APPENDIX

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APPENDIX A

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.

CHARLES B. KLEIN, Winston & Strawn LLP, Washington, DC, argued for defendants-appellees. Also represented by CLAIRE A. FUNDAKOWSKI; ALISON MICHELLE KING, Chicago, IL; EIMERIC REIG-PLESSIS, San Francisco, CA.

SARA WEXLER KOBLITZ, Hyman, Phelps & McNamara, Washington, DC, for amicus curiae Association for Accessible Medicines.

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.

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

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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.

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]

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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

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 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

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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.

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.

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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_0402202 4.mp3.

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 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. McLella*nd, 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 piece-meal. 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 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.

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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.

Those, however, are not the facts of this case. Hikma's press releases do *no*t 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

APPENDIX B

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

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

Plaintiffs

v.

HIKMA PHARMACEUTICALS USA INC., HIKMA PHARMACEUTICALS PLC, AND HEALTH NET, LLC

Defendants

Civil Action No. 20-1630-RGA-JLH

ORDER

For the reasons stated in the accompanying Memorandum Opinion, Hikma's motion to dismiss the First Amended Complaint (D.I. 19) is **GRANTED**. Hikma's motion to dismiss the original complaint (D.I. 11) is **DISMISSED AS MOOT**. Health Net's motion to dismiss the First Amended Complaint (D.I. 30) is **DENIED**. The first amended complaint (D.I. 17) as to the Hikma Defendants is **DISMISSED** without prejudice.[1]

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[1] Plaintiffs requested leave to amend if the first amended complaint was dismissed. (D.1. 22 at 20). Plaintiffs gave no indication as to what more they could plead, but if they have something more, they may file a motion in compliance with the Local Rules seeking leave to amend.

IT IS SO ORDERED this 4th day of January 2022.

/s/ Richard G. Andrews
UNITED STATES DISTRICT JUDGE

APPENDIX C

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

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

Plaintiffs

v.

HIKMA PHARMACEUTICALS USA INC., HIKMA PHARMACEUTICALS PLC, AND HEALTH NET, LLC

Defendants

Civil Action No. 20-1630-RGA-JLH

MEMORANDUM OPINION

Jeremy D. Anderson, FISH & RICHARDSON P.C., Wilmington, DE, Elizabeth M. Flanagan, Michael Kane (argued), Deanna J. Reichel, FISH & RICHARDSON P.C., Minneapolis, MN; Jonathan E. Singer, Fish & Richardson P.C., San Diego, CA;

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John C. Phillips, Jr., David A. Bilson, PHILLIPS MCLAUGHLIN & HALL, P.A., Wilmington, DE; Don J. Mizerk (argued), HUSCH BLACKWELL LLP, Chicago, IL; Dustin L. Taylor, HUSCH BLACKWELL LLP, Denver, CO;

Attorneys for Defendant Health Net.

ANDREWS, U.S. DISTRICT JUDGE:

I referred this very interesting case to a magistrate judge. (D.I. 16). She wrote a Report and Recommendation on three pending motions to dismiss. (D .I. 64). Defendants filed objections (D.1. 70, 71), to which Plaintiffs responded (D.1. 77, 78). There is even an amicus brief. (D.I. 75). I heard oral argument on October 14, 2021. For the following reasons, I will ADOPT-IN-PART the Report and Recommendation. (D.I. 64). Hikma's motion to dismiss the First Amended Complaint (D.I. 19) is GRANTED. Hikma's motion to dismiss the original complaint (D.I. 11) is DISMISSED AS MOOT. Health Net's motion to dismiss the First Amended Complaint (D.I. 30) is DENIED.

I. BACKGROUND

Plaintiffs sued Defendants for induced infringement of three patents that describe methods of using icosapent ethyl for the reduction of cardiovascular risk. (D.I. 17). Plaintiffs manufacture and sell VASCEPA, a branded version of icosapent ethyl. (*Id*. at ¶¶ 1, 57-58). Defendant Hikma is a generic manufacturer of icosapent ethyl. (*Id*. at ¶ 1). Defendant Health Net is an insurer that provides coverage for Vascepa and Hikma's generic version. (*Id*. at ¶¶ 139-40).

