IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MARYLAND
Northern Division

MEDICIS PHARMACEUTICAL CORPORATION,	:	
Plaintiff	:	
v.	:	CIVIL ACTION NO. 09-3062 (JFM)
LUPIN LTD., & LUPIN PHARMACEUTICALS INC.,	:	
Defendants.	:	

SIXTH AMENDED COMPLAINT FOR PATENT INFRINGEMENT

Plaintiff Medicis Pharmaceutical Corporation ("Medicis") for its Sixth Amended Complaint against Defendants Lupin Ltd. ("Lupin Limited") and Lupin Pharmaceuticals Inc. ("Lupin Pharma") (collectively, the "Defendants") alleges as follows:[1]

I. 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. Defendant Lupin Limited is a corporation organized and existing under the laws of India, with corporate offices located at B/4 Laxmi Towers, Bandra Kurla Complex, Bandra (W), Mumbai 400 051, India, and registered offices located at 159 CST Road, Kalina,

[1] Counsel for Defendants has authorized Plaintiff to state that Defendants consent to the filing of the Sixth Amended Complaint.

Santacruz (E), Mumbai 400 098, India. Lupin Limited is in the business of manufacturing pharmaceutical drugs, including generic pharmaceutical drugs, that it markets, distributes, and sells in the State of Maryland and throughout the United States.

3. Defendant Lupin Pharma is a corporation organized and existing under the laws of the Commonwealth of Virginia, with its principal place of business at Harborplace Tower, 21st Floor, 111 South Calvert Street, Baltimore, MD 21202, and is a wholly-owned subsidiary of Lupin Limited. Lupin Pharma is in the business of marketing, distributing, and selling, in the State of Maryland and throughout the United States, pharmaceutical drugs, including generic pharmaceutical drugs, manufactured by Lupin Limited. Lupin Pharma is also the United States agent for Lupin Limited for purposes including, but not limited to, making regulatory submissions to the United States Food and Drug Administration ("FDA").

4. On information and belief, Lupin Limited and Lupin Pharma 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 Maryland 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 (the "Asserted Claims") 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. Lupin Limited, by and with Lupin Pharma, filed Abbreviated New Drug Application No. 91-424 (the "Lupin ANDA") under § 505(j) of the Federal Food, Drug, and Cosmetic Act (the "FFDCA"), to obtain approval to commercially manufacture and sell a generic version of SOLODYN™ minocycline HCl extended release tablets in its 45 milligrams ("mg"), 90 mg, and 135 mg strengths for the treatment of acne. Lupin Limited and Lupin Pharma 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 Lupin ANDA with a Paragraph IV certification and seeking FDA approval of the Lupin ANDA prior to the expiration of the '838 patent.

7. Lupin Limited and Lupin Pharma 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 Lupin ANDA seeking FDA approval of the Lupin ANDA prior to the expiration of the '705 patent.

8. On information and belief, Lupin Limited, by and with Lupin Pharma, filed a supplement[2] to the aforementioned Lupin ANDA (the "Lupin ANDA 65 mg Supplement"), under § 505(j) of the FFDCA, to obtain approval to commercially manufacture and sell a generic version of SOLODYN™ minocycline HCl extended release tablets in its 65 mg strength for the treatment of acne. Lupin Limited and Lupin Pharma have infringed one or -

[2] Defendants have described the filing for the 105 mg strength of SOLODYN™, as well as the filing for the 55 mg and 80 mg strengths of SOLODYN™, *see infra*, as an "Amendment" to the Lupin ANDA. Defendants have described the filing for the 65 mg strength of SOLODYN™ and the filing for the 115 mg strength of SOLODYN™, *see infra*, as a "Supplement" to the Lupin ANDA. Medicis is without sufficient information to know whether any of these strength filings constitutes a "Supplement" to the Lupin ANDA or an "Amendment" to the Lupin ANDA. For the sake of clarity, Medicis, without conceding that either filing is either a Supplement or an Amendment, will refer to all the filings as a "Supplement" or "Supplements" throughout this Sixth Amended Complaint.

