NOT FOR PUBLICATION

UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY

SUNOVION PHARMACEUTICALS INC., Plaintiff, v. TEVA PHARMACEUTICALS USA, INC. et al., Defendants.	**Hon. Dennis M. Cavanaugh** **OPINION** Civil Action No. 09-cv-01302 (DMC)(MF)

DENNIS M. CAVANAUGH, U.S.D.J.:

This matter comes before the Court upon Defendants Dr. Reddy Laboratories, Ltd.'s and Dr. Reddy's Laboratories, Inc.'s (collectively "Defendants" or "DRL") Renewed Motion for Summary Judgment of Non-Infringement of U.S. Patent No, 6,444,673 (the "'673 Patent"), pursuant to FED. R. CIV. P. 56. (ECF No. 448). Pursuant to FED. R. CIV. P. 78, no oral argument was heard. After carefully considering the submissions of the parties, and based upon the following, it is the finding of this Court that Defendants' Renewed Motion for Summary Judgment is **granted.**

I. BACKGROUND[1]

The instant suit arises out of the alleged infringement of Plaintiff Sunovion Pharmaceuticals Inc.'s ("Plaintiff" or "Sunovion") patents for eszopiclone, used to market the sleep medication

[1] The facts set-forth in this Opinion are taken from the Parties' statements in their respective moving papers.

Lunesta®.[2] Eszopiclone is the active ingredient in Lunesta® and is the "dextrorotatory" or "(+)" isomer of a compound known as zoplicone. (Pl.'s Opp. Br. 2, Nov. 17, 2011, ECF No. 386). Zopiclone consists of a mixture of two isomers, the levorotatory isomer (also known as the "R-isomer" or "l-isomer") and the dextrorotatory isomer (known as the S- or d-isomer). U.S. Patent Numbers 6,319,926 ("the '926 Patent"), 6,444,673 (the "'673 Patent"), 6,864,257 ("the '257 Patent"), and 7,381,724 ("the '724 Patent") are assigned on their face to Sepracor, Inc. and generally cover eszopiclone "essentially free" of its other "(-) isomer" as well as formulations of and methods of administering the same. (Pl.'s Opp. Br. 2). Each of the aforementioned patents belong to the same patent family and share the same specification, although the '673 Patent alone is at issue in the instant matter.

The '673 Patent issued with eight claims, three of which (claims 1, 2, and 8) Sunovion asserts against DRL. Sunovion alleges that DRL infringed these claims with the filing of an Abbreviated New Drug Application ("ANDA") on December 15, 2008, seeking approval from the Food and Drug Administration ("FDA") to market DRL's eszopiclone 1 mg, 2 mg, and 3 mg tablets as generic versions of Sunovion's Lunesta®. (Defs.' Mot. Br. 8, Oct. 13, 2011, ECF No. 372). On October 13, 2011, Defendants filed a Motion for Summary Judgment of Non-Infringement of asserted claims 1, 2, and 8, claiming the then-existing ANDA did not infringe upon Sunovion's '673 Patent. (Defs.' Mot. Br. 8).

A *Markman* Hearing was held on February 22, 2012 and, in an April 10, 2012 Opinion, this Court construed the term "essentially free" to mean "less than 0.25% of [its/the] levorotatory isomer." (*Markman* Opinion and Order 13, April 10, 2012, ECF Nos. 417, 418). After finding no plain meaning for the term "essentially free" and upon consideration of the prosecution history of the '673 Patent, this

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[2]The instant suit was originally filed by Sepracor, Inc. on March 20, 2009. On October 12, 2010, Sepracor Inc. changed its name to Sunovion Pharmaceuticals Inc. The caption has been revised to reflect this change. All references made to Plaintiff herein will be made to Sunovion.

Court determined that the record evidence supported the 0.25 percent claim construction. (*Markman* Opinion 6-7).

