2023-1169

UNITED STATES COURT OF APPEALS FOR THE FEDERAL CIRCUIT

AMARIN PHARMA, INC., AMARIN PHARMACEUTICALS IRELAND LIMITED, MOCHIDA PHARMACEUTICAL CO., LTD.,

Plaintiffs-Appellants,

v.

HIKMA PHARMACEUTICALS USA INC., HIKMA PHARMACEUTICALS PLC,

Defendants-Appellees,

HEALTH NET LLC,

Defendant

Appeal from the United States District Court for the District of Delaware
Case No. 1:20-cv-01630-RGA-JLH, Judge Richard G. Andrews

APPELLANTS' RESPONSE TO HIKMA'S PETITION FOR REHEARING EN BANC

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October 1, 2024

UNITED STATES COURT OF APPEALS
FOR THE FEDERAL CIRCUIT

CERTIFICATE OF INTEREST

Case Number 23-1169

Short Case Caption Amarin Pharma, Inc. v. Hikma Pharmaceuticals USA Inc.

Filing Party/Entity Amarin Pharma, Inc., Amarin Pharmaceuticals Ireland Limited, Mochida Pharmaceutical Co., Ltd.

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Mochida Pharmaceutical Co., Ltd.		N/A

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☑ None/Not Applicable ☐ Additional pages attached

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’537 patent	U.S. Patent No. 9,700,537
’861 patent	U.S. Patent No. 10,568,861
AAM Br. __	Amicus Brief filed by Association for Accessible Medicines, page __
Appx__	joint appendix page __
Amarin	plaintiffs–appellants Amarin Pharma, Inc., Amarin Pharmaceuticals Ireland Ltd., and Mochida Pharmaceutical Co., Ltd., collectively
CV indication	Amarin’s patented indication for treating cardiovascular risk
Hikma	defendants–appellees Hikma Pharmaceuticals USA Inc. and Hikma Pharmaceuticals PLC, collectively
Op. __	panel decision, page __
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SH indication	Hikma’s approved indication for treating severe hypertriglyceridemia
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INTRODUCTION

The panel decision reasonably concluded that Amarin's inducement claim was at least plausible, and Hikma's disagreement with that conclusion does not warrant en banc review, especially given Hikma's attempt to gloss over the very focus of the decision. The panel decision was not an expansion of *GSK*. The issue that animated the en banc briefing in that case—whether *intent* to induce infringement can be inferred from a label intended to carve out an infringing use—was not at dispute in this appeal. Even the district court accepted that Amarin's pleadings cited evidence that could be relevant to Hikma's intent to induce infringement, and the panel decision correctly understood that issue to be beyond the scope of this appeal.

Unlike *GSK* and nearly every other skinny label case this Court has considered, this appeal is from a dismissal on the pleadings and lacks the type of deep factual evidence present in those other cases. But what it does have are allegations about specific active steps Hikma took to induce infringement beyond its label.

Hikma's narrow approval was for treating *severe* hypertriglyceridemia, an indication that accounts for only a small amount of Amarin's Vascepa® sales. Most Vascepa sales are for its other, patented indication: reducing cardiovascular risk in the much broader class of patients with non-severe hypertriglyceridemia. That is

where the demand is and Hikma knew it: Hikma relied on the disparity in sales between the two indications during earlier litigation between the parties, and it did so *before* issuing the press releases Amarin relies on here. In those press releases, which followed a ruling in that earlier litigation, Hikma heralded the anticipated approval of its "generic version" of Vascepa while touting Amarin's *total* U.S. Vascepa sales. Meanwhile, its website identified the therapeutic category of its generic product as hyperglyceridemia, not severe hypertriglyceridemia. The panel decision concluded merely that Amarin's induced infringement pleadings were at least plausible in view of those communications.

The panel decision was consistent with all nine opinions Hikma cites in its Rule 35(b)(2) statement and does not warrant en banc review. Nor does it suggest the sky is going to fall on the generic pharmaceutical industry, which should be capable of drafting accurate press releases and correctly identifying therapeutic categories on its websites.

I. Background

A. Vascepa's dual uses for different patient groups

Triglycerides are a necessary fat that circulates in human blood, but high triglyceride levels can lead to serious conditions. Hypertriglyceridemia refers to a blood triglyceride level above the normal acceptable level of 150 mg/dL. The primary concern for patients with hypertriglyceridemia is cardiovascular risk.

Appx866 ¶7. *Severe* hypertriglyceridemia, meanwhile, refers to a blood triglyceride level over 500 mg/dL. Appx696 §1. The primary concern with severe hypertriglyceridemia is pancreatitis. Appx952; Appx866 ¶7.

The FDA approved Amarin's Vascepa® in 2012 as the only treatment for severe hypertriglyceridemia that does not raise bad cholesterol levels. Op. 3; Appx508 ¶30. After receiving that first approval, Amarin continued to investigate other uses of Vascepa, including through a five-year clinical trial with over 8,000 patients to assess cardiovascular risk reduction in patients with hypertriglyceridemia. Appx509 ¶¶31, 33; Appx832. Based on that trial's success, the FDA approved Vascepa for a second indication: as a treatment to reduce cardiovascular risk in patients with hypertriglyceridemia. *See* Appx509-510 ¶34; Appx517 ¶62. The Vascepa label thus includes two approved indications, the earlier severe hypertriglyceridemia indication (the SH indication) and the later cardiovascular risk-reduction indication (the CV indication) relevant to patients with hypertriglyceridemia. Appx514 ¶56. Amarin's '861 and '537 patents cover the CV indication, which accounts for more than 90% of Vascepa sales. Appx923-925; Appx540 ¶152.

B. Hikma's SH indication approval and public communications

In 2020, Hikma received FDA approval for the use of its generic product to treat severe hypertriglyceridemia based on an abbreviated new drug application

(ANDA) that included a statement under 21 U.S.C. § 355(j)(2)(A)(viii) ("paragraph viii") that it was not seeking approval for the CV indication covered by Amarin's '537 and '861 patents. Appx526 ¶¶ 102, 104; Op. 4-5.

In connection with that approval only for the SH indication, Hikma issued pre-launch press releases stating that: (1) Vascepa is indicated only "in part" for severe hypertriglyceridemia; (2) Hikma's product is the "generic version" of Vascepa without any qualification; (3) Hikma "received FDA approval" without explaining that approval was limited to the CV indication; and (4) the value of domestic Vascepa sales that mostly comprised sales associated with Amarin's patented CV indication for which Hikma had not sought approval. Appx709; Appx712; Appx529 ¶¶ 112-13; Appx531 ¶¶ 119-120. Beyond those press releases, Hikma's website described its product as within the therapeutic category of "Hypertriglyceridemia," even though its approved SH indication was for patients with *severe* hypertriglyceridemia, Appx532-533 ¶¶ 125-26.

C. The district court dismissed Amarin's claims for induced infringement after considering the categories of evidence in isolation

Amarin sued Hikma for inducing infringement of the '861 and '537 patents. Amarin's amended complaint, Appx504-557, alleged that Hikma induced infringement through its label, press releases, and website. Op. 9; *see also* Appx533 ¶¶ 127-128. Hikma moved to dismiss. The magistrate judge recommended denying

Hikma's motion because "there is a real dispute about what [the contents of Hikma's label and public statements] communicate to others" that is not appropriate to resolve on the pleadings. Appx1427, Appx1430.