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 Lupin ANDA 65 mg Supplement with a Paragraph IV certification and seeking FDA approval of the Lupin ANDA 65 mg Supplement prior to the expiration of the '838 patent.

9. Lupin Limited and Lupin Pharma 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 Lupin ANDA 65 mg Supplement seeking FDA approval of the Lupin ANDA 65 mg Supplement prior to the expiration of the '705 patent.

10. On information and belief, Lupin Limited, by and with Lupin Pharma, filed a second supplement to the aforementioned Lupin ANDA (the "Lupin ANDA 115 mg Supplement"), under § 505(j) of the FFDCA, to obtain approval to commercially manufacture and sell a generic version of SOLODYN™ minocycline HCl extended release tablets in its 115 mg strength for the treatment of acne. Lupin Limited and Lupin Pharma 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 Lupin ANDA 115 mg Supplement with a Paragraph IV certification and seeking FDA approval of the Lupin ANDA 115 mg Supplement prior to the expiration of the '838 patent.

11. Lupin Limited and Lupin Pharma 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 Lupin ANDA 115 mg Supplement seeking FDA approval of the Lupin ANDA 115 mg Supplement prior to the expiration of the '705 patent.

12. On information and belief, Lupin Limited, by and with Lupin Pharma, filed a third Supplement to the aforementioned Lupin ANDA (the "Lupin ANDA 55 mg and 80

mg Supplement") [collectively with the Lupin ANDA 65 mg Supplement and the Lupin ANDA 115 mg Supplement, the "Lupin ANDA Supplements"], under § 505(j) of the FFDCA, to obtain approval to commercially manufacture and sell a generic version of SOLODYN™ minocycline HCl extended release tablets in its 55 mg and 80 mg strengths for the treatment of acne. Lupin Limited and Lupin Pharma 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 Lupin ANDA 55 mg and 80 mg Supplement with a Paragraph IV certification and seeking FDA approval of the Lupin ANDA 55 mg and 80 mg Supplement prior to the expiration of the '838 patent.

13. Lupin Limited and Lupin Pharma 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 Lupin ANDA 55 mg and 80 mg Supplement seeking FDA approval of the Lupin ANDA 55 mg and 80 mg Supplement prior to the expiration of the '705 patent.

14. On information and belief, Lupin Limited, by and with Lupin Pharma, filed a fourth Supplement to the aforementioned Lupin ANDA (the "Lupin ANDA 105 mg Supplement") [collectively with the Lupin ANDA 65 mg Supplement, the Lupin ANDA 115 mg Supplement, and the Lupin ANDA 55 and 80 mg Supplement, the "Lupin ANDA Supplements"], under § 505(j) of the FFDCA, to obtain approval to commercially manufacture and sell a generic version of SOLODYN™ minocycline HCl extended release tablets in its 105 mg strength for the treatment of acne. Lupin Limited and Lupin Pharma 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 Lupin ANDA 105 mg Supplement with a Paragraph

IV certification and seeking FDA approval of the Lupin ANDA 105 mg Supplement prior to the expiration of the '838 patent.

15. Lupin Limited and Lupin Pharma 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 Lupin ANDA 105 mg Supplement seeking FDA approval of the Lupin ANDA 105 mg Supplement prior to the expiration of the '705 patent.

III. JURISDICTION AND VENUE

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

17. This Court has personal jurisdiction over Lupin Pharma by virtue of, inter alia, Lupin Pharma having its principal place of business at Harborplace Tower, 21st Floor, 111 South Calvert Street, Baltimore, Maryland, having conducted business in Maryland, having availed itself of the rights and benefits of Maryland law, and having engaged in substantial and continuing contacts with the State.

