UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY

WARNER CHILCOTT COMPANY, LLC, Plaintiff(s), v. LUPIN LTD, et al. Defendant(s).	Civil Action No. 11-5048 (JAP)
WARNER CHILCOTT COMPANY, LLC, Plaintiff(s), v. AMNEAL PHARMACEUTICALS, LLC et al., Defendant(s).	Civil Action No. 12-2928 (JAP) **OPINION**

PISANO, District Judge.

I. INTRODUCTION

These are patent infringement actions brought by plaintiff Warner Chilcott Company, LLC against defendants Lupin Ltd, Lupin Pharmaceuticals, Inc., Amneal Pharmaceuticals, LLC, Amneal Pharmaceuticals of NY, LLC, Inc. with respect to U.S. Patent No. 7,704,984 ("the '984 patent"). A seven-day bench trial was held during the period of October 7 through October 17, 2013, and the issue for trial was defendants' assertion that the '984 patent was

invalid based on obviousness. This Opinion constitutes the Court's findings of fact and conclusions of law. After careful consideration of the evidence before it, the Court finds in favor of Plaintiffs.

II. BACKGROUND

A. The Parties and the Nature of the Case

These are actions for patent infringement under 35 U.S.C. § 271(e)(2)(A). Plaintiff Warner Chilcott Company, LLC ("Warner" or "Plaintiff") is a limited liability company organized and existing under the laws of Puerto Rico. Final Pretrial Order ("FPO") at 4. Warner is the holder of New Drug Application ("NDA") No. 22-501, for Lo Loestrin Fe (referred to herein as "Lo Loestrin"), an oral female contraceptive product.

Defendant Lupin Limited is a corporation organized and existing under the laws of India. *Id.* Defendant Lupin Pharmaceuticals, Inc. is a wholly-owned subsidiary of Lupin Ltd., and is a corporation organized and existing under the laws of the State of Virginia. *Id.* Lupin Ltd. and Lupin Pharmaceuticals, Inc. (collectively, "Lupin") filed an Abbreviated New Drug Application ("ANDA") No. 20-3113 with the U.S. Food and Drug Administration ("FDA") seeking approval to market a product that is the subject of Lupin's ANDA, which Lupin contends is bioequivalent to, and refers to, Warner's Lo Loestrin. Pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV), Lupin's ANDA certified to the FDA that the '984 patent is invalid, unenforceable, and/or will not be infringed by the manufacture, use or sale of Lupin's ANDA Product. FPO at 5. Pursuant to 21 U.S.C. § 355(j)(2)(B), in a letter dated July 19, 2011, Lupin notified Warner that Lupin had filed its ANDA, which included a Paragraph IV Certification with respect to the '984 patent. *Id.*

On September 1, 2011, Warner filed a complaint against Lupin alleging that the filing of Lupin's ANDA infringed the'984 patent under 35 U.S.C. § 271(e)(2)(A). Lupin has since stipulated that the manufacture, use, offer for sale or sale of Lupin's ANDA product within the United States or importation of Lupin's ANDA product into the United States would infringe claims 1-9 of the '984 patent, assuming the claims are not invalid and are enforceable. *Id.* at p. 6. Lupin has asserted counterclaims against Warner alleging that the '984 patent, including all of its claims, are invalid. *Id.*

Amneal Pharmaceuticals of NY, LLC, Inc. and its parent Amneal Pharmaceuticals, LLC (collectively "Amneal") are also defendants in this matter. By Stipulation and Order dated October 7, 2013, Amneal was substituted as a defendant in Civil Action 12-2928 for Watson Laboratories, Inc. ("Watson"). Civ. Action No. 12-2928, D.E. No. 79. Watson had filed an ANDA (No. 20-2982) with the FDA, seeking approval to market a product ("Watson's ANDA Product") that Watson contended is bioequivalent to, and refers to, Lo Loestrin. FPO at 6. Pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV), Watson's ANDA certified to the FDA that the '984 patent is invalid, unenforceable, and/or will not be infringed by the manufacture, use or sale of Watson's ANDA Product. *Id.* Pursuant to 21 U.S.C. § 355(j)(2)(B), in a letter dated April 4, 2012, Watson notified Warner that Watson had filed its ANDA, which included a Paragraph IV Certification with respect to the '984 patent. *Id.* On May 16, 2012, Warner filed the instant action against Watson.

On or about October 1, 2013, Watson sold the ANDA for the Watson ANDA Product to Amneal. *Id.* Amneal has stipulated that it stands in the shoes of Watson for purposes of this litigation. Civ. Action No. 12-02928, D.E. No. 79. Further, Amneal has adopted "everything that Lupin has done through the trial as if Amneal had presented that evidence"

and agreed that "whatever decision comes down in the Lupin case with respect to the validity of the patent-in-suit … will also be entered in the Amneal suit with Warner Chilcott." Tr. 994:14–22.

B. The '984 Patent

The '984 patent, entitled "Extended Estrogen Dosing Contraceptive Regimen" was issued by the United States Patent and Trademark Office on April 27, 2010. FPO at 7-8. The 11/112,290 application that led to the '984 patent was filed on April 22, 2005. *Id.* at 8. Roger M. Boissonneault is the named inventor of the '984 patent. *Id.*

The '984 patent is directed to a method of contraception with three compositions for administration:

- the first composition containing a progestin and ethinyl estradiol;
- the second composition containing only ethinyl estradiol; and
- a final composition containing no active ingredient (progestin or estrogen), but optionally containing an iron supplement.

JTX-1 at col. 2, ll.33−46, col. 3, ll.56−63.

The nine claims of the '984 patent read as follows:

> 1. A method of contraception comprising the steps of sequentially administering to a female of child-bearing age: (a) a first composition containing a progestin in an amount equivalent to about 0.3 to about 1.5 mg norethindrone acetate wherein the progestin is selected from norethindrone acetate or norethindrone and 5 to 15 μg of ethinyl estradiol for 24 days; (b) a second composition containing 5 to 15 μg of ethinyl estradiol and substantially free of a progestin for 2 days; and (c) a third composition that is a placebo,

wherein the sequential administration of the first composition, the second composition and the third composition, is performed on a daily basis over a 28 day cycle.

2. The method according to claim 1, wherein the sequential administration is repeated beginning the day after completion of the 28 day cycle.

3. The method according to claim 1, wherein the progestin in the first composition is norethindrone acetate.

4. The method according to claim 3, wherein the amount of norethindrone acetate in the first composition is about 1 mg.

5. The method according to claim 1, wherein the placebo contains about 75 mg of ferrous fumarate.

6. The method according to claim 4, wherein the amount of ethinyl estradiol in the first and second composition is the same.[1]

7. A method of contraception comprising the steps of sequentially administering to a female of child-bearing age: (a) a first composition containing about 0.3 to about 1.5 mg norethindrone acetate and 5 to 15 μg ethinyl estradiol for 24 days; (b) a second composition containing 5 to 15 μg of ethinyl estradiol and substantially free of progestin for 2 days; (c) a third composition that is a placebo for 2 days, wherein the sequential administration of the first composition, the second composition and the third composition is performed on a daily basis over a 28 day cycle.

[1] As Plaintiff's points out, claim 6 is the narrowest of the claims and if claim 6 is invalid then the patent's other claims are invalid as well.

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