**IN THE UNITED STATES DISTRICT COURT FOR THE SOUTHERN DISTRICT OF FLORIDA**
**CASE NO. _____**

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| PFIZER INC., | ) |
| WYETH LLC, and | ) |
| WYETH PHARMACEUTICALS INC., | ) |
| | ) |
| Plaintiffs, | ) |
| | ) |
| v. | ) |
| | ) |
| WATSON PHARMACEUTICALS, INC., | ) |
| WATSON LABORATORIES, INC.–FLORIDA, | ) |
| WATSON LABORATORIES, INC., and | ) |
| WATSON PHARMA, INC., | ) |
| | ) |
| Defendants. | ) |

## COMPLAINT

Plaintiffs Pfizer Inc., Wyeth LLC, and Wyeth Pharmaceuticals Inc. (collectively "Pfizer") for their Complaint against Defendants Watson Pharmaceuticals, Inc. (hereinafter "Watson Pharmaceuticals"), Watson Laboratories, Inc.–Florida (hereinafter "Watson Florida"), Watson Laboratories, Inc. (hereinafter "Watson Laboratories"), and Watson Pharma, Inc. (collectively "Watson") hereby allege as follows:

## PARTIES

1. Plaintiff Pfizer Inc. is a corporation organized and existing under the laws of the State of Delaware and has a place of business at 235 East 42nd Street, New York, New York 10017.

2. Plaintiff Wyeth LLC is a company organized and existing under the laws of the State of Delaware and has a place of business at Five Giralda Farms, Madison, NJ 07940.

3. Plaintiff Wyeth Pharmaceuticals Inc. is a corporation organized and existing under the laws of the State of Delaware and has a place of business at 500 Arcola Road, Collegeville, PA 19426.

4. Upon information and belief, Defendant Watson Pharmaceuticals is a corporation organized and existing under the laws of the State of Nevada, having a principal place of business at 311 Bonnie Circle, Corona, California 92880.

5. Upon information and belief, Defendant Watson Florida is a corporation organized and existing under the laws of the State of Florida, having a place of business at 4955 Orange Drive, Davie, Florida 33314. Upon information and belief, Watson Florida was formerly known as Andrx Pharmaceuticals, Inc.

6. Upon information and belief, Watson Florida is a wholly-owned subsidiary of Defendant Watson Pharmaceuticals. Upon information and belief, Watson Florida has identified its mailing address as 311 Bonnie Circle, Corona, California 92880. Upon information and belief, Watson Florida and Watson Pharmaceuticals have common officers and directors.

7. Upon information and belief, Defendant Watson Pharma, Inc. is an actively registered foreign corporation in Florida. Upon information and belief, Watson Pharma, Inc. is a corporation organized and existing under the laws of Delaware, having a principal place of business at 360 Mount Kemble Avenue, Morristown, New Jersey 07962.

8. Upon information and belief, Watson Pharma, Inc. is a wholly-owned subsidiary of Watson Pharmaceuticals, and the two have common officers and directors.

9. Upon information and belief, Defendant Watson Laboratories is a corporation organized and existing under the laws of Delaware, having a principal place of business at 311 Bonnie Circle, Corona, California 92880.

10. Upon information and belief, Watson Laboratories is a wholly-owned subsidiary of Watson Pharmaceuticals, and the two have common officers and directors.

11. Upon information and belief, Defendant Watson Pharmaceuticals is engaged in the development, manufacture, marketing, sale and distribution of generic pharmaceutical products in the United States, including in this judicial district, through its own actions and through the actions of its agents and operating subsidiaries, including its wholly-owned subsidiaries Watson Florida, Watson Pharma, Inc., and Watson Laboratories.

