IN THE UNITED STATES DISTRICT COURT

FOR THE DISTRICT OF DELAWARE

AUXILIUM PHARMACEUTICALS, INC. and FCB I, LLC.,	)	
Plaintiffs,	)	
v.	)	Civ. No. 13-148-SLR
UPSHER-SMITH LABORATORIES, INC.,	)	
Defendant.	)	

Steven J. Balick, Esquire, Lauren E. Maguire, Esquire and Andrew C. Mayo, Esquire of Ashby & Geddes, Wilmington, Delaware. Counsel for Plaintiff Auxilium Pharmaceuticals, Inc. Of Counsel: Paul J. Berman, Esquire, Keith A. Teel, Esquire, Tracy O. Ebanks, Esquire, Michael N. Kennedy, Esquire and Erica N. Andersen, Esquire of Covington & Burling LLP.

John M. Seaman, Esquire of Abrams & Bayliss LLP, Wilmington, Delaware. Counsel for Plaintiff FCB I, LLC. Of Counsel: Thomas J. Fleming, Esquire and Howard J. Smith, Esquire of Olshan Frome Wolosky LLP.

Frederick L. Cottrell, III, Esquire and Travis S. Hunter, Esquire of Richards, Layton & Finger, P.A., Wilmington, Delaware. Counsel for Defendant. Of Counsel: Jake M. Holdreith, Esquire, Lars P. Taavola, Esquire and Jaime R. Kurtz, Esquire of Robins, Kaplan, Miller & Ciresi L.L.P.

MEMORANDUM OPINION

Dated: December 4, 2013
Wilmington, Delaware

ROBINSON, District Judge

I. INTRODUCTION

On January 28, 2013, plaintiffs Auxilium Pharmaceuticals, Inc. ("Auxilium") and FCB I, LLC ("FBI") (collectively, "plaintiffs") filed this infringement action against defendant Upsher-Smith Laboratories, Inc. ("defendant") alleging infringement of U.S. Patent Nos. 7,320,968 ("the '968 patent"); 7,608,605 ("the '605 patent"); 7,608,606 ("the '606 patent"); 7,608,607 ("the '607 patent"); 7,608,608 ("the '608 patent"); 7,608,609 ("the '609 patent"); 7,608,610 ("the '610 patent"); 7,935,690 ("the '690 patent"); 8,063,029 ("the '029 patent"); and 8,178,518 ("the '518 patent") (collectively, "the patents-in-suit"). (D.I. 1) Defendant answered the complaint on January 30, 2013 and counterclaimed against plaintiffs for non-infringement of each of the patents-in-suit. (D.I. 7) Plaintiffs answered the counterclaims on February 20, 2013. (D.I. 16)

Auxilium is a Delaware corporation, with its principal place of business in Malvern, Pennsylvania. (D.I. 1 at ¶ 1) Auxilium develops and markets pharmaceutical products. (*Id.*) FCB is a limited liability corporation organized and existing under the laws of the State of Delaware, with its principal place of business in Wilmington, Delaware. (D.I. 1 at ¶ 2) Defendant is a Minnesota corporation, with its principal place of business in Maple Grove, Minnesota. (D.I. 7 at 25 ¶ 1) Defendant is a pharmaceutical company that develops, manufactures and markets a variety of patented and generic pharmaceutical products. (*Id.*)

Presently before the court is defendant's motion for summary judgment of non-infringement of the patents-in-suit (D.I. 26) and plaintiffs' motion to strike the reply brief

(D.I. 67). The court has jurisdiction pursuant to 28 U.S.C. §§ 1331 and 1338(a).

