UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY

WARNER CHILCOTT COMPANY, LLC, Plaintiff, v. AMNEAL PHARMACEUTICALS LLC, Defendant.

C.A. No. _____

COMPLAINT FOR PATENT INFRINGEMENT

Plaintiff Warner Chilcott Company, LLC, by its undersigned attorneys, brings this action against Defendant Amneal Pharmaceuticals LLC ("Amneal"), and hereby alleges as follows:

THE PARTIES

1. Plaintiff Warner Chilcott Company, LLC ("Warner Chilcott") is a limited liability company organized and existing under the laws of Puerto Rico, having offices at Union St., Road 195, Km 1.1, Fajardo, Puerto Rico.

2. Upon information and belief, Defendant Amneal Pharmaceuticals LLC is a limited liability company organized and existing under the laws of Delaware, and having a principal place of business at 400 Crossing Boulevard, Third Floor, Bridgewater, NJ 08807-2863.

3. Upon information and belief, Amneal is in the business of development, manufacturing, marketing, distributing, and directly and/or indirectly selling generic pharmaceutical products throughout the United States, including in this judicial district.

JURISDICTION AND VENUE

4. This is an action for patent infringement arising under the patent laws of the United States, 35 U.S.C. § 271(e)(2) and 21 U.S.C. § 355. This Court has subject matter jurisdiction over this action based on 28 U.S.C. §§ 1331 and 1338(a).

5. This Court has personal jurisdiction over Amneal Pharmaceuticals LLC at least because it has agreed not to contest personal jurisdiction in this judicial district, and has its principal place of business in Bridgewater, NJ.

6. Venue is proper in this Court under 28 U.S.C. §§ 1391 and 1400(b).

COUNT I: CLAIM FOR INFRINGEMENT OF THE '050 PATENT

Regulatory Requirements for New and Generic Drugs

7. A person wishing to market a new drug that has not previously been approved by the U.S. Food and Drug Administration ("FDA") (a "pioneering" drug) must file a New Drug Application ("NDA") with FDA demonstrating that the drug is safe and effective for its intended use. 21 U.S.C. § 355(b).

8. A person wishing to market a generic copy of a drug that previously has been approved by FDA may follow a truncated approval process by filing an Abbreviated New Drug Application ("ANDA") for a generic version of that drug. In the ANDA, the applicant must demonstrate, among other things, bioequivalence of the generic copy with the pioneering drug. 21 U.S.C. § 355(j)(2)(A)(iv).

9. Unlike an NDA applicant, an ANDA applicant is not required to include safety and effectiveness data. Instead, the ANDA applicant is permitted to rely on the approval of the NDA applicant's drug—in essence, piggybacking on the NDA application and safety and effectiveness conclusions. 21 U.S.C. § 355(j).

10. Nor does an ANDA applicant establish any new conditions of use for the proposed drug product. Instead, an ANDA applicant may seek approval only for conditions of use that previously have been approved in connection with an approved NDA. 21 U.S.C.§ 355(j)(2)(A)(i).

The Approved Drug Product

11. Warner Chilcott Company, LLC is the holder of New Drug Application ("NDA") No. 203667 for Minastrin® 24 Fe, which contains the active ingredients ethinyl estradiol and norethindrone acetate. Minastrin® 24 Fe was approved by FDA on May 8, 2013, and is indicated for use by women to prevent pregnancy. Minastrin® 24 Fe is sold as a 28-day oral contraceptive regimen that includes 24 chewable tablets comprising 1.0 mg norethindrone acetate and 0.020 mg ethinyl estradiol, and 4 chewable ferrous fumarate tablets (placebo).

12. FDA has listed U.S. Patent No. 6,667,050 (the "'050 Patent") in the Orange Book—formally known as *Approved Drug Products with Therapeutic Equivalence Evaluations*—in connection with NDA No. 203667.

13. Warner Chilcott is the sole owner of the '050 Patent.

ANDA No. 207514

14. Upon information and belief, Amneal submitted Abbreviated New Drug Application ("ANDA") No. 207514 to FDA seeking approval to engage in the commercial manufacture, use, offer for sale, and sale of a generic version of Minastrin® 24 Fe before the expiration of the '050 Patent. Amneal's manufacture, use, offer for sale, or sale in the United States, or importation into the United States, of such product would infringe the claims of the '050 Patent under 35 U.S.C. § 271(a), (b), and/or (c).

15. As part of its ANDA filing, Amneal has purportedly provided written certification ("Paragraph IV certification") to FDA that the claims of the '050 Patent

are invalid and/or will not be infringed by the manufacture, use, or sale of Amneal's generic version of Minastrin® 24 Fe.

