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Attorneys for Plaintiff
Medicis Pharmaceutical Corp.

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

MEDICIS PHARMACEUTICAL CORPORATION,	)	
Plaintiff,	)	
v.	)	C.A. No.
AUROBINDO PHARMA LTD.; and AUROBINDO PHARMA USA, INC.,	)	
Defendants.	)	

COMPLAINT FOR PATENT INFRINGEMENT

Plaintiff Medicis Pharmaceutical Corporation ("Medicis") for its Complaint against Defendants Aurobindo Pharma Ltd. ("Aurobindo Limited") and Aurobindo Pharma USA, Inc. ("Aurobindo USA") (collectively "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, AZ 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 Aurobindo Limited is a corporation organized and existing under the laws of India, with a principal place of business at Plot #2, Maitri Vihar, Ameerpet, Hyderabad, Andhra Pradesh 500038, India. On information and belief, Aurobindo Limited is in the business of manufacturing generic pharmaceutical drugs that it distributes and sells in the State of New Jersey and throughout the United States, by and with its US subsidiary, Aurobindo USA.

3. On information and belief, Defendant Aurobindo USA is a corporation organized and existing under the laws of the State of Delaware with its principal place of business at 2400 Route 130, North Dayton, New Jersey 08810, and is a wholly-owned subsidiary of Aurobindo Limited. Aurobindo USA is in the business of marketing, distributing, and selling, in the State of New Jersey and throughout the United States, pharmaceutical drugs, including generic pharmaceutical drugs, manufactured by Aurobindo Limited. Aurobindo USA is also the United States agent for Aurobindo Limited for purposes including, but not limited to, submitting regulatory submissions to the United States Food and Drug Administration ("FDA").

4. On information and belief, Aurobindo Limited and Aurobindo USA 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 New Jersey 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, 13, 19, 21, 23, 25, and 27-34 of Medicis's U.S. Patent No. 5,908,838, as set forth in the duly issued Ex Parte Reexamination Certificate on June 1, 2010, entitled "METHOD FOR THE TREATMENT OF ACNE" ("the '838 patent"), relating generally to the field of acne treatment, and/or infringement of one or more claims of Medicis's U.S. Patent No. 7,790,705, that issued on September 7, 2010, entitled "MINOCYCLINE ORAL DOSAGE FORMS FOR THE TREATMENT OF ACNE" ("the '705 patent"), relating generally to the field of acne treatment.

6. On information and belief, Aurobindo Limited, by and with Aurobindo USA, filed Abbreviated New Drug Application No. 202-261 (the "Aurobindo 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 their 45 milligram ("mg"), 65 mg, 90 mg, 115 mg, and 135 mg strengths for the treatment of acne. Aurobindo Limited and Aurobindo USA have infringed one or more of claims 3, 4, 12, 13, 19, 21, 23, 25, and 27-34 of the '838 patent under 35 U.S.C. § 271(e)(2)(A) by virtue of their filing the Aurobindo ANDA with a Paragraph IV certification and seeking FDA approval of the Aurobindo ANDA prior to the expiration of the '838 patent.

7. Aurobindo Limited and Aurobindo USA have infringed one or more claims of the '705 patent under 35 U.S.C. § 271(e)(2)(A) by virtue of their filing of the Aurobindo ANDA seeking FDA approval of the Aurobindo ANDA prior to expiration of the '705 patent.

III. JURISDICTION AND VENUE

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

9. This Court has personal jurisdiction over Aurobindo Limited, by virtue of, inter alia, maintaining a branch office in this State, having availed itself of the rights and benefits of New Jersey law, having conducted business in New Jersey, and having engaged in substantial and continuing contacts with the State.