II. STANDARD OF REVIEW

"The court shall grant summary judgment if the movant shows that there is no genuine dispute as to any material fact and the movant is entitled to judgment as a matter of law." Fed. R. Civ. P. 56(a). The moving party bears the burden of demonstrating the absence of a genuine issue of material fact. *Matsushita Elec. Indus. Co. v. Zenith Radio Corp.*, 415 U.S. 574, 586 n.10 (1986). A party asserting that a fact cannot be—or, alternatively, is—genuinely disputed must support the assertion either by citing to "particular parts of materials in the record, including depositions, documents, electronically stored information, affidavits or declarations, stipulations (including those made for the purposes of the motions only), admissions, interrogatory answers, or other materials," or by "showing that the materials cited do not establish the absence or presence of a genuine dispute, or that an adverse party cannot produce admissible evidence to support the fact." Fed. R. Civ. P. 56(c)(1)(A) & (B). If the moving party has carried its burden, the nonmovant must then "come forward with specific facts showing that there is a genuine issue for trial." *Matsushita*, 415 U.S. at 587 (internal quotation marks omitted). The court will "draw all reasonable inferences in favor of the nonmoving party, and it may not make credibility determinations or weigh the evidence." *Reeves v. Sanderson Plumbing Prods., Inc.*, 530 U.S. 133, 150 (2000).

To defeat a motion for summary judgment, the non-moving party must "do more than simply show that there is some metaphysical doubt as to the material facts." *Matsushita*, 475 U.S. at 586-87; *see also Podohnik v. U.S. Postal Service*, 409 F.3d

584, 594 (3d Cir. 2005) (stating party opposing summary judgment "must present more than just bare assertions, conclusory allegations or suspicions to show the existence of a genuine issue") (internal quotation marks omitted). Although the "mere existence of some alleged factual dispute between the parties will not defeat an otherwise properly supported motion for summary judgment," a factual dispute is genuine where "the evidence is such that a reasonable jury could return a verdict for the nonmoving party." *Anderson v. Liberty Lobby, Inc.*, 411 U.S. 242, 247-48 (1986). "If the evidence is merely colorable, or is not significantly probative, summary judgment may be granted." *Id.* at 249-50 (internal citations omitted); *see also Celotex Corp. v. Catrett*, 411 U.S. 317, 322 (1986) (stating entry of summary judgment is mandated "against a party who fails to make a showing sufficient to establish the existence of an element essential to that party's case, and on which that party will bear the burden of proof at trial").

III. INFRINGEMENT

A patent is infringed when a person "without authority makes, uses or sells any patented invention, within the United States . . . during the term of the patent." 35 U.S.C. § 271(a). A two-step analysis is employed in making an infringement determination. *See Markman v. Westview Instruments, Inc.*, 52 F.3d 967, 976 (Fed. Cir. 1995). First, the court must construe the asserted claims to ascertain their meaning and scope. *See id.* Construction of the claims is a question of law subject to de novo review. *See Cybor Corp. v. FAS Techs.*, 138 F.3d 1448, 1454 (Fed. Cir. 1998). The trier of fact must then compare the properly construed claims with the accused infringing product. *See Markman*, 52 F.3d at 976. This second step is a question of

fact. *See Bai v. L & L Wings, Inc.*, 160 F.3d 1350, 1353 (Fed. Cir. 1998).

"Direct infringement requires a party to perform each and every step or element of a claimed method or product." *BMC Res., Inc. v. Paymentech, L.P.*, 498 F.3d 1373, 1378 (Fed. Cir. 2007), *overruled on other grounds by* 692 F.3d 1301 (Fed. Cir. 2012). "If any claim limitation is absent from the accused device, there is no literal infringement as a matter of law." *Bayer AG v. Elan Pharm. Research Corp.*, 212 F.3d 1241, 1247 (Fed. Cir. 2000). If an accused product does not infringe an independent claim, it also does not infringe any claim depending thereon. *See Wahpeton Canvas Co. v. Frontier, Inc.*, 870 F.2d 1546, 1553 (Fed. Cir. 1989). However, "[o]ne may infringe an independent claim and not infringe a claim dependent on that claim." *Monsanto Co. v. Syngenta Seeds, Inc.*, 503 F.3d 1352, 1359 (Fed. Cir. 2007) (quoting *Wahpeton Canvas*, 870 F.2d at 1552) (internal quotations omitted). A product that does not literally infringe a patent claim may still infringe under the doctrine of equivalents if the differences between an individual limitation of the claimed invention and an element of the accused product are insubstantial. *See Warner-Jenkinson Co. v. Hilton Davis Chem. Co.*, 520 U.S. 17, 24 (1997). The patent owner has the burden of proving infringement and must meet its burden by a preponderance of the evidence. *See SmithKline Diagnostics, Inc. v. Helena Lab. Corp.*, 859 F.2d 878, 889 (Fed. Cir. 1988) (citations omitted).

