

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

ALCON PHARMACEUTICALS, LTD. and)	
ALCON RESEARCH, LTD.,)	
)	
Plaintiffs,)	
)	
v.)	C.A. No. _____
)	
WATSON LABORATORIES INC.,)	
WATSON PHARMACEUTICALS, INC.)	
and WATSON PHARMA, INC.,)	
)	
Defendants.)	

COMPLAINT

Plaintiffs Alcon Pharmaceuticals, Ltd. and Alcon Research, Ltd. (collectively “Alcon”), by their attorneys, for their Complaint, allege as follows:

1. This is an action for patent infringement under the patent laws of the United States, Title 35, United States Code, that arises out of Watson’s filing of an Abbreviated New Drug Application (“ANDA”) with the U.S. Food and Drug Administration (“FDA”) seeking approval to manufacture and sell a generic version of VIGAMOX® ophthalmic solution, a drug product containing moxifloxacin hydrochloride, prior to the expiration of various U.S. patents.

PARTIES

2. Plaintiff Alcon Pharmaceuticals, Ltd. is a corporation organized and existing under the laws of Switzerland, having its principal place of business at Route des Arsenaux 41, 1701 Fribourg, Switzerland.

3. Plaintiff Alcon Research, Ltd. is a corporation organized and existing under the laws of the State of Delaware, having its principal place of business at 6201 South Freeway, Fort Worth, Texas 76134.

4. Upon 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.

5. Upon 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. Upon 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.

7. Upon information and belief, Watson Laboratories and Watson Pharma are wholly owned subsidiaries of Watson Pharmaceuticals. Watson Laboratories, Watson Pharmaceuticals, and Watson Pharma are collectively referred to herein as “Watson.”

JURISDICTION AND VENUE

8. Jurisdiction and venue are proper in this district pursuant to 28 U.S.C. §§ 1331, 1338(a), 1391 and 1400(b), and 2201 and 2202.

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

10. Upon information and belief, Watson Pharmaceuticals, Watson Laboratories, and/or Watson Pharma share common employees, officers and directors.

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

12. Upon 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, and Watson Pharma.

13. 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.

14. Upon information and belief, Watson Pharma, acting as the agent of Watson Pharmaceuticals and/or Watson Laboratories, distributes and sells in Delaware and elsewhere in the United States generic pharmaceutical products that are manufactured by Watson Laboratories or for which Watson Laboratories is the named applicant on approved ANDAs. 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 at less than arm's length.

15. Upon information and belief, Watson Pharmaceuticals and/or Watson Laboratories earns 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.

16. 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. 202525, the ANDA at issue in this

litigation. For instance, by letter dated February 24, 2011, Watson Laboratories directed Alcon to send any written notice regarding confidential access concerning ANDA No. 202525 to Mr. Brian Anderson, who is registered with the State Bar of California as an attorney employed by Watson Pharmaceuticals, Inc.

COUNT I-INFRINGEMENT OF THE '830 PATENT

17. Alcon incorporates each of the preceding paragraphs 1-16 as if fully set forth herein.

18. United States Patent No. 6,716,830 (“the ’830 patent”), titled “Ophthalmic Antibiotic Compositions Containing Moxifloxacin” (Exhibit A hereto), was duly and legally issued on April 6, 2004 to Alcon, Inc., as assignee of Gerald Cagle, Robert L. Abshire, David W. Stroman, and John M. Yanni.

19. Alcon, Inc.’s interest in the ’830 patent has been subsequently assigned to Alcon Pharmaceuticals, Ltd. Alcon Pharmaceuticals, Ltd. owns the ’830 patent and will be substantially and irreparably damaged by infringement of the ’830 patent.

20. Alcon Research, Ltd. has been granted an exclusive license under the ’830 patent. Alcon Research, Ltd. will be substantially and irreparably damaged by infringement of the ’830 patent.

21. The ’830 patent claims, *inter alia*, topical ophthalmic pharmaceutical compositions comprising moxifloxacin or a pharmaceutically useful hydrate or salt thereof in a concentration of 0.1 to 1.0 wt. % of moxifloxacin and a pharmaceutically acceptable vehicle therefor.

22. The FDA's "Orange Book" lists patents associated with approved drugs. The '830 patent is listed in the "Orange Book" in association with VIGAMOX[®] ophthalmic solution.

23. By letter dated February 24, 2011 (the "Notice Letter"), Watson notified Alcon that Watson had submitted ANDA No. 202525 to the FDA. 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, and sale of an ophthalmic drug product containing moxifloxacin hydrochloride (the "Watson Product") prior to the expiration of, *inter alia*, the '830 patent.

