NOT FOR PUBLICATION

UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY

ALTANA PHARMA AG and WYETH, Plaintiffs, v. TEVA PHARMACEUTICALS USA INC., ET AL. Defendants.	CIVIL ACTION NO. 04-2355 (JLL) **OPINION**

LINARES, District Judge.

This matter comes before the Court on Plaintiff Altana Pharma AG's (now known as Nycomed GmbH) and Wyeth's (now known as Wyeth LLC) (collectively, "Plaintiffs") motion for reconsideration of this Court's order denying relief under 35 U.S.C. § 271(e)(4)(A) solely with respect to the KUDCo defendants (hereinafter, "KUDCo").[1] (D.I. 881). KUDCo opposes the motion. No oral argument was held. Fed. R. Civ. P. 78. For the reasons stated below, Plaintiffs' motion is GRANTED.

I. PROCEDURAL BACKGROUND

On February 26, 2007, Magistrate Judge Cecchi consolidated the "KUDCo action" with the previously consolidated Teva and Sun actions "for all purposes." (D.I. 127). A trial was conducted from April 5, 2010 to April 22, 2010. The KUDCo action was tried non-jury, while the Teva and Sun actions were tried to a jury.

On July 16, 2010, this Court rendered a bench opinion in favor of Plaintiffs as to

[1] Schwarz Pharma Inc. and KUDCo Ireland Ltd.

KUDCo. Said opinion resolved all claims, counterclaims, and defenses between Plaintiffs and KUDCo. Accordingly, this Court entered final judgment against KUDCo. (D.I. 874). Also on July 16, 2010, this Court denied Defendant Teva's and Defendant Sun's Rule 50(b) Motions. However, final judgment was not entered with respect to Defendant Teva and Defendant Sun as these parties' unenforceability defenses of patent misuse and unclean hands, as well as several other claims, remained pending before this Court.

On May 20, 2010, Plaintiffs moved for relief under 35 U.S.C. § 271(e)(4)(A) with respect to all Defendants seeking an order mandating that the effective dates of the Abbreviated New Drug Applications ("ANDAs") submitted by them to the U.S. Food and Drug Administration ("FDA") be set for a date after January 19, 2011 when United States Patent No. 4,758,579 ("the '579 patent") and Plaintiffs' pediatric exclusivity[2] period will have expired.

On July 16, 2010, this Court denied said motion with respect to all defendants on the basis that the remaining defendants (Teva and Sun) in this consolidated action had outstanding defenses challenging the enforceability of the patent at issue. (D.I. 873). Plaintiff now seeks reconsideration of that order solely with respect to KUDCo.

II. LEGAL STANDARD

Federal Rule of Civil Procedure 59(e) provides that a party may file a motion with the Court to alter or amend a judgment within ten days of the entry of the judgment. Local Civil Rule 7.1(i) states that a motion for reconsideration "setting forth concisely the matter or controlling decisions which the party believes the Judge or Magistrate Judge has overlooked" may be filed within ten business days after entry of an order. L.Civ.R. 7.1(i).[3] Reconsideration,

[2] Plaintiffs have obtained "pediatric exclusivity" through January 19, 2011. See Pretrial Order ¶¶ 3.C.4, 3.C.5 (D.I. 744).

[3] This rule was previously Local Civil Rule 7.1(g).

however, is an extraordinary remedy and should be granted "very sparingly." See L. Civ. R. 7.1(i) cmt.6(d); see also Fellenz v. Lombard Investment Corp., Nos. 04-3993, 04-5768, 04-3992, 04-6105, 2005 WL 3104145, at *1 (D.N.J. Oct.18, 2005) (citing Maldonado v. Lucca, 636 F.Supp. 621, 630 (D.N.J. 1986)). The motion may not be used to re-litigate old matters or argue new matters that could have been raised before the original decision was reached. See, e.g., P. Schoenfeld Asset Mgmt., L.L.C. v. Cendant Corp., 161 F. Supp 2d 349, 352 (D.N.J. 2001).

There are three grounds for granting a motion for reconsideration: (1) an intervening change in controlling law has occurred; (2) evidence not previously available has become available; or (3) it is necessary to correct a clear error of law or prevent manifest injustice. See, e.g., Carmichael v. Everson, No. 03-4787, 2004 WL 1587894, at *1 (D.N.J. May 21, 2004); Brackett v. Ashcroft, No. Civ. 03-3988, 2003 WL 22303078, at *2 (D.N.J. Oct. 7, 2003).

III. DISCUSSION

a. 35 U.S.C. Section 271(e)(4)(A)

Where a patent holder proves infringement of a valid patent resulting from the filing of an ANDA, 35 U.S.C. Section 271(e)(4)(A) "require[es] the district court to 'order the effective date of any approval of the drug or veterinary biological product involved in the infringement to be a date which is not earlier than the date of the expiration of the patent which has been infringed.'" In re Omeprazole Patent Litigation, 536 F.3d 1361, 1367 (Fed. Cir. 2008).

Plaintiffs argue that "because the judgment against KUDCo is final and complete, Plaintiffs are entitled under the statute to, at a minimum, an order resetting the approval date of KUDCo's ANDA to a date which is not earlier than the expiration of the patent, i.e., July 19, 2010." (Pl. Br. at 1). Plaintiff takes the position that the consolidated nature of this action has no bearing on the Court's analysis with respect to the relief sought as to KUDCo.

KUDCo argues that the Court correctly denied Plaintiffs' original motion because there are pending claims that concern the enforceability of Plaintiffs' patent, namely Defendants' (Teva and Sun) unenforceability defenses of patent misuse and unclean hands.

