IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

ALCON RESEARCH, LTD.,	)	
	)	
Plaintiff,	)	
	)	
v.	)	C.A. No. _____
	)	
LUPIN LTD. and LUPIN PHARMACEUTICALS, INC.,	)	
	)	
	)	
Defendants.	)	

COMPLAINT

Plaintiff Alcon Research, Ltd. ("Alcon"), by its attorneys, for its Complaint, alleges as follows:

1. This is an action for patent infringement under the patent laws of the United States, Title 35, United States Code, and for a declaratory judgment of patent infringement under 28 U.S.C. §§ 2201 and 2202, that arises out of Lupin'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 PAZEO® ophthalmic solution, a drug product containing olopatadine hydrochloride, prior to the expiration of U.S. Patent No. 8,791,154 (the "'154 patent").

2. By letter dated March 11, 2016 (the "Notice Letter"), Lupin Ltd. notified Alcon that it had submitted to the FDA an ANDA, No. 208896, seeking approval from the FDA to engage in the commercial manufacture, use and/or sale of a generic olopatadine ophthalmic solution ("Lupin's ANDA Product") prior to the expiration of the '154 patent. Upon information and belief, Lupin's ANDA Product is a drug product that is a generic version of PAZEO® ophthalmic solution, containing the same or equivalent ingredients in the same or equivalent amounts.

PARTIES

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 a corporation organized and existing under the laws of India, with a principal place of business at B/4 Laxmi Towers, Bandra-Kurla Complex, Bandra (E), Mumbai 400 051, India. Upon information and belief, Lupin Ltd. is in the business of, among other things, manufacturing and selling generic versions of branded pharmaceutical drugs through various operating subsidiaries, including Lupin Pharmaceuticals, Inc.

5. Upon information and belief, defendant Lupin Pharmaceuticals, Inc. ("Lupin Pharmaceuticals") is a corporation organized and existing under the laws of the Commonwealth of Virginia, having a principal place of business at Harborplace Tower, 111 South Calvert Street, Baltimore, Maryland 21202. Upon information and belief, Lupin Pharmaceuticals is in the business of, among other things, manufacturing and selling generic versions of branded pharmaceutical products for the U.S. market.

6. Upon information and belief, Lupin Pharmaceuticals is a wholly-owned subsidiary of Lupin Ltd.

7. Upon information and belief, and consistent with their practice with respect to other generic products, Lupin Ltd. and Lupin Pharmaceuticals acted in concert to prepare and submit ANDA No. 208896.

8. Upon information and belief, Lupin Ltd. and Lupin Pharmaceuticals contemplate that upon approval of ANDA No. 208896, Lupin Ltd. will manufacture Lupin's

ANDA Product and Lupin Pharmaceuticals will directly or indirectly market, sell, and distribute Lupin's ANDA Product throughout the United States, including in Delaware. Upon information and belief, Lupin Ltd. and Lupin Pharmaceuticals are agents of each other and/or operate in concert as integrated parts of the same business group, including with respect to Lupin's ANDA Product, and enter into agreements with each other that are nearer than arm's length. Upon information and belief, Lupin Pharmaceuticals participated in, assisted, and cooperated with Lupin Ltd. in the acts complained of herein. Lupin Ltd. and Lupin Pharmaceuticals are collectively referred to herein as "Lupin."

9. Upon information and belief, and consistent with their practice with respect to other generic products, following any FDA approval of ANDA No. 208896, Lupin Ltd. and Lupin Pharmaceuticals will act in concert to distribute and sell Lupin's ANDA Product throughout the United States, including within Delaware.

10. Upon information and belief, following any FDA approval of ANDA No. 208896, Lupin Ltd. and Lupin Pharmaceuticals know and intend that Lupin's ANDA Product will be distributed and sold throughout the United States, including in Delaware.

JURISDICTION AND VENUE

11. 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.

