NOT FOR PUBLICATION

UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY

SCHERING CORP., ET AL., Plaintiffs, v. GLENMARK PHARMACEUTICALS, INC. USA, ET AL., Defendants.	CIVIL ACTION NO. 07-1334 (JLL) **OPINION**

LINARES, District Judge.

This matter comes before the Court by way of Defendant Glenmark's motion for partial summary judgment of invalidity of claims 1-5 and 7-13 based on double patenting. Plaintiff Schering ("Schering") opposes the motion. This Court has considered the submissions made in support of and in opposition to the motion and decides this matter without oral argument pursuant to Rule 78 of the Federal Rules of Civil Procedure. For the reasons set forth below, the Court denies Glenmark's motion for partial summary judgment.

I. FACTS

The '365 patent includes process claims only. (Def. Supp. Fact Statement ¶ 20). The claimed process of the '365 patent is described in the specification as "Method A" which produces azetidinone compounds of interest, including ezetimibe. (Id. ¶23). The '365 specification describes processes other than "Method A" for making the compounds of interest, but they are not claimed in the '365 patent. (Pl's Resp. St. of Facts at ¶¶ 28 & 29). The '365 patent does not claim any compounds or any method of use of compounds. (Id. ¶ 8). The '721 patent claims azetidinone compounds, including ezetimibe, but does not claim any processes. (See Def.'s Br. at 16; See also Pl.'s Br at 12).

II. LEGAL STANDARD

A court shall grant summary judgment under Rule 59(c) of the Federal Rules of Civil Procedure "if the pleadings, the discovery and disclosure materials on file, and any affidavits show that there is no genuine issue as to any material fact and that the movant is entitled to judgment as a matter of law." Fed.R.Civ.P. 56(c). The moving party first must show that no genuine issue of material fact exists. Celotex Corp. v. Catrett, 477 U.S. 317, 323 (1986). The burden then shifts to the non-moving party to present evidence that a genuine issue of material fact compels a trial. Id. at 324. The Court must consider all facts presented and the reasonable inferences drawn from them in the light most favorable to the non-moving party. See Pa. Coal Ass'n v. Babbitt, 63 F.3d 231, 236 (3d Cir.1995).

A patent is presumed to be valid, and each of its claims are presumed valid independent of the validity of other claims. 35 U.S.C. § 282. A party asserting the invalidity of a patent or one or more of its claims has the burden of establishing such invalidity by clear and convincing evidence. Id.; Bausch & Lomb, Inc. v. Barnes-Hind/Hydrocurve, Inc., 796 F.2d 443, 446 (Fed.Cir.1986). "It is black letter law that the ultimate question of obviousness is a question of law." Richardson-Vicks Inc. v. Upjohn Co., 122 F.3d 1476, 1479 (Fed. Cir. 1997).

III. DISCUSSION

There are two forms of double patenting: statutory and non-statutory. Perricone v. Medicis Pharm. Corp., 432 F.3d 1368, 1372 (Fed. Cir. 2005). Defendant's motion concerns non-statutory double patenting. Non-statutory double patenting, also referred to an "obviousness-type" double patenting, is a judicially created doctrine. A claim is invalid under obvious- type double patenting if it is merely an obvious variation of the earlier claim as considered from the vantage point of an ordinarily skilled artisan. In re Baseel Poliotefine Italia S.p.A., 547 F.2d 1371 (Fed. Cir. 2008). Obviousness-type double patenting is a two step analysis. First the court must construe the claims of the patents in issue and identify any differences. Second, the court determines whether those differences render the claims patentably distinct. Eli Lilly & Co. v. Barr Labs., Inc., 251 f.3d 955, 968 (Fed. Cir. 2001). "A later patent is not patentably distinct from an earlier patent claim if the latter claim is obvious over, or anticipated by, the earlier claim." Id. at 968 (citing In re Longi, 759 F.2d 887, 896 (Fed. Cir. 1985)).

1. Prong One: Claim construction and comparison.

First, the court must construe the claims of the patents in issue and identify any differences. Eli Lilly & Co. v. Barr Labs., Inc., 251 f.3d 955, 968 (Fed. Cir. 2001). For purposes of this motion, based on the parties statements of facts submitted to the Court, the Court construes the claims of the '365 patent to be "process" claims directed to methods of preparing azetidinone compounds, including ezetimibe. (See Def. Supp. Fact Statement ¶ 20). The Court has already construed the claims of the '721 patent cover numerous compounds, including ezetimibe. The Court construes the claimed processes of the '365 patent as processes to create the claimed compounds of the '721 patent.

2. Prong Two: Are the claims patentably distinct?

Second, the court must determine whether those differences render the claims patentably distinct. Eli Lilly & Co. v. Barr Labs., Inc., 251 f.3d 955, 968 (Fed. Cir. 2001). Although in dicta, the Federal Circuit has stated that "product and process claims are patentably distinct if multiple processes for creating a product exist at the time of invention." See Takeda Pharmaceutical Co., Ltd. v. Doll, 561 F.3d 1372, 1373 (Fed. Cir. 2009) (citing In re Cady, 77 F.2d 106, 109 (C.C.C.P.A 1935) (see also In re Taylor, 360 F.2d 232, 236 (Fed. Cir. 1966) (finding that double patenting does not necessarily exist where a process produces a product that is claimed in a later claim). In Takeda, the precise issue before the Court was "whether later developed alternative processes are relevant in the product-process 'patentably distinct' inquiry." Takeda Pharmaceutical, 561 F.3d at 1375. Ultimately, the Court held that

> the relevant time frame for determining whether a product and process are 'patentably distinct' should be at the filing date of the secondary application. This approach allows an applicant to rely on some later-developed methods to show that the product and process are 'patentably distinct,' even though the alternative processes for making that product may not have been known at the filing date of the primary application. This rule gives the applicant the benefit of future developments in the art.

Takeda Pharmaceutical Co., Ltd. v. Doll, 561 F.3d 1372, 1377 (Fed. Cir. 2009). The Court notes that even though the Federal Circuit's holding in Takeda was not directed at the precise issue before this Court, its reasoning in support of its ultimate holding supports the conclusion that if multiple processes for creating a product exist at the time of the invention, then the product and

the process are patentably distinct. If when determining whether multiple processes for creating a product exist at the time of invention a Patentee is allowed the benefit of future developments up until the filing of the secondary application, then it logically follows that a Patentee must enjoy the benefit of the art at the time of invention.

Here, Schering alleges that in addition to the "Method A" process claimed in the '365 patent, the specification also describes other processes for making . . . the compounds of interest." (Def. Resp. Fact Statement ¶ 28). Glenmark, solely for purposes of this motion, does not dispute this, Glenmark fails to provide clear and convincing evidence that these alternative processes were ineffective to produce the compound at issue. Id. Therefore, the Court finds that a material issue of facts exists with regard to whether multiple processes to create ezetimibe existed at the time of invention. As such, Glenmark's motion for summary judgment on this ground is DENIED.

IV. CONCLUSION

For the foregoing reasons, Glenmark's motion for partial summary judgment of invalidity of claims 1-5 and 7-13 based on double patenting is DENIED.

An appropriate order accompanies this Opinion.

DATED: April 19, 2010

/s/ Jose L. Linares
UNITED STATES DISTRICT JUDGE