IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

ABBOTT LABORATORIES and ABBOTT RESPIRATORY LLC, Plaintiffs, v. TEVA PHARMACEUTICALS USA, INC. and TEVA PHARMACEUTICAL INDUSTRIES LTD., Defendants.	)	C.A. No. _____

COMPLAINT

Plaintiffs Abbott Laboratories and Abbott Respiratory LLC (collectively, "Abbott"), by their attorneys, hereby allege as follows:

NATURE OF THE ACTION

This is an action for patent infringement of U.S. Patent Nos. 6,080,428 ("the '428 patent"), 6,129,930 ("the '930 patent"), 6,406,715 ("the '715 patent"), 6,469,035 ("the '035 patent"), 6,676,967 ("the '967 patent"), 6,746,691 ("the '691 patent"), 6,818,229 ("the '229 patent"), and 7,011,848 ("the '848 patent"), arising under the patent laws of the United States, Title 35, United States Code, 35 U.S.C. §§ 271 and 281. This action relates to Abbreviated New Drug Application ("ANDA") No. 200478 filed by Teva Pharmaceuticals USA, Inc. ("Teva USA") with the U.S. Food and Drug Administration ("FDA") for approval to market 500 mg / 40 mg niacin extended release / simvastatin tablets, which is a generic version of the 500 mg / 40 mg form of Abbott's SIMCOR® drug product.

RELATED ACTIONS

Abbott has filed several other patent infringement actions involving the same patents that are currently pending before the Court as described below:

- Consolidated cases *Abbott Laboratories & Abbott Respiratory LLC v. Teva Pharmaceutical Industries, Ltd. & Teva Pharmaceuticals USA, Inc.*, Nos. 10-57-SLR-MPT, 10-302-SLR-MPT, 10-766-SLR and 11-239-SLR (D. Del.), which relate to ANDA No. 200478 filed by Teva for approval to market generic versions of SIMCOR® in 1000 / 20 mg, 750 / 20 mg, 500 / 20 mg, and 1000 / 40 mg dosage strengths, respectively, and involve the ’930, ’715, ’035, ’967, ’691, ’848, ’229, and ’428 patents, and *Abbott Laboratories & Abbott Respiratory LLC v. Watson Laboratories, Inc. – Florida*, No. 10-373-SLR, 11-251-SLR, 11-607-SLR (D. Del.), which relate to ANDA No. 200601 filed by Watson for approval to market a generic version of SIMCOR® in 1000 / 20 mg , 500 / 40 mg, and 1000 / 40 mg dosage strengths, respectively, and also involve the ’930, ’715, ’035, ’967, ’691, ’848, ’229, and ’428 patents;
- Consolidated cases *Abbott Laboratories & Abbott Respiratory LLC v. Sun Pharmaceutical Industries Ltd. & Sun Pharma Global FZE*, No. 10-112-SLR-MPT (D. Del.), and *Abbott Laboratories & Abbott Respiratory LLC v. Sun Pharmaceutical Industries Ltd. & Sun Pharma Global FZE*, No. 10-488-SLR (D. Del.), which relate to ANDA Nos. 200484 and 201273 filed by Sun for approval to market generic versions of NIASPAN®, and involve the ’428 and ’035 patents;
- *Abbott Laboratories & Abbott Respiratory LLC v. Sandoz Inc.*, No. 10-538-SLR (D. Del.), which relates to ANDA No. 201403 filed by Sandoz for approval to market a

generic version of NIASPAN®, and involves the '428 and '035 patents; and *Abbott Laboratories & Abbott Respiratory LLC v. Sandoz Inc.*, No 11-145-SLR which also relates to ANDA No. 201403 filed by Sandoz for approval to market a generic version of NIASPAN®, and involves the '428 and '035 patents.

- *Abbott Laboratories & Abbott Respiratory LLC v. Mylan Inc. & Mylan Pharmaceuticals, Inc.*, No. 10-559-SLR (D. Del.), which relates to ANDA No. 201521 filed by Mylan for approval to market a generic version of SIMCOR®, and involves the '930, '715, '035, '967, '691, '848, '229, and '428 patents.
- *Abbott Laboratories & Abbott Respiratory LLC v. Impax Laboratories, Inc.*, No. 10-1029-SLR (D. Del.), which relates to ANDA No. 202149 filed by Impax for approval to market a generic version of SIMCOR®, and involves the '930, '715, '035, '967, '691, '848, '229, and '428 patents.

