

**IN THE UNITED STATES DISTRICT COURT  
FOR THE DISTRICT OF DELAWARE**

PFIZER INC., ALPHARMA )  
PHARMACEUTICALS LLC, and KING )  
PHARMACEUTICALS, INC., )  
 )  
Plaintiffs, )

v. )

C.A. No. \_\_\_\_\_ )

)  
WATSON PHARMACEUTICALS, INC., )  
WATSON LABORATORIES INC., )  
WATSON PHARMA, INC., and WATSON )  
LABORATORIES, INC. – FLORIDA, )  
 )  
Defendants. )

**COMPLAINT**

Plaintiffs Pfizer Inc., Alpharma Pharmaceuticals LLC, and King Pharmaceuticals, Inc. (collectively “Pfizer”), for their Complaint, allege as follows:

1. This is an action for infringement of U.S. Patent Nos. 7,682,633 (“the ’633 patent”), 7,682,634 (“the ’634 patent”), and 7,815,934 (“the ’934 patent”). It arises out of the submission by defendant Watson Laboratories, Inc. – Florida of an Abbreviated New Drug Application (“ANDA”) to the U.S. Food and Drug Administration (“FDA”) seeking approval to manufacture and sell a generic version of Pfizer’s breakthrough extended-release pain medicine, EMBEDA®, prior to the expiration of the ’633 patent, the ’634 patent, and the ’934 patent.

**PARTIES**

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

3. Plaintiff Alpharma Pharmaceuticals LLC is a company organized and existing under the laws of the State of Delaware, having its principal place of business at 400 Crossing Boulevard, Bridgewater NJ 08807.

4. Plaintiff King Pharmaceuticals, Inc. is a corporation organized and existing under the laws of the State of Tennessee, having its principal place of business at 501 Fifth Street, Bristol, TN 37620.

5. On information and belief, defendant Watson Pharmaceuticals, Inc. (“Watson Pharmaceuticals”) is a corporation organized and existing under the laws of the State of Nevada, having its principal place of business at 311 Bonnie Circle, Corona, CA 92880.

6. On information and belief, defendant Watson Laboratories Inc. (“Watson Laboratories”) is a corporation organized and existing under the laws of the State of Nevada, having its principal place of business at 311 Bonnie Circle, Corona, CA 92880.

7. On information and belief, defendant Watson Pharma, Inc. (“Watson Pharma”) is a corporation organized and existing under the laws of the State of Delaware, having its principal place of business at 360 Mount Kemble Avenue, Morristown, New Jersey 07960.

8. On information and belief, Watson Laboratories, Inc. – Florida (“Watson Laboratories Florida”) is a corporation organized and existing under the laws of the State of Florida, having its principal place of business at 4955 Orange Drive, Davie, Florida 33314.

9. On information and belief, Watson Laboratories Florida was formerly known as Andrx Pharmaceuticals, Inc., and is a wholly-owned subsidiary of Andrx Corp., a Delaware corporation that is a wholly-owned subsidiary of Watson Pharmaceuticals. On information and belief, Watson Laboratories and Watson Pharma are wholly owned subsidiaries

of Watson Pharmaceuticals. Watson Laboratories, Watson Laboratories Florida, Watson Pharmaceuticals, and Watson Pharma are collectively referred to herein as “Watson.”

**JURISDICTION AND VENUE**

10. Jurisdiction is proper in this judicial district pursuant to 28 U.S.C. §§ 1331, 1338(a), 2201 and 2202.

11. Venue is proper in this judicial district pursuant to 28 U.S.C. §§ 1391 and 1400(b).

12. Watson is subject to personal jurisdiction in Delaware because, among other things, it regularly transacts and/or solicits business in Delaware, has consented to jurisdiction in Delaware in cases arising out of its filing of ANDAs, and has purposefully availed itself of this forum such that it should reasonably anticipate being haled into court here.

13. On information and belief, Watson Pharmaceuticals, Watson Laboratories, Watson Laboratories Florida, and/or Watson Pharma share common employees, officers and directors.

14. On information and belief, Watson Pharmaceuticals organizes its operations by division, including at least Generic, Brand, and Distribution.

15. On information and belief, Watson’s Generic division is responsible for developing, manufacturing, marketing, and selling generic copies of branded pharmaceutical products for the U.S. market, and relies on contributions from Watson Pharmaceuticals, Watson Laboratories, Watson Laboratories Florida, and Watson Pharma.

