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

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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.I. 70, 71), to which Plaintiffs responded (D.I. 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 72.1(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.*

Twombly, 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 1335-37. 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 VASCEPA 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 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. U.S.A., 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)

[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.

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 ≥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. HEALTH 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 pled, could be affirmative acts under the law of induced infringement. Health Net argues that the selection of its formulary is automatic, based on Plaintiff's 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.