

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

ABBOTT LABORATORIES and)
ABBOTT RESPIRATORY LLC,)
)
Plaintiffs,)
) C.A. No. _____
v.)
)
WATSON PHARMACEUTICALS, INC.,)
WATSON LABORATORIES, INC – FLORIDA)
and WATSON PHARMA, INC.)
)
Defendants.)

COMPLAINT

Plaintiffs Abbott Laboratories and Abbott Respiratory LLC (collectively, “Abbott”), for their Complaint against Defendants Watson Pharmaceuticals, Inc. (“Watson Pharmaceuticals”), Watson Laboratories, Inc. – Florida (“Watson Laboratories”), and Watson Pharma, Inc. (“Watson Pharma”) (collectively, “Watson”), 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 §§ 271 and 281. This action relates to Abbreviated New Drug Application (“ANDA”) No. 200601 filed by Watson with the U.S. Food and Drug Administration (“FDA”) for approval to market 1000 mg / 40 mg niacin extended release / simvastatin tablets, which are a generic version of the 1000 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-UNA (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 and 11-251-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 and 500 / 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 principle place of business at 100 Abbott Park Road, Abbott Park, Illinois 60064.

3. Upon information and belief, Watson Laboratories is a Florida corporation, having a place of business at 4955 Orange Drive, Davie, Florida 33314 and 360 Mount Kemble Avenue, Morristown, New Jersey 07962. Upon information and belief, Watson Laboratories has identified its mailing address as 311 Bonnie Circle, Corona, California 92880. Upon information and belief, Watson Laboratories formerly did business as Andrx Pharmaceuticals, Inc., and is a wholly owned subsidiary of Andrx Corporation, a corporation organized and existing under the laws of the State of Delaware. On information and belief, Andrx Corporation is a wholly-owned subsidiary of Watson Pharmaceuticals. On information and belief, Watson Laboratories is in the business of, among other things, developing and manufacturing generic copies of branded pharmaceutical products for the U.S. market.

4. Upon information and belief, Watson Pharmaceuticals, Inc. (“Watson Pharmaceuticals”) is a Nevada corporation, having a principal place of business at 311 Bonnie Circle, Corona, California 92880 and 360 Mount Kemble Avenue, Morristown, New Jersey 07962. On information and belief, Watson Pharmaceuticals is in the business of, among other things, developing, manufacturing and selling generic copies of branded pharmaceutical products

for the U.S. market through various directly or indirectly owned operating subsidiaries, including Watson Laboratories and Watson Pharma.

5. Upon information and belief, Watson Pharma, Inc. (“Watson Pharma”) is a corporation organized and existing under the laws of the State of Delaware, having a principal place of business at 360 Mount Kemble Avenue, Morristown, New Jersey 07960. Upon information and belief, Watson Pharma distributes pharmaceutical products throughout the United States including in this judicial district and is the distributor of drugs that Watson Laboratories manufactures or for which Watson Laboratories is the named applicant on approved ANDAs. Upon information and belief, Watson Pharma is a wholly-owned subsidiary of Watson Pharmaceuticals.

6. Upon information and belief, Watson Laboratories, Watson Pharmaceuticals, and Watson Pharma work in concert with one another, and with other Watson subsidiaries, to develop, manufacture, and market pharmaceutical products throughout the United States, including in this judicial district.

7. Upon information and belief, following any FDA approval of ANDA No. 200601, Watson Laboratories, Watson Pharmaceuticals, and Watson Pharma will work in concert with one another, and with other Watson subsidiaries, to make, use, offer to sell, and/or sell the generic products that are the subject of ANDA No. 200601 throughout the United States, and/or import such generic products 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 Watson Laboratories, Watson Pharmaceuticals, and Watson Pharma because, *inter alia*, they have each committed, or aided, abetted, actively induced, contributed to, or participated in the commission of, a tortious act of patent infringement in filing ANDA No. 200601 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.

10. This Court also has personal jurisdiction over Watson Laboratories, Watson Pharmaceuticals, and Watson Pharma because, *inter alia*, they have purposely availed themselves of the benefits and protections of Delaware's laws such that they should reasonably anticipate being haled into court here. On information and belief, Watson Pharmaceuticals, Watson Laboratories and Watson Pharma have had persistent, systematic and continuous contacts with Delaware, DEL. CODE ANN. tit. 10, § 3104(c)(4), as set forth below, and for other reasons that will be presented to the Court if jurisdiction is challenged.

11. Watson Laboratories, Watson Pharmaceuticals, and Watson Pharma directly or through an agent, including each other, regularly do or solicit business in Delaware, engage in persistent courses of conduct in Delaware, and/or derive substantial revenue from the development, manufacture and/or sale of pharmaceutical products that are sold in Delaware.

