IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

ALCON PHARMACEUTICALS LTD. and ALCON RESEARCH, LTD.,	)	
Plaintiffs,	)	
	)	C.A. No. _____
v.	)	
AKORN, INC.,	)	
Defendant.	)	

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 defendant Akorn, Inc.'s ("Akorn") filing of Abbreviated New Drug Application ("ANDA") No. 021598 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 Rue Louis d'Affry 6, Case Postale, 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 Akorn is a corporation organized and existing under the laws of the State of Louisiana, having its principal place of business at 1925 West Field Court, Suite 300, Lake Forest, Illinois.

JURISDICTION AND VENUE

5. 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.

6. Akorn is subject to personal jurisdiction in this Court for at least the reasons, among others, set forth below in paragraphs 7-15.

7. Akorn has purposefully availed itself of the benefits and protections of Delaware's laws such that it should reasonably anticipate being haled into court here.

8. Upon information and belief, Akorn is a generic pharmaceutical company that develops, manufactures, imports, markets, offers to sell, and/or sells generic drugs throughout the United States, including in the State of Delaware and therefore transacts business within the State of Delaware. Upon information and belief, Akorn has previously used the process contemplated by the Drug Price Competition and Patent Term Restoration Act of 1984, 21 U.S.C. § 355(j) ("the Hatch-Waxman Act"), to challenge branded pharmaceutical companies' patents by filing a certification of the type described in Section 505(j)(2)(A)(vii)(IV) of the Federal Food, Drug, and Cosmetic Act ("FFDCA"), 21 U.S.C. § 355(j)(2)(A)(vii)(IV), serving a notice letter on those companies, and engaging in patent litigation arising from the process contemplated by the Hatch-Waxman Act.

9. Upon information and belief, with knowledge of the Hatch-Waxman Act process, Akorn directed the Notice Letter to, *inter alia*, Alcon Research, Ltd., an entity incorporated in Delaware, and alleged in the Notice Letter that Alcon's patents are invalid.

Upon information and belief, Akorn knowingly and deliberately challenged Alcon's patent rights, and knew when it did so that it was triggering a forty-five day period for Alcon to bring an action for patent infringement under the Hatch-Waxman Act. Moreover, upon information and belief, Akorn knew that other Hatch-Waxman Act infringement actions relating to the same patents had been brought and litigated in Delaware.

10. Because Alcon Research, Ltd., is a corporation incorporated in Delaware, the injury and consequences from Akorn's filing of ANDA No. 021598, challenging Alcon's patent rights, are suffered in Delaware. Upon information and belief, Akorn knew that it was deliberately challenging the patent rights of a Delaware entity and seeking to invalidate intellectual property held in Delaware.

11. Upon information and belief, Akorn is registered, under 24 Del. C. § 2540, to distribute its generic pharmaceutical products in Delaware and holds current and valid "Distributor/Manufacturer CSR" and "Pharmacy-Wholesale" licenses from the Delaware Board of Pharmacy.

12. Upon information and belief, Akorn wholly owns five subsidiaries that are incorporated in Delaware: Oak Pharmaceuticals, Inc.; Advanced Vision Research, Inc.; Akorn Ophthalmics, Inc.; Akorn Enterprises, Inc.; and Akorn Animal Health, Inc. Upon information and belief, Akorn is a 50 percent owner of Akorn-Strides, LLC, a company organized under the laws of Delaware.

13. Upon information and belief, if ANDA No. 021598 is approved, Akorn will manufacture, market, and/or sell the product that is the subject of the ANDA ("Akorn's ANDA Product") within the United States, including in Delaware, consistently with Akorn's practices for the marketing and distribution of other generic pharmaceutical products. Upon

information and belief, Akorn regularly does business in Delaware, and its practices with other generic pharmaceutical products have involved placing those products into the stream of commerce for distribution throughout the United States, including in Delaware. Upon information and belief, Akorn's generic pharmaceutical products are used and/or consumed within and throughout the United States, including in Delaware.

