IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

ALLERGAN, INC.,

Plaintiff,

v.

AKORN INC. and
AKORN OPHTHALMICS, INC.,

Defendants.

Civil Action No. _____

Jury Trial Demanded

ALLERGAN'S COMPLAINT FOR PATENT INFRINGEMENT

Plaintiff Allergan, Inc. ("Allergan" or "Plaintiff") by its attorneys, Fish & Richardson P.C., for its complaint against Akorn Inc. and Akorn Ophthalmics, Inc. (collectively "Akorn" or "Defendants") alleges as follows:

The Nature of the Action

1. This is an action for infringement of United States Patent No. 7,842,714 ("the '714 patent") under 35 U.S.C. § 271(e)(2) and for declaratory judgment of infringement under 28 U.S.C. § 2201 and 2002 and 35 U.S.C. § 271.

The Parties

2. Allergan is a corporation organized and existing under the laws of the State of Delaware, with a principal place of business at 2525 Dupont Drive, Irvine, California 92612.

3. On information and belief, Akorn, Inc. is a corporation incorporated under the laws of the State of Louisiana, with a place of business at 1925 West Field Court, Suite 300, Lake Forest, Illinois 60045.

4. On information and belief, Akorn Ophthalmics, Inc. is a subsidiary of Akorn, Inc. incorporated under the laws of the State of Delaware, with a place of business at 1925 West Field Court, Suite 300, Lake Forest, Illinois 60045.

5. On information and belief, Akorn, Inc. is in the business of manufacturing, distributing and selling drug products throughout the United States, including in this judicial district.

6. On information and belief, Akorn Ophthalmics, Inc. is in the business of manufacturing, distributing and selling drug products throughout the United States, including in this judicial jurisdiction.

7. On information and belief, Akorn, Inc. and Akorn Ophthalmics, Inc. closely coordinate and hold themselves out to the public as one entity. For example, Akorn, Inc. has done business under the name "Akorn Ophthalmics." Furthermore, Akorn, Inc. and Akorn Ophthalmics share the same place of business and have corporate officers in common.

Jurisdiction and Venue

8. This action arises under the patent laws of the United States of America, United States Code, Title 35, Section 1, *et seq*, the Declaratory Judgment Act, 28 U.S.C. § 2201 and 2002. This Court has subject matter jurisdiction over the action under 28 U.S.C. §§ 1331 and 1338.

9. Based on the facts and causes alleged herein, this Court has personal jurisdiction over Akorn.

10. This Court has personal jurisdiction over Akorn by virtue of the fact that, *inter alia*, it has committed the tortious act of patent infringement pursuant to 35 U.S.C. § 271(e)(2)(A) that has led to foreseeable harm and injury to Plaintiff, a Delaware corporation.

11. This Court has personal jurisdiction over Akorn by virtue of, *inter alia*, its systematic and continuous contacts with this jurisdiction.

12. This Court has personal jurisdiction over Akorn, Inc. by virtue of, *inter alia*, its activities in connection with its subsidiaries incorporated in Delaware and its joint-venture Akorn-Strides LLC, a Delaware limited liability company.

13. On information and belief, Akorn, Inc. has three subsidiaries incorporated in Delaware, namely Akorn Ophthalmics, Inc., Oak Pharmaceuticals, Inc. and Advanced Vision Research, Inc.

14. On information and belief, Akorn, Inc. conducts business in the State of Delaware, including as a result of its activities in connection with its subsidiaries and Akorn-Strides LLC.

15. On information and belief, Akorn, Inc. conducts business in the State of Delaware, including as a result of its activities in connection with Akorn Ophthalmics, Inc.

16. On information and belief, Akorn, Inc. conducts business in the State of Delaware under the name Akorn Ophthalmics.

17. This Court has personal jurisdiction over Akorn Ophthalmics, Inc. by virtue of, *inter alia*, its incorporation in the State of Delaware and its activities in connection with Akorn, Inc.

18. On information and belief, Akorn Ophthalmics, Inc. conducts business in the State of Delaware.

19. On information and belief, Akorn Inc. and Akorn Ophthalmics, Inc. (collectively "Akorn") are agents of each other and of other Akorn subsidiaries that market and sell products in Delaware.

20. On information and belief, Akorn markets and sells products in Delaware, including those it has developed in connection with Akorn-Strides LLC.

21. On information and belief, Akorn markets and sells products in the State of Delaware through sales representatives located in this jurisdiction.

22. On information and belief, Akorn has derived substantial revenue as a result of its activities in Delaware, including as a result of its activities in connection with its subsidiaries and Akorn-Strides LLC.

23. On information and belief, Akorn, Inc. has entered into contracts with Delaware companies, including at least Amerisource Bergen and McKesson.

