IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

AMARIN PHARMA, INC., AMARIN PHARMACEUTICALS IRELAND LIMITED, MOCHIDA PHARMACEUTICAL CO., LTD.,	)	
Plaintiffs,	)	
v.	)	C.A. No. 20-1630-RGA-JLH
HIKMA PHARMACEUTICALS USA INC., HIKMA PHARMACEUTICALS PLC, AND HEALTH NET, LLC,	)	
Defendants.	)	

REPORT AND RECOMMENDATION

Plaintiffs Amarin Pharma, Inc., Amarin Pharmaceuticals Ireland Limited (collectively, "Amarin"), and Mochida Pharmaceutical Co., Ltd. ("Mochida") filed this suit against Defendants Hikma Pharmaceuticals USA Inc., Hikma Pharmaceuticals PLC (collectively, "Hikma"), and Health Net, LLC ("Health Net"). Plaintiffs allege that Hikma and Health Net have each induced infringement of U.S. Patent Nos. 9,700,537 (the '537 patent), 8,642,077 (the '077 patent), and 10,568,861 (the '861 patent) under 35 U.S.C. § 271(b). Hikma and Health Net have separately moved to dismiss under Federal Rule of Civil Procedure 12(b)(6).

Plaintiffs' infringement case against Hikma is what is referred to by those in the know as a "skinny label" case. Amarin developed and markets a branded prescription drug that has two FDA-approved indications. One of those indications is patented, the other is not. Hikma launched a generic version after receiving FDA approval for the non-patented indication only. Notwithstanding the limited approval, Plaintiffs allege that Hikma—through its product label,

website, and press releases—instructs and encourages physicians to use its generic version for the patented indication, making Hikma liable for inducing infringement under 35 U.S.C. § 271(b).

Plaintiffs have an entirely different (and apparently novel) theory as to Health Net. Health Net is a health insurance provider. It does not prescribe drugs, but it does pay for drugs that are prescribed to its beneficiaries by physicians. Plaintiffs allege that the way that Health Net has set up its approval and payment process for Amarin's product and Hikma's generic version amounts to active encouragement to use Hikma's generic version for the patented indication, making Health Net liable for inducing infringement under 35 U.S.C. § 271(b).

This case is at the pleadings stage. I cannot make factual findings about what Hikma's label and advertisements communicate to physicians. Nor is it appropriate at this stage to make findings about how Health Net's prescription drug coverage operates and whether it actually has any effect on anyone's decision to use Hikma's product for the patented use. The only determination at this stage is whether Plaintiffs' allegations state plausible claims for relief.

"The plausibility standard is not akin to a 'probability requirement,'"[1] and "a well-pleaded complaint may proceed even if it strikes a savvy judge that actual proof of the facts alleged is improbable, and that a recovery is very remote and unlikely."[2] I conclude that Plaintiffs' claims satisfy the plausibility standard. According, I recommend that both motions to dismiss be DENIED.

[1] *Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009) (quoting *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 556 (2007)).

[2] *Twombly*, 550 U.S. at 556 (2007) (internal marks omitted).

I. BACKGROUND

The statutory scheme for obtaining FDA approval of a generic drug for only non-patented uses has been well explained in numerous cases and I could do no better here.[3] Accordingly, this Report and Recommendation assumes familiarity with the key features of the Hatch-Waxman generic drug approval process as it relates to "carve out" labels (aka "skinny" labels) and associated infringement litigation.

A. Amarin's VASCEPA®[4]

The active ingredient in Amarin's Vascepa product is icosapent ethyl, an ethyl ester of an omega-3 fatty acid (EPA) commonly found in fish oils. (D.I. 17 ¶¶ 25, 28, 54, Ex. D.) Vascepa currently has two FDA-approved indications: (1) treatment of severe hypertriglyceridemia (the "SH indication"); and (2) cardiovascular risk reduction (the "CV indication"). (*Id.* ¶¶ 1, 56.)