When an accused infringer moves for summary judgment of non-infringement, such relief may be granted only if one or more limitations of the claim in question does not read on an element of the accused product, either literally or under the doctrine of

equivalents. *See Chimie v. PPG Indus., Inc.*, 402 F.3d 1371, 1376 (Fed. Cir. 2005); *see also TechSearch, L.L.C. v. Intel Corp.*, 286 F.3d 1360, 1369 (Fed. Cir. 2002) ("Summary judgment of noninfringement is ... appropriate where the patent owner's proof is deficient in meeting an essential part of the legal standard for infringement, because such failure will render all other facts immaterial."). Thus, summary judgment of non-infringement can only be granted if, after viewing the facts in the light most favorable to the non-movant, there is no genuine issue as to whether the accused product is covered by the claims (as construed by the court). *See Pitney Bowes, Inc. v. Hewlett–Packard Co.*, 182 F.3d 1298, 1304 (Fed. Cir. 1999).

For there to be infringement under the doctrine of equivalents, the accused product or process must embody every limitation of a claim, either literally or by an equivalent. *Warner-Jenkinson*, 520 U.S. at 41. An element is equivalent if the differences between the element and the claim limitation are "insubstantial." *Zelinski v. Brunswick Corp.*, 185 F.3d 1311, 1316 (Fed. Cir. 1999). One test used to determine "insubstantiality" is whether the element performs substantially the same function in substantially the same way to obtain substantially the same result as the claim limitation. *See Graver Tank & Mfg. Co. v. Linde Air Products Co.*, 339 U.S. 605, 608 (1950). This test is commonly referred to as the "function-way-result" test. The mere showing that an accused device is equivalent overall to the claimed invention is insufficient to establish infringement under the doctrine of equivalents. The patent owner has the burden of proving infringement under the doctrine of equivalents and must meet its burden by a preponderance of the evidence. *See SmithKline*

Diagnostics, Inc. v. Helena Lab. Corp., 859 F.2d 878, 889 (Fed. Cir. 1988) (citations omitted).

IV. DISCUSSION

The parties agree that defendant's formulation does not literally infringe the claims of the patents-in-suit, as each of these requires a specific formulation of testosterone gel with specific ingredients, not contained in defendant's formulation. (D.I. 27 at 3) Rather, plaintiffs argue that defendant's formulation infringes under the doctrine of equivalents.

The court starts with the premise that the claims and specification of a patent serve a public notice function. *See, e.g., Johnson & Johnston Associates Inc. v. R.E. Service Co., Inc.*, 285 F.3d 1046, 1052 (Fed. Cir. 2002) (citing *Mahn v. Harwood*, 112 U.S. 354, 361 (1884)) (claims give notice to the public of the scope of the patent). "Consistent with its scope definition and notice functions, the claim requirement presupposes that a patent applicant defines his invention in the claims, not in the specification. After all, the claims, not the specification, provide the measure of the patentee's right to exclude." *Id.* (citing *Milcor Steel Co. v. George A. Fuller Co.*, 316 U.S. 143, 146 (1942) ("Out of all the possible permutations of elements which can be made from the specifications, [a patentee] reserves for himself only those contained in the claims.") (quoting *Milcor Steel Co. v. George A. Fuller Co.*, 122 F.2d 292, 294 (2d Cir. 1941)). "In making this connection, foreseeability reconciles the preeminent notice function of patent claims with the protective function of the doctrine of equivalents." *See Honeywell Int'l, Inc. v. Hamilton Sundstrand Corp.*, 523 F.3d 1304, 1313 (Fed. Cir.

2008).

A. The Patents and the Prosecution

Each of the patents-in-suit claim priority to the same application, which issued as the '968 patent. The patents-in-suit claim methods for treating hypogonadism using a pharmaceutical composition containing a specific formulation of a testosterone gel.[1] (*See, e.g.,* '968 patent, 4:3-10; 24:2-26) The claimed compositions each contain an "enhancer," which is "a material which is capable of increasing the rate of passage of androgen through the skin or other body membrane." (*See, e.g.,* '968 patent, 3:47-51) For example, independent claim 1 of the '968 patent recites in part:

> A method for maintaining an effective concentration of testosterone in the blood serum of a male for treating hypogonadism which comprises transdermally delivering to the male by applying to the skin a composition . . . compris[ing]: . . . (B) about 0.5 to about 15 wt. % of oxacyclohexadecan-2-one . . .

