IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

IGI Laboratories, Inc.,

Plaintiff,

v.

Mallinckrodt LLC, Mallinckrodt Inc., and **Nuvo Research Inc.,**

Defendants.

Civil Action No. 13-2044-RGA

MEMORANDUM ORDER

Before the Court is IGI's Motion to Dismiss Counterclaim Pursuant to Rule 12(b)(6) (D.I. 15) and related briefing. (D.I. 16, 21, 22). Mallinckrodt holds the NDA for a diclofenac topical solution sold under the trade name Pennsaid. (D.I. 10 at ¶ 13). IGI submitted an ANDA to the FDA seeking approval to market diclofenac topical solution for the treatment of signs and symptoms of osteoarthritis of the knees. Mallinckrodt owns patents which cover the use of diclofenac, in combination with agents such as non-steroidal anti-inflammatory drugs ("NSAIDs"), for treating osteoarthritis of the knees. IGI filed a declaratory judgment action seeking a declaration of non-infringement of U.S. Patent Nos. 8,217,078 and 8,546,450. (D.I. 1). Defendants counterclaimed for infringement under 35 U.S.C. §§ 271(e)(2)(A) and 271(b). (D.I. 10). IGI moved to dismiss the counterclaims. (D.I. 15).

Section 271(b) states that "[w]hoever actively induces infringement of a patent shall be liable as an infringer." 35 U.S.C. § 271(b). Section 271(e)(2)(A) states that it is an act of infringement to file an ANDA "for a drug claimed in a patent or the use of which is claimed in a

patent." 35 U.S.C. § 271(e)(2)(A). This section has been described "as creating a highly artificial act of infringement...so that courts could promptly resolve infringement and validity disputes before the ANDA applicant had engaged in the traditional statutorily defined acts of infringement." *AstraZeneca Pharm. LP v. Apotex Corp.*, 669 F.3d 1370, 1377 (Fed. Cir. 2012) (internal citations and quotation marks omitted). "Once jurisdiction is established, however, the substantive determination whether actual infringement or inducement will take place is determined by traditional patent infringement analysis." *Warner-Lambert Co. v. Apotex Corp.*, 316 F.3d 1348, 1365 (Fed. Cir. 2003).

Here, all of Defendants' counterclaims sound in induced infringement. Mallinckrodt's patents do not claim the composition, but a particular method of using the drug. Defendants claim that IGI's proposed label will induce infringement of the patented methods. This does not state a claim under § 271(b). Section 271(b) imposes liability on those who "actively induce[] infringement," not on those who might some day induce infringement. "A claim is not ripe for adjudication if it rests on contingent future events that may not occur as anticipated, or indeed may not occur at all." *Texas v. United States*, 523 U.S. 296, 300 (1998) (internal quotations omitted). Therefore I dismiss Defendants' § 271(b) counterclaims, counts II and IV.

As for Defendants' counterclaims under § 271(e)(2)(A), IGI argues that the FDA approved use for the drug is not claimed in the '078 and '450 patents, and therefore Defendants fail to state a claim. IGI is correct that "section 271(e)(2)(A) lies only against a patented use that has been approved by the FDA." *Bayer Schering Pharma AG v. Lupin, Ltd.*, 676 F.3d 1316, 1319 (Fed. Cir. 2012) (internal quotation marks omitted). It is also true that "[t]he FDA does not grant across-the-board approval to market a drug... [I]t grants approval to make, use, and sell a

drug for a specific purpose for which that drug has been demonstrated to be safe and efficacious." *Warner-Lambert Co. v. Apotex Corp.*, 316 F.3d at 1356.

The parties agree that the only FDA approved use of diclofenac is "the treatment of signs and symptoms of osteoarthritis of the knee(s)." (D.I. 10 at ¶¶ 15, 16). The patents cover using diclofenac for treating osteoarthritis of the knee via applying the diclofenac, waiting for it to dry, and applying either a second medication, sunscreen, or insect repellent. (*See* '078 patent, claim 1; '450 patent, claim 10). The parties disagree as to whether the FDA approved use is the same as that claimed in the patents.[1] (D.I. 10 at ¶¶ 23-28).