10. Aurobindo Limited has previously accepted this Court's jurisdiction and availed itself of this Court's privileges and protections, including, for example, the adjudication of counterclaims. For example, Aurobindo Limited submitted to the jurisdiction of this Court and asserted counterclaims in patent infringement actions initiated in this jurisdiction styled Teva Pharms. Indus. Et al. v. Aurobindo Pharma Ltd. et al., No. 07-cv-621 (D.N.J.), and Wyeth LLC v. Aurobindo Pharma Limited et al., No. 3:10-cv-02084 (D.N.J.). Furthermore, in an action brought against Aurobindo Limited in the District of Delaware, Aurobindo Limited argued to the court that personal jurisdiction over it is proper in New Jersey. See In re Rosuvastatin Calcium Patent Litigation, MDL No. 08-1949, Dkt. 24 at 8 (D. Del. Feb 15, 2008) ("Aurobindo India is not contesting [the District of New Jersey]'s exercise of personal jurisdiction because Aurobindo India does maintain an office in New Jersey.").

11. This Court has personal jurisdiction over Aurobindo USA, by virtue of, inter alia, residing in New Jersey, having availed itself of the rights and benefits of New Jersey

law, having conducted business in New Jersey, and having engaged in substantial and continuing contacts with the State.

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

IV. THE PATENTS-IN-SUIT (U.S. PATENT NO. 5,908,838 AND 7,790,705)

13. The allegations of ¶¶ 1-12 are incorporated herein by reference.

14. Medicis is the owner of all rights, title and interest in the '838 patent. The United States Patent and Trademark Office ("USPTO") 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 to this Complaint as Exhibit A.

15. On May 8, 2006, the FDA approved Medicis's new drug application 50-808 for SOLODYN® minocycline HCl extended release tablets in their 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. On July 23, 2009, the FDA approved Medicis's supplement to new drug application 50-808 for SOLODYN® minocycline HCl extended release tablets in its 65 mg and 115 mg strengths under § 505(b) of the FFDCA, 21 U.S.C. § 355(b), for the treatment of acne.

16. 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.

17. In June 2008 a request for reexamination was filed on the '838 patent. In August 2008, the USPTO granted the request for reexamination. During the reexamination proceedings, Medicis cancelled claims 1-2, 5-11, and 15-18 of the '838 patent, amended claims 3, 4, 12 and 13 to be independent claims (the "Asserted Claims"), and provided additional new claims 19-34.

18. On March 11, 2010, the USPTO issued a Notice of Intent to Issue a Reexamination Certificate stating that the USPTO has closed the reexamination proceedings and intends to issue a Reexamination Certificate as to patentable claims 3, 4, 12, and 13, and new claims 19-34.

19. On June 1, 2010, the USPTO issued the Ex Parte Reexamination Certificate, reaffirming the validity of original claims 3, 4, 12, and 13, and issuing new claims 19-34. A true and correct copy of the Ex Parte Reexamination Certificate is attached as Exhibit A. Ex. A at 4-14.

20. Medicis is the owner of and has the right to enforce the ’838 patent. While the Ex Parte Reexamination Certificate incorrectly identifies Norwest Bank Arizona, National Association, n/k/a Wells Fargo Bank Arizona, as the Assignee of the ’838 patent, the USPTO issued a Certificate of Correction on October 12, 2010, indicating that the correct assignee of the ’838 patent is Medicis. A true and correct copy of the Certificate of Correction is attached as Exhibit A. Ex. A at 15.

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, and on August 14, 2009 for SOLODYN® minocycline HCl extended release tablets in their 65 mg and 115 mg strengths. On June 24, 2010, Medicis submitted updated information to the FDA regarding the claims of the ’838 patent in the Reexamination Certificate.

22. On information and belief, the Defendants submitted the Aurobindo ANDA to the FDA after the ’838 patent was listed in the Orange Book.

23. Medicis is the owner of all rights, title and interest in the ’705 patent. The USPTO duly and legally issued the ’705 patent on September 7, 2010, to Mitchell Wortzman, R.

Todd Plott, Kuljit Bhatia, and Bhiku Patel, which was assigned to Medicis. A true and correct copy of the '705 patent is attached as Exhibit B.

