IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

MEDICIS PHARMACEUTICAL CORPORATION,	)	
Plaintiff,	)	C.A. No.
v.	)	
ZYDUS PHARMACEUTICALS USA, INC. and CADILA HEALTHCARE LTD. D/B/A/ ZYDUS CADILA,	)	
Defendants.	)	

COMPLAINT FOR PATENT INFRINGEMENT

Plaintiff Medicis Pharmaceutical Corporation ("Medicis") for its Complaint against Defendants Zydus Pharmaceuticals USA, Inc. ("Zydus USA") and Cadila Healthcare Ltd. d/b/a/ Zydus Cadila ("Zydus Cadila") (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 Zydus Cadila is a corporation organized and existing under the laws of India, with a principal place of business at Zydus Tower, Satellite Cross Roads, Ahmedabad-380015 Gujurat, India. On information and belief, Zydus Cadila is in the business of manufacturing generic pharmaceutical drugs that it distributes

and sells in the State of Delaware and throughout the United States, by and with its US subsidiary, Zydus USA.

3. On information and belief, Defendant Zydus USA is a corporation organized and existing under the laws of the State of New Jersey, with its principal place of business at 73 Route 31 N., Pennington, NJ 08534, and is a wholly-owned subsidiary of Zydus Cadila. Zydus USA is in the business of marketing, distributing, and selling, in the State of Delaware and throughout the United States, pharmaceutical drugs, including generic pharmaceutical drugs, manufactured by Zydus Cadila.

4. Zydus USA is also the United States agent for Zydus Cadila for purposes including, but not limited to, submitting regulatory submissions to and corresponding with the United States Food and Drug Administration ("FDA").

5. On information and belief, Zydus Cadila and Zydus 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 Delaware and the United States.

6. On information and belief, Zydus USA is so controlled and/or dominated by Zydus Cadila that, in effect, Zydus USA does not have a separate corporate existence.

II. 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, 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 ("the '838 patent"), and/or infringement of one or more claims of Medicis's U.S. Patent No. 7,790,705 ("the '705 patent"),

and/or infringement of and one or more claims of Medicis's U.S. Patent No. 7,919,483 ("the '483 patent"). These patents relate generally to the field of acne treatment.

8. On information and belief, Zydus USA, by and with Zydus Cadila, filed Abbreviated New Drug Application No. 203553 (the "Zydus 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"), 55 mg, 65 mg, 80 mg, 90 mg, 105 mg, and 135 mg strengths for the treatment of acne.

9. Zydus Cadila and Zydus 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), 271(b), and/or 271(c) by virtue of their filing of the Zydus ANDA seeking FDA approval of the Zydus ANDA prior to expiration of the '838 patent.

10. Zydus Cadila and Zydus USA have infringed one or more claims of the '705 patent under 35 U.S.C. §§ 271(e)(2)(A), 271(b), and/or 271(c) by virtue of their filing of the Zydus ANDA seeking FDA approval of the Zydus ANDA prior to expiration of the '705 patent.

11. Zydus Cadila and Zydus USA have infringed one or more claims of the '483 patent under 35 U.S.C. §§ 271(e)(2)(A), 271(b), and/or 271(c) by virtue of their filing of the Zydus ANDA seeking FDA approval of the Zydus ANDA prior to expiration of the '483 patent.

III. 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 Zydus Cadila 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, Zydus Cadila has previously availed itself of this forum for purposes of litigating its patent disputes. For example, Zydus Cadila has submitted to the jurisdiction of this Court by asserting counterclaims in other civil actions initiated in this jurisdiction. Specifically, Zydus Cadila and/or its wholly-owned subsidiary, Zydus USA, admitted jurisdiction (for purposes of the litigation) and filed counterclaims in at least the following action in this Court: Abbott Laboratories v. Cadila Healthcare Ltd. (d/b/a Zydus Cadila) and Zydus Pharmaceuticals (USA), Inc., Civil Action No. 12-065 (D. Del.); Somaxon Pharmaceuticals, Inc. and Procom One, Inc. v. Zydus Pharmaceuticals USA Inc. and Cadila Healthcare Limited (d/b/a Zydus Cadila), Civil Action No. 11-537 (D. Del.); Shire Development, Inc. et al. v. Cadila Healthcare Limited (d/b/a Zydus Cadila) and Zydus Pharmaceuticals (USA) Inc., Civil Action No. 10-581 (D. Del.).