Severe hypertriglyceridemia (SH) is a condition where patients have triglyceride levels greater than 500 mg/dL. (*Id.* ¶ 30, Ex. D.) Vascepa received FDA approval for the SH indication in 2012. (*Id.* ¶ 30.) At that time, and up until 2019, the Vascepa label contained the following "limitation of use" regarding the CV indication: "The effect of VASCEPA on cardiovascular mortality and morbidity in patients with severe hypertriglyceridemia has not been determined." (*Id.* ¶ 60, Exs. E, F.)

After receiving FDA approval to market Vascepa for the SH indication, Amarin conducted further clinical studies to examine the effects of Vascepa on cardiovascular risk reduction. (*Id.*

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[3] *See, e.g., AstraZeneca LP v. Apotex, Inc.*, 633 F.3d 1042, 1045-46 (Fed. Cir. 2010) (describing Hatch-Waxman scheme and carve out labels); *GlaxoSmithKline LLC v. Teva Pharms. USA, Inc.*, No. 14-878-LPS-CJB, 2016 WL 3946770, at *2-3 (D. Del. July 20, 2016) (same), *report and recommendation adopted*, No. 14-878-LPS-CJB, 2017 WL 1050574 (D. Del. Mar. 20, 2017).

[4] I assume the facts alleged in Plaintiffs' First Amended Complaint to be true for purposes of resolving the motions to dismiss for failure to state a claim. *Iqbal*, 556 U.S. at 678.

¶¶ 31-33.) One clinical study assessed the effectiveness of Vascepa as an add-on to statin therapy to reduce major cardiovascular events in patients with persistent elevated triglycerides. (*Id.* ¶ 33.) Based on the results of the study, the FDA approved Vascepa in December 2019 for the CV indication, that is, "as an adjunct to maximally tolerated statin therapy to reduce the risk of myocardial infarction, stroke, coronary revascularization, and unstable angina requiring hospitalization in adult patients with elevated triglyceride (TG) levels (≥ 150 mg/dL) and established cardiovascular disease or diabetes mellitus and 2 or more additional risk factors for cardiovascular disease." (*Id.* ¶ 34, Ex. D.) When the FDA approved the use of Vascepa for the CV indication, Amarin was permitted to add the CV indication to the Vascepa label and remove the CV limitation of use. (*Id.* ¶ 63; *compare id.*, Ex. D *with id.*, Exs. E, F.)

B. The asserted patents

Plaintiffs have patents covering methods of using icosapent ethyl to reduce the risk of cardiovascular events in patients. The '537 patent was issued on July 11, 2017 and is assigned to Mochida. Amarin has an exclusive license. (*Id.* ¶¶ 41-43.) Claim 1 of the '537 patent describes a method of reducing the risk of a cardiovascular event by administering icosapent ethyl with a statin to a patient with high cholesterol, elevated triglycerides, and reduced HDL-C (good cholesterol).[5] It recites as follows:

> 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

[5] I am attempting to describe the invention in a way that facilitates ease of understanding. In so doing, I make some generalizations about the claim elements. Nothing I say here should be taken as the Court's views on any current or future claim construction (or any other) issues.

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.

(*Id*., Ex. C ('537 Patent).)

The '077 patent was issued on February 4, 2014 and is assigned to Amarin. (*Id.* ¶¶ 46-48.) Claim 1 describes a method of reducing triglycerides in a patient with mixed dyslipidemia (abnormal lipid levels) on statin therapy by administering icosapent ethyl. Claims 1 and 8 of the '077 patent recite as follows:

> 1. A method of reducing triglycerides in a subject with mixed dyslipidemia on statin therapy comprising, administering to the subject a pharmaceutical composition comprising about 2500 mg to 5000 mg per day of ethyl eicosapentaenoate and not more than about 5%, by weight of all fatty acids, docosahexaenoic acid or its esters to effect a reduction in fasting triglyceride levels in the subject.
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> 8. The method of claim 1 wherein the subject exhibits a reduction in hs-CRP compared to placebo control.

(*Id.*, Ex. O ('077 Patent).)