The district court rejected the magistrate judge's recommendation after considering Amarin's allegations in isolation. Looking at only Hikma's label, the district court found no instruction "as to [cardiovascular] risk reduction," while dismissing the patient population and "side effect[]" language on the label related to cardiovascular risk reduction. Appx6. The district court separately analyzed Amarin's non-label allegations, Appx7, but it failed to weigh the full allegations as a whole against the plausibility standard. Dicing the allegations finer, the court demanded that plausible evidence of inducement come from the press releases or website alone. Appx8 (reasoning that the question was whether referring to the broad "hyperglyceridemia" category on its website, "without a label or other public statements instructing as to infringing use" was enough to induce infringement).

D. The panel reversed because the district court demanded too much at the pleading stage

Unlike the district court, the panel decision "review[ed] the allegations of inducement as a whole, not piecemeal," to determine "whether the *totality* of the allegations, taken as true, plausibly plead that Hikma induced infringement." Op. 13. The panel decision recognized that, unlike other paragraph viii cases, this case was dismissed on the pleadings, where allegations are reviewed for plausibility. *Id*. As a

result, the case lacked the factual development of the Court's other paragraph viii decisions, and thus received the most permissive standard of review of the "*allegations*, not findings, for *plausibility*, not probability." Op. 13 (citing *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 556 (2007)).

On the allegations, the panel decision considered Hikma's label and recognized that "Amarin's theory of induced infringement is not based solely on the label," but "on the label *in combination* with Hikma's public statements and marketing materials." Op. 16-17. Considering the website and press releases together, the panel decision concluded that "[t]hose allegations, taken together with those relating to Hikma's label, at least plausibly state a claim for induced infringement." Op. 17. This was so because "many of the allegations depend on what Hikma's label and public statements would communicate to physicians and the marketplace," which "is a question of fact—not law—and is therefore not proper for resolution on a motion to dismiss." Op. 17 (citing *GlaxoSmithKline LLC v. Teva Pharms. USA, Inc.*, 7 F.4th 1320, 1330 (Fed. Cir. 2021)).

ARGUMENT

I. The panel decision was true to precedent and does not require en banc review

A. A pleading is sufficient when it raises plausible allegations

The panel correctly focused on the pleading standard by "review[ing] the allegations of inducement as a whole, not piecemeal," to determine "whether the

totality of the allegations, taken as true, plausibly plead that Hikma induced infringement." Op. 13 (citing *GSK*, 7 F.4th at 1338). Following precedent, the panel explained that inducement can occur with a skinny label "where, as here, *other evidence* is asserted with regard to inducement." Op. 14 (citing *GSK*, 7 F.4th at 1338) (emphasis added). The panel noted it was undisputed Amarin pleaded Hikma's intent and healthcare providers' direct infringement when prescribing Hikma's generic for the CV indication. Op. 14.

Contrary to Hikma's arguments (at 10-13), the panel decision followed precedent and required active inducement steps. Amarin's allegations turned on "what Hikma's label and public statements would communicate to physicians and the marketplace." Op. 17. Because it was undisputed that giving Hikma's generic to patients with non-severe hypertriglyceridemia would reduce cardiovascular risk and infringe the asserted patents, the issue was whether Amarin alleged sufficient communications to plausibly encourage healthcare providers to prescribe Hikma's generic to patients with hypertriglyceridemia. The panel stepped through Hikma's communications and concluded that Amarin's allegations relating to Hikma's website and press releases, "taken together with those relating to Hikma's label, at least plausibly state a claim for induced infringement." Op. 15-17.

B. The panel recognized and followed the principles in all nine precedents Hikma cites in its Rule 35(b)(2) statement

Hikma claims the panel decision conflicts with nine earlier decisions. Pet. vii. In fact, the panel's decision conflicts with none of them.

1. The panel decision required active steps

Hikma relies on four of those nine cases as requiring active or affirmative steps to prove induced infringement. Pet. 10 (citing *Glob.-Tech Appliances, Inc. v. SEB S.A.*, 563 U.S. 754, 760 (2011); *DSU Med. Corp. v. JMS Co.*, 471 F.3d 1293, 1305-06 (Fed. Cir. 2006); *Takeda Pharms. U.S.A., Inc. v. W.-Ward Pharm. Corp.*, 785 F.3d 625, 630-31 (Fed. Cir. 2015); *Warner-Lambert Co. v. Apotex Corp.*, 316 F.3d 1348, 1364 (Fed. Cir. 2003)). The panel decision was not to the contrary. It acknowledged inducement requires a "clear expression or other affirmative steps," Op. 14 (quoting *DSU*, 471 F.3d at 1304), and it framed the question before it as "whether Amarin's complaint plausibly pleads that Hikma 'actively' induced healthcare providers' direct infringement," Op. 15 (citing *Takeda*, 785 F.3d at 631).

Hikma, not the panel decision, fails to consider that precedent. Active steps include communications like advertising or instructing. *See Takeda*, 785 F.3d at 631. As the panel decision noted, Hikma advertised its generic for use in the hypertriglyceridemia category on its website and touted sales figures for the patented use through its press releases. Op. 17. The panel decision also relied on Hikma's press releases that referred to its "generic version" of Vascepa while telling the

public that Vascepa was indicated "in part" for the SH indication. The panel concluded that Amarin's allegations about Hikma's label together with those steps at least plausibly stated a claim for induced infringement. Op. at 17. Hikma's soundbites (at 10) from *Global-Tech*, *DSU*, and *Warner-Lambert* all similarly focus on the need for active or affirmative steps. None cast doubt on *Takeda*'s or the panel decision's reasoning that advertising or other communications can satisfy that requirement.

Moreover, the question is what those statements would plausibly communicate to physicians. Op. 17. The panel decision explained in detail why it was at least plausible that a physician would read those various communications as instructing or encouraging the use of Hikma's product for any of Vascepa's uses, and the panel explained why Hikma's marketing its drug in the therapeutic category of "Hypertriglyceridemia" was encouraging an off-label use. Op. 18. Hikma is free to disagree with those conclusions, but its disagreement does not justify the unreasonable argument that rehearing is necessary "to reconcile this case with precedent" that the panel decision followed.

2. The panel decision required inducement of the claimed invention

Hikma argues (at 10-11) that the panel decision conflicts with three more cases, *Ericsson, Inc. v. D-Link Systems, Inc.*, 773 F.3d 1201, 1219 (Fed. Cir. 2014), *Grunenthal GMBH v. Alkem Laboratories Ltd.*, 919 F.3d 1333, 1339-40 (Fed. Cir.

2019), and *Power Integrations, Inc. v. Fairchild Semiconductor International, Inc.*, 843 F.3d 1315 (Fed. Cir. 2016), either because the panel decision failed to address whether Hikma's communications referred to every claimed step (*Ericsson* and *Grunenthal*) or because it relied on Amarin's actions (*Power Integrations*) to fill the gaps. Those arguments misconstrue the panel decision.

