Elvin Esteves
GIBBONS P.C.
One Gateway Center
Newark, New Jersey 07102-5310
(973) 596-4500

Of Counsel:
Bryan C. Diner
Justin J. Hasford
FINNEGAN, HENDERSON,
FARABOW, GARRETT & DUNNER, LLP
901 New York Avenue, NW
Washington, DC 20001-4413
(202) 408-4000

Attorneys for Plaintiff
Medicis Pharmaceutical Corporation

UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY

MEDICIS PHARMACEUTICAL CORPORATION, Plaintiff, v. APOTEX INC. and APOTEX CORP., Defendants.	Civil Action No. _____ *Document Electronically Filed*

COMPLAINT FOR PATENT INFRINGEMENT

Plaintiff Medicis Pharmaceutical Corporation ("Medicis") by way of Complaint against Defendants Apotex Inc. ("Apotex") and Apotex Corp. (collectively, "Defendants") alleges as follows:

THE PARTIES

1. Plaintiff Medicis is a corporation organized and existing under the laws of Delaware, with a principal place of business at 400 Somerset Corporate Blvd., Bridgewater, NJ 08807. Medicis is the registered holder of approved New Drug Application No. N050808, which covers Solodyn®.

2. Upon information and belief, defendant Apotex is a corporation organized and existing under the laws of Canada, having a principal place of business at 150 Signet Drive, Toronto, Ontario, Canada M9L 1T9.

3. Upon information and belief, defendant Apotex Corp. is a corporation organized and existing under the laws of Delaware, having a principal place of business at 2400 North Commerce Parkway, Suite 400, Weston, Florida 33326. Upon information and belief, defendant Apotex Corp. is a wholly-owned subsidiary of defendant Apotex.

NATURE OF THE ACTION

4. This is an action for infringement of United States Patent Nos. 5,908,838 ("the '838 patent"), 7,790,705 ("the '705 patent"), 7,919,483 ("the '483 patent"), 8,252,776 ("the '776 patent"), and 8,268,804 ("the '804 patent) arising under the United States patent laws, Title 35, United States Code, § 100 et seq., including 35 U.S.C. §§ 271 and 281. This action relates to Apotex's filing of an Abbreviated New Drug Application ("ANDA") under Section 505(j) of the Federal Food, Drug, and Cosmetic Act ("the Act"), 21 U.S.C. § 355(j), seeking U.S. Food and Drug Administration ("FDA") approval to market generic minocycline hydrochloride 115 mg and 135 mg extended release tablets ("Apotex's generic minocycline hydrochloride extended release tablets").

JURISDICTION AND VENUE

5. This Court has subject matter jurisdiction under 28 U.S.C. §§ 1331 and 1338(a).

6. Upon information and belief, this Court has jurisdiction over Apotex. Upon information and belief, Apotex is in the business of manufacturing, marketing, importing and selling pharmaceutical products, including generic drug products. Upon information and belief, Apotex directly manufactures, markets and sells generic drug products throughout the United States and in this judicial district, and this judicial district is a likely destination for Apotex's generic minocycline hydrochloride extended release tablets. Upon information and belief, Apotex purposefully has conducted and continues to conduct business in this judicial district.

7. Upon information and belief, this Court has jurisdiction over Apotex Corp. Upon information and belief, Apotex Corp. directly, or indirectly, manufactures, markets and sells generic drug products, including generic drug products manufactured by Apotex, throughout the United States and in this judicial district, and this judicial district is a likely destination for Apotex's generic minocycline hydrochloride extended release tablets. Upon information and belief, Apotex Corp. purposefully has conducted and continues to conduct business in this judicial district.

8. Upon information and belief, venue is proper in this judicial district under 28 U.S.C. §§ 1391(c) and (d), and § 1400(b).

THE PATENTS IN SUIT

9. The U.S. Patent and Trademark Office ("PTO") issued the '838 patent on June 1, 1999. The '838 patent claims, *inter alia*, methods for the treatment of acne involving the use of oral tetracycline antibiotics. Medicis is the assignee of the '838 patent. A copy of the '838 patent is attached hereto as Exhibit A.

10. The U.S. Patent and Trademark Office ("PTO") issued the '705 patent on September 7, 2010. The '705 patent claims, *inter alia*, controlled-release oral dosage forms of

minocycline and methods of using them to treat acne. Medicis is the assignee of the '705 patent. A copy of the '705 patent is attached hereto as Exhibit B.