24. On information and belief, Akorn, Inc. is registered with the Delaware Board of Pharmacy as a licensed "Distributor/Manufacturer CSR" (License No. DS0270) and "Pharmacy-Wholesale" (License Nos. A4-0000687 and A4-0000573).

25. Venue is proper in this Court under 28 U.S.C. §§ 1391 and 1400(b).

Background

26. The '714 patent, entitled "Ketorolac Tromethamine Compositions for Treating Ocular Pain," issued to Eldon Q. Farnes, Mayssa Attar, Rhett M. Schiffman, Chin-Ming Chang, Richard S. Graham and Devin F. Welty, on November 30, 2010. A copy of the '714 patent is attached to this complaint as Exhibit A.

27. Allergan, as assignee, owns the entire right, title, and interest in the '714 patent.

28. Allergan is the holder of approved New Drug Application ("NDA") No. 22-427 for ketorolac tromethamine ophthalmic solution (0.45%), sold under the ACUVAIL® trademark.

29. In conjunction with that NDA, Allergan has listed with the United States Food and Drug Administration ("FDA") the '714 patent that covers the approved formulation of

ACUVAIL®. The FDA has published the '714 patent in the Approved Drug Products with Therapeutic Equivalence Evaluations, commonly referred to as the "Orange Book."

30. ACUVAIL® is covered by at least one claim of the '714 patent.

31. On November 9, 2011, Allergan received a letter, dated November 8, 2011, signed on behalf of Akorn by Alejandro Menchaca ("Paragraph IV Letter"). The letter stated that Akorn had filed Abbreviated New Drug Application ("ANDA") No. 20-3376 with the FDA under section 505(j) of the Federal Food, Drug, and Cosmetic Act ("FDCA") seeking approval to market a generic version of Allergan's ACUVAIL® product before expiration of the '714 patent.

32. The stated purpose of the Paragraph IV Letter was to notify Allergan that Akorn's ANDA contained a certification under 21 U.S.C. § 355(j)(2)(A)(vii)(IV) regarding the '714 patent.

33. Akorn's Paragraph IV Letter does not provide any basis for contesting the validity of any claims in the '714 patent. Instead, in its Paragraph IV Letter Akorn alleges that its proposed generic product will not infringe any of the claims of the '714 patent.

34. In support of its claim of non-infringement, Akorn's Paragraph IV Letter contains extremely limited information about its proposed generic product. The only information Akorn provided in its Paragraph IV Letter about its proposed generic product is the following: "Akorn's ANDA Product will not literally infringe any of the claims of the '714 patent because Akorn's ANDA Product does not have one of the carboxymethyl cellulose components as required by the claims."

35. With its Paragraph IV Letter, Akorn included an "Offer of Confidential Access" to certain information from its ANDA No. 20-3376 to Allergan.

36. Under 21 U.S.C. § 355(j)(5)(C)(i)(III), an offer of confidential access "shall contain such restrictions as to persons entitled to access, and on the use and disposition of any information accessed, as would apply had a protective order been entered for the purpose of protecting trade secrets and other confidential business information."

37. Since receiving the Paragraph IV Letter and the accompanying "Offer of Confidential Access," Allergan has attempted to negotiate with Akorn to procure a copy of ANDA No. 20-3376, however, Akorn was unwilling to produce the entire ANDA nor was Akorn willing to represent that the information it would produce would be true and correct as contained in its ANDA as supplied to the FDA. Because of conditions like this, the negotiations were unsuccessful.

38. By requiring these inappropriate restrictions, Akorn has effectively refused to provide information that would allow Allergan to confirm that Akorn's proposed generic version of ACUVAIL® is within the lawful scope of one or more claims of the '714 patent.

39. Allergan is not aware of any other means of obtaining information regarding Akorn's proposed generic product. In the absence of such information, Allergan resorts to the judicial process and the aid of discovery to obtain, under appropriate judicial safeguards, such information as is required to confirm its allegations of infringement and to present to the Court evidence that Akorn's proposed generic version of ACUVAIL® falls within the scope of one or more claims of the '714 patent.

40. On information and belief, in filing its ANDA, Akorn has requested the FDA's approval to market a generic version of Allergan's ACUVAIL® product throughout the United States, including in Delaware.

41. On information and belief, following FDA approval of its ANDA, Akorn will sell the approved generic version of Allergan's ACUVAIL® product throughout the United States, including in Delaware.

Count I

(Infringement of the '714 Patent Under 35 U.S.C. § 271(e)(2) by Akorn's proposed generic ketorolac tromethamine ophthalmic solution (0.45%))

42. Paragraphs 1 to 41 are incorporated herein as set forth above.

43. Akorn submitted ANDA No. 20-3376 to the FDA under section 505(j) of the FDCA to obtain approval to engage in the commercial manufacture, use or sale of its proposed ketorolac tromethamine ophthalmic solution (0.45%) product throughout the United States. By submitting this application, Akorn has committed an act of infringement under 35 U.S.C. § 271(e)(2)(A).

