IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MARYLAND
Northern Division

MEDICIS PHARMACEUTICAL CORPORATION,
7720 North Dobson Road
Scottsdale, Arizona 85256

Plaintiff,

v.

JFM 09CV3062

CIVIL ACTION NO. _____

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

Serve:
Dr. Desh Bandhu Gupta, Chairman
Lupin, Ltd.
Laxmi Towers "B" Wing, 5th Floor
Bandra Kurla Complex
Mumbai 400 051
India

OR

Serve Resident Agent:
Robert F. Green
Leydig, Voit & Mayer, Ltd.
Two Prudential Plaza, Suite 4900
180 N. Stetson Avenue
Chicago, Illinois 60601-6731

And

LUPIN PHARMACEUTICALS INC.,
Harborplace Tower, 21st Floor,
111 South Calvert Street
Baltimore, Maryland 21202

Serve Registered Agent:
Vinita Gupa
Harborplace Tower, 21st Floor
111 South Calvert Street
Baltimore, Maryland 21202

Defendants.

COMPLAINT FOR PATENT INFRINGEMENT

Plaintiff Medicis Pharmaceutical Corporation ("Medicis") for its Complaint against Defendants Lupin Ltd. ("Lupin Limited") and Lupin Pharmaceuticals Inc. ("Lupin Pharma") (collectively, the "Defendants") alleges as follows:

I. THE PARTIES

1. Medicis is a Delaware corporation with its principal place of business at 7720 North Dobson Road, Scottsdale, Arizona 85256. Medicis is a leading independent specialty pharmaceutical company in the United States focusing on the treatment of dermatological conditions. Medicis's products have earned wide acceptance by both physicians and patients, including Medicis's SOLODYN™ extended release tablets for acne treatment.

2. Defendant Lupin Limited is a corporation organized and existing under the laws of India, with corporate offices located at B/4 Laxmi Towers, Bandra Kurla Complex, Bandra (W), Mumbai 400 051, India, and registered offices located at 159 CST Road, Kalina, Santacruz (E), Mumbai 400 098, India. Lupin Limited is in the business of manufacturing pharmaceutical drugs, including generic pharmaceutical drugs, that it markets, distributes, and sells in the State of Maryland and throughout the United States.

3. Defendant Lupin Pharma is a corporation organized and existing under the laws of the Commonwealth of Virginia, with its principal place of business at Harborplace Tower, 21st Floor, 111 South Calvert Street, Baltimore, MD 21202, and is a wholly-owned subsidiary of Lupin Limited. Lupin Pharma is in the business of marketing, distributing, and selling, in the State of Maryland and throughout the United States, pharmaceutical drugs, including generic pharmaceutical drugs, manufactured by Lupin Limited. Lupin Pharma is also the United States agent for Lupin Limited for purposes including, but not limited to, making regulatory submissions to the United States Food and Drug Administration ("FDA").

4. On information and belief, Lupin Limited and Lupin Pharma collaborate to manufacture, import, market, distribute, and sell pharmaceutical products (including generic drug products manufactured and sold pursuant to approved abbreviated new drug applications) in the State of Maryland and the United States.

II. NATURE OF THE ACTION

5. This is an action arising under the patent laws of the United States (Title 35, United States Code, § 100, et seq.) based upon Defendants' infringement of one or more of claims 3, 4, 12, and 13 of Medicis's U.S. Patent No. 5,908,838, entitled "METHOD FOR THE TREATMENT OF ACNE" ("the '838 patent"), relating generally to the field of acne treatment.

6. Lupin Limited, by and with Lupin Pharma, filed Abbreviated New Drug Application No. 91-424 (the "Lupin ANDA") under § 505(j) of the Federal Food, Drug, and Cosmetic Act (the "FFDCA"), to obtain approval to commercially manufacture and sell a generic version of SOLODYN™ minocycline HCl extended release tablets for the treatment of acne. Lupin Limited and Lupin Pharma have infringed one or more of claims 3, 4, 12, and 13 of the '838 patent under 35 U.S.C. § 271(e)(2)(A) by virtue of their filing of the Lupin ANDA with a Paragraph IV certification and seeking U.S. Food and Drug Administration ("FDA") approval of the Lupin ANDA prior to the expiration of the '838 patent.

