ZOETIS LLC et al v. ROADRUNNER PHARMACY, INC.

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UNITED STATES DISTRICT COURT

DISTRICT OF NEW JERSEY

HONORABLE NOEL L. HILLMAN CIVIL ACTION NO. 15-3193

OPINION

APPEARANCES: BUCHANAN INGERSOLL & ROONEY PC By: Philip L. Hirschhorn, Esq. 1290 Avenue of the Americas, 30 th

Floor New York, New York 10104-3001 Counsel for Plaintiffs FOX ROTHSCHILD LLP By: Christopher R. Kinkade, Esq. Nancy E. Halpern, Esq. 997 Lenox Drive, Building 3 Lawrenceville, New Jersey 08648 and ERICKSON KERNELL DERUSSEAU & KLEYPAS, LLC By: James J. Kernell, Esq. Kyle D. Donnelly, Esq. 8900 State Line Road, Suite 500 Leawood, Kansas 66206

Counsel for Defendant

HILLMAN, United States District Judge: This is a trademark and patent infringement suit concerning Apoquel (oclacitinib maleate), a drug prescribed to treat severe

ZOETIS LLC, et al.,

Plaintiffs, v. ROADRUNNER PHARMACY, INC.,

Defendant.

skin itching in dogs. Plaintiff Zoetis 1

asserts that Defendant Roadrunner Pharmacy has been "passing off" an oclacitinib free base product 2

as Apoquel "and/or an Apoquel-equivalent." (Amend. Compl. ¶ 1) The Amended Complaint contains seven counts: (1) trademark infringement in violation of the Lanham Act; (2) false designation of origin in violation of the Lanham Act; (3) false advertising in violation of the Lanham Act; (4) unfair

competition / trademark infringement / false advertising in violation of the New Jersey Fair Trade Act; (5) common law unfair competition; (6) infringement of U.S. Patent No. 8,133,899 ("the '899 patent"); and (7) infringement of U.S. Patent No. 8,987,283 ("the '283 patent"). Defendant moves to dismiss the Amended Complaint, asserting that the facts pled do not meet the standard set by Fed. R. Civ. P. 8, Twombly 3

and Iqbal. 4 For the reasons stated herein, the motion will be denied as to Counts 1 through 5, and granted as to Counts 6 and 7 (the

1 Three corporate entities are named as Plaintiffs: Zoetis LLC, Zoetis Services LLC, and Zoetis US LLC. The parties refer to all three, collectively, as "Zoetis." The Court will do the same. 2 Zoetis' product and Roadrunner's product allegedly differ in chemical composition at least insofar as Zoetis' oclacitinib product has an appended salt whereas Roadrunner's does not. (Amend. Compl. ¶ 28, 38) 3 Bell Atlantic Corp. v. Twombly, 550 U.S. 544, 555 (2007). 4 Ashcroft v. Iqbal, 556 U.S. 662, 678 (2009).

patent infringement counts). However, Zoetis will be given an opportunity to attempt to cure the pleading deficiencies of the patent counts.

I. When Zoetis launched Apoquel in the spring of 2014, the drug "became an immediate success." (Amend. Compl. ¶ 20-21) Allegedly, "[t]his immediate uptake by the veterinarian community has resulted in a shortage of the product." (Id. at ¶ 20) According to Zoetis, Roadrunner saw this shortage as an opportunity to "aggressively market[] [its] oclacitinib free base [product] to veterinarians and pet owners, via personal contact, fax mailings and at veterinary conferences." (Amend. Compl. ¶ 28) "As early as August of 2014," Roadrunner began making written and oral representations to veterinarians either "that its product is Apoquel," or "its product is equivalent to Apoquel." (Amend. Compl. ¶¶ 30-31, 33, 35) "[I]n October 2014," Roadrunner "began further advertising that it would soon be able to supply its alleged compounded Apoquel." (Amend. Compl. ¶ 34)

