IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MARYLAND

OSCIENT PHARMACEUTICALS CORP., GUARDIAN II ACQUISITION CORP. and ETHYPHARM S.A., Plaintiffs, v. LUPIN LIMITED, and LUPIN PHARMACEUTICALS, INC. (BALTIMORE CITY), Defendants.	Civil Action No. _____

COMPLAINT FOR PATENT INFRINGEMENT

Plaintiffs Oscient Pharmaceuticals Corporation, Guardian II Acquisition Corporation, and Ethypharm S.A. (collectively, "Plaintiffs"), by their attorneys, for their complaint against Lupin Limited and Lupin Pharmaceuticals, Inc. (collectively "Lupin") allege as follows:

The Parties

1. Plaintiff Oscient Pharmaceuticals Corp. ("Oscient") is a corporation organized and existing under the laws of Massachusetts and has its principal place of business at 1000 Winter Street, Suite 2200, Waltham, MA 02451.

2. Plaintiff Guardian II Acquisition Corp. ("Guardian II") is a corporation organized and existing under the laws of Delaware. Guardian II is a wholly owned subsidiary of Oscient.

3. Plaintiff Ethypharm S.A. ("Ethypharm") is a corporation organized and existing under the laws of France, with its principal offices at 194 Bureaux de la Colline, 922 13 Saint Cloud, France.

4. Upon information and belief, Defendant Lupin Ltd. is a corporation organized and existing under the laws of India and having an office and place of business at Laxmi Towers, B Wing, Bandra Kurla Complex, Bandra (East), Mumbai, Maharashtra 400 051, India.

5. Upon information and belief, Lupin Ltd. manufactures numerous generic drugs for sale and use throughout the United States, including in the State of Maryland.

6. Upon information and belief, Defendant Lupin Pharmaceuticals, Inc. is a corporation organized and existing under the laws of Virginia and having an office and place of business at Harborplace Tower, 111 S. Calvert Street, 21st Floor, Baltimore, Maryland 21202.

7. Upon information and belief, Lupin Pharmaceuticals, Inc. is registered to do business in Maryland as a foreign profit corporation.

8. Upon information and belief, Lupin Pharmaceuticals, Inc. is the United States agent for Lupin Ltd. for purposes including, but not limited to, making regulatory submissions to the United States Food and Drug Administration ("FDA").

9. Upon information and belief, Lupin Pharmaceuticals, Inc. also is the United States marketing and sales agent for Lupin Ltd. wherein, following FDA approval of an Abbreviated New Drug Application ("ANDA"), Lupin Ltd. manufactures and supplies the approved generic drug product to Lupin Pharmaceuticals, Inc., which then markets and sells the product throughout the United States, including in the State of Maryland.

10. Upon information and belief, Lupin Pharmaceuticals, Inc. is a wholly owned subsidiary and alter ego of Lupin Ltd.

11. Upon information and belief, Lupin Ltd. and Lupin Pharmaceuticals, Inc. collaborated in the research and development of Lupin's Abbreviated New Drug Application No. 90-859 ("the Lupin ANDA") for fenofibrate capsules, 43 mg and 130 mg, ("the Lupin ANDA Product") continue to collaborate in seeking approval of that application from the Food and Drug Administration ("FDA"), and intend to collaborate in the commercial manufacture, marketing, and sale of the Lupin ANDA Product, in the event the FDA approves the Lupin ANDA.

Jurisdiction and Venue

12. This is a civil action for patent infringement arising under the patent laws of the United States, Title 35 of the United States Code, for infringement of United States Patent No. 7,101,574 ("the '574 patent"). This Court has jurisdiction over the subject matter of this action pursuant to 28 U.S.C. §§ 1331 and 1338(a).

13. Lupin Pharmaceuticals, Inc. is subject to personal jurisdiction in this judicial district by virtue of, *inter alia,* Lupin Pharmaceuticals, Inc.'s presence in Maryland, as evidenced by Lupin Pharmaceuticals, Inc.'s office and place of business in Maryland, its qualification to do business in Maryland, and its widespread and continuous contact with Maryland.

14. Lupin Ltd. is subject to personal jurisdiction in this judicial district by virtue of, *inter alia,* Lupin Ltd.'s presence in Maryland through its subsidiary, agent and alter ego Lupin Pharmaceuticals, Inc., and its widespread and continuous contacts with Maryland, including through its subsidiary, agent, and alter ego Lupin Pharmaceuticals, Inc.

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

Count for Infringement of U.S. Patent No. 7,101,574

16. Plaintiffs reallege paragraphs 1 through 15 above as if fully set forth herein.

17. On September 5, 2006, the United States Patent and Trademark Office duly and legally issued the '574 patent, entitled "Pharmaceutical Composition Containing Fenofibrate and the Preparation Method." A true and correct copy of the '574 patent is attached hereto as Exhibit A.

18. Ethypharm is the owner of the '574 patent, which discloses and claims, *inter alia*, a pharmaceutical composition containing fenofibrate and the method for preparing said composition.

19. Guardian II is the exclusive licensee under the '574 patent with the right to make, use, and sell certain pharmaceutical preparations containing micronized fenofibrate in the United States and other territories.

