IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

ALCON PHARMACEUTICALS LTD. and ALCON RESEARCH, LTD.,	)	
Plaintiffs,	)	
v.	)	C.A. No. _____
LUPIN LTD. and LUPIN PHARMACEUTICALS, 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 Lupin's submission of Abbreviated New Drug Application ("ANDA") No. 204079 to the U.S. Food and Drug Administration ("FDA") seeking approval to manufacture and sell a generic version of MOXEZA® 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 Lupin Ltd. is an Indian corporation having a place of business at B/4 Laxmi Towers, Bandra-Kurla Complex, Bandra (W), Mumbai 400 051, India, and having a registered office at 159 CST Road, Kalina, Santacruz (E), Mumbai 400 098, India. Upon information and belief, Lupin Ltd. is in the business of, among other things, manufacturing and selling generic versions of branded pharmaceutical products through various operating subsidiaries, including Lupin Pharmaceuticals, Inc.

5. Upon information and belief, defendant Lupin Pharmaceuticals, Inc. is a corporation organized and existing under the laws of the Commonwealth of Virginia, having a place of business at Harborplace Tower, 111 South Calvert Street, Baltimore, Maryland, 21202. On information and belief, Lupin Pharmaceuticals, Inc. is in the business of, among other things, manufacturing and selling generic versions of branded pharmaceutical products for the U.S. market. On information and belief, Lupin Pharmaceuticals, Inc. is a wholly owned subsidiary and alter-ego of Lupin Ltd. Lupin Ltd. and Lupin Pharmaceuticals, Inc. are sometimes collectively referred to herein as "Lupin."

6. Upon information and belief, and consistent with their practice with respect to other generic products, following any FDA approval of ANDA No. 204079, Lupin Ltd. and Lupin Pharmaceuticals, Inc. will act in concert to distribute and sell Lupin's ophthalmic drug product containing moxifloxacin hydrochloride described in the ANDA (the "Lupin Product") throughout the United States, including within Delaware. Upon information and belief, following any FDA approval of ANDA No. 204079, Lupin Ltd. and Lupin Pharmaceuticals, Inc. know and intend that the Lupin Product will be distributed and sold in the United States, including within Delaware.

7. Upon information and belief, and consistent with their practice with respect to other generic products, Lupin Ltd. and Lupin Pharmaceuticals, Inc., acted in concert to prepare and submit ANDA No. 204079. Upon information and belief, Lupin Ltd. and Lupin Pharmaceuticals, Inc., actively participated in the preparation of ANDA No. 204079 and both entities submitted it to the FDA. Upon information and belief, Lupin Pharmaceuticals, Inc. acted as the agent of Lupin Ltd. in submitting ANDA No. 204079 to the FDA.

JURISDICTION AND VENUE

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

9. Upon information and belief, Lupin Ltd. is subject to personal jurisdiction in Delaware because, among other things, Lupin Ltd., itself and through its wholly owned subsidiary Lupin Pharmaceuticals, Inc., has purposely availed itself of the benefits and protections of Delaware's laws such that it should reasonably anticipate being haled into court here. Upon information and belief, Lupin Ltd., itself and through its wholly owned subsidiary Lupin Pharmaceuticals, Inc., manufactures, markets and/or sells generic drugs throughout the United States and within the State of Delaware and therefore transacts business within the State of Delaware related to Plaintiffs' claims, and/or has engaged in systematic and continuous business contacts within the State of Delaware. Lupin Ltd. is subject to jurisdiction in Delaware on the basis of its inducement of and/or contribution to Lupin Pharmaceuticals, Inc.'s acts of infringement in Delaware. In addition, Lupin Ltd. is subject to personal jurisdiction in Delaware because, on information and belief, it controls and dominates Lupin Pharmaceuticals, Inc. and therefore the activities of Lupin Pharmaceuticals, Inc., in this jurisdiction are attributed to Lupin Ltd.

10. Upon information and belief, this Court has personal jurisdiction over Lupin Pharmaceuticals, Inc. because Lupin Pharmaceuticals, Inc. has purposely availed itself of the benefits and protections of Delaware's laws such that it should reasonably anticipate being haled into court here. Upon information and belief, Lupin Pharmaceuticals, Inc. manufactures, markets and/or sells generic drugs throughout the United States and within the State of Delaware and therefore transacts business within the State of Delaware related to Plaintiffs' claims, and/or has engaged in systematic and continuous business contacts within the State of Delaware.

11. In addition, this Court has personal jurisdiction over Lupin Ltd. and Lupin Pharmaceuticals, Inc. because Lupin Ltd. and Lupin Pharmaceuticals, Inc. have consented to jurisdiction in this judicial district in previous litigation and because Lupin Ltd. and Lupin Pharmaceuticals, Inc. have affirmatively availed themselves of the courts of this district by filing claims in this district.

COUNT I - INFRINGEMENT OF THE '830 PATENT

12. Alcon incorporates each of the preceding paragraphs 1-11 as if fully set forth herein.

13. 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.

14. Alcon, Inc.'s interest in the '830 patent was 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.

15. 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.

16. 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.

17. The FDA's *Approved Drug Products with Therapeutic Equivalence Evaluations*, commonly referred to as the "Orange Book," lists patents associated with approved drugs. The '830 patent is listed in the "Orange Book" in association with MOXEZA® ophthalmic solution.

18. By letter dated June 22, 2012 (the "Notice Letter"), Lupin notified Alcon that Lupin had submitted ANDA No. 204079 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 the Lupin Product prior to the expiration of, *inter alia*, the '830 patent.

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

20. Lupin's submission of the ANDA for the purpose of obtaining FDA approval to engage in the commercial manufacture, use, or sale of the Lupin 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).

