IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

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

**COMPLAINT**

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

**NATURE OF THE ACTION**

1. This is an action for patent infringement of U.S. Patent No. 6,080,428 ("the '428 patent") and 6,469,035 ("the '035 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. 203570 filed by Watson Laboratories, Inc. - Florida with the U.S. Food and Drug Administration ("FDA") for approval to market 750 mg niacin extended release tablets, which are generic versions of the 750 mg forms of AbbVie's NIASPAN® drug product.

**PARTIES**

2. AbbVie Inc. is a corporation organized and existing under the laws of the State of Delaware, with its principal place of business at 1 N Waukegan Road, North Chicago IL, 60064.

3. 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.

4. Upon information and belief, Watson Laboratories, Inc. – Florida ("Watson Laboratories") is a Florida corporation, having a place of business at 4955 Orange Drive, Davie, Florida 33314. 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.

5. Upon information and belief, Watson Pharmaceuticals, Inc. ("Watson Pharmaceuticals") is a Nevada corporation, having a principal place of business at Morris Corporate Center III, 400 Interpace Parkway, Parsippany, NJ 07054 and a place of business at 311 Bonnie Circle, Corona, California. 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 Inc.

6. 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 Morris Corporate Center III, 400 Interpace Parkway, Parsippany, NJ 07054.

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.

7. 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.

8. Upon information and belief, following any FDA approval of ANDA No. 203570, 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. 203570 throughout the United States, and/or import such generic products into the United States.

## JURISDICTION AND VENUE

9. 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).

10. This Court has personal jurisdiction over Watson Laboratories, Watson Pharmaceuticals, and Watson Pharma because, *inter alia*, they have each committed, aided, abetted, actively induced, contributed to, or participated in the commission of, a tortious act of

patent infringement in filing ANDA No. 203570 that has led to foreseeable harm and injury to Delaware corporations AbbVie Inc. and Abbott Respiratory.

11. 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.

12. 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.

13. 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.

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

15. 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.

16. Upon information and belief, and according to its website, http://www.watson.com, 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, rather than its subsidiaries.

17. 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.

18. 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.

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

20. 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, which is located at http://www.watson.com.

21. 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, a place of business for Watson Pharmaceuticals. Watson Pharmaceuticals also displays on its website a "Return Goods Policy" for Watson Pharma that applies to all pharmaceutical and diagnostic products.

22. Upon information and belief, Watson Pharmaceuticals and Watson Pharma participated in, contributed to, aided, abetted and/or induced the submission to the FDA

of ANDA No. 203570, the ANDA at issue in this litigation. For instance, by letter dated September 24, 2012, Watson Laboratories directed Abbott to send any correspondence or requests for confidential access concerning ANDA No. 203570 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.

23. Watson Pharmaceuticals' website states that its Global Generics Division has a U.S. portfolio of more than 160 generic prescription pharmaceutical product families (including products for which Watson Laboratories is the named ANDA applicant); that it filed over 30 new ANDAs with the FDA in 2011; and that it filed more than 175 applications globally in 2011.

24. 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.

25. 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.

26. Upon information and belief, Watson Pharma is licensed to do business in Delaware and maintains active "Pharmacy – Wholesale" and "Distributor/Manufacturer CSR" licenses in Delaware. On its licenses, Watson Pharma regularly lists its mailing address as Corona, CA 92880, an address for Watson Laboratories and Watson Pharmaceuticals. Other

Watson entities with various mailing addresses also have pharmacy-related licenses to do business in Delaware.

27. 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.

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 AndaNet®, AndaCSOS™, and AndaConnect™ 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 Anda 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 750 mg niacin extended release tablets described in Watson's ANDA No. 203570 if

FDA approval is granted. If ANDA No. 203570 is approved, the generic 750 mg niacin extended release 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. This Court also has personal jurisdiction over Watson because it has availed itself of the legal protections of the State of Delaware by, *inter alia*, asserting counterclaims in several lawsuits in this District involving the ’428 patent and the ’035 patent: *AbbVie Inc. & Abbott Respiratory LLC v. Watson Laboratories, Inc. – Florida*, Civil Action No. 1:12-cv-00324-SLR (D. Del.); *Abbott Laboratories & Abbott Respiratory LLC v. Watson Laboratories, Inc. – Florida*, Civil Action No. 1:10-cv-00373-SLR (D. Del.); and *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.). In addition, Watson has joined as a plaintiff with other parties filing complaints for patent infringement in the District of Delaware (*e.g. Sciele Pharma, Inc. v. Lupin Ltd.*, Civil Action No. 1:09-cv-00037-JJF (D. Del.); *Shionogi Pharma, Inc. v. Mylan Inc.*, Civil Action No. 1:10-cv-00135-RBK (D. Del.))

and admitting jurisdiction and asserting counterclaims in lawsuits filed in the District of Delaware (*e.g.*, *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.).)