('968 patent, 24:2-26)

The enhancer, oxacylohexadecan-2-one, is "a cyclic enhancer of the type described in U.S. Pat. No. 5,023,252 to Hsieh" ("Hsieh enhancer"). The compositions recited in the claims of the '518 patent, '605 patent, '606 patent, '607 patent, and '609 patent are similarly limited to the Hsieh enhancer, oxacylohexadecan-2-one. ('518 patent, 24:14-15; '605 patent, 23:12; '606 patent, 23:39; '607 patent, 23:39, 24:24; '609 patent, 23:40, 24:25) The '608 patent, '610 patent, '690 patent, and '029 patent require that the compositions contain a macrocyclic Hsieh enhancer from a group containing

---

[1]With the exception of the '518 patent which claims the composition.

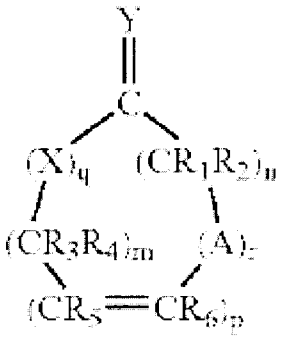
oxacylohexadecan-2-one and four other closely related macrocyclic Hsieh enhancers.[2]

('608 patent, 24:3-7; '610 patent, 23:39-43; '690 patent, 23:8-12; '029 patent, 24:3-6)

The specification of the '968 patent describes

> a pharmaceutical composition comprising: (A) an androgen; (B) a cyclic enhancer of the type described in U.S. Pat. No. 5,023,252 to Hsieh (assigned to the same assignee as that of the present invention); and (C) a thickening agent. In preferred form, such a composition exists in the form of a gel and comprises an enhancer which is a cyclic ester or a cyclic ketone.

('968 patent, 4:3-10) More specifically, "[t]he enhancer of the present invention is a compound of the structural formula:



[2]For example, independent claim 1 of the '608 patent recites in part:

> A method for maintaining a therapeutically effective concentration of testosterone in the blood serum of a male for treating hypogonadism which comprises transdermally delivering to the male by applying to the skin a composition . . . compris[ing]: . . . (B) about 0.5 to about 25 wt. % of a macrocyclic enhancer selected from the group consisting of 3-methylcyclopentadecanone, 9-cycloheptadecen-1-one, cyclohexadecanone, cyclopentadecanone, oxacyclohexadecan-2-one and mixtures thereof.

('608 patent 23:32-24:7)

wherein X and Y are oxygen, sulfur or an imino group . . . . ('968 patent, 6:20-37)

A large number of enhancers were known in the art at the time of the filing and prosecution of the '968 patent.

> The ability of an androgen gel to deliver androgen effectively is often dependent on whether an enhancer, that is, a material which is capable of increasing the rate of passage of androgen through the skin or other body membrane, is used and the type of enhancer used. Examples of topical androgen gels include those described in U.S. Pat. No. 5,968,919 to Samour et al. and U.S. Pat. No. 6,503,894 to Dudley et al. The '919 patent describes a topical testosterone gel comprising also a dioxolane or a dioxane compound which functions as an enhancer. The topical testosterone gel described in the '894 patent (sold as AndroGel® by Solvay Pharmaceuticals, Inc., Marietta, Ga., U.S.A.) also contains an enhancer, namely, isopropyl myristate.
>
> Disadvantages associated with the aforementioned topical androgen gels include, for example, the inconsistency of the gels and the lack of emollient properties; their use leads to drying of the skin and skin irritation. In addition, the gel of the '894 patent is capable of delivering a relatively low amount of testosterone through the skin and the gel of the '919 patent contains an enhancer which tends to irritate the skin.