16. On information and belief, Watson Pharmaceuticals, Watson Laboratories, Watson Laboratories Florida, and Watson Pharma are agents of each other and/or operate in concert as integrated parts of Watson’s Generic division.

17. On information and belief, Watson Pharmaceuticals has consolidated its activities and financial results in its most recent SEC filings and Annual Report with, among other entities, Watson Laboratories, Watson Laboratories Florida, and Watson Pharma.

18. On information and belief, Watson Pharma, acting as the agent of Watson Pharmaceuticals, Watson Laboratories, and/or Watson Laboratories Florida, distributes and sells in Delaware and elsewhere in the United States generic pharmaceutical products that are manufactured by Watson Laboratories and/or Watson Laboratories Florida or for which Watson Laboratories and/or Watson Laboratories Florida is the named applicant on approved ANDAs. Upon information and belief, Watson Pharma, Watson Laboratories, and/or Watson Laboratories Florida are parties to one or more contractual agreements regarding the distribution of such generic pharmaceutical products. Upon information and belief, such agreements are at less than arm's length.

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

20. On information and belief, various products for which Watson Laboratories and/or Watson Laboratories Florida is the named applicant on approved ANDAs are available at retail pharmacies in Delaware, and are available for direct purchase by pharmacies in Delaware and elsewhere through a link provided on Watson Pharmaceuticals' website.

21. On information and belief, Watson Pharmaceuticals, Watson Laboratories, and Watson Pharma participated in, contributed to, aided, abetted and/or induced the submission to the FDA of ANDA No. 201888, the ANDA at issue in this litigation. For instance, by letter dated August 24, 2011, Watson Laboratories Florida directed Pfizer to send any written notice regarding confidential access concerning ANDA No. 201888 to G. Michael Bryner, who is Vice President, Intellectual Property and Patent Counsel for Watson Pharmaceuticals. Mr. Bryner is also registered with the U.S. Patent and Trademark Office as an attorney employed by Watson Pharmaceuticals.

22. On information and belief, Watson Pharma, Watson Pharmaceuticals, and Watson Laboratories will manufacture, market, and/or sell within the United States the generic product described in Watson's ANDA No. 201888 if FDA approval is granted. If ANDA No. 201888 is approved, the generic product charged with infringing the '633, '634, and '934 patents 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 patients in Delaware, all of which would have a substantial effect on Delaware.

### **BACKGROUND**

23. EMBEDA® is a pain medication containing a combination of morphine sulfate and naltrexone hydrochloride. EMBEDA® is FDA-approved and is indicated for the management of moderate to severe pain when a continuous, around-the-clock opioid analgesic is needed for an extended period of time.

24. King Pharmaceuticals, Inc. has sold EMBEDA® in the United States in various dosage strengths, including 20mg/0.8mg, 30mg/1.2mg, 50mg/2mg, 60mg/2.4mg, 80mg/3.2mg, and 100mg/4mg (morphine sulfate/naltrexone hydrochloride), pursuant to New Drug Application (NDA) No. 022321 approved by the FDA.

25. The '633 patent, entitled "Pharmaceutical Composition" (Exhibit A hereto), was duly and legally issued on March 23, 2010 to Alpharma Pharmaceuticals LLC, as assignee.

26. The '634 patent, entitled "Pharmaceutical Compositions" (Exhibit B hereto), was duly and legally issued on March 23, 2010 to Alpharma Pharmaceuticals LLC, as assignee.

27. The '934 patent, entitled "Sequestering Subunit and Related Compositions and Methods" (Exhibit C hereto), was duly and legally issued on October 19, 2010 to Alpharma Pharmaceuticals LLC, as assignee.

28. EMBEDA® and the use thereof are covered by one or more claims of the '633 patent, the '634 patent, and the '934 patent, which have been listed in connection with EMBEDA® in the FDA's publication *Approved Drug Products with Therapeutic Equivalence Evaluations*, also known as the "Orange Book."

29. Pfizer Inc., Alpharma Pharmaceuticals LLC, and/or King Pharmaceuticals, Inc. have all right, title, and interest in the '633 patent, the '634 patent, and the '934 patent, including the right to sue for infringement thereof.