PARTIES

1. Abbott Laboratories is a corporation organized and existing under the laws of the State of Illinois, with its principal place of business at 100 Abbott Park Road, Abbott Park, Illinois 60064.

2. Abbott Respiratory LLC ("Abbott Respiratory") is a limited liability corporation organized and existing under the laws of the State of Delaware, with its principal place of business at 100 Abbott Park Road, Abbott Park, Illinois 60064.

3. Upon information and belief, Teva Pharmaceutical Industries, Ltd. ("Teva Industries") is an Israeli corporation, having a principal place of business at 5 Basel Street, Petach Tikva 49131, Israel. Upon information and belief, Teva Industries, itself and through its

wholly-owned subsidiary and agent, Teva USA, manufactures, distributes and/or imports generic drugs for sale and use throughout the United States, including in this judicial district.

4. Upon information and belief, Teva USA is a corporation organized and existing under the laws of the State of Delaware, with its principal place of business at 1090 Horsham Road, North Wales, Pennsylvania. Upon information and belief, Teva USA is a wholly-owned subsidiary of Teva Industries and is controlled and/or dominated by Teva Industries. Upon information and belief, Teva USA manufactures and/or distributes generic drugs for sale and use throughout the United States and in this judicial district at the direction, under the control, and for the direct benefit of Teva Industries.

5. Upon information and belief, Teva Industries established Teva USA, its wholly-owned subsidiary, for the purposes of distributing, marketing, offering for sale and selling its generic drug products throughout the United States.

6. Upon information and belief, Teva USA and Teva Industries (collectively "Teva") acted collaboratively in the preparation and submission of ANDA No. 200478. Upon information and belief, Teva USA's preparation and submission of ANDA No. 200478 was done at the direction, under the control, and for the direct benefit of Teva Industries.

7. Upon information and belief, following any FDA approval of ANDA No. 200478, Teva Industries itself and through its wholly-owned subsidiary, Teva USA, will make, use, offer to sell, and/or sell its generic product throughout the United States, and/or import its generic product into the United States.

JURISDICTION AND VENUE

8. This action arises under the patent laws of the United States, 35 U.S.C. §§ 100, *et seq.*, and this Court has jurisdiction over the subject matter of this action under 28

U.S.C. §§ 1331 and 1338(a). Venue is proper in this Court under 28 U.S.C. §§ 1391 and 1400(b).

9. This Court has personal jurisdiction over each of the Defendants because, *inter alia*, they each have committed, or aided, abetted, contributed to, or participated in the commission of, a tortious act of patent infringement in filing ANDA No. 200478 that has led to foreseeable harm and injury to Abbott Respiratory, a Delaware corporation, and Abbott Laboratories, a corporation actively engaged in business in Delaware. This Court also has personal jurisdiction over the Defendants by virtue of, *inter alia*, their systematic and continuous contacts with Delaware as set forth below, and for other reasons that will be presented to the Court if jurisdiction is challenged.

10. Upon information and belief, Teva USA currently manufactures and distributes for sale hundreds of drug products throughout the United States, including in this judicial district. Upon information and belief, Teva USA maintains a website, www.tevausa.com, listing the drug products it manufactures, markets, and/or sells in the United States. On its website, Teva USA represents that it "is the leading generic pharmaceutical company, marketing products from a wide range of therapeutic areas including cardiovascular" and that "Teva USA is a wholly-owned subsidiary of Teva Pharmaceutical Industries, Ltd."

11. Upon information and belief, Teva Industries directs the operations, management and activities of Teva USA in the United States.

12. Upon information and belief, Teva USA and Teva Industries collaborate in the manufacture, marketing, and sale of many pharmaceutical products (including generic drug products manufactured and sold pursuant to approved ANDAs) throughout the United States, including in this judicial district.

13. Upon information and belief, Teva USA sells generic drug products in the United States, including in this judicial district, that are manufactured by Teva Industries.