44. The commercial manufacture, use, offer for sale, sale and/or importation of Akorn's proposed generic ketorolac tromethamine ophthalmic solution (0.45%) product will constitute an act of infringement of the '714 patent.

45. The commercial manufacture, use, offer for sale, sale and/or importation of Akorn's proposed generic ketorolac tromethamine ophthalmic solution (0.45%) product in violation of Allergan's patent rights will cause irreparable injury to Allergan for which monetary damages are inadequate.

Count II

(Declaratory Judgment of Infringement of the '714 Patent under 35 U.S.C. § 271 against Defendants)

46. Paragraphs 1 through 45 are incorporated herein by reference.

47. These claims arise under the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202.

48. There is an actual case or controversy such that the Court may entertain Plaintiff's request for declaratory relief consistent with Article III of the United States Constitution, and that actual case or controversy requires a declaration of rights by this Court.

49. Defendants and/or their agents have made, and will continue to make, substantial preparation in the United States to manufacture, sell, offer to sell, and/or import generic versions of ACUVAIL® products.

50. Defendants' actions indicate a refusal to change the course of their action in the face of acts by Plaintiff.

51. On information and belief, any commercial manufacture, use, offer for sale, and/or importation of generic versions of ACUVAIL® by Defendants before patent expiry will directly and/or indirectly infringe, contribute to the infringement of and/or induce infringement of the '714 patent.

52. Plaintiff is entitled to a declaratory judgment that future commercial manufacture, use, offer for sale, sale, and/or importation of Defendants' proposed generic ACUVAIL® products by Defendants, prior to patent expire, will infringe the '714 patent.

53. The commercial manufacture, use, offer for sale, sale and/or importation of Akorn's proposed generic ketorolac tromethamine ophthalmic solution (0.45%) product in violation of Allergan's patent rights will cause irreparable injury to Allergan for which monetary damages are inadequate.

Jury Trial Demand

Pursuant to Federal Rule of Civil Procedure 38(b), Plaintiff hereby demands a trial by jury of all issues so triable.

Prayer for Relief

Plaintiff respectfully prays for the following relief:

a. That judgment be entered that Akorn has infringed the '714 patent under 35 U.S.C. § 271(e)(2)(A) by submitting an ANDA under section 505(j) of the Federal Food, Drug, and Cosmetic Act, and that the commercial manufacture, use, offer for sale, sale and/or importation of Akorn's proposed generic ketorolac tromethamine ophthalmic solution (0.45%) product will constitute an act of infringement of the '714 patent;

b. That an order be issued under 35 U.S.C. § 271(e)(4)(A) that the effective date of any FDA approval of Akorn's ANDA shall be a date which is not earlier than the expiration date of the '714 patent, plus any applicable exclusivities;

c. Than an injunction be issued under 35 U.S.C. § 271(e)(4)(B) permanently enjoining Akorn, Inc. and Akorn Ophthalmic, Inc., their officers, agents, servants, employees, licensees, representatives, and attorneys, and all other persons acting or attempting to act in active concert or participation with it or acting on its behalf, from engaging in the commercial manufacture, use, offer to sell, or sale within the United States, or importation into the United States, of any drug product covered by the '714 patent;

d. If Akorn attempts to engage in the commercial manufacture, use, offer to sell, sale or importation of Akorn's generic product disclosed in its ANDA prior to the expiration of the '714 patent, as extended by any applicable period of exclusivity, a preliminary injunction be entered enjoining such conduct;

e. If Akorn attempts to engage in the commercial manufacture, use, offer to sell, sale or importation of Akorn's generic product disclosed in its ANDA prior to the expiration of the '714 patent, as extended by any applicable period of exclusivity, judgment awarding Allergan

damages resulting from such infringement under 35 U.S.C. § 271(e)(4)(C), increased to treble the amount found or assessed together with interest pursuant to 35 U.S.C. § 284;

f. That a declaration be issued under 28 U.S.C. § 2201 that if Akorn, Inc., Akorn Ophthalmics, Inc., their officers, agents, servants, employees, licensees, representative, and attorneys, and all other persons acting or attempting to act in active concert or participation with any of them or acting on their behalf, engage in the commercial manufacture, use, offer for sale, sale, and/or importation of Defendants' proposed generic ACUVAIL® products before patent expiry, it will constitute an act of direct and/or indirect infringement of the '714 patent.

g. That this is an exceptional case under 35 U.S.C. § 285, and that Allergan be awarded reasonable attorneys' fees and costs;

h. An accounting for infringing sales not presented at trial and an award by the court of additional damages for any such infringing sales; and

i. That this Court award such other and further relief as it may deem just and proper.

Dated: December 21, 2011

FISH & RICHARDSON P.C.

By: _____

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