The panel decision correctly understood the issue was not the precise mapping of the language in Hikma's various press-release and website statements to the specific claim elements. The issue was what Hikma's label *together* with those statements "would communicate to physicians and the marketplace," a question that is not appropriately resolved on a motion to dismiss. Op. 17 (citing *GSK*, 7 F.4th at 1330). The panel did not hold that one could induce infringement without inducing performance of the claimed invention and therefore did not conflict with either *Ericsson* or *Grunenthal*.[1]

As for *Power Integrations*, Hikma is mistaken (at 3) that the panel decision relied on Amarin's label. Amarin alleged that portions of Hikma's own label taught

[1] Hikma's allegation (at 11) that the panel decision identified no Hikma statement about using its product "with a statin" is both misleading and irrelevant. As Hikma knows, Amarin's complaint relied at least on Hikma's label for the statin use limitation. RB14; *see also* Op. 15 (discussing Amarin's allegations regarding Hikma's label and "statin-treated patients"). The district court did not reach Hikma's arguments about statin use, Appx6, and Hikma did not raise them on appeal as an alternative basis for affirmance.

physicians that its product could be used to treat cardiovascular risk. Op. 15. And while the panel decision questioned whether Hikma's label alone was enough, it consistently referred to the combination of Hikma's public statements and *its* label. *See* Op. 9-10 (discussing magistrate judge's conclusions); Op. 12-13 (referring to "the generic manufacturer's skinny label *as well* as its public statements"); Op. 15 (discussing Amarin's allegations); Op. 16-17 (same); Op. 17 (referring to allegations "relating to Hikma's label").

3. The panel decision did not turn on Hikma's "generic version" language or "market realities"

For the remaining two cases, *GSK* and *AstraZeneca Pharmaceuticals LP v. Apotex Corp.*, 669 F.3d 1370 (Fed. Cir. 2012), Hikma argues (at 13-15) that the panel decision conflicted with those precedents for allegedly premising inducement on Hikma's use of the term "generic version" (*GSK*) or on "market realities" (*AstraZeneca*). Hikma is wrong on both scores.

As for Hikma calling its product a "generic version" of Vascepa, the panel decision did not conclude that was enough to establish inducement. Even Hikma acknowledges the panel's statement that "Hikma did much more" than simply call its product a generic equivalent. Pet. 14 (quoting Op. 20). Hikma's argument boils down to disagreement with the panel's assessment of Amarin's pleadings as a whole. Hikma's press releases called its product a generic equivalent of Vascepa, *and* indicated that Vascepa has multiple indications, *and* touted the complete sales

figures for all Vascepa sales. Meanwhile, Hikma's website associated its generic product with "Hypertriglyceridemia" generally as opposed to treating *severe* hypertriglyceridemia, i.e., the SH indication for which its product was approved. The panel decision expressly "[did] not … hold[] that a mere statement that a generic manufacturer's product is the 'generic version' of a brand-name drug is enough to be liable for induced infringement." Op. 19-20. Consistent with *GSK*, 7 F.4th at 1335-38, Amarin pleaded "that Hikma did much more than call its product a 'generic version' of Vascepa." Op. 20. *GSK* is also procedurally distinguishable, having been appealed after a trial rather than after a dismissal on the pleadings. *GSK*, 7 F.4th at 1325-26.

As for market realities, Hikma is wrong (at 14-15) that the panel decision's reliance on Hikma's promotion of Vascepa's overall sales figures was "nearly identical" to the approach rejected in *AstraZeneca*. *AstraZeneca* did not involve press releases touting brand sales figures. Instead, AstraZeneca premised its inducement case on the assumption that the generic would be substituted for the brand's indications even if the generic was not similarly approved. 669 F.3d at 1380. Thus, in its suit under 35 U.S.C. § 271(e)(2) based on Apotex's ANDA filings, AstraZeneca argued that the mere use of a paragraph viii carve-out "ignore[d] market realities because even if a generic drug is formally approved only for unpatented

uses, pharmacists and doctors will nonetheless substitute the generic for all indications once it becomes available." *Id*.

Neither Amarin nor the panel decision relied on a "market reality" theory. Amarin relied on Hikma's active promotion of its generic version of Vascepa, which Hikma said was indicated "in part" for the SH indication while touting Vascepa's total U.S. sales, the large majority of which it knew were for the CV indication.[2] Appx529 ¶¶ 112, 113; Appx709; Appx712.

II. The government's concerns with deriving intent from labeling are not relevant to this appeal where intent was not disputed

Hikma (at 5) (and amicus curiae Teva (at 10)) invoke the Solicitor General's amicus brief filed during consideration of Teva's *certiorari* petition from this Court's *GSK* decision. Brief for the United States as Amicus Curiae, *Teva Pharms. USA, Inc. v. GlaxoSmithKline LLC*, 143 S.Ct. 2483 (2023) (No. 22-327), 2023 WL 2717391 ("U.S. Br."). The government's concern in that brief was with the notion

[2] Amicus Teva criticizes the panel decision's focus on the sales data touted by Hikma because, in Teva's view, referencing total sales revenue "is standard for skinny-label launches because indication-by-indication revenues for brand name drugs is the stuff of expert testimony at trial, not generic manufacturer business records." Teva Br. 9. Whether Teva is correct is a factual issue itself, and certainly nothing Hikma argued in this case. Nor could it have. The amount of Vascepa sales attributable to the patented CV indication is something *Hikma* raised in earlier litigation. Appx846 ¶ 115 (Hikma's proposed finding of fact from the earlier Nevada litigation over Amarin's patents covering the SH indication).

of inferring intent to induce from a carved-out label. *See* U.S. Br. at *13 (asserting that this Court's *GSK* decision was incorrect because "[n]o reasonable jury could have concluded that the carved-out labeling for petitioner's generic … was itself evidence of intent to induce infringement"). While Hikma cites the government's concerns that *GSK*'s holding could "deter use of the section viii pathway," Pet. 5 (quoting U.S. Br. at *22), the government there was discussing the ramifications of finding intent to induce infringement merely from the existence of a carved-out label. U.S. Br. at *22-23.

The government's concerns in *GSK* are irrelevant here for two reasons. First, the issue in this case does not involve intent. *See* Op. 14 (explaining that, for this appeal, it is undisputed that Amarin's complaint sufficiently alleges that Hikma had the requisite intent to induce infringement). Second, even were intent relevant, the panel decision focused on evidence *beyond* the label. *See* Op. 17-18.

III. The additional concerns raised by amici curiae distort both the panel opinion and the dispute

A. Teva is merely continuing its *GSK* battle

While Hikma argues (at vii, 4, 13) that the panel decision is contrary to *GSK*, Teva says the opposite and argues that both cases follow the same reasoning. Teva Br. 1-2, 5, 7, 8. Focusing on the issues it lost in *GSK*, Teva urges that this Court should "completely revisit its recently changed approach to skinny-label inducement claims." Teva Br. 10. But Teva does not explain what that "recently changed

approach" is, or how it departs from either 35 U.S.C. § 271(b) or 21 U.S.C. § 355(j)(2)(A)(viii), though it claims (at 2) that the panel decision represents a shift in interpretation of *both* statutes. Citing *Takeda*, Teva argues (at 4) that "launching with a *carved-out* label is not affirmative encouragement," but neither *GSK* nor the panel decision held otherwise. The panel decision expressly focused on evidence beyond the label, and Teva cannot avoid that reality by dismissing the additional evidence that was central to the panel decision's reasoning. *See* Teva Br. 8-9 (referring to the panel decision's "mistaken[] view" about the intended target of press releases without acknowledging the pleading posture of this case).

B. AAM is wrong that skinny labels shield generics from inducement claims regardless of their other actions

AAM argues for a rule that finds no foothold in the law, i.e., that a party cannot plausibly state a claim for induced infringement when the accused infringer's actions "include successfully carving out the infringing method." AAM Br. 7. AAM cites no precedent supporting its theory that a skinny label excuses other inducing acts. The issue is not whether Hikma's website and press releases "plausibly convert a non-infringing label into an infringing one," AAM Br. 8, the issue is whether Hikma's statements in press releases and on its website when combined with its label plausibly induced infringement even if its label alone did not (which Amarin has never conceded).

