IN THE UNITED STATES DISTRICT COURT

FOR THE DISTRICT OF DELAWARE

ELI LILLY AND COMPANY, Plaintiff, v. EAGLE PHARMACEUTICALS, INC., Defendant.	)	Civ. No. 17-1293- MSG

M. GOLDBERG, J. **OCTOBER 25, 2018**

MEMORANDUM OPINION

Plaintiff Eli Lilly & Company ("Lilly") initiated this patent infringement action pursuant to the Hatch-Waxman Act in response to defendant Eagle Pharmaceuticals, Inc. ("Eagle") filing a New Drug Application ("NDA") with the U.S. Food and Drug Administration ("FDA") seeking approval to manufacture and sell a pemetrexed injection, 25mg/mL, 500 mg vial product (the "NDA Product") before the expiration of U.S. Patent No. 7,772,209 ("the '209 patent"). Lilly is the assignee of the '209 patent. Lilly also makes and sells ALIMTA®, a drug containing pemetrexed disodium that is used for treatment of various types of cancer. Lilly believes that Eagle's NDA product will be marketed as a competing product to ALIMTA®.

Currently pending is Eagle's motion for judgment on the pleadings pursuant to Fed. R. Civ. P. 12(c). (D.I. 28). I have subject matter jurisdiction over this action pursuant to 28 U.S.C.

§§ 1331 and 1338(a). Venue is proper under 28 U.S.C. §§ 1391 and 1400(b).[1] For the reasons set forth below, I will deny Eagle's motion for judgment on the pleadings.

I. BACKGROUND

A. Procedural History

On August 7, 2017, Eagle advised Lilly that it had submitted NDA No. 209472 to the FDA, seeking to market its own pemetrexed product based on Lilly's ALIMTA®, and that it had submitted a certification pursuant to 21 U.S.C. § 355(b)(2)(A)(iv) that Lilly's '209 patent will not be infringed by the manufacture, use, offer for sale, sale, or importation of Eagle's NDA product, or alternatively, that the '209 patent is invalid. (D.I. 7 at ¶ 1). Lilly then sued Eagle under 35 U.S.C. § 271(e)(2), alleging that the use of Eagle's proposed NDA Product will infringe the '209 patent either literally or under the doctrine of equivalents and that Eagle will induce and contribute to that infringement. (D.I. 1).

Eagle answered Lilly's complaint on October 3, 2017, and asserted counterclaims for, inter alia, declaratory judgment of non-infringement. (D.I. 7). On October 24, 2017, Lilly answered Eagle's counterclaims, denying some of the factual allegations and denying that Eagle was entitled to any relief whatsoever. (D.I. 12). On May 31, 2018, Eagle filed this motion, which has been fully briefed. (D.I. 28; D.I. 35; D.I. 40).

B. The '209 Patent

The '209 Patent has two independent claims, claims 1 and 12, both directed to a method of administering pemetrexed disodium. Claim 1 reads:

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[1] On May 18, 2017, Chief Judge D. Brooks Smith of the United States Court of Appeals for the Third Circuit designated me as a visiting judge for the District of Delaware, pursuant to 28 U.S.C. § 292(b), to handle this and other Delaware cases.

> A method for administering pemetrexed disodium to a patient in need thereof comprising administering an effective amount of folic acid and an effective amount of a methylmalonic acid lowering agent followed by administering an effective amount of pemetrexed disodium, wherein the methylmalonic acid lowering agent is selected from the group consisting of vitamin B12, hydroxycobalamin, cyano-10-chlorocobalamin, aquocobalamin perchlorate, aquo-10-cobalamin perchlorate, azidocobalamin, cobalamin, cyanocobalamin, or chlorocobalamin.

(D.I. 1-1 at 10:60-65). Claim 12 reads:

> An improved method for administering pemetrexed disodium to a patient in need of chemotherapeutic treatment, wherein the improvement comprises:
>
> a) administration of between about 350 μg and about 1000 μg of folic acid prior to the first administration of pemetrexed disodium;
>
> b) administration of about 500 μg to about 1500 μg of vitamin B12, prior to the first administration of pemetrexed disodium; and
>
> c) administration of pemetrexed disodium.

II. STANDARD OF REVIEW

A. Motion for Judgment on the Pleadings

A Rule 12(c) motion will not be granted "unless the movant clearly establishes that no material issue of fact remains to be resolved and that he is entitled to judgment as a matter of law." Jablonski v. Pan Am. World Airways, Inc., 863 F.2d 289, 290 (3d Cir. 1988). The court must view the facts and inferences to be drawn from the pleadings in the light most favorable to the non-moving party. Green v. Fund Asset Mgmt., L.P., 245 F.3d 214, 220 (3d Cir. 2001); Janney Montgomery Scott, Inc. v. Shepard Niles, Inc., 11 F.3d 399, 406 (3d Cir. 1993). However, the court need not adopt conclusory allegations or statements of law. In re Gen. Motors Class E Stock Buyout Sec. Litig., 694 F. Supp. 1119, 1125 (D. Del. 1988). "The purpose of judgment on the pleadings is to dispose of claims where the material facts are undisputed and judgment can be entered on the competing pleadings and exhibits thereto, and documents

incorporated by reference." Venetec *Int'*l, Inc. v. Nexus Med., LLC, 541 F. Supp. 2d 612, 617 (D. Del. 2008). "The issue is not whether a plaintiff will ultimately prevail but whether the claimant is entitled to offer evidence to support the claims." In re Burlington Coat Factory Sec. Litig., 114 F.3d 1410, 1426 (3d Cir. 1997).