14. Teva Industries has taken advantage of the jurisdiction of this Court by affirmatively filing claims and counterclaims in other actions pending before this Court, including *Teva Pharmaceutical Industries, Ltd. & Teva Pharmaceuticals USA, Inc. v. Torrent Pharmaceuticals Ltd. & Torrent Pharma Inc.*, No. 07-24-JJF (D. Del.); *Takeda Pharmaceutical Company Ltd., Tap Pharmaceutical Products Inc., & Ethypharm, S.A. v. Teva Pharmaceuticals USA, Inc. & Teva Pharmaceutical Industries, Ltd.*, No. 07-331-SLR (D. Del); and *The Brigham & Women's Hospital, Inc., NPS Pharmaceuticals, Inc., & Amgen Inc. v. Teva Pharmaceuticals USA, Inc., Teva Pharmaceutical Industries, Ltd., & Barr Laboratories, Inc.*, No. 08-464-HB (D. Del.).

15. This Court has personal jurisdiction over Teva USA by virtue of, *inter alia*, its systematic and continuous contacts with Delaware.

16. This Court has personal jurisdiction over Teva Industries by virtue of, *inter alia*, its systematic and continuous contacts with Delaware.

PATENTS IN SUIT

17. Abbott Respiratory is the owner by assignment of the '428 patent, entitled "Nicotinic Acid Compositions for Treating Hyperlipidemia and Related Methods Thereof," which the U.S. Patent and Trademark Office duly and legally issued on June 27, 2000. A true and correct copy of the '428 patent is attached hereto as Exhibit A. The claims of the '428 patent are valid and enforceable. Abbott Laboratories is an exclusive licensee of the '428 patent with respect to SIMCOR®, with the right to sue for and obtain equitable relief and damages for infringement of the '428 patent.

18. Abbott Respiratory is the owner by assignment of the ’930 patent, entitled “Methods and Sustained Release Nicotinic Acid Compositions for Treating Hyperlipidemia at Night,” which the U.S. Patent and Trademark Office duly and legally issued on October 10, 2000. A true and correct copy of the ’930 patent is attached hereto as Exhibit B. The claims of the ’930 patent are valid and enforceable. Abbott Laboratories is an exclusive licensee of the ’930 patent with respect to SIMCOR®, with the right to sue for and obtain equitable relief and damages for infringement of the ’930 patent.

19. Abbott Respiratory is the owner by assignment of the ’715 patent, entitled “Intermediate Release Nicotinic Acid Compositions for Treating Hyperlipidemia Having Unique Urinary Metabolite Profiles,” which the U.S. Patent and Trademark Office duly and legally issued on June 18, 2002. A true and correct copy of the ’715 patent is attached hereto as Exhibit C. The claims of the ’715 patent are valid and enforceable. Abbott Laboratories is an exclusive licensee of the ’715 patent with respect to SIMCOR®, with the right to sue for and obtain equitable relief and damages for infringement of the ’715 patent.

20. Abbott Respiratory is the owner by assignment of the ’035 patent, entitled “Methods of Pretreating Hyperlipidemic Individuals with a Flush Inhibiting Agent Prior to the Start of Single Daily Dose Nicotinic Acid Therapy to Reduce Flushing Provoked by Nicotinic Acid,” which the U.S. Patent and Trademark Office duly and legally issued on October 22, 2002. A true and correct copy of the ’035 patent is attached hereto as Exhibit D. The claims of the ’035 patent are valid and enforceable. Abbott Laboratories is an exclusive licensee of the ’035 patent with respect to SIMCOR®, with the right to sue for and obtain equitable relief and damages for infringement of the ’035 patent.

21. Abbott Respiratory is the owner by assignment of the ’967 patent, entitled “Methods for Reducing Flushing in Individuals Being Treated with Nicotinic Acid for Hyperlipidemia,” which the U.S. Patent and Trademark Office duly and legally issued on January 13, 2004. A true and correct copy of the ’967 patent is attached hereto as Exhibit E. The claims of the ’967 patent are valid and enforceable. Abbott Laboratories is an exclusive licensee of the ’967 patent with respect to SIMCOR®, with the right to sue for and obtain equitable relief and damages for infringement of the ’967 patent.