III. JURISDICTION AND VENUE

7. This Court has subject matter jurisdiction over Medicis's patent infringement claims under 28 U.S.C. §§ 1331 and 1338(a).

8. This Court has personal jurisdiction over Lupin Pharma by virtue of, inter alia, Lupin Pharma having its principal place of business at Harborplace Tower, 21st Floor, 111 South Calvert Street, Baltimore, Maryland, having conducted business in Maryland, having availed itself of the rights and benefits of Maryland law, and having engaged in substantial and continuing contacts with the State.

9. This Court has personal jurisdiction over Lupin Limited for a variety of reasons. First, Lupin Limited has previously consented to this Court's jurisdiction and thus taken advantage of the rights and protections provided by this Court. Second, Lupin Limited does substantial business, derives substantial revenue, and engages in persistent conduct in Maryland, with and through Lupin Pharma as well as through sales to Maryland residents. Third, the infringement claims alleged in this action arise partially out of Lupin Limited's actions in Maryland. Finally, Lupin Limited has such substantial control over Lupin Pharma to justify treating Lupin Pharma as a mere alter ego of Lupin Limited and imputing Lupin Pharma's Maryland contacts to Lupin Limited.

10. Lupin Limited has previously consented to this Court's jurisdiction and availed itself of this Court's protections. See, e.g., Abbott Labs. v. Lupin Ltd., C.A. No. 09-152-JJF (D. Del.); Sciele Pharma, Inc. v. Lupin Ltd., C.A. No. 06-37-JJF (D. Del.); Genzyme Corp. v. Lupin Ltd., Civil Action No. 09-1258-JFM (D. Md.); Abbott Labs. v. Lupin Ltd., Civil Action No. 09-564-WMN (D. Md.); Genzyme Corp. v. Lupin Ltd., Civil Action No. 09-563-JFM (D. Md.); Sciele Pharma, Inc. v. Lupin Ltd., Civil Action No. 09-105-AMD (D. Md.). Lupin Limited has also *de facto* acknowledged that it is subject to personal jurisdiction in Maryland by twice moving to transfer cases to Maryland pursuant to 28 U.S.C. § 1404(a). See Abbott Labs. v. Lupin Ltd., C.A. No. 09-152-JJF (D. Del.); Sciele Pharma, Inc. v. Lupin Ltd., C.A. No. 06-37-JJF (D. Del.); see also 28 U.S.C. § 1404(a) (allowing district court to "transfer any civil action to any other district or division where it might have been brought") (emphasis added).

11. On information and belief, by its relationship with Lupin Pharma and its sales to Maryland residents, Lupin Limited does substantial business in Maryland, derives substantial revenue from Maryland, and engages in other persistent courses of conduct in Maryland. Pursuant to the Maryland Long Arm statute, which is co-extensive with the limits of due process, Maryland can exercise personal jurisdiction over persons who "directly or by an agent . . . [c]ause[] tortuous injury . . . if he regularly does or solicits business, engages in any other persistent course of conduct in the State or

derives substantial revenue from goods, food, services, or manufactured products used or consumed in the State." Md. Code Ann., Cts. & Jud. Proc. § 6-103(b)(4). Lupin Limited regularly does millions of dollars of business in Maryland through its relationship with and control over Lupin Pharma, and through it sales to Maryland residents, by and through Lupin Pharma. For the same reasons, Lupin Limited also derives substantial revenue from its business in Maryland. Finally, Lupin Limited engages in a persistent course of conduct in Maryland by regularly filing ANDAs with the FDA in Maryland, by and through its agent, Lupin Pharma. These continuous and systematic contacts, including but not limited to those described above and below, are more than sufficient for this Court to exercise general personal jurisdiction over Lupin Limited.

