UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY

UNITED THERAPEUTICS CORP., Plaintiff, v. SANDOZ, INC., et al., Defendants.	Civil Action Nos. 12-CV-1617 13-CV-316 **MEMORANDUM AND ORDER**

This matter comes before the Court on a motion for summary judgment by Sandoz, Inc. ("Sandoz") declaring U.S. Patent No. 6,765,117 ('117 patent) invalid since it was previously disclosed in Patent No. 4,668,814 ('814 Patent). (13-316 ECF No. 52; and 12-1617 ECF No. 129). That is, the '117 Patent is invalid since it was anticipated by the prior art as set forth in the '814 Patent about a decade earlier (May 26, 1987).

I.

Summary judgment is appropriate under Fed. R. Civ. P. 56(c) when the moving party demonstrates that there is no genuine issue of material fact and the evidence establishes the moving party's entitlement to judgment as a matter of law. *Celotex Corp. v. Catrett*, 477 U.S. 317, 322-23 (1986). A factual dispute is genuine if a reasonable jury could return a verdict for the non-movant, and it is material if, under the substantive law, it would affect the outcome of the suit. *Anderson v. Liberty Lobby, Inc*., 477 U.S. 242, 248 (1986). The Court may grant summary judgment "only when no reasonable jury could return a verdict for the nonmoving party." *Monon Corp. v. Stoughton Trailers, Inc.*, 239 F.3d 1253, 1257 (Fed. Cir. 2001). In considering a motion for summary judgment, the Court must "view the evidence in a light most

favorable to the party opposing the motion with doubts resolved in the favor of the opponent." *Ethicon Endo-Surgery, Inc. v. U.S. Surgical Corp.*, 149 F.3d 1309, 1315 (Fed. Cir. 1998); *see also Marino*, 358 F.3d at 247 (quoting *Anderson*, 477 U.S. at 255) ("In considering a motion for summary judgment, a district court may not make credibility determinations or engage in any weighing of the evidence; instead, the non-moving party's evidence 'is to be believed and all justifiable inferences are to be drawn in his favor.'"). Evidence in support of summary judgment "is viewed through the prism of the evidentiary standard of proof that would pertain at a trial on the merits." *TriMed, Inc. v. Stryker Corp.*, 608 F.3d 1333, 1339-40 (Fed. Cir. 2010) (internal quotations omitted).

Because a patent is presumed valid under 35 U.S.C. § 282, on summary judgment, the party challenging the patent must present undisputed facts that establish the invalidity of the patent by clear and convincing evidence. *Pozen Inc. v. Par Pharm., Inc.*, 696 F.3d 1151, 1165 (Fed. Cir. 2012). Not only does "the patent challenger bear[] the burden of proving the factual elements of invalidity by clear and convincing evidence[,] [t]hat burden of proof never shifts to the patentee to prove validity." *Pfizer, Inc. v. Apotex, Inc*., 480 F.3d 1348, 1359–60 (Fed. Cir. 2007); see also *Symbol Techs., v. Opticon, Inc*., 935 F.2d 1569, 1580 (Fed. Cir. 1991) (describing the burden of proving invalidity by clear and convincing evidence as "a heavy and unshifting burden.").

The defense of anticipation arises from language in the patent statute (35 U.S.C. §102(b)). The patent statute reads "a person shall be entitled to a patent unless . . . the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of the application for a patent in the United States . . ." 35 U.S.C. § 102(b). See *Schering v. Apotex*, 2012 U.S. Dist. Lexis 83414 *

41. In one hornbook, summary judgment based on the defense of anticipation appears to be a high hill to climb because it usually concerns issues of fact, and it "must submit such clear and convincing evidence of invalidity so that no reasonable jury could find otherwise." See, Fed. Judicial Ctr., Anatomy of a Patent Case 108 (2d ed. 2012). The defense of anticipation is often a question of fact. *Minn. Mining & Mfg. Co. v. Chemque, Inc.*, 303 F.3d 1294, 1301 (Fed. Cir. 2002); *see also*, *Green Edge Enters., LLC v. Rubber Mulch Etc., LLC,* 620 F.3d 1287, 1297 (Fed. Cir. 2010) (summary judgment of anticipation found improper where triable issues existed regarding whether patent claims were disclosed by a prior art reference or were barred by a prior sale). Since the Court must view the motion through the "prism of the evidentiary burden the parties would face at trial," the facts and the credibility of those witnesses asserting same are reviewed to determine whether it meets the rigorous standard.