22. Abbott Respiratory is the owner by assignment of the ’691 patent, entitled “Intermediate Release Nicotinic Acid Compositions for Treating Hyperlipidemia Having Unique Biopharmaceutical Characteristics,” which the U.S. Patent and Trademark Office duly and legally issued on June 8, 2004. A true and correct copy of the ’691 patent is attached hereto as Exhibit F. The claims of the ’691 patent are valid and enforceable. Abbott Laboratories is an exclusive licensee of the ’691 patent with respect to SIMCOR®, with the right to sue for and obtain equitable relief and damages for infringement of the ’691 patent.

23. Abbott Respiratory is the owner by assignment of the ’229 patent, entitled “Intermediate Release Nicotinic Acid Compositions for Treating Hyperlipidemia,” which the U.S. Patent and Trademark Office duly and legally issued on November 16, 2004. A true and correct copy of the ’229 patent is attached hereto as Exhibit G. The claims of the ’229 patent are valid and enforceable. Abbott Laboratories is an exclusive licensee of the ’229 patent with respect to SIMCOR®, with the right to sue for and obtain equitable relief and damages for infringement of the ’229 patent.

24. Abbott Respiratory is the owner by assignment of the ’848 patent, entitled “Hydrophobic Component Free Sustained Release Nicotinic Acid Compositions for Treating

Hyperlipidemia and Related Methods Therefor," which the U.S. Patent and Trademark Office duly and legally issued on March 14, 2006. A true and correct copy of the '848 patent is attached hereto as Exhibit H. The claims of the '848 patent are valid and enforceable. Abbott Laboratories is an exclusive licensee of the '848 patent with respect to SIMCOR®, with the right to sue for and obtain equitable relief and damages for infringement of the '848 patent.

25. Abbott Laboratories is the holder of New Drug Application ("NDA") No 02-2078, by which the FDA granted approval for 500 mg / 20 mg, 750 mg / 20 mg, 1000 mg / 20 mg, 1000 mg / 40 mg, and 500 mg / 40 mg strength niacin extended-release / simvastatin tablets, which Abbott markets in the United States under the trade name SIMCOR®. The formulation and dosing of SIMCOR® is covered by certain claims of the '428 patent, the '930 patent, the '715 patent, the '035 patent, the '967 patent, the '691 patent, the '229 patent, and the '848 patent. The FDA's official publication of approved drugs (the "Orange Book") includes SIMCOR® together with the '428 patent, the '930 patent, the '715 patent, the '035 patent, the '967 patent, the '691 patent, the '229 patent, and the '848 patent.

INFRINGEMENT BY TEVA

26. By letter dated June 30, 2011, ("the Notice Letter"), Teva notified Abbott that Teva had submitted ANDA No. 200478 to the FDA under Section 505(j) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. § 355(j)) seeking approval to engage in the commercial manufacture, use, and sale of its 500 / 40 mg generic niacin extended-release / simvastatin tablets before the expiration of the '428 patent, the '930 patent, the '715 patent, the '035 patent, the '967 patent, the '691 patent, the '229 patent, and the '848 patent. Upon information and belief, Teva intends to engage in commercial manufacture, use, and sale of its 500 / 40 mg generic niacin extended-release / simvastatin tablets promptly upon receiving FDA approval to do so.

27. By filing ANDA No. 200478, Teva has necessarily represented to the FDA that the components of its 500 / 40 mg generic niacin extended-release / simvastatin tablets have the same active ingredients as those of the corresponding components of SIMCOR®, have the same route of administration, dosage form, and strengths as the corresponding components of SIMCOR®, and are bioequivalent to the corresponding components of SIMCOR®.

28. In the Notice Letter, Teva notified Abbott that its ANDA contained a "Paragraph IV certification" asserting that, in Teva's opinion, the '428 patent, the '930 patent, the '715 patent, the '035 patent, the '967 patent, the '691 patent, the '229 patent, and the '848 patent are invalid and/or will not be infringed by the commercial manufacture, use or sale of its 500 / 40 mg generic niacin extended-release / simvastatin tablets.