16. On information and belief, Zydus Cadila controls Zydus Healthcare (USA) LLC, its subsidiary that is incorporated in the State of Delaware.

17. On information and belief, through its relationship with Zydus USA and Zydus Healthcare (USA) LLC, Zydus Cadila does substantial business in Delaware, derives substantial revenue from Delaware, and engages in other persistent courses of conduct in Delaware. 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 Zydus Cadila.

18. This Court has personal jurisdiction over Zydus USA 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.

19. On information and belief, Zydus USA has previously availed itself of this forum for purposes of litigating its patent disputes. For example, Zydus USA has submitted to the jurisdiction of this Court by asserting counterclaims in other civil actions initiated in this jurisdiction. Specifically, Zydus USA admitted jurisdiction (for purposes of the litigation) and filed counterclaims in Abbott Laboratories v. Cadila Healthcare Ltd. (d/b/a Zydus Cadila) and Zydus Pharmaceuticals (USA), Inc., Civil Action No. 12-065 (D. Del.); Somaxon Pharmaceuticals, Inc. and Procom One, Inc. v. Zydus Pharmaceuticals USA Inc. and Cadila Healthcare Limited (d/b/a Zydus Cadila), Civil Action No. 11-537 (D. Del.); Shire Development, Inc. et al. v. Cadila Healthcare Limited (d/b/a Zydus Cadila) and Zydus Pharmaceuticals (USA) Inc., Civil Action No. 10-581 (D. Del.); Wyeth. v. Cadila Healthcare Ltd. and Zydus Pharmaceuticals (USA) Inc., Civil Action No. 09-239 (D. Del.).

20. On information and belief, the clams in this action partially arise out of acts committed by Zydus Cadila and Zydus USA in Delaware. Zydus Cadila and Zydus USA collaborate to develop, manufacture, seek approval for, and sell FDA-approved generic pharmaceutical drugs, which are being marketed, distributed, and sold in Delaware and in the United States. On information and belief, Zydus Cadila and Zydus USA collaborate to develop, manufacture, seek approval for, and sell the disputed generic pharmaceutical drug, which will cause tortious injury to Medicis, a Delaware corporation. Moreover, on information and belief,

Zydus Cadila and Zydus USA, following any FDA approval of the Zydus ANDA, will sell the generic product that is the subject of the infringement claims in this action in the State of Delaware and throughout the United States, using Zydus USA as its marketer, distributor, and seller.

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

IV. PATENTS-IN-SUIT

22. The allegations of ¶¶ 1-21 are incorporated herein by reference.

23. Medicis is the owner of all rights, title and interest in the ’838 patent, entitled “Method for the Treatment of Acne.” 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.

24. 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 strength under § 505(b) of the FFDCA, 21 U.S.C. § 355(b), for the treatment of acne. On August 27, 2010, the FDA approved Medicis’s supplement to new drug application 50-808 for SOLODYN® minocycline HCl extended release tablets in its 55 mg, 80 mg, and 105 mg strengths under § 505(b) of the FFDCA, 21 U.S.C. § 355(b), for the treatment of acne.

25. 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.

26. 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 added new claims 19-34.

27. 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.

28. Medicis is the owner of and has the right to enforce the '838 patent. Although 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.

29. 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, on August 14, 2009 for SOLODYN® minocycline HCl extended release tablets in their 65 mg strength, and by September 6, 2010 for SOLODYN® minocycline HCl extended release tablets in their 55 mg, 80 mg, and 105 mg strengths. On June 24, 2010, Medicis submitted updated information to the FDA regarding the claims of the '838 patent in the Reexamination Certificate.

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

31. Medicis is the owner of all rights, title and interest in the ’705 patent, entitled “Minocycline Oral Dosage Forms for the Treatment of Acne.” 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.

32. 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.

33. The FDA listed the ’705 patent in the Orange Book by September 16, 2010 for SOLODYN® in its 45 mg, 55 mg, 65 mg, 80 mg, 90 mg, 105 mg and 135 mg strengths.

34. Medicis is the owner of all rights, title and interest in the ’483 patent, entitled “Method for the Treatment of Acne.” The USPTO duly and legally issued the ’483 patent on April 5, 2011, to Mitchell Wortzman, R. Todd Plott, Kuljit Bhatia, and Bhiku Patel, which was assigned to Medicis. A true and correct copy of the ’483 patent is attached as Exhibit C.

35. The use of SOLODYN® minocycline HCl extended release tablets is covered by the ’483 patent, and Medicis has the right to enforce the ’483 patent.