The '861 patent was issued on February 25, 2020. It is also assigned to Amarin. (*Id.* ¶¶ 50-52.) Claim 1 describes a method of reducing the risk of cardiovascular death in a patient with established cardiovascular disease by administering icosapent ethyl. Dependent claim 2 specifies that the patient must have a triglyceride level "of about 135 mg/dL to about 500 mg/dL" (*i.e.*, potentially elevated but not necessarily severely high) and an LDL-C (bad cholesterol) level within a specified range. Claims 1 and 2 of the '861 patent recite as follows:

> 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.

(*Id.*, Ex. P ('861 Patent).)

After Amarin received FDA approval for the CV indication, it listed the '537, '077, and '861 patents (the "asserted patents") in the Orange Book for Vascepa. (*Id.* ¶¶ 70-79.)

C. Hikma's generic product

On November 5, 2020, Hikma launched a generic version of Vascepa after receiving FDA approval of its Abbreviated New Drug Application (ANDA). (*Id.* ¶¶ 11, 13.) Hikma's ANDA contained a so-called "section viii carve out" regarding the asserted patents. (*Id.* ¶¶ 104, 105.) That is, Hikma represented to the FDA that it would not market its generic product for the uses covered by those patents.

When Hikma originally submitted its ANDA in 2016, it only sought approval for the SH indication, as the FDA had not yet approved Vascepa for the CV indication. (*Id.* ¶ 108.) At that time, Hikma's proposed generic label (like the Vascepa label at that time) referred only to the SH indication and contained the CV limitation of use. (*Id.*) After Amarin received approval for the CV indication and listed the asserted patents in the Orange Book, Hikma submitted section viii statements with respect to those patents. (*Id.* ¶¶ 104, 108.) Hikma did not propose to add the CV indication to its label, but Hikma did remove the CV limitation of use from its proposed label. (*Id.* ¶ 108.)

The FDA approved Hikma's ANDA on May 21, 2020. (*Id.* ¶ 105.) The "Indications and Usage" section of Hikma's approved label refers only to the SH indication, but it does not contain the CV limitation of use. (*Id.*, ¶ 107 Ex. K.) By the time Hikma's product hit the market in

November 2020, the majority of doctors who prescribed Vascepa did so for uses other than the SH indication, and Hikma was aware of that fact. (*Id.* ¶ 110.)

Hikma issued press releases in 2020 regarding its generic product. In a March 31, 2020 press release, Hikma referred to its then-unapproved product as a "generic version of Amarin Corporation's Vascepa® 1 gm (icosapent ethyl) capsules." (*Id.* ¶¶ 111-113, Ex. L.) The press release further stated 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" (emphasis added), and that the prior year's "US sales of Vascepa® were approximately $919 million." (*Id.*) The Vascepa sales figure cited by Hikma in the press release included sales for the CV indication, and Hikma knew that. (*Id.*) Hikma issued another press release on September 3, 2020 that contained similar statements. (*Id.* ¶¶ 118-120, Ex. M.) Hikma's March and September 2020 press releases were still accessible on Hikma's website when Plaintiffs filed this action. (*Id.* ¶¶ 117, 124.)

Hikma's website also advertises its generic version as being "AB" rated in the "Therapeutic Category: Hypertriglyceridemia." (*Id.* ¶ 125-126, Ex. T.) That webpage does not refer to the fact that Hikma's product is only FDA-approved for "severe hypertriglyceridemia." (*Id.*)

According to the First Amended Complaint, Hikma's label, press releases, and website "instruct, promote, and encourage" healthcare providers and patients to administer Hikma's product in a way that infringes the asserted patents. (*Id.* ¶ 127.)

D. Health Net

Health Net is a health insurance provider. (*Id.* ¶ 137.) Vascepa is covered by Health Net's insurance plans and appears on Health Net's formularies as a covered drug. (*Id.* ¶ 139.) When Hikma launched its generic version, Health Net added the generic to its formularies, meaning that

it would provide insurance coverage and/or payment for Hikma's product. (*Id.* ¶ 140.) Some of Health Net's formularies currently list Hikma's generic version as a Tier 1 drug and Vascepa as a Tier 3 drug. (*Id.* ¶¶ 143, 157.) The result is that plan beneficiaries have to pay a higher copay for Vascepa than they do for Hikma's generic version. (*Id.* ¶ 145.)

