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Hikma v. Amarin: What the Supreme Court's Decision Means for Pleading Induced Infringement

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On June 4, 2026, the US Supreme Court unanimously decided *Hikma Pharmaceuticals USA Inc. v. Amarin Pharma, Inc.*, holding that induced patent infringement under § 271(b) requires a plaintiff to plausibly allege affirmative steps to encourage infringement, and that "passive" statements that recipients merely could read as instructions to infringe were not sufficient. In doing so, the Supreme Court explicitly rejected the US Court of Appeals for the Federal Circuit's approach that focused on "whether the relevant statements could be read by medical providers as instructions to infringe."[1] While finding that Amarin's complaint did not sufficiently allege affirmative steps to encourage infringement, the Supreme Court left open the possibility that induced infringement can be implicit. *Hikma* involved induced infringement in the "skinny-label" context, but the Supreme Court's analysis could apply to induced infringement more broadly.

The Hatch-Waxman skinny-label pathway

The Hatch-Waxman Act allows generic manufacturers to seek US Food and Drug Administration (FDA) approval through an abbreviated new drug application (ANDA) that piggybacks on the brand manufacturer's clinical data, avoiding the costly and time-consuming studies required for a pioneer drug. A generic manufacturer whose product would infringe a patented method of use has three main options: wait until the patent expires to enter the market, file a paragraph IV certification asserting the patent is invalid or will not be infringed (which constitutes an act of infringement and triggers litigation), or submit a "skinny label" that removes (i.e., "carves out") the patented use and only includes unpatented methods of use and file a so-called section viii statement informing FDA of the carve-out. Even if a generic manufacturer pursues a skinny label, the branded company may still sue for induced infringement if the generic takes affirmative steps to encourage use of its product for the patented method of use, including for failing to successfully carve out the patented use from the skinny label. Cases like *GlaxoSmithKline LLC v. Teva Pharms. USA, Inc.,* 7 F.4th 1320, 1323 (Fed. Cir. 2021) and *AstraZeneca LP v. Apotex, Inc.,* 633 F.3d 1042, 1060 (Fed. Cir. 2010) make this clear.

Amarin's complaint and the proceedings below

Amarin markets Vascepa (icosapent ethyl), which FDA approved in 2012 for severe hypertriglyceridemia (SH Indication).[2] At that time, Vascepa was not yet approved for cardiovascular uses, and its original label included a statement that its effect "on cardiovascular mortality and morbidity in patients with severe hypertriglyceridemia has not been determined" (CV Limitation of Use).[3] In 2016, Hikma submitted an ANDA for its generic icosapent ethyl for the SH Indication.[4]

In 2019, FDA approved Vascepa for a second use, reducing cardiovascular risk in patients who already take statins (CV Indication).[5] At that time, Amarin removed the CV Limitation of Use from Vascepa's label and obtained two method-of-use patents covering the CV Indication and listed those patents in the Orange Book.[6]

In response to the new patents, Hikma supplemented its ANDA with a section viii statement that it was seeking a skinny label for only the SH Indication and not the CV Indication. Hikma also removed the CV Limitation of Use from its label.[7] In 2020, after Amarin's SH patents were found invalid, FDA approved Hikma's ANDA with a skinny label limited to the SH Indication, assigning Hikma's generic an "AB" rating indicating therapeutic equivalence to Vascepa when used according to its labeling.[8] Amarin alleged that because Hikma's generic is therapeutically equivalent to Vascepa, it is routinely dispensed in place of Vascepa under generic substitution laws, including for the patented CV use, despite the carve-out on Hikma's label.

Amarin sued in the US District Court for the District of Delaware, alleging Hikma actively induced infringement of its CV Indication patents based on the totality of Hikma's statements across several documents.[9] Specifically, Amarin made allegations based upon:

1. The Hikma label's omission of the CV Limitation of Use, while retaining information about a clinical study in which some patients were taking statins.[10]
2. A Hikma patient information leaflet that warned about possible side effects for "people who have heart (cardiovascular) disease," which is the target population for the CV Indication, noting that "[m]edicines are sometimes prescribed for purposes other than those listed in a Patient Information leaflet."[11]
3. Hikma's website that described its icosapent ethyl drug as "AB" rated and listed its therapeutic category as "hypertriglyceridemia," a category that includes, but is broader than, the approved SH Indication.[12]
4. Pre-launch press releases that described Hikma's product as "generic Vascepa" without disclosing that the approved use was limited to the SH Indication, and that featured Vascepa's sales figures attributable to both indications.[13]