18. This Court has personal jurisdiction over Lupin Limited for a variety of reasons. First, Lupin Limited has previously consented to this Court's jurisdiction and thus taken advantage of the rights and protections provided by this Court. Second, Lupin Limited does substantial business, derives substantial revenue, and engages in persistent conduct in Maryland, with and through Lupin Pharma as well as through sales to Maryland residents. Third, the infringement claims alleged in this action arise partially out of Lupin Limited's actions in Maryland. Finally, Lupin Limited has such substantial control over Lupin Pharma to justify treating Lupin Pharma as a mere alter ego of Lupin Limited and imputing Lupin Pharma's Maryland contacts to Lupin Limited.

19. Lupin Limited has previously consented to this Court's jurisdiction and availed itself of this Court's protections. See, e.g., Abbott Labs. v. Lupin Ltd., C.A. No. 09-152-JJF (D. Del.); Sciele Pharma, Inc. v. Lupin Ltd., C.A. No. 06-37-JJF (D. Del.); Genzyme Corp. v. Lupin Ltd., Civil Action No. 09-1258-JFM (D. Md.); Abbott Labs. v. Lupin Ltd., Civil Action No. 09-564-WMN (D. Md.); Genzyme Corp. v. Lupin Ltd., Civil Action No. 09-563-JFM (D. Md.); Sciele Pharma, Inc. v. Lupin Ltd., Civil Action No. 09-105-AMD (D. Md.). Lupin Limited has also *de facto* acknowledged that it is subject to personal jurisdiction in Maryland by twice moving to transfer cases to Maryland pursuant to 28 U.S.C. § 1404(a). See Abbott Labs. v. Lupin Ltd., C.A. No. 09-152-JJF (D. Del.); Sciele Pharma, Inc. v. Lupin Ltd., C.A. No. 06-37-JJF (D. Del.); see also 28 U.S.C. § 1404(a) (allowing district court to "transfer any civil action to any other district or division where it might have been brought") (emphasis added).

20. On information and belief, by its relationship with Lupin Pharma and its sales to Maryland residents, Lupin Limited does substantial business in Maryland, derives substantial revenue from Maryland, and engages in other persistent courses of conduct in Maryland. Pursuant to the Maryland Long Arm statute, which is co-extensive with the limits of due process, Maryland can exercise personal jurisdiction over persons who "directly or by an agent . . . [c]ause[] tortuous injury . . . if he regularly does or solicits business, engages in any other persistent course of conduct in the State or derives substantial revenue from goods, food, services, or manufactured products used or consumed in the State." Md. Code Ann., Cts. & Jud. Proc. § 6-103(b)(4). Lupin Limited regularly does millions of dollars of business in Maryland through its relationship with and control over Lupin Pharma, and through it sales to Maryland residents, by and through Lupin Pharma. For the same reasons, Lupin Limited also derives substantial revenue from its business in Maryland. Finally, Lupin Limited engages in a

persistent course of conduct in Maryland by regularly filing ANDAs with the FDA in Maryland, by and through its agent, Lupin Pharma. 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 Lupin Limited.

21. On information and belief, the claims in this action partially arise out of acts committed by Lupin Limited and its agent, Lupin Pharma, in Maryland. Pursuant to the Maryland Long Arm Statute, Maryland can exercise personal jurisdiction over persons who "directly or by an agent . . . [c]ause[] tortious injury in the State by an act or omission in the State." Md. Code Ann., Cts. & Jud. Proc. § 6-103(b)(3). On information and belief, Lupin Limited's relationship with and control over Lupin Pharma, and the plan and agreement between the two to develop, manufacture, acquire approval, and sell the disputed generic pharmaceutical drug occurred in part in Maryland, and caused tortious injury to Medicis. Moreover, on information and belief, Lupin Limited will, following any FDA approval of the Lupin ANDA and/or the Lupin ANDA Supplements, sell the generic product that is the subject of the infringement claims in this action in the State of Maryland and throughout the United States, using Lupin Pharma as its marketer, distributor, and seller. Finally, Lupin Pharma, as Lupin Limited's authorized agent and thus acting as Lupin Limited, participated in Maryland in the preparation and/or submission of the Lupin ANDA and the Lupin ANDA Supplements, which constitute acts in Maryland that directly give rise to Medicis's present claims of patent infringement.