At least one of Health Net's plans requires "Prior Authorization" before it will cover and pay for either Vascepa or Hikma's generic version. (*Id.* ¶¶ 153, 159.) To obtain prior authorization from the plan, the patient's medical provider must submit documentation demonstrating that the prescription is being given for either the SH or the CV indication.[6] (*Id.* ¶¶ 153, 154, 159, 160, Exs. EE, HH.)

Plaintiffs allege that Health Net is aware that use of Hikma's generic for the CV indication infringes Plaintiffs' patents because (among other reasons) Plaintiffs sent a letter in December 2020 to Mr. Mike Flynn at Envolve Pharmacy Solutions, Inc. (*Id.* ¶ 87.) Envolve is Health Net's Pharmacy Benefit Manager, and Mr. Flynn is Amarin's point of contact for both Envolve and Health Net. (*Id*.) The letter stated that "[t]he Hikma generic does not have an FDA-approved indication for CV risk reduction." (*Id.* ¶¶ 87-90, Ex. GG.) The letter further stated that Amarin "had sued Hikma for patent infringement for encouraging use of its generic product in the CV risk reduction indication" and that "the Hikma generic should not be dispensed for this indication." (*Id.*)

[6] For example, Health Net's Essential Drug List formulary requires a prior authorization before covering either Vascepa or Hikma's generic version. The prior authorization has criteria that (Amarin contends) map to the SH indication and the CV indication:

> (1) "Hypertriglyceridemia without ASCVD," where the patient has "[f]asting triglycerides ≥ 500 mg/dL," or
> (2) "Reduction of Cardiovascular Disease Risk" with "[d]ocumentation (labs must be within 90 days) of fasting triglycerides between 150-499 mg/dL" and, "[f]or members on statin therapy," "Vascepa is prescribed in conjunction with a statin at the maximally tolerated dose."

(*Id.* ¶ 153, Ex. HH; *see also id.* ¶¶ 154, 159-60, Ex. EE.)

According to the First Amended Complaint, Health Net's implementation of the above-described formulary and prior authorization arrangement amounts to encouragement to providers and patients to administer Hikma's product for the CV indication, which, Plaintiffs allege, results in infringement of the asserted patents.

E. Procedural background

Plaintiffs filed their original Complaint on November 30, 2020. (D.I. 1.) The original Complaint only contained claims against Hikma. On January 4, 2021, Hikma filed a motion to dismiss the Complaint for failure to state a claim. (D.I. 11.)

On January 25, 2021, Plaintiffs filed a First Amended Complaint. (D.I. 17.) The First Amended Complaint added new factual allegations against Hikma and added new claims against Health Net. Counts I-III allege that Hikma induces infringement of the '537, '077, and '861 patents under 35 U.S.C. § 271(b). Counts IV-VI allege that Health Net induces infringement of the '537, '077, and '861 patents under 35 U.S.C. § 271(b).

Hikma and Health Net each filed motions to dismiss the claims against them for failure to state a claim. (D.I. 19; D.I. 30.) Health Net also moved to sever Plaintiffs' claims against Health Net from Plaintiffs' claims against Hikma. (D.I. 32.) The Court heard oral argument on all pending motions on May 26, 2021. This is my Report and Recommendation on Hikma's and Health Net's motions to dismiss.

II. LEGAL STANDARD

A defendant may move to dismiss a complaint under Federal Rule of Civil Procedure 12(b)(6) for failure to state a claim. "To survive a motion to dismiss, a complaint must contain sufficient factual matter, accepted as true, to 'state a claim to relief that is plausible on its face.'" *Iqbal*, 556 U.S at 678 (quoting *Twombly*, 550 U.S. at 570). A claim is plausible on its face when the complaint contains "factual content that allows the court to draw the reasonable inference that the defendant is liable for the misconduct alleged." *Id.* (citing *Twombly*, 550 U.S. at 556). A possibility of relief is not enough. *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.'" *Id.* (quoting *Twombly*, 550 U.S. at 557). In determining the sufficiency of the complaint under the plausibility standard, all "well-pleaded facts" are assumed to be true, but legal conclusions are not. *Id.* at 679.

