IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

ALCON RESEARCH, LTD.,	)	
	)	
Plaintiff,	)	
	)	
v.	)	C.A. No. _____
	)	
AKORN INC.,	)	
	)	
Defendant.	)	

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 the submission by defendant Akorn, Inc. ("Akorn") of an Abbreviated New Drug Application ("ANDA") 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 April 30, 2015 (the "Notice Letter"), Akorn notified Alcon that Akorn had submitted to the FDA an ANDA, No. 20-4423, seeking approval from the FDA to engage in the commercial manufacture, use and/or sale of a generic travoprost ophthalmic solution USP 0.004% ("Akorn's ANDA Product") prior to the expiration of the '299 patent, the '630 patent, and the '941 patent. Upon information and belief, Akorn'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 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), 2201, 1391, and 1400(b).

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. 20-4423, 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. 20-4423 is approved, Akorn will manufacture, market, and/or sell Akorn's ANDA Product within the United States, 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. 20-4423 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.

BACKGROUND

16. 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.

17. 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.

18. 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.

19. 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.

20. 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."

21. The purpose of Akorn's submission of ANDA No. 20-4423 was to obtain approval under the FFDCA to engage in the commercial manufacture, use, and/or sale of Akorn's ANDA Product prior to the expiration dates of the '299 patent, the '630 patent, and the

'941 patent. Upon information and belief, Akorn is seeking approval under the FFDCA to engage in the commercial manufacture, use, and/or sale of Akorn'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)

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

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

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

25. Upon information and belief, Akorn filed as a part of ANDA No. 20-4423 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 Akorn's ANDA Product.

26. Akorn's submission of ANDA No. 20-4423 for the purpose of obtaining approval to engage in the commercial manufacture, use, and/or sale of Akorn'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).

27. 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 FDA approval of ANDA No. 20-4423.

28. Upon information and belief, Akorn has knowledge of the claims of the '299 patent. Notwithstanding this knowledge, Akorn has continued to assert its intent to 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. 20-4423.

29. Upon information and belief, Akorn plans and intends to, and will, actively induce infringement of the '299 patent when ANDA No. 20-4423 is approved, and plans and intends to, and will, do so immediately and imminently upon approval.

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

31. Upon information and belief, Akorn 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.

32. Alcon will be substantially and irreparably damaged by infringement of the '299 patent. Accordingly, unless Akorn 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.

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

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

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

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

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

37. Upon information and belief, Akorn filed as a part of ANDA No. 20-4423 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 Akorn's ANDA Product.

38. Akorn's submission of ANDA No. 20-4423 for the purpose of obtaining approval to engage in the commercial manufacture, use, and/or sale of Akorn'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).

39. 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 FDA approval of ANDA No. 20-4423.

40. Upon information and belief, Akorn has knowledge of the claims of the '630 patent. Notwithstanding this knowledge, Akorn has continued to assert its intent to 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. 20-4423.

41. Upon information and belief, Akorn plans and intends to, and will, actively induce infringement of the '630 patent when ANDA No. 20-4423 is approved, and plans and intends to, and will, do so immediately and imminently upon approval.

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

43. Upon information and belief, Akorn 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.

44. Alcon will be substantially and irreparably damaged by infringement of the '630 patent. Accordingly, unless Akorn 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.

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

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

46. Alcon incorporates each of the preceding paragraphs 1–45 as if fully set forth herein.

47. Upon information and belief, Akorn'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 Akorn's ANDA Product falls within the scope of one or more claims of the '941 patent.

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

49. Upon information and belief, Akorn filed as a part of ANDA No. 20-4423 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 Akorn's ANDA Product.

50. Akorn's submission of ANDA No. 20-4423 for the purpose of obtaining approval to engage in the commercial manufacture, use, and/or sale of Akorn'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).

51. 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 FDA approval of ANDA No. 20-4423.

52. Upon information and belief, Akorn has knowledge of the claims of the '941 patent. Notwithstanding this knowledge, Akorn has continued to assert its intent to 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. 20-4423.

53. Upon information and belief, Akorn plans and intends to, and will, actively induce infringement of the '941 patent when ANDA No. 20-4423 is approved, and plans and intends to, and will, do so immediately and imminently upon approval.

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

55. Upon information and belief, Akorn 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.

56. Alcon will be substantially and irreparably damaged by infringement of the '941 patent. Accordingly, unless Akorn 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.

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

WHEREFORE, Alcon requests the following relief:

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

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

(c) A judgment that Akorn 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 Akorn to make, use, offer for sale, sell, market, distribute, or import Akorn'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 Akorn, and all persons acting in concert with Akorn, from making, using, selling, offering for sale, marketing, distributing, or importing Akorn'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 Akorn'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 Akorn'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 Akorn'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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