IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

MEDICIS PHARMACEUTICAL CORPORATION, Plaintiff, v. RANBAXY INC. and RANBAXY LABORATORIES LTD., Defendants.	)	C.A. No. _____

COMPLAINT FOR PATENT INFRINGEMENT

Plaintiff Medicis Pharmaceutical Corporation ("Medicis") for its Complaint against Defendants Ranbaxy Inc. and Ranbaxy Laboratories Ltd. ("Ranbaxy Labs") alleges as follows:

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. On information and belief, Defendant Ranbaxy Inc., formerly known as Ranbaxy Pharmaceuticals Inc., is a Delaware corporation, with a principal place of business at 600 College Road East, Suite 2100, Princeton, New Jersey 08540. On information and belief, Ranbaxy Inc. is in the business of manufacturing generic pharmaceutical drugs that it distributes and sells in the State of Delaware and throughout the United States.

3. On information and belief, Defendant Ranbaxy Labs is a corporation organized and existing under the laws of India, with corporate offices located at 19, Nehru Place New Delhi, 110019 India.

4. On information and belief, Ranbaxy Inc. is a wholly-owned subsidiary of Ranbaxy Labs.

5. On information and belief, Ranbaxy Inc. acts as the U.S. agent for Ranbaxy Labs for purposes of correspondence with the U.S. Food and Drug Administration ("FDA").

6. On information and belief, Ranbaxy Inc. and Ranbaxy Labs collaborate to manufacture, import, distribute, and sell pharmaceutical products (including generic drug products manufactured and sold pursuant to approved abbreviated new drug applications) in the United States generally, and in the State of Delaware.

NATURE OF THE ACTION

7. 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.

8. Ranbaxy Labs, by and with Ranbaxy Inc., filed Abbreviated New Drug Application No. 91-118 (the "Ranbaxy ANDA") under § 505(j) of the Federal Food, Drug, and Cosmetic Act (the "FFDCA"), to obtain approval to commercially manufacture and sell generic minocycline HCl extended release tablets in its 135 milligram ("mg") strength for the treatment of acne. Ranbaxy Inc. and Ranbaxy Labs 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 Ranbaxy ANDA

with a Paragraph IV certification and seeking FDA approval of the Ranbaxy ANDA prior to the expiration of the '838 patent.

9. On information and belief, Ranbaxy Labs, by and with Ranbaxy Inc., filed a supplement and/or amendment to the aforementioned Ranbaxy ANDA (the "Ranbaxy ANDA Supplement/Amendment"), under § 505(j) of the FFDCA, to obtain approval to commercially manufacture and sell generic minocycline HCl extended release tablets in their 45 mg and 90 mg strengths for the treatment of acne.[1] Ranbaxy Inc. and Ranbaxy Labs 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 Ranbaxy ANDA Supplement/Amendment with a Paragraph IV certification and seeking FDA approval of the Ranbaxy ANDA Supplement/Amendment prior to the expiration of the '838 patent.

JURISDICTION AND VENUE

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

11. This Court has personal jurisdiction over each of the Defendants by virtue of the fact that, inter alia, each Defendant has committed, or aided, abetted, contributed to and/or participated in the commission of, the tortious act of patent infringement that has led to foreseeable harm and injury to Medicis, a Delaware corporation. This Court has personal jurisdiction over each of the Defendants for the additional reasons set forth below.

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[1] Medicis is without sufficient information to know whether the Ranbaxy ANDA Supplement/Amendment is a supplement or an amendment to the Ranbaxy ANDA. Ranbaxy Inc. represented in its January 5, 2010 letter that Defendants "supplemented" the Ranbaxy ANDA.

12. This Court has personal jurisdiction over Ranbaxy Inc. by virtue of, inter alia, being incorporated in Delaware, having availed itself of the rights and benefits of Delaware law, and having engaged in substantial and continuing contacts with the State.

13. This Court has personal jurisdiction over Ranbaxy Labs by virtue of, inter alia, its being registered to do business in Delaware, having conducted business in Delaware, having availed itself of the rights and benefits of Delaware law, selling products within the State of Delaware, and having engaged in substantial and continuing contacts with the State.

14. On information and belief, Ranbaxy Labs controls Ranbaxy Inc, its wholly-owned subsidiary, which is incorporated in Delaware.

15. On information and belief, Ranbaxy Inc. acts as the U.S. agent for Ranbaxy Labs for purposes of correspondence with the FDA.

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

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

17. The allegations of ¶¶ 1-16 are incorporated herein by reference.

18. 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.

