

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

MEDICIS PHARMACEUTICAL)
CORPORATION,)

Plaintiff,)

v.)

MYLAN INC.;)
MATRIX LABORATORIES LTD.;)
MATRIX LABORATORIES INC.;)
SANDOZ, INC.; and)
BARR LABORATORIES, INC.)

C.A. No. _____

Defendants.

COMPLAINT FOR PATENT INFRINGEMENT

Plaintiff Medicis Pharmaceutical Corporation (“Medicis”) for its Complaint against Defendants Mylan Inc. (“Mylan”), Matrix Laboratories Ltd. and Matrix Laboratories Inc. (collectively, “Matrix”), Sandoz, Inc. (“Sandoz”), and Barr Laboratories, Inc. (“Barr”) alleges as follows:

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 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.

3. On information and belief, Defendant Matrix Laboratories Ltd. 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, Defendant Matrix Laboratories Inc. is a subsidiary and the U.S. agent of Matrix Laboratories Ltd., organized and existing under the laws of the State of Delaware with a principal place of business at 76 South Orange Avenue, Suite 301, South Orange, NJ 07079.

5. On information and belief, Mylan, Matrix Laboratories Ltd., and Matrix Laboratories Inc. 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 the State of Delaware specifically.

6. On information and belief, Defendant Sandoz is a corporation organized and existing under the laws of the State of Colorado, with a principal place of business at 506 Carnegie Center, Suite 400, Princeton, NJ 08540. On information and belief, Sandoz is in the business of manufacturing generic pharmaceutical drugs that it distributes and sells in the United States generally, and the State of Delaware specifically.

7. On information and belief, Defendant Barr is a corporation organized and existing under the laws of the State of Delaware, with a principal place of business at 223 Quaker Road, Pomona, NY 10970. On information and belief, Barr is in the business of manufacturing

generic pharmaceutical drugs that it distributes and sells in the State of Delaware and throughout the United States.

NATURE OF THE ACTION

8. 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.

9. 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 "FDCA"), to obtain approval to commercially manufacture and sell generic minocycline HCl extended release tablets for the treatment of acne. Mylan and Matrix 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 the Matrix ANDA with a Paragraph IV certification and seeking U.S. Food and Drug Administration ("FDA") approval of the Matrix ANDA prior to the expiration of the '838 patent.

10. Sandoz filed Abbreviated New Drug Application No. 90-422 (the "Sandoz ANDA") under § 505(j) of the FDCA, to obtain approval to commercially manufacture and sell generic minocycline HCl extended release tablets for the treatment of acne. Sandoz has 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 its filing the Sandoz ANDA with a Paragraph IV certification and seeking FDA approval of the Sandoz ANDA prior to the expiration of the '838 patent.

11. Barr filed Abbreviated New Drug Application No. 65-485 (the "Barr ANDA") under § 505(j) of the FDCA, to obtain approval to commercially manufacture and sell generic minocycline HCl extended release tablets for the treatment of acne. Barr has 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 its filing the Barr ANDA with a Paragraph IV certification and seeking FDA approval of the Barr ANDA prior to the expiration of the '838 patent.

JURISDICTION AND VENUE

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

13. 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.

14. This Court has personal jurisdiction over Mylan by virtue of, inter alia, its 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, 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 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.).

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

17. This Court has personal jurisdiction over Matrix Laboratories Ltd. and Matrix Laboratories Inc. by virtue of, inter alia, their having conducted business in Delaware, having availed themselves of the rights and benefits of Delaware law, and having engaged in substantial and continuing contacts with the State.

18. On information and belief, Matrix Laboratories, Inc., the United States agent and subsidiary of Matrix Laboratories Ltd., is a Delaware corporation. Matrix Laboratories Ltd., through Matrix Laboratories Inc., 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.

19. This Court has personal jurisdiction over Sandoz by virtue of, inter alia, its 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.

20. On information and belief, Sandoz has previously availed itself of this forum for purposes of litigating its patent disputes. For example, Sandoz has submitted to the jurisdiction of this Court by asserting counterclaims in other civil actions initiated in this jurisdiction. Specifically, Sandoz admitted jurisdiction (for purposes of the litigation) and filed

counterclaims in Endo Pharmaceuticals Inc. v. Sandoz, Inc., C.A. No. 08-534 (D. Del.); Wyeth v. Sandoz, Inc., C.A. No. 08-317 (D. Del.); and AstraZeneca Pharmaceuticals LP v. Sandoz, Inc., C.A. No. 07-807 (D. Del.).

21. This Court has personal jurisdiction over Barr, 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.

22. 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)

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

24. 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 to this Complaint as Exhibit A.

25. 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 FDCA, 21 U.S.C. § 355(b), for the treatment of acne.

26. 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.

27. The FDA listed the '838 patent in the Orange Book on December 3, 2008. Prior to October 8, 2008, however, Medicis was not permitted, under the FDA's interpretation of the law, to list the '838 patent in the Orange Book.

28. On information and belief, Defendants were aware of the existence of the '838 patent prior to its listing in the Orange Book.

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

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

30. On information and belief, Mylan and Matrix filed the Matrix ANDA under § 505(j) of the FDCA 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.

31. 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 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 any claim of the '838 patent, as required under 21 U.S.C. § 355(b)(3)(D)(ii).

32. On information and belief, the FDA has not approved the Matrix ANDA.

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

34. Mylan and Matrix have infringed the '838 patent under 35 U.S.C. § 271(e)(2)(A) by virtue of their submission of the Matrix 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.

35. Mylan is jointly and severally liable for any infringement of one or more of claims 3, 4, 12, and 13 of the '838 patent. Mylan's participation in, contribution to, aiding, abetting, and/or inducement of the submission of the Matrix 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).

