NOT FOR PUBLICATION

UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY

GILEAD SCIENCES, INC., HOFFMANN-LAROCHE INC., F. HOFFMANN-LA ROCHE LTD. and GENENTECH, INC., Plaintiffs, v. NATCO PHARMA LIMITED and NATCO PHARMA INC., Defendants.	Civil Action No. 11-CV-1455 (SDW-MCA) Consolidated with Civil Action No. 11-CV-4969 (SDW-MCA) **OPINION** December 21, 2012

WIGENTON, District Judge.

Before this Court is Plaintiffs Gilead Sciences, Inc., Hoffmann-La Roche Inc., F. Hoffmann-La Roche Ltd. and Genentech, Inc.'s motion for summary judgment pursuant to Federal Rule of Civil Procedure 56 and Defendants Natco Pharma Limited and Natco Pharma Inc.'s cross-motion for summary judgment also pursuant to Federal Rule of Civil Procedure 56. This Court, having considered the parties' submissions, decides this matter without oral argument pursuant to Federal Rule of Civil Procedure 78. For the reasons stated below, this Court **GRANTS** Plaintiffs' motion and **DENIES** Defendants' motion.

I. BACKGROUND

This case concerns a dispute between Plaintiffs Gilead Sciences, Inc., Hoffmann-La Roche Inc., F. Hoffmann-La Roche Ltd. and Genentech, Inc. ("Gilead") and Natco Pharma Limited and Natco Pharma Inc. ("Natco") over access to a patented pharmaceutical product. Gilead owns the patent at issue and seeks to prevent Natco from marketing a generic version of Gilead's patented product. The narrow issue before this Court concerns whether,

between two closely related patents, the later-issued but earlier-expiring patent can be used as a reference patent to invalidate the earlier-issued and later-expiring patent.

II. FACTS

Researchers at Gilead Sciences Inc., led by Dr. Choung Kim, developed Oseltamivir, a highly potent neuraminidase inhibitor. (*See* Pls.' Statement of Uncontested Material Facts ("Pls.' Facts") ¶ 9.) Oseltamivir was developed in response to the "need for a potent and safe anti-influenza agent that could be used to treat a wide range of influenza strains, and be administered orally." (Pls.' Opening Mem. in Supp. of Motion for Summ. J. ("Pls.' Br. in Supp.") 2.) Oseltamivir is "the first of its kind to be orally bioavailable; having [an] excellent safety profile; and [is] broadly effective against various flu types." (*Id.*) In June 1999, the United States Food and Drug Administration ("FDA") approved Oseltamivir, which is currently marketed as TAMIFLU®. (*See* Pls.' Facts ¶ 9.) U.S. Patent No. 5,763,483 (the "'483 patent"), titled Carbocylic Compounds, is assigned to Gilead Sciences, Inc. (*See* Pls.' Facts ¶ 24.) The '483 patent "covers TAMIFLU® (oseltamivir phosphate), its metabolite (oseltamivir carboxylate), oseltamivir-based formulations, methods of inhibiting neuraminidase and treatment or prophylaxis of influenza infection." (Pls.' Br. in Supp. 3-4)(citing Pls.' Facts ¶ 5-6). The '483 patent issued from non-provisional application 08/774,345 (the "'345 application"), which claimed the benefit of priority to provisional application 60/009,306 (the "'306 application"), which was filed on December 29, 1995. (*See* Pls.' Facts ¶ 26.) The '483 patent issued on June 9, 1998, which is before any other patent in the Oseltamivir patent family was issued. (*See id.*)

U.S. Patent No. 5,952,375 (the "'375 patent") and U.S. patent No. 5,866,601 (the "'601 patent") issued on September 14, 1999 from a series of continuation-in-part ("CIP") applications (collectively the "'245 CIP family"). (*See* Pls.' Facts ¶ 13.) The earliest of the '245 CIP family

was application 08/395,245 (the "'245 application"), which was filed on February 27, 1995. (*See id.*) The '375 patent and the '601 patent both claim priority to: (1) the '245 application; (2) CIP application 08/476,946 (the "'946 application"), which was filed on June 6, 1995, and issued as the '601 patent; (3) and CIP application 08/580,567 (the " '567 application"), which was filed on December 29, 1995. (*See id.* at ¶ 14.) Application 08/606,624 (the " '624 application") was filed on February 26, 1996 as a CIP of the '567 application. (*See id.* at ¶ 21.) The '624 application eventually issued as the '375 patent. (*See id.*) The '375 patent is also assigned to Gilead Sciences, Inc. (*See id.*at ¶ 11.) The '483 patent, '375 patent, and '601 patent are listed in the FDA's Approved Drug Products with Therapeutic Equivalence Evaluations (commonly referred to as the "Orange Book") as patents for TAMIFLU®. (*See* Pls.' Facts ¶ 27.) Only the '375 and'483 patents are relevant to this opinion.