24. The use of SOLODYN® minocycline HCl extended release tablets is covered by the '705 patent, and Medicis has the right to enforce the '705 patent.

25. The FDA listed the '705 patent in the Orange Book for SOLODYN™ in its 45 mg, 65 mg, 90 mg, 115 mg, and 135 mg strengths after Medicis submitted information regarding the '705 patent to the FDA on September 9, 2010 for SOLODYN® in its 45 mg, 65 mg, 90 mg, 115 mg, and 135 mg strengths.

COUNT I
(INFRINGEMENT OF THE '838 PATENT BY DEFENDANTS)

26. The allegations of ¶¶ 1-25 are incorporated herein by reference.

27. On information and belief, Aurobindo Limited filed the Aurobindo 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.

28. On or about October 27, 2010, Medicis received a letter ("Aurobindo Notice Letter") dated October 26, 2010, from Aurobindo Limited's counsel, Leydig, Voit, & Mayer, Ltd., stating that Aurobindo Limited had filed the Aurobindo ANDA seeking approval to manufacture, use, offer for sale and sell a generic version of SOLODYN® minocycline HCl extended release tablets in their 45 mg, 65 mg, 90 mg, 115 mg, and 135 mg strengths for the treatment of acne before the expiration of the '838 patent. The letter notifies Medicis that the Aurobindo ANDA was submitted with a Paragraph IV certification that the '838 patent purportedly is invalid. The Aurobindo Notice Letter did not provide a "detailed statement of the

factual and legal basis" for any claim of noninfringement of any claim of the '838 patent, as required under 21 U.S.C. § 355(j)(2)(B)(iv)(II).

29. On information and belief, Aurobindo USA participated in, contributed to, aided, abetted, and/or induced Aurobindo Limited's submission of the Aurobindo ANDA and its Paragraph IV allegations, and the Paragraph IV certifications to the FDA contained therein.

30. Aurobindo Limited and Aurobindo USA have infringed the '838 patent under 35 U.S.C. § 271(e)(2)(A) by virtue of their submission of the Aurobindo ANDA to the FDA for generic SOLODYN® minocycline HCl extended release tablets in their 45 mg, 65 mg, 90 mg, 115 mg and 135 mg strengths, which are covered by one or more of the following claims of the '838 patent: claims 3, 4, 12, 13, 19, 21, 23, 25, and 27-34.

31. Aurobindo Limited and Aurobindo USA are jointly and severally liable for any infringement of one or more of claims 3, 4, 12, 13, 19, 21, 23, 25, and 27-34 of the '838 patent. Aurobindo Limited and Aurobindo USA's participation in, contribution to, aiding, abetting, and/or inducement of the submission of the Aurobindo ANDA and its § 505(j)(2)(A)(vii)(IV) allegations to the FDA constitutes direct, contributory, and/or induced infringement of one or more of claims 3, 4, 12, 13, 19, 21, 23, 25, and 27-34 of the '838 patent under 35 U.S.C. § 271(e)(2)(A).

32. The commercial manufacture, use, sale, offer to sell, importation or distribution of products under the Aurobindo ANDA would infringe directly or contribute to or induce the infringement of one or more of claims 3, 4, 12, 13, 19, 21, 23, 25, and 27-34 of the '838 patent.

33. Medicis is entitled to an order requiring that Aurobindo Limited amend its Paragraph IV certification in the Aurobindo ANDA 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).

34. 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 Aurobindo ANDA be a date that is not earlier than the expiration of the '838 patent, or any later expiration of exclusivity for the '838 patent to which Medicis becomes entitled.

35. Medicis will be irreparably harmed if Aurobindo Limited and Aurobindo USA are not enjoined from infringing and/or actively inducing or contributing to infringement of one or more of claims 3, 4, 12, 13, 19, 21, 23, 25, and 27-34 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.