II. LEGAL STANDARD

A motion to dismiss for failure to state a claim upon which relief may be granted is considered a dispositive

motion. D. Del. LR 72. l(a)(3). A magistrate judge's Report and Recommendation regarding a case-dispositive motion is reviewed *de novo*. Fed. R. Civ. P. 72(b)(3).

When reviewing a motion to dismiss pursuant to Federal Rule of Civil Procedure 12(b)(6), the Court must accept the complaint's factual allegations as true. *See Bell Atl. Corp. v. Trombly*, 550 U.S. 544, 555–56 (2007). Rule 8(a) requires "a short and plain statement of the claim showing that the pleader is entitled to relief." *Id* at 555. The factual allegations do not have to be detailed, but they must provide more than labels, conclusions, or a "formulaic recitation" of the claim elements. *Id.* ("Factual allegations must be enough to raise a right to relief above the speculative level . . . on the assumption that all the allegations in the complaint are true (even if doubtful in fact)."). Moreover, there must be sufficient factual matter to state a facially plausible claim to relief. *Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009). The facial plausibility standard is satisfied when the complaint's factual content "allows the court to draw the reasonable inference that the defendant is liable for the misconduct alleged." *Id.* ("Where a 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." (internal quotation marks omitted)).

Section 271(b) provides, "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, the complaint must allege that there has been direct infringement, that the defendant knowingly induced infringement, and that the defendant has the intent to encourage another's infringement. *MEMC Elec. Materials, Inc. v. Mitsubishi*

Materials Silicon Corp., 420 F.3d 1369, 1378 (Fed. Cir. 2005). A generic manufacturer can be liable for inducing infringement of a patented method even when the generic has attempted to "carve out" the patented indications. *GlaxoSmithKline LLC v. Teva Pharmaceuticals USA, Inc.*, 7 F.4th 1320, 1338 (Fed. Cir. 2021) (per curiam).

III. HIKMA'S MOTION TO DISMISS

A. BACKGROUND

Amarin sells Vascepa (icosapent ethyl) for the treatment of severe hypertriglyceridemia (the "SH indication") and cardiovascular risk reduction (the "CV indication"). (D.I. 17 at ¶¶ 1, 56). Only the CV indication is covered by Plaintiffs' patents. (*See* D.I. 22 at 1). Hikma received FDA approval to sell a generic version for the SH indication under the "skinny label" or "section viii carveout" regime. (D.I. 17 at ¶¶ 11, 95, 108). This regime allows a generic to sidestep the typical FDA requirement that a generic's labeling is the same as the brand's labeling. 21 U. S.C. §§ 355(j)(2)(A)(viii). The generic does so by removing the portions of the label associated with the patented use, resulting in a "skinny label." Plaintiffs allege that Defendant Hikma's label is "not-skinny-enough" and that the label, along with Hikma's public statements, induce infringement of Plaintiffs' patents for the CV indication. (D.I. 22 at 1).

B. DISCUSSION

1. The Federal Circuit's GSK Decision

Two days after the Report issued, the Court of Appeals issued the most recent authoritative opinion concerning skinny labels, albeit after the case was fully litigated in the district court. *See GlaxoSmithKline*

LLC v. Teva Pharmaceuticals USA, Inc. [hereinafter "*GSK*"], 7 F.4th 1320 (Fed. Cir. 2021). The Federal Circuit affirmed a jury's findings that Teva's "partial label" induced infringement of GSK's patent, notwithstanding Teva's attempt to exclude the patented use from its label under the skinny label regime. (*Id*. at 1338). Ultimately, the Federal Circuit concluded, "Teva's partial label did not successfully carve out the patented use, and thus, Teva was selling its generic with a label which infringed the method claim." *Id*. Accordingly, Teva's label was "not a skinny label." *Id.* at 1328.