III. DISCUSSION

Section 271(b) of Title 35 provides that "[w]hoever actively induces infringement of a patent shall be liable as an infringer." 35 U.S.C. § 271(b). To state a claim of induced infringement under § 271(b), the complaint must plausibly allege that (1) there has been direct infringement, (2) the defendant knowingly induced infringement, and (3) the defendant possessed the intent to encourage another's infringement. *MEMC Elec. Materials, Inc. v. Mitsubishi Materials Silicon Corp.*, 420 F.3d 1369, 1378 (Fed. Cir. 2005); *FO2GO LLC v. KeepItSafe, Inc.*, No. 18-807-RGA, 2019 WL 1615398, at *3 (D. Del. Apr. 16, 2019).

In the pharmaceutical drug context, a generic manufacturer can be liable under § 271(b) for inducing infringement of a patented method even where the FDA has not approved the generic

product for use in accordance with the patented method.[7] *See AstraZeneca*, 633 F.3d at 1056-61 (affirming district court's grant of preliminary injunction against generic manufacturer for inducing infringement of patented method under § 271(b) even though generic product was not approved for patented once-daily use); *GlaxoSmithKline*, 2016 WL 3946770, at *15 ("The decision in *AstraZeneca 2010* indicates that there can, in fact, be situations where a generic manufacturer seeks and obtains a section viii carve-out for a use of a drug that is (according to the FDA) a 'different' use from a patented use—and yet the generic's label could nevertheless be written in such a way that it evidences active steps to induce patent infringement."); *see also id.*, 2017 WL 1050574, at *1-2 (denying generic defendant's motion to dismiss inducement claim notwithstanding section viii carve out, where plaintiff alleged that defendant's label and other conduct encouraged use of the generic product in an infringing manner).

The assessment of whether a complaint plausibly alleges inducement in a pharmaceutical case is thus no different than the analysis in any other case. The court must determine whether the complaint plausibly alleges that the generic manufacturer "offer[ed] a product with the object of promoting its use to infringe, as shown by clear expression or other affirmative steps taken to foster infringement." *DSU Med. Corp. v. JMS Co.*, 471 F.3d 1293, 1305-06 (Fed. Cir. 2006) (en banc in relevant part). Such "affirmative steps" may include allegations that a defendant "advertis[ed] an infringing use or instruct[ed] how to engage in an infringing use." *Takeda Pharms. U.S.A., Inc. v. West-Ward Pharm. Corp.*, 785 F.3d 625, 630-31 (Fed. Cir. 2015) (quoting *Metro-Goldwyn-Mayer Studios Inc. v. Grokster, Ltd.*, 545 U.S. 913, 935-36 (2005)).

To be clear, it is not enough to allege that a defendant had "mere knowledge" that its

[7] In contrast, in an ANDA case, a generic manufacturer cannot be liable under 35 U.S.C. § 271(e)(2) for infringing a method patent unless its ANDA seeks FDA approval for the patented use. *Bayer Schering Pharma AG v. Lupin, Ltd.*, 676 F.3d 1316, 1321-22 (Fed. Cir. 2012); *Warner-Lambert Co. v. Apotex Corp.*, 316 F.3d 1348 (Fed. Cir. 2003).

product could be—or is being—used to infringe. *Warner-Lambert*, 316 F.3d at 1364. Rather, the allegations must plausibly suggest "culpable conduct, directed to encouraging another's infringement." *DSU Med.*, 471 F.3d at 1306. Moreover, a defendant who sells a product having substantial noninfringing uses has no duty to take affirmative steps to make sure that others avoid infringement. *Takeda*, 785 F.3d at 632 n.4.

