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UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY

ALCON LABORATORIES, INC.; ALCON PHARMACEUTICALS LTD.; SENJU PHARMACEUTICAL CO., LTD.; and MITSUBISHI CHEMICAL CORPORATION, Plaintiffs, v. AKORN, INC., Defendant.	Filed Electronically CIVIL ACTION NO. _____ **COMPLAINT FOR PATENT INFRINGEMENT**

COMPLAINT

Plaintiffs Alcon Laboratories, Inc.; Alcon Pharmaceuticals Ltd.; Senju Pharmaceutical Co., Ltd.; and Mitsubishi Chemical Corporation (collectively, "Plaintiffs") by way of this Complaint against Defendant Akorn, Inc. ("Akorn") allege as follows:

THE PARTIES

1. Plaintiff Alcon Laboratories, Inc. ("Alcon Laboratories") is a corporation organized and existing under the laws of the State of Delaware, with a principal place of business at 6201 South Freeway, Fort Worth, Texas 76134.

2. Plaintiff Alcon Pharmaceuticals Ltd. ("Alcon Pharmaceuticals," collectively with Alcon Laboratories, "Alcon") is a corporation organized and existing under the laws of

Switzerland, having a principal place of business at Rue Louis d'Affry 6, Case postale, 1701 Fribourg, Switzerland.

3. Plaintiff Senju Pharmaceutical Co., Ltd. ("Senju") is a corporation organized and existing under the laws of Japan, with a principal place of business at 2-5-8, Hirano-machi, Chuo-ku, Osaka 541-0046, Japan.

4. Plaintiff Mitsubishi Chemical Corporation ("Mitsubishi Chemical") is a corporation organized and existing under the laws of Japan with a principal place of business at 1-1-1 Marunouchi, Chiyoda-ku, Tokyo 100-8251, Japan.

5. Upon information and belief, Defendant Akorn is a corporation organized and existing under the laws of the State of Louisiana with a principal place of business at 1925 West Field Court, Suite 300, Lake Forest, Illinois 60045.

NATURE OF THE ACTION

6. This is an action for infringement of United States Patent No. 6,114,319 ("the '319 patent") under 35 U.S.C. § 271(e)(2) and for declaratory judgment of infringement under 28 U.S.C. §§ 2201-02 and 35 U.S.C. § 271(a), (b), and (c). The action arises out of the submission by Akorn of Abbreviated New Drug Application ("ANDA") No. 207284 to the U.S. Food and Drug Administration ("FDA") seeking approval to manufacture and sell a generic version ("Akorn's ANDA product") of Alcon Laboratories' DUREZOL® (difluprednate ophthalmic emulsion) 0.05% product prior to the expiration of the '319 patent.

JURISDICTION AND VENUE

7. This action arises under the patent laws of the United States of America, United States Code, Title 35, Section 1, *et seq.* and the Declaratory Judgment Act. This Court has subject matter jurisdiction over the action under 28 U.S.C. §§ 1331, 1338, 2201, and 2202.

8. Upon information and belief, this Court has personal jurisdiction over Akorn. Upon information and belief, Akorn is in the business of manufacturing, marketing, importing, and selling pharmaceutical drug products, including generic drug products. Upon information and belief, Akorn directly manufactures, markets, and sells generic drug products throughout the

United States and in this judicial district, and this judicial district is a likely destination for Akorn's ANDA Product. Upon information and belief, Akorn purposefully has conducted and continues to conduct business in this judicial district.

9. According to its website, Akorn employs 100 people and maintains an ophthalmic product manufacturing facility in Somerset, New Jersey, located at 72 Veronica Avenue. Akorn's ANDA product is an ophthalmic product.

10. Akorn is currently registered to do business in New Jersey, appointed an agent for service of process in New Jersey, and filed an annual report in New Jersey on September 25, 2013. Additionally, the status report for Akorn from the New Jersey Business Gateway lists Akorn's principal business address as 72 Veronica Ave Ste 6, Somerset, NJ, 08873.

11. Akorn obtained a Drug and Medical Device Certificate of Registration in New Jersey, issued on January 10, 2014 and expiring January 31, 2015, and is currently registered in New Jersey as "Manufacturer and Wholesale."