29. This Complaint is being filed before the expiration of the forty-five days from the date Abbott received the Notice Letter.

COUNT I
(INFRINGEMENT OF THE '428 PATENT)

30. Each of the preceding paragraphs 1 to 29 is incorporated as if fully set forth.

31. Teva's submission of ANDA No. 200478 to obtain approval to engage in the commercial manufacture, use, offer to sell, or sale of its 500 / 40 mg generic niacin extended-release / simvastatin tablets prior to the expiration of the '428 patent constitutes infringement of one or more of the claims of the '428 patent under 35 U.S.C. § 271(e)(2)(A).

32. Upon FDA approval of Teva's ANDA No. 200478, Teva will further infringe the '428 patent by making, using, offering to sell, and selling its 500 / 40 mg generic niacin extended-release / simvastatin tablets in the United States and/or importing such tablets

into the United States, and by actively inducing and contributing to infringement by others, in violation of 35 U.S.C. § 271(a)-(c) unless enjoined by the Court.

33. Upon information and belief, Teva had actual and constructive knowledge of the '428 patent prior to filing ANDA No. 200478 and was aware that filing of the aforementioned ANDA with the FDA constituted an act of infringement of the '428 patent.

34. If Teva's infringement of the '428 patent is not enjoined, Abbott will suffer substantial and irreparable harm for which there is no remedy at law.

COUNT II
(INFRINGEMENT OF THE '930 PATENT)

35. Each of the preceding paragraphs 1 to 34 is incorporated as if fully set forth.

36. Teva's submission of ANDA No. 200478 to obtain approval to engage in the commercial manufacture, use, offer to sell, or sale of its 500 / 40 mg generic niacin extended-release / simvastatin tablets prior to the expiration of the '930 patent constitutes infringement of one or more of the claims of the '930 patent under 35 U.S.C. § 271(e)(2)(A).

37. Upon FDA approval of Teva's ANDA No. 200478, Teva will further infringe the '930 patent by making, using, offering to sell, and selling its 500 / 40 mg generic niacin extended-release / simvastatin tablets in the United States and/or importing such tablets into the United States, and by actively inducing and contributing to infringement by others, in violation of 35 U.S.C. § 271(a)-(c) unless enjoined by the Court.

38. Upon information and belief, Teva had actual and constructive knowledge of the '930 patent prior to filing ANDA No. 200478 and was aware that filing of the aforementioned ANDA with the FDA constituted an act of infringement of the '930 patent.

39. If Teva's infringement of the '930 patent is not enjoined, Abbott will suffer substantial and irreparable harm for which there is no remedy at law.

COUNT III
(INFRINGEMENT OF THE '715 PATENT)

40. Each of the preceding paragraphs 1 to 39 is incorporated as if fully set forth.

41. Teva's submission of ANDA No. 200478 to obtain approval to engage in the commercial manufacture, use, offer to sell, or sale of its 500 / 40 mg generic niacin extended-release / simvastatin tablets prior to the expiration of the '715 patent constitutes infringement of one or more of the claims of the '715 patent under 35 U.S.C. § 271(e)(2)(A).

42. Upon FDA approval of Teva's ANDA No. 200478, Teva will further infringe the '715 patent by making, using, offering to sell, and selling its 500 / 40 mg generic niacin extended-release / simvastatin tablets in the United States and/or importing such tablets into the United States, and by actively inducing and contributing to infringement by others, in violation of 35 U.S.C. § 271(a)-(c) unless enjoined by the Court.

43. Upon information and belief, Teva had actual and constructive knowledge of the '715 patent prior to filing ANDA No. 200478 and was aware that filing of the aforementioned ANDA with the FDA constituted an act of infringement of the '715 patent.

44. If Teva's infringement of the '715 patent is not enjoined, Abbott will suffer substantial and irreparable harm for which there is no remedy at law.

COUNT IV
(INFRINGEMENT OF THE '035 PATENT)

45. Each of the preceding paragraphs 1 to 44 is incorporated as if fully set forth.

46. Teva's submission of ANDA No. 200478 to obtain approval to engage in the commercial manufacture, use, offer to sell, or sale of its 500 / 40 mg generic niacin extended-release / simvastatin tablets prior to the expiration of the '035 patent constitutes infringement of one or more of the claims of the '035 patent under 35 U.S.C. § 271(e)(2)(A).