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

37. Medicis is entitled to the relief provided by 21 U.S.C. § 355(j)(5)(B)(iii) and 35 U.S.C. § 271(e)(4)(A), including an order of this Court that the effective date of any FDA approval of the Matrix ANDA be a date that is not earlier than thirty months from the date of receipt by Medicis of the Mylan Notice Letter.

38. Medicis is entitled to an order requiring that Matrix 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).

39. 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 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.

40. 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, 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.

41. To the extent Mylan or Matrix commercialize their product, Medicis will also be entitled to damages under 35 U.S.C. § 284.

SECOND COUNT FOR RELIEF
(INFRINGEMENT OF THE '838 PATENT BY DEFENDANT SANDOZ)

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

43. On information and belief, Sandoz filed the Sandoz ANDA under § 505(j) of the FDCA 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.

44. On or about December 8, 2008, Medicis received a letter (“Sandoz Notice Letter”) dated December 4, 2008, from Sandoz stating that Sandoz had filed the Sandoz 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 Sandoz ANDA was submitted with a Paragraph IV certification that the '838 patent purportedly is invalid. The Sandoz 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(b)(3)(D)(ii).

45. On information and belief, the FDA has not approved the Sandoz ANDA.

46. Sandoz has infringed the '838 patent under 35 U.S.C. § 271(e)(2)(A) by virtue of its submission of the Sandoz 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.

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

48. Medicis is entitled to the relief provided by 21 U.S.C. § 355(j)(5)(B)(iii) and 35 U.S.C. § 271(e)(4)(A), including an order of this Court that the effective date of any FDA approval of the Sandoz ANDA be a date that is not earlier than thirty months from the date of receipt by Medicis of the Sandoz Notice Letter.

49. Medicis is entitled to an order requiring that Sandoz amend its Paragraph IV certification to a Paragraph III certification as provided in 21 C.F.R. § 314.94(a)(12)(viii)(A).

50. 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 the approval of the Sandoz 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.

51. Medicis will be irreparably harmed if Sandoz is 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.

52. To the extent Sandoz commercializes its product, Medicis will also be entitled to damages under 35 U.S.C. § 284.

THIRD COUNT FOR RELIEF
(INFRINGEMENT OF THE '838 PATENT BY DEFENDANT BARR)

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

54. On information and belief, Barr filed the Barr ANDA under § 505(j) of the FDCA 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.

55. On or about December 23, 2008, Medicis received a letter (“Barr Notice Letter”) dated December 22, 2008, from Barr’s counsel, Peter A. Jackman of Sterne, Kessler, Goldstein & Fox P.L.L.C., stating that Barr had filed the Barr 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 Barr ANDA was submitted with a Paragraph IV certification that the manufacture, use, or sale of the ANDA product purportedly will not infringe claims 7-9 and 16-18 of the '838 patent and that the '838 patent purportedly is invalid and unenforceable. The Barr 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(b)(3)(D)(ii).

56. On information and belief, the FDA has not approved the Barr ANDA.

57. Barr has infringed the '838 patent under 35 U.S.C. § 271(e)(2)(A) by virtue of its submission of the Barr 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.

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

59. Medcis is entitled to the relief provided by 21 U.S.C. § 355(j)(5)(B)(iii) and 35 U.S.C. § 271(e)(4)(A), including an order of this Court that the effective date of any FDA approval of the Barr ANDA be a date that is not earlier than thirty months from the date of receipt by Medcis of the Barr Notice Letter.

60. Medcis is entitled to an order requiring that Barr amend its Paragraph IV certification to a Paragraph III certification as provided in 21 C.F.R. § 314.94(a)(12)(viii)(A).

61. Medcis 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 the approval of the Barr 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 Medcis becomes entitled.

62. Medcis will be irreparably harmed if Barr is 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, Medcis is entitled to a permanent injunction against further infringement. Medcis does not have an adequate remedy at law.

63. To the extent Barr commercializes its product, Medcis 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 their respective ANDAs 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 pursuant to 21 U.S.C. § 355(j)(5)(B)(iii) and 35 U.S.C. § 271(e)(4)(A), providing that the effective date of any FDA approval of Defendants' respective ANDAs for generic SOLODYN® minocycline HCl extended release tablets be a date that is not earlier than thirty months from the date of receipt by Medicis of Defendants' respective Notice Letters;

C. 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);

D. an order pursuant to 35 U.S.C. § 271(e)(4)(A) providing that the effective date of any FDA approval of Defendants' respective ANDAs 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 expiration of exclusivity for these patent to which Medicis is or become entitled;

E. 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 Defendants' respective ANDAs;

F. 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 Defendants' respective ANDAs while the litigation is pending;

G. a judgment declaring that the manufacture, use, sale, offer to sell, importation or distribution of the products described in Defendants' respective ANDAs 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).

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



Jack B. Blumenfeld (#1014)
Karen Jacobs Louden (#2881)
1201 North Market Street
Wilmington, DE 19899-1347
(302) 658-9200
Jblumenfeld@mnat.com
klouden@mnat.com

Attorneys for Plaintiff Medicis Pharmaceutical Corporation

OF COUNSEL:

Matthew D. Powers
WEIL, GOTSHAL & MANGES LLP
Silicon Valley Office
201 Redwood Shores Parkway
Redwood Shores, CA 94065
Telephone: (650) 802-3000
Facsimile: (650) 802-3100

Elizabeth Stotland Weiswasser
Peter Sandel
Jennifer H. Wu
WEIL, GOTSHAL & MANGES LLP
767 Fifth Avenue
New York, NY 10153
Telephone: (212) 310-8000
Facsimile: (212) 310-8007

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