Hikma moved to dismiss the complaint for failure to state a claim, and the district court granted the motion. The Federal Circuit reversed, finding it "at least plausible that a physician could read" Hikma's label, website and press releases "as an instruction or encouragement to prescribe [Hikma's generic] for any of the approved uses of icosapent ethyl."[14]

The legal framework for pleading induced infringement

The Supreme Court's analysis begins with the "well-established" *Iqbal-Twombly* standard for pleading that "asks for more than a sheer possibility that a defendant has acted unlawfully."[15] A complaint that "pleads facts that are merely consistent with a defendant's liability" "stops short of the line between possibility and plausibility of entitlement to relief."[16] Therefore, to "nudge a claim 'across the line from conceivable to plausible,'" the "plaintiff must plead facts that 'allo[w] the court to draw the reasonable inference that the defendant is liable for the misconduct alleged,'" and "rule out 'obvious alternative explanation[s]' for the defendant's conduct."[17]

The three elements of inducement are: (1) direct infringement by a third party; (2) knowledge that "the induced acts constitute patent infringement;" and (3) "active steps … to encourage direct infringement."[18] The question before the Supreme Court was limited to whether Amarin had satisfied the pleading standard for the third element.

The 'active steps' requirement

The Supreme Court held that a plausible inducement claim must include "active steps" to encourage infringement and, by contrast, that "ordinary acts incident to product distribution" are not enough."[19] The Supreme Court explained that active steps require "statements or actions directed to promoting infringement" and cited with approval previous inducement cases that required "'the taking of affirmative,' as opposed to passive, 'steps to bring about the desired result' of patent infringement" or "purposeful, culpable expression and conduct."[20]

Nor can allegations of inducement "be based only on 'vague' language 'combined with speculation about how others may act.'"[21] The Supreme Court drew a line between the insufficiency of alleging "a plausible chain of events" that merely "could lead a healthcare provider … to prescribe or dispense" the generic drug in an infringing manner,[22] and statements "designed to stimulate others to commit violations."[23] The Supreme Court noted that "statements *designed* to stimulate others form a narrower category than statements that *could* stimulate others."[24] The Supreme Court explicitly "reject[ed]" the Federal Circuit's "recent approach … which has increasingly trained its focus on whether the relevant statements could be read by medical providers as instructions to infringe."[25]

Importantly, the Supreme Court rejected Hikma's argument that active inducement must always be "express."[26]

"But implicit or explicit, the necessary inducement must be 'clear' to the relevant audience and 'affirmative.'"[27]

Applying the standard: Three reasons Amarin's complaint failed

The Supreme Court reasoned that the statements Amarin relied on fell into three categories.

Category 1: Obvious alternative explanation

The Supreme Court determined that some of Hikma's statements had an "obvious alternative explanation" besides inducing infringement.[28] The Supreme Court pointed out that Hikma's label omitted the CV Limitation of Use and retained clinical study information about patients taking statins because the duty-of-sameness statute, 21 USC §355(j)(2)(A)(v), required it to mirror Vascepa's label except for the carved-out indication.[29] The Supreme Court concluded Hikma's press releases describing its product as "generic Vascepa" reflected "normal industry practice" of "truthfully describ[ing]" a generic drug as "equivalent" to the brand-name comparator.[30] The Supreme Court reasoned that finding statements "complying with the law or with standard industry practice" to also be "affirmative steps to encourage infringement" would "put generic manufacturers between a rock and a hard place."[31]

Category 2: Mere omissions and inactions

The Supreme Court also found that "mere omissions, inactions, or nonfeasance" did not amount to "*affirmative* 'statements or actions.'"[32] Therefore, the Supreme Court determined Hikma's omission of the CV Limitation of Use from its label and silence about the SH-only approval in its press releases were not enough to plausibly allege liability. The Supreme Court reasoned that it must "look for *affirmative* 'statements or actions' precisely to avoid 'trenching on regular commerce,'" and doing otherwise could make "ordinary merchants … liable for any misuse of their goods and services, no matter how attenuated their relationship with the wrongdoer.'"[33]