A. Hikma

The First Amended Complaint alleges that Hikma's product label, press releases, and website encourage infringement of the asserted patents. Hikma contends that the claims against it must be dismissed because the allegations fail to state a plausible claim of inducement. I disagree.

The First Amended Complaint alleges 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. For example, claim 1 of the '537 patent covers a method of treating hypercholesterolemia patients with elevated triglyceride (TG) levels of at least 150 mg/dL and HDL-C less than 40 mg/mL, and who are on a statin, in order to reduce the risk of a cardiovascular event. The "Dosage and Administration" section of Hikma's label instructs providers to "[a]ssess lipid levels before initiating therapy." (D.I. 17 ¶ 130, Ex. K § 2.1.) The "Indications and Usage" section instructs administration to patients with TG levels ≥ 500 mg/dL, which, by definition, is at least 150 mg/dL. In addition, the "Clinical Studies" section of Hikma's label describes treatment of patients with (1) median total cholesterol of 254 mg/dL (*i.e.*, hypercholesterolemia); (2) baseline TG levels between 500 and 2,000 mg/dL, with a median baseline of 684 mg/dL (*i.e.*, ≥ 150 mg/dL); (3) a median baseline HDL-C level of 27 mg/dL; and (4) with 25% of the patients on concomitant statin therapy. (*Id.*

¶ 130, Ex. K § 14.2.) The "Patient Information" section describes that the product may be used by patients at risk of having a cardiovascular event. (*Id.* Ex. K.) And, Hikma removed the CV limitation of use from its proposed label, which, according to Plaintiffs, "communicat[es] to the market that Hikma's generic product has been shown to reduce CV risk." (*Id.* ¶ 133.) The First Amended Complaint contains similar allegations regarding the '861 and '077 patents. (*Id.* ¶¶ 131, 134, Ex. K.)

The FAC further alleges that Hikma is aware that the majority of Vascepa prescriptions are for uses other than the SH indication and that Hikma's public statements encourage the use of its product for the same indications that Vascepa is used for. (*Id.* ¶¶ 110, 115, 122.) Plaintiffs point to Hikma's March and September 2020 press releases, which describe its product as a generic version of Vascepa and refer to sales figures that—Hikma knew—include sales for the CV indication. (*Id.* ¶¶ 111, 113, 118, 120.) Plaintiffs also point to Hikma's website, which advertises its generic version as "AB" rated in the "Therapeutic Category: Hypertriglyceridemia," which is broader than the "severe hypotriglyceridemia" (SH) indication for which it has FDA approval, and which may suggest administration to patients having merely elevated triglycerides as required by certain claims of the asserted patents. (*Id.* ¶¶ 125-126, Ex. T.)

Those allegations, taken together and viewed in the light most favorable to Plaintiffs, plausibly suggest the following: (1) that Hikma's label and public statements could instruct and/or encourage third parties to use its product for the CV indication, which Plaintiffs allege is covered by the asserted patents; and (2) that Hikma both knew and intended that third parties would use its product for that purpose. In my view, that is enough.

I am not persuaded by Hikma's arguments to the contrary. Hikma contends that Plaintiffs have not alleged sufficient "active steps" to encourage infringement. (D.I. 20 at 13-14.) But

Hikma's decision to continue to seek FDA approval after removing the CV limitation of use from its proposed label, its decision to sell its product accompanied by the current version of its label, and its public statements all constitute actions that are alleged to encourage infringement. And, at this stage, those allegations must be viewed in the light most favorable to Plaintiffs.

Hikma also points out that mere knowledge of direct infringement is insufficient to support an inducement claim. That is true. But Plaintiffs allege more than mere knowledge.

