IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

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

COMPLAINT FOR PATENT INFRINGEMENT

Plaintiff Medicis Pharmaceutical Corporation ("Medicis") for its Complaint against Defendants Mylan Inc. ("Mylan") and Matrix Laboratories Ltd. ("Matrix"), 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 Mylan, formerly known as Mylan Laboratories, Inc., is a corporation organized and existing under the laws of the Commonwealth of Pennsylvania, with a principal place of business at 1500 Corporate Drive, Suite 400, Canonsburg, Pennsylvania 15317. On information and belief, Mylan is in the business of manufacturing generic pharmaceutical drugs that it distributes and sells in the State of Delaware

and throughout the United States through its wholly owned subsidiary Mylan Pharmaceuticals Inc.

3. On information and belief, Defendant Matrix is a majority owned subsidiary of Mylan with a principal place of business at 1-1-151/1, 4th Floor Sai Ram Towers, Alexander Road, Secunderabad 500-003 India.

4. On information and belief, Mylan acts as the U.S. agent for Matrix for purposes of correspondence with the U.S. Food and Drug Administration ("FDA").

5. On information and belief, Mylan, through its wholly owned subsidiary Mylan Pharmaceuticals Inc., and Matrix 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 specifically.

NATURE OF THE ACTION

6. 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.

7. Mylan, through its majority owned subsidiary, Matrix, filed Abbreviated New Drug Application No. 90-911 (the "Matrix 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 45 milligram ("mg"), 90 mg, and 135 mg strengths for the treatment of acne. Mylan and Matrix 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 Matrix ANDA with a Paragraph IV certification and seeking FDA approval of the Matrix ANDA prior to the expiration of the '838 patent.

8. On information and belief, Mylan, through its majority owned subsidiary, Matrix, filed ANDA No. 20-1467 (the "Second Matrix ANDA"), under § 505(j) of the FFDCA, to obtain approval to commercially manufacture and sell generic minocycline HCl extended release tablets in its 65 mg and 115 mg strengths for the treatment of acne. Mylan and Matrix 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 of the Second Matrix ANDA with a Paragraph IV certification and seeking FDA approval of the Second Matrix ANDA prior to the expiration of the '838 patent.

JURISDICTION AND VENUE

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

10. 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.

11. This Court has personal jurisdiction over Mylan by virtue of, inter alia, its having its subsidiary Mylan Pharmaceuticals Inc. registered to do business in Delaware, having conducted business in Delaware, having availed itself of the rights and benefits of Delaware law, and having engaged in substantial and continuing contacts with the State.

12. On information and belief, Mylan has previously availed itself of this forum for purposes of litigating its patent disputes. For example, in 2002, Mylan, through its wholly-owned subsidiary, Mylan Pharmaceuticals, Inc., filed a patent infringement lawsuit styled Mylan Pharmaceuticals Inc. v. Kremers Development Company et al., C.A. No. 02-1628 (D. Del.). Mylan also has submitted to the jurisdiction of this Court by asserting counterclaims in other civil actions initiated in this jurisdiction. Specifically, Mylan and/or its wholly-owned subsidiary, Mylan Pharmaceuticals, Inc., admitted jurisdiction (for purposes of the litigation) and filed counterclaims in Medicis Pharmaceuticals Corp. v. Mylan Inc., C.A. No. 09-033 (D. Del.); AstraZeneca LP v. Mylan Pharmaceuticals, Inc., C.A. No. 08-453 (D. Del.); Forest Laboratories, Inc. v. Dr. Reddy's Laboratories, Inc., C.A. No. 08-52 (D. Del.); AstraZeneca Pharmaceuticals LP v. Mylan Pharmaceuticals, Inc., C.A. No. 07-805 (D. Del.); Sciele Pharmaceuticals v. Mylan Pharmaceuticals Inc., C.A. No. 07-664 (D. Del.); Sanofi-Aventis v. Actavis, C.A. No. 07-572 (D. Del.); Boehringer Ingelheim International GmbH v. Mylan Pharmaceuticals Inc., C.A. No. 05-854 (D. Del.); and Janssen Pharmaceutica N.V. v. Mylan Pharmaceuticals Inc., C.A. No. 05-371 (D. Del.).

