

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MARYLAND

WARNER CHILCOTT COMPANY, LLC,
Union St., Road 195, Km. 1.1
Fajardo, Puerto Rico

Plaintiff,

v.

C.A. No. _____

LUPIN ATLANTIS HOLDINGS SA
Mühlentalstrasse 2
8200 Schaffhausen
Schaffhausen, Switzerland

LUPIN LTD.
B/4 Laxmi Towers,
Bandra Kurla Complex, Bandra (E),
Mumbai 400 051 India

LUPIN PHARMACEUTICALS, INC.
111 S. Calvert Street,
21st Floor,
Baltimore, MD 21202
Baltimore City

Defendants.

COMPLAINT FOR PATENT INFRINGEMENT

Janssen Ex. 2037

Plaintiff Warner Chilcott Company, LLC, by its undersigned attorneys, brings this action against Defendants Lupin Atlantis Holdings SA; Lupin Ltd.; and Lupin Pharmaceuticals, Inc. (collectively “Lupin”), 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 Lupin Limited (“Lupin Ltd.”) is a corporation organized and existing under the laws of India.
3. Upon information and belief, Defendant Lupin Atlantis Holdings SA (“Lupin Atlantis”) is a wholly-owned subsidiary of Lupin Ltd., and is a corporation organized and existing under the laws of Switzerland.
4. Upon information and belief, Defendant Lupin Pharmaceuticals, Inc. (“Lupin Pharmaceuticals”) is a wholly-owned subsidiary of Lupin Ltd. and is a corporation organized and existing under the laws of the Commonwealth of Virginia. Lupin Pharmaceuticals has a principal place of business located at 111 S. Calvert Street, 21st Floor, Baltimore, MD 21202.
5. Upon information and belief, Lupin Ltd. has engaged in continuous and systemic contacts with the United States by, among other things, filing with the United States Food and Drug Administration (“FDA”) Abbreviated New Drug Applications (“ANDAs”) to sell various products in the United States. Upon information and belief,

Lupin Ltd. manufactures generic drug products for sale and use in the United States, including in this judicial district.

6. Upon information and belief, Lupin Ltd., Lupin Atlantis, and Lupin Pharmaceuticals are agents of each other with respect to the development, regulatory approval, marketing, sale and/or distribution of generic pharmaceutical products. Upon information and belief, Lupin Ltd. and Lupin Pharmaceuticals, through their affiliate, agent, and alter-ego Lupin Atlantis, filed the ANDA with FDA that is at issue in this patent infringement suit. Upon information and belief, the acts of Lupin Atlantis complained of herein were done and are being done with the cooperation, participation, and assistance of, and at least in part for the benefit of, Lupin Ltd. and Lupin Pharmaceuticals.

JURISDICTION AND VENUE

7. 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).

8. This Court has personal jurisdiction over Lupin Pharmaceuticals by virtue of, at least, its principal place of business in Baltimore, MD.

9. This Court has personal jurisdiction over Lupin Atlantis at least under Federal Rule of Civil Procedure 4(k)(2).

10. This Court has personal jurisdiction over Lupin Ltd. at least under Federal Rule of Civil Procedure 4(k)(2).

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

COUNT I: CLAIM FOR INFRINGEMENT OF THE '050 PATENT

12. Warner Chilcott 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).

13. U.S. Patent No. 6,667,050 (the “’050 Patent”) 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.

14. Warner Chilcott is the sole owner of the ’050 Patent.

15. 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.

16. Minastrin[®] 24 Fe and its use in accordance with the FDA-approved labeling are covered by the claims of the ’050 Patent. The ’050 Patent is listed in FDA’s *Approved Drug Products with Therapeutic Equivalence Evaluations* (the “Orange Book”) for Minastrin[®] 24 Fe.

17. Upon information and belief, Lupin Ltd. and Lupin Pharmaceuticals, through their affiliate, agent, and alter-ego Lupin Atlantis, submitted ANDA No. 206287 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. Defendants' 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).

18. Defendants' 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. 206287 would actively induce and contribute to infringement of the '050 Patent, and Defendants would be liable under 35 U.S.C. § 271(b) and/or (c).

19. As part of their ANDA filing, Lupin Ltd. and Lupin Pharmaceuticals, through their affiliate, agent, and alter-ego Lupin Atlantis, have 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 Defendants' generic version of Minastrin[®] 24 Fe.

20. By letter dated April 24, 2014, Defendants' counsel gave written notice of the certification of invalidity and/or noninfringement of the '050 Patent, alleging that the claims of the '050 Patent are invalid due to obviousness, indefiniteness, and lack of enablement, and that claims 18, 36, and 54 are not infringed by Defendants' generic

Explore Litigation Insights

Docket Alarm provides insights to develop a more informed litigation strategy and the peace of mind of knowing you're on top of things.

Real-Time Litigation Alerts



Keep your litigation team up-to-date with **real-time alerts** and advanced team management tools built for the enterprise, all while greatly reducing PACER spend.

Our comprehensive service means we can handle Federal, State, and Administrative courts across the country.

Advanced Docket Research



With over 230 million records, Docket Alarm's cloud-native docket research platform finds what other services can't. Coverage includes Federal, State, plus PTAB, TTAB, ITC and NLRB decisions, all in one place.

Identify arguments that have been successful in the past with full text, pinpoint searching. Link to case law cited within any court document via Fastcase.

Analytics At Your Fingertips



Learn what happened the last time a particular judge, opposing counsel or company faced cases similar to yours.

Advanced out-of-the-box PTAB and TTAB analytics are always at your fingertips.

API

Docket Alarm offers a powerful API (application programming interface) to developers that want to integrate case filings into their apps.

LAW FIRMS

Build custom dashboards for your attorneys and clients with live data direct from the court.

Automate many repetitive legal tasks like conflict checks, document management, and marketing.

FINANCIAL INSTITUTIONS

Litigation and bankruptcy checks for companies and debtors.

E-DISCOVERY AND LEGAL VENDORS

Sync your system to PACER to automate legal marketing.