Hikma further points out that it has no duty to discourage infringement. Also true. But it cannot present information in a way that encourages infringement. The above-described allegations make it plausible that Hikma, rather than merely failing to prevent infringement, intended to cause others to infringe and knew that their acts would infringe.[8]

To the extent Hikma is suggesting that it cannot be liable for inducement absent FDA approval to use its product for CV therapy and/or explicit instructions in the "Indications and Usage" section of its label to use its product for a CV indication, I disagree. As explained above, lack of FDA approval for an infringing use does not preclude a finding of inducement. *See AstraZeneca*, 633 F.3d at 1060; *see also GlaxoSmithKline*, 2016 WL 3946770, at *13. Many of the cases relied on by Hikma at best establish that were this an ANDA case, and were Plaintiffs' allegations based solely on the label, Plaintiffs' inducement theory might lack merit as a matter of law.[9] But this is not an ANDA case, and Plaintiffs' allegations are not based solely on the label.

[8] Of course, in the absence of other evidence of intent, the Court could not find that Defendants are liable for inducement based solely on their failure to take affirmative steps to prevent others' infringement. But Defendants' knowledge that others are using Hikma's product in an infringing way, combined with their failure to take steps to deter such use, could be relevant to their intent to encourage others' infringement. *Cf. Grokster, Ltd.*, 545 U.S. at 939 n.12.

[9] *See, e.g., Bayer Schering*, 676 F.3d at 1321-24; *AstraZeneca LP v. Apotex, Inc.*, 669 F.3d 1370, 1378-1380 (Fed. Cir. 2012); *Warner-Lambert*, 316 F.3d at 1362-65; *see also GlaxoSmithKline*, 2017 WL 1050574, at *2 (acknowledging difference between claims under § 271(e)(2) and § 271(b)).

Hikma urges the Court to resolve this case at the pleadings stage, pointing out that the contents of its label and public statements are undisputed. But there is a real dispute about what those contents communicate to others, and I do not think it is appropriate to resolve it on a motion to dismiss. Stated another way, at this stage of the case, I am not prepared to say that Hikma's label and public statements—as a matter of law—could never amount to instruction and encouragement to infringe the asserted patents.

In support of its contention that its actions cannot constitute inducement, Hikma cites the Federal Circuit's opinions in *HZNP Medicines LLC v. Actavis Laboratories UT, Inc.*, 940 F.3d 680 (Fed. Cir. 2019), *Grunenthal GMBH v. Alkem Laboratories Ltd.*, 919 F.3d 1333 (Fed. Cir. 2019), and *Takeda*, 785 F.3d 625. But none of those cases was resolved at the motion to dismiss stage. *See HZNP*, 940 F.3d at 687-88 (bench trial); *Grunenthal*, 919 F.3d at 1338 (same); *Takeda*, 785 F.3d at 628 (preliminary injunction). And, unlike the allegations in this case, the evidence in those cases related solely to the effects of the generic labels. *See HZNP*, 940 F.3d at 702; *Grunenthal*, 919 F.3d at 1338-39 ("Here, [the plaintiffs] point only to the indications of the proposed labels as grounds for inducement . . . ."); *Takeda*, 785 F.3d at 632.[10]

I conclude that Plaintiffs have pleaded an inducement claim against Hikma that is at least plausible. While Hikma may be right that Plaintiffs will ultimately be unable to prove inducement, I cannot make that determination at this stage. I recommend that Hikma's motion to dismiss be denied.

B. Health Net

According to the First Amended Complaint, Health Net's implementation of its prior

[10] Moreover, while I need not decide whether Plaintiffs' allegations regarding the label alone state a plausible claim of inducement, I do note that the Federal Circuit in *Takeda* expressly declined to decide "whether evidence as to the invariable response of physicians could ever transform a vague label into active encouragement." *Takeda*, 785 F.3d at 632.

authorization process for icosapent ethyl prescriptions, combined with its placement of Hikma's generic on the formulary as a tier 1 drug and Vascepa as a tier 3 drug, amounts to encouragement to providers and patients to administer Hikma's product for the unapproved CV indication, which, Plaintiffs allege, results in infringement of the asserted patents.

To my knowledge, this is a novel theory. Neither side has cited any case in which a health insurer has been found liable to a pharmaceutical company for inducing infringement of a drug method of use patent. Viewing the allegations in the light most favorable to Plaintiffs, and in the absence of precedent to the contrary, I cannot say at this stage that Plaintiffs' theory is so implausible as to require dismissal at the pleadings stage.