12. This Court has personal jurisdiction over Lupin Ltd. and Lupin Pharmaceuticals.

13. Lupin Ltd. is subject to personal jurisdiction in Delaware because, among other things, Lupin Ltd., itself and through its wholly-owned subsidiary Lupin Pharmaceuticals, has purposefully 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, 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 related to Plaintiffs' claims, and/or has engaged in systematic and continuous business contacts within the State of Delaware. In addition, Lupin Ltd. is subject to personal jurisdiction in Delaware because, upon information and belief, it controls and dominates Lupin Pharmaceuticals and therefore the activities of Lupin Pharmaceuticals in this jurisdiction are attributed to Lupin Ltd.

14. Lupin Pharmaceuticals is subject to personal jurisdiction in Delaware because, among other things, it 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 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 related to Plaintiffs' claims, and/or has engaged in systematic and continuous business contacts within the State of Delaware. In addition, upon information and belief, Lupin Pharmaceuticals is qualified to do business in Delaware and has appointed a registered agent for service of process, and therefore has consented to general jurisdiction in Delaware.

15. Lupin 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.

16. Upon information and belief, Lupin, with knowledge of the Hatch-Waxman Act process, 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, Lupin 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, Lupin knew that another Hatch-Waxman Act infringement action relating to the same patent has been brought in Delaware.

17. Because Alcon Research, Ltd. is a corporation incorporated in Delaware, Alcon suffers injury and consequences from Lupin's filing of ANDA No. 208896, challenging Alcon's patent rights, in Delaware. Upon information and belief, Lupin knew that it was deliberately challenging the patent rights of a Delaware entity and seeking to invalidate intellectual property held in Delaware. Lupin has been a litigant in connection with other infringement actions under the Hatch-Waxman Act, and reasonably should have anticipated that by sending the Notice Letter to Alcon, a Delaware corporation, that it would be sued in Delaware for patent infringement.

18. In addition, this Court has personal jurisdiction over Lupin because Lupin Ltd. and Lupin Pharmaceuticals regularly engage in patent litigation concerning FDA-approved branded drug products in this District, do not contest personal jurisdiction in this district, and have purposefully availed themselves of the rights and benefits of this Court by asserting claims and/or counterclaims in this Court. *See, e.g.*, *Vanda Pharmaceuticals Inc. v. Lupin Ltd., et al.*,

15-cv-01073, D.I. 10 (D. Del. Dec. 14, 2015) (Lupin Ltd.); *Unimed Pharmaceuticals, et al., v. Lupin Atlantics Holdings SA, et al.*, 15-cv-00904, D.I. 6 (D. Del. Dec. 11, 2015) (Lupin Pharmaceuticals and Lupin Ltd.); *iCeutica Pty Ltd. v. Lupin Ltd., et al.*, 14-cv-01515, D.I. 9 (D. Del. Feb. 27, 2015) (Lupin Ltd.); *Forest Labs., LLC v. Lupin Ltd., et al.*, 14-cv-01058, D.I. 15 (D. Del. Sept. 8, 2014) (Lupin Pharmaceuticals and Lupin Ltd.); *VIIV Healthcare UK Ltd. v. Lupin Ltd.*, et al., No. 14-cv-00369, D.I. 10 (D. Del. June 12, 2014) (Lupin Ltd.); *Teijin Ltd. v. Lupin Ltd., et al.*, 14-cv-00184, D.I. 20 (D. Del. Apr. 1, 2014) (Lupin Pharmaceuticals).

19. Upon information and belief, if ANDA No. 208896 is approved, Lupin will manufacture, market, and/or sell Lupin's ANDA Product within the United States, including in Delaware, consistently with Lupin's practices for the marketing and distribution of other generic pharmaceutical products. Upon information and belief, Lupin 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, Lupin's generic pharmaceutical products are used and/or consumed within and throughout the United States, including in Delaware.

20. Upon information and belief, if ANDA No. 208896 is approved, Lupin will directly or indirectly market and distribute Lupin's ANDA Product in Delaware. Upon information and belief, Lupin'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 patent in the event that Lupin's ANDA Product is approved before the patent expires.