AAM also misstates the scope of the dispute when it says (at 2) that it was undisputed that Hikma had carved out infringing uses from its label, which allegedly did not induce infringement "as a matter of law." It was Hikma's intent and knowledge, and the actual infringement by healthcare providers that was not disputed. Op. 14. The panel noted only the lack of dispute over whether the label's "Indication & Usage" section instructed the CV indication. Op. 15. As for whether the label induced infringement as a matter of law, the panel said only that it "may agree" with the district court that, taken on its own, the Hikma label does not induce the CV indication. *Id.*

C. The 15 Scholars' complaints about the panel's discussion of AB ratings does not warrant review

The Scholars (at 4) fault the panel decision for noting the difference between equivalence generally, and the identification of a generic as an AB-rated equivalent to a brand therapeutic. As a threshold matter, whether a clinician would view those terms as interchangeable is a factual question inappropriate for resolution at the pleadings. More importantly, the panel decision is consistent with *GSK*'s discussion of the significance of a generic AB rating. *GSK*, 7 F.4th 1320, 1324 n.2.

The panel decision's discussion of AB rating is also consistent with the Law360 commentary Hikma relies on in its petition. *See* Pet. 1, n.2 (citing https://www.law360.com/ip/articles/1863857/the-fed-cir-in-june-more-liability-for-generic-drug-makers (explaining that "[a]n AB-rated drug means there is generic

equivalence for only the labeled uses, and no others")). *See also* U.S. Br. at *17 n.5 (explaining that an "AB-rated generic equivalent" "is required to be therapeutically equivalent to its brand-named reference drug *if used as directed on the labeling*" (emphasis added) (citing 21 U.S.C. §§ 355(j)(2)(A)(iv) and (4)(F))). *Takeda* is not to the contrary. Hikma quotes that opinion for the proposition that "AB-rated" and "generic version" are vague phrases that cannot be combined with "speculation" to find inducement. Pet. at 15 (quoting *Takeda*, 785 F.3d at 632). But *Takeda* did not refer to an AB rating or generic version at all; the "vague" phrase at issue in *Takeda* was a warning instruction. *Takeda*, 785 F.3d at 632.

The Scholars further argue (at 10) that the panel decision will harm patients by encouraging generics "to describe … products as something other than generic equivalents." Generic manufacturers *should* describe their products accurately, including that they are only indicated for their approved uses. Regardless, the issue in this case is not about how press releases or Hikma's website would be viewed by patients. The question is whether those communications plausibly induced infringement by healthcare providers.

CONCLUSION

Hikma's petition for rehearing en banc should be denied.

Respectfully submitted,

PERKINS COIE LLP

by /s/Nathan K. Kelley

Nathan K. Kelley

Counsel for Appellants Amarin Pharma, Inc., Amarin Pharmaceuticals Ireland Ltd., and Mochida Pharmaceutical Co., Ltd.

FORM 19. Certificate of Compliance with Type-Volume Limitations **Form 19**
July 2020

UNITED STATES COURT OF APPEALS
FOR THE FEDERAL CIRCUIT

CERTIFICATE OF COMPLIANCE WITH TYPE-VOLUME LIMITATIONS

Case Number: 23-1169

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United States Court of Appeals for the Federal Circuit

AMARIN PHARMA, INC., AMARIN PHARMACEUTICALS IRELAND LIMITED, MOCHIDA PHARMACEUTICAL CO., LTD.,
Plaintiffs-Appellants

v.

HIKMA PHARMACEUTICALS USA INC., HIKMA PHARMACEUTICALS PLC,
Defendants-Appellees

HEALTH NET LLC,
Defendant

2023-1169

Appeal from the United States District Court for the District of Delaware in No. 1:20-cv-01630-RGA-JLH, Judge Richard G. Andrews.

Decided: June 25, 2024

NATHAN K. KELLEY, Perkins Coie LLP, Washington, DC, argued for plaintiffs-appellants. Also represented by NATHANAEL D. ANDREWS.

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Before MOORE, *Chief Judge*, LOURIE, *Circuit Judge*, and ALBRIGHT, *District Judge*.[1]

LOURIE, *Circuit Judge.*

Amarin Pharma, Inc., Amarin Pharmaceuticals Ireland Limited, and Mochida Pharmaceutical Co., Ltd. (collectively, "Amarin") appeal from a decision of the United States District Court for the District of Delaware granting Hikma Pharmaceuticals USA Inc.'s and Hikma Pharmaceuticals PLC's (collectively, "Hikma") motion to dismiss Amarin's complaint for failure to state a claim. *Amarin Pharma, Inc. v. Hikma Pharms. USA Inc.*, 578 F. Supp. 3d 642 (D. Del. 2022) ("*Decision*").[2] Because Amarin's allegations against Hikma plausibly state a claim for induced infringement, we reverse.

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[1] Honorable Alan D Albright, District Judge, United States District Court for the Western District of Texas, sitting by designation.

[2] In the same decision, the court denied Health Net LLC's motion to dismiss the complaint for failure to state a claim for induced infringement. *See Decision*, 578 F. Supp. 3d at 643. Amarin's claims against that defendant, which appear to have settled, *see* J.A. 35, are therefore not at issue in this appeal.

BACKGROUND

I

Amarin markets and sells icosapent ethyl, an ethyl ester of an omega-3 fatty acid commonly found in fish oils, under the brand name Vascepa®. In 2012, the U.S. Food and Drug Administration ("FDA") approved Vascepa for the treatment of severe hypertriglyceridemia ("the SH indication"), a condition in which a patient's blood triglyceride level is at least 500 mg/dL. As part of its labeling for Vascepa, Amarin included an express "limitation of use," disclosing that "[t]he effect of VASCEPA on cardiovascular mortality and morbidity in patients with severe hypertriglyceridemia has not been determined." J.A. 650 ("the CV Limitation of Use"). But observing that clinical testing data demonstrated that Vascepa was capable of lowering triglyceride levels without increasing "bad" cholesterol (*i.e.*, LDL-C), Amarin continued its research into potential cardiovascular uses of the drug.

In 2019, following the success of Amarin's additional research and clinical trials, the FDA approved Vascepa for a second use: as a treatment to reduce cardiovascular risk (*i.e.*, myocardial infarction, stroke, coronary revascularization, and unstable angina requiring hospitalization) in patients having blood triglyceride levels of at least 150 mg/dL ("the CV indication"). Upon receiving that approval, Amarin added the CV indication to its label and removed the CV Limitation of Use. *Compare* J.A. 650 (pre-CV indication approval), *and* J.A. 663 (same), *with* J.A. 635 (post-CV indication approval). It also timely listed U.S. Patent 9,700,537 ("the '537 patent") and U.S. Patent 10,568,861 ("the '861 patent") (collectively, "the asserted patents"),

which each claim methods directed to the CV indication, in the Orange Book.[3]

In 2016, when Vascepa was still only approved for the SH indication, Hikma submitted an Abbreviated New Drug Application ("ANDA") for approval of its generic icosapent ethyl product.[4] That ANDA remained pending in 2019 when the FDA approved the use of icosapent ethyl for the CV indication. At that juncture, Hikma was required to either amend its proposed label to match the revised Vascepa label including the CV indication and corresponding information, *see* 21 U.S.C. § 355(j)(2)(A)(vii), or file a "section viii statement" to "carve-out" that indication, *see*

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[3] The '537 patent is assigned to Mochida Pharmaceutical Co., Ltd. and exclusively licensed to Amarin Pharma, Inc. J.A. 512. The '861 patent is assigned to Amarin Pharmaceuticals Ireland Limited and exclusively licensed to Amarin Pharma, Inc. *Id.* at 513. In its operative complaint, Amarin also asserted U.S. Patent 8,642,077 against Hikma, but the parties' dispute as to that patent has been resolved. *See* Amarin Br. at 12 n.2.

