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 and 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. 20-7040 to the U.S. Food and Drug Administration ("FDA") seeking approval to manufacture and sell a generic version of Alcon's TRAVATAN Z® (travoprost ophthalmic solution) 0.004% ("TRAVATAN Z") prior to the expiration of U.S. Patent Nos. 8,268,299 ("the '299 patent"), 8,323,630 ("the '630 patent"), and 8,388,941 ("the '941 patent").

2. By letter dated June 12, 2015 (the "Notice Letter"), Lupin Ltd. notified Alcon that Lupin Ltd. had submitted to the FDA an ANDA, No. 20-7040, seeking approval from the FDA to engage in the commercial manufacture, use and/or sale of a generic travoprost ophthalmic solution USP 0.004% ("Lupin's ANDA Product") prior to the expiration of the '299 patent, the '630 patent, and the '941 patent. Upon information and belief, Lupin's ANDA

Product is a drug product that is a generic version of TRAVATAN Z, containing the same or equivalent ingredients in the same or equivalent amounts.

PARTIES

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

4. Upon information and belief, defendant Lupin Ltd. is a corporation organized and existing under the laws of India, having its principal 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. ("Lupin Pharmaceuticals") is a corporation organized and existing under the laws of the Commonwealth of Virginia, having its 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. 20-7040.

8. Upon information and belief, Lupin Ltd. and Lupin Pharmaceuticals contemplate that upon approval of ANDA No. 20-7040, 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. 20-7040, 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. 20-7040, 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), 2201, 1391, and 1400(b).

12. 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.

13. 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.

14. In addition, this Court has personal jurisdiction over Lupin because it has consented to jurisdiction in Delaware in prior cases, including cases arising out of the filing of their ANDAs, and has filed counterclaims in such cases.

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, with knowledge of the Hatch-Waxman Act process, Lupin 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 other Hatch-Waxman Act infringement actions relating to the same patents had been brought and litigated 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. 20-7040, 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.

18. Upon information and belief, if ANDA No. 20-7040 is approved, Lupin will manufacture, market, and/or sell Lupin's ANDA Product within the United States, 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.

19. If ANDA No. 20-7040 is approved, upon information and belief, 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 patents in the event that Lupin's ANDA Product is approved before those patents expire.

20. 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.

BACKGROUND

21. TRAVATAN Z is an ophthalmic solution for topical administration to the eye. The active ingredient in TRAVATAN Z is travoprost. TRAVATAN Z is indicated for the reduction of elevated intraocular pressure in patients with open angle glaucoma or ocular hypertension.

22. The '299 patent, entitled "Self Preserved Aqueous Pharmaceutical Compositions," was duly and legally issued on September 18, 2012. Alcon Research, Ltd. is the assignee of and owns the '299 patent. A true and correct copy of the '299 patent is attached hereto as Exhibit A and is incorporated herein by reference.

23. The '630 patent, entitled "Self-Preserved Aqueous Pharmaceutical Compositions," was duly and legally issued on December 4, 2012. Alcon Research, Ltd. is the assignee of and owns the '630 patent. A true and correct copy of the '630 patent is attached hereto as Exhibit B and is incorporated herein by reference.

24. The '941 patent, entitled "Self Preserved Aqueous Pharmaceutical Compositions," was duly and legally issued on March 5, 2013. Alcon Research, Ltd. is the assignee of and owns the '941 patent. A true and correct copy of the '941 patent is attached hereto as Exhibit C and is incorporated herein by reference.

25. The '299 patent, '630 patent, and '941 patent have each been listed in connection with TRAVATAN Z in the publication, *Approved Drug Products with Therapeutic Equivalence Evaluations*, maintained by the FDA, commonly known as the "Orange Book."

26. The purpose of Lupin's submission of ANDA No. 20-7040 was to obtain approval under the FFDCA to engage in the commercial manufacture, use, and/or sale of Lupin's ANDA Product prior to the expiration dates of the '299 patent, the '630 patent, and the '941

patent. Upon information and belief, Lupin is seeking approval under the FFDCA to engage in the commercial manufacture, use, and/or sale of Lupin's ANDA Product prior to the expiration of the '299, '630, and '941 patents.

COUNT I
(Infringement of U.S. Patent No. 8,268,299)

27. Alcon incorporates each of the preceding paragraphs 1–26 as if fully set forth herein.

28. Upon information and belief, Lupin's ANDA Product falls within the scope of one or more claims of the '299 patent.

29. The manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of Lupin's ANDA Product would infringe one or more claims of the '299 patent.