12. Upon information and belief, Defendant Watson Pharmaceuticals, through its own actions and through the actions of its agents and operating subsidiaries, including Watson Florida, Watson Pharma, Inc., and Watson Laboratories, markets, sells and distributes generic pharmaceutical products throughout the United States, including this judicial district. Upon information and belief, Defendant Watson Pharma, Inc. is the distributor of drugs that Watson Florida or Watson Laboratories manufacture or for which Watson Florida is the named applicant on approved Abbreviated New Drug Applications ("ANDAs").

13. Upon information and belief, Defendant Watson Pharmaceuticals directed, authorized, participated in, assisted and cooperated with Defendants Watson Florida, Watson Pharma, Inc. and Watson Laboratories, in all of the acts complained of herein. Upon information and belief, the acts complained of herein were done by, at the direction of, with the authorization, cooperation, participation or assistance of, or at least in part for the benefit of Watson Pharmaceuticals.

## NATURE OF THE ACTION

14. This is a civil action for the infringement of United States Patent No. 5,100,899 ("the '899 patent"). This action relates to ANDA No. 200566 submitted by Watson Florida to the

United States Food and Drug Administration ("FDA") for approval to market generic versions of Pfizer's Rapamune® drug product for the prophylaxis of organ rejection in patients aged 13 years or older receiving renal transplants.

## JURISDICTION AND VENUE

15. This action arises under the patent laws of the United States, 35 U.S.C. § 100, *et seq*. generally, and 35 U.S.C. § 271(e)(2) specifically.

16. This Court has jurisdiction over the subject matter of this action pursuant to 28 U.S.C. §§ 1331 and 1338.

17. Venue is proper in this judicial district pursuant to, *inter alia*, 28 U.S.C. §§ 1391 and 1400(b).

18. Upon information and belief, this Court has personal jurisdiction over Defendants Watson Pharmaceuticals, Watson Florida, Watson Laboratories, and Watson Pharma, Inc., because, *inter alia*, they, either directly or through agents, including each other, regularly do or solicit business in Florida, engage in other persistent courses of conduct in Florida, and/or derive substantial revenue from services or things used or consumed in Florida. These activities further demonstrate that Watson Pharmaceuticals, Watson Florida, Watson Laboratories, and Watson Pharma, Inc. have continuous and systematic contacts with Florida.

19. Watson Pharmaceuticals is in the business of making and selling generic drug products. Upon information and belief, Watson Pharmaceuticals operates and manages its business as three operating segments, Generic, Brand, and Distribution. Upon information and belief, the Generic segment, which is responsible for developing and submitting ANDAs, as well as manufacturing and marketing generic pharmaceuticals, relies upon contributions from Defendants Watson Pharmaceuticals, Watson Florida, Watson Laboratories, and Watson

Pharma, Inc., each of whom are agents of each other and/or work in concert with respect to the development, regulatory approval, marketing, sale, and distribution of pharmaceutical products, including Watson's generic drug product Sirolimus Tablets, 1 and 2 mg described in ANDA No. 200566 (defined below).

20. Upon information and belief, Watson Pharmaceuticals, Watson Florida, Watson Laboratories, and Watson Pharma, Inc. share common employees, officers, and directors.

21. Upon information and belief, this Court has personal jurisdiction over Defendant and ANDA sponsor, Watson Florida, by virtue of its incorporation in Florida and its continuous and systematic contacts with Florida, including the manufacture of generic pharmaceutical products.

22. Upon information and belief, this Court has personal jurisdiction over Watson Pharma, Inc. because it is an actively registered foreign corporation in Florida.

23. Upon information and belief, Watson Pharmaceuticals' Generic segment relies on the efforts of Watson Pharma, Inc. in marketing and selling its generic products. Upon information and belief, Watson Pharma, Inc. has sales personnel assigned to cover Florida for the purpose of marketing, selling and distributing generic pharmaceutical products, including generic products manufactured under Watson Florida ANDAs.

24. Upon information and belief, Watson Pharmaceuticals and/or Watson Florida realize revenue from the distribution of generic drugs by Watson Pharma, Inc. where such distribution results in sales of the drugs in Florida or to persons in Florida.