36. The FDA listed the ’483 patent in the Orange Book by April 19, 2011 for SOLODYN® in its 45 mg, 55 mg, 65 mg, 80 mg, 90 mg, 105 mg and 135 mg strengths.

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

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

38. On information and belief, Zydus Cadila filed the Zydus 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.

39. On or about April 27, 2012, Medicis received a letter ("Zydus Notice Letter") dated April 26, 2012, from Zydus USA, stating that Zydus USA had filed the Zydus 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, 55 mg, 65 mg, 80 mg, 90 mg, 105 mg and 135 mg strengths for the treatment of acne before the expiration of the '838 patent. The letter notified Medicis that the Zydus ANDA was submitted with a Paragraph IV certification that the '838 patent purportedly is invalid.

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

41. Zydus Cadila and Zydus USA have infringed the '838 patent under 35 U.S.C. §§ 271(e)(2)(A), 271(b), and/or 271(c) by virtue of their submission of the Zydus ANDA to the FDA for generic SOLODYN® minocycline HCl extended release tablets in their 45 mg, 55 mg, 65 mg, 80 mg, 90 mg, 105 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.

42. Zydus Cadila and Zydus 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. Zydus Cadila and Zydus USA's participation in, contribution to, aiding, abetting, and/or inducement of the submission of the Zydus 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), 271(b), and/or 271(c).

43. The commercial manufacture, use, sale, offer to sell, importation or distribution of products under the Zydus 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.

44. Pursuant to 21 C.F.R. § 314.94(a)(12)(viii)(A), an order should be entered requiring that Zydus USA amend its Paragraph IV certification in the Zydus ANDA to a certification pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(III) ("Paragraph III certification").

45. Under 35 U.S.C. § 271(e)(4), an order should be entered providing that the effective date of any FDA approval of the Zydus 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.

46. Medicis will be irreparably harmed if Zydus Cadila and Zydus 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, a permanent injunction should be entered preventing further infringement. Medicis does not have an adequate remedy at law.

47. To the extent Zydus Cadila and Zydus USA commercialize their product, they will become liable for damages under 35 U.S.C. § 284.

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

48. The allegations of ¶¶ 1-47 are incorporated herein by reference.

49. On information and belief, Zydus Cadila filed the Zydus 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 '705 patent.

50. On or about April 27, 2012, Medicis received the Zydus Notice Letter dated April 26, 2012, from Zydus USA, stating that Zydus USA had filed the Zydus 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, 55 mg, 65 mg, 80 mg, 90 mg, 105 mg and 135 mg strengths for the treatment of acne before the expiration of the '705 patent. The letter notifies Medicis that the Zydus ANDA was submitted with a Paragraph IV certification that the '705 patent purportedly is invalid.

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

52. Zydus Cadila and Zydus USA have infringed the '705 patent under 35 U.S.C. §§ 271(e)(2)(A), 271(b), and/or 271(c) by virtue of their submission of the Zydus ANDA to the FDA for generic SOLODYN® minocycline HCl extended release tablets in their 45 mg, 55 mg, 65 mg, 80 mg, 90 mg, 105 mg and 135 mg strengths, which is covered by one or more claims of the '705 patent.

53. Zydus Cadila and Zydus USA are jointly and severally liable for any infringement of one or more claims of the '705 patent. Zydus Cadila and Zydus USA's participation in, contribution to, aiding, abetting, and/or inducement of the submission of the Zydus ANDA and its § 505(j)(2)(A)(vii)(IV) allegations to the FDA constitutes direct,

contributory, and/or induced infringement of one or more claims of the '705 patent under §§ 271(e)(2)(A), 271(b), and/or 271(c).

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

55. Pursuant to 21 C.F.R. § 314.94(a)(12)(viii)(A), an order should be entered requiring that Zydus USA amend its Paragraph IV certification in the Zydus ANDA to a Paragraph III certification.

56. Under 35 U.S.C. § 271(e)(4), an order should be entered providing that the effective date of any FDA approval of the Zydus 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.

57. Medicis will be irreparably harmed if Zydus Cadila and Zydus USA are not enjoined from infringing and/or actively inducing or contributing to infringement of one or more claims of the '705 patent. Pursuant to 35 U.S.C. § 283, a permanent injunction should be entered preventing further infringement. Medicis does not have an adequate remedy at law.

58. To the extent Zydus Cadila and Zydus USA commercialize their product, they will become liable for damages under 35 U.S.C. § 284.