12. Watson Laboratories, Watson Pharmaceuticals, and Watson Pharma are agents of each other and/or work in concert with each other and/or other direct and indirect subsidiaries of Watson Pharmaceuticals with respect to the development, regulatory approval, marketing, sale and distribution of pharmaceutical products throughout the United States, including in this district.

13. Upon information and belief, Watson Pharmaceuticals, Watson Laboratories, and Watson Pharma share numerous common employees, officers, and directors.

14. Upon information and belief, Watson Pharmaceuticals, Watson Laboratories, and Watson Pharma operate in whole or in part from one or more shared facilities in New Jersey and California.

15. Upon information and belief, Watson Pharmaceuticals organizes its operations by division—Global Generics, Global Brands, and Distribution—rather than by subsidiary, and reports its financial results to investors by reference to its divisions not to its subsidiaries.

16. Upon information and belief, the Global Generics Division, which is responsible for developing and submitting ANDAs, as well as manufacturing and marketing generic pharmaceuticals, relies on the concerted efforts of Watson Laboratories, Watson Pharmaceuticals, and Watson Pharma.

17. Upon information and belief, Watson Pharmaceuticals, Watson Laboratories and Watson Pharma are agents of each other and/or operate in concert as integrated parts of Watson's Generic division.

18. Upon information and belief, Watson Pharmaceuticals consolidates its financial results and does not provide separate financial reports for each Watson subsidiary.

19. Upon information and belief, neither Watson Pharma nor Watson Laboratories maintains an independent website; instead Watson Pharmaceuticals maintains a single website for all Watson entities.

20. Watson Pharmaceuticals displays on its website Watson Pharma's "Terms and Conditions of Sale." Watson Pharma's address is listed as 311 Bonnie Circle, Corona, CA

92880, the principal place of business for Watson Pharmaceuticals. Watson Pharmaceuticals also displays on its website a “Return Goods Policy” for Watson Pharma that applies to all brand, generic, and diagnostic products.

21. Upon information and belief, Watson Pharmaceuticals and Watson Pharma participated in, contributed to, aided, abetted and/or induced the submission to the U.S. Food and Drug Administration (“FDA”) of ANDA No. 200601, the ANDA at issue in this litigation. For instance, by letter dated May 25, 2011, Watson Laboratories directed Abbott to send any correspondence or requests for confidential access concerning ANDA No. 200601 to its “in-house counsel,” Mr. G. Michael Bryner, who is registered with the U.S. Patent and Trademark Office as an attorney employed by Watson Pharmaceuticals.

22. Watson Pharmaceuticals’ website states that its Global Generics Division has a U.S. portfolio of more than 160 pharmaceutical products (including products for which Watson Laboratories is the named ANDA applicant); that it filed 34 new ANDAs with the FDA in 2010; and that it filed more than 145 applications globally in 2010.

23. Upon information and belief, Watson Laboratories is the named applicant on ANDAs for numerous generic drugs, including many that are actively manufactured, sold and used in Delaware and elsewhere in the United States.

24. Upon information and belief, Watson Pharma, a Delaware corporation, is the distributor of drugs for which Watson Laboratories is the named applicant in the FDA’s Approved Drug Product List. Upon information and belief, Watson Pharma, acting as the agent of Watson Laboratories and Watson Pharmaceuticals, markets and sells Watson’s drug products in Delaware and elsewhere in the United States.

25. Upon information and belief, Watson Pharma is licensed to do business in Delaware and maintains at least active “Pharmacy CSR” and “Distributor/Manufacturer CSR” licenses in Delaware. On its licenses, Watson Pharma regularly lists its mailing address as Corona, CA 92880, the principal place of business for Watson Pharmaceuticals. Other Watson entities with various mailing addresses also have pharmacy-related licenses to do business in Delaware.

26. Upon information and belief, various drugs for which Watson Laboratories is the named ANDA applicant are distributed by Watson Pharma and are available at retail pharmacies in Delaware including Walgreens/Happy Harry’s, Rite Aid, and CVS.

27. Upon information and belief, Watson Pharma and Watson Laboratories are parties to one or more contractual agreements regarding the distribution of such generic pharmaceutical products. Upon information and belief, such agreements are not arm’s length.

28. Upon information and belief, Watson Pharmaceuticals and/or Watson Laboratories earn revenue from the distribution in Delaware by Watson Pharma of generic pharmaceutical products that are manufactured by Watson Laboratories or for which Watson Laboratories is the named applicant on approved ANDAs.

29. Watson Pharmaceuticals’ website provides links to its distribution network where physicians, pharmacies, and distributors in Delaware and elsewhere are able to directly order Watson’s products, including products manufactured by Watson Laboratories and products for which Watson Laboratories is the named ANDA applicant, via Watson Pharmaceutical’s internet distribution network.