The Federal Circuit also found that two Teva press releases supported the jury's verdict. *Id*. at 1 335-37. The first press release advertised Teva's drug as "indicated for treatment of heart failure" and did "not parse between congestive heart failure [the patented indication] or post-MI LVD [an unpatented indication]." *Id.* at 1336. The second press release stated that Teva received approval to market "its Generic version of GlaxoSmithKline's cardiovascular agent Coreg." *Id.* Expert testimony established that the phrase "'cardiovascular agent' 'indicated to doctors they could use Teva's carvedilol 'for all indications,' including heart failure." *Id*.

The Court held that *GSK* is a "narrow, case-specific review" and that it is still the law 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. An "AB rating," as the complaint explains, "reflects a decision [by the FDA] that a generic drug is therapeutically equivalent to a branded drug when the generic drug is used as labeled [.]" (D.I. 17 at ¶ 98). As *GSK*'s

discussion of Teva's press releases illustrates, where a generic label does not effectively carve out a patented use, advertisement that the drug is "AB rated" can support a finding of inducement. *GSK*, 7 F.4th at 1335.

2. Amarin's Complaint

Amarin's complaint pleads several factual allegations in support of its claim that Hikma induces infringement. These allegations fall into two categories: Hikma's label and Hikma's public statements. The Magistrate Judge recommends I deny Hikma's motion to dismiss because "several . . . 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." (D.I. 64 at 12). The bulk of the briefing and oral argument was directed to Hikma' s label, and I will address those arguments first.

As to the label, Hikma objects that Amarin's complaint fails to plead instruction as to at least two claim limitations—the requirement that icosapent ethyl be administered to reduce CV risk and the requirement to co-administer with a statin. (D.I. 71 at 7-8). Because I agree with Hikma that there has been no instruction as to CV risk reduction, I will not address Hikma's argument regarding co-administration with a statin.

Amarin contends that Hikma' s label teaches CV risk reduction for two reasons. First, Hikma's label contains a notice regarding side effects for patients with CV disease. (D.I. 78 at 5-6). Second, Hikma's label does not "state that Hikma's 'generic version' of V ASCEPA should not be used for the CV Indication or that the effect of icosapent ethyl on cardiovascular mortality and morbidity in patients with severe hypertriglyceridemia has not been determined" (the "CV

limitation"). (D.I. 17 at ¶¶ 108, 121). Hikma responds that (1) the notice regarding side effects is a warning and thus not an instruction to use icosapent ethyl to reduce cardiovascular risk, and (2) the removal of the CV risk reduction limitation is mere silence and that Hikma has no duty to discourage infringing use.

Regarding the warning as to side effects, I agree with Hikma. The label states, "Icosapent ethyl may cause serious side effects, including: ... Heart rhythm problems which can be serious and cause hospitalization have happened in people who take icosapent ethyl, especially in people who have heart (cardiovascular) disease or diabetes with a risk factor for heart (cardiovascular) disease[.]" (D.I. 17, Ex. K at 12-13 of 15). This is hardly instruction or encouragement. *See*, *e.g.*, *Otsuka Pharm. Co. v. Torrent Pharms. Ltd.*, 99 F. Supp. 3d 461, 490 (D.N.J. 2015) ("[A] warning is just that—a warning. It is not an instruction[.]").

Amarin also argues that Hikma "removed"[1] the CV limitation from its label, which would be "understood in the field to teach that Hikma's product *has* been proven to reduce CV risk and to encourage its use for

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[1] Hikma contests Plaintiffs' use of the word "removal," noting, "*Amarin* removed the limitation of use from Vascepa's label *before* Hikma launched its product, and Hikma was required to use 'the same [labeling] as the labeling approved for the listed drug.'" (D.I. 71 at 7 n.2 (citing 21 U.S.C. § 355(j)(2)(A)(v))). The facts pled in the complaint state that the removal happened during the FDA approval process. (D.I. 17 at ¶ 108). At any rate, it appears that there is no allegation that Hikma's product was ever marketed with a label containing the CV limitation.

that purpose" because other drugs in the same class have not been shown to reduce CV risk. (D.I. 78 at 4). This amounts to an "affirmative statement" that it can be used for cardiovascular risk reduction, according to Plaintiffs. (D.I. 85 at 62:16-62:5).