('968 patent, 3:17-59)

U.S. Pat. No. 6,503,894 (the '894 patent) describes straight chain enhancers which are a "functional derivative of a fatty acid, which includes isosteric modifications of fatty acids or non-acidic derivatives of the carboxylic functional group of a fatty acid or isosteric modifications thereof" ("Dudley enhancer"). ('894 patent, 12:35-39) The '894 patent provides a non-limiting list of Dudley enhancers, with four to twenty-four carbon atoms. ('894 patent, 39-59) Defendant's formulation uses a combination of three non-cyclic, straight chain, Dudley enhancers - oleyl alcohol, methyllaurate and

diisopropyl adipate. (D.I. 27 at 13)

The '968 patent initially claimed "a Hsieh enhancer" as the enhancer used in the composition, with a dependant claim referring specifically to oxacyclohexadecan-2-one.[3] (D.I. 28, ex. 1 at 3-4) During patent prosecution, the inventors narrowed their claims to a single Hsieh enhancer, oxacylohexadecan-2-one, to overcome rejections by the USPTO.[4]

The patentee specifically distinguished Dudley enhancers throughout prosecution of the '968 patent. For example:

> Claims 40-47, 57-72, and 74-80 have been rejected under 35 U.S.C. § 103(a) as being obvious based on the

---

[3]Pending claims recited:

> 40. A method for delivering at least one androgen to a patient in need thereof comprising the step of administering to said patient a composition comprising: (A) an androgen; (B) a Hsieh enhancer; and (C) a thickening agent.
>
> 62. A method according to Claim 40 wherein said enhancer is oxacyclohexadecan-2-one.

(D.I. 28, ex. 1 at 4, 5)

[4]The patentee argued:

> Reference is made to the Examiner's "Interview Summary," mailed June 19, 2007, which indicates the allowability of the claims (that is, the elected method claims) if the claims are amended to define the composition which is referred to in the claims as containing oxacyclohexadecan-2-one (hereafter OXA-2-one), which is the enhancer referred to in dependent claim 62, and testosterone. By virtue of the present claim amendments, all pending claims now define the composition as containing testosterone and OXA-2-one.

(D.I. 28, ex. 5 at 9)

> disclosure of Dudley et al. (U.S. Patent No. 6,503,894-hereafter "Dudley et al.") in view of the disclosure of Hsieh (U.S. Patent No. 5,023,252 -hereafter "the Hsieh patent"). Applicant traverses respectfully.
> . . .
> As recognized by the Examiner, applicant's claims distinguish over the Dudley et al. disclosure at least in the respect of defining the enhancer as a "Hsieh" enhancer, that is, an enhancer which, as acknowledged by the Examiner, is different from the Dudley et al. enhancer.
> . . .
> This evidence includes test data demonstrating the superiority of the use of applicant's claimed development relative to the use of a composition encompassed by and, indeed exemplified by a specific embodiment of, the Dudley et al. development . . . .
> . . .
> As can be seen readily from Figure 1, the development defined in the present claims provides for testosterone delivery that is superior, and indeed, unexpected, compared to that which may be attained using a composition as disclosed by Dudley et al.

(D.I. 28, ex. 1 at 19-21)

The patentee limited the claims of the '605 patent, '606 patent, '607 patent, and '609 patent to oxacylohexadecan-2-one and the claims of the '608 patent and the '610 patent to oxacylohexadecan-2-one and the four closely-related compounds. (D.I. 28, ex. 9-14) During the prosecution of the '518 patent, the patentee amended the claims to recite only oxacylohexadecan-2-one to overcome the examiner's rejections. (D.I. 28, ex. 8 at 6) Similarly, for the '690 patent and '029 patent, the patentee initially broadly claimed Hsieh enhancers, but amended the claims to specifically recite oxacylohexadecan-2-one and the four closely-related compounds. (D.I 28, ex. 15-16; 17 at 5; ex. 18 at 2; ex. 19 at 2; ex. 20 at 2; ex. 21 at 2)