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

COUNT I – INFRINGEMENT OF THE '154 PATENT

22. Alcon incorporates each of the preceding paragraphs 1-21 as if fully set forth herein.

23. The '154 patent, entitled "High Concentration Olopatadine Ophthamalic Composition" (Exhibit A hereto), was duly and legally issued on July 29, 2014, to Alcon Research, Ltd., as assignee of Daniel A. Gamache, Laman Alani, Malay Ghosh, Francisco Javier Galan, Nuria Carreras Perdiguer, and Onkar N. Singh.

24. The '154 patent claims, *inter alia*, an aqueous ophthalmic solution for treatment of ocular allergic conjunctivitis, the solution comprising at least 0.67 w/v% olopatadine dissolved in the solution, PEG having a molecular weight of 300 to 500, polyvinylpyrrolidone, hydroxypropyl-γ-cyclodextrin, benzalkonium chloride, and water.

25. The '154 patent also claims, *inter alia*, a method of treating at least one ocular allergy symptom in humans by topically applying to the eye of a human an amount sufficient to treat at least one ocular allergy symptom of an aqueous ophthalmic solution for treatment of ocular allergic conjunctivitis, the solution comprising at least 0.67 w/v% but no greater than 1.0 w/v% olopatadine dissolved in the solution; 2.0 w/v% to 6.0 w/v% PEG having a molecular weight of 300 to 500; 2.0 w/v% to 6.0 w/v% polyvinylpyrrolidone; at least 0.5 w/v%

but no greater than 2.0 w/v% cyclodextrin derivative selected from the group consisting of SAE-β-cyclodextrin, HP-γ-cyclodextrin; HP-β-cyclodextrin and combinations thereof; and water.

26. Alcon owns the ’154 patent.

27. Alcon will be substantially and irreparably damaged by infringement of the ’154 patent.

28. PAZEO® ophthalmic solution, and the use of PAZEO® ophthalmic solution, are covered by one or more claims of the ’154 patent, and the ’154 patent has been listed in connection with that drug product in the FDA’s Orange Book.

29. In its Notice Letter, Lupin notified Plaintiff that Lupin Ltd. had submitted to the FDA ANDA No. 208896. The purpose of the submission of the ANDA was to obtain approval under the FDCA to engage in the commercial manufacture, use, offer for sale, sale and/or importation of Lupin’s ANDA Product prior to the expiration of the ’154 patent.

30. In the Notice Letter, Lupin also notified Plaintiff 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), with respect to, *inter alia*, the ’154 patent. Upon information and belief, Lupin submitted ANDA No. 208896 to the FDA containing a certification pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV) asserting that the ’154 patent is invalid, unenforceable, and/or will not be infringed by the manufacture, use, offer for sale, sale, and/or importation of Lupin’s ANDA Product.

31. Lupin’s ANDA Product and the use of Lupin’s ANDA Product are covered by one or more claims of the ’154 patent, including at least claim 1 and claim 12.

32. In the Notice Letter, Lupin did not contest the infringement of claims 1-6, 8-10, 15-18, and 20-24 of the ’154 patent.

33. Lupin has knowledge of the ’154 patent.

34. Lupin’s submission of ANDA No. 208896 for the purpose of obtaining approval to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of Lupin’s ANDA Product before the expiration of the ’154 patent was an act of infringement of that patent under 35 U.S.C. § 271(e)(2)(A).

35. Upon information and belief, Lupin will engage in the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of Lupin’s ANDA Product immediately and imminently upon approval of ANDA No. 208896.

36. The manufacture, use, sale, offer for sale, or importation of Lupin’s ANDA Product would infringe one or more claims of the ’154 patent, including at least Claim 1 and Claim 12.

37. Upon information and belief, the manufacture, use, sale, offer for sale, or importation of Lupin’s ANDA Product in accordance with, and as directed by Lupin’s proposed product labeling would infringe one or more claims of the ’154 patent, including at least Claim 1 and Claim 12.