22. Lupin Limited is also subject to general jurisdiction in Maryland because, on information on belief, Lupin Pharma is a mere alter ego of Lupin Limited, and this Court can

impute Lupin Pharma's Maryland contacts to Lupin Limited. In support, Medicis pleads the following:

23. Lupin Limited is in the business of developing, manufacturing, marketing, and selling pharmaceutical drugs. On information and belief, Lupin Limited established Lupin Pharma for the sole purpose of distributing, marketing, and selling its pharmaceutical drug products, including generic drug products, in the United States;

24. On information and belief, Lupin Pharma is entirely reliant on Lupin Limited as the source of its products. On information and belief, there is no independent reason for the existence of Lupin Pharma except to function as the U.S.-based marketing, sales, and distribution arm for Lupin Limited and to serve as agent for Lupin Limited's ANDAs;

25. On information and belief, Lupin Limited exercises considerable control over Lupin Pharma, and approves significant decisions of Lupin Pharma such as allowing Lupin Pharma to act as the agent for Lupin Limited in connection with preparing and filing the Lupin ANDA and the Lupin ANDA Supplements, and acting as Lupin Limited's agent in the United States;

26. Lupin Limited knew that Lupin Pharma's principal place of business was in Maryland;

27. Lupin Limited and Lupin Pharma hold themselves out as a unitary entity and have represented to the public that the activities of Lupin Limited and Lupin Pharma are directed, controlled, and carried out by a single entity, namely, Lupin Limited. For example, Lupin Limited maintains an Internet website at the URL www.lupinworld.com at which Lupin Limited describes Lupin Pharma as a "Business Segment" of Lupin Limited. Moreover, the

President and CEO of Lupin Pharma, Vinita Gupta, is held out in Lupin Limited's Annual Report as part of Lupin Limited's "Senior Management Team;"

28. On information and belief, Lupin Limited maintains and controls a broad distribution network in the United States for Lupin Limited's products that annually results in the distribution and sale of millions of dollars of Lupin Limited products. On information and belief, Lupin Limited's business and market strategy includes the distribution, through Lupin Pharma, of substantial volumes of Lupin Limited's pharmaceutical drug products in Maryland and the United States. In this way, Lupin Pharma is an integral part of Lupin Limited's business;

29. On information and belief, Lupin Pharma is actively involved with planning Lupin Limited's new products and filing the Lupin ANDA and Lupin ANDA Supplements for the generic drug in dispute and the ANDAs for other drugs;

30. Lupin Pharma's President and CEO, Vinita Gupta, is a member of the Board of Directors of Lupin Limited;

31. Lupin Pharma's President and CEO, Vinita Gupta, is the daughter of Lupin Limited's Chairman, and the brother of Lupin Limited's Executive Director;

32. On information and belief, Lupin Limited in entirely reliant on Lupin Pharma for access to the lucrative U.S. market, and sells or distributes few, if any, products to the U.S. market except through Lupin Pharma;

33. On information and belief, Lupin Limited uses Lupin Pharma as its resident agent for each and every ANDA filing;

34. On information and belief, the products manufactured by Lupin Limited and sold, directly or indirectly through Lupin Pharma in the United States and Maryland, indicate that they are manufactured by Lupin Limited; and

35. On information and belief, Lupin Pharma acted in concert with Lupin Limited to develop Lupin Limited's generic version of SOLODYN™ minocycline HCl extended release tablets for the treatment of acne, and to seek approval from the FDA to sell Lupin Limited's generic version of SOLODYN™ minocycline HCl extended release tablets for the treatment of acne in the State of Maryland and throughout the United States.

