

**IN THE UNITED STATES DISTRICT COURT  
FOR THE DISTRICT OF NEW JERSEY**

ORTHO-MCNEIL-JANSSEN )  
PHARMACEUTICALS, INC. )

Plaintiff, )

v. )

Civil Action No. \_\_\_\_\_

LUPIN PHARMACEUTICALS, )  
INC. and LUPIN LTD. )

Defendants. )

**COMPLAINT FOR PATENT INFRINGEMENT**

Plaintiff Ortho-McNeil-Janssen Pharmaceuticals, Inc. (“OMJPI”), by its attorneys, for its complaint against Lupin Pharmaceuticals, Inc. (“Lupin Pharmaceuticals”) and Lupin Ltd. (collectively “Defendants”) alleges as follows:

**The Parties**

1. Plaintiff OMJPI is a corporation organized and existing under the laws of Pennsylvania with its principal place of business at 1125 Trenton-Harbourton Road, Titusville, New Jersey.

2. Upon information and belief, Defendant Lupin Pharmaceuticals is a Virginia corporation and a wholly owned subsidiary, agent and alter-ego of Defendant Lupin Ltd. Upon information and belief, Lupin Pharmaceuticals has its principal place of business at Harborplace Tower, 111 South Calvert Street, Baltimore, MD 21202, is registered to do business in New Jersey and has appointed National Registered Agents, Inc. of Princeton, New Jersey as its registered agent in New Jersey for the receipt of service of process.

3. Upon information and belief, Defendant Lupin Ltd. is an Indian corporation having places of business at 159 CST Road, Kalina, Santacruz (E), Mumbai 400 098, India and Laxmi Towers, "B" Wing, 5th Floor, Bandra Kurla Complex, Mumbai, 400 051, India. Upon information and belief, Defendant Lupin Ltd. manufactures numerous generic drugs for sale and use throughout the United States, including in this judicial district, alone and/or through its wholly owned subsidiary, agent and alter-ego Lupin Pharmaceuticals.

4. Upon information and belief, Lupin Ltd., itself or through its subsidiary, agent and alter ego Lupin Pharmaceuticals, holds various Abbreviated New Drug Applications on file with the U.S. Food and Drug Administration ("FDA"), pursuant to which it manufactures, sells, and distributes generic copies of pharmaceutical products.

#### **Jurisdiction and Venue**

5. This is a civil 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.

6. This Court has jurisdiction over the subject matter of this action pursuant to 28 U.S.C. §§ 1331 and 1338(a).

7. This Court has personal jurisdiction over each of Lupin Pharmaceuticals and Lupin Ltd. by virtue of the fact that, *inter alia*, each Defendant has committed, or aided, abetted, contributed to and/or participated in the commission of, a tortious act of patent infringement that has led to foreseeable harm and injury to a corporation having its principal place of business in New Jersey, Plaintiff OMJPI.

8. Lupin Pharmaceuticals is also subject to personal jurisdiction in this judicial district by virtue of, *inter alia*, Lupin Pharmaceuticals' presence in New Jersey, as evidenced by Lupin Pharmaceuticals' qualification to do business in New Jersey, and its widespread and continuous contacts with New Jersey.

9. Lupin Ltd. is also subject to personal jurisdiction in this judicial district by virtue of, *inter alia*, Lupin Ltd.'s presence in New Jersey through its subsidiary, agent and alter-ego Lupin Pharmaceuticals, and its widespread and continuous contacts with New Jersey through its subsidiary, agent and alter-ego Lupin Pharmaceuticals.

10. Lupin Ltd. and Lupin Pharmaceuticals have previously submitted to the jurisdiction of the U.S. District Court for the District of New Jersey.

11. Venue is proper in this judicial district pursuant to 28 U.S.C. §§ 1391 and 1400(b).

**Count 1: Patent Infringement**

12. OMJPI incorporates by reference the allegations contained in paragraphs 1 to 11 above.

13. United States Patent No. 6,214,815 ("the '815 Patent") entitled "TRIPHASIC ORAL CONTRACEPTIVE" duly and legally issued by the United States Patent and Trademark Office ("USPTO") on April 10, 2001. OMJPI is the owner of the '815 Patent. A copy of the '815 Patent is attached hereto as Exhibit A.

14. OMJPI currently markets a prescription oral contraceptive product under the trademark ORTHO TRI-CYCLEN LO®. ORTHO TRI-CYCLEN LO® is covered by the claims of the '815 Patent.