47. Upon FDA approval of Teva's ANDA No. 200478, Teva will further infringe the '035 patent by making, using, offering to sell, and selling its 500 / 40 mg generic niacin extended-release / simvastatin tablets in the United States and/or importing such tablets into the United States, and by actively inducing and contributing to infringement by others, in violation of 35 U.S.C. § 271(a)-(c) unless enjoined by the Court.

48. Upon information and belief, Teva had actual and constructive knowledge of the '035 patent prior to filing ANDA No. 200478 and was aware that filing of the aforementioned ANDA with the FDA constituted an act of infringement of the '035 patent.

49. If Teva's infringement of the '035 patent is not enjoined, Abbott will suffer substantial and irreparable harm for which there is no remedy at law.

COUNT V
(INFRINGEMENT OF THE '967 PATENT)

50. Each of the preceding paragraphs 1 to 49 is incorporated as if fully set forth.

51. Teva's submission of ANDA No. 200478 to obtain approval to engage in the commercial manufacture, use, offer to sell, or sale of its 500 / 40 mg generic niacin extended-release / simvastatin tablets prior to the expiration of the '967 patent constitutes infringement of one or more of the claims of the '967 patent under 35 U.S.C. § 271(e)(2)(A).

52. Upon FDA approval of Teva's ANDA No. 200478, Teva will further infringe the '967 patent by making, using, offering to sell, and selling its 500 / 40 mg generic

niacin extended-release / simvastatin tablets in the United States and/or importing such tablets into the United States, and by actively inducing and contributing to infringement by others, in violation of 35 U.S.C. § 271(a)-(c) unless enjoined by the Court.

53. Upon information and belief, Teva had actual and constructive knowledge of the '967 patent prior to filing ANDA No. 200478 and was aware that filing of the aforementioned ANDA with the FDA constituted an act of infringement of the '967 patent.

54. If Teva's infringement of the '967 patent is not enjoined, Abbott will suffer substantial and irreparable harm for which there is no remedy at law.

COUNT VI
(INFRINGEMENT OF THE '691 PATENT)

55. Each of the preceding paragraphs 1 to 54 is incorporated as if fully set forth.

56. Teva's submission of ANDA No. 200478 to obtain approval to engage in the commercial manufacture, use, offer to sell, or sale of its 500 / 40 mg generic niacin extended-release / simvastatin tablets prior to the expiration of the '691 patent constitutes infringement of one or more of the claims of the '691 patent under 35 U.S.C. § 271(e)(2)(A).

57. Upon FDA approval of Teva's ANDA No. 200478, Teva will further infringe the '691 patent by making, using, offering to sell, and selling its 500 / 40 mg generic niacin extended-release / simvastatin tablets in the United States and/or importing such tablets into the United States, and by actively inducing and contributing to infringement by others, in violation of 35 U.S.C. § 271(a)-(c) unless enjoined by the Court.

58. Upon information and belief, Teva had actual and constructive knowledge of the '691 patent prior to filing ANDA No. 200478 and was aware that filing of the aforementioned ANDA with the FDA constituted an act of infringement of the '691 patent.

59. If Teva's infringement of the '691 patent is not enjoined, Abbott will suffer substantial and irreparable harm for which there is no remedy at law.

COUNT VII
(INFRINGEMENT OF THE '229 PATENT)

60. Each of the preceding paragraphs 1 to 59 is incorporated as if fully set forth.

61. Teva's submission of ANDA No. 200478 to obtain approval to engage in the commercial manufacture, use, offer to sell, or sale of its 500 / 40 mg generic niacin extended-release / simvastatin tablets prior to the expiration of the '229 patent constitutes infringement of one or more of the claims of the '229 patent under 35 U.S.C. § 271(e)(2)(A).