24. In the Notice Letter, Watson also notified Alcon that, as part of its ANDA, Watson 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).

25. Watson's submission of the ANDA for the purpose of obtaining approval to engage in the commercial manufacture, use, or sale of the Watson Product before the expiration of the '830 patent is an act of infringement of that patent under 35 U.S.C. § 271(e)(2)(A).

26. Upon information and belief, Watson will engage in the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of the Watson Product immediately and imminently upon approval of ANDA No. 202525.

27. The drug product containing moxifloxacin hydrochloride that is the subject of ANDA No. 202525 is covered by one or more claims of the '830 patent.

28. The manufacture, use, sale, offer for sale, or importation of the Watson Product would infringe one or more claims of the '830 patent.

29. Upon information and belief, the use of the Watson Product in accordance with and as directed by Watson's proposed product labeling would infringe one or more claims of the '830 patent.

30. Upon information and belief, Watson plans and intends to, and will, actively induce infringement of the '830 patent when its ANDA is approved, and plans and intends to, and will, do so immediately and imminently upon approval.

31. Upon information and belief, Watson has knowledge of the claims of the '830 patent. Notwithstanding this knowledge, Watson has continued to assert its intent to manufacture, offer for sale, sell, distribute, and/or import the Watson Product with its product labeling following upon FDA approval of ANDA No. 202525 prior to the expiration of the '830 patent.

32. The foregoing actions by Watson constitute and/or will constitute infringement and active inducement of infringement of the '830 patent.

33. Upon information and belief, Watson has acted with full knowledge of the '830 patent and without a reasonable basis for believing that it would not be liable for infringement of the '830 patent and/or active inducement of infringement of the '830 patent.

34. Unless defendant Watson is enjoined from infringing and inducing infringement of the '830 patent, Alcon will suffer irreparable injury. Alcon has no adequate remedy at law.

COUNT II-INFRINGEMENT OF THE '070 PATENT

35. Alcon incorporates each of the preceding paragraphs 1-16 as if fully set forth herein.

36. United States Patent No. 7,671,070 (“the ’070 patent”), titled “Method of Treating Ophthalmic Infections with Moxifloxacin Compositions” (Exhibit B hereto), was duly and legally issued on March 2, 2010 to Alcon, Inc., as assignee of Gerald Cagle, Robert L. Abshire, David W. Stroman, and John M. Yanni.

37. Alcon, Inc.’s interest in the ’070 patent has been subsequently assigned to Alcon Pharmaceuticals, Ltd. Alcon Pharmaceuticals, Ltd. owns the ’070 patent and will be substantially and irreparably damaged by infringement of the ’070 patent.

38. Alcon Research, Ltd. has been granted an exclusive license under the ’070 patent. Alcon Research, Ltd. will be substantially and irreparably damaged by infringement of the ’070 patent.

39. The ’070 patent claims, *inter alia*, a method of treating ophthalmic infections, which comprises topically applying to the eye a therapeutically effective amount of a pharmaceutical composition comprising moxifloxacin or a pharmaceutically useful hydrate or salt thereof in a concentration of 0.1 to 1.0 wt. % of moxifloxacin and a pharmaceutically acceptable vehicle therefor.

40. The ’070 patent is listed in the “Orange Book” in association with VIGAMOX[®] ophthalmic solution.

41. In the Notice Letter described in paragraph 23 above, Watson notified Alcon that Watson had submitted ANDA No. 202525, to the FDA. The purpose of the ANDA was to obtain approval under the FDCA to engage in the commercial manufacture, use, and sale of the Watson Product prior to the expiration of, *inter alia*, the ’070 patent.

42. In the Notice Letter, Watson also notified Alcon that, as part of its ANDA, Watson 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).

43. Watson's filing of the ANDA for the purpose of obtaining approval to engage in the commercial manufacture, use, or sale of the Watson Product before the expiration of the '070 patent is an act of infringement of that patent under 35 U.S.C. § 271(e)(2)(A).

44. Upon information and belief, Watson will engage in the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of the Watson Product immediately and imminently upon approval of ANDA No. 202525.

45. The approved use of VIGAMOX® is covered by one or more claims of the '070 patent.

46. Upon information and belief, the use of the Watson Product in accordance with and as directed by Watson's proposed product labeling would infringe one or more claims of the '070 patent.

47. Upon information and belief, Watson plans and intends to, and will, actively induce infringement of the '070 patent when its ANDA is approved, and plans and intends to, and will, do so immediately and imminently upon approval.