25. Upon information and belief, this Court has personal jurisdiction over Defendant Watson Pharmaceuticals by virtue of, *inter alia*: (1) its presence in Florida through its wholly-owned subsidiaries, including Watson Florida; and (2) its continuous and systematic contacts

with Florida, including through its wholly-owned subsidiary Watson Florida, a Florida corporation.

26. Upon information and belief, Watson Pharmaceuticals markets, sells and distributes its generic products throughout the United States, including this judicial district, through its subsidiaries, including Watson Pharma, Inc. and telemarketing and on-line distributors Anda, Inc. and Anda Pharmaceuticals, Inc., both Florida corporations, and Valmed Pharmaceutical Inc. (also known as "VIP").

27. Upon information and belief, this Court has personal jurisdiction over Watson Laboratories because it is a wholly-owned subsidiary of Watson Pharmaceuticals, which is subject to the jurisdiction of this Court by virtue of its direct and indirect contacts with Florida, including through its wholly-owned subsidiary, Watson Florida.

28. Upon information and belief, if ANDA No. 200566 is approved, Watson's generic Sirolimus Tablets, 1 and 2 mg that are indicated for the prophylaxis of organ rejection in patients aged 13 years or older receiving renal transplants, and that infringe the '899 patent (defined below), would be marketed and distributed in Florida, prescribed by physicians practicing and dispensed by pharmacies located within Florida, and/or used by persons in Florida prior to the expiration of that patent.

## US PATENT NO. 5,100,899

29. On March 31, 1992, the United States Patent and Trademark Office issued the '899 patent entitled: "Methods of Inhibiting Transplant Rejection in Mammals Using Rapamycin and Derivatives and Prodrugs Thereof." A true and correct copy of the '899 patent is attached hereto as Exhibit A.

30. The '899 patent claims methods of inhibiting organ or tissue transplant rejection with rapamycin.

31. The '899 patent covers Pfizer's product Rapamune®, which is indicated for the prophylaxis of organ rejection in patients aged 13 years or older receiving renal transplants.

32. The '899 patent was exclusively licensed to Wyeth LLC.

33. The '899 patent is subject to a patent term extension of 1,492 days.

34. The '899 patent will expire on July 7, 2013.

## RAPAMUNE®

35. Rapamune® is indicated for the prophylaxis of organ rejection in patients aged 13 years or older receiving renal transplants.

36. Rapamune® is covered by New Drug Application ("NDA") No. 21-110, which was approved by the FDA on August 25, 2000. The active ingredient in Rapamune® is sirolimus.

37. The '899 patent is listed in the Approved Drug Products With Therapeutic Equivalence Evaluations ("Orange Book"), maintained by the FDA, in connection with NDA No. 21-110 as a patent "with respect to which a claim of patent infringement could reasonably be asserted if a person not licensed by the owner engaged in the manufacture, use, or sale of the drug." 21 U.S.C. § 355(b)(1).

38. Pursuant to 21 U.S.C. § 355a, Pfizer is entitled to a six-month period of pediatric exclusivity for Rapamune® beyond the date of expiration of the '899 patent.

## WATSON'S ANDA

39. Upon information and belief, Watson Florida submitted ANDA No. 200566 to the FDA seeking approval to market a generic copy of Pfizer's Rapamune® product, Sirolimus

Tablets, 1 mg and 2 mg (the "Watson product") for the prophylaxis of organ rejection in patients aged 13 years or older receiving renal transplants, prior to expiration of the '899 patent.

40. Upon information and belief, with its ANDA, Watson Florida included a "Paragraph IV" certification under 21 U.S.C. § 355(j)(2)(A)(vii)(IV) alleging that the '899 patent is invalid, unenforceable, or not infringed by the commercial manufacture, use or, sale of the Watson product.