II. Federal Rule of Civil Procedure 12(b)(6) provides that a court may dismiss a complaint "for failure to state a claim upon

which relief can be granted." In order to survive a motion to dismiss, a complaint must allege facts that raise a right to relief above the speculative level. Bell Atlantic Corp. v. Twombly, 550 U.S. 544, 555 (2007); see also Fed. R. Civ. P. 8(a)(2). While a court must accept as true all factual allegations in the plaintiff's complaint, and view them in the light most favorable to the plaintiff, Phillips v. County of Allegheny, 515 F.3d 224, 231 (3d Cir. 2008), a court is not required to accept sweeping legal conclusions cast in the form of factual allegations, unwarranted inferences, or unsupported conclusions. Morse v. Lower Merion Sch. Dist., 132 F.3d 902, 906 (3d Cir. 1997).

The complaint must state sufficient facts to show that the legal allegations are not simply possible, but plausible. Phillips, 515 F.3d at 234. "A claim has facial plausibility when the plaintiff pleads

factual content that allows the court to draw the reasonable inference that the defendant is liable for the misconduct alleged." Ashcroft v. Iqbal, 556 U.S. 662, 678 (2009). "[I]f a complaint is subject to a Rule 12(b)(6) dismissal, a district court must permit a curative amendment unless such an amendment would be inequitable or futile." Great Western Mining & Mineral Co. v. Fox Rothschild LLP, 615 F.3d 159, 174 (3d Cir. 2010) (internal citation and quotation omitted; emphasis added).

III. A. For the purposes of this motion, the parties agree that the analysis for the New Jersey state law claims (Counts 4 and 5) does not materially differ from the analysis for the Lanham Act claims (Counts 1 through 3). Accordingly, the parties have primarily focused on the Lanham Act analysis, and the Court will as well.

1. Trademark infringement and false designation of origin under the Lanham Act (Counts 1 and 2) "We measure federal trademark infringement, 15 U.S.C. § 1114, and federal unfair competition, 15 U.S.C. § 1125(a)(1)(A), by identical standards. To prove either form of Lanham Act violation, a plaintiff must demonstrate that (1) it has a valid and legally protectable mark; (2) it owns the mark; and (3) the defendant's use of the mark to identify goods or services causes a likelihood of confusion." A&H Sportswear, Inc. v. Victoria's Secret Stores, Inc., 237 F.3d 198, 210 (3d Cir. 2000) (internal citation and quotation omitted). 5

5 See also Arrowpoint Capital Corp. v. Arrowpoint Asset Mgmt., LLC, 793 F.3d 313, 319 (3d Cir. 2015) ("To prevail on a claim for trademark infringement or unfair competition under the Lanham Act, the owner of a valid and legally protectable mark . . . must show that a defendant's use of a similar mark for its goods 'causes a likelihood of confusion.'") (citing A&H Sportswear); Kos Pharms., Inc. v. Andrx Corp., 369 F.3d 700, 709 (3d Cir. 2004) (quoting A&H Sportswear).

Only the third element is at issue. Roadrunner argues that the Amended Complaint does not allege anywhere that Roadrunner used the Apoquel mark to identify its goods. This argument fails. The very first paragraph of the Amended Complaint alleges that Roadrunner has been "passing off" its oclacitinib free base product "as Zoetis' Apoquel (oclacitinib maleate) and/or as an Apoquel-equivalent." (Amend. Compl. ¶ 1) Again at paragraph 30, the Amended Complaint alleges, "[Roadrunner] has directly or implicitly represented that its product is Apoquel." (Amend. Comp. ¶ 30)(emphasis added) The Motion to Dismiss Counts 1 and 2 will be denied. 6

2. False advertising under the Lanham Act (Count 3) "To establish a claim for false advertising, a Lanham Act plaintiff must prove five elements: 1) that the defendant has made false or misleading statements as to his own product [or another's]; 2) that there is actual deception or at least a tendency to deceive a substantial portion of the intended