30. By letter dated August 24, 2011 (the "Notice Letter"), Watson notified Alpharma Pharmaceuticals LLC and King Pharmaceuticals, Inc., that Watson Laboratories Florida had submitted to the FDA ANDA No. 201888, for Watson's Morphine Sulfate/Naltrexone Hydrochloride Extended-Release Capsules, in strengths of 30mg/1.2mg, 50mg/2mg, 60mg/2.4mg, 80mg/3.2mg, and 100mg/4mg (morphine sulfate/naltrexone hydrochloride), a generic version of EMBEDA® ("Watson's ANDA Products"). The purpose of the ANDA was to obtain approval under the Federal Food, Drug, and Cosmetic Act ("FDCA") to

engage in the commercial manufacture, use, offer for sale, and/or sale of Watson's ANDA Products prior to the expiration of the '633 patent, the '634 patent, and the '934 patent.

31. In the Notice Letter, Watson Laboratories Florida also stated that, as part of its ANDA, it had filed certifications of the type described in Section 505(j)(2)(A)(vii)(IV) of the FDCA, 21 U.S.C. 355(j)(2)(A)(vii)(IV) ("Paragraph IV certification") asserting that no valid claim of the '633 patent, the '634 patent, or the '934 patent will be infringed by the manufacture, use, sale or importation of Watson's ANDA Products. The letter was signed by "Janet Vaughn, Director, Regulatory Affairs" of "Watson Laboratories, Inc. – Florida," on information and belief, on behalf of Watson Laboratories, Watson Pharmaceuticals, and Watson Pharma.

32. This action is being commenced before the expiration of forty-five days from the date of the receipt of the Notice Letter.

**COUNT I – INFRINGEMENT OF U.S. PATENT NO. 7,682,633**

33. Plaintiffs repeat and reallege each and every allegation contained in paragraphs 1 through 32 hereof, as if more fully set forth herein.

34. Watson's submission to the FDA of ANDA No. 201888 for the purpose of obtaining approval to engage in the commercial manufacture, use, offer for sale, and/or sale of Watson's ANDA Products before expiration of the '633 patent was an act of infringement of the '633 patent under 35 U.S.C. § 271(e)(2)(A).

35. On information and belief, Watson will engage in the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of its ANDA Products immediately and imminently upon approval of ANDA No. 201888.

36. On information and belief, the manufacture, use, sale, offer for sale, or importation of Watson's ANDA Products would infringe one or more claims of the '633 patent.

37. On information and belief, the use of Watson's ANDA Products in accordance with and as directed by Watson's proposed product labeling would infringe one or more claims of the '633 patent.

38. On information and belief, Watson plans and intends to, and will, actively induce infringement of the '633 patent when its ANDA No. 201888 is approved, and plans and intends to, and will, do so immediately and imminently upon approval.

39. Watson has knowledge of the claims of the '633 patent. Notwithstanding this knowledge, Watson has continued to assert its intent to manufacture, offer for sale, sell, distribute, and/or import its ANDA Products with their product labeling upon FDA approval of ANDA No. 201888 prior to the expiration of the '633 patent.

40. On information and belief, Watson knows that its ANDA Products and their proposed labeling are especially made or adapted for use in infringing the '633 patent, and that Watson's ANDA Products and their proposed labeling are not suitable for substantial noninfringing use.

41. The foregoing actions by Watson constitute and/or will constitute infringement of the '633 patent under 35 U.S.C. § 271(e)(2) and 35 U.S.C. § 271(a), active inducement of infringement of the '633 patent under 35 U.S.C. § 271(b), and/or contributing to the infringement by others of the '633 patent under 35 U.S.C. § 271(c).

42. On information and belief, Watson acted without a reasonable basis for believing that it would not be liable for infringement of the '633 patent, for actively inducing infringement of the '633 patent, and for contributing to the infringement by others of the '633 patent.



43. The Court should declare that the commercial manufacture, use, sale, offer for sale or importation of the Watson ANDA Products, or any product whose use is covered by the '633 patent, will infringe, induce the infringement of, and/or contribute to the infringement by others of that patent.

44. Unless Watson is enjoined from infringement of the '633 patent, from actively inducing infringement of the '633 patent, and from contributing to the infringement by others of the '633 patent, Pfizer will suffer irreparable injury. Pfizer has no adequate remedy at law.

**COUNT II – INFRINGEMENT OF U.S. PATENT NO. 7,682,634**

45. Plaintiffs repeat and reallege each and every allegation contained in paragraphs 1 through 44 hereof, as if more fully set forth herein.