DRL's original eszopiclone ANDA provided for an R-isomer specification of "not less than 0.3% and not more than 1.0%." (See Pl.'s Opp. Br. 12, Nov. 17, 2011, ECF No. 386). DRL received a deficiency from the FDA in regards to that application and its subsequent proposal requested the specification for the levorotatory content in its drug product and drug substance be revised to not more than 1.0 percent. (Pl.'s Opp. Br. 12). The FDA recommended further "tightening" of the R-isomer limit. (Pl.'s Opp. Br. 13). The FDA has expressed that setting the limit between 0.3 percent and 1.0 percent is "not acceptable." (Pl.s Opp. Br. 13). The limits were later restricted to the 0.0 percent to 0.6 percent in a revised ANDA submitted to the FDA on April 26, 2012.

On May 25, 2012, this Court denied DRL's Motion for Summary Judgment of Non-Infringement without prejudice and permitted DRL to file a renewed motion accompanied by a certification assuring this Court DRL would not market a product containing less than 0.3 percent of the levorotatory isomer of eszopiclone ("May 25th Order"). (ECF No. 437). DRL has subsequently submitted a certification stating it will not market an eszopiclone tablet with an levorotatory isomer content below 0.3 percent. (Nicholas Cappuccino, Ph.D. Certification ("the Certification"), June 8, 2012, ECF No. 449). The May 25th Order also prevented further briefing and declared that the Renewed Motion for Summary Judgment would be decided upon consideration of the Certification and the motion papers already before the Court. Sunovion previously moved for this Court to reconsider certain portions of the May 25th Order, specifically parts of the Order suggesting that the Certification by DRL providing it will not market generic eszopiclone tablets containing less than 0.3 percent levorotatory isomer would be sufficient to avoid infringement. In a opinion dated December 14, 2012,

this Court denied Sunovion's Motion for Reconsideration. This Court now considers DRL's Renewed Motion for Summary Judgment of Non-Infringement of the '673 Patent.

II. STANDARD OF REVIEW

Summary judgment is granted only if all probative materials of record, viewed with all inferences in favor of the non-moving party, demonstrate that there is no genuine issue of material fact and that the movant is entitled to judgment as a matter of law. FED. R. CIV. P. 56(c); Celotex Corp. v. Catrett, 477 U.S. 317, 330 (1986). The moving party bears the burden of showing either (1) there is no genuine issue of fact and it must prevail as a matter of law; or (2) that the non-moving party has not shown facts relating to an essential element of an issue for which he bears the burden. Celotex, 477 U.S. at 331. If either showing is made then the burden shifts to the non-moving party, who must demonstrate facts that support each element for which he bears the burden, as well as the existence of genuine issues of material fact. Id. A material fact is one that might affect the outcome of the case, and "summary judgment will not lie if the dispute about a material fact is 'genuine,' that is, if the evidence is such that a reasonable jury could return a verdict for the nonmoving party. Anderson v. Liberty Lobby, Inc., 477 U.S. 242, 248 (1986).

The Court will consider all facts and their reasonable inferences in the light most favorable to the non-moving party. See Penn. Coal Ass'n v. Babbitt, 63 F.3d 231, 236 (3d Cir. 1995); Newsome v. Admin. Office of the Courts of the State of N.J., 103 F. Supp.2d 807, 815 (D.N.J. 2000), aff'd, 51 Fed. App'x. 76 (3d Cir. 2002) (citing Watts v. Univ. of Del., 622 F.2d 47, 50 (D.N.J. 1980)). While a court must draw reasonable inferences in the light most favorable to the non-moving party, the non-moving party "may not rest upon the mere allegations or denials of his pleading" to satisfy this burden, and rather must produce sufficient evidence to support a jury verdict in his favor. See FED. R. CIV. P. 56(e);

see also Matsushita Elec. Indus. Co. v. Zenith Radio Corp., 475 U.S. 574, 586 (1986). "[U]nsupported allegations in memorandum and pleadings are insufficient to repel summary judgment." Schoch v. First Fid. Bancorporation, 912 F.2d 654, 657 (3d Cir. 1990), and conclusory allegations are insufficient to establish genuine issues of fact. Lujan v. Nat'l Wildlife Fed'n, 497 U.S. 871, 902 (1990). The non-moving party "must do more than simply show that there is some metaphysical doubt as to the material facts." Matsushita Elec. Indus. Co., 475 U.S. at 586.