36. Additionally, and in the alternative, Medicis alleges that to the extent Lupin Limited is not subject to the jurisdiction of the courts of general jurisdiction of the State of Maryland, Lupin Limited likewise is not subject to the jurisdiction of the courts of general jurisdiction of any state, and accordingly is amenable to service of process based on its aggregate contacts with the United States, including but not limited to the above described contacts, as authorized by Rule 4(k)(2) of the Federal Rules of Civil Procedure.

37. 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 NOS. 5,908,838 AND 7,790,705)

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

39. Medicis is the owner of all right, title and interest in the '838 patent. The United States Patent and Trademark Office duly and legally issued the '838 patent on June 1, 1999, to Eugene H. Gans, which was assigned to Medicis. A true and correct copy of the '838 patent is attached as pages 1-3 of Exhibit A.

40. On May 8, 2006, the FDA approved Medicis's new drug application 50-808 for SOLODYN™ minocycline HCl extended release tablets in its 45 mg, 90 mg, and 135 mg strengths under § 505(b) of the FFDCA, 21 U.S.C. § 355(b), for the treatment of acne. 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 July 23, 2009, the FDA approved Medicis's supplement to new drug application 50-808 for SOLODYN™ minocycline HCl extended release tablets in its 115 mg strength under § 505(b) of the FFDCA, 21 U.S.C. § 355(b), for the treatment of acne.

41. 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.

42. 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.

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

44. 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 pages 4-14 of Exhibit A.

45. 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 page 15 of Exhibit A.

46. The FDA listed the '838 patent in the Orange Book on December 3, 2008 for SOLODYN™ in its 45 mg, 90 mg and 135 mg strengths, and on August 14, 2009 for SOLODYN™ in its 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. The FDA also listed the '838 patent in the Orange Book for SOLODYN™ in its 55 mg, 80 mg and 105 mg strengths after Medicis submitted information regarding the '838 patent to the FDA on August 30, 2010 for SOLODYN™ in its 55 mg, 80 mg, and 105 mg strengths.

47. On information and belief, Defendants submitted the Lupin ANDA and the Lupin ANDA Supplements to the FDA after the '838 patent was listed in the Orange Book.

48. Medicis is the owner of all right, title and interest in the '705 patent. The United States Patent and Trademark Office 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.

49. 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.

50. The FDA listed the '705 patent in the Orange Book for SOLODYN™ in its 45 mg, 55 mg, 65 mg, 80 mg, 90 mg, 105 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, 55 mg, 65 mg, 80 mg, 90 mg, 105 mg, 115 mg, and 135 mg strengths.

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

51. The allegations of ¶¶ 1-50 are incorporated herein by reference.

52. On information and belief, Lupin Limited filed the Lupin ANDA and the Lupin ANDA Supplements under § 505(j) of the FFDCA to obtain approval to commercially manufacture, use, offer for sale and sell generic versions of SOLODYN™ minocycline HCl extended release tablets for the treatment of acne before the expiration of the '838 patent.

53. On or about October 8, 2009, Medicis received a letter ("Lupin Limited Notice Letter") dated October 7, 2009, from Lupin Limited's counsel, Leydig, Voit & Mayer, Ltd., stating that Lupin Limited had filed the Lupin ANDA seeking approval to manufacture, use, offer for sale and sell a generic version of SOLODYN™ minocycline HCl extended release tablets in its 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 Lupin ANDA was submitted with a Paragraph IV certification that the '838 patent purportedly is invalid. The Lupin Limited Notice Letter did not provide a "detailed statement of the factual and legal basis" for any claim of noninfringement of original claims 3, 4, 12, and 13 of the '838 patent, as required under 21 U.S.C. § 355(j)(2)(B)(iv)(II).