**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. AbbVie Inc. is an exclusive licensee of the '428 patent with respect to NIASPAN®, 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 '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 B. The claims of the '035 patent are valid and enforceable. AbbVie Inc. is an exclusive licensee of the '035 patent with respect to NIASPAN®, with the right to sue for and obtain equitable relief and damages for infringement of the '035 patent.

38. AbbVie Inc. is the holder of New Drug Application ("NDA") No. 20-0381 by which the FDA granted approval for the marketing and sale of 500 mg, 750 mg, and 1000 mg strength niacin extended-release tablets, which AbbVie markets in the United States under the

trade name "NIASPAN®". The formulation and dosing of NIASPAN® is covered by certain claims of the '428 and '035 patents. The FDA's official publication of approved drugs (the "Orange Book") includes NIASPAN® together with the '428 and '035 patents.

**INFRINGEMENT BY WATSON**

39. By letter dated September 24, 2012, ("the Notice Letter"), Watson notified AbbVie that Watson had submitted an Amendment to ANDA No. 203570 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 750 mg generic niacin extended-release tablets before the expiration of the '428 and '035 patents. Upon information and belief, Watson intends to engage in the commercial manufacture, use, and sale of its 750 mg generic niacin extended-release tablets promptly upon receiving FDA approval to do so.

40. By filing ANDA No. 203570, Watson has necessarily represented to the FDA that its generic niacin extended-release tablets have the same active ingredient as NIASPAN®, have the same route of administration, dosage form, and strengths as NIASPAN®, and are bioequivalent to NIASPAN®.

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

**COUNT I**
**(INFRINGEMENT OF THE '428 PATENT)**

42. Each of the preceding paragraphs 1 to 41 is incorporated as if fully set forth herein.

43. Watson's submission of ANDA No. 203570 to obtain approval to engage in the commercial manufacture, use, offer to sell, or sale of its 750 mg generic niacin extended-

release 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).

44. Upon FDA approval of Watson’s ANDA No. 203570, Watson will further infringe the ’428 patent by making, using, offering to sell, and selling its 750 mg generic niacin extended-release 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.

45. Upon information and belief, Watson had actual and constructive knowledge of the ’428 patent prior to filing ANDA No. 203570 and was aware that the filing of the aforementioned ANDA with the FDA constituted an act of infringement of the ’428 patent.

46. If Watson’s infringement of the ’428 patent is not enjoined, AbbVie will suffer substantial and irreparable harm for which there is no remedy at law.

**COUNT II**
**(INFRINGEMENT OF THE ’035 PATENT)**

47. Each of the preceding paragraphs 1 to 46 is incorporated as if fully set forth herein.

48. Watson’s submission of ANDA No. 203570 to obtain approval to engage in the commercial manufacture, use, offer to sell, or sale of its 750 mg generic niacin extended-release 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).

49. Upon FDA approval of Watson’s ANDA No. 203570, Watson will further infringe the’035 patent by making, using, offering to sell, and selling its 750 mg generic niacin extended-release 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.

50. Upon information and belief, Watson had actual and constructive knowledge of the'035 patent prior to filing ANDA No. 203570 and was aware that the filing of the aforementioned ANDA with the FDA constituted an act of infringement of the'035 patent.

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

**PRAYER FOR RELIEF**

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

1. A judgment that one or more claims of the '428 and '035 patents are infringed by Watson's submission of ANDA No. 203570, and that Watson's making, using, offering to sell, or selling in the United States, or importing into the United States Watson's 750 mg generic niacin extended-release tablets will infringe the '428 and '035 patents.

2. An order pursuant to 35 U.S.C. § 271(e)(4)(A) providing that the effective date of any approval of ANDA No. 203570 shall be a date which is not earlier than the latest expiration date of the '428 and '035 patents, including any extensions and/or additional periods of exclusivity to which AbbVie is or becomes entitled.

3. 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 Watson's 750 mg generic niacin extended-release tablets until after the latest expiration date of the '428 and '035 patents, including any extensions and/or additional periods of exclusivity to which AbbVie is or becomes entitled.

4. Damages or other monetary relief to AbbVie if Watson engages in commercial manufacture, use, offers to sell, sale, or importation in or into the United States of Watson's 750 mg generic niacin extended-release tablets prior to the latest expiration date of the '428 and '035 patents, including any extensions and/or additional periods of exclusivity to which AbbVie 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

*/s/ Mary B. Graham*

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