21. Upon information and belief, Lupin will engage in the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of the Lupin Product immediately and imminently upon FDA approval of ANDA No. 204079.

22. The Lupin Product is covered by one or more claims of the '830 patent.

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

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

25. Upon information and belief, Lupin plans and intends to, and will, actively induce infringement of the '830 patent once its ANDA is approved by the FDA, and plans and intends to, and will, do so immediately and imminently upon such approval.

26. Upon information and belief, Lupin has knowledge of the claims of the '830 patent. Notwithstanding this knowledge, Lupin has continued to assert its intent to manufacture, offer for sale, sell, distribute, and/or import the Lupin Product, along with its product labeling, following upon FDA approval of ANDA No. 204079 prior to the expiration of the '830 patent.

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

28. Upon information and belief, Lupin 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.

29. Unless defendant Lupin 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

30. Alcon incorporates each of the preceding paragraphs 1-29 as if fully set forth herein.

31. 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.

32. Alcon, Inc.'s interest in the '070 patent was 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.

33. 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.

34. 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.

35. The '070 patent is listed in the "Orange Book" in association with MOXEZA® ophthalmic solution.

36. In the Notice Letter described in paragraph 18 above, Lupin notified Alcon that Lupin had submitted ANDA No. 204079, 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 Lupin Product prior to the expiration of, *inter alia*, the '070 patent.

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

38. Lupin's filing of the ANDA for the purpose of obtaining FDA approval to engage in the commercial manufacture, use, or sale of the Lupin 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).

39. Upon information and belief, Lupin will engage in the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of the Lupin Product immediately and imminently upon FDA approval of ANDA No. 204079.

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

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

42. Upon information and belief, Lupin plans and intends to, and will, actively induce infringement of the '070 patent once its ANDA is approved by the FDA, and plans and intends to, and will, do so immediately and imminently upon such approval.

43. Upon information and belief, Lupin has knowledge of the claims of the '070 patent. Notwithstanding this knowledge, Lupin has continued to assert its intent to

manufacture, offer for sale, sell, distribute, and/or import the Lupin Product, along with its product labeling, following FDA approval of ANDA No. 204079 prior to the expiration of the '070 patent.

44. Upon information and belief, Lupin knows that the Lupin Product and its product labeling are especially made or adapted for use in infringing the '070 patent, the Lupin Product is not a staple article or commodity of commerce, and that the Lupin Product and its product labeling are not suitable for substantial noninfringing use. Upon information and belief, Lupin plans and intends to, and will, contribute to infringement of the '070 patent immediately and imminently upon approval of ANDA No. 204079 by the FDA.

45. The foregoing actions by Lupin 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.

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

47. Unless Lupin 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

48. Alcon incorporates each of the preceding paragraphs 1-47 as if fully set forth herein.

49. 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 Lupin on the other regarding Lupin's infringement of the '830 patent and active inducement of infringement of the '830 patent.

50. 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.

51. In the Notice Letter described in paragraph 18 above, Lupin notified Alcon that Lupin had submitted ANDA No. 204079 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 Lupin Product prior to the expiration of, *inter alia*, the '830 patent.

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

53. Upon information and belief, Lupin will engage in the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of the Lupin Product immediately and imminently upon FDA approval of ANDA No. 204079.

54. The Lupin Product is covered by one or more claims of the '830 patent.

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

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

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

58. Upon information and belief, Lupin has knowledge of the claims of the '830 patent. Notwithstanding this knowledge, Lupin has continued to assert its intent to manufacture, offer for sale, sell, distribute, and/or import the Lupin Product, along with its product labeling, following upon FDA approval of ANDA No. 204079 prior to the expiration of the '830 patent.

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

60. Upon information and belief, Lupin 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.

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

62. The Court should declare that the commercial manufacture, use, sale, offer for sale or importation of the Lupin 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

63. Alcon incorporates each of the preceding paragraphs 1-62 as if fully set forth herein.

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

65. 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.

66. In the Notice Letter described in paragraph 18 above, Lupin notified Alcon that Lupin had submitted ANDA No. 204079, 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 Lupin Product prior to the expiration of, *inter alia*, the '070 patent.

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

68. Upon information and belief, Lupin will engage in the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of the Lupin Product immediately and imminently upon FDA approval of ANDA No. 204079.

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

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

71. Upon information and belief, Lupin plans and intends to, and will, actively induce infringement of the '070 patent once its ANDA is approved by the FDA, and plans and intends to, and will, do so immediately and imminently upon such approval.

72. Upon information and belief, Lupin has knowledge of the claims of the '070 patent. Notwithstanding this knowledge, Lupin has continued to assert its intent to manufacture, offer for sale, sell, distribute, and/or import the Lupin Product, along with its product labeling, following FDA approval of ANDA No. 204079 prior to the expiration of the '070 patent.

73. Upon information and belief, Lupin knows that the Lupin Product and its product labeling are especially made or adapted for use in infringing the '070 patent, the Lupin Product is not a staple article or commodity of commerce, and that the Lupin Product and its product labeling are not suitable for substantial noninfringing use. Upon information and belief, Lupin plans and intends to, and will, contribute to infringement of the '070 patent immediately and imminently upon FDA approval of ANDA No. 204079.

74. The foregoing actions by Lupin 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.

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

76. Unless Lupin 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.

77. The Court should declare that the commercial manufacture, use, sale, offer for sale or importation of the Lupin 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 have been infringed under 35 U.S.C. § 271(e)(2) by Lupin's submission to the FDA of its ANDA No. 204079;

(b) A judgment providing that the effective date of any FDA approval of commercial manufacture, use, or sale of the Lupin 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 Lupin 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 Lupin 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 Lupin 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 Lupin 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 Lupin 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 Lupin 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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July 24, 2012