36. To the extent Aurobindo Limited or Aurobindo USA commercialize their product, Medicis will also be entitled to damages under 35 U.S.C. § 284.

COUNT II
(INFRINGEMENT OF THE '705 PATENT BY DEFENDANTS)

37. The allegations of ¶¶ 1-36 are incorporated herein by reference.

38. On information and belief, Aurobindo Limited filed the Aurobindo 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 in its 45 mg, 65 mg, 90 mg, 115 mg, and 135 mg strengths for the treatment of acne before the expiration of the '705 patent.

39. On or about October 27, 2010, Medicis received the Aurobindo Notice Letter dated October 26, 2010, from Aurobindo Limited's counsel, Leydig, Voit & Mayer, Ltd., stating that Aurobindo Limited had filed the Aurobindo ANDA seeking approval to manufacture,

use, offer for sale and sell a generic version of SOLODYN® minocycline HCl extended release tablets in their 45 mg, 65 mg, 90 mg, 115 mg, and 135 mg strengths for the treatment of acne before the expiration of the '705 patent. The letter notifies Medicis that the Aurobindo ANDA was submitted with a Paragraph IV certification that the '705 patent purportedly is not infringed. The Aurobindo Notice Letter did not provide a "detailed statement of the factual and legal basis" for any claim of invalidity of the Asserted Claims of the '705 patent, as required under 21 U.S.C. § 355(j)(2)(B)(iv)(II).

40. On information and belief, Aurobindo USA participated in, contributed to, aided, abetted, and/or induced Aurobindo Limited's submission of the Aurobindo ANDA to the FDA.

41. Aurobindo Limited and Aurobindo USA have infringed the '705 patent under 35 U.S.C. § 271(e)(2)(A) by virtue of their submission of the Aurobindo ANDA to the FDA for generic SOLODYN® minocycline HCl extended release tablets in their 45 mg, 65 mg, 90 mg, 115 mg and 135 mg strengths, which are covered by one or more claims of the '705 patent.

42. Aurobindo Limited and Aurobindo USA are jointly and severally liable for any infringement of one or more of claims of the '705 patent. Aurobindo Limited and Aurobindo USA's participation in, contribution to, aiding, abetting, and/or inducement of the submission of the Aurobindo ANDA and its § 505(j)(2)(A)(vii)(IV) allegations to the FDA constitutes direct, contributory, and/or induced infringement of one or more of claims of the '705 patent under 35 U.S.C. § 271(e)(2)(A).

43. The commercial manufacture, use, sale, offer to sell, importation or distribution of products under the Aurobindo ANDA would infringe directly or contribute to or induce the infringement of one or more of claims of the '705 patent.

44. Medicis is entitled to an order requiring that Aurobindo Limited amend its Paragraph IV certification in the Aurobindo ANDA 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).

45. 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 Aurobindo ANDA be a date that is not earlier than the expiration of the '705 patent, or any later expiration of exclusivity for the '705 patent to which Medicis becomes entitled.

46. Medicis will be irreparably harmed if Aurobindo Limited and Aurobindo USA are not enjoined from infringing and/or actively inducing or contributing to infringement of one or more of claims of the '705 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.

47. To the extent Aurobindo Limited or Aurobindo USA 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 directly and/or contributed to and/or induced the infringement of one or more of the following claims of the '838 patent:

claims 3, 4, 12, 13, 19, 21, 23, 25, and 27-34, under 35 U.S.C. § 271(e)(2)(A), by submitting to the FDA the Aurobindo 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 adjudication that Defendants have infringed directly and/or contributed to and/or induced the infringement of one or more claims of the '705 patent, under 35 U.S.C. § 271(e)(2)(A), by submitting to the FDA the Aurobindo 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 '705 patent;

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

D. an order pursuant to 35 U.S.C. § 271(e)(4)(A) providing that the effective date of any FDA approval of the Aurobindo 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 may become entitled;