[4] As part of its ANDA, Hikma submitted a paragraph IV certification averring that Amarin's then-Orange Book listed patents directed to the treatment of severe hypertriglyceridemia were invalid or would not be infringed by the manufacture, use, or sale of Hikma's generic product. *See* 21 U.S.C. § 355(j)(2)(A)(vii)(IV). Based on the ANDA filing, Amarin sued Hikma in the United States District Court for the District of Nevada for patent infringement ("the Nevada litigation"). Following a bench trial, and subsequent appeal, Amarin's asserted severe hypertriglyceridemia-related patents were held invalid as obvious. *Amarin Pharma, Inc. v. Hikma Pharms. USA Inc.*, 449 F. Supp. 3d 967, 1015 (D. Nev.), *aff'd summarily*, 819 F. App'x 932 (Fed. Cir. 2020). Those patents are therefore not at issue here.

id. § 355(j)(2)(A)(viii). Hikma opted for the latter and submitted a statement seeking FDA approval only for uses not covered by Amarin's newly listed CV indication patents. In other words, Hikma sought the FDA's approval of a "skinny label" for its generic product that would include only the SH indication and not the CV indication. The FDA approved Hikma's ANDA, including its proposed skinny label, on May 21, 2020.

Hikma's approved label refers only to the SH indication in the "Indications and Usage" section. J.A. 694 (providing that the drug is indicated only "as an adjunct to diet to reduce triglyceride (TG) levels in adult patients with severe (≥ 500 mg/dL) hypertriglyceridemia"). It further identifies potential side effects, stating that people with cardiovascular disease or diabetes with a risk factor for cardiovascular disease may experience "[h]eart rhythm problems (atrial fibrillation and atrial flutter)." *Id.* at 704–05. And it acknowledges that "[m]edicines are sometimes prescribed for purposes other than those listed in a Patient Information leaflet." *Id.* at 705. Like the current Vascepa label, Hikma's approved label does not include the CV Limitation of Use that was present on the Vascepa label during the time when icosapent ethyl was approved for only the SH indication. *Compare id.* at 694 (Hikma label), *and id.* at 635 (current Vascepa label), *with id.* at 650 (Vascepa label pre-CV indication approval). Although Hikma's original proposed label included the CV Limitation of Use, Hikma later amended the label to remove that limitation around the same time it submitted its section viii statement carving out the uses covered by the asserted patents.

Throughout 2020, Hikma issued a series of press releases regarding its efforts to provide a generic icosapent ethyl product. First, in March, it publicly announced the favorable district court outcome in the Nevada litigation against Amarin regarding the SH indication ("the March 2020 Press Release"). J.A. 709; *see supra* note 4. That press release referred to Hikma's product as the "generic

version" of Vascepa, which it described as "medicine that is indicated, in part, [to treat] severe (≥ 500 mg/dL) hypertriglyceridemia." J.A. 709. It also provided sales data for Vascepa, stating that sales of the product in the United States "were approximately $919 million in the 12 months ending February 2020." *Id.*

Then, the day after the FDA granted Hikma's ANDA, Hikma issued a press release announcing the approval ("the May 2020 Press Release"). *Id.* at 613. The press release stated that Hikma had received FDA approval for its icosapent ethyl tablets, "the generic equivalent to Vascepa®." *Id.* It further included a quote from Hikma's President of Generics that "[t]he approval for our generic version of Vascepa® is an important milestone towards bringing this product to market." *Id.*

A little over three months later, on September 3, 2020, Hikma issued a press release announcing the positive outcome in the appeal of the Nevada litigation regarding its alleged infringement of Amarin's SH indication patents ("the September 2020 Press Release"). J.A. 712; *see supra* note 4. Similar to the prior press releases, the September 2020 Press Release referred to Hikma's product as "Hikma's generic version of Vascepa®" and "generic Vascepa®." J.A. 712. And, like the March 2020 Press Release, it further provided the following description of Vascepa:

> Vascepa® is a prescription medicine that is indicated, in part, as an adjunct to diet to reduce triglyceride levels in adult patients with severe (≥ 500 mg/dL) hypertriglyceridemia. According to IQVIA, US sales of Vascepa® were approximately $1.1 billion in the 12 months ending July 2020.

Id. The $1.1 billion referenced in the press release (and the $919 million referenced in the March 2020 Press Release) accounted for sales of Vascepa for *all* uses, including the

CV indication, which undisputedly made up more than 75% of the drug's sales.

Hikma issued a final press release upon its official launch of its generic product ("the November 2020 Press Release"). J.A. 715. That press release stated:

> Hikma's FDA-approved Icosapent Ethyl Capsule product is indicated for the following indication: as an adjunct to diet to reduce triglyceride levels in adult patients with severe (≥ 500 mg/dL) hypertriglyceridemia. Hikma's product is not approved for any other indication for the reference listed drug VASCEPA®.

Id.

Following the approval of its ANDA, Hikma also began marketing its product on its website. There, Hikma listed its generic icosapent ethyl capsules in the "Therapeutic Category: Hypertriglyceridemia" and indicated that it was "AB" rated. J.A. 820. That rating, developed and assigned by the FDA, reflects the FDA's determination that a generic drug is therapeutically equivalent to a branded drug when the generic drug is used as labeled. It does not reflect a decision of therapeutic equivalence for off-label use. Below the product summary on the website, in small lettering, is a disclaimer that reads: "Hikma's generic version is indicated for fewer than all approved indications of the Reference Listed Drug." *Id.*

II

In November 2020, less than a month after Hikma launched its generic icosapent ethyl product, Amarin sued under 35 U.S.C. § 271(b), alleging that Hikma had induced infringement of at least claim 1 of the '537 patent, and at least claims 1 and 2 of the '861 patent. Claim 1 of the '537 patent recites:

1. A method of reducing occurrence of a cardiovascular event in a hypercholesterolemia patient consisting of:

identifying a patient having triglycerides (TG) of at least 150 mg/DL and HDL-C of less than 40 mg/dL in a blood sample taken from the patient as a risk factor of a cardiovascular event, wherein the patient has not previously had a cardiovascular event, and administering ethyl icosapentate in combination with a 3-hydroxy-3-methylglutaryl coenzyme A reductase inhibitor,

wherein said 3-hydroxyl-3-methylglutaryl coenzyme A reductase inhibitor is administered to the patient at least one of before, during and after administering the ethyl icosapentate; and

wherein the 3-hydroxy-3-methylglutaryl coenzyme A reductase inhibitor is selected from the group consisting of pravastatin, lovastatin, simvastatin, fluvastatin, atorvastatin, pitavastatin, rosuvastatin, and salts thereof, and

wherein daily dose of the 3-hydroxy-3-methylglutaryl coenzyme A reductase inhibitor are 5 to 60 mg for pravastatin, 2.5 to 60 mg for simvastatin, 10 to 180 mg for fluvastatin sodium, 5 to 120 mg for atorvastatin calcium hydrate, 0.5 to 12 mg for pitavastatin calcium, 1.25 to 60 mg for rosuvastatin calcium, 5 to 160 mg for lovastatin, and 0.075 to 0.9 mg for cerivastatin sodium.

