OpenNap program." *Grokster*, 545 U. S., at 937, 938. But implicit or explicit, the necessary inducement must be "clear" to the relevant audience and "affirmative." See *id.*, at 937.

III

Applying these standards to the complaint here, Amarin fails to allege "more than a sheer possibility" that Hikma actively induced infringement of Amarin's CV-indication patents. *Iqbal*, 556 U. S., at 678. Amarin's allegations, whether viewed together or separately, fail to establish that Hikma took any affirmative steps to encourage infringement.

First, several of the relevant statements have an "obvious alternative explanation," *Twombly*, 550 U. S., at 567:

Hikma was just complying with the law or with standard industry practice. Start with the law. It is true, as Amarin complains, that Hikma's label omitted the CV Limitation of Use and retained information about a clinical study involving patients taking statins, just as Amarin's label did. But that is because, by statute, Hikma's label must be identical to Amarin's except for the carved-out use, barring specified circumstances not applicable here. 21 U. S. C. §355(j)(2)(A)(v); see also 21 CFR §314.94(a)(8)(iv); *PLIVA, Inc.* v. *Mensing*, 564 U. S. 604, 616 (2011) (explaining the "duty of sameness" for generic drug manufacturers).[4]

Amarin also finds fault in Hikma's statements describing its product as "'generic Vascepa'" or the "'generic equivalent' of Vascepa" in the prelaunch press releases. Brief for Respondents 23–24. But as we have explained, it is "normal industry practice" to "truthfully describe" a generic drug as "'equivalent'" to the brand-name comparator. See *Inwood Laboratories*, 456 U. S., at 847–848; §353d(a)(3) (defining the term "generic version" as "a drug approved under [§355] whose reference listed drug is a covered drug"). We 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, Amarin may not rely on "mere omissions, inactions, or nonfeasance" to allege active inducement. *Twitter, Inc.* v. *Taamneh*, 598 U. S. 471, 489 (2023). With a healthy stretch of the imagination, one might believe that some medical providers could read between the lines and draw improper conclusions from the skinny label's omission of

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[4] Even if Hikma could have deviated from what Amarin had put on its label, Hikma's skinny label does not come close to inducing infringement. Amarin does not dispute that the clinical study on the label was for patients suffering from SH—the off-patent method of use for which Hikma was approved. And Hikma's omission of the CV Limitation of Use cannot support Amarin's case for *active* inducement of infringement, as we discuss below.

the CV Limitation of Use and 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. But we look for *affirmative* "statements or actions" precisely to avoid "trenching on regular commerce" based on such a contingent chain of events. *Grokster*, 545 U. S., at 935, 937. Otherwise, "ordinary merchants could become liable for any misuse of their goods and services, no matter how attenuated their relationship with the wrongdoer." *Twitter*, 598 U. S., at 489.

Third, Amarin comes up short in resting the remainder of its inducement claim on "vague" statements "combined with speculation about how [medical providers] may act" in response to those statements. *Takeda*, 785 F. 3d, at 632. Take, to start, Amarin's argument that medical providers "would plausibly understand" the label's patient information leaflet to encourage infringing uses because it identifies potential side effects for people with cardiovascular diseases and notes that medication is sometimes prescribed for uses other than those specifically indicated. Brief for Respondents 31 (internal quotation marks omitted). Again, §271(b) requires "activ[e]," not passive, inducement. So the question is not merely whether the statements could be "plausibly underst[oo]d" to induce infringement, but whether they plausibly constitute "affirmative steps to bring about the desired result" of infringement. *Global-Tech.*, 563 U. S., at 760. Viewed in that light, the statements in the leaflet (a warning and a disclaimer, really) are implausibly roundabout ways to induce medical providers to infringe. Treating them otherwise would turn any statement extraneous to the unpatented method of use—even one warning people *against* the patented method of use—into active inducement of infringement. Our case law leaves generic manufacturers more breathing room than that.

Amarin is wrong to rely on the statements on Hikma's website for the same reason. The website describes the therapeutic category for its drug as "hypertriglyceridemia," and indicates that the drug is "AB" rated. It is not plausible that Hikma "designed" these statements "to stimulate others to commit" infringement. *Grokster*, 545 U. S., at 937. For one thing, describing the therapeutic category as "hypertriglyceridemia" (as opposed to "severe hypertriglyceridemia") is generally akin to describing a drug for leukemia as a "'cancer drug'" (as opposed to a "leukemia drug"). Reply Brief 12. "Cancer drug" is a broad category, not an instruction to prescribe the drug for a patented use treating a specific type of cancer. Furthermore, an "AB" rating means that the product is equivalent to the brand-name drug only "under the conditions specified in the generic's label," which excludes unapproved, patented methods of use. *GlaxoSmithKline LLC* v. *Teva Pharmaceuticals USA, Inc.*, 7 F. 4th 1320, 1335 (CA Fed. 2021). In any event, Hikma's website clarifies that "Hikma's generic version is indicated for fewer than all approved indications of the Reference Listed Drug," Vascepa. 2 App. 195.

Finally, the sales figures in Hikma's press releases are the vaguest of "vague" statements alleged in Amarin's complaint. *Takeda*, 785 F. 3d, at 632. Amarin argues that, by including the sales figures attributable to *both* the SH-indication *and* the CV-indication methods of use, Hikma encouraged using its generic for the patented CV indication. But there are myriad steps between those statements and induced infringement that Amarin fails to mention. For Amarin's speculation to bear out, a medical provider would have to look up and read the press releases, which were directed to investors rather than doctors and pharmacists; have enough background knowledge of pharmaceutical sales to understand the quoted sales figures to be attributable to both the SH-indication and the CV-indication methods of use; and draw from this fact a subtle encouragement

to start prescribing Hikma's generic to hypertriglyceridemia patients who already take statins. Perhaps this chain of events is "possib[le]" (anything is possible). *Iqbal*, 556 U. S., at 678. But, without more, it is not a "'plausible'" scenario of active inducement giving rise to liability under §271(b). *Ibid.*

* * *

For the reasons we've explained, Amarin has failed to state a claim for active inducement in violation of §271(b), so its complaint cannot withstand Hikma's Rule 12(b)(6) motion. We therefore reverse the judgment of the Federal Circuit and remand the case for further proceedings consistent with this opinion.

It is so ordered.