30. Upon information and belief, Lupin filed as a part of ANDA No. 20-7040 a certification of the type described in Section 505(j)(2)(A)(vii)(IV) of the FFDCA, 21 U.S.C. § 355(j)(2)(A)(vii)(IV), with respect to the '299 patent, asserting that the claims of the '299 patent are invalid, unenforceable, and/or not infringed by the manufacture, use, offer for sale, or sale of Lupin's ANDA Product.

31. Lupin's submission of ANDA No. 20-7040 for the purpose of obtaining approval to engage in the commercial manufacture, use, and/or sale of Lupin's ANDA Product prior to the expiration of the '299 patent was an act of infringement of the '299 patent under 35 U.S.C. § 271(e)(2)(A).

32. 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 FDA approval of ANDA No. 20-7040.

33. Upon information and belief, Lupin has knowledge of the claims of the '299 patent. Notwithstanding this knowledge, Lupin has continued to assert its intent to 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. 20-7040.

34. Upon information and belief, Lupin plans and intends to, and will, actively induce infringement of the '299 patent when ANDA No. 20-7040 is approved, and plans and intends to, and will, do so immediately and imminently upon approval.

35. The foregoing actions by Lupin constitute and/or will constitute infringement of the '299 patent and active inducement of infringement of the '299 patent.

36. Upon information and belief, Lupin has acted, and will continue to act, with full knowledge of the '299 patent and without a reasonable basis for believing that it would not be liable for infringing the '299 patent and actively inducing infringement of the '299 patent.

37. Alcon will be substantially and irreparably damaged by infringement of the '299 patent. Accordingly, unless Lupin is enjoined from infringing the '299 patent and actively inducing infringement of the '299 patent, Alcon will suffer irreparable injury. Alcon has no adequate remedy at law.

38. An actual case or controversy exists between Alcon and Lupin with respect to infringement of the '299 patent.

COUNT II
(Infringement of U.S. Patent No. 8,323,630)

39. Alcon incorporates each of the preceding paragraphs 1–38 as if fully set forth herein.

40. Upon information and belief, Lupin's ANDA Product falls within the scope of one or more claims of the '630 patent.

41. The manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of Lupin's ANDA Product would infringe one or more claims of the '630 patent.

42. Upon information and belief, Lupin filed as a part of ANDA No. 20-7040 a certification of the type described in Section 505(j)(2)(A)(vii)(IV) of the FFDCA, 21 U.S.C. § 355(j)(2)(A)(vii)(IV), with respect to the '630 patent, asserting that the claims of the '630 patent are invalid, unenforceable, and/or not infringed by the manufacture, use, offer for sale, or sale of Lupin's ANDA Product.

43. Lupin's submission of ANDA No. 20-7040 for the purpose of obtaining approval to engage in the commercial manufacture, use, and/or sale of Lupin's ANDA Product prior to the expiration of the '630 patent was an act of infringement of the '630 patent under 35 U.S.C. § 271(e)(2)(A).

44. 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 FDA approval of ANDA No. 20-7040.

45. Upon information and belief, Lupin has knowledge of the claims of the '630 patent. Notwithstanding this knowledge, Lupin has continued to assert its intent to 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. 20-7040.

46. Upon information and belief, Lupin plans and intends to, and will, actively induce infringement of the '630 patent when ANDA No. 20-7040 is approved, and plans and intends to, and will, do so immediately and imminently upon approval.

47. The foregoing actions by Lupin constitute and/or will constitute infringement of the '630 patent and active inducement of infringement of the '630 patent.

48. Upon information and belief, Lupin has acted, and will continue to act, with full knowledge of the '630 patent and without a reasonable basis for believing that it would not be liable for infringing the '630 patent and actively inducing infringement of the '630 patent.

49. Alcon will be substantially and irreparably damaged by infringement of the '630 patent. Accordingly, unless Lupin is enjoined from infringing the '630 patent and actively inducing infringement of the '630 patent, Alcon will suffer irreparable injury. Alcon has no adequate remedy at law.

50. An actual case or controversy exists between Alcon and Lupin with respect to infringement of the '630 patent.

COUNT III
(Infringement of U.S. Patent No. 8,388,941)

51. Alcon incorporates each of the preceding paragraphs 1–50 as if fully set forth herein.

52. Upon information and belief, Lupin's ANDA Product falls within the scope of one or more claims of the '941 patent. In addition, upon information and belief, the manufacture of Lupin's ANDA Product falls within the scope of one or more claims of the '941 patent.