On February 2, 2011, Natco sent a letter to Gilead, pursuant to 21 U.S.C. § 355(j)(2)(vii)(IV), making Defendants aware that Natco filed Abbreviated New Drug Application ("ANDA") No. 202-595 with the FDA seeking approval to market a generic version of TAMIFLU® 75 mg oseltamivir phosphate prior to the expiration of the '483 patent. (*See* Pls.' Facts ¶ 2.) On March, 15, 2011, Gilead filed a complaint in this Court against Natco, alleging, *inter alia*, that Natco's filing of an ANDA infringed on the '483 patent. (*See id.* at ¶ 3; Dkt. no. 1.) On August 5, 2011, Natco notified Gilead that it submitted an amended ANDA seeking a generic version of TAMIFLU® but for dosages of 30mg and 45 mg instead of 75mg. (*See id.* at ¶ 4.) On August 29, 2011, Gilead filed another complaint against Natco alleging that Natco's amended ANDA also infringed on the '483 patent. (*See id.*) On September 30, 2011, Natco filed its answer and counterclaims, alleging, *inter alia*, that the claims of the '483 patent are invalid due to obviousness-type double-patenting, thereby negating Gilead's claim of patent

infringement. (*See id.* at ¶ 5.) Also, Natco alleged that the '375 is the reference patent for its claim of double-patenting. (*See id.*) On January 20, 2012, Natco provided Gilead with its Invalidity and Non-Infringement Contentions, wherein Natco asserted that the claims of the '483 patent are invalid due to obviousness-type double-patenting of claim eight of the '375 patent. (*See id.* at ¶ 6.)

III. LEGAL STANDARD

Summary judgment shall be granted "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). A factual dispute is genuine if a reasonable jury could return a verdict for the nonmovant, and it is material if, under the substantive law, it would affect the outcome of the suit. *See Anderson v. Liberty Lobby, Inc.*, 477 U.S. 242, 248 (1986). The moving party must show that if the evidentiary material of record were reduced to admissible evidence in court, it would be insufficient to permit the nonmoving party to carry its burden of proof. *See Celotex Corp. v. Catrett*, 477 U.S. 317, 322-23 (1986).

Once the moving party meets the initial burden, the burden then shifts to the nonmovant who must set forth specific facts showing a genuine issue for trial and may not rest upon the mere allegations or denials of its pleadings. *See Shields v. Zuccarini*, 254 F.3d 476, 481 (3d Cir. 2001). The court may not weigh the evidence and determine the truth of the matter but rather should determine whether there is a genuine issue as to a material fact. *See Anderson*, 477 U.S. at 249. In doing so, the court must construe the facts and inferences in "a light most favorable" to the nonmoving party. *Masson v. New Yorker Magazine, Inc.*, 501 U.S. 496, 521 (1991). The nonmoving party "must present more than just 'bare assertions, conclusory allegations or suspicions' to show the existence of a genuine issue." *Podobnik v. United States Postal Serv.*,

409 F.3d 584, 594 (3d Cir. 2005) (quoting *Celotex Corp.*, 477 U.S. at 325). If the nonmoving party "fail[s] to make a sufficient showing on an essential element of [its] case with respect to which [it] has the burden of proof," then the moving party is entitled to judgment as a matter of law. *Celotex Corp.*, 477 U.S. at 323.

IV. DISCUSSION

Obviousness-type double-patenting is a judicially created doctrine that seeks to preclude an inventor from unjustifiably extending patent protection past the statutory limit. *See In re Berg*, 140 F.3d 1428, 1431-32 (Fed. Cir. 1998). "It requires rejection of an application claim when the claimed subject matter is not patentably distinct from the subject matter claimed in the commonly owned patent." *See id.* (citing *In re Braat*, 937 F.2d 589, 592 (Fed. Cir. 1991). The obviousness-type double-patenting inquiry requires a two-step analysis: "[f]irst, as a matter of law, a court construes the claim in the earlier patent and the claim in the later patent and determines the differences." *Eli Lilly & Co. v. Barr Labs., Inc.*, 251 F.3d 955, 968 (Fed. Cir. 2001). Second, a court must decide if the differences between the two claims demonstrate patentable distinction. *See id.* Regarding the second step, a later claim is "not patentably distinct from an earlier patent claim if the later claim is obvious over, or anticipated by, the earlier claim." *Eli Lilly*, 251 F.3d at 968. The party asserting the defense of obviousness-type double-patenting must prove it by clear and convincing evidence. *See Symbol Tech., Inc. v. Opticon, Inc.*, 935 F.2d 1569, 1580 (Fed. Cir. 1991). While, on a macro level, the dispute between the parties concerns the issue of double-patenting, the narrow issue before this Court is whether the '375 patent can be used as a reference patent for purposes of determining if the '483 patent is an unlawful extension of the '375 patent.