B. Analysis

The claims of the patents-in-suit focus narrowly on one or a subset of five cyclic Hsieh enhancers. The specification describes the family of cyclic Hsieh enhancers and recites the cyclic structures. Plaintiffs assert that their narrow claims directed to specific cyclic enhancers nevertheless should cover defendant's formulation, which uses a combination of three straight chain Dudley enhancers. The court disagrees. Plaintiffs cannot now use the doctrine of equivalents to reach beyond what is claimed and described in the patents-in-suit. *See W.M. Wrigley Jr. Co. v. Cadbury Adams USA LLC*, 683 F.3d 1356, 1365-66 (Fed. Cir. 2012) (when a specification narrowly describes a particular group of chemical compounds and the claims themselves are narrowly drawn to a subset thereof, the patentee may not "expand the coverage of its patent" using the doctrine of equivalents to include other structurally dissimilar compounds); *Festo Corp. v. Shoketsu Kinzoku Kogyo Kabushiki Co.*, 493 F.3d 1368, 1379 (Fed. Cir. 2007) ("*Festo XIII*") ("The theory of the doctrine of equivalents is that an applicant through the doctrine of equivalents should only be able to protect the scope of his inventions, not to expand the protectable scope of the claimed invention to cover a new and unclaimed invention.") (citing *Wilson Sproting Goods Co. v. David Geoffrey & Assocs.*, 904 F.2d 677, 684 (Fed. Cir. 1990)).

Plaintiffs contend that they are justified in relying on the doctrine of equivalents because they can prove that the Hsieh enhancers are equivalent to the Dudley enhancers. The court recognizes that in *Abraxis BioScience, Inc. v. Mayne Pharma Inc.*, 467 F.3d 1370 (Fed. Cir. 2006), the Federal Circuit held that the patentees in that case were not precluded from relying on the doctrine of equivalents to argue that

"DTPA was an equivalent of edetate,"[5] when the patentees did not clearly and unmistakably give up DTPA during prosecution and DTPA was unforeseeable at the time of the invention. *Id.* at 1381; *see also Kinzenbaw v. Deere & Co.*, 741 F.2d 383, 389 (Fed. Cir. 1984) ("The doctrine of equivalents is designed to protects inventors from unscrupulous copyists and unanticipated equivalents.").

Contrary to the situation in *Abraxis*, in the case at bar, a large number of enhancers were known in the art, many of which the patentees referenced in their specification. The patentees specifically discussed the straight chain Dudley enhancers in the specification and, thereafter, differentiated the cyclic Hsieh enhancers. The patentees then argued during prosecution that their invention was not obvious in light of Dudley enhancers, because of the differences between the types of enhancers and the superiority of their Hsieh enhancer compositions. Consequently, the Dudley enhancers (and combinations thereof)[6] were foreseeable alternatives to Hsieh enhancers and, given the record at bar, a competitor would reasonably believe that the patentees had surrendered enhancers other than Hsieh enhancers. *See, e.g., Cordis Corp. v. Medtronic AVE, Inc.*, 511 F.3d 1157, 1177 (Fed. Cir. 2008) ("the statements in question

---

[5]Edetate and DTPA are both compounds belonging to "a broad class of structurally analogous compounds known as polyaminocarboxylic acids." *Id.* at 1379-81 & n.7.

[6]Plaintiffs' argument that the particular combination of three Dudley enhancers used by defendant was unforeseeable is inapposite. The Dudley enhancers were known in the art, as was the use of enhancers in combination. "An equivalent is foreseeable if one skilled in the art would have known that the alternative existed in the field of art as defined by the original claim scope, even if the suitability of the alternative for the particular purposes defined by the amended claim scope were unknown." *Festo XIII*, 493 F.3d at 1382.

must be such that 'a competitor would reasonably believe that the applicant had surrendered the relevant subject matter.'") (citing *Cybor Corp. v. FAS Techs., Inc.*, 138 F.3d 1448, 1457 (Fed. Cir. 1998)); *Augustine Med., Inc. v. Gaymar Indus. Inc.*, 181 F.3d 1291, 1299 (Fed. Cir. 1999) (finding that "[t]he specifications and file histories of the Augustine patents contain clear representations that not only define the scope of the "self-erecting" limitation, but also show that the claims cover only convective warming blankets which are "self-erecting"); *Pall Corp. v. Micron Separations, Inc.*, 66 F.3d 1211, 1219, 36 U.S.P.Q.2d 1225, 1230 (Fed. Cir. 1995) ("[A] patentee is estopped from recovering through equivalency that which was deemed unpatentable in view of the prior art.").

VI. CONCLUSION

For the foregoing reasons, the court grants defendant's motion for summary judgment of non-infringement of the patents-in-suit (D.I. 26) and denies as moot plaintiffs' motion to strike the reply brief (D.I. 67). An appropriate order shall issue.