48. Upon information and belief, Watson has knowledge of the claims of the '070 patent. Notwithstanding this knowledge, Watson has continued to assert its intent to manufacture, offer for sale, sell, distribute, and/or import the Watson Product with its product labeling following FDA approval of ANDA No. 202525 prior to the expiration of the '070 patent.

49. Upon information and belief, Watson knows that the Watson Product and its product labeling are especially made or adapted for use in infringing the '070 patent, the Watson Product is not a staple article or commodity of commerce, and that the Watson Product and its product labeling are not suitable for substantial noninfringing use. Upon information and belief, Watson plans and intends to, and will, contribute to infringement of the '070 patent immediately and imminently upon approval of ANDA No. 202525.

50. The foregoing actions by Watson constitute and/or will constitute infringement of the '070 patent, active inducement of infringement of the '070 patent, and contribution to the infringement by others of the '070 patent.

51. Upon information and belief, Watson has acted with full knowledge of the '070 patent and without a reasonable basis for believing that it would not be liable for active inducement of infringement of the '070 patent, and/or contributing to the infringement by others of the '070 patent.

52. Unless Watson is enjoined from infringing, inducing infringement and contributing to the infringement of, the '070 patent, Alcon will suffer irreparable injury. Alcon has no adequate remedy at law.

**COUNT III-DECLARATORY JUDGMENT
OF INFRINGEMENT OF THE '830 PATENT**

53. Alcon incorporates each of the preceding paragraphs as if fully set forth herein.

54. The Court may declare the rights and legal relations of the parties pursuant to 28 U.S.C. §§ 2201 and 2202 because there is a case of actual controversy between Alcon on the one hand and Watson on the other regarding Watson's infringement of the '830 patent and active inducement of infringement of the '830 patent.

55. The '830 patent claims, *inter alia*, topical ophthalmic pharmaceutical compositions comprising moxifloxacin or a pharmaceutically useful hydrate or salt thereof in a concentration of 0.1 to 1.0 wt. % of moxifloxacin and a pharmaceutically acceptable vehicle therefor.

56. In the Notice Letter described in paragraph 23 above, Watson notified Alcon that Watson had submitted ANDA No. 202525 to the FDA. The purpose of the ANDA was to obtain approval under the FDCA to engage in the commercial manufacture, use, and sale of the Watson Product prior to the expiration of, *inter alia*, the '830 patent.

57. In the Notice Letter, Watson also notified Alcon that, as part of its ANDA, Watson 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).

58. Upon information and belief, Watson will engage in the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of the Watson Product immediately and imminently upon approval of ANDA No. 202525.

59. The drug product containing moxifloxacin hydrochloride that is the subject of ANDA No. 202525 is covered by one or more claims of the '830 patent.

60. The manufacture, use, sale, offer for sale, or importation of the Watson Product would infringe one or more claims of the '830 patent.

61. Upon information and belief, the use of the Watson Product in accordance with and as directed by Watson's proposed product labeling would infringe one or more claims of the '830 patent.

62. Upon information and belief, Watson plans and intends to, and will, actively induce infringement of the '830 patent when its ANDA is approved, and plans and intends to, and will, do so immediately and imminently upon approval.

63. Upon information and belief, Watson has knowledge of the claims of the '830 patent. Notwithstanding this knowledge, Watson has continued to assert its intent to manufacture, offer for sale, sell, distribute, and/or import the Watson Product with its product labeling following upon FDA approval of ANDA No. 202525 prior to the expiration of the '830 patent.

64. The foregoing actions by Watson constitute and/or will constitute infringement and active inducement of infringement of the '830 patent.

65. Upon information and belief, Watson has acted with full knowledge of the '830 patent and without a reasonable basis for believing that it would not be liable for infringement of the '830 patent and/or active inducement of infringement of the '830 patent.

66. Unless defendant Watson is enjoined from infringing and inducing infringement of the '830 patent, Alcon will suffer irreparable injury. Alcon has no adequate remedy at law.

67. The Court should declare that the commercial manufacture, use, sale, offer for sale or importation of the Watson Product, or any other drug product that is covered by United States Patent No. 6,716,830, will infringe and/or induce the infringement of that patent.

**COUNT IV-DECLARATORY JUDGMENT
OF INFRINGEMENT OF THE '070 PATENT**

68. Alcon incorporates each of the preceding paragraphs as if fully set forth herein.

69. The Court may declare the rights and legal relations of the parties pursuant to 28 U.S.C. §§ 2201 and 2202 because there is a case of actual controversy between Alcon on the one hand and Watson on the other regarding Watson's active inducement of infringement of the '070 patent, and/or contributing to the infringement by others of the '070 patent.