62. Upon FDA approval of Teva's ANDA No. 200478, Teva will further infringe the '229 patent by making, using, offering to sell, and selling its 500 / 40 mg generic niacin extended-release / simvastatin tablets in the United States and/or importing such tablets into the United States, and by actively inducing and contributing to infringement by others, in violation of 35 U.S.C. § 271(a)-(c) unless enjoined by the Court.

63. Upon information and belief, Teva had actual and constructive knowledge of the '229 patent prior to filing ANDA No. 200478 and was aware that filing of the aforementioned ANDA with the FDA constituted an act of infringement of the '229 patent.

64. If Teva's infringement of the '229 patent is not enjoined, Abbott will suffer substantial and irreparable harm for which there is no remedy at law.

COUNT VIII
(INFRINGEMENT OF THE '848 PATENT)

65. Each of the preceding paragraphs 1 to 64 is incorporated as if fully set forth.

66. Teva's submission of ANDA No. 200478 to obtain approval to engage in the commercial manufacture, use, offer to sell, or sale of its 500 / 40 mg generic niacin extended-release / simvastatin tablets prior to the expiration of the '848 patent constitutes infringement of one or more of the claims of the '848 patent under 35 U.S.C. § 271(e)(2)(A).

67. Upon FDA approval of Teva's ANDA No. 200478, Teva will further infringe the '848 patent by making, using, offering to sell, and selling its 500 / 40 mg generic niacin extended-release / simvastatin tablets in the United States and/or importing such tablets into the United States, and by actively inducing and contributing to infringement by others, in violation of 35 U.S.C. § 271(a)-(c) unless enjoined by the Court.

68. Upon information and belief, Teva had actual and constructive knowledge of the '848 patent prior to filing ANDA No. 200478 and was aware that filing of the aforementioned ANDA with the FDA constituted an act of infringement of the '848 patent.

69. If Teva's infringement of the '848 patent is not enjoined, Abbott will suffer substantial and irreparable harm for which there is no remedy at law.

PRAYER FOR RELIEF

WHEREFORE, Abbott prays that this Court grant the following relief:

1. A judgment that one or more claims of the '428 patent, the '930 patent, the '715 patent, the '035 patent, the '967 patent, the '691 patent, the '229 patent, and the '848 patent are infringed by Teva's submission of ANDA No. 200478, and that Teva's making, using, offering to sell, or selling in the United States, or importing into the United States, of Teva's 500 / 40 mg generic niacin extended-release / simvastatin tablets will infringe the '428 patent, the '930 patent, the '715 patent, the '035 patent, the '967 patent, the '691 patent, the '229 patent, and the '848 patent;

2. An order pursuant to 35 U.S.C. § 271(e)(4)(A) providing that the effective date of any approval of ANDA No. 200478 shall be a date which is not earlier than the latest expiration date of the ’428 patent, the ’930 patent, the ’715 patent, the ’035 patent, the ’967 patent, the ’691 patent, the ’229 patent, and the ’848 patent, including any extensions and/or additional periods of exclusivity to which Abbott is or becomes entitled;

3. An order permanently enjoining Teva, its affiliates, subsidiaries, and each of its officers, agents, servants and employees and those acting in privity or concert with them, from making, using, offering to sell, or selling in the United States, or importing into the United States Teva’s 500 / 40 mg generic niacin extended-release / simvastatin tablets until after the latest expiration date of the ’428 patent, the ’930 patent, the ’715 patent, the ’035 patent, the ’967 patent, the ’691 patent, the ’229 patent, and the ’848 patent, including any extensions and/or additional periods of exclusivity to which Abbott is or becomes entitled;

4. Damages or other monetary relief to Abbott if Teva engages in commercial manufacture, use, offers to sell, sale, or importation in or into the United States of Teva’s 500 / 40 mg generic niacin extended-release / simvastatin tablets prior to the latest expiration date of the ’428 patent, the ’930 patent, the ’715 patent, the ’035 patent, the ’967 patent, the ’691 patent, the ’229 patent, and the ’848 patent, including any extensions and/or additional periods of exclusivity to which Abbott is or becomes entitled.

5. Such further and other relief as this Court deems proper and just, including any appropriate relief under 35 U.S.C. § 285.

MORRIS, NICHOLS, ARSHT & TUNNELL LLP

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