6 As to these Counts, Roadrunner repeatedly asserts that the exhibits to the Amended Complaint are of questionable authenticity and do not actually support the allegations made in the Amended Complaint. Related to this issue, Roadrunner also emphasizes Zoetis' lack of "evidence." (See, e.g.,

Moving Brief at pp. 6, 8, 9)

Neither of these issues is appropriate for resolution on a Rule 12(b)(6) motion. Fed. R. Civ. P. 11(b) governs the content of pleadings and exhibits attached thereto. Moreover, Zoetis need not present evidence at the pleading stage, prior to discovery.

audience; 3) that the deception is material in that it is likely to influence purchasing decisions; 4) that the advertised goods traveled in interstate commerce; and 5) that there is a likelihood of injury to the plaintiff in terms of declining sales, loss of good will, etc." Groupe SEB United States, Inc. v. Euro-Pro Operating LLC, 774 F.3d 192, 198 (3d Cir. 2014)(internal citation and quotation omitted); see generally Lexmark Int'l, Inc. v. Static Control Components, Inc., 134 S. Ct. 1377, 1393 (2014) (describing "the classic Lanham Act false-advertising claim" as one "in which [a] competitor directly injures another by making false statements about his own goods or the competitor's goods and thus inducing customers to switch.")(internal citation and quotation omitted). Roadrunner argues that Zoetis' factual allegations fail as to all five elements. The Court disagrees. As discussed above, the Amended Complaint alleges that Roadrunner is "offering for sale, selling, and actively marketing to veterinarians, pet owners, and other consumers, through direct marketing and over the internet" (Amend. Compl. ¶ 1), "counterfeit Apoquel." (Amend. Compl. Ex. G) Such advertising is plausibly false because the Amended Complaint alleges that Roadrunner is representing that its product is Apoquel when it is not (Amend. Compl. ¶ 30), and that its product is "equivalent to Apoquel" (Amend. Compl. ¶ 31), when: (a) "Roadrunner's compounded product does not contain the same active

ingredient as Apoquel," (Amend. Compl. ¶ 29); and (b) Roadrunner's active pharmaceutical ingredient has not been approved by the FDA (Amend. Comp. ¶ 42), whereas Apoquel is FDA-approved. (Amend. Compl. ¶ 19) A factfinder could also plausibly conclude that there is actual deception. The alleged deception concerns the chemical composition of a drug, which is not something a veterinarian, pet owner or other consumer could determine on their own; they must trust the representation made by the pharmacy.

Such deception could plausibly influence purchasing decisions. Given the alleged shortage of Apoquel, a purchaser may opt to buy Roadrunner's product which may be more broadly available, if the purchaser believes he or she is buying Apoquel or the pharmaceutical equivalent of Apoquel.

The allegations are also sufficient to plausibly support a conclusion that Roadrunner's product traveled in interstate commerce. The Amended Complaint alleges that "Defendant Roadrunner is an Arizona business operating [in] . . . Phoenix, Arizona" (Amend. Compl. ¶ 5), and that it advertised to veterinarians in Meridian, Idaho (Amend. Compl. Ex. F), and Manalapan, New Jersey. (Amend. Compl. Ex. D)

Further, the Amended Complaint alleges that Apoquel is "distributed around the [United States]" to veterinarians, and that Roadrunner is targeting these same veterinarians with its

offers for sale, plausibly suggesting that Roadrunner's product has crossed state lines in a sale to a veterinarian.