III. DISCUSSION

A. CLAIM CONSTRUCTION LEGAL STANDARDS

Claim construction is a question of law. See Markman v. Westview Instruments, Inc., 517 U.S. 370 (1996). In interpreting a patent claim, the court should look first to the intrinsic evidence of record (i.e., the patent itself). See Vitronics Corp. v. Conceptronic, Inc., 90 F.3d 1576, 1582 (Fed.Cir.1996). The Federal Circuit has established an analytical framework for analyzing the scope and meaning of disputed claim terms. See Phillips v. AWH Corp., 415 F.3d 1303 (Fed. Cir. 2005). "It is a 'bedrock principle' of patent law that 'the claims of a patent define the invention to which the patentee is entitled the right to exclude.'" Id. at 1312 (citation omitted). The words contained in the claim are "generally given their ordinary and customary meaning . . . to a person of ordinary skill in the art in question at the time of the invention, i.e., as of the effective filing date of the patent application." Phillips, at 1312–13 (citations and internal quotations omitted). In addition to the claim language, the patent specification "'is always highly relevant to the claim construction analysis.'" Phillips, 415 F.3d at 1315 (citation omitted).

The prosecution history should also be considered because it can show "how the [Patent and Trademark Office] and the inventor understood the patent." Phillips, 415 F.3d at 1317. Prosecution

history is illustrative of "the course of dealing with the Patent Office, which may show a particular meaning attached to the terms, or a position taken by the applicant" to secure the patent. Markman v. Westview Instruments, Inc., 52 F.3d 967, 991 (Fed. Cir. 1995), aff'd, 517 U.S. 370 (1996).

B. INFRINGEMENT LEGAL STANDARDS

1. Literal Infringement

Literal infringement requires a showing that each limitation set forth in a claim appear in the accused product. Frank's Casing Crew & Rental Tools, Inc. v. Weatherford Int'l, Inc., 389 F.3d 1370, 1378 (Fed. Cir. 2004); Forest Labs., Inc. v. Abbott Labs., 239 F.3d 1305, 1310 (Fed.Cir.2001). If even one limitation is missing in the accused product, there is no literal infringement. See Dolly, Inc. v. Spaulding & Evenflo Cos., 16 F.3d 394, 397 (Fed.Cir.1994); Kraft Foods, Inc. v. Int'l Trading Co., 203 F.3d 1362, 1370 (Fed.Cir.2000).

2. Doctrine of Equivalents

The doctrine of equivalents allows a plaintiff to establish, in certain instances, that a claim element, though not literally present, is nevertheless met by demonstrating that the missing element has been replaced by a structure that performs the same function in the same way to achieve the same result as the claim element in the patented device. See, e.g., Warner–Jenkinson Co. v. Hilton Davis Chem. Co., 520 U.S. 17, 35 (1997). The doctrine of equivalents, however, is an "equitable" tool that is applicable "only when the changes [in the accused product] are so insubstantial as to result in a fraud on the patent." Slimfold Mfg. Co. v. Kinkead Indus., Inc., 932 F.2d 1453, 1457 (Fed.Cir.1991). There are several well-settled limitations to the application of the doctrine of equivalents. First, the doctrine of prosecution history estoppel serves to presumptively bar the doctrine of equivalents for claim limitations that were narrowed during prosecution for reasons related to patentability. See, e.g.,

Festo Corp. v. Shoketsu Kinzoku Kogyo Kabushiki Co., 535 U.S. 722, 741 (2002). Second, the doctrine of equivalents cannot be used to encompass prior art or if the application of the doctrine would read an element out of the claim language. See Warner–Jenkinson, 520 U.S. at 33–40; Marquip, Inc. v. Fosber Am., Inc., 198 F.3d 1363, 1367 (Fed.Cir.1999). Furthermore, "the patentee bears the burden of proving infringement . . . and [the patentee] is responsible for [any] shortcoming" in the evidence regarding the accused products." See Ultra–Tex Surfaces, Inc. v. Hill Bros. Chem. Co., 204 F.3d 1360, 1364 (Fed.Cir.2000).