'537 patent, col. 15, l. 64–col. 16, l. 22.

Claims 1 and 2 of the '861 patent recite:

1. A method of reducing risk of cardiovascular death in a subject with established

cardiovascular disease, the method comprising administering to said subject about 4 g of ethyl icosapentate per day for a period effective to reduce risk of cardiovascular death in the subject.

2. The method of claim 1, wherein the subject has a fasting baseline triglyceride level of about 135 mg/dL to about 500 mg/dL and a fasting baseline LDL-C level of about 40 mg/dL to about 100 mg/dL.

'861 patent, col. 45, ll. 49–57.[5]

According to Amarin, the content of Hikma's press releases, website, and product label evidence Hikma's specific intent to actively encourage physicians to directly infringe the asserted patents by prescribing its generic icosapent ethyl product for the off-label CV indication, an indication for which Hikma did not get FDA approval. Hikma moved to dismiss under Federal Rule of Civil Procedure 12(b)(6), arguing that Amarin had failed, as a matter of law, to allege facts that Hikma had taken active steps to specifically encourage infringement.

The district court referred the case to a magistrate judge, who recommended denying the motion. *Amarin Pharma, Inc. v. Hikma Pharms. USA Inc.*, No. 20-1630, 2021 WL 3396199 (D. Del. Aug. 3, 2021) ("*Report & Recommendation*"). The magistrate judge concluded that, based on the totality of the allegations, which relied not only on the content of the skinny label but also Hikma's press

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[5] At oral argument, counsel for Amarin noted that the parties had agreed that the preamble of the asserted claims was limiting, such that infringement of the claims requires use of icosapent ethyl to reduce cardiovascular risk. Oral Arg. 31:13–23, *available at* https://oralarguments.cafc.uscourts.gov/default.aspx?fl=23-1169_04022024.mp3.

releases and website, Amarin had "pleaded an inducement claim . . . that is at least plausible." *Id.* at *8. Specifically, she noted that, "notwithstanding the lack of an express instruction regarding the CV indication in the 'Indications and Usage' section of Hikma's label, several other portions of Hikma's label, taken together with Hikma's public statements, instruct physicians to use Hikma's product in a way that infringes the asserted patents." *Id.* at *6. She therefore rejected Hikma's attempt to resolve the case at the pleadings stage where there was "a real dispute about what [Hikma's public statements and label] communicate to others." *Id.* at *8. Hikma timely objected to the magistrate judge's recommendation.

On *de novo* review, the district court declined to adopt the magistrate judge's recommendation and granted Hikma's motion to dismiss. *Decision*, 578 F. Supp. 3d at 643–44. The district court separated Amarin's allegations into two categories—Hikma's label and Hikma's public statements—addressing each separately. *See id.* at 645–47.

With respect to Hikma's label, the district court concluded that the warning as to side effects for patients with cardiovascular disease was "hardly instruction or encouragement" to prescribe the drug for the CV indication. *Id.* at 646. It was similarly unpersuaded by Amarin's allegation that Hikma's removal of the CV Limitation of Use would be understood by physicians as an indication that Hikma's product *had* been shown to reduce cardiovascular risk and to encourage its use for that purpose. *Id.* The court concluded as a matter of law that "[e]ven if [Amarin is] right that Hikma's label's silence regarding CV risk reduction communicates to the public that icosapent ethyl can be used to reduce CV risk, 'merely describing an infringing mode is not the same as recommending, encouraging, or promoting an infringing use.'" *Id.* (quoting, with alterations, *Takeda Pharms. U.S.A., Inc. v. W.-Ward Pharm. Corp.*, 785 F.3d 625, 631 (Fed Cir. 2015)). The

district court therefore found that Hikma's label does not plausibly induce infringement. *Id.*

Turning to Hikma's public statements, the district court concluded that, although the press releases may be relevant to Hikma's *intent* to induce infringement, they did not plausibly evidence "an inducing act," a separate element for a claim arising under § 271(b). *Id.* at 647. And with respect to the website, the court determined that Hikma's advertisement of its product as AB-rated in the therapeutic category "Hypertriglyceridemia"—which the court accepted as broad enough to include infringing uses—did not "rise to the level of encouraging, recommending, or promoting taking Hikma's generic for the reduction of CV risk." *Id.* (comparing *GlaxoSmithKline LLC v. Teva Pharms. USA, Inc.*, 7 F.4th 1320, 1336 (Fed. Cir. 2021) (per curiam) ("*GSK*"), with *Grunenthal GMBH v. Alkem Lab'ys Ltd.*, 919 F.3d 1333, 1339 (Fed. Cir. 2019)).

Because it found that Amarin's complaint failed to plead inducement based on either Hikma's label or public statements, the district court granted Hikma's motion to dismiss. *Id.* at 648.

Amarin timely appealed. We have jurisdiction under 28 U.S.C. § 1295(a)(1).

DISCUSSION

We review a district court's grant of a motion to dismiss for failure to state a claim under the law of the regional circuit. *Yu v. Apple Inc.*, 1 F.4th 1040, 1042 (Fed. Cir. 2021). Under Third Circuit law, we review such dismissals *de novo*, accepting all well-pleaded factual allegations as true and drawing all reasonable inferences from such allegations in favor of the complainant. *See Matrix Distributors, Inc. v. Nat'l Ass'n of Boards of Pharmacy*, 34 F.4th 190, 195 (3d Cir. 2022). "We may affirm only if it is certain no relief could be granted under any set of facts that could be proven." *Warden v. McLelland*, 288 F.3d 105, 110 (3d

Cir. 2002). We apply our own law, however, with respect to patent law issues. *Midwest Indus., Inc. v. Karavan Trailers, Inc.*, 175 F.3d 1356 (Fed. Cir. 1999) (en banc in relevant part).

I

We begin by noting what this case is not.

Unlike the earlier Nevada litigation between the parties, this appeal is not a Hatch-Waxman case arising under 35 U.S.C. § 271(e)(2)(A), in which the alleged act of infringement was Hikma's submission of its ANDA. That is, this is not a traditional "ANDA case" in which the patent owner seeks to establish that *if* a generic manufacturer's drug is put on the market, it would infringe the asserted patent. *See, e.g.*, *Genentech, Inc. v. Sandoz Inc.*, 55 F.4th 1368, 1379 (Fed. Cir. 2022); *Grunenthal*, 919 F.3d at 1337; *Vanda Pharms. Inc. v. W.-Ward Pharms. Int'l Ltd.*, 887 F.3d 1117, 1130 (Fed. Cir. 2018) ("A § 271(e)(2)(A) infringement suit differs from typical infringement suits in that the infringement inquiries are hypothetical because the allegedly infringing product has not yet been marketed." (internal quotation marks and citation omitted)). Unlike those cases, Hikma's ANDA has already been approved by the FDA and Hikma has already launched its generic product.