11. The U.S. Patent and Trademark Office ("PTO") issued the '483 patent on April 5, 2011. The '483 patent claims, *inter alia*, methods for treatment of acne involving the use of oral minocycline. Medicis is the assignee of the '483 patent. A copy of the '483 patent is attached hereto as Exhibit C.

12. The U.S. Patent and Trademark Office ("PTO") issued the '776 patent on August 28, 2012. The '776 patent claims, *inter alia*, methods for treatment of acne involving the use of oral minocycline. Medicis is the assignee of the '776 patent. A copy of the '776 patent is attached hereto as Exhibit D.

13. The U.S. Patent and Trademark Office ("PTO") issued the '804 patent on September 18, 2012. The '804 patent claims, *inter alia*, methods for treatment of acne including the use of oral dosage form of minocycline. Medicis is the assignee of the '804 patent. A copy of the '804 patent is attached hereto as Exhibit E.

14. Medicis is the holder of New Drug Application ("NDA") No. N050808 for Solodyn®, which the FDA approved on July 23, 2009. In conjunction with NDA No. N050808, the '838, the '705, the '483, the '776, and the '804 patents are listed in the FDA's Approved Drug Products with Therapeutic Equivalence Evaluations ("the Orange Book").

15. Minocycline hydrochloride 115 mg and 135 mg extended release tablets are sold in the United States under the trademark Solodyn®.

APOTEX'S INFRINGING ANDA SUBMISSION

16. Upon information and belief, Apotex filed with the FDA ANDA No. 20-7748, under Section 505(j) of the Act and 21 U.S.C. § 355(j).

17. Upon information and belief, Apotex's ANDA No. 20-7748 seeks FDA approval to sell in the United States Apotex's generic minocycline hydrochloride extended release tablets, intended to be a generic version of Solodyn®.

18. Medicis received a letter from Apotex dated March 5, 2015, purporting to be a Notice of Certification for ANDA No. 20-7748 ("Apotex's notice letter") under Section 505(j)(2)(B)(ii) of the Act, 21 U.S.C. § 355(j)(2)(B)(ii), and 21 § C.F.R. 314.95(c).

19. Apotex's notice letter alleges that Apotex has submitted to the FDA ANDA No. 20-7748 seeking FDA approval to sell generic minocycline hydrochloride extended release tablets, intended to be a generic version of Solodyn®.

20. Upon information and belief, ANDA No. 20-7748 seeks approval of Apotex's generic minocycline hydrochloride extended release tablets that is the same, or substantially the same, as Solodyn®.

21. Upon information and belief, Apotex's actions relating to ANDA No. 20-7748 complained of herein were done with the cooperation, the participation, the assistance of, and at least in part for the benefit of Apotex Corp.

COUNT I

Infringement of the '838 Patent under § 271(e)(2)

22. Paragraphs 1-21 are incorporated herein as set forth above.

23. Under 35 U.S.C. § 271(e)(2), Apotex has infringed at least one claim of the '838 patent by submitting, or causing to be submitted to the FDA, ANDA No. 20-7748 seeking approval for the commercial marketing of Apotex's generic minocycline hydrochloride extended release tablets before the expiration date of the '838 patent.

24. Upon information and belief, Apotex's generic minocycline hydrochloride extended release tablets will, if approved and marketed, infringe at least one claim of the '838 patent.

25. Upon information and belief, Apotex will, through the manufacture, use import, offer for sale and/or sale of Apotex's generic minocycline hydrochloride extended release tablets, directly infringe, contributorily infringe and/or induce infringement of at least one claim of the '838 patent.

COUNT II

Declaratory Judgment of Infringement of the '838 Patent

26. Paragraphs 1-25 are incorporated herein as set forth above.

27. These claims arise under the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202.

28. There is an actual case or controversy such that the Court may entertain Medicis' request for declaratory relief consistent with Article III of the United States Constitution, and this actual case or controversy requires a declaration of rights by this Court.

29. Apotex has made, and will continue to make, substantial preparation in the United States to manufacture, use, offer to sell, sell and/or import Apotex's generic minocycline hydrochloride extended release tablets before the expiration date of the '838 patent, including Apotex's filing of ANDA No. 20-7748.