C. Claim Construction of Disputed Terms

As several Defendants have already withdrawn from this matter, there remained only one disputed term for the Court's construction, namely the "essentially free" claim term. In its *Markman* decision, this Court determined the purity level claimed by the patents-in-suit by construing the term "essentially free." The Court found that no plain meaning for the term "essentially free " existed. (*Markman* Opinion 5, Apr. 10, 2012, ECF No. 417). It was undisputed that neither the claims nor the specifications of the patents defined the degree of purity of the d-isomer of zopiclone composition that was "essentially free" of the levorotatory isomer, thus this Court turned to the to the prosecution history of the patents-in-suit to properly construe the disputed term. (*Markman* Opinion 5). This Court concluded that the term "essentially free" is properly defined as "less than 0.25% of [its/the] levorotatory isomer." (*Markman* Opinion 5).

D. Summary Judgment of Non-Infringement

Having construed the disputed term, the Court now turns to whether DRL's formulation falls within its scope. The ultimate burden of proving infringement rests with the patentee. Thus, "an accused infringer seeking summary judgment of non-infringement may meet its initial responsibility

either by providing evidence that would preclude a finding of infringement, or by showing that the evidence on file fails to establish a material issue of fact essential to the patentee's case." Novartis Corp. v. Ben Venue Laboratories, Inc., 271 F. 3d 1043, 1046 (Fed. Cir. 2001).

It is an act of infringement to submit an ANDA "if the purpose of such a submission is to obtain approval . . . to engage in the commercial manufacture, use, or sale of a drug . . . claimed in a patent or the use of which is claimed in a patent before the expiration of such patent." 35 U.S.C. § 271(e)(2)(C)(iii). However, the scope of the ANDA is not the sole factor in an infringement analysis and does not alter a patentee's normal burden of proving infringement. Glaxo, Inc. v. Novopharm, Ltd., 110 F.3d 1562, 1567 (Fed. Cir. 1997). The relevant inquiry centers upon "whether the patentee has proven by a preponderance of the evidence that the alleged infringer will likely market an infringing product." Glaxo, Inc. v. Novopharm, Ltd., 110 F.3d 1562, 1570 (Fed. Cir. 1997); Bayer AG v. Elan Pharmaceutical Research Corp., 212 F.3d 1241, 1248 (Fed. Cir. 2000) (citing 35 U.S.C. § 271(e)(2)(A)). This inquiry depends upon a determination of "[w]hat is likely to be sold, or, preferably, what will be sold, will ultimately determine whether infringement exists." Glaxo, Inc. v. Novopharm, Ltd., 110 F.3d 1562, 1570 (Fed. Cir. 1997). A court may properly consider the ANDA itself, materials submitted by the ANDA applicant in support of the ANDA, and any additional relevant material submitted by the applicant or the patent holder. Bayer AG, 212 F.3d at 1248-49.