The Federal Circuit has previously rejected the argument that generic labels must contain a "clear statement" discouraging use of the patented indication. *Takeda Pharms. USA., Inc. v. W.-Ward Pharm. Corp.*, 785 F.3d 625, 632 n.4 (Fed. Cir. 2015). Plaintiffs must plead that "Hikma took affirmative steps to induce, not affirmative steps to make sure others avoid infringement." *Id.* Even if Plaintiffs are 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.* at 631 (cleaned up). I therefore find that the lack of a CV limitation on Hikma' s label does not plausibly teach CV risk reduction.

Since I find that the label does not instruct CV risk reduction, the question is whether Hikma's public statements, including press releases and Hikma's website, induce infringement. (D.I. 17 at ¶ 127). Hikma's press releases state that its product is the "generic equivalent to Vascepa®" and that "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 $919 million in the 12 months ending February 2020." (*Id.* at ¶ 112). The sales figures cited by Hikma include Vascepa's sales of the patented indication. The complaint further alleges that Hikma's

website states that Hikma's generic is "AB rated" in the "Therapeutic Category: Hypertriglyceridemia." (*Id*. at ¶ 125).

Hikma' s press releases might be relevant to intent but they do not support actual inducement. Hikma's advertising of icosapent ethyl as the "generic equivalent" of Vascepa does not expose Hikma to liability. *GSK*, 7 F.4th at 1335 n.7. The citation of Vascepa's sales figures go to Hikma's intent to induce. Intent alone is not enough; Amarin must plead an inducing act.

Amarin also alleges that Hikma's website induces infringement by advertising its product in the therapeutic category "hypertriglyceridemia." The complaint pleads, "hypertriglyceridemia . . . does not match and is broader than the Indications and Usage sections of Hikma's Label, which includes only Severe Hypertriglyceridemia Indication (i.e., triglycerides $\geq$500 mg/dL)." (D.I. 17 at ¶ 126). Accepting the facts in the light most favorable to Amarin, Amarin has pled that the category "hypertriglyceridemia" includes infringing uses. The question is whether this is enough, without a label or other public statements instructing as to infringing use, to induce infringement.

I hold that it is not. This statement does not rise to the level of encouraging, recommending, or promoting taking Hikma's generic for the reduction of CV risk.

Two recent Federal Circuit cases are instructive on this point. The GSK majority found that Teva' s advertising of "its Generic version of GlaxoSmithKline's cardiovascular agent," when "cardiovascular agent" was a category that included both infringing and non-infringing uses, supported a jury's finding of inducement. 7 F.4th at 1336. The Court emphasized that:

> Teva did not merely say its drug is a cardiovascular agent, leaving the world to wonder about its uses. It said its product is a generic equivalent of GSK's cardiovascular agent Coreg®. It was reasonable for the jury to conclude, especially in light of the prior press release that expressly mentioned heart failure, that Teva was again encouraging the substitution of its product for all of Coreg's® cardiovascular indications, including as claimed in the '000 patent.

Id. at 1337. In contrast, the Federal Circuit has found that a label indicated for "[m]oderate to severe chronic pain," which included both infringing and non-infringing uses, did "not specifically encourage use" of the generic for the patented treatment. *Grunenthal GMBH v. Alkem Lab'ys Ltd.*, 919 F.3d 1333, 1339 (Fed. Cir. 2019) ("[E]ven if severe chronic pain includes polyneuropathic pain, it also includes mononeuropathic pain and nociceptive pain. Therefore, the proposed ANDA labels do not specifically encourage use of tapentadol hydrochloride for treatment of polyneuropathic pain.").

Here, Hikma stated that its product was "AB Rated" in a category that includes both patented and non-patented uses. The "AB rating" points to the label, as the GSK court explained:

> We do not hold that an AB rating in a true section viii carve-out (one in which a label was produced that had no infringing indications) would be evidence of inducement. In this case, Teva's representation of AB rating would point physicians to its partial label, which, for the reasons above, the jury was free to credit as evidence of induced infringement.

GSK, 7 F.4th at 1335 n.7. Unlike Teva's press release in *GSK*, Hikma has not pointed to Vascepa's patented uses in describing itself as Vascepa's generic equivalent. This case is more like *Grunenthal*, where the broader category simply includes both infringing and non-infringing uses, without "specifically encourage[ing]" the use of the generic for the non-infringing uses. 919 F.3d at 1339.