19. On May 8, 2006, the FDA approved Medicis's new drug application 50-808 for SOLODYN® minocycline HCl extended release tablets in its 45 mg, 90 mg, and 135 mg strengths under § 505(b) of the FFDCA, 21 U.S.C. § 355(b), for the treatment of acne.

20. 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.

21. The FDA listed the '838 patent in the Orange Book on December 3, 2008 for SOLODYN® minocycline HCl extended release tablets in their 45 mg, 90 mg, and 135 mg strengths.

22. On information and belief, Defendants submitted the Ranbaxy ANDA and the Ranbaxy ANDA Supplement/Amendment to the FDA after the '838 patent was listed in the Orange Book.

COUNT FOR RELIEF
(INFRINGEMENT OF THE '838 PATENT
BY DEFENDANTS RANBAXY INC. AND RANBAXY LABS)

23. The allegations of ¶¶ 1-22 are incorporated herein by reference.

24. On information and belief, Ranbaxy Labs, by and with Ranbaxy Inc., filed the Ranbaxy ANDA and the Ranbaxy ANDA Supplement/Amendment under § 505(j) of the FFDCA seeking 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.

25. On or about May 6, 2009, Medicis received a letter of the same date ("Ranbaxy Notice Letter") from Ranbaxy Inc. The Ranbaxy Notice Letter stated that Ranbaxy Labs had filed the Ranbaxy ANDA seeking approval to manufacture, use, offer for sale and sell a generic version of SOLODYN® minocycline HCl extended release tablets in their 135 mg strength for the treatment of acne before the expiration of the '838 patent. The letter notified Medicis that the Ranbaxy ANDA was submitted with a Paragraph IV certification that the '838 patent purportedly is invalid. The Ranbaxy 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).

26. On or about January 6, 2010, Medicis received a letter ("Ranbaxy Supplemental Notice Letter") dated January 5, 2010, from Ranbaxy Inc. stating that Ranbaxy Labs had filed the Ranbaxy ANDA Supplement/Amendment seeking approval to manufacture, use, offer for sale and sell a generic version of SOLODYN® minocycline HCl extended release tablets in its 45 mg and 90 mg strengths for the treatment of acne before the expiration of the '838 patent. The letter notified Medicis that the Ranbaxy ANDA was submitted with a Paragraph IV certification that the '838 patent purportedly is invalid and unenforceable. The Ranbaxy 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).

27. On information and belief, Ranbaxy Inc. participated in, contributed to, aided, abetted, and/or induced Ranbaxy Labs' submission of the Ranbaxy ANDA, the Ranbaxy ANDA Supplement/Amendment, and the Paragraph IV certifications to the FDA contained therein.

28. Ranbaxy Inc. and Ranbaxy Labs have infringed the '838 patent under 35 U.S.C. § 271(e)(2)(A) by virtue of their submission of the Ranbaxy ANDA and the Ranbaxy ANDA Supplement/Amendment 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.

29. Ranbaxy Inc. is jointly and severally liable for any infringement of one or more of claims 3, 4, 12, and 13 of the '838 patent. Ranbaxy Inc.'s participation in, contribution

to, aiding, abetting, and/or inducement of the submission of the Ranbaxy ANDA, the Ranbaxy ANDA Supplement/Amendment, and concomitant § 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).

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

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

32. 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 Ranbaxy ANDA and the Ranbaxy ANDA Supplement/Amendment 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.

33. Medicis will be irreparably harmed if Ranbaxy Inc. and Ranbaxy Labs 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.

34. To the extent Ranbaxy Inc. or Ranbaxy Labs 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 Ranbaxy ANDA and the Ranbaxy ANDA Supplement/Amendment 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 Ranbaxy ANDA and the Ranbaxy ANDA Supplement/Amendment 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 Ranbaxy ANDA and the Ranbaxy ANDA Supplement/Amendment;

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 Ranbaxy ANDA and the Ranbaxy ANDA Supplement/Amendment while the litigation is pending;

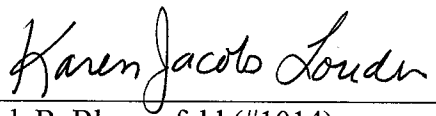
F. a judgment declaring that the manufacture, use, sale, offer to sell, importation or distribution of the products described in the Ranbaxy ANDA and the Ranbaxy ANDA Supplement/Amendment would constitute infringement of one or more of claims 3, 4, 12, and 13 of the '838 patent, or inducing or contributing 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.

MORRIS, NICHOLS, ARSHT & TUNNELL LLP



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