30. Watson Pharmaceuticals’ website also provides links to its VIPConnect™, VIPpharm™, and VIPCSOS.com™ product-ordering systems. Upon information and belief,

physicians and pharmacies located in Delaware directly order Watson's products, including products manufactured by Watson Laboratories and products for which Watson Laboratories is the named ANDA applicant, through the VIP ordering systems accessible via Watson Pharmaceuticals' website.

31. Upon information and belief, Watson Pharmaceuticals, Watson Pharma, and Watson Laboratories will manufacture, market, and/or sell within the United States the generic 1000 mg / 40 mg niacin extended release / simvastatin tablets described in Watson's ANDA No. 200601 if FDA approval is granted. If ANDA No. 200601 is approved, the generic 1000 mg / 40 mg niacin extended release / simvastatin tablets charged with infringing the patents-in-suit, would, among other things, be marketed and distributed in Delaware, prescribed by physicians practicing in Delaware, and dispensed by pharmacies located within Delaware, and/or used by persons in Delaware, all of which would have a substantial effect on Delaware.

32. This Court has personal jurisdiction over Watson Laboratories by virtue of, *inter alia*, its systematic and continuous contacts with Delaware.

33. This Court has personal jurisdiction over Watson Pharma by virtue of, *inter alia*, its systematic and continuous contacts with Delaware.

34. This Court has personal jurisdiction over Watson Pharmaceuticals by virtue of, *inter alia*, its systematic and continuous contacts with Delaware.

35. Upon information and belief, Watson Laboratories has purposely availed itself of Delaware courts by, *inter alia*:

a. joining as plaintiff with other parties filing a complaint for patent infringement in the District of Delaware on January 15, 2009 against Lupin Ltd. and Lupin

Pharmaceuticals, Inc., *Sciele Pharma, Inc. v. Lupin Ltd.*, Civil Action No. 1:09-cv-00037-JJF (D. Del.);

b. joining as a plaintiff with other parties, including other Watson parties, filing a complaint for patent infringement in the District of Delaware on February 18, 2010 against Mylan Inc. and Mylan Pharmaceuticals, Inc., *Shionogi Pharma, Inc. v. Mylan Inc.*, Civil Action No. 1:10-cv-00135-RBK (D. Del.);

c. filing counterclaims in the District of Delaware on February 18, 2010 in *Allergan, Inc. v. Watson Pharms., Inc.*, Civil Action No. 1:09-cv-00511-GMS (D. Del.), and *Takeda Pharm. Co. v. Watson Labs., Inc.*, Civil Action No. 1:09-cv-00917-SLR (D. Del.); and

d. filing counterclaims in the District of Delaware on May 25, 2010 in *Abbott Laboratories & Abbott Respiratory LLC v. Watson Laboratories, Inc. – Florida*, Civil Action No. 1:10-cv-00373-SLR (D. Del.).

e. filing amended counterclaims in the District of Delaware on April 14, 2011 in *Abbott Laboratories & Abbott Respiratory LLC v. Teva Pharmaceutical Industries, Ltd. & Teva Pharmaceuticals USA, Watson Pharmaceuticals, Inc., Watson Laboratories, Inc. – Florida, & Watson Pharma, Inc.*, Civil Action No. 10-57-SLR-MPT (Consolidated) (D. Del.).

Patents in Suit

36. 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.

37. 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.

38. 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.

39. 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.

40. 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.

41. 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.

42. 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.

43. 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.

44. 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 Watson

45. By letter dated May 25, 2011 ("the Notice Letter"), Watson notified Abbott that it had submitted ANDA No. 200601 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 a 1000 / 40 mg dosage strength of 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, Watson intends to engage in commercial manufacture, use, and sale of generic niacin extended-release / simvastatin tablets promptly upon receiving FDA approval to do so.

46. By filing ANDA No. 200601, Watson has necessarily represented to the FDA that the components of its 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[®].

47. In the Notice Letter, Watson notified Abbott that its ANDA contained a "Paragraph IV certification" asserting that, in Watson'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, unenforceable and/or will not be infringed by the commercial manufacture, use or sale of its generic niacin extended-release / simvastatin tablets.

48. 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)

49. Each of the preceding paragraphs 1 to 48 is incorporated as if fully set forth herein.

50. Watson's submission of ANDA No. 200601 to obtain approval to engage in the commercial manufacture, use, offer to sell, or sale of 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).

51. Upon FDA approval of Watson's ANDA No. 200601, Watson will further infringe the '428 patent by making, using, offering to sell, and selling 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.

52. Upon information and belief, Watson had actual and constructive knowledge of the '428 patent prior to filing ANDA No. 200601 and was aware that filing of the aforementioned ANDA with the FDA constituted an act of infringement of the '428 patent.

53. If Watson'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)

54. Each of the preceding paragraphs 1 to 53 is incorporated as if fully set forth herein.

55. Watson's submission of ANDA No. 200601 to obtain approval to engage in the commercial manufacture, use, offer to sell, or sale of 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).