Since I find that Amarin's complaint has failed to plead inducement based on Hikma's label or public statements, I will grant Hikma's motion to dismiss.

IV. HEAL TH NET'S MOTION TO DISMISS

A. BACKGROUND

Defendant Health Net provides insurance coverage for Plaintiffs' branded Vascepa and Defendant Hikma's generic version. According to Plaintiffs, Health Net's formulary placement induces infringement of Plaintiffs' patents by encouraging the use of Hikma's generic for the CV indication. Health Net's formulary lists Hikma's generic in a lower tier than Amarin's Vascepa, resulting in lower copays when a patient opts for Hikma's generic. (D.I. 17 at ¶ 143). Since it is common for pharmacies to automatically substitute an AB-rated generic such as Hikma's for the branded version, Plaintiffs allege that this formulary placement leads to substitution on "all VESCEPA prescriptions, not just the prescriptions directed to the" SH indication. (*Id.* at ¶ 151).

B. DISCUSSION

The Report recommends I deny Health Net's motion to dismiss because there are factual questions regarding whether Health Net has taken an affirmative act to induce infringement and whether Health Net's

actions actually cause others to infringe. (D.I. 64 at 17). Health Net objects, "Plaintiffs fail to allege facts (not conclusions or speculation) supporting a plausible conclusion that Health Net was aware of the asserted patents, and once aware, took affirmative steps with the specific intent to induce another's infringement of those patents–rather than merely acting despite knowledge that others may infringe." (D.I. 70 at 2). I disagree.

I find that the complaint pleads enough facts to plausibly allege knowledge of the asserted patents. Amarin sent a pre-suit letter to its point of contact for Health Net. (D.I. 17 at ¶ 87). It is true that the pre-suit letter did not specify the patent numbers. However, the letter states that Amarin has patent exclusivity for the CV indication, and the complaint elsewhere pleads that the patents associated with the CV indication are readily available through a resource well-known in the industry, the FDA's Orange Book. (*Id.* at ¶¶ 84, 88). Thus, I agree with the Magistrate Judge that these facts, taken together in the light most favorable to the Plaintiffs, make it plausible that Health Net had specific knowledge of the patents at issue.

Read in the light most favorable to Amarin, the complaint also plausibly alleges affirmative acts taken with a specific intent to induce another's infringement. Formulary selection and the prior authorization process, as pied, could be affirmative acts under the law of induced infringement. Health Net argues that the selection of its formulary is automatic, based on Plaintiffs own pricing as compared to the generic. (D.I. 85 at 75:5-12 (noting that "this is done by a computer program")). This may be true, but it is not a shield. Health Net added generic icosapent ethyl capsules to its

formularies. (D.I. 17 at ¶¶ 140-143). It is immaterial whether the placement was done by a human or a computer.

Amarin also plausibly pleads specific intent to induce. At the very least, Health Net's prior authorization form supports an inference of specific intent because it lists the patented indication on the generic icosapent ethyl capsules form. (D.I. 17 at ¶ 159). Health Net's placement of generic icosapent ethyl on a preferred tier encourages the substitution of the generic for the branded drug, including for the patented indication. (Id at ¶¶ 145, 151). Together, this is enough to plead specific intent to induce.

In its objections, Health Net argues that the "preferred" language in its formularies cannot be an active step because they are required by state law to disclose which drugs are "preferred." (*Id.* at 5). This may be true, but it is not the language of the formulary that is at issue; it is the incentives the formulary puts in place. (*See id.* at ¶¶ 145, 151).