15. OMJPI is the holder of an approved New Drug Application (“NDA”) covering ORTHO TRI-CYCLEN LO®.

16. Upon information and belief, Lupin Ltd., itself or through its subsidiary, agent and alter-ego Lupin Pharmaceuticals, submitted Abbreviated New Drug Application (“ANDA”) No. 200541 to the FDA seeking approval to engage in the commercial manufacture, use, offer for sale, and sale of a generic version of ORTHO TRI-CYCLEN LO® before the expiration of the '815 Patent. Defendants' manufacture, use, offer for sale, or sale of such product would infringe the claims of the '815 patent under 35 U.S.C. § 271(a), (b), and/or (c).

17. As part of its ANDA filing, Lupin Ltd., itself or through its subsidiary, agent and alter-ego Lupin Pharmaceuticals, has purportedly provided written certification to the FDA that the claims of the '815 Patent are invalid and/or will not be infringed by the manufacture, use, or sale of Lupin Ltd.'s generic version of ORTHO TRI-CYCLEN LO®.

18. By letter dated December 22, 2009, Lupin Ltd. gave written notice of its certification of invalidity and/or noninfringement of the '815 Patent, alleging that the '815 Patent is anticipated, obvious, and invalid, and informing OMJPI that Lupin Ltd. seeks approval to engage in the commercial manufacture, use, and sale of a product bioequivalent to ORTHO TRI-CYCLEN LO® prior to the expiration of the '815 Patent.

19. Lupin Ltd. has infringed the '815 Patent under 35 U.S.C. § 271(e)(2)(A) by virtue of submitting ANDA No. 200541 with a Paragraph IV certification and seeking FDA approval of ANDA No. 200541 prior to the expiration of the '815 Patent. Moreover, if Lupin Ltd. commercially uses, offers for sale or sells its

generic version of ORTHO TRI-CYCLEN LO®, or induces or contributes to such conduct, it would further infringe the '815 patent under § 271(a), (b), and/or (c).

20. Lupin Pharmaceuticals is jointly and severally liable for any infringement of the '815 Patent. Upon information and belief, Lupin Pharmaceuticals participated in, contributed to, aided, abetted and/or induced the submission of ANDA 200541 and its Paragraph IV certification to the FDA. Additionally, upon information and belief, Lupin Pharmaceuticals will market and/or distribute Lupin Ltd.'s generic version of ORTHO TRI-CYCLEN LO® if ANDA 200541 is approved by the FDA.

21. Lupin Pharmaceuticals' participation in, contribution to, aiding, abetting and/or inducement of the submission of ANDA 200541 and its Paragraph IV certification to the FDA constitutes infringement of the '815 Patent under 35 U.S.C. § 271(e)(2)(A). Moreover, if Lupin Pharmaceuticals commercially uses, offers for sale, or sells Lupin Ltd.'s generic version of ORTHO TRI-CYCLEN LO®, or induces or contributes to such conduct, it would further infringe the '815 patent under 35 U.S.C. § 271(a), (b), and/or (c).

22. This case is an exceptional one, and OMJPI is entitled to an award of its reasonable attorney fees under 35 U.S.C. § 285.

23. OMJPI will be irreparably harmed if Defendants are not enjoined from infringing or actively inducing or contributing to infringement of the '815 Patent. OMJPI does not have an adequate remedy at law.

**Prayer for Relief**

WHEREFORE, OMJPI seeks the following relief:

A. A judgment that Defendants have infringed the '815 Patent under 35 U.S.C. § 271(e)(2)(A);

B. An order pursuant to 35 U.S.C. § 271(e)(4)(A) providing that the effective date of any FDA approval of ANDA No. 200541 is not earlier than the expiration date of the '815 Patent, or any later expiration of exclusivity for the '815 Patent to which OMJPI is or becomes entitled;

C. A permanent injunction restraining and enjoining Defendants and their officers, agents, servants, and employees, and those persons in active concert or participation with any of them, from making, using, selling, offering to sell, or importing the product described in ANDA No. 200541;

D. A judgment declaring that the making, using, selling, offering to sell, or importing of the product described in ANDA No. 200541 would constitute infringement of the '815 Patent, or inducing or contributing to such conduct, by Defendants pursuant to 35 U.S.C. § 271(a), (b), and/or (c);

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 further and other relief as this Court determines to be just and proper.

McCARTER & ENGLISH, LLP

By: /s/ William J. Heller  
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