46. Watson's submission to the FDA of ANDA No. 201888 for the purpose of obtaining approval to engage in the commercial manufacture, use, offer for sale, and/or sale of Watson's ANDA Products before expiration of the '634 patent was an act of infringement of the '634 patent under 35 U.S.C. § 271(e)(2)(A).

47. On information and belief, Watson will engage in the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of its ANDA Products immediately and imminently upon approval of ANDA No. 201888.

48. On information and belief, the manufacture, use, sale, offer for sale, or importation of Watson's ANDA Products would infringe one or more claims of the '634 patent.

49. On information and belief, the use of Watson's ANDA Products in accordance with and as directed by Watson's proposed product labeling would infringe one or more claims of the '634 patent.

50. On information and belief, Watson plans and intends to, and will, actively induce infringement of the '634 patent when its ANDA No. 201888 is approved, and plans and intends to, and will, do so immediately and imminently upon approval.

51. Watson has knowledge of the claims of the '634 patent. Notwithstanding this knowledge, Watson has continued to assert its intent to manufacture, offer for sale, sell, distribute, and/or import its ANDA Products with their product labeling upon FDA approval of ANDA No. 201888 prior to the expiration of the '634 patent.

52. On information and belief, Watson knows that its ANDA Products and their proposed labeling are especially made or adapted for use in infringing the '634 patent, and that Watson's ANDA Products and their proposed labeling are not suitable for substantial noninfringing use.

53. The foregoing actions by Watson constitute and/or will constitute infringement of the '634 patent under 35 U.S.C. § 271(e)(2) and 35 U.S.C. § 271(a), active inducement of infringement of the '634 patent under 35 U.S.C. § 271(b), and/or contributing to the infringement by others of the '634 patent under 35 U.S.C. § 271(c).

54. On information and belief, Watson acted without a reasonable basis for believing that it would not be liable for infringement of the '634 patent, for actively inducing infringement of the '634 patent, and for contributing to the infringement by others of the '634 patent.

55. The Court should declare that the commercial manufacture, use, sale, offer for sale or importation of the Watson ANDA Products, or any product whose use is covered by the '634 patent, will infringe, induce the infringement of, and/or contribute to the infringement by others of that patent.

56. Unless Watson is enjoined from infringement of the '634 patent, from actively inducing infringement of the '634 patent, and from contributing to the infringement by others of the '634 patent, Pfizer will suffer irreparable injury. Pfizer has no adequate remedy at law.

**COUNT III – INFRINGEMENT OF U.S. PATENT NO. 7,815,934**

57. Plaintiffs repeat and reallege each and every allegation contained in paragraphs 1 through 56 hereof, as if more fully set forth herein.

58. Watson's submission to the FDA of ANDA No. 201888 for the purpose of obtaining approval to engage in the commercial manufacture, use, offer for sale, and/or sale of Watson's ANDA Products before expiration of the '934 patent was an act of infringement of the '934 patent under 35 U.S.C. § 271(e)(2)(A).

59. On information and belief, Watson will engage in the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of its ANDA Products immediately and imminently upon approval of ANDA No. 201888.

60. The manufacture, use, sale, offer for sale, or importation of Watson's ANDA Products would infringe one or more claims of the '934 patent.

61. On information and belief, the use of Watson's ANDA Products in accordance with and as directed by Watson's proposed product labeling would infringe one or more claims of the '934 patent.

62. On information and belief, Watson plans and intends to, and will, actively induce infringement of the '934 patent when its ANDA No. 201888 is approved, and plans and intends to, and will, do so immediately and imminently upon approval.

63. Watson has knowledge of the claims of the '934 patent. Notwithstanding this knowledge, Watson has continued to assert its intent to manufacture, offer for sale, sell, distribute, and/or import its ANDA Products with their product labeling upon FDA approval of ANDA No. 201888 prior to the expiration of the '934 patent.

64. On information and belief, Watson knows that its ANDA Products and their proposed labeling are especially made or adapted for use in infringing the '934 patent, and that Watson's ANDA Products and their proposed labeling are not suitable for substantial noninfringing use.

65. The foregoing actions by Watson constitute and/or will constitute infringement of the '934 patent under 35 U.S.C. § 271(e)(2) and 35 U.S.C. § 271(a), active inducement of infringement of the '934 patent under 35 U.S.C. § 271(b), and/or contributing to the infringement by others of the '934 patent under 35 U.S.C. § 271(c).