II.

Procedurally, on December 2, 2011, Sandoz filed ANDA No. 203649 seeking approval to market a pharmaceutical product containing 10 mg/ml treprostinil sodium for the treatment of pulmonary arterial hypertension ("PAH"). This is a a rare and life-threatening disease involving the progressive narrowing and destruction of arteries of the lungs with no known cure. By filing ANDA No. 203649, Sandoz sought approval to market a generic version of United Therapeutics Corp.'s (UTC) REMODULIN® which contains an active pharmaceutical ingredient (API) known as treprostinil, for the treatment of symptoms associated with PAH. On December 7, 2012, Sandoz filed an amendment to its ANDA No. 203649, adding three additional dosages: 1.0 mg/mL, 2.5 mg/mL, and 5.0 mg/mL concentrations of treprostinil sodium. As a result, a second complaint was filed, and there are two law suits covering each and every concentration of Sandoz's treprostinil sodium ANDA products which allegedly infringe claims 1-4 of the'117

patent. As noted above, Sandoz claims that treprostinil was previously disclosed in the prior art within the '814 patent, and accordingly, the '117 patent should be declared invalid by virtue of the defense of anticipation. For the reasons set forth below, the Court finds there are too many disputed facts to grant summary judgment. There are four factual disputes outlined below. The disputed facts are very similar, but from a review of the Statement of Material Facts, they are separately listed.

First, Sandoz argues that in each of the four claims of the '117 patent, the "invention relates to a process for preparing 9-deoxy-PGF1-type compounds (treprostinil) by a process that is stereoselective and requires fewer steps than the prior art." (Exhibit A, '117 patent, Col. 4:23-26). Sandoz furthers that since the '117 patent claims the development of the compound treprostinil there is nothing new within the '117 patent because of the '814 disclosure. In response to that assertion as set forth in the Statement of Material Facts, UTC claims otherwise. UTC acknowledges that treprostinil may have been known, but the limited description of the '117 patent by Sandoz is a glaring "misrepresentation" of the invention as a whole. According to UTC, the Sandoz statement ignores the '117 invention's disclosed stereoselectively produced isomeric compound. According to UTC, each claim requires not only the formula for treprostinil or its derivatives, but the "stereoselectively produced isomeric compound" of treprostinil and the other novel intermediates as a source limitation of the product synthesis. Moreover, UTC contends that each claim is also directed to a source limitation being the novel starting material enyne, an intramolecular cyclization reaction to cyclize the enyne, as well as a novel claimed cyclized claimed intermediate. ('117 patent Col. 21:23-24:65). In short, the stereoselectively produced isometric compound is an important factual difference between the oversimplified statement of Sandoz and UTC's description of the "117 patent.

Second, Sandoz claims the ‘117 patent and the ‘814 patent are the same. In UTC’s response to the Statement of Material Facts, it states the ‘117 patent and the ‘814 patent are substantially different: a) the ’814 patent does not disclose the claimed enyne starting material present in claims 1-4 of the ’117 patent; b) the intramolecular cyclization step disclosed in claims 1-4 of the ’117 patent is not disclosed in the ’814 patent; c) the ’814 patent differs from the ’117 patent invention because it does not disclose a “stereoselectively produced isomeric compound” of treprostinil; d) the overall yield of the treprostinil product of the ’814 patent and the treprostinil product of the ’117 patent are vastly different (Aristoff ¶120-122); and e) the product of the ’814 patent is structurally and/or functionally different than the product of the ’117 patent. As such, these factual disputes present fact questions for the trier of fact to decide.