DRL filed its Renewed Motion for Summary Judgment for Non-Infringement on the grounds that DRL's proposed range for which it is seeking FDA approval was outside the purity range claimed by Sunovion's patents. Claims 1, 2, and 8 of the '673 Patent refer to a composition "essentially free of

its levorotatory isomer."[3] Sunovion argues that "speculation about what [the] FDA may or may not do in the future is insufficient to establish undisputed facts in support of summary judgment." (Pl.'s Opp. Br. 18). Sunovion asserts summary judgment is precluded based on the uncertainty that exists as to whether the FDA will accept DRL's proposed R-isomer specifications and previous rejections of DRL's specifications by the FDA. (Pl.'s Opp. Br. 18, 20). This Courts analysis, however, centers around a determination of whether DRL would likely sell an infringing composition pursuant to an approved ANDA. See Glaxo, Inc. v. Novopharm, Ltd., 110 F.3d 1562, 1570 (Fed. Cir. 1997). At the time the original summary judgment motions were filed, DRL's ANDA was pending before the FDA. To supplement its ANDA, DRL submitted an eszopiclone Drug Master File containing two alternate proposed specifications. DRL's first proposed specification indicated that the content of the R-isomer will be between 0.3 percent and 1.0 percent. DRL's alternate proposed specification provided that the content of R-isomer will be Not More Than ("NMT") 1.0 percent. DRL maintains that both proposed specifications support a defense of non-infringement. (Defs.' Mot. Br. 6-7). According to DRL, even if the alternate proposed specification is adopted by the FDA, DRL's tablets will still be outside the infringing range of less than 0.25 percent of the R-isomer, in accordance with this Court's construction of the "essentially free" claim term. (Id. at 7; Cappuccino Certification ¶ 14). DRL claims this is so

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[3] Claims 1, 2, and 8 of the '673 Patent read as follows:

1. 6-(5-chloro-2-pyridyl)-5-[(4-methyl-1-piperazinyl) carbonyloxy]-7-oxo-6, 7 dihydro-5H-pyrrolo[3,4-b] pyrazine, or a pharmaceutically acceptable salt thereof, in the form of its dextrorotatory isomer and essentially free of its levorotatory isomer.

2. A pharmaceutical composition comprising an effective amount of the dextrorotatory isomer, essentially free of the levorotatory isomer of 6-(5-chloro-2-pyridy1)-5-[(4-methyll-piperazinyl)-carbonyloxy]-7-oxo-6,7-dihydro-5H-pyrrolo [3,4-blpyrazine, or a pharmaceutically acceptable salt thereof, and a pharmaceutically acceptable carrier.

8. The pharmaceutically composition according to claim 2, wherein the pharmaceutically acceptable carrier compromises a diluent.

because the specific process employed, known as "Process I, " results in an eszopiclone product having an R-isomer content of between 0.3 percent and 0.6 percent. (Def.'s Mot. Br. 7, Oct. 13, 2011, ECF No. 372; Cappuccino Cert. ¶ 14).

DRL concedes that DRL's Drug Master File also supports an alternative manufacturing process, known as "Process II," which utilizes additional steps to yield eszopiclone with an R-isomer content below 0.3 percent. (Cappuccino Cert. ¶ 14). According to DRL, this process is exclusively used to manufacture a product for a third party and DRL has certified it will not market an eszopiclone tablet with a levorotatory isomer content below 0.3 percent. (Cappuccino Cert. ¶ 17). Both internal regulations and the Certification preclude DRL from marketing a product made using Process II and marketing a tablet with a levorotatory isomer content under 0.3 percent.

DRL's ANDA specification and other materials it has submitted to the FDA in connection to its ANDA demonstrate the process used to manufacture DRL's eszopiclone create a product having an R-isomer content of not less than 0.3 percent and not more than 1.0 percent. (See e.g., Cappuccino Cert. ¶¶ 5, 6; Product Specification, Oct. 13, 2011, ECF No. 374 1, Exh. 1). DRL's release specifications similarly require that DRL's eszopiclone tablets and API have an R-isomer content of between 0.3 percent and 1.0 percent. (See, e.g., Cappuccino Cert. ¶13; DRL Finished Product Release Specification, Oct. 13, 2011, ECF No. 374-2, pp 5, 9). The batch records submitted by DRL with the ANDA show R-isomer contents between 0.31 percent and 0.91 percent. (See DRL's FDA Letter of Eszopiclone Batches Trend, Oct. 13, 2011, ECF No. 374-1, Exh. 8, pp 38-40). Even if the FDA approves DRL's alternate proposed specification that the content of the R-isomer will remain NMT 1.0 percent, the product marketed would remain outside the infringing range of less than 0.25% of [its/the] levorotatory isomer. "The ANDA must be judged on its face for what an accused infringer seeks the