The Defendants allege that IGI will induce infringement of Mallinckrodt's patents via IGI's proposed product label.[2] IGI's proposed product label is identical to that of the Pennsaid label, except for the manufacturer. (D.I. 1 at ¶ 30). In the "Dosage and Administration" section, the FDA approved label for Pennsaid instructs the reader to "[w]ait until the treated area is dry before applying sunscreen, insect repell[e]nt, lotion, moisturizer, cosmetics, or other topical medication." (D.I. 1 Ex. A at 3). These allegations appear to be enough to state a claim for induced infringement under § 271(e)(2)(A). "The pertinent question is whether the proposed label instructs users to perform the patented method. If so, the proposed label may provide evidence of [the accused infringer's] affirmative intent to induce infringement." *AstraZeneca LP v. Apotex, Inc.*, 633 F.3d at 1060.

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[1] IGI points out that Defendants did not allege that its patented methods were approved by the FDA, and argues that this alone is fatal to Defendants' 271(e)(2)(A) claims. (D.I. 16 at 10). While Defendants did not explicitly state that the FDA approved use is claimed in Mallinckrodt's patents, Defendants did answer paragraphs 23-28 of IGI's complaint, which stated that the claims of the '078 and '450 patents do not cover the only FDA approved indication for diclofenac, with denials. In the counterclaims, reading the allegations in the light most favorable to Defendants, they alleged that the patented methods are the same as what the FDA has approved. (D.I. 10 ¶¶ 20-25).

[2] These allegations are under the § 271(b) claims. While I am dismissing those claims, I understand that the Defendants intended these allegations to be a part of the basis for their induced infringement claims arising under § 271(e)(2)(A).

IGI argues that the patented methods are also not FDA approved uses because "indications or uses must not be implied or suggested in other sections of the labeling if not included in [the Indications and Usage] section." *Bayer Schering Pharma AG v. Lupin, Ltd.*, 676 F.3d at 1323. The Indications and Usage section of IGI's proposed label states that the drug is "indicated for the treatment of signs and symptoms of osteoarthritis of the knee(s)." (D.I. 1 Ex. A at 2). IGI argues that this is like *Bayer*, where the Court decided that an FDA approved indication for contraception did not include the uses of achieving anti-mineralocorticoid and anti-androgenic activity, where the latter two uses were not listed in the Indications and Usage section. 676 F.3d at 1324. However, in *Bayer*, the parties agreed that the "patent [could] be infringed only if the defendants' ANDAs [sought] FDA approval to market Yasmin for the three simultaneous effects covered by the '652 patent." *Id.* at 1320-21. It was essentially agreed by the parties in *Bayer* that the three effects were three separate indications. It is not so clear here that treating osteoarthritis of the knee along with sunscreen, insect repellent, or an NSAID is a different indication than just treating osteoarthritis of the knee.[3] Without context, deciding this issue is inappropriate at the motion to dismiss stage.

The real issue, I think, is whether judgment on the pleadings is appropriate at this juncture. Defendants point out that IGI seeks to dismiss counterclaims which are mirror images of IGI's declaratory judgment claims. (D.I. 21 at 6). It makes little sense to me that a plaintiff's declaratory judgment claims state a claim, and yet defendant's equivalent counterclaims do not. I therefore hold that Defendants have set forth sufficient factual allegations that the patents cover

[3] It would seem odd for the FDA to have to approve as a separate use the application of sunscreen or insect repellent on top of a medication.

the FDA approved use, and, even if I were to interpret IGI's motion to dismiss as a motion for judgment on the pleadings, I would find that it is inappropriate to do so.

Therefore, the Motion to Dismiss (D.I. 15) is **GRANTED IN PART** and **DENIED IN PART**. Counterclaims II and IV are **DISMISSED**.

Entered this 22nd day of April, 2014.

Richard G. Andrews
United States District Judge