66. On information and belief, Watson acted without a reasonable basis for believing that it would not be liable for infringement of the '934 patent, for actively inducing infringement of the '934 patent, and for contributing to the infringement by others of the '934 patent.

67. The Court should declare that the commercial manufacture, use, sale, offer for sale or importation of the Watson ANDA Products, or any product whose use is covered by the '934 patent, will infringe, induce the infringement of, and/or contribute to the infringement by others of that patent.

68. Unless Watson is enjoined from infringement of the '934 patent, from actively inducing infringement of the '934 patent, and from contributing to the infringement by

others of the '934 patent, Pfizer will suffer irreparable injury. Pfizer has no adequate remedy at law.

WHEREFORE, Plaintiffs request the following relief:

(a) A judgment that U.S. Patent No. 7,682,633 is valid and enforceable, and has been infringed under 35 U.S.C. § 271(e)(2) by Watson's submission to the FDA of its ANDA No. 201888;

(b) A judgment that U.S. Patent No. 7,682,634 is valid and enforceable, and has been infringed under 35 U.S.C. § 271(e)(2) by Watson's submission to the FDA of its ANDA No. 201888;

(c) A judgment that U.S. Patent No. 7,815,934 is valid and enforceable, and has been infringed under 35 U.S.C. § 271(e)(2) by Watson's submission to the FDA of its ANDA No. 201888;

(d) A judgment providing that the effective date of any FDA approval of commercial manufacture, use, or sale of Watson's ANDA Products, or any other drug product that infringes or the use of which infringes U.S. Patent No. 7,682,633, be no earlier than the expiration date of that patent, inclusive of any extension(s) and additional period(s) of exclusivity;

(e) A judgment providing that the effective date of any FDA approval of commercial manufacture, use, or sale of Watson's ANDA Products, or any other drug product that infringes or the use of which infringes U.S. Patent No. 7,682,634, be no earlier than the expiration date of that patent, inclusive of any extension(s) and additional period(s) of exclusivity;

(f) A judgment providing that the effective date of any FDA approval of commercial manufacture, use, or sale of Watson's ANDA Products, or any other drug product that infringes or the use of which infringes U.S. Patent No. 7,815,934, be no earlier than the expiration dates of that patent, inclusive of any extension(s) and additional period(s) of exclusivity;

(g) A preliminary and permanent injunction against any infringement, inducement of infringement, or contribution to infringement, by Watson of U.S. Patent No. 7,682,633, through the commercial manufacture, use, sale, offer for sale, or importation into the United States of the Watson ANDA Products or any other drug product that is, or whose use is, covered by that patent;

(h) A preliminary and permanent injunction against any infringement, inducement of infringement, or contribution to infringement, by Watson of U.S. Patent No. 7,682,634, through the commercial manufacture, use, sale, offer for sale, or importation into the United States of the Watson ANDA Products or any other drug product that is, or whose use is, covered by that patent;

(i) A preliminary and permanent injunction against any infringement, inducement of infringement, or contribution to infringement, by Watson of U.S. Patent No. 7,815,934, through the commercial manufacture, use, sale, offer for sale, or importation into the United States of the Watson ANDA Products or any other drug product that is, or whose use is, covered by that patent;

(j) A judgment declaring that the commercial manufacture, use, sale, offer for sale or importation of the Watson ANDA Products, or any other drug product that is covered by

U.S. Patent No. 7,682,633, will infringe, induce the infringement of, and/or contribute to the infringement by others of that patent;

(k) A judgment declaring that the commercial manufacture, use, sale, offer for sale or importation of the Watson ANDA Products, or any product whose use is covered by U.S. Patent No. 7,682,634, will infringe, induce the infringement of, and/or contribute to the infringement by others of that patent;

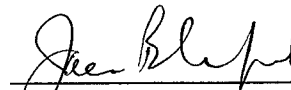
(l) A judgment declaring that the commercial manufacture, use, sale, offer for sale or importation of the Watson ANDA Products, or any product whose use is covered by U.S. Patent No. 7,815,934, will infringe, induce the infringement of, and/or contribute to the infringement by others of that patent;

(m) A declaration that this in an exceptional case and an award of attorneys' fees to plaintiffs pursuant to 35 U.S.C. § 285;

(n) Costs and expenses in this action; and

(o) Such further and other relief as this Court may deem just and proper.

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