Furthermore, this is not a section viii case in which the patent owner's claims rest *solely* on allegations that the generic manufacturer's proposed label is "not skinny enough," such that the label alone induces infringement. *See, e.g.*, *H. Lundbeck A/S v. Lupin Ltd.*, 87 F.4th 1361, 1370 (Fed. Cir. 2023); *HZNP Meds. LLC v. Actavis Lab'ys UT, Inc.*, 940 F.3d 680, 699 (Fed. Cir. 2019); *see also Takeda*, 785 F.3d at 630. Rather, the allegations of the complaint transform this case from a pre-approval, label-only induced infringement claim to one where the alleged infringement is based on the generic manufacturer's

skinny label *as well as* its public statements and marketing of its already-approved generic product.

Put otherwise, although this case has underlying features of a traditional Hatch-Waxman case, at bottom, it is nothing more than a run-of-the-mill induced infringement case arising under 35 U.S.C. § 271(b). In such a case, we review the allegations of inducement as a whole, not piecemeal. Accordingly, we must consider whether the *totality* of the allegations, taken as true, plausibly plead that Hikma induced infringement. *See GSK*, 7 F.4th at 1338 (concluding that a skinny label, in combination with marketing materials and press releases, provided substantial evidence to support a jury verdict of induced infringement); *Broadcom Corp. v. Qualcomm Inc.*, 543 F.3d 683, 700 (Fed. Cir. 2008) (affirming a jury instruction to consider "all of the circumstances" relevant to the alleged induced infringement and concluding that "[t]aken as a whole," the record provided substantial evidence to support the jury verdict).

And critically, unlike any of our section viii-related decisions, this case does not reach us on an appeal from a post-trial motion, *see, e.g.*, *GSK*, 7 F.4th at 1323, an entry of judgment following a bench trial, *see, e.g.*, *H. Lundbeck*, 87 F.4th at 1368; *Grunenthal*, 919 F.3d at 1338, a summary judgment motion, *see, e.g.*, *HZNP*, 940 F.3d at 699, or any other motion in which the parties (and court) have the benefit of discovery. Nor does it reach us on a denial of a preliminary injunction, which we would review for an abuse of discretion. *See Takeda*, 785 F.3d at 629.

Instead, this case reaches us at its most nascent stage: on a motion to dismiss under Federal Rule of Civil Procedure 12(b)(6), where we are tasked with reviewing *allegations*, not findings, for *plausibility*, not probability. *See Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 556 (2007) ("[A] well-pleaded complaint may proceed even if it strikes a savvy judge that actual proof of those facts is improbable, and

that a recovery is very remote and unlikely." (internal quotation marks and citation omitted)). Accordingly, while our prior Hatch-Waxman and section viii cases are informative to the unique issues presented here, none is dispositive.

With those principles in mind, we proceed to the merits.

II

"Whoever actively induces infringement of a patent shall be liable as an infringer." 35 U.S.C. § 271(b). To state a claim for induced infringement, a patent owner must plausibly allege facts establishing that there has been direct infringement by a third party and that the alleged infringer affirmatively induced that infringement with knowledge that the induced acts constituted patent infringement. *See Power Integrations, Inc. v. Fairchild Semiconductor Int'l, Inc.*, 843 F.3d 1315, 1332 (Fed. Cir. 2016); *DSU Med. Corp. v. JMS Co.*, 471 F.3d 1293, 1304 (Fed. Cir. 2006) (en banc in relevant part) ("[I]f an entity offers a product with the object of promoting its use to infringe, as shown by clear expression or other affirmative steps taken to foster infringement, it is then liable for the resulting acts of infringement by third parties."). As relevant here, a generic manufacturer can be liable for inducing infringement of a patented method even if it has attempted to "carve out" the patented indications from its label under 21 U.S.C. § 355(j)(2)(A)(viii), where, as here, other evidence is asserted with regard to inducement. *See GSK*, 7 F.4th at 1338.

For purposes of this appeal, it is undisputed that Amarin's complaint sufficiently alleges (1) that healthcare providers directly infringe the asserted patents by prescribing Hikma's generic icosapent ethyl product for the off-label CV indication, and (2) that Hikma had the requisite intent and knowledge to induce that infringement. *See Decision*, 578 F. Supp. 3d at 647 ("Hikma's press releases might be relevant to intent but . . . . [i]ntent alone is not enough;

Amarin must plead an inducing act."); Oral Arg. at 11:36–47 (counsel for Hikma emphasizing that "[t]he Patent Act does not impose liability for *inferred* inducement. The statute expressly requires *actively* induced infringement."); *see generally* Hikma's Mot. Dismiss, J.A. 948–67 (arguing only that Amarin fails to allege that Hikma "actively" induced infringement).

We therefore focus narrowly on the question whether Amarin's complaint plausibly pleads that Hikma "actively" induced healthcare providers' direct infringement, *i.e.*, that Hikma "encourage[d], recommend[ed], or promote[d] infringement." *Takeda*, 785 F.3d at 631. Accepting all well-pleaded facts as true and drawing all reasonable inferences in Amarin's favor, we conclude that it does.

As an initial matter, it is undisputed that the "Indications & Usage" section of Hikma's label does not provide an implied or express instruction to prescribe the drug for the CV indication. J.A. 694. Notwithstanding that fact, Amarin alleges that other portions of the label, such as the clinical studies section, which describes statin-treated patients with the same cardiovascular event history and lipid levels covered by the asserted patents, *id.* at 702, would be understood by physicians as a teaching that the product could be prescribed to treat cardiovascular risk. *Id.* at 534–36. That is particularly so because, as Amarin alleges, the patient population for the SH indication (*i.e.*, triglyceride levels ≥500 mg/dL) overlaps with that for the CV indication (*i.e.*, triglyceride levels ≥150 mg/dL). *Id.* at 803. Amarin further argues that while the FDA's approval of the CV indication allowed Amarin to remove the CV Limitation of Use from its label, it did not so authorize Hikma. *See id.* at 528. That is, the complaint alleges that Hikma's removal of the CV Limitation of Use (despite not being approved for the CV Indication), as well as its warning of potential side effects for patients with cardiovascular disease, communicate to physicians that Hikma's generic product could be used for the off-label CV indication. In

Amarin's view, the absence of the CV Limitation of Use is particularly notable because other drugs approved for only the SH indication, *e.g.*, Lovaza®, do contain the CV Limitation of Use. *Id.* at 516.

Hikma counters that none of the portions of the label relied upon by Amarin plausibly supports the element of active inducement. In its view, Amarin's case relies on the absence of language discouraging infringement, which is contrary to law. Hikma Br. at 26–28 (citing *Takeda*, 785 F.3d at 632 n.4). According to Hikma, it only removed the CV Limitation of Use from its draft label to comply with requirements that a generic label be "the same as the labeling approved for the listed drug." 21 U.S.C. § 355(j)(2)(A)(v). Its silence as to the product's effect on cardiovascular risk, Hikma argues, therefore cannot plausibly instruct infringement. Hikma further takes issue with Amarin's reliance on the clinical studies and warning regarding side effects in patients with cardiovascular disease, arguing that Hikma's position that such information would encourage a physician to prescribe the drug for the CV indication is implausible and "borderline frivolous." Hikma Br. at 28–30.

Taken on its own, we may agree with the district court (and Hikma) that the label does not, as a matter of law, "recommend[], encourag[e], or promot[e] an infringing use." *Decision*, 578 F. Supp. 3d at 646 (quoting *Takeda*, 785 F.3d at 631). Indeed, even the magistrate judge, who recommended denying Hikma's motion to dismiss, concluded that, "were [Amarin's] allegations based solely on the label, [Amarin's] inducement theory might lack merit as a matter of law." *Report & Recommendation*, 2021 WL 3396199, at *7. But, as the magistrate judge correctly observed, Amarin's theory of induced infringement is not based solely on the label. *Id.*; Oral Arg. at 2:15–20 (counsel for Amarin explaining that "our case is not about the label standing alone, but to be clear, we do rely on portions of the label"). Rather, it is based on the label *in combination* with

Hikma's public statements and marketing materials. We therefore turn to those materials.

