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.

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

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