The language of Section 271(e)(4)(A) requires that a "patent holder prove infringement of a valid patent resulting from the filing of an ANDA." In re Omeprazole Patent Litigation, 536 F.3d at 1367. Here, Plaintiffs and KUDCo stipulated that "KUDCo's submission of the ANDA was an act of infringement of claims 22 and 25 of [the '579 patent], if those claims are valid and enforceable." (D.I. 618). On April 21, 2010, this Court dismissed with prejudice KUDCo's sole counterclaim related to enforceability, namely inequitable conduct. (D.I. 813). Following a non-jury trial, the Court found that KUDCo failed to demonstrate by clear and convincing evidence that the asserted claims of the '579 patent are invalid (D.I. 879) and entered judgment for Plaintiff against KUDCo. (D.I. 874). Therefore, by the terms of the parties' stipulation, KUDCo's submission of the ANDA was an act of infringement of the relevant claims of the '579 patent and 35 U.S.C. Section 271(e)(4)(A) "require[es] [this Court] to 'order the effective date of any approval of the drug . . . involved in the infringement to be a date which is not earlier than the date of the expiration of the patent which has been infringed,'" which is July 19, 2010. In re Omeprazole Patent Litigation, 536 F.3d 1361, 1367 (Fed. Cir. 2008). Accordingly, Plaintiff's motion for reconsideration with respect to Section 271(e)(4)(A) is GRANTED so as to prevent manifest injustice to Plaintiffs.

b. Pediatric Exclusivity

21 U.S.C. Section 355a "provides an incentive for a drug patent holder to conduct studies of a drug which the FDA believes may have beneficial pediatric use. If the FDA requests that the drug patent holder conduct studies to confirm such a use and the patent holder satisfactorily

completes the studies, then the patent holder is eligible to receive a six-month period of market exclusivity for the drug beyond the patent expiration date. This is known as a 'pediatric exclusivity period.'" Apotex Inc. v. U.S. Food and Drug Admin., 508 F.Supp.2d 78, 81 (D.D.C. 2007) (internal citations omitted). In cases where the patent holder is entitled to pediatric exclusivity "the period during which an ANDA may not be approved under section 355(j)(5)(B) 'shall be extended by a period of six months [i.e., the period of pediatric or market exclusivity] after the date the patent expires (including any patent extensions).'" In re Omeprazole Patent Litigation, 536 F.3d 1361. 1368 (Fed. Cir. 2008) quoting 21 U.S.C. §§ 355a(b)(2)(B), 355a(c)(2)(B).

Plaintiffs argue that this Court should issue an order that "the period during which [KUDCo's] ANDA may not be approved under section 355(j)(5)(B) 'shall be extended by a period of six months [i.e., the period of pediatric or market exclusivity] after the date the patent expires,'" i.e., January 19, 2011. Id. Defendant, however, argues that this Court lacks statutory authorization to grant Plaintiffs' request and that any such extension must come from the FDA.

Here, it undisputed that Plaintiffs have been awarded a period of pediatric exclusivity that expires on January 19, 2011. (D.I. 744). Although the statute governing pediatric exclusivity, 12 U.S.C. Section 355a, does not explicitly grant this Court the authority to reset the effective date of KUDCo's ANDA, several district courts have granted such relief under § 271(e)(4)(A). See,e.g., Alcon, Inc. v. Teva Pharmaceuticals USA, Inc., No. 06-234, 2010 WL 3081327, at *1 (D. Del. Aug. 5, 2010) ("[I]t is appropriate for the court to order that the FDA not approve ANDA No. 78-073 until [six months after the date the patent expires]."). See also, Final Judgment Order, Takeda Pharma. Co. v. Teva Pharma.USA, Inc., 1:06-cv-33 (D. Del. Apr. 15, 2008) ("Pursuant to 35 U.S.C. § 271(e)(4)(A), the effective date of any Food and Drug

Administration approval of Teva's ANDA No. 77-255 and ANDA No. 78-730 shall be no earlier than the date of the expiration of claims 10 of the '098 patent and any pediatric exclusivity that applies to the '098 patent, if applicable") See also Astrazeneca AB v. Impax Labs., Inc., 490 F. Supp.2d 368, 379 (S.D.N.Y. 2007), aff'd, In re Omeprazole Patent Litig., 536 F.3d 1361 (Fed. Cir. 2008). Although the precise issue before the Federal Circuit in In re Omeprazole Patent Litigation was whether the district court had jurisdiction to order relief under Section 271(e)(4)(A), the Federal Circuit ultimately affirmed the district court's order setting the effective date of the relevant ANDA to the end of the pediatric exclusivity period.

In opposition, KUDCo has failed to cite a case declining to enter the requested relief under the specific facts of this case. Therefore, in light of the fact that Plaintiffs are entitled to pediatric exclusivity, the ample case law supporting this Court's power to enforce grants of pediatric exclusivity, and KUDCo's failure to demonstrate that this Court clearly lacks jurisdiction to enter such an order enforcing this exclusivity, Plaintiffs motion for reconsideration is GRANTED so as to prevent manifest injustice to Plaintiffs. Accordingly, the effective date of any final approval of KUDCo's ANDA 78-281 shall be a date which is not earlier than January 20, 2011, the first day after the date on which Plaintiffs' pediatric exclusivity period ends.

IV. CONCLUSION

For the foregoing reasons, Plaintiffs' motion is GRANTED. An appropriate order accompanies this opinion.

DATED: August 13, 2010

/s/ Jose L. Linares
United States District Judge