Hikma's website promotes its product as AB-rated (*i.e.*, therapeutically equivalent for only the labeled indications) in the therapeutic category "Hypertriglyceridemia," a category that we accept, at this stage, as broad enough to encompass both infringing and non-infringing uses. *See* J.A. 532. On the other hand, Hikma's press releases, at least prior to November 2020, consistently referred to Hikma's product as a "generic equivalent to Vascepa®," "generic Vascepa®," or "Hikma's generic version of Vascepa®," without any indication that its product was AB-rated. *Id.* at 613, 709, 712. And the press releases further referred to Vascepa as indicated "in part" for the SH indication. *Id.* at 709, 712. Together, those statements, according to Amarin, "made clear that Vascepa® was indicated for more than one use and then identified its own product as a generic version of Vascepa®." Amarin Br. at 15. Further, the complaint alleges that, in its press releases, Hikma touted sales figures for Vascepa that Hikma knew were largely attributable to the off-label CV indication. J.A. 529, 531. Indeed, the complaint cites Hikma's own demonstrative from the Nevada litigation showing that at least 75% of sales of Vascepa were for the patented CV indication. *Id.* at 529 (citing *id.* at 803).

Those allegations, taken together with those relating to Hikma's label, at least plausibly state a claim for induced infringement. As Amarin notes, and the magistrate judge observed, many of the allegations depend on what Hikma's label and public statements would communicate to physicians and the marketplace. *See* Amarin Br. at 39–41. As we observed in *GSK*, that is a question of fact—not law—and is therefore not proper for resolution on a motion to dismiss. *See* 7 F.4th at 1330 ("Critically, the district court erred by treating this fact question—whether the [approved] indication instructs a physician to prescribe [the drug] for a claimed use—as though it were a legal one

for it to decide *de novo*."). Hikma disagrees, arguing that the factual contents of Hikma's label and public statements are undisputed, such that we can resolve this case as a matter of law, just as we have when disposing of other, similar inducement claims. Hikma Br. at 47 (citing *HZNP*, 940 F.3d at 701). We are unpersuaded.

As noted above, *HZNP* was a label-only case. *See* 940 F.3d at 702. Furthermore, and critically, that case was resolved at summary judgment, where the parties and court had the benefit of fact discovery and expert testimony. *See id.* Here, without such discovery and testimony, we must accept as true Amarin's allegations and all reasonable inferences supported by those allegations. Applying this standard of review, we find it at least plausible that a physician could read Hikma's press releases—touting sales figures attributable largely to an infringing use, and calling Hikma's product the "generic version" of a drug that is indicated "in part" for the SH indication—as an instruction or encouragement to prescribe that drug for *any* of the approved uses of icosapent ethyl, particularly where the label suggests that the drug may be effective for an overlapping patient population. Further, it is at least plausible that a physician may recognize that, by marketing its drug in the broad therapeutic category of "Hypertriglyceridemia" on its website, Hikma was encouraging prescribing the drug for an off-label use. To be sure, the website clearly labels the drug as AB-rated, indicating generic equivalence for only labeled uses.[6] But we decline to hold, at this stage, that one notation of the AB rating on Hikma's website—and nowhere else—insulates it from a claim for induced infringement, particularly where we have upheld

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[6] And, as noted above, the website includes an express disclaimer that Hikma's product is FDA-approved for fewer than all uses of Vascepa.

jury verdicts based, in part, on marketing materials containing similar language. *See GSK*, 7 F.4th at 1335–36.

Hikma challenges Amarin's reliance on *GSK*, arguing that in that case we expressly declined to hold that calling a product a "generic version" or a "generic equivalent" is enough for induced infringement. 7 F.4th at 1336 ("The dissent criticizes our analysis, claiming that we have weakened intentional encouragement because 'simply calling a product a "generic version" or "generic equivalent"—is now enough.' That is not our holding or the facts." (internal citation omitted)). In Hikma's view, a reversal in this case would run afoul of that clear limitation of *GSK* and would realize the concerns raised in its dissent. We disagree. Not only does this case differ procedurally from *GSK* (which was decided on a post-trial motion for judgment as a matter of law), but it also differs factually. There, we held that substantial evidence supported the jury's finding that the generic manufacturer's label had unsuccessfully carved out the patented use. *See id.* at 1338. Accordingly, because the label itself taught an infringing use, it was reasonable for the jury to find that the generic manufacturer's marketing of its product as an "AB rated generic equivalent" encouraged physicians to prescribe the drug for the infringing use instructed by the label. *Id.* at 1335–36.

Those, however, are not the facts of this case. Hikma's press releases do *not* refer to its product as AB-rated. If they had, Hikma's distinction of *GSK* may have been more persuasive as even Amarin seems to agree that the label alone does not instruct infringement. Instead, Hikma's press releases broadly refer to the product as a "generic version" of Vascepa and provide usage information and sales data for the brand-name drug from which it is plausible that a physician could discern an encouragement to use the generic for purposes beyond the approved SH indication. This conclusion—that the totality of the allegations plausibly states a claim for induced infringement—does

not evoke the concern espoused by the dissent in *GSK*, much less hold, that a mere statement that a generic manufacturer's product is the "generic version" of a brand-name drug is enough to be liable for induced infringement. Nor does it run afoul of our observation in *GSK* that "generics could *not* be held liable for merely marketing and selling under a 'skinny' label omitting all patented indications, or for merely noting (without mentioning any infringing uses) that FDA had rated a product as therapeutically equivalent to a brand-name drug." *Id.* at 1326. Amarin has pleaded that Hikma did much more than call its product a "generic version" of Vascepa. Taking those allegations as true, Hikma has neither "merely" marketed its drug under a skinny label that omits all patented indications nor "merely" noted that the FDA has rated its drug as AB-rated. Though the merits of Amarin's allegations have not yet been tested or proven, we cannot say at this stage that those allegations are not at least plausible.

Finally, we reject Hikma's inflated characterizations that a reversal in this case would "effectively eviscerate section viii carve-outs." Hikma Br. at 48; Oral Arg. at 20:10–26 (counsel for Hikma asserting that "the entire industry is watching this case. It's a test case . . . . And if merely calling a generic product a 'generic version' is sufficient to get past the pleading stage, section viii is dead."). Our holding today is limited to the allegations before us and guided by the standard of review appropriate for this stage of proceedings. We continue to acknowledge, as we did in *GSK*, that there is a "careful balance struck by the Hatch-Waxman Act regarding section viii carve-outs." 7 F.4th at 1326. That balance benefits both brand manufacturers and generic manufacturers alike. What we can also say is that clarity and consistency in a generic manufacturer's communications regarding a drug marketed under a skinny label may be essential in avoiding liability for induced infringement. Here, because Amarin has plausibly pleaded that, despite its section viii carve-out, Hikma

has induced infringement of the asserted patents, Hikma is not entitled, at least at this stage, to benefit from that balance.

CONCLUSION

For the foregoing reasons, we hold that Amarin has plausibly pleaded that Hikma has induced infringement of the asserted patents. We therefore reverse.

REVERSED