38. Upon information and belief, Lupin plans and intends to, and will, actively induce infringement of the ’154 patent when its ANDA is approved, and plans and intends to, and will, do so immediately and imminently upon approval.

39. Upon information and belief, Lupin knows that Lupin’s ANDA Product and its proposed labeling are especially made or adapted for use in infringing the ’154 patent, that Lupin’s ANDA Product is not a staple article or commodity of commerce, and that Lupin’s ANDA Product and its proposed labeling are not suitable for substantial noninfringing use.

Upon information and belief, Lupin plans and intends to, and will, contribute to infringement of the ’154 patent immediately and imminently upon approval of ANDA No. 208896.

40. Notwithstanding Lupin’s knowledge of the claims of the ’154 patent, Lupin has continued to assert its intent to manufacture, offer for sale, sell, distribute, and/or import Lupin’s ANDA Product with its product labeling following upon FDA approval of ANDA No. 208896 prior to the expiration of the ’154 patent.

41. The foregoing actions by Lupin constitute and/or will constitute infringement of the ’154 patent, active inducement of the ’154 patent, and contribution to the infringement by others of the ’154 patent.

42. Upon information and belief, Lupin has acted with full knowledge of the ’154 patent and without a reasonable basis for believing that it would not be liable for infringement of the ’154 patent, active inducement of the ’154 patent, and/or contribution to the infringement by others of the ’154 patent.

43. Unless Lupin is enjoined from infringing the ’154 patent, actively inducing infringement of the ’154 patent, and contributing to the infringement by others of the ’154 patent, Alcon will suffer irreparable injury. Alcon has no adequate remedy at law.

COUNT II – DECLARATORY JUDGMENT OF INFRINGEMENT OF THE ’154 PATENT

44. Alcon incorporates each of the preceding paragraphs 1-43 as if fully set forth herein.

45. 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, active inducement of infringement, and contribution to the infringement by others of the ’154 patent.

46. The ’154 patent claims, *inter alia*, an aqueous ophthalmic solution for treatment of ocular allergic conjunctivitis, the solution comprising at least 0.67 w/v% olopatadine dissolved in the solution, PEG having a molecular weight of 300 to 500, polyvinylpyrrolidone, hydroxypropyl-γ-cyclodextrin, benzalkonium chloride, and water.

47. The ’154 patent also claims, *inter alia*, a method of treating at least one ocular allergy symptom in humans by topically applying to the eye of a human an amount sufficient to treat at least one ocular allergy symptom of an aqueous ophthalmic solution for treatment of ocular allergic conjunctivitis, the solution comprising at least 0.67 w/v% but no greater than 1.0 w/v% olopatadine dissolved in the solution; 2.0 w/v% to 6.0 w/v% PEG having a molecular weight of 300 to 500; 2.0 w/v% to 6.0 w/v% polyvinylpyrrolidone; at least 0.5 w/v% but no greater than 2.0 w/v% cyclodextrin derivative selected from the group consisting of SAE-β-cyclodextrin, HP-γ-cyclodextrin; HP-β-cyclodextrin and combinations thereof; and water.

48. In the Notice Letter, Lupin notified Plaintiff that Lupin Ltd. had submitted ANDA No. 208896 to the FDA. The purpose of the ANDA was to obtain approval under the FDCA to engage in the commercial manufacture, use, offer for sale, sale and/or importation of Lupin’s ANDA Product prior to the expiration of the ’154 patent.

49. In the Notice Letter, Lupin also notified Plaintiff 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).

50. Upon information and belief, Lupin will engage in the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of Lupin’s ANDA Product immediately and imminently upon approval of ANDA No. 208896.

51. Lupin's ANDA Product and use of Lupin's ANDA Product is covered by one or more claims of the '154 patent, including at least claim 1 and claim 12.

52. The manufacture, use, sale, offer for sale, or importation of Lupin's ANDA Product would infringe one or more claims of the '154 patent, including at least Claim 1 and Claim 12.