54. On or about November 24, 2009, Medicis received a letter ("Lupin Limited 65 mg Supplemental Notice Letter") dated November 23, 2009, from Lupin Limited's counsel, Leydig, Voit & Mayer, Ltd., stating that Lupin Limited had filed the Lupin ANDA 65 mg Supplement seeking approval to manufacture, use, offer for sale and sell a generic version of SOLODYN™ minocycline HCl extended release tablets in its 65 mg strength for the treatment of acne before the expiration of the '838 patent. The letter notifies Medicis that the Lupin ANDA 65 mg Supplement was submitted with a Paragraph IV certification that the '838 patent

purportedly is invalid. The Lupin Limited 65 mg Supplemental Notice Letter did not provide a "detailed statement of the factual and legal basis" for any claim of noninfringement of original claims 3, 4, 12, and 13 of the '838 patent, as required under 21 U.S.C. § 355(j)(2)(B)(iv)(II).

55. On or about December 23, 2009, Medicis received a letter ("Lupin Limited 115 mg Supplemental Notice Letter") dated December 23, 2009, from Lupin Limited's counsel, Leydig, Voit & Mayer, Ltd., stating that Lupin Limited had filed the Lupin ANDA 115 mg Supplement seeking approval to manufacture, use, offer for sale and sell a generic version of SOLODYN™ minocycline HCl extended release tablets in its 115 mg strength for the treatment of acne before the expiration of the '838 patent. The letter notifies Medicis that the Lupin ANDA 115 mg Supplement was submitted with a Paragraph IV certification that the '838 patent purportedly is invalid. The Lupin Limited 115 mg Supplemental Notice Letter did not provide a "detailed statement of the factual and legal basis" for any claim of noninfringement of original claims 3, 4, 12, and 13 of the '838 patent, as required under 21 U.S.C. § 355(j)(2)(B)(iv)(II).

56. On or about December 3, 2010, Medicis received a letter ("Lupin Limited 55 mg and 80 mg Supplemental Notice Letter") dated December 2, 2010, from Lupin Limited's counsel, Leydig, Voit & Mayer, Ltd., stating that Lupin Limited had filed the Lupin ANDA 55 mg and 80 mg Supplement seeking approval to manufacture, use, offer for sale and sell a generic version of SOLODYN™ minocycline HCl extended release tablets in its 55 mg and 80 mg strengths for the treatment of acne before the expiration of the '838 patent. The letter notifies Medicis that the Lupin ANDA 55 mg and 80 mg Supplement was submitted with a Paragraph IV certification that the '838 patent purportedly is invalid. The Lupin Limited 55 mg and 80 mg Supplemental 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).

57. On or about January 24, 2011, Medicis received a letter ("Lupin Limited 105 mg Supplemental Notice Letter") dated January 21, 2011, from Lupin Limited's counsel, Leydig, Voit & Mayer, Ltd., stating that Lupin Limited had filed the Lupin ANDA 105 mg Supplement seeking approval to manufacture, use, offer for sale and sell a generic version of SOLODYN™ minocycline HCl extended release tablets in its 105 mg strength for the treatment of acne before the expiration of the '838 patent. The letter notifies Medicis that the Lupin ANDA 105 mg Supplement was submitted with a Paragraph IV certification that the '838 patent purportedly is invalid. The Lupin Limited 105 mg Supplemental 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).

58. On information and belief, Lupin Pharma participated in, contributed to, aided, abetted, and/or induced Lupin Limited's submission of the Lupin ANDA and the Lupin ANDA Supplements, and the Paragraph IV certifications to the FDA contained therein.

59. Lupin Limited and Lupin Pharma have infringed the '838 patent under 35 U.S.C. § 271(e)(2)(A) by virtue of their submission of the Lupin ANDA and the Lupin ANDA Supplements 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, 13, 19, 21, 23, 25, and 27-34.