30. Upon information and belief, any commercial manufacture, use, offer for sale, sale, and/or importation of Apotex's generic minocycline hydrochloride extended release tablets will directly infringe, contributorily infringe and/or induce infringement of at least one claim of the '838 patent.

31. Medicis is entitled to a declaratory judgment that future commercial manufacture, use, offer for sale, sale, and/or importation of Apotex's generic minocycline hydrochloride extended release tablets will constitute infringement of at least one claim of the '838 patent.

COUNT III

Infringement of the '705 patent under § 271(e)(2)

32. Paragraphs 1-31 are incorporated herein as set forth above.

33. Under 35 U.S.C. § 271(e)(2), Apotex has infringed at least one claim of the '705 patent by submitting, or causing to be submitted to the FDA, ANDA No. 20-7748 seeking approval for the commercial marketing of Apotex's generic minocycline hydrochloride extended release tablets before the expiration date of the '705 patent.

34. Upon information and belief, Apotex's generic minocycline hydrochloride extended release tablets will, if approved and marketed, infringe at least one claim of the '705 patent.

35. Upon information and belief, Apotex will, through the manufacture, use import, offer for sale and/or sale of Apotex's generic minocycline hydrochloride extended release tablets, directly infringe, contributorily infringe and/or induce infringement of at least one claim of the '705 patent.

COUNT IV

Declaratory Judgment of Infringement of the '705 Patent

36. Paragraphs 1-35 are incorporated herein as set forth above.

37. These claims arise under the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202.

38. There is an actual case or controversy such that the Court may entertain Medicis' request for declaratory relief consistent with Article III of the United States Constitution, and this actual case or controversy requires a declaration of rights by this Court.

39. Apotex has made, and will continue to make, substantial preparation in the United States to manufacture, use, offer to sell, sell and/or import Apotex's generic minocycline hydrochloride extended release tablets before the expiration date of the '705 patent, including Apotex's filing of ANDA No. 20-7748.

40. Upon information and belief, any commercial manufacture, use, offer for sale, sale, and/or importation of Apotex's generic minocycline hydrochloride extended release tablets will directly infringe, contributorily infringe and/or induce infringement of at least one claim of the '705 patent.

41. Medicis is entitled to a declaratory judgment that future commercial manufacture, use, offer for sale, sale, and/or importation of Apotex's generic minocycline hydrochloride extended release tablets will constitute infringement of at least one claim of the '705 patent.

COUNT V

Infringement of the '483 patent under § 271(e)(2)

42. Paragraphs 1-41 are incorporated herein as set forth above.

43. Under 35 U.S.C. § 271(e)(2), Apotex has infringed at least one claim of the '483 patent by submitting, or causing to be submitted to the FDA, ANDA No. 20-7748 seeking approval for the commercial marketing of Apotex's generic minocycline hydrochloride extended release tablets before the expiration date of the '483 patent.

44. Upon information and belief, Apotex's generic minocycline hydrochloride extended release tablets will, if approved and marketed, infringe at least one claim of the '483 patent.

45. Upon information and belief, Apotex will, through the manufacture, use import, offer for sale and/or sale of Apotex's generic minocycline hydrochloride extended release tablets, directly infringe, contributorily infringe and/or induce infringement of at least one claim of the '483 patent.

COUNT VI

Declaratory Judgment of Infringement of the '483 Patent

46. Paragraphs 1-45 are incorporated herein as set forth above.

47. These claims arise under the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202.

48. There is an actual case or controversy such that the Court may entertain Medicis' request for declaratory relief consistent with Article III of the United States Constitution, and this actual case or controversy requires a declaration of rights by this Court.

49. Apotex has made, and will continue to make, substantial preparation in the United States to manufacture, use, offer to sell, sell and/or import Apotex's generic minocycline hydrochloride extended release tablets before the expiration date of the '483 patent, including Apotex's filing of ANDA No. 20-7748.

50. Upon information and belief, any commercial manufacture, use, offer for sale, sale, and/or importation of Apotex's generic minocycline hydrochloride extended release tablets will directly infringe, contributorily infringe and/or induce infringement of at least one claim of the '483 patent.

51. Medicis is entitled to a declaratory judgment that future commercial manufacture, use, offer for sale, sale, and/or importation of Apotex's generic minocycline hydrochloride extended release tablets will constitute infringement of at least one claim of the '483 patent.