The thrust of the allegations against Health Net are (1) that it provides coverage and payment for Hikma's generic product even in cases where Health Net actually knows that a particular beneficiary is using the generic version for an unapproved—and allegedly infringing—CV use, and (2) that Health Net actually encourages use of Hikma's product instead of Vascepa for the CV use because Health Net requires its beneficiaries to pay a higher copay for Vascepa than for Hikma's generic version, even when Hikma's version has been prescribed for the infringing/CV use. Plaintiffs allege that Health Net knows when a particular beneficiary is using Hikma's product for the CV use because Health Net's prior authorization process requires the beneficiary's provider to submit documentation supporting the use for which it has been prescribed. Plaintiffs further allege that Health Net had knowledge that its beneficiaries' use of Hikma's product for the CV indication amounted to infringement of Plaintiffs' patents because Amarin sent a pre-suit letter to its point of contact for Health Net informing it of that fact.[11] Taken

[11] While the letter did not identify the asserted patents by number, the First Amended Complaint plausibly alleges that "[i]t is known in the field, and Health Net would have been aware, that any patents covering a branded drug, such as VASCEPA®, are listed in the Orange Book." (D.I. 17 ¶ 84.)

together, and in the light most favorable to Plaintiffs, it is at least plausible that Health Net knowingly induced infringement and that it had specific intent to do so.

I understand Health Net's position that it merely provides coverage for drugs after they have been prescribed: it neither prescribes medication nor fills the prescriptions. It may ultimately turn out, as Health Net contends, that it has not taken any affirmative acts with the intent to foster infringement. It may also 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 for icosapent ethyl prescriptions 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 or otherwise encourage infringement. It may turn out, as Health Net contends, that "it is Plaintiffs' own pricing decision that encourages use of the generic product over Plaintiffs' brand product." (D.I. 31 at 17.) But all of those are factual issues that are inappropriate for resolution on a motion to dismiss. Plaintiffs allege otherwise, and Plaintiffs' allegations must be taken as true at this stage.

Like Hikma, Health Net points out that it has no duty to discourage others' infringement. While that is true, Plaintiffs also allege that Health Net took active steps—including adopting its formulary and prior authorization procedure for icosapent ethyl prescriptions and taking coverage and payment actions—that are alleged to encourage others' infringement.[12]

I again stress that I am not concluding that this novel claim against a health insurer will or is likely to succeed on the merits. I merely conclude that Plaintiffs have stated a plausible claim and can move forward with discovery.

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[12] *See also* n.8, *supra*.

IV. CONCLUSION

I note that the parties' extensive briefing on the pending motions contained several sub-arguments and cited to several cases not discussed above. I have reviewed those arguments and cases and conclude that they do not warrant further discussion as they do not affect the outcome of the pending motions.

For the reasons set forth above, I recommend that the pending motions to dismiss be DENIED:

1. The Court should deny Hikma's motion to dismiss the First Amended Complaint. (D.I. 19.)

2. The Court should deny Hikma's motion to dismiss the original Complaint as moot. (D.I. 11.)

3. The Court should deny Health Net's motion to dismiss the First Amended Complaint. (D.I. 30.)

This Report and Recommendation is filed pursuant to 28 U.S.C. § 636(b)(1)(B),(C), Federal Rule of Civil Procedure 72(b)(1), and District of Delaware Local Rule 72.1. Any objections to the Report and Recommendation shall be filed within fourteen days and limited to ten pages. Any response shall be filed within fourteen days thereafter and limited to ten pages. The failure of a party to object to legal conclusions may result in the loss of the right to *de novo* review in the district court.

The parties are directed to the Court's "Standing Order for Objections Filed Under Fed. R. Civ. P. 72," dated October 9, 2013, a copy of which can be found on the Court's website.

Dated: August 3, 2021

Jennifer L. Hall
UNITED STATES MAGISTRATE JUDGE