60. Lupin Limited and Lupin Pharma 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. Lupin Limited and Lupin Pharma's participation in, contribution to, aiding, abetting, and/or

inducement of the submission of the Lupin ANDA and the Lupin ANDA Supplements to the FDA to obtain approval to commercially manufacture, use, offer for sale and sell generic versions of SOLODYN™ minocycline HCl extended release tablets in its 45 mg, 55 mg, 65 mg, 80 mg, 90 mg, 105 mg, 115 mg, and 135 mg strengths for the treatment of acne before the expiration of the '838 patent, and concomitant § 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).

61. The commercial manufacture, use, sale, offer to sell, importation or distribution of products under the Lupin ANDA and the Lupin ANDA Supplements would infringe directly and/or contribute to and/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.

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

63. 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 Lupin ANDA and the Lupin ANDA Supplements be a date that is not earlier than the expiration of the '838 patent, or any later period of exclusivity for the '838 patent to which Medicis becomes entitled.

64. Medicis will be irreparably harmed if Lupin Limited and Lupin Pharma are not enjoined from infringing and/or actively inducing and/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.

65. To the extent Lupin Limited and/or Lupin Pharma commercialize their product, Medicis will also be entitled to damages under 35 U.S.C. § 284.

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

66. The allegations of ¶¶ 1-65 are incorporated herein by reference.

67. On information and belief, Lupin Limited filed the Lupin ANDA and the Lupin ANDA Supplements under § 505(j) of the FFDCA to obtain approval to commercially manufacture, use, offer for sale and sell generic versions of SOLODYN™ minocycline HCl extended release tablets for the treatment of acne before the expiration of the '705 patent.

68. On or about September 17, 2010, Medicis received a letter ("Lupin Limited '705 Notice Letter") dated September 17, 2010, from Lupin Limited's counsel, Leydig, Voit & Mayer, Ltd., stating that Lupin Limited had amended the Lupin ANDA and the Lupin ANDA Supplements seeking approval to manufacture, use, offer for sale and sell a generic version of SOLODYN™ minocycline HCl extended release tablets in its 45 mg, 90 mg, and 135 mg strengths, as well as in its 65 mg and 115 mg strengths, for the treatment of acne before the expiration of the '705 patent. The letter notifies Medicis that the Lupin ANDA and the Lupin ANDA Supplements were submitted with a Paragraph IV certification that the '705 patent purportedly is not infringed. The Lupin Limited Notice Letter did not provide a "detailed statement of the factual and legal basis" for any claim of invalidity of the claims of the '705 patent, as required under 21 U.S.C. § 355(j)(2)(B)(iv)(II).

69. On or about December 3, 2010, Medicis received the Lupin Limited 55 mg and 80 mg Supplemental Notice Letter, from Lupin Limited's counsel, Leydig, Voit & Mayer, Ltd., stating that Lupin Limited had amended the Lupin ANDA and the Lupin ANDA Supplements seeking approval to manufacture, use, offer for sale and sell a generic version of

SOLODYN™ minocycline HCl extended release tablets in its 55 mg and 80 mg strengths, for the treatment of acne before the expiration of the '705 patent. The letter notifies Medicis that the Lupin ANDA 55 mg and 80 mg Supplement was submitted with a Paragraph IV certification that the '705 patent purportedly is not infringed. The Lupin Limited 55 mg and 80 mg Supplemental Notice Letter did not provide a "detailed statement of the factual and legal basis" for any claim of invalidity of the claims of the '705 patent, as required under 21 U.S.C. § 355(j)(2)(B)(iv)(II).