Category 3: Vague statements combined with speculation

The Supreme Court found the remaining statements Amarin invoked to support inducement liability were too vague to constitute plausible active steps.[34] The patient leaflet's cardiovascular side effect warning and off-label use disclaimer were considered "implausibly roundabout ways to induce" infringement.[35] The Hikma website's reference to its product as a treatment for "hypertriglyceridemia," as opposed to "severe hypertriglyceridemia," was considered merely a description of the category of drugs, "akin to describing a drug for leukemia as a "cancer drug.'"[36] The Supreme Court concluded the Hikma website's clarification that its generic is "indicated for fewer than all approved indications" of Vascepa negated any inference of deliberate promotion.[37] And the Supreme Court considered Hikma's press release sales figures as "the vaguest of 'vague' statements" that would require multiple, speculative steps to occur for those statements to result in infringement – a chain of events that is "possible" but not "plausible."[38]

Practical implications

For brand-name patent owners, the decision sets the bar for pleading induced infringement but does not close the door to finding infringement where a generic uses a skinny label. The Supreme Court did not foreclose inducement claims in skinny-label cases based on a totality-of-circumstances theory and confirmed that implicit encouragement can suffice. However, the totality of statements must plausibly reflect affirmative steps by the defendant to encourage infringing use. Allegations that depend on assuming a subjective, inferential leap by the healthcare provider are more likely to be found "possible" but not "plausible." Statements or conduct directed at the patented use that cannot be explained by regulatory obligation or industry practice are likely to provide more plausible allegations of active inducement.

Brand-name patent owners should also consider patent strategies that are not susceptible to indication carve-outs – for example, by patenting safety and efficacy information that relates to all approved indications. This can include dose adjustments based on patient characteristics, such as renal, hepatic or metabolizer status, and

dose adjustments to address interactions with other drugs. Because this information is required to appear in a generic label, it will provide clearer evidence of induced infringement.

For generic manufacturers, *Hikma* demonstrates that companies that pursue the skinny-label pathway, mirror the brand label as required by statute and describe their products using standard industry terminology may be better positioned to avoid induced infringement liability.

Conclusion

Hikma v. Amarin is a significant decision for pleading induced patent infringement claims. Patentees should heed the Supreme Court's emphasis that "the key question is whether a defendant actively encouraged infringement through its statements, not merely how others may understand those statements,"[39] because "implicit or explicit, the necessary inducement must be 'clear' to the relevant audience and 'affirmative.'"[40]

Notes

1. Slip op. at 9 n.3.
2. Slip op. at 5.
3. Id.
4. Id.
5. Id.
6. Id.
7. Id.
8. Id. at 6, citing the Federal Circuit decision, 104 F.4th 1370, 1373–1374.
9. 578 F.Supp. 3d 642, 645–647 (D. Del. 2022); slip op. at 6–7.
10. Slip op. at 6.
11. Id.
12. Id.
13. Id. at 6–7.
14. 104 F.4th 1370, 1378–1380 (Fed. Cir. 2024).
15. Slip op. at 7, quoting *Ashcroft v. Iqbal*, 556 US 662, 678 (2009).
16. Id.
17. Id. at 7–8, quoting *Iqbal,* 556 US at 678, 680, and *Bell Atlantic Corp. v. Twombly,* 550 US 544, 567 (2007).
18. Id. at 7–8, quoting *Iqbal,* 556 US at 678, 680, and *Bell Atlantic Corp. v. Twombly*, 550 US 544, 567 (2007).
19. Id. at 8, quoting *Global-Tech*, 563 US at 760.
20. Id. at 8, quoting *Global-Tech*, 563 US at 760, and *Grokster*, 545 US at 935, 937.)
21. Id. at 10, citing *Takeda Pharms. v. Westward Pharm. Corp.*, 785 F.3d 625, 632 (Fed. Cir. 2015).
22. Id. at 8, quoting Amarin's brief.
23. Id. at 9, quoting *Grokster*, 545 US at 937.
24. Id., emphases in original.
25. Id. at 9 n.3.
26. Id. at 10.
27. Id., citing *Grokster*, 545 US at 937.
28. Slip op. at 10–11, quoting *Twombly*, 550 US at 567.
29. Slip op. at 11.
30. Id., citing *Inwood Laboratories, Inc. v. Ives Laboratories, Inc.*, 456 US 844, 847–848 (1982).
31. Id. at 10-11.
32. Slip op. at 11–12 (emphasis in original).
33. Id. (emphasis in original), citing *Grokster*, 545 US, at 935, 937, and *Twitter, Inc. v. Taamneh,* 598 US 471, 489 (2023).
34. Slip op. at 12.
35. Id.
36. Id. at 13.
37. Id. at 12–13.
38. Id. at 13–14.
39. Slip op. at 9 n.3.
40. Id. at 10.

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