12. On information and belief, the claims in this action partially arise out of acts committed by Lupin Limited and its agent, Lupin Pharma, in Maryland. Pursuant to the Maryland Long Arm Statute, Maryland can exercise personal jurisdiction over persons who "directly or by an agent . . . [c]ause[] tortious injury in the State by an act or omission in the State." Md. Code Ann., Cts. & Jud. Proc. § 6-103(b)(3). On information and belief, Lupin Limited's relationship with and control over Lupin Pharma, and the plan and agreement between the two to develop, manufacture, acquire approval, and sell the disputed generic pharmaceutical drug occurred in part in Maryland, and caused tortious injury to Medicis. Moreover, on information and belief, Lupin Limited will, following any FDA approval of the Lupin ANDA, sell the generic product that is the subject of the infringement claims in this action in the State of Maryland and throughout the United States, using Lupin Pharma as its marketer, distributor, and seller. Finally, Lupin Pharma, as Lupin Limited's authorized agent and thus acting as Lupin Limited, participated in Maryland in the preparation and/or submission of the Lupin ANDA, which constitute acts in Maryland that directly give rise to Medicis's present claims of patent infringement.

13. Lupin Limited is also subject to general jurisdiction in Maryland because, on information on belief, Lupin Pharma is a mere alter ego of Lupin Limited, and this Court can impute Lupin Pharma's Maryland contacts to Lupin Limited. In support, Medicis pleads the following:

14. Lupin Limited is in the business of developing, manufacturing, marketing, and selling pharmaceutical drugs. On information and belief, Lupin Limited established Lupin Pharma for the sole purpose of distributing, marketing, and selling its pharmaceutical drug products, including generic drug products, in the United States;

15. On information and belief, Lupin Pharma is entirely reliant on Lupin Limited as the source of its products. On information and belief, there is no independent reason for the existence of Lupin Pharma except to function as the U.S.-based marketing, sales, and distribution arm for Lupin Limited and to serve as agent for Lupin Limited's ANDAs;

16. On information and belief, Lupin Limited exercises considerable control over Lupin Pharma, and approves significant decisions of Lupin Pharma such as allowing Lupin Pharma to act as the agent for Lupin Limited in connection with preparing and filing the Lupin ANDA, and acting as Lupin Limited's agent in the United States;

17. Lupin Limited knew that Lupin Pharma's principal place of business was in Maryland;

18. Lupin Limited and Lupin Pharma hold themselves out as a unitary entity and have represented to the public that the activities of Lupin Limited and Lupin Pharma are directed, controlled, and carried out by a single entity, namely, Lupin Limited. For example, Lupin Limited maintains an Internet website at the URL www.lupinworld.com at which Lupin Limited describes Lupin Pharma as a "Business Segment" of Lupin Limited. Moreover, the President and CEO of Lupin Pharma, Vinita Gupta, is held out in Lupin Limited's Annual Report as part of Lupin Limited's "Senior Management Team;"

19. On information and belief, Lupin Limited maintains and controls a broad distribution network in the United States for Lupin Limited's products that annually results in the distribution and sale of millions of dollars of Lupin Limited products. On information and belief, Lupin Limited's business and market strategy includes the distribution, through Lupin Pharma, of substantial volumes of Lupin Limited's pharmaceutical drug products in Maryland and the United States. In this way, Lupin Pharma is an integral part of Lupin Limited's business;

20. On information and belief, Lupin Pharma is actively involved with planning Lupin Limited's new products and filing the Lupin ANDA for the generic drug in dispute and the ANDAs for other drugs;

21. Lupin Pharma's President and CEO, Vinita Gupta, is a member of the Board of Directors of Lupin Limited;

22. Lupin Pharma's President and CEO, Vinita Gupta, is the daughter of Lupin Limited's Chairman, and the brother of Lupin Limited's Executive Director;

23. On information and belief, Lupin Limited in entirely reliant on Lupin Pharma for access to the lucrative U.S. market, and sells or distributes few, if any, products to the U.S. market except through Lupin Pharma;

24. On information and belief, Lupin Limited uses Lupin Pharma as its resident agent for each and every ANDA filing;

25. On information and belief, the products manufactured by Lupin Limited and sold, directly or indirectly through Lupin Pharma in the United States and Maryland, indicate that they are manufactured by Lupin Limited; and

26. On information and belief, Lupin Pharma acted in concert with Lupin Limited to develop Lupin Limited's generic version of SOLODYN™ minocycline HCl extended release tablets for the treatment of acne, and to seek approval from the FDA to sell Lupin Limited's generic version of

SOLODYN™ minocycline HCl extended release tablets for the treatment of acne in the State of Maryland and throughout the United States.