Important to this Court's consideration of the present issue is a brief discussion of the change in patent law concerning patent terms. The Uruguay Round Agreements Act of 1994, which became effective on June 8, 1995, changed the term for a U.S. patent from seventeen years from the patent issue date to twenty years from the earliest effective filing date. *See* Uruguay Round Agreements Act, Pub.L. No. 103-465, § 532(a), 108 Stat. 4809, 4983-85 (1994). Patents that issued prior to June 8, 1995 expire on the later of two dates: either (1) seventeen years from the issue date or (2) twenty years from the effective filing date. Patents issued after June 8, 1995 have a twenty year term set from the earliest effective filing date.

Here, Natco argues that the '375 patent can serve as a double-patenting reference for the '483 patent. (*See* Defs.' Opp'n to Pls.' Summ. J. Mot. And Br. in Supp. of Defs.' Cross-Mot. for Partial Summ. J. ("Defs.' Opp'n" 6-7.) Following that premise, Natco also argues that the '483 patent unlawfully extends the terms of the '375 patent. (*See* id. 4-5.) Gilead contends that Natco's positions are untenable given the existing case law regarding obviousness-type double-patenting. (*See* Pls.' Opening Mem. In Supp. 2.) More specifically, Gilead argues that the '375 patent cannot serve as a reference for double-patenting because it issued after the '483 patent and terminates before the '483; thereby not making the '483 patent an unlawful extension of the '375 patent. (*See id.* at 10-12.)

Gilead relies on two district court decisions to support its contention that the '375 patent cannot serve as double-patenting reference for the '483 patent: (1) *Abbott Labs. v. Lupin Ltd.*, Civ. A. No. 09-152,-LPS, 2011 WL 1897322 (D. Del. May 19, 2011) and (2) *Brigham & Women's Hosp. Inc. v. Teva Pharm. USA, Inc.*, 761 F. Supp. 2d 210 (D. Del. 2011). In both cases the district court in the district of Delaware had to address whether a later-issued but earlier-expiring patent can serve as a double-patenting reference against an earlier-issued but

later-expiring patent. Both times, the Delaware district court held that a later-issued but earlier-expiring patent cannot be used as an invalidating reference against an earlier-issued but later-expiring patent because logically a later-issued patent cannot be extended by a patent that was already in existence. *See Abbott Labs.*, 2011 WL 1897322 at * 8; *Brigham & Women's Hosp. Inc.*, 761 F. Supp. 2d at 226. Similarly here, the '375 patent cannot serve as a reference patent as it issued after and terminates before the '483 patent. Therefore the '483 does not unlawfully extend Gilead's right to exclusivity.

In both cases, the district court also found that the extensions of the patent terms at issue were not unlawful because the extensions were not a result of gamesmanship, but instead were a result of changes to patent laws. *See Abbott Labs.*, 2011 WL 1897322 at 10; *Brigham & Women's Hosp. Inc.*, 761 F. Supp. 2d at 225. Natco argues that Gilead obtained the '483 patent in part because Gilead failed to disclose the '624 application, which ultimately issued as the '375 patent, to the United States Patent and Trademark Office ("PTO"). (*See* Natco Opp. Br./Br. in Supp. of Cross-Motion ("Natco Opp. Br.") 5.) Natco highlights this nondisclosure because the '567 application, the parent application to the '624 application, contained a similar disclosure to the '306 provisional application, which is the parent application for the '483 patent. (*See* Natco's L.R. 56.1 Statement of Uncontested Facts ("NSOF") ¶ 4; Decl. of Diane C. Ragosa ("Ragosa Decl.") 11.) Natco contends that had the PTO known about the '375 patent application, the patent examiner "would have conditioned the allowance of the '483 patent on Gilead terminally disclaiming any term of the '483 patent that extended beyond twenty years after the filing date of the '375 patent. (Defs.' Opp'n 5.) Natco's argument, however, is ineffective.

Gilead notified the PTO of the ’375 patent family of applications, including the ’567 application, which contained a similar disclosure to the ’306 provisional application. (*See* Gilead’s Reply Br. 8.) Therefore, the nondisclosure of the ’624 application, though it also contained a similar disclosure to the ’306 provisional application, is not detrimental to Gilead’s case because of Gilead’s disclosure of the ’567 application. Similar to *Abbott Labs.* and *Brigham*, the lifespan of Gilead’s patents seem to be a result of changes in patent law, and not any gamesmanship from Gilead. Since the issuance of the ’483 patent is not the result of any strategic abuse of the patent system by Gilead, the ’375 patent cannot serve as a reference patent to invalidate the ’483 patent because of obviousness-type double-patenting.

V. CONCLUSION

For the reasons set forth above, Plaintiffs’ motion for summary judgment is **GRANTED** and Defendants’ cross-motion is **DENIED**.

s/Susan D. Wigenton, U.S.D.J.

Orig: Clerk
Cc: Madeline Cox Arleo, U.S.M.J.
Parties