Lastly, the Amended Complaint plausibly alleges injury to Zoetis by stating:

Because Zoetis has no control over the quality of Defendant's products or its marketing campaign, Defendant's use of the Apoquel mark results in Zoetis' loss of control of its business reputation and a loss of its goodwill. Further, since, under federal law, Defendant's use of an unapproved active pharmaceutical ingredient, i.e., oclacitinib free base, and its representation that such is an equivalent to Apoquel, Plaintiff is likely to suffer adverse consequences to the reputation of the genuine oclacitinib maleate active pharmaceutical ingredient present in Apoquel. Plaintiff and its former parent company, Pfizer, have spent millions of dollars in obtaining a legitimate and approved NADA for the oclacitinib maleate-containing Apoquel, which investment is being tarnished by the Defendant's product which it has represented as a legitimately compounded form of Apoquel. (Amend. Compl. ¶ 42) The Amended Complaint's allegations in support of its Lanham Act false advertising count raise the claim above the speculative level. Roadrunner's Motion to Dismiss this count will be denied.

3. New Jersey state law claims (Counts 4 and 5)

The parties agree that the analyses for the New Jersey Fair Trade Act and common law unfair competition claims are the same as the analyses for the claims' Lanham Act analogs. See, e.g., Advanced Oral Techs., L.L.C. v. Nutrex Research, Inc., 2011 U.S.

Dist. LEXIS 5266 (D.N.J. Jan. 20, 2011)("it is clear that the Lanham Act and New Jersey Fair Trade Act are designed to prohibit a broad array of misleading representations that undermine commercial interests."); CSC Holdings, LLC v. Optimum Networks, Inc., 731 F. Supp. 2d 400 (D.N.J. 2010) ("Because, as discussed, plaintiff has stated a claim for unfair competition under Section 43(a) of the Lanham Act, the Court finds that plaintiff also has stated a claim for unfair competition under New Jersey statutory and common law."). Accordingly, the Motion to Dismiss will be denied as to Counts 4 and 5.

B. Counts 6 and 7 assert infringement of the '899 and '283 patents, respectively. Each count asserts both direct and indirect infringement. This is somewhat problematic in that direct infringement, and the two types of indirect infringement-- contributory and induced-- are "distinct concepts with distinct standards." In re Bill of Lading Transmission and Processing System Patent Litig. (R+L Carriers, Inc. v. Drivertech LLC), 681 F.3d 1323, 1333 (Fed. Cir. 2012). Indeed, in some circumstances, a direct infringement claim has a different pleading standard than an indirect infringement claim. See id. at 1336 ("Form 18 should

be strictly construed as measuring only the sufficiency of allegations of direct infringement, and not

indirect infringement. . . . [W]e must look to [Iqbal and Twombly] for guidance regarding the pleading requirements for claims of indirect infringement."). Thus, combining what amounts to three separate claims into one count results in a muddled pleading. (See, e.g., Amend. Compl. ¶ 12)("Roadrunner's manufacture, use, sale, offer for sale, and/or importation of oclacitinib free base product constitutes direct and/or indirect infringement of the claims of the '899 patent and the '283 patent.") To avoid a similarly muddled opinion, the Court will discuss the indirect infringement allegations before turning to the direct infringement allegations.

1. Indirect infringement Roadrunner argues that the Amended Complaint contains insufficient factual allegations concerning indirect infringement of the patents at issue. The Court agrees. With respect to the '899 patent, the Amended Complaint does not even indicate whether its one conclusory reference to "indirect infringement" at paragraph 80 means contributory infringement, induced infringement, or both. There are no factual allegations at all from which one might even infer which type(s) of indirect infringement is asserted.

The allegations concerning the '283 patent are somewhat better insofar that the Amended Complaint specifically states that "Defendant has actively induced the infringement of Zoetis' '283 patent in violation of 35 U.S.C. § 271(b)" (Amend. Compl. ¶ 87), but the allegations still fall short.

The Amended Complaint fails to sufficiently articulate how Roadrunner induced infringement. It merely states that Roadrunner has sold its product "to veterinarians, pet owners, and other professionals or end-users, with advertising or instructions relating to a use that directly infringes on one or more claims of the '283 patent." (Id.) This single sentence, without more, is too vague and conclusory to plausibly support a claim for induced infringement.