41. On or about March 17, 2010, Pfizer received a letter from Watson Florida, signed by Janet Vaughn, Director, Regulatory Affairs, Watson Florida, purporting to be the notice of Watson Florida's ANDA containing the "Paragraph IV" certification required by 21 U.S.C. § 355(j)(2)(B)(ii).

42. Watson Florida's "Paragraph IV" certification letter states that "Watson Florida's products will be marketed for the currently approved indication for Rapamune®," which is covered by the '899 patent. (Watson Florida March 16, 2010 letter, Detailed Factual and Legal Bases for Watson Florida's Paragraph IV Certifications, p. 1). Watson Florida's certification letter does not assert that Watson Florida's products will be marketed for any use that is not covered by the '899 patent.

43. This action is being brought before the expiration of forty-five days from the date Pfizer received Watson Florida's notice letter.

## COUNT I

## Infringement of the '899 Patent by Watson

44. Pfizer incorporates the preceding paragraphs as if fully set forth herein.

45. Watson has infringed the '899 patent, pursuant to 35 U.S.C. § 271(e)(2)(A), by submitting ANDA No. 200566, by which Watson seeks FDA approval to engage in the

commercial manufacture, use, or sale of the Watson product for the prophylaxis of organ rejection in patients aged 13 years or older receiving renal transplants prior to the expiration of the '899 patent.

46. If Watson commercially manufactures, uses, offers to sell, or sells the Watson product within the United States, or imports the Watson product into the United States, for the prophylaxis of organ rejection in patients aged 13 years or older receiving renal transplants, or induces or contributes to any such conduct during the term of the '899 patent, it would further infringe the '899 patent under 35 U.S.C. § 271(a), (b), and/or (c).

47. Pfizer will be irreparably harmed if Watson's infringement is not enjoined. Pfizer does not have an adequate remedy at law.

48. This is an exceptional case within the meaning of 35 U.S.C. § 285, which warrants reimbursement of Pfizer's reasonable attorney fees.

## PRAYER FOR RELIEF

**WHEREFORE**, Pfizer prays for a judgment in its favor and against Watson as follows:

(1) That pursuant to 35 U.S.C. § 271, Watson has infringed the '899 patent;

(2) That judgment be entered that the manufacture, use, sale or offer to sell within the United States, or importation into the United States, of the Watson product described in ANDA No. 200566 for the prophylaxis of organ rejection in patients aged 13 years or older receiving renal transplants, will infringe the '899 patent.

(3) That the Court enter an order that the effective date of any FDA approval of the Watson product for the prophylaxis of organ rejection in patients aged 13 years or older receiving renal transplants be not earlier than the expiration of the '899 patent, including extensions;

(4) That Watson, its officers, agents, servants and employees, and those persons in active concert or participation with any of them, be preliminarily and permanently enjoined from commercially manufacturing, using, offering for sale or selling the Watson product described in ANDA No. 200566 for the prophylaxis of organ rejection in patients aged 13 years or older receiving renal transplants, and any other product that infringes or induces or contributes to the infringement of the '899 patent, prior to the expiration of the '899 patent, including any extensions;

(5) That Pfizer be awarded monetary relief if Watson commercially uses, offers to sell, or sells its proposed generic version of Rapamune® for the prophylaxis of organ rejection in patients aged 13 years or older receiving renal transplants, or any other product that infringes or induces or contributes to the infringement of the '899 patent, within the United States prior to the expiration of that patent, including any extensions, and that any such monetary relief be awarded to Pfizer with prejudgment interest;

(6) That judgment be entered that this is an exceptional case under 35 U.S.C. § 285;

(7) That pursuant to 35 U.S.C. § 285, Pfizer recover its reasonable attorney fees incurred in connection with this action;

(8) For an assessment of costs and expenses against Watson; and

(9) For such other and further relief as the Court may deem just and proper.

Respectfully submitted,

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