53. Upon information and belief, the manufacture, use, sale, offer for sale, or importation of Lupin's ANDA Product in accordance with, and as directed by, Lupin's proposed product labeling would infringe one or more claims of the '154 patent, including at least Claim 1 and Claim 12.

54. Upon information and belief, Lupin plans and intends to, and will, actively induce infringement of the '154 patent when its ANDA is approved, and plans and intends to, and will, do so immediately and imminently upon approval.

55. Upon information and belief, Lupin knows that Lupin's ANDA Product and its product labeling are especially made or adapted for use in infringing the '154 patent, that Lupin's ANDA Product is not a staple article or commodity of commerce, and that Lupin's ANDA 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 '154 patent immediately and imminently upon approval of ANDA No. 208896.

56. Notwithstanding Lupin's knowledge of the claims of the '154 patent, Lupin has continued to assert its intent to manufacture, offer for sale, sell, distribute, and/or import Lupin's ANDA Product with its product labeling following FDA approval of ANDA No. 208896 prior to the expiration of the '154 patent.

57. The foregoing actions by Lupin will constitute infringement of, active inducement of infringement of, and contribute to the infringement by others of the ’154 patent.

58. Upon information and belief, Lupin has acted with full knowledge of the ’154 patent and without a reasonable basis for believing that it would not be liable for infringement of the ’154 patent, active inducement of infringement of the ’154 patent, and contribution to the infringement by others of the ’154 patent.

59. Unless Lupin is enjoined from infringing, inducing infringement of, and contributing to the infringement by others of, the ’154 patent, Alcon will suffer irreparable injury. Alcon has no adequate remedy at law.

60. The Court should declare that the commercial manufacture, use, sale, offer for sale or importation of Lupin’s ANDA Product, or any other drug product which is covered by or whose use is covered by United States Patent No. 8,791,154, will infringe, induce the infringement of, and contribute to the infringement by others of, that patent.

WHEREFORE, Plaintiff requests the following relief:

(a) A judgment that United States Patent No. 8,791,154 has been infringed under 35 U.S.C. § 271(e)(2) by Lupin’s submission to the FDA of its ANDA No. 208896;

(b) A judgment providing that the effective date of any FDA approval of commercial manufacture, use, or sale of Lupin’s ANDA Product, or any other drug product that infringes or the use of which infringes United States Patent No. 8,791,154 be not earlier than the latest of the expiration dates of that patent, inclusive of any extension(s) and additional period(s) of exclusivity;

(c) A preliminary and permanent injunction enjoining Lupin, and all persons acting in concert with Lupin, from the commercial manufacture, use, sale, offer for sale, or

importation into the United States of Lupin's ANDA Product, or any other drug product covered by or whose use is covered by United States Patent No. 8,791,154, prior to the expiration of United States Patent No. 8,791,154, inclusive of any extension(s) and additional period(s) of exclusivity;

(d) A judgment declaring that the commercial manufacture, use, sale, offer for sale or importation of Lupin's ANDA Product, or any other drug product which is covered by or whose use is covered by United States Patent No. 8,791,154, prior to the expiration of United States Patent No. 8,791,154, will infringe, induce the infringement of, and contribute to the infringement by others of, that patent;

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

(f) Costs and expenses in this action;

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

MORRIS, NICHOLS, ARSHT & TUNNELL LLP

/s/ Maryellen Noreika

Jack B. Blumenfeld (#1014)
Maryellen Noreika (#3208)
1201 North Market Street
P.O. Box 1347
Wilmington, DE 19899-1347
(302) 658-9200
jblumenfeld@mnat.com
mnoreika@mnat.com

Attorneys for Plaintiff Alcon Research, Ltd.

OF COUNSEL:

Adam L. Perlman
Thomas H.L. Selby
Christopher J. Mandernach
Casey L. White
WILLIAMS & CONNOLLY LLP
725 Twelfth Street, N.W.
Washington, DC 20005
(202) 434-5000

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