14. If ANDA No. 021598 is approved, upon information and belief, Akorn will directly or indirectly market and distribute Akorn's ANDA Product in Delaware. Upon information and belief, Akorn's ANDA Product will be prescribed by physicians practicing in Delaware, dispensed by pharmacies located within Delaware, and used by patients in Delaware. Each of these activities would have a substantial effect within Delaware and would constitute infringement of Alcon's patents in the event that Akorn's ANDA Product is approved before those patents expire.

15. Upon information and belief, Akorn derives substantial revenue from generic pharmaceutical products that are used and/or consumed within Delaware, and which are manufactured by Akorn and/or for which Akorn is the named applicant on approved ANDAs. Upon information and belief, various products for which Akorn is the named applicant on approved ANDAs are available at retail pharmacies in Delaware.

COUNT I
INFRINGEMENT OF THE '830 PATENT

16. Alcon incorporates each of the preceding paragraphs 1-15 as if fully set forth herein.

17. 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.

18. 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.

19. 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.

20. 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.

21. 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.

22. By letter dated September 25, 2015 (the "Notice Letter"), Akorn notified Alcon that it had submitted ANDA No. 021598 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 prior to the expiration of, *inter alia*, the '830 patent.

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

24. Akorn's submission of ANDA No. 021598 for the purpose of obtaining approval to engage in the commercial manufacture, use, or sale of Akorn's ANDA 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).

25. Upon information and belief, Akorn will engage in the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of Akorn's ANDA Product immediately and imminently upon approval of ANDA No. 021598.

26. The drug product containing moxifloxacin hydrochloride that is the subject of ANDA No. No. 021598 is covered by one or more claims of the '830 patent.

27. The manufacture, use, sale, offer for sale, or importation of Akorn's ANDA Product would infringe one or more claims of the '830 patent.

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

29. Upon information and belief, Akorn 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.

30. Upon information and belief, Akorn has knowledge of the claims of the '830 patent. Notwithstanding this knowledge, Akorn has continued to assert its intent to manufacture, offer for sale, sell, distribute, and/or import Akorn's ANDA Product with its product labeling following upon FDA approval of ANDA No. 021598 prior to the expiration of the '830 patent.

31. The foregoing actions by Akorn constitute and/or will constitute infringement and active inducement of infringement of the ’830 patent.

32. Upon information and belief, Akorn 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.

33. Unless Akorn 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

34. Alcon incorporates each of the preceding paragraphs 1-33 as if fully set forth herein.

35. 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.

36. 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.

37. 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.

38. 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.

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

40. In the Notice Letter described in paragraph 22 above, Akorn notified Alcon that it had submitted ANDA No. 021598 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 Akorn’s ANDA Product prior to the expiration of, *inter alia*, the ’070 patent.

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

42. Akorn’s filing of ANDA No. 021598 for the purpose of obtaining approval to engage in the commercial manufacture, use, or sale of Akorn’s ANDA 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).

43. Upon information and belief, Akorn will engage in the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of Akorn’s ANDA Product immediately and imminently upon approval of ANDA No. 021598.

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

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

46. Upon information and belief, Akorn 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.

47. Upon information and belief, Akorn has knowledge of the claims of the ’070 patent. Notwithstanding this knowledge, Akorn has continued to assert its intent to manufacture, offer for sale, sell, distribute, and/or import Akorn’s ANDA Product with its product labeling following FDA approval of ANDA No. 021598 prior to the expiration of the ’070 patent.

48. Upon information and belief, Akorn knows that Akorn’s ANDA Product and its product labeling are especially made or adapted for use in infringing the ’070 patent, Akorn’s ANDA Product is not a staple article or commodity of commerce, and that Akorn’s ANDA Product and its product labeling are not suitable for substantial noninfringing use. Upon information and belief, Akorn plans and intends to, and will, contribute to infringement of the ’070 patent immediately and imminently upon approval of ANDA No. 021598.