B. Infringement

Eagle's Product is not yet on the market because it has not received final FDA approval (and cannot receive it due to the 30-month stay triggered by this suit). Thus, the inquiry is whether Eagle's Product would infringe based on the content of its NDA. See AstraZeneca Pharms. LP v. Apotex Corp., 669 F.3d 1370, 1376-77, 79 (Fed. Cir. 2012). It is an act of infringement to submit an NDA "if the purpose of such submission is to obtain approval . . . to engage in the commercial manufacture, use, or sale of a drug . . . claimed in a patent . . . before the expiration of such patent." 35 U.S.C. § 271(e)(2). The filing of an NDA alone does not prove infringement. Glaxo, Inc. v. Novopharm, Ltd., 110 F.3d 1562, 1570 (Fed. Cir. 1997). Rather, the patentee must show, using "traditional patent infringement analysis," that "the alleged infringer will likely market an infringing product." Id. at 1569-70; see also Warner-Lambert Co. v. Apotex Corp., 316 F.3d 1348, 1365–66 (Fed. Cir. 2003).

Traditional infringement analysis employs a two-step inquiry. First, the court must construe the asserted claims to ascertain their meaning and scope. Markman v. Westview Instruments, Inc., 52 F.3d 967, 979–81 (Fed. Cir. 1995), aff'd, 517 U.S. 370 (1996). Second, the trier-of-fact must compare the properly construed claims with the accused infringing product. Id. Step one is a question of law, and step two is a question of fact. Id. Infringement may be proven under one of two theories: literal infringement or the doctrine of equivalents. Id.; Baxter Healthcare Corp. v. Spectramed, Inc., 49 F.3d 1575, 1582 (Fed. Cir. 1995). Literal infringement

occurs when each element of at least one claim of the patent is found in the alleged infringer's product. Panduit Corp. v. Dennison Mfg. Co., 836 F.2d 1329, 1330 n. 1 (Fed. Cir. 1987). The party asserting infringement has the burden of proof and must meet its burden by a preponderance of the evidence. SmithKline Diagnostics, Inc. v. Helena Lab. Corp., 859 F.2d 878, 889 (Fed. Cir. 1988).

III. DISCUSSION

Eagle argues that its NDA Product cannot literally infringe the '209 patent, because the active pharmaceutical ingredient in its NDA Product is "[p]emtrexed, also known as pemetrexed diacid." (D.I. 29 at 1-2). The '209 patent requires use of "pemetrexed disodium," which Eagle claims "is not pemetrexed disodium." (Id. at 2).

According to Lilly, the claims of the '209 patent are not directed to a product, but to a method of administering pemetrexed disodium. (D.I. 35 at 2). Thus, "the question for literal infringement is not whether [Eagle's NDA Product] contains pemetrexed disodium when it is in the vial from the factory, but whether administering [the NDA Product] according to its labeling (the prescribing information for physicians and patient information) is 'administering pemetrexed disodium' as that phrase is used in the '209 patent." (Id. at 2-3). Lilly takes the position that it is.

Lilly also argues that administering pemetrexed disodium consists of giving patients an intravenous solution containing pemetrexed and sodium ions, separate from one another. (Id. at 1-3). Specifically, ALIMTA® is sold in the form of a solid compound where pemetrexed is ionically bonded to sodium. (Id.). Because a solid compound cannot be administered to patients intravenously, ALIMTA® must be dissolved in a liquid solution. (Id.). In solution, pemetrexed and sodium separate, or "dissociate," from each other, and it is pemetrexed—not pemetrexed

disodium—that actually gets into and kills cancer cells. (Id.). Lilly claims the evidence will show that administering Eagle's NDA Product in accordance with its proposed labeling involves administering a solution covered by the '209 patent.

To resolve the parties' dispute, I must first determine the scope of the claims in the '209 patent, including the meaning of "administering pemetrexed disodium." Questions of claim construction are not suitable for resolution on a Rule 12 motion. Nalco Co. v. Chem-Mod, LLC, 883 F.3d 1337, 1349 (Fed. Cir. 2018) (claim construction disputes are "not suitable for resolution on a motion to dismiss"). Accordingly, for the reasons stated, Eagle's motion for judgment on the pleadings is denied. (D.I. 28). An appropriate order will be entered.