70. The '070 patent claims, *inter alia*, a method of treating ophthalmic infections, which comprises topically applying to the eye a therapeutically effective amount of a pharmaceutical composition comprising moxifloxacin or a pharmaceutically useful hydrate or salt thereof in a concentration of 0.1 to 1.0 wt. % of moxifloxacin and a pharmaceutically acceptable vehicle therefore.

71. In the Notice Letter described in paragraph 23 above, Watson notified Alcon that Watson had submitted ANDA No. 202525, to the FDA. The purpose of the ANDA was to obtain approval under the FDCA to engage in the commercial manufacture, use, and sale of the Watson Product prior to the expiration of, *inter alia*, the '070 patent.

72. In the Notice Letter, Watson also notified Alcon that, as part of its ANDA, Watson 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).

73. Upon information and belief, Watson will engage in the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of the Watson Product immediately and imminently upon approval of ANDA No. 202525.

74. The approved use of VIGAMOX® is covered by one or more claims of the '070 patent.

75. Upon information and belief, the use of the Watson Product in accordance with and as directed by Watson's proposed product labeling would infringe one or more claims of the '070 patent.

76. Upon information and belief, Watson plans and intends to, and will, actively induce infringement of the '070 patent when its ANDA is approved, and plans and intends to, and will, do so immediately and imminently upon approval.

77. Upon information and belief, Watson has knowledge of the claims of the '070 patent. Notwithstanding this knowledge, Watson has continued to assert its intent to manufacture, offer for sale, sell, distribute, and/or import the Watson Product with its product labeling following FDA approval of ANDA No. 202525 prior to the expiration of the '070 patent.

78. Upon information and belief, Watson knows that the Watson Product and its product labeling are especially made or adapted for use in infringing the '070 patent, the Watson Product is not a staple article or commodity of commerce, and that the Watson Product and its product labeling are not suitable for substantial noninfringing use. Upon information and belief, Watson plans and intends to, and will, contribute to infringement of the '070 patent immediately and imminently upon approval of ANDA No. 202525.

79. The foregoing actions by Watson constitute and/or will constitute infringement of the '070 patent, active inducement of infringement of the '070 patent, and contribution to the infringement by others of the '070 patent.

80. Upon information and belief, Watson has acted with full knowledge of the '070 patent and without a reasonable basis for believing that it would not be liable for active

inducement of infringement of the '070 patent, and/or contributing to the infringement by others of the '070 patent.

81. Unless Watson is enjoined from infringing, inducing infringement and contributing to the infringement of, the '070 patent, Alcon will suffer irreparable injury. Alcon has no adequate remedy at law.

82. The Court should declare that the commercial manufacture, use, sale, offer for sale or importation of the Watson Product, or any product whose use is covered by United States Patent No. 7,671,070, will infringe, induce the infringement of, and/or contribute to the infringement by others of that patent.

WHEREFORE, Plaintiffs request the following relief:

(a) A judgment that United States Patent Nos. 6,716,830 and 7,671,070 are valid and enforceable, and have been infringed under 35 U.S.C. § 271(e)(2) by Watson's submission to the FDA of its ANDA No. 202525;

(b) A judgment providing that the effective date of any FDA approval of commercial manufacture, use, or sale of the Watson Product, or any other drug product that infringes or the use of which infringes United States Patent No. 6,716,830 or United States Patent No. 7,671,070, be not earlier than the latest of the expiration dates of those patents, inclusive of any extension(s) and additional period(s) of exclusivity;

(c) A preliminary and permanent injunction against any infringement, or inducement of infringement, by Watson of United States Patent No. 6,716,830, through the commercial manufacture, use, sale, offer for sale, or importation into the United States of the Watson Product or any other drug product that is covered by that patent;

(d) A preliminary and permanent injunction against any inducement of infringement, or contribution to infringement, by Watson of United States Patent No. 7,671,070, through the commercial manufacture, use, sale, offer for sale, or importation into the United States of the Watson Product or any other drug product whose use is covered by that patent;

(e) A judgment declaring that the commercial manufacture, use, sale, offer for sale or importation of the Watson Product, or any other drug product that is covered by United States Patent No. 6,716,830, will infringe and/or induce the infringement of that patent;

(f) A judgment declaring that the commercial manufacture, use, sale, offer for sale or importation of the Watson Product, or any product whose use is covered by United States Patent No. 7,671,070, will infringe, induce the infringement of, and/or contribute to the infringement by others of that patent;

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

(h) Costs and expenses in this action; and

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

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