COUNT III
(INFRINGEMENT OF THE '483 PATENT BY DEFENDANTS)

59. The allegations of ¶¶ 1-58 are incorporated herein by reference.

60. On information and belief, Zydus Cadila filed the Zydus 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 ’483 patent.

61. On or about April 27, 2012, Medicis received the Zydus Notice Letter dated April 26, 2012, from Zydus USA, stating that Zydus USA had filed the Zydus 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, 55 mg, 65 mg, 80 mg, 90 mg, 105 mg and 135 mg strengths for the treatment of acne before the expiration of the ’483 patent. The letter notifies Medicis that the Zydus ANDA was submitted with a Paragraph IV certification that the ’483 patent purportedly is invalid.

62. On information and belief, Zydus Cadila participated in, contributed to, aided, abetted, and/or induced Zydus USA’s submission of the Zydus ANDA and its Paragraph IV allegations, and the Paragraph IV certifications to the FDA contained therein.

63. Zydus Cadila and Zydus USA have infringed the ’483 patent under 35 U.S.C. §§ 271(e)(2)(A), 271(b), and/or 271(c) by virtue of their submission of the Zydus ANDA to the FDA for generic SOLODYN® minocycline HCl extended release tablets in their 45 mg, 55 mg, 65 mg, 80 mg, 90 mg, 105 mg and 135 mg strengths, which is covered by one or more claims of the ’483 patent.

64. Zydus Cadila and Zydus USA are jointly and severally liable for any infringement of one or more claims of the ’483 patent. Zydus Cadila and Zydus USA’s participation in, contribution to, aiding, abetting, and/or inducement of the submission of the Zydus ANDA and its § 505(j)(2)(A)(vii)(IV) allegations to the FDA constitutes direct, contributory, and/or induced infringement of one or more claims of the ’483 patent under 35 U.S.C. §§ 271(e)(2)(A), 271(b), and/or 271(c).

65. The commercial manufacture, use, sale, offer to sell, importation or distribution of products under the Zydus ANDA would infringe directly or contribute to or induce the infringement of one or more claims of the ’483 patent.

66. Pursuant to 21 C.F.R. § 314.94(a)(12)(viii)(A), an order should be entered requiring that Zydus USA amend its Paragraph IV certification in the Zydus ANDA to a Paragraph III certification.

67. Under 35 U.S.C. § 271(e)(4), an order should be entered providing that the effective date of any FDA approval of the Zydus ANDA be a date that is not earlier than the expiration of the ’483 patent, or any later expiration of exclusivity for the ’483 patent to which Medicis becomes entitled.

68. Medicis will be irreparably harmed if Zydus Cadila and Zydus USA are not enjoined from infringing and/or actively inducing or contributing to infringement of one or more claims of the ’483 patent. Pursuant to 35 U.S.C. § 283, a permanent injunction should be entered preventing further infringement. Medicis does not have an adequate remedy at law.

69. To the extent Zydus Cadila and Zydus USA commercialize their product, they will become liable for 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), 271(b), and/or 271(c), by submitting to the FDA the Zydus 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), 271(b), and/or 271(c), by submitting to the FDA the Zydus 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 adjudication that Defendants have infringed directly and/or contributed to and/or induced the infringement of one or more claims of the '483 patent, under 35 U.S.C. §§ 271(e)(2)(A), 271(b), and/or 271(c), by submitting to the FDA the Zydus 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 '483 patent;

D. 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);

E. an order pursuant to 35 U.S.C. § 271(e)(4)(A) providing that the effective date of any FDA approval of the Zydus 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;

F. an order pursuant to 35 U.S.C. § 271(e)(4)(A) providing that the effective date of any FDA approval of the Zydus 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;

G. an order pursuant to 35 U.S.C. § 271(e)(4)(A) providing that the effective date of any FDA approval of the Zydus ANDA for generic SOLODYN® minocycline HCl extended release tablets be a date that is not earlier than the date of the expiration of the ’483 patent or any later period of exclusivity to which Medicis is or may become entitled;

H. 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;

I. 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;

J. 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 ’483 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;

K. 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;

L. 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;

M. 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 ’483 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;

N. 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);

O. 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 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);

P. 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 claims of the '483 patent, and/or inducing and/or contributing to such conduct, by Defendants pursuant to 35 U.S.C. § 271 (a), (b) and/or (c); and

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

MORRIS, NICHOLS, ARSHT & TUNNELL LLP

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