Additionally, the indirect infringement claims fail because, as explained below, the direct infringement claims are not adequately pled. See In re Bill of Lading Transmission and Processing Sys. Patent Litig., 681 F.3d at 1333 ("Because liability for indirect infringement of a patent requires direct infringement, [the] amended complaints must plausibly allege that the [patent at issue] was directly infringed to survive [a] motion to dismiss."). The Court holds that the allegations concerning indirect infringement of both the '899 patent and the '283 patent do not satisfy the requirements of Fed. R. Civ. P. 8, Twombly, and Iqbal.

The Motion to Dismiss will be granted as to the indirect infringement portions of Counts 6 and 7. However, the Court will grant leave to Zoetis to amend those claims in an attempt to cure the pleading deficiencies.

2. Direct infringement As the Federal Circuit has explained, a complaint for direct patent infringement must contain:

(1) an allegation of jurisdiction; (2) a statement that the plaintiff owns the patent; (3) a statement that

defendant has been infringing the patent 'by making, selling, and using [the device] embodying the patent'; (4) a statement that the plaintiff has given the defendant notice of its infringement; and (5) a demand for an injunction and damages. In re Bill of Lading Transmission and Processing Sys. Patent Litig., 681 F.3d at 1334 (citing Form 18 and quoting McZeal v. Sprint Nextel Corp., 501 F.3d 1354 (Fed. Cir. 2007)). Roadrunner takes issue with the third element arguing, "[Zoetis] ha[s] not even alleged that [Roadrunner's] oclacitinib product is the same as the chemical compound in the '899 patent claims." (Moving Brief p. 11) The Court agrees that the Amended Complaint lacks this basic information. First, the patent's title is "Pyrrolo[2,3- D]Pyrimidine Compounds." (Amend. Compl. Ex. B) What this has to do with oclacitinb is not at all apparent to the Court. Indeed,

if the word "oclacitinib" appears at all in the patent, Zoetis has not cited it. 7 Further, claim 1 of the '899 patent contains a graphical representation of the patented chemical structure, yet Zoetis includes no similar graphical representation of either the active ingredient in Apoquel, or the alleged active ingredient in Roadrunner's product. Thus, the Amended Complaint leaves unanswered a fundamental question: Does the '899 patent cover the active ingredient in Apoquel? At the very least, Zoetis must connect the dots between its product and the '899 patent. The allegations concerning direct infringement of the '283 patent are similarly deficient. The '283 patent claims "a method for treating allergic reactions . . . or puritis in a mammal comprising administering to a mammal in need" the chemical compound[s] claimed by the '899 patent. (Amend. Compl. Ex. H) The Amended Complaint does not allege that Roadrunner is "administering" its product to any mammal. Rather, the Amended Complaint alleges only that Roadrunner-- a compounding pharmacy, not a veterinarian or consumer-- is "marketing, offering for sale, and selling its oclacitinib product." (Amend. Compl. ¶ 87)

7 The Court's independent search of the patent revealed no appearance of "oclacitinib" in the entire document.

The Amended Complaint, as currently drafted, fails to state a claim for direct infringement of the method patent. The Motion to Dismiss will be granted as to the direct infringement portions of Counts 6 and 7. However, the Court will grant leave to Zoetis to amend those claims in an attempt to cure the pleading deficiencies.

IV. In light of the foregoing, the Motion to Dismiss will be denied as to Counts 1 through 5 of the Amended Complaint; and granted as to Counts 6 and 7 (the patent infringement counts). Plaintiffs will be granted leave to file a Second Amended Complaint as to the patent infringement counts only within thirty (30) days. An appropriate Order accompanies this Opinion.

Dated: February 25, 2016

At Camden, New Jersey __s/ Noel L. Hillman_____ Noel L. Hillman, U.S.D.J.