27. Additionally, and in the alternative, Medicis alleges that to the extent Lupin Limited is not subject to the jurisdiction of the courts of general jurisdiction of the State of Maryland, Lupin Limited likewise is not subject to the jurisdiction of the courts of general jurisdiction of any state, and accordingly is amenable to service of process based on its aggregate contacts with the United States, including but not limited to the above described contacts, as authorized by Rule 4(k)(2) of the Federal Rules of Civil Procedure.

28. Venue is proper in this Court pursuant to 28 U.S.C. §§ 1391(b) and (c) and 1400(b).

IV. THE PATENT-IN-SUIT (U.S. PATENT NO. 5,908,838)

29. The allegations of ¶¶ 1-28 are incorporated herein by reference.

30. Medicis is the owner of all right, title and interest in the '838 patent. The United States Patent and Trademark Office duly and legally issued the '838 patent on June 1, 1999, to Eugene H. Gans, which was assigned to Medicis. A true and correct copy of the '838 patent is attached as Exhibit A.

31. On May 8, 2006, the FDA approved Medicis's new drug application 50-808 for SOLODYN™ minocycline HCl extended release tablets under § 505(b) of the FFDCA, 21 U.S.C. § 355(b), for the treatment of acne.

32. The use of SOLODYN™ minocycline HCl extended release tablets is covered by the '838 patent, and Medicis has the right to enforce the '838 patent.

33. The FDA listed the '838 patent in the Orange Book on December 3, 2008.

34. On information and belief, Defendants submitted the Lupin ANDA to the FDA after the '838 patent was listed in the Orange Book.

V. COUNT FOR RELIEF
(INFRINGEMENT OF THE '838 PATENT BY DEFENDANTS)

35. The allegations of ¶¶ 1-34 are incorporated herein by reference.

36. On information and belief, Lupin Limited filed the Lupin ANDA under § 505(j) of the FFDCA to obtain approval to commercially manufacture, use, offer for sale and sell a generic version of SOLODYN™ minocycline HCl extended release tablets for the treatment of acne before the expiration of the '838 patent.

37. On or about October 8, 2009, Medicis received a letter ("Lupin Limited Notice Letter") dated October 7, 2009, from Lupin Limited's counsel, Leydig, Voit & Mayer, Ltd., stating that Lupin Limited had filed the Lupin ANDA seeking approval to manufacture, use, offer for sale and sell a generic version of SOLODYN™ minocycline HCl extended release tablets for the treatment of acne before the expiration of the '838 patent. The letter notifies Medicis that the Lupin ANDA was submitted with a Paragraph IV certification that the '838 patent purportedly is invalid. The Lupin Limited Notice Letter did not provide a "detailed statement of the factual and legal basis" for any claim of noninfringement of claims 3, 4, 12, and 13 of the '838 patent, as required under 21 U.S.C. § 355(j)(2)(B)(iv)(II).

38. On information and belief, Lupin Pharma participated in, contributed to, aided, abetted, and/or induced Lupin Limited's submission of the Lupin ANDA and its Paragraph IV allegations to the FDA.

39. Lupin Limited and Lupin Pharma have infringed the '838 patent under 35 U.S.C. § 271(e)(2)(A) by virtue of their submission of the Lupin ANDA to the FDA for generic SOLODYN™ minocycline HCl extended release tablets that are covered by one or more of the following claims of the '838 patent: claims 3, 4, 12, and 13.