20. Oscient is the holder of approved New Drug Application ("NDA") 21-695 under Section 505(a) of the Federal Food, Drug and Cosmetic Act ("FFDCA"), 21 U.S.C. § 355(a), for fenofibrate capsules, 43 mg and 130 mg, marketed under the trademark ANTARA®.

21. The manufacture and use of ANTARA® is covered by the claims of the '574 patent, and Plaintiffs have the right to enforce the '574 patent.

22. Upon information and belief, Lupin Ltd., itself and/or through its subsidiary, agent and alter ego Lupin Pharmaceuticals, Inc., submitted the Lupin ANDA to the FDA under § 505(j) of the FFDCA, 21 U.S.C. § 355(j), seeking approval to engage in the commercial manufacture, use, offer for sale and sale of the Lupin ANDA Product before the expiration of the '574 patent. Lupin's manufacture, use, offer for sale or sale of such Lupin ANDA Product would infringe the claims of the '574 patent under 35 U.S.C. §§ 271(a), (b),

and/or (c).

23. On or about December 2, 2008, Plaintiffs received a letter dated December 1, 2008, stating that Lupin Ltd. had filed the Lupin ANDA seeking approval to manufacture, use, and sell the Lupin ANDA Product before the expiration of the '574 patent. The letter purports to notify Plaintiffs that the Lupin ANDA was submitted under 21 U.S.C. § 355(j)(1) and (2)(A) and purports to contain a Paragraph IV certification that Lupin's commercial manufacture, use, or sale of the Lupin ANDA Product will not infringe any claims of the '574 patent and that the '574 patent is invalid.

24. Lupin Ltd. is liable for infringement of the '574 patent under 35 U.S.C. § 271(e)(2)(A) by virtue of its filing of the Lupin ANDA with a Paragraph IV certification, alone and/or through Lupin Pharmaceuticals, Inc., and seeking FDA approval of the Lupin ANDA to make, use, offer for sale or sell the Lupin ANDA Product prior to the expiration of the '574 patent. Moreover, if Lupin Ltd. commercially uses, offers for sale or sells the Lupin ANDA Product, or induces or contributes to such conduct, it would further infringe the '574 patent under 35 U.S.C. §§ 271(a), (b) and/or (c).

25. Lupin Pharmaceuticals, Inc. is jointly and severally liable for any infringement of the '574 patent. Upon information and belief, Lupin Pharmaceuticals, Inc. participated in, contributed to, aided, abetted and/or induced the submission of the Lupin ANDA and its Paragraph IV certification allegation to the FDA. Additionally, upon information and belief, Lupin Pharmaceuticals, Inc. will market and/or distribute the Lupin ANDA Product in the United States if the Lupin ANDA is approved by the FDA.

26. Lupin Pharmaceuticals, Inc.'s participation in, contribution to, aiding, abetting and/or inducement of the submission of the Lupin ANDA and its Paragraph IV certification allegation to the FDA constitutes infringement of the '574 patent under 35 U.S.C.

§ 271(e)(2)(A). Moreover, if Lupin Pharmaceuticals, Inc. commercially uses, offers for sale or sells the Lupin ANDA Product within the United States, or induces or contributes to such conduct, it would further infringe the '574 patent under 35 U.S.C. §§ 271(a), (b) and/or (c).

27. Upon information and belief, Lupin had actual and constructive notice of the '574 patent prior to filing the Lupin ANDA and Lupin's infringement of the '574 patent has been, and continues to be, willful.

28. Plaintiffs are entitled to the relief provided by 35 U.S.C. § 271(e)(4), including an order of this Court that the effective date of the approval of the Lupin ANDA be a date that is not earlier than the expiration of the '574 patent, or any later expiration of exclusivity for the '574 patent to which Plaintiffs become entitled.

29. Plaintiffs will be irreparably harmed if Lupin Pharmaceuticals, Inc. and Lupin Ltd. are not enjoined from infringing or actively inducing or contributing to infringement of the '574 patent. Plaintiffs do not have an adequate remedy at law.

Prayer for Relief

WHEREFORE, Plaintiffs seek the following relief:

A. A judgment that Lupin Pharmaceuticals, Inc. and Lupin Ltd. have infringed the '574 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 the Lupin ANDA be not earlier than the expiration date of the '574 patent or any later expiration of exclusivity for this patent to which Plaintiffs are or become entitled;

C. A permanent injunction pursuant to 35 U.S.C. § 271(e)(4)(B) restraining and enjoining Lupin Pharmaceuticals, Inc. and Lupin Ltd., and each of their officers, agents,

servants and employees, and those persons in active concert or participation with any of them, from engaging in the commercial manufacture, use, offer to sell or sale within the United States, or importation into the United States, of any fenofibrate capsule described in the Lupin ANDA, or any product that infringes or induces or contributes to the infringement of the '574 patent;

D. Costs and expenses in this action; and

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

George F. Pappas (D. MD Bar # 01539)
Jeffrey B. Elikan (D. MD Bar # 26179)
COVINGTON & BURLING LLP
1201 Pennsylvania Avenue, N.W.
Washington, D.C. 20004
(202) 662-6000

Attorneys for Plaintiffs

January 14, 2009