12. Akorn has previously been sued in this district, did not challenge this Court's assertion of personal jurisdiction over it, and asserted counterclaims for the purpose of litigating a patent infringement dispute in this district. *See, e.g., Novartis Pharms. Corp. v. Akorn, Inc.*, Case No. 2:13-cv-06835-SDW-MCA (D.N.J. filed Nov. 8, 2013); *Bausch & Lomb Inc. et al. v. Akorn, Inc. et al*., Case No. 1:14-cv-01866-NLH-JS (D.N.J. filed Mar. 23, 2014).

13. Through Akorn's outside counsel, Akorn agreed not to contest jurisdiction in this district for this matter.

14. Upon information and belief, venue is proper in this Court under 28 U.S.C. §§ 1391, and 1400(b).

BACKGROUND

A. The Patent-in-Suit

15. The U.S. Patent and Trademark Office ("USPTO") duly and legally issued the '319 patent, entitled "Compositions Containing Difluprednate," on September 5, 2000. The USPTO issued an ex parte reexamination certificate for the '319 patent on May 18, 2004. Senju

and Mitsubishi Chemical are the assignees of the '319 patent. Plaintiffs hold all substantial rights in the '319 patent and have the right to sue for infringement thereof. A copy of the '319 patent is attached as Exhibit A.

16. Alcon Pharmaceuticals is the exclusive licensee of the '319 patent in the ophthalmic field throughout the United States.

B. Alcon's NDA

17. Alcon Pharmaceuticals is the holder of New Drug Application ("NDA") No. 022212 for difluprednate ophthalmic emulsion 0.05%, sold in the United States by Alcon Laboratories under the trademark DUREZOL®. The FDA approved NDA No. 022212 on June 23, 2008.

18. DUREZOL® (difluprednate ophthalmic emulsion) 0.05% is covered by one or more claims of the '319 patent, which has been listed in connection with DUREZOL® in the FDA's publication, Approved Drug Products with Therapeutic Equivalence Evaluations, commonly known as the "Orange Book."

C. Akorn's ANDA

19. By no earlier than December 3, 2014, Alcon Pharmaceuticals received a letter from Akorn dated December 2, 2014 ("Notice Letter"), purporting to be a Notice of Certification for ANDA No. 207284 pursuant to § 505(j)(2)(B)(iv) of the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. § 355(j)(2)(B)(iv) and 21 C.F.R. § 314.95 ("Paragraph IV Certification").

20. By no earlier than December 4, 2014, Senju received Akorn's Notice Letter dated December 2, 2014.

21. By no earlier than December 4, 2014, Mitsubishi Chemical received Akorn's Notice Letter dated December 2, 2014.

22. Akorn's Notice Letter states that Akorn has submitted ANDA No. 207284 to the FDA seeking approval from the FDA to engage in the commercial manufacture, use, and/or sale of Akorn's ANDA Product before the expiration of the '319 patent.

23. Upon information and belief, the purpose of Akorn's Paragraph IV Certification submitted with Akorn's ANDA is to obtain approval to engage in the commercial manufacture, use, import, offer for sale and/or sale of Akorn's ANDA Product before the expiration of the '319 patent.

24. Upon information and belief, Akorn was aware of the '319 patent when Akorn filed ANDA No. 207284 with a Paragraph IV Certification.

25. Upon information and belief, Akorn's ANDA product is the same, or substantially the same, as DUREZOL® (difluprednate ophthalmic emulsion) 0.05%.

26. Upon information and belief, Akorn's ANDA No. 207284 refers to and relies upon NDA No. 022212 and contains data that, according to Akorn, demonstrate the bioequivalence of Akorn's ANDA Product and DUREZOL® (difluprednate ophthalmic emulsion) 0.05%.

27. Akorn's Notice Letter lacks any legal or factual basis for non-infringement of any claim of the '319 patent.

COUNT I

(INFRINGEMENT OF THE '319 PATENT BY AKORN)

28. Plaintiffs incorporate each of the preceding paragraphs 1-27 as if fully set forth herein.

29. Defendant Akorn's ANDA Product is covered by one or more claims of the '319 patent.

30. Defendant Akorn's submission of ANDA No. 207284 for the purposes of obtaining approval to engage in the commercial manufacture, use, import, offer for sale and/or sale of Akorn's ANDA Product before the expiration of the '319 patent is an act of infringement under 35 U.S.C. § 271(e)(2)(A) of the '319 patent.

COUNT II

(DECLARATORY JUDGMENT OF INFRINGEMENT OF THE '319 PATENT BY AKORN)

31. Plaintiffs incorporate each of the preceding paragraphs 1-30 as if fully set forth herein.

32. Upon information and belief, Akorn intends to engage in the commercial manufacture, use, import, offer for sale and/or sale of Akorn's ANDA Product immediately and imminently upon approval of Akorn's ANDA No. 207284.