E. an order pursuant to 35 U.S.C. § 271(e)(4)(A) providing that the effective date of any FDA approval of the Aurobindo ANDA for generic SOLODYN® minocycline HCl extended release tablets be a date that is not earlier than the date of the expiration of the '705 patent or any later period of exclusivity to which Medicis is or may become entitled;

F. a permanent injunction enjoining Defendants, their officers, agents, servants, employees, attorneys, affiliates, divisions, subsidiaries, and those persons in active

concert or participation with any of them, from infringing the ’838 patent, or contributing to or inducing anyone to do the same, including the manufacture, use, offer to sell, sale, importation or distribution of any current or future versions of the product described in Defendants’ ANDA;

G. a permanent injunction enjoining Defendants, their officers, agents, servants, employees, attorneys, affiliates, divisions, subsidiaries, and those persons in active concert or participation with any of them, from infringing the ’705 patent, or contributing to or inducing anyone to do the same, including the manufacture, use, offer to sell, sale, importation or distribution of any current or future versions of the product described in Defendants’ ANDA;

H. an order enjoining Defendants, their officers, agents, servants, employees, attorneys, affiliates, divisions, subsidiaries, and those persons in active concert or participation with any of them, from infringing the ’838 patent, and/or contributing to and/or inducing anyone to do the same, including the manufacture, use, offer to sell, sale, importation or distribution of any current or future versions of the product described in Defendants’ ANDA while the litigation is pending;

I. an order enjoining Defendants, their officers, agents, servants, employees, attorneys, affiliates, divisions, subsidiaries, and those persons in active concert or participation with any of them, from infringing the ’705 patent, and/or contributing to and/or inducing anyone to do the same, including the manufacture, use, offer to sell, sale, importation or distribution of any current or future versions of the product described in Defendants’ ANDA while the litigation is pending;

J. a judgment declaring that the manufacture, use, sale, offer to sell, importation or distribution of the products described in Defendants’ ANDA would constitute infringement of one or more of claims 3, 4, 12, 13, 19, 21, 23, 25, and 27-34 of the ’838 patent,

and/or inducing and/or contributing to such conduct, by Defendants pursuant to 35 U.S.C. § 271 (a), (b) and/or (c);

K. a judgment declaring that the manufacture, use, sale, offer to sell, importation or distribution of the products described in Defendants' ANDA would constitute infringement of one or more of claims of the '705 patent, and/or inducing and/or contributing to such conduct, by Defendants pursuant to 35 U.S.C. § 271 (a), (b) and/or (c);

I. 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

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

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December 6, 2010

CERTIFICATION PURSUANT TO LOCAL CIVIL RULE 11.2

Pursuant to Local Civil Rule 11.2, I hereby certify that the matter in controversy is the subject of a parallel litigation, *Medicis Pharmaceutical Corporation v. Aurobindo Pharma Ltd. and Aurobindo Pharma USA, Inc.*, Civil Action No. 10-1050, initiated on Friday, December 3, 2010, in the United States District Court for the District of Delaware. Other than that litigation, the matter in controversy is not the subject of any other action pending in any court or of any pending arbitration or administrative proceeding. However, the patents-in-suit here are the subject of two matters currently pending in the United States District Court for the District of Maryland: *Medicis Pharmaceutical Corporation v. Lupin Ltd. et al.*, Civil Action No. 09-3062 (JFM); and *Medicis Pharmaceutical Corporation v. Barr Laboratories et al.*, Civil Action No. 09-3464 (JFM).

Dated: December 6, 2010

s/Liza M. Walsh
Liza M. Walsh

CERTIFICATION PURSUANT TO LOCAL CIVIL RULE 201.1

I hereby certify that the matter in controversy is not subject to compulsory arbitration in that Plaintiff seeks, *inter alia*, injunctive relief and monetary relief in excess of $150,000.00.

Dated: December 6, 2010

s/Liza M. Walsh
Liza M. Walsh