56. Upon FDA approval of Watson's ANDA No. 200601, Watson will further infringe the '930 patent by making, using, offering to sell, and selling 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.

57. Upon information and belief, Watson had actual and constructive knowledge of the '930 patent prior to filing ANDA No. 200601 and was aware that filing of the aforementioned ANDA with the FDA constituted an act of infringement of the '930 patent.

58. If Watson'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)

59. Each of the preceding paragraphs 1 to 58 is incorporated as if fully set forth herein.

60. Watson's submission of ANDA No. 200601 to obtain approval to engage in the commercial manufacture, use, offer to sell, or sale of 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).

61. Upon FDA approval of Watson's ANDA No. 200601, Watson will further infringe the '715 patent by making, using, offering to sell, and selling 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.

62. Upon information and belief, Watson had actual and constructive knowledge of the '715 patent prior to filing ANDA No. 200601 and was aware that filing of the aforementioned ANDA with the FDA constituted an act of infringement of the '715 patent.

63. If Watson'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)

64. Each of the preceding paragraphs 1 to 63 is incorporated as if fully set forth herein.

65. Watson's submission of ANDA No. 200601 to obtain approval to engage in the commercial manufacture, use, offer to sell, or sale of 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).

66. Upon FDA approval of Watson's ANDA No. 200601, Watson will further infringe the '035 patent by making, using, offering to sell, and selling 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.

67. Upon information and belief, Watson had actual and constructive knowledge of the '035 patent prior to filing ANDA No. 200601 and was aware that filing of the aforementioned ANDA with the FDA constituted an act of infringement of the '035 patent.

68. If Watson'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)

69. Each of the preceding paragraphs 1 to 68 is incorporated as if fully set forth herein.

70. Watson's submission of ANDA No. 200601 to obtain approval to engage in the commercial manufacture, use, offer to sell, or sale of 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).

71. Upon FDA approval of Watson's ANDA No. 200601, Watson will further infringe the '967 patent by making, using, offering to sell, and selling 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.

72. Upon information and belief, Watson had actual and constructive knowledge of the '967 patent prior to filing ANDA No. 200601 and was aware that filing of the aforementioned ANDA with the FDA constituted an act of infringement of the '967 patent.

73. If Watson'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)

74. Each of the preceding paragraphs 1 to 73 is incorporated as if fully set forth herein.

75. Watson's submission of ANDA No. 200601 to obtain approval to engage in the commercial manufacture, use, offer to sell, or sale of 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).

76. Upon FDA approval of Watson's ANDA No. 200601, Watson will further infringe the '691 patent by making, using, offering to sell, and selling 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.

77. Upon information and belief, Watson had actual and constructive knowledge of the '691 patent prior to filing ANDA No. 200601 and was aware that filing of the aforementioned ANDA with the FDA constituted an act of infringement of the '691 patent.

78. If Watson'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)

79. Each of the preceding paragraphs 1 to 78 is incorporated as if fully set forth herein.

80. Watson's submission of ANDA No. 200601 to obtain approval to engage in the commercial manufacture, use, offer to sell, or sale of 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).

81. Upon FDA approval of Watson's ANDA No. 200601, Watson will further infringe the '229 patent by making, using, offering to sell, and selling 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.

82. Upon information and belief, Watson had actual and constructive knowledge of the '229 patent prior to filing ANDA No. 200601 and was aware that filing of the aforementioned ANDA with the FDA constituted an act of infringement of the '229 patent.

83. If Watson'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)

84. Each of the preceding paragraphs 1 to 83 is incorporated as if fully set forth herein.

85. Watson's submission of ANDA No. 200601 to obtain approval to engage in the commercial manufacture, use, offer to sell, or sale of 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).

86. Upon FDA approval of Watson's ANDA No. 200601, Watson will further infringe the '848 patent by making, using, offering to sell, and selling 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.

87. Upon information and belief, Watson had actual and constructive knowledge of the '848 patent prior to filing ANDA No. 200601 and was aware that filing of the aforementioned ANDA with the FDA constituted an act of infringement of the '848 patent.

88. If Watson'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:

a) 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 Watson's submission of ANDA No. 200601, and that Watson's making, using, offering to sell, or selling in the United States, or importing into the United States, of a 1000 / 40 mg dosage strength of generic niacin extended-release / simvastatin tablets will infringe 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;

b) An order pursuant to 35 U.S.C. § 271(e)(4)(A) providing that the effective date of any approval of ANDA No. 200601 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;

c) An order permanently enjoining Watson, 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 of a 1000 / 40 mg dosage strength of 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;

d) Damages or other monetary relief to Abbott if Watson engages in commercial manufacture, use, offers to sell, sale, or importation in or into the United States of a

1000 / 40 mg dosage strength of 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.

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

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