COUNT VII

Infringement of the '776 patent under § 271(e)(2)

52. Paragraphs 1-51 are incorporated herein as set forth above.

53. Under 35 U.S.C. § 271(e)(2), Apotex has infringed at least one claim of the '776 patent by submitting, or causing to be submitted to the FDA, ANDA No. 20-7748 seeking approval for the commercial marketing of Apotex's generic minocycline hydrochloride extended release tablets before the expiration date of the '776 patent.

54. Upon information and belief, Apotex's generic minocycline hydrochloride extended release tablets will, if approved and marketed, infringe at least one claim of the '776 patent.

55. Upon information and belief, Apotex will, through the manufacture, use import, offer for sale and/or sale of Apotex's generic minocycline hydrochloride extended release tablets, directly infringe, contributorily infringe and/or induce infringement of at least one claim of the '776 patent.

COUNT VIII

Declaratory Judgment of Infringement of the '776 Patent

56. Paragraphs 1-55 are incorporated herein as set forth above.

57. These claims arise under the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202.

58. There is an actual case or controversy such that the Court may entertain Medicis' request for declaratory relief consistent with Article III of the United States Constitution, and this actual case or controversy requires a declaration of rights by this Court.

59. Apotex has made, and will continue to make, substantial preparation in the United States to manufacture, use, offer to sell, sell and/or import Apotex's generic minocycline hydrochloride extended release tablets before the expiration date of the '776 patent, including Apotex's filing of ANDA No. 20-7748.

60. Upon information and belief, any commercial manufacture, use, offer for sale, sale, and/or importation of Apotex's generic minocycline hydrochloride extended release tablets will directly infringe, contributorily infringe and/or induce infringement of at least one claim of the '776 patent.

61. Medicis is entitled to a declaratory judgment that future commercial manufacture, use, offer for sale, sale, and/or importation of Apotex's generic minocycline hydrochloride extended release tablets will constitute infringement of at least one claim of the '776 patent.

COUNT IX

Infringement of the '804 patent under § 271(e)(2)

62. Paragraphs 1-61 are incorporated herein as set forth above.

63. Under 35 U.S.C. § 271(e)(2), Apotex has infringed at least one claim of the '804 patent by submitting, or causing to be submitted to the FDA, ANDA No. 20-7748 seeking approval for the commercial marketing of Apotex's generic minocycline hydrochloride extended release tablets before the expiration date of the '804 patent.

64. Upon information and belief, Apotex's generic minocycline hydrochloride extended release tablets will, if approved and marketed, infringe at least one claim of the '804 patent.

65. Upon information and belief, Apotex will, through the manufacture, use import, offer for sale and/or sale of Apotex's generic minocycline hydrochloride extended release tablets, directly infringe, contributorily infringe and/or induce infringement of at least one claim of the '804 patent.

COUNT X

Declaratory Judgment of Infringement of the '804 Patent

66. Paragraphs 1-65 are incorporated herein as set forth above.

67. These claims arise under the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202.

68. There is an actual case or controversy such that the Court may entertain Medicis' request for declaratory relief consistent with Article III of the United States Constitution, and this actual case or controversy requires a declaration of rights by this Court.

69. Apotex has made, and will continue to make, substantial preparation in the United States to manufacture, use, offer to sell, sell and/or import Apotex's generic minocycline hydrochloride extended release tablets before the expiration date of the '804 patent, including Apotex's filing of ANDA No. 20-7748.

70. Upon information and belief, any commercial manufacture, use, offer for sale, sale, and/or importation of Apotex's generic minocycline hydrochloride extended release tablets will directly infringe, contributorily infringe and/or induce infringement of at least one claim of the '804 patent.

71. Medicis is entitled to a declaratory judgment that future commercial manufacture, use, offer for sale, sale, and/or importation of Apotex's generic minocycline hydrochloride extended release tablets will constitute infringement of at least one claim of the '804 patent.