Third, Sandoz argues that all four claims of the ‘117 patent describe one compound treprostinil. UTC contends Sandoz’s description is wrong or mischaracterized, and states different reasons from those listed above. More specifically, Sandoz alleges that claim 1 is directed to a genus of stereoselectively produced isomeric compounds, but UTC contends Sandoz “mischaracterized” claim 1. UTC argues that Claim 1 is not only directed toward a genus of stereoselectively produced isomeric product compounds according to the molecular formula shown in the claim, it is also a specified process for making such compounds, which comprises a step of cyclizing a starting compound into an intermediate compound via an intramolecular enyne-cyclization. (’117 patent, Col. 21:23-60). Moreover, Claim 1 is also directed toward a genus of starting compounds and a genus of intermediates compound, both specified in the claim, for use in the claimed process. At the very least, the distinctions made by UTC are factually different and must be evaluated at trial.

A fourth area of factual dispute concerns the scope of the prior art. The parties agree that

there was some prior art in circulation before the issuance of the ‘117 Patent. That prior art includes (a) the ‘814 patent disclosing a class of compounds having a certain structure that includes treprostinil; (b) European Patent Publication No. 0159784 (“EP ’784”) containing treprostinil and a substantially similar process for making treprostinil disclosed in Example 3 of the ’814 patent; and (c) Numerous other prior art references disclosing treprostinil and processes for making treprostinil, including U.S. Patent No. 5,153,222 at Col. 3:1-19, Col. 5:55-Col. 6:39, Col. 6:51-63, U.S. Patent No. 4,306,075 at Col. 62:4-39, Col. 97:46-47; and Aristoff, et al., “Synthesis and Structure-Activity Relationship of Novel Stable Prostacyclin Analogues,” Adv. In Prostaglandin, Thromboxane and Leukotriene Research, Vol. 11, pp. 267-74 (1983).

While Sandoz argues the articles squarely resolve the anticipation argument in its favor, UTC claims that the ‘117 patent is different from each article because none of the alleged prior art discusses the “stereoselectively produced isomeric compounds” resulting from cyclizing a starting enyne compound. UTC outlines why the prior art is different from the ‘117 patent. To UTC, the ‘117 patent requires not only the formula for treprostinil, but the “stereoselectively produced isomeric compound” of treprostinil and further identifies novel intermediates as a source limitation of the product synthesis. (Id.; Aristoff ¶ 82). To UTC, the term “stereoselectively produced” refers to the compound – and not the process – because it reflects the purity and yield, which are characteristics of the product. (Aristoff ¶ 81; Aristoff Tr. 153:16-154:8; 183:6-19; 186:22-187:6). This includes the structural and functional differences of the source material, the enyne and the way it is produced by intramolecular cyclization of enyne precursors.” (Aristoff Tr. 184:21-185:10; 187:14-22). Thus, the structure of the product of the claims within the ’117 patent are different from the alleged prior art because of the large presence of impurities that result in the ‘814 product.

Here, there are questions of fact as to whether the previously issued '814 patent was prior art. Obviously, the experts of the parties cannot agree. Aristoff opines that the '814 patent does not disclose the requirement of a "stereoselectively produced isomeric compounds" upon which the '117 patent relies. On the other hand, Sandoz's expert simply argues that all four claims of the '117 patent revolve around the development of treprostinil just as it was published in the "814 patent. These opinions could not be farther apart. As a result, the opinions of two experts must be weighed as fact questions best determine at trial. Moreover, the structural differences of the '814 patent and the '117 patent in terms of impurities, and the theoretical and actual yields of products should be weighted against each other to determine whether the '117 product is different.

In conclusion, there are fact questions which must be resolved by a fact finder. The motion to dismiss due to anticipation is denied.

ORDER

This matter having come before the Court on a motion for summary judgment by Sandoz, Inc. ("Sandoz"); and for the reasons set forth above;

IT IS on this 9th day of April, 2014

ORDERED that the motion for summary judgment (13-316 ECF No. 52; and 12-1617 ECF No. 129) is denied.

s/Peter G. Sheridan
PETER G. SHERIDAN, U.S.D.J.