70. On or about January 24, 2011, Medicis received the Lupin Limited 105 mg Supplemental Notice Letter from Lupin Limited's counsel, Leydig, Voit & Mayer, Ltd., stating that Lupin Limited had filed the Lupin ANDA 105 mg Supplement seeking approval to manufacture, use, offer for sale and sell a generic version of SOLODYN™ minocycline HCl extended release tablets in its 105 mg strength for the treatment of acne before the expiration of the '705 patent. The letter notifies Medicis that the Lupin ANDA 105 mg Supplement was submitted with a Paragraph IV certification that the '705 patent purportedly is not infringed. The Lupin Limited 105 mg Supplemental Notice Letter did not provide a "detailed statement of the factual and legal basis" for any claim of invalidity of the claims of the '705 patent, as required under 21 U.S.C. § 355(j)(2)(B)(iv)(II).

71. On information and belief, Lupin Pharma participated in, contributed to, aided, abetted, and/or induced Lupin Limited's submission of the Lupin ANDA and the Lupin ANDA Supplements to the FDA.

72. Lupin Limited and Lupin Pharma have infringed the '705 patent under 35 U.S.C. § 271(e)(2)(A) by virtue of their submission of the Lupin ANDA and the Lupin ANDA Supplements to the FDA for generic SOLODYN™ minocycline HCl extended release tablets that are covered by one or more claims of the '705 patent.

73. Lupin Limited and Lupin Pharma are jointly and severally liable for any infringement of one or more claims of the '705 patent. Lupin Limited and Lupin Pharma's participation in, contribution to, aiding, abetting, and/or inducement of the submission of the Lupin ANDA and the Lupin ANDA Supplements to the FDA to obtain approval to commercially manufacture, use, offer for sale and sell generic versions of SOLODYN™ minocycline HCl extended release tablets in its 45 mg, 55 mg, 65 mg, 80 mg, 90 mg, 105 mg, 115 mg, and 135 mg strengths, for the treatment of acne before the expiration of the '705 patent, and concomitant § 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 35 U.S.C. § 271(e)(2)(A).

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

75. Medicis is entitled to an order requiring that Lupin Limited amend any Paragraph IV certifications as to the '705 patent to Paragraph III certifications as provided in 21 C.F.R. § 314.94(a)(12)(viii)(A).

76. 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 Lupin ANDA and the Lupin ANDA Supplements be a date that is not earlier than the expiration of the '705 patent, or any later period of exclusivity for the '705 patent to which Medicis becomes entitled.

77. Medicis will be irreparably harmed if Lupin Limited and Lupin Pharma are not enjoined from infringing and/or actively inducing and/or contributing to infringement of one or more 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.

78. To the extent Lupin Limited and/or Lupin Pharma 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 Lupin ANDA and the Lupin ANDA Supplements 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 Lupin ANDA and the Lupin ANDA Supplements 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 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 the Lupin ANDA and the Lupin ANDA Supplements 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 Lupin ANDA and the Lupin ANDA Supplements 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, and/or contributing to and/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 Lupin ANDA and the Lupin ANDA Supplements;

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, and/or contributing to and/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 Lupin ANDA and the Lupin ANDA Supplements;

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 commercial manufacture, use, offer to sell, sale, importation or distribution of any current or future versions of the product described in the Lupin ANDA and the Lupin ANDA Supplements 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 commercial manufacture, use, offer to sell, sale, importation or distribution of any current or future versions of the product described in the Lupin ANDA and the Lupin ANDA Supplements 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 the Lupin ANDA and the Lupin ANDA Supplements 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);

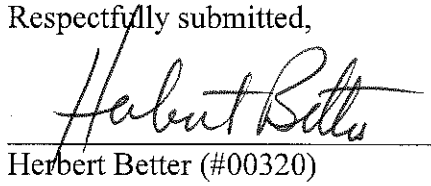
K. a judgment declaring that the manufacture, use, sale, offer to sell, importation or distribution of the products described in the Lupin ANDA and the Lupin ANDA Supplements would constitute infringement of one or more claims of the '705 patent, and/or inducing and/or contributing to such conduct, by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

L. a judgment declaring this to be an exceptional case;

M. 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

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

Respectfully submitted,



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