13. On information and belief, Mylan controls numerous subsidiaries that are incorporated in the State of Delaware, including Mylan Delaware Holding Inc., Mylan Delaware Inc., and Matrix Laboratories Inc.

14. This Court has personal jurisdiction over Matrix by virtue of, inter alia, having conducted business in Delaware, having availed itself of the rights and benefits of Delaware law, and having engaged in substantial and continuing contacts with the State.

15. On information and belief, Matrix controls Matrix Laboratories, Inc., its U.S. subsidiary that is incorporated in the State of Delaware.

16. Matrix is registered to do business in Delaware and has a registered agent in Delaware. In addition, it sells various products and does business throughout the United States, including specifically within the State of Delaware.

17. 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)

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

19. Medicis is the owner of all right, 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 as Exhibit A.

20. 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 their 65 mg and 115 mg strengths under § 505(b) of the FFDCA, 21 U.S.C. § 355(b), for the treatment of acne.

21. 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.

22. 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.

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

24. 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, and provided additional new claims 19-34.

25. 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.

26. 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 B. (Medicis is the owner of and has the right to enforce the '838 patent. 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. Norwest Bank Arizona had a security interest in the '838 patent, but that interest has been terminated. A true and correct copy of the Recordation of Release, available at the USPTO Assignment Search Room at Reel and Frame No. 023153/0614, is attached as Exhibit C.)

COUNT FOR RELIEF
(INFRINGEMENT OF THE '838 PATENT
BY DEFENDANTS MYLAN AND MATRIX)

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

28. On information and belief, Mylan and Matrix filed the Matrix ANDA and the Second Matrix 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.

29. On or about December 5, 2008, Medicis received a letter ("Mylan Notice Letter") dated December 4, 2008, from Mylan stating that Matrix had filed the Matrix 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, 90 mg, and 135 mg strengths for the treatment of acne before the expiration of the '838 patent. The letter notifies Medicis that the Matrix ANDA was submitted with a Paragraph IV certification that the '838 patent purportedly is invalid. The Mylan Notice Letter did not provide a "detailed statement of the factual and legal basis" for any claim of noninfringement of the asserted claims of the '838 patent, as required under 21 U.S.C. § 355(j)(2)(B)(iv)(II).

30. On or about May 7, 2010, Medicis received a letter ("Second Mylan Notice Letter") dated May 6, 2010, from Mylan stating that Matrix had filed the Second Matrix ANDA seeking approval to manufacture, use, offer for sale and sell a generic version of SOLODYN® minocycline HCl extended release tablets in their 65 mg and 115 mg strengths for the treatment of acne before the expiration of the '838 patent. The letter notifies Medicis that the Second Matrix ANDA was submitted with a Paragraph IV certification that the '838 patent purportedly is invalid and not infringed.

31. On information and belief, Mylan participated in, contributed to, aided, abetted, and/or induced Matrix's submission of the Second Matrix ANDA and its Paragraph IV allegations to the FDA.

32. Mylan and Matrix have infringed the '838 patent under 35 U.S.C. §§ 271(b), (c), and (e)(2)(A), by virtue of their submission of the Second Matrix ANDA to the

FDA for generic SOLODYN® minocycline HCl extended release tablets in their 65 mg and 115 mg strengths that 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.

33. Mylan and Matrix 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. Mylan and Matrix's participation in, contribution to, aiding, abetting, and/or inducement of the submission of the Second Matrix 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).

34. The commercial manufacture, use, sale, offer to sell, importation or distribution of products under the Second Matrix 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.

35. Medicis is entitled to an order requiring that Matrix amend its Paragraph IV certification in the Second Matrix 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).

36. 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 Second Matrix 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.

37. Medicis will be irreparably harmed if Mylan and Matrix are not enjoined from infringing 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.

38. To the extent Mylan or Matrix commercialize their product under the Second Matrix ANDA, 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(b), (c), and (e)(2)(A), by submitting to the FDA the Second Matrix 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 Paragraph IV certification to a Paragraph III certification 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 Second Matrix 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, 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 commercial manufacture, use, offer to sell, sale, importation or distribution of any current or future versions of the product described in the Second Matrix ANDA;

E. 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, or contributing to or inducing anyone to do the same, including the commercial manufacture, use, offer to sell, sale, importation or distribution of any current or future versions of the product described in the Second Matrix 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 Second Matrix 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, 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.

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