FDA's approval to do" and that the ANDA remains under review does not create a material issue of disputed fact as to the eszopiclone product DRL is seeking approval to market. See Warner-Lambert Co. v. Apotex Corp., 316 F.3d 1348, 1364 (Fed. Cir. 2003). The eszopiclone product produced and marketed by DRL will be the same in either potential approval situation, and contain between 0.3 percent and 1.0 percent of the R-isomer. In considering the ANDA, material submitted by DRL to the FDA, and "other pertinent evidence provided by the parties," this Court concludes it has not been shown by a "preponderance of the evidence that the alleged infringer will likely market an infringing product." See Glaxo, Inc. v. Novopharm, Ltd., 110 F.3d 1562, 1570 (Fed. Cir. 1997).

In cases where literal infringement is not shown, the doctrine of equivalents may be utilized to demonstrate infringement. Mosaid Technologies Inc., 262 F. Supp. 2d at 533. An accused product may infringe under the doctrine of equivalents if "it performs substantially the same function in substantially the same way to obtain the same result." Southwall Technologies, Inc., v. Cardinal IG Company, 54 F. 3d 1570, 1579 (Fed. Cir. 1995) (citing Graver Tank & Mfg. Co. v. Linde Air Prods. Co., 339 U.S. 605, 608 (1950)). The doctrine of equivalents, however, is not a tool for expanding the protection of a patent after examination has been completed. Hormone Research Foundation, Inc. v. Genentech, Inc., 904 F.2d 1558, 1564, 15 USPQ2d 1039, 1044 (Fed.Cir.1990). Thus, prosecution history estoppel limits the range of equivalents available to a patentee by preventing recapture of subject matter surrendered during prosecution of the patent. Townsend Eng'g Co. v. HiTec Co., 829 F.2d 1086, 1090, 4 USPQ2d 1136, 1139 (Fed.Cir.1987).

Here, there is no possible equivalent under the doctrine of equivalents. In no case can "the doctrine of equivalents ignore the individual claim elements." Abbott Laboratories v. Sandoz, Inc., 566 F.3d 1282, 1297 (Fed. Cir. 2009) (citing Warner-Jenkinson Co. v. Hilton Davis Chemical Co., 520 U.S.

17, 40 (1997)). Equivalency for purposes of patent infringement requires an element-by-element comparison looking for equivalent function, way, and result. Id. Though Sunovion has provided data suggesting DRL's product will benefit the end user in a manner that is substantially similar to Sunovion's Lunesta®, this is insufficient to support a finding that Sunovion is entitled to equivalents to the "essentially free" limitation above 0.3 percent of the R-isomer. Sunovion may not now attempt to broaden statements made during the prosecution leading to the issuance of the '673 Patent. See Pharmacia & Upjohn Co. v. Mylan Pharms., Inc., 170 F.3d 1373, 1376-77 (Fed. Cir. 1999). As the asserted claims of the '673 Patent require eszipoclone which is "essentially free" of the R-isomer, construed as less than 0.25% of [its/the] levorotatory isomer and as DRL's ANDA and API product will demonstrably contain a 0.3 percent to 1.0 percent R-isomer content, DRL will not infringe either literally or under the doctrine of equivalents.

IV. CONCLUSION

For the reasons stated, it is the finding of this Court that Defendants' Motion for Summary Judgment is **granted**. An appropriate Order accompanies this Opinion.

Dennis M. Cavanaugh, U.S.D.J.

DATE: 1/17/13

Orig.: Clerk
cc: Hon. Mark Falk, U.S.M.J.
All Counsel of Record
File