49. The foregoing actions by Akorn 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.

50. Upon information and belief, Akorn 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.

51. Unless Akorn 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

52. Alcon incorporates each of the preceding paragraphs 1-51 as if fully set forth herein.

53. 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 Akorn on the other regarding Akorn’s infringement of the ’830 patent and active inducement of infringement of the ’830 patent.

54. 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.

55. In the Notice Letter described in paragraph 22 above, Akorn notified Alcon that Akorn had submitted ANDA No. 021598 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 Akorn’s ANDA Product prior to the expiration of, *inter alia*, the ’830 patent.

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

57. Upon information and belief, Akorn will engage in the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of Akorn's ANDA Product immediately and imminently upon approval of ANDA No. 021598.

58. The drug product containing moxifloxacin hydrochloride that is the subject of ANDA No. 021598 is covered by one or more claims of the '830 patent.

59. The manufacture, use, sale, offer for sale, or importation of Akorn's ANDA Product would infringe one or more claims of the '830 patent.

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

61. Upon information and belief, Akorn 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.

62. Upon information and belief, Akorn has knowledge of the claims of the '830 patent. Notwithstanding this knowledge, Akorn has continued to assert its intent to manufacture, offer for sale, sell, distribute, and/or import Akorn's ANDA Product with its product labeling following upon FDA approval of ANDA No. 021598 prior to the expiration of the '830 patent.

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

64. Upon information and belief, Akorn 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.

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

66. The Court should declare that the commercial manufacture, use, sale, offer for sale or importation of Akorn's ANDA 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

67. Alcon incorporates each of the preceding paragraphs 1-66 as if fully set forth herein.

68. 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 Akorn on the other regarding Akorn's active inducement of infringement of the '070 patent, and/or contributing to the infringement by others of the '070 patent.

69. 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.

70. In the Notice Letter described in paragraph 22 above, Akorn notified Alcon that Akorn had submitted ANDA No. 021598, 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 Akorn's ANDA Product prior to the expiration of, *inter alia*, the '070 patent.

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

72. Upon information and belief, Akorn will engage in the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of Akorn's ANDA Product immediately and imminently upon approval of ANDA No. 021598.

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

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

75. Upon information and belief, Akorn 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.

76. Upon information and belief, Akorn has knowledge of the claims of the '070 patent. Notwithstanding this knowledge, Akorn has continued to assert its intent to manufacture, offer for sale, sell, distribute, and/or import Akorn's ANDA Product with its product labeling following FDA approval of ANDA No. 021598 prior to the expiration of the '070 patent.

77. Upon information and belief, Akorn knows that Akorn's ANDA Product and its product labeling are especially made or adapted for use in infringing the '070 patent, Akorn's ANDA Product is not a staple article or commodity of commerce, and that Akorn's ANDA Product and its product labeling are not suitable for substantial noninfringing use. Upon

information and belief, Akorn plans and intends to, and will, contribute to infringement of the '070 patent immediately and imminently upon approval of ANDA No. 021598.

78. The foregoing actions by Akorn 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.

79. Upon information and belief, Akorn 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.

80. Unless Akorn 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.

81. The Court should declare that the commercial manufacture, use, sale, offer for sale or importation of Akorn's ANDA 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 Akorn's submission to the FDA of its ANDA No. 021598;

(b) A judgment providing that the effective date of any FDA approval of ANDA No. 021598 for Akorn's ANDA 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 Akorn of United States Patent No. 6,716,830, through the commercial manufacture, use, sale, offer for sale, or importation into the United States of Akorn's ANDA 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 Akorn of United States Patent No. 7,671,070, through the commercial manufacture, use, sale, offer for sale, or importation into the United States of Akorn's ANDA 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 Akorn's ANDA 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 Akorn's ANDA 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 in 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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October 21, 2015