Health Net stresses that they are just a payer, not the physician writing the prescription nor the pharmacist making the substitution. (D.I. 70 at 9). As the Report points out, "It may ... turn out that, despite knowledge of infringement by its beneficiaries and their providers, Health Net's actions in selecting its formulary and adopting its prior authorization procedure . . . do not, in fact, influence the decisions of beneficiaries, pharmacists, and medical providers to use, dispense, and prescribe Hikma's generic product in an infringing way[.]" (D.I. 64 at 17; *see Warner-Lambert Co. v. Apotex Corp.*, 316 F.3d 1348, 1364 (Fed. Cir. 2003) ("[I]f a physician, without inducement by Apotex, prescribes a use of gabapentin in an infringing

manner, Apotex's knowledge is legally irrelevant. In the absence of any evidence that Apotex has or will promote or encourage doctors to infringe the neurodegenerative method patent, there has been raised no genuine issue of material fact.")). These are factual questions that cannot be resolved on a motion to dismiss.

Ultimately, I agree with the Magistrate Judge that Plaintiffs have pled enough to proceed with their case against Health Net.

V. CONCLUSION

An appropriate order will follow.

APPENDIX D

NOTE: This order is nonprecedential.

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 Nos. 1:20-cv-01630-RGA-JLH, Judge Richard G. Andrews.

ON PETITION FOR REHEARING EN BANC

Before MOORE, *Chief Judge*, LOURIE, DYK, PROST, REYNA, TARANTO, CHEN, HUGHES, STOLL,, *Circuit Judges*[1], and ALBRIGHT.[2]

PER CURIAM.

O R D E R

Hikma Pharmaceuticals PLC and Hikma Pharmaceuticals USA Inc. filed a petition for rehearing en banc. A response was invited by the court and filed by Amarin Pharma, Inc., Amarin Pharmaceuticals Ireland Limited and Mochida Pharmaceutical Co., Ltd.

Association for Accessible Medicines, Teva Pharmaceuticals USA, Inc., and 15 Scholars of Law and Medicine[3] separately requested leave to file briefs as amicus curiae, which the court granted.

The petition was first referred as a petition to the panel that heard the appeal, and thereafter the

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[1] Circuit Judge Newman, Circuit Judge Cunningham, and Circuit Judge Stark did not participate.

[2] Honorable Alan D Albright, District Judge, United States District Court for the Western District of Texas, sit-ting by designation.

[3] Michael Carrier, Thomas Cheng, Jonathan J. Darrow, Charles Duan, William Feldman, Aaron S. Kesselheim, Mark A. Lemley, Yvette Joy Liebesman, Lee Ann Wheelis Lockridge, Tyler Ochoa, Jordan Paradise, Joshua D. Sarnoff, Michael S. Sinha, S. Sean Tu, and Liza Vertinsky.

petition was referred to the circuit judges who are in regular active service.

Upon consideration thereof,

IT IS ORDERED THAT:

The petition for panel rehearing is denied.

The petition for rehearing en banc is denied.

The mandate of the court will issue October 24, 2024.

FOR THE COURT

October 17, 2024
Date

/s/Jarret B. Perlow
Jarret B. Perlow
Clerk of Court

APPENDIX E

STATUTORY PROVISIONS INVOLVED

1. 35 U.S.C. § 271 provides in pertinent part:

§ 271. Infringement of patent

* * * *

(b) Whoever actively induces infringement of a patent shall be liable as an infringer.

* * * *

2. 21 U.S.C. § 355 provides in pertinent part:

§ 355. New drugs

* * * *

(j) Abbreviated new drug applications

* * *

(2)(A) An abbreviated application for a new drug shall contain—

(i) information to show that the conditions of use prescribed, recommended, or suggested in the labeling proposed for the new drug have been previously approved for a drug listed under paragraph (7) (hereinafter in this subsection referred to as a "listed drug");

* * *

(vii) a certification, in the opinion of the applicant and to the best of his knowledge, with respect to each patent which claims the listed drug referred to in clause (i) or which claims a

use for such listed drug for which the applicant is seeking approval under this subsection and for which information is required to be filed under subsection (b) or (c)—

(I) that such patent information has not been filed,

(II) that such patent has expired,

(III) of the date on which such patent will expire, or

(IV) that such patent is invalid or will not be infringed by the manufacture, use, or sale of the new drug for which the application is submitted; and

(viii) if with respect to the listed drug referred to in clause (i) information was filed under sub-section (b) or (c) for a method of use patent which does not claim a use for which the applicant is seeking approval under this subsection, a statement that the method of use patent does not claim such a use.

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