40. Lupin Pharma is jointly and severally liable for any infringement of one or more of claims 3, 4, 12, and 13 of the '838 patent. Lupin Pharma's participation in, contribution to, aiding,

abetting, and/or inducement of the submission of the Lupin ANDA and its § 505(j)(2)(A)(vii)(IV) allegations to the FDA constitutes infringement of one or more of claims 3, 4, 12, and 13 of the '838 patent under 35 U.S.C. § 271(e)(2)(A).

41. The commercial manufacture, use, sale, offer to sell, importation or distribution of products under the Lupin ANDA would infringe one or more of claims 3, 4, 12, and 13 of the '838 patent.

42. Medicis is entitled to an order requiring that Lupin Limited amend its Paragraph IV certification to a certification pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(III) ("Paragraph III certification") as provided in 21 C.F.R. § 314.94(a)(12)(viii)(A).

43. Medicis is entitled to the relief provided by 35 U.S.C. § 271(e)(4), including an order of this Court that the effective date of any FDA approval of the Lupin ANDA be a date that is not earlier than the expiration of the '838 patent, or any later period of exclusivity for the '838 patent to which Medicis becomes entitled.

44. Medicis will be irreparably harmed if Lupin Limited and Lupin Pharma are not enjoined from infringing or actively inducing or contributing to infringement of one or more of claims 3, 4, 12, and 13 of the '838 patent. Pursuant to 35 U.S.C. § 283, Medicis is entitled to a permanent injunction against further infringement. Medicis does not have an adequate remedy at law.

45. To the extent Lupin Limited and/or Lupin Pharma commercialize their product, Medicis will also be entitled to damages under 35 U.S.C. § 284.

PRAYER FOR RELIEF

WHEREFORE, Medicis respectfully requests that this Court enter judgment in its favor against Defendants and grant the following relief:

A. an adjudication that Defendants have infringed one or more of the following claims of the '838 patent: claims 3, 4, 12, and 13, under 35 U.S.C. § 271(e)(2)(A), by submitting to the FDA the Lupin ANDA to obtain approval for the commercial manufacture, use, offer for sale, sale, or

distribution in and/or importation into the United States of generic SOLODYN™ minocycline HCl extended release tablets for the treatment of acne before the expiration of the '838 patent;

B. an order requiring that Defendants amend their respective Paragraph IV certifications to Paragraph III certifications as provided in 21 C.F.R. § 314.94(a)(12)(viii)(A);

C. 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 for generic SOLODYN™ minocycline HCl extended release tablets be a date that is not earlier than the date of the expiration of the '838 patent or any later period of exclusivity to which Medicis is or become entitled;

D. a permanent injunction enjoining Defendants, their officers, agents, servants, employees, attorneys, and those persons in active concert or participation with any of them, from infringing the '838 patent, including the manufacture, use, offer to sell, sale, importation or distribution of any current or future versions of the product described in the Lupin ANDA;

E. an order enjoining Defendants, their officers, agents, servants, employees, attorneys, and those persons in active concert or participation with any of them, from infringing the '838 patent, including the manufacture, use, offer to sell, sale, importation or distribution of any current or future versions of the product described in the Lupin ANDA while the litigation is pending;

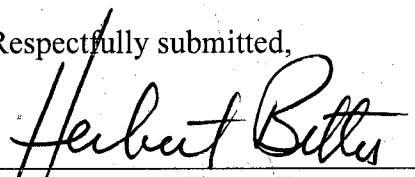
F. a judgment declaring that the manufacture, use, sale, offer to sell, importation or distribution of the products described in the Lupin ANDA would constitute infringement of one or more of claims 3, 4, 12, and 13 of the '838 patent, or inducing or contributing to such conduct, by Defendants pursuant to 35 U.S.C. § 271 (a), (b) and/or (c);

G. a judgment declaring this to be an exceptional case;

H.. an assessment of pre-judgment and post-judgment interest and costs against Defendants, together with an award of such interest and costs, in accordance with 35 U.S.C. § 284; and

I. such other and further relief as this Court may deem just and proper.

Respectfully submitted,



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