16. By letter dated April 15, 2015, Amneal gave written notice of the certification of invalidity and/or noninfringement of the '050 Patent, alleging that claims 1–17 and 19–35 of the '050 Patent are invalid due to obviousness, and that claims 18, 36, and 37–60 are not infringed by Amneal's generic Minastrin® 24 Fe product. The letter additionally informed Warner Chilcott that Amneal intends to engage in the commercial manufacture, use, and sale of a product bioequivalent to Minastrin® 24 Fe prior to the expiration of the '050 Patent.

Patent Infringement of the '050 Patent

17. Warner Chilcott incorporates by reference the allegations contained in paragraphs 1 to 16 above.

18. United States Patent No. 6,667,050, entitled "Chewable Oral Contraceptive" was lawfully issued by the United States Patent and Trademark Office on December 23, 2003. A copy of the '050 Patent is attached as Exhibit A.

19. The '050 Patent claims, among other things, chewable, palatable oral contraceptive tablets; methods of administering said tablets to a human female; and methods of enhancing compliance with the oral contraception regimen. Minastrin® 24 Fe and its use in accordance with the FDA-approved labeling are covered by the claims of the '050 Patent.

20. Upon information and belief, Amneal submitted ANDA No. 207514 to FDA seeking approval to engage in the commercial manufacturer, use, offer for sale,

and sale of a generic version of Minastrin® 24 Fe before the expiration of the '050 Patent.

21. Amneal's manufacture, use, offer for sale, or sale in the United States, or importation into the United States, of the generic Minastrin® 24 Fe product for which approval is sought in ANDA No. 207514 would infringe the claims of the '050 Patent under 35 U.S.C. § 271(a), (b), and/or (c).

22. Amneal's manufacture, use, offer for sale, or sale in the United States, or importation into the United States, of the generic Minastrin® 24 Fe product for which approval is sought in ANDA No. 207514 would actively induce and contribute to infringement of the '050 Patent, and Amneal would be liable under 35 U.S.C. § 271(b) and/or (c).

23. Amneal has infringed the '050 Patent under 35 U.S.C. § 271(e)(2)(A) by virtue of submitting ANDA No. 207514 with a Paragraph IV certification and seeking FDA approval of ANDA No. 207514 prior to the expiration of the '050 Patent. Moreover, if Amneal commercially manufactures, uses, offers for sale, or sells in the United States, or imports into the United States its generic version of Minastrin® 24 Fe, it would further infringe the '050 Patent under 35 U.S.C. § 271(a), (b), and/or (c). Upon approval of ANDA No. 207514, Amneal will actively induce and/or contribute to infringement of the '050 Patent under 35 U.S.C. § 271(b) and/or (c).

24. This case is an exceptional one, and Warner Chilcott is entitled to an award of its reasonable attorneys' fees under 35 U.S.C. § 285.

25. Warner Chilcott will be irreparably harmed if Amneal is not enjoined from infringing or actively inducing or contributing to infringement of the '050 Patent. Warner Chilcott does not have an adequate remedy at law.

PRAYER FOR RELIEF

WHEREFORE, Warner Chilcott respectfully requests the following relief:

A. A judgment that Amneal has infringed one or more claims of the '050 Patent by submitting ANDA No. 207514;

B. A permanent injunction restraining and enjoining Amneal, its officers, agents, servants, employees, parents, subsidiaries, divisions, affiliates, and those persons in active concert or participation with any of them, from making, using, selling, offering to sell, or importing any product that infringes the '050 Patent, including the product described in ANDA No. 207514;

C. A judgment declaring that making, using, selling, offering to sell, or importing the product described in ANDA No. 207514, or inducing or contributing to such conduct, would constitute infringement of the '050 Patent by Amneal pursuant to 35 U.S.C. § 271(a), (b), and/or (c);

D. An order that the effective date of any approval of Amneal's ANDA be a date that is not earlier than the expiration of the '050 Patent or any later expiration of exclusivity to which Warner Chilcott is or becomes entitled;

E. A finding that this is an exceptional case, and an award of attorneys' fees in this action pursuant to 35 U.S.C. § 285;

F. Costs and expenses in this action; and

G. Such other and further relief as the Court may deem just and proper.

Dated: May 28, 2014

Respectfully submitted,

McCarter & English, LLP

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CERTIFICATION PURSUANT TO L. CIV. R. 11.2

Pursuant to Local Civil Rule 11.2, I certify that this action alleges infringement of the same patent at issue in the consolidated matters *Warner Chilcott Co., LLC v. Mylan Inc. et al.*, 3:11-cv-06844 (D.N.J.) and *Warner Chilcott Co., LLC v. Lupin Ltd. and Lupin Pharmaceuticals, Inc.*, 3:11-cv-07228 (D.N.J.) (Appeal No. 14-1582 (Fed. Cir.)); and the same patent at issue in *Warner Chilcott Co., LLC v. Lupin Atlantis Holdings SA et al.*, 1:14-cv-01827-RWT (D. Md.).

/s/ Nicholas M. Insua
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