PRAYER FOR RELIEF

WHEREFORE, Medicis respectfully requests that the Court enter judgment in their favor and against Defendants on the patent infringement claim set forth above and respectfully requests that this Court:

1. enter judgment that, under 35 U.S.C. § 271(e)(2), Defendants have infringed at least one claim of the '838 patent through Apotex's submission of ANDA No. 20-7748 to the FDA to obtain approval for the commercial manufacture, use, import, offer for sale and/or sale in the United States of Apotex's generic minocycline hydrochloride extended release tablets before the expiration of the '838 patent;

2. enter judgment that, under 35 U.S.C. § 271(e)(2), Defendants have infringed at least one claim of the '705 patent through Apotex's submission of ANDA No. 20-7748 to the FDA to obtain approval for the commercial manufacture, use, import, offer for sale and/or sale in the United States of Apotex's generic minocycline hydrochloride extended release tablets before the expiration of the '705 patent;

3. enter judgment that, under 35 U.S.C. § 271(e)(2), Defendants have infringed at least one claim of the '483 patent through Apotex's submission of ANDA No. 20-7748 to the FDA to obtain approval for the commercial manufacture, use, import, offer for sale and/or sale in the United States of Apotex's generic minocycline hydrochloride extended release tablets before the expiration of the '483 patent;

4. enter judgment that, under 35 U.S.C. § 271(e)(2), Defendants have infringed at least one claim of the '776 patent through Apotex's submission of ANDA No. 20-7748 to the FDA to obtain approval for the commercial manufacture, use, import, offer for sale and/or sale in the United States of Apotex's generic minocycline hydrochloride extended release tablets before the expiration of the '776 patent;

5. enter judgment that, under 35 U.S.C. § 271(e)(2), Defendants have infringed at least one claim of the '804 patent through Apotex's submission of ANDA No. 20-7748 to the FDA to obtain approval for the commercial manufacture, use, import, offer for sale and/or sale in the United States of Apotex's generic minocycline hydrochloride extended release tablets before the expiration of the '804 patent;

6. order that the effective date of any approval by the FDA of Apotex's generic minocycline hydrochloride extended release tablets be a date that is not earlier than the expiration of the '838 patent, the '705 patent, the '483 patent, the '776 patent, and the '804 patent, or such later date as the Court may determine;

7. enjoin Defendants from the commercial manufacture, use, import, offer for sale and/or sale of Apotex's generic minocycline hydrochloride extended release tablets until expiration of the '838 patent, the '705 patent, the '483 patent, the '776 patent, and the '804 patent, or such later date as the Court may determine;

8. enjoin Defendants and all persons acting in concert with Defendants from seeking, obtaining or maintaining approval of Apotex's ANDA No. 20-7748 until expiration of the '838 patent, the '705 patent, the '483 patent, the '776 patent, and the '804 patent;

9. declare this to be an exceptional case under 35 U.S.C. §§ 285 and 271(e)(4) and award Medicis costs, expenses and disbursements in this action, including reasonable attorneys fees;

10. award Medicis such further and additional relief as this Court deems just and proper.

Dated: April 15, 2015
Newark, New Jersey

Respectfully submitted,

By: s/ Elvin Esteves
Elvin Esteves
GIBBONS P.C.
One Gateway Center
Newark, New Jersey 07102-5310
Tel: (973) 596-4500
Fax: (973) 596-0545
eesteves@gibbonslaw.com

Of Counsel:
Bryan C. Diner
Justin J. Hasford
FINNEGAN, HENDERSON, FARABOW, GARRETT & DUNNER, LLP
901 New York Avenue, NW
Washington, DC 20001-4413
(202) 408-4000

Attorneys for Plaintiff
Medicis Pharmaceutical Corporation

CERTIFICATION OF NON-ARBITRABILITY PURSUANT TO LOCAL CIVIL RULE 201.1(d)

Pursuant to Local Civil Rule 201.1(d), the undersigned counsel hereby certifies that this action seeks declaratory and injunctive relief and, therefore, is not subject to mandatory arbitration.

I hereby certify that the foregoing statements made by me are true. I am aware that if any of the statements made by me are willfully false, I am subject to punishment.

Dated: April 15, 2015
Newark, New Jersey

Respectfully submitted,

By: s/ Elvin Esteves
Elvin Esteves
GIBBONS P.C.
One Gateway Center
Newark, New Jersey 07102-5496
Tel: (973) 596-4500
Fax: (973) 596-0545
eesteves@gibbonslaw.com

Of Counsel:
Bryan C. Diner
Justin J. Hasford
FINNEGAN, HENDERSON, FARABOW, GARRETT & DUNNER, LLP
901 New York Avenue, NW
Washington, DC 20001-4413
(202) 408-4000

Attorneys for Plaintiff
Medicis Pharmaceutical Corporation