33. The commercial manufacture, use, import, offer for sale and/or sale of Akorn's ANDA Product would infringe one or more claims of the '319 patent.

34. Upon information and belief, Akorn has knowledge of the claims of the '319 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. 207284.

35. Upon information and belief, Akorn plans and intends to, and will, contribute to the infringement of the '319 patent when ANDA No. 207284 is approved, and plans and intends to, and will, do so immediately and imminently upon such approval.

36. Upon information and belief, Akorn plans and intends to, and will, actively induce infringement of the '319 patent when ANDA No. 207284 is approved, and plans and intends to, and will, do so immediately and imminently upon such approval.

37. The commercial manufacture, use, import, offer for sale and/or sale of Akorn's ANDA Product will constitute direct infringement of one or more claims of the '319 patent under 35 U.S.C. § 271(a), inducement of infringement of one or more claims of the '319 patent under 35 U.S.C. § 271(b), and contributory infringement of one or more claims of the '319 patent under 35 U.S.C. § 271(c).

38. Upon information and belief, Akorn has acted, and will continue to act, with full knowledge of the '319 patent and without a reasonable basis for believing that it would not be

liable for infringing the '319 patent, contributing to the infringement of the '319 patent, and actively inducing infringement of the '319 patent.

39. There is an actual and justiciable case or controversy between Plaintiffs and Defendant Akorn concerning the infringement of the '319 patent. Plaintiffs are entitled to a declaration that Defendant Akorn's commercial manufacture, use, import, offer for sale and/or sale of Akorn's ANDA Product will infringe one or more claims of the '319 patent.

40. Unless Defendant Akorn is enjoined from infringing the '319 patent, Plaintiffs will suffer irreparable injury. Plaintiffs have no adequate remedy at law.

41. Akorn's actions have created in Plaintiffs a reasonable apprehension of irreparable harm and loss resulting from Akorn's threatened imminent actions.

42. Upon information and belief, Akorn will knowingly and willfully infringe the '319 patent.

PRAYER FOR RELIEF

WHEREFORE, Plaintiffs pray for judgment as follows:

A. Declaring that under 35 U.S.C. § 271(e)(2), Akorn has infringed at least one claim of the '319 patent through Akorn's submission of ANDA No. 207284 to the FDA to obtain approval for the commercial manufacture, use, import, offer for sale, and/or sale in the United States of Akorn's ANDA Product prior to the expiration date of the '319 patent;

B. Declaring that the making, using, offering to sell, selling, marketing, distributing or importing of Akorn's ANDA Product prior to the expiration of the '319 patent will infringe, actively induce infringement, and/or contribute to the infringement of one or more claims of the '319 patent;

C. Ordering that under 35 U.S.C. § 271(e)(4)(A) the effective date of any approval by the FDA of Akorn's ANDA Product be a date that is not earlier than the expiration of the '319 patent and any related regulatory exclusivities, or such later date as the Court may determine;

D. Enjoining under 35 U.S.C. § 271(e)(4)(D) Akorn and its affiliates, subsidiaries,

officers, agents, servants, attorneys, and employees, and those acting in privity or in concert with them, from making, using, importing into the United States, offering to sell and/or selling in the United States Akorn's ANDA Product until after the expiration date of the '319 patent and any related regulatory exclusivities, or such later date as the Court may determine;

E. Enjoining Akorn and its affiliates, subsidiaries, officers, agents, servants, attorneys, and employees, and those acting in privity or in concert with them from seeking, obtaining or maintaining approval of Akorn's ANDA No. 207284 until expiration of the '319 patent and any related regulatory exclusivities;

F. Declaring this to be an exceptional case under 35 U.S.C. §§ 285 and 271(e)(4) and awarding Plaintiffs costs, expenses and disbursements in this action, including reasonable attorneys' fees; and

G. Awarding Plaintiffs such further and additional relief as this Court deems proper and just.

Dated: January 14, 2015

By: /s/ John E Flaherty
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CERTIFICATION PURSUANT TO L. CIV. R. 11.2

Plaintiffs, by their undersigned counsel, hereby certify pursuant to L. Civ. R. 11.2 that the matter in controversy is not the subject of any other action pending in any court, or of any pending arbitration or administrative proceeding.

Dated: January 14, 2015

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