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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January 4, 2022

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).

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