53. The manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of Lupin's ANDA Product would infringe one or more claims of the '941 patent.

54. Upon information and belief, Lupin filed as a part of ANDA No. 20-7040 a certification of the type described in Section 505(j)(2)(A)(vii)(IV) of the FFDCA, 21 U.S.C. § 355(j)(2)(A)(vii)(IV), with respect to the '941 patent, asserting that the claims of the '941 patent are invalid, unenforceable, and/or not infringed by the manufacture, use, offer for sale, or sale of Lupin's ANDA Product.

55. Lupin's submission of ANDA No. 20-7040 for the purpose of obtaining approval to engage in the commercial manufacture, use, and/or sale of Lupin's ANDA Product prior to the expiration of the '941 patent was an act of infringement of the '941 patent under 35 U.S.C. § 271(e)(2)(A).

56. 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 FDA approval of ANDA No. 20-7040.

57. Upon information and belief, Lupin has knowledge of the claims of the '941 patent. Notwithstanding this knowledge, Lupin has continued to assert its intent to 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. 20-7040.

58. Upon information and belief, Lupin plans and intends to, and will, actively induce infringement of the '941 patent when ANDA No. 20-7040 is approved, and plans and intends to, and will, do so immediately and imminently upon approval.

59. The foregoing actions by Lupin constitute and/or will constitute infringement of the '630 patent and active inducement of infringement of the '941 patent.

60. Upon information and belief, Lupin has acted, and will continue to act, with full knowledge of the '941 patent and without a reasonable basis for believing that it would not be liable for infringing the '941 patent and actively inducing infringement of the '941 patent.

61. Alcon will be substantially and irreparably damaged by infringement of the '941 patent. Accordingly, unless Lupin is enjoined from infringing the '941 patent and actively inducing infringement of the '941 patent, Alcon will suffer irreparable injury. Alcon has no adequate remedy at law.

62. An actual case or controversy exists between Alcon and Lupin with respect to infringement of the '941 patent.

WHEREFORE, Alcon requests the following relief:

(a) A judgment that Lupin has infringed the '299 patent and will infringe and actively induce infringement of the '299 patent;

(b) A judgment that Lupin has infringed the '630 patent and will infringe and actively induce infringement of the '630 patent;

(c) A judgment that Lupin has infringed the '941 patent and will infringe and actively induce infringement of the '941 patent;

(d) A judgment ordering that the effective date of any FDA approval for Lupin to make, use, offer for sale, sell, market, distribute, or import Lupin's ANDA Product, or any product the making, using, offering for sale, sale, marketing, distributing, or importation of which infringes the '299, '630, or '941 patents, be not earlier than the latest of the expiration dates of the '299, '630, and '941 patents, inclusive of any extension(s) and additional period(s) of exclusivity;

(e) A preliminary and permanent injunction enjoining Lupin, and all persons acting in concert with Lupin, from making, using, selling, offering for sale, marketing, distributing, or importing Lupin's ANDA Product, or any product the making, using, offering for sale, sale, marketing, distributing, or importation of which infringes the '299, '630, or '941 patents, or the inducement of any of the foregoing, prior to the latest of the expiration dates of the '299, '630, and '941 patents, inclusive of any extension(s) and additional period(s) of exclusivity;

(f) A judgment declaring that making, using, selling, offering for sale, marketing, distributing, or importing Lupin's ANDA Product, or any product the making, using, offering for sale, sale, marketing, distributing, or importation of which infringes the '299 patent, prior to the expiration date of the '299 patent, will infringe and/or actively induce infringement of the '299 patent;

(g) A judgment declaring that making, using, selling, offering for sale, marketing, distributing, or importing Lupin's ANDA Product, or any product the making, using, offering for sale, sale, marketing, distributing, or importation of which infringes the '630 patent, prior to the expiration date of the '630 patent, will infringe and/or actively induce infringement of the '630 patent;

(h) A judgment declaring that making, using, selling, offering for sale, marketing, distributing, or importing Lupin's ANDA Product, or any product the making, using, offering for sale, sale, marketing, distributing, or importation of which infringes the '941 patent, prior to the expiration date of the '941 patent, will infringe and/or actively induce infringement of the '941 patent;

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

(j) An award of Alcon's costs and expenses in this action; and

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

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