UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF NEW YORK

13 CV 6080

SENJU PHARMACEUTICAL CO., LTD., BAUSCH & LOMB, INC. and BAUSCH & LOMB PHARMA HOLDINGS CORP.

Plaintiffs,

v.

AKORN, INC.,

Defendant.

Civil Action No. _____

COMPLAINT FOR PATENT INFRINGEMENT

Plaintiffs Senju Pharmaceutical Co., Ltd., Bausch & Lomb Incorporated and Bausch & Lomb Pharma Holdings Corp. (collectively, "Plaintiffs"), by and through their undersigned counsel, bring this action for patent infringement and allege as follows:

NATURE OF THE ACTION

1. This is an action for patent infringement. This action relates to an Abbreviated New Drug Application ("ANDA") submitted by and/or for the benefit of Akorn, Inc. ("Akorn") to the United States Food and Drug Administration (the "FDA") for approval to market a generic copy of ISTALOL™ (timolol maleate ophthalmic solution), 0.5%, which is sold in the United States.

THE PARTIES

2. 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.

3. Plaintiff Bausch & Lomb Incorporated ("B+L") is a corporation organized and existing under the laws of New York, with a principal place of business at One Bausch & Lomb Place, Rochester, New York 14604. B+L is the registered holder of approved New Drug Application No. N021516, which covers ISTALOL™ (timolol maleate ophthalmic solution), 0.5%.

4. Plaintiff Bausch & Lomb Pharma Holdings Corp. ("B+L Pharma Holdings") is a corporation organized and existing under the laws of Delaware, with a principal place of business at 7 Giralda Farms, Madison, New Jersey 07940.

5. B+L Pharma Holdings is a wholly-owned subsidiary of B+L and the exclusive licensee of the patent-in-suit in this litigation.

6. Upon information and belief, defendant Akorn, Inc. is a corporation organized and existing under the laws of Louisiana, with a principal place of business at 1925 W. Field Ct., Suite 300, Lake Forest, Illinois 60045.

JURISDICTION AND VENUE

7. This action arises under the patent laws of the United States of America, 35 U.S.C. §§ 1, *et seq.*, including 35 U.S.C. § 271. This Court has jurisdiction over the subject matter of this action pursuant to 28 U.S.C. §§ 1331 and 1338(a).

8. Upon information and belief, Akorn is in the business of manufacturing, marketing, and selling pharmaceutical drug products, including generic drug products. On information and belief, Akorn directly, or through its affiliates and agents, manufactures, exports, markets and sells drug products throughout the United States and this Judicial District.

9. Upon information and belief, Akorn is subject to personal jurisdiction and venue in this Court by virtue of the facts alleged in this Complaint, including Akorn's presence and activities within this District and in the State of New York, and by having systematic, purposeful

and continuous contacts with the State of New York so as to reasonably allow personal jurisdiction to be exercised over them.

10. Personal jurisdiction over Akorn is proper because, *inter alia* and upon information and belief, Akorn regularly does and solicits business in New York and this Judicial District by distributing and selling drug products, and is, therefore, engaged in a persistent, continuous and systematic course of conduct in New York.

11. Personal jurisdiction over Akorn is proper because, *inter alia* and upon information and belief, Akorn transacts business throughout the United States, including in New York and this Judicial District, by distributing and selling drug products.

12. Personal jurisdiction over Akorn is proper because, *inter alia* and upon information and belief, Akorn has engaged in conduct intended to obtain FDA approval for the proposed generic product at issue in this litigation, and upon receiving FDA approval, Akorn intends to offer to sell and sell the proposed generic product at issue in this litigation throughout the United States, including in New York and this Judicial District.

13. Personal jurisdiction over Akorn is proper because, *inter alia* and upon information and belief, Akorn has evinced and continues to evince a course of conduct that is designed to cause the performance of tortious acts that will result in foreseeable harm in New York, and which Akorn should reasonably expect to have consequences in the State of New York.

14. Personal jurisdiction over Akorn is proper because, *inter alia* and upon information and belief, Akorn derives substantial revenue from services or things used or consumed in the State of New York and this Judicial District, including the sales of its generic products and ophthalmic products.

15. Personal jurisdiction over Akorn is proper because Akorn has availed and continues to avail itself of the legal protections of the State of New York. Upon information and belief, Akorn is registered as a foreign business corporation with the New York State Department of State, Division of Corporations (DOS ID # 3475754). The Registration has an active status. Upon information and belief, Akorn is registered as a non-resident wholesaler in the State of New York by the New York State Department of Education, Office of the Professions (Registration No. 028232). The Registration has an active status and is valid through January 31, 2016.

16. Upon information and belief, consistent with their practice with respect to other generic products, Akorn will distribute and sell the proposed generic product at issue in this litigation throughout the United States and within New York following approval of ANDA No. 204912 by the FDA.

17. Upon information and belief, Akorn knows and intends that the proposed generic product at issue in this litigation will be distributed in the United States and within New York.

Venue

18. The activities alleged, with respect to the defendant, took and take place in substantial part in this District. Venue is proper in this District as to the defendant under 28 U.S.C. §§ 1391(b), 1391(c) and 1400(b).

BACKGROUND

19. ISTALOL™ (timolol maleate ophthalmic solution), 0.5% is the subject of New Drug Application ("NDA") No. N021516, which was approved by the FDA. ISTALOL™ is indicated in the treatment of elevated intraocular pressure in patients with ocular hypertension or open-angle glaucoma. B+L is the registered holder of NDA No. N021516.

20. United States Patent No. 6,335,335 ("the '335 patent"), entitled "Prolonged-Action Eye Drop," was duly and legally issued by the United States Patent and Trademark Office on January 1, 2002. The named inventors are Masayo Higashiyama and Akira Ohtori. Senju is the assignee of the '335 patent. A true and correct copy of the '335 patent is attached to this Complaint as Exhibit A.

21. The '335 patent is listed in the *Approved Drug Products With Therapeutic Equivalence Evaluation* (published by the FDA and commonly known as "the Orange Book") as covering ISTALOL™ (timolol maleate ophthalmic solution), 0.5%.

22. Upon information and belief, Akorn submitted ANDA No. 204912 to the FDA, under § 505(j) of the Federal Food, Drug and Cosmetic Act (21 U.S.C. § 355(j)), seeking approval to engage in the commercial manufacture, use, sale, offer for sale and/or importation of a generic timolol maleate ophthalmic solution, 0.5% (the "Akorn ANDA Product") as a generic version of ISTALOL™, before the expiration of the '335 patent.

23. By letter dated July 12, 2013 (the "Notice Letter"), Akorn informed Senju and B+L that Akorn had submitted ANDA No. 204912 to the FDA seeking approval to engage in the commercial manufacture, use and sale of the Akorn ANDA Product, which is a generic version of ISTALOL™ (timolol maleate ophthalmic solution), 0.5%, prior to the expiration of the '335 patent.

24. Senju did not receive the Notice Letter until July 16, 2013 by UPS.

25. Upon information and belief, Akorn made, and included in ANDA No. 204912, a "Paragraph IV" certification under 21 U.S.C. § 355(j)(2)(A)(vii)(IV) alleging that the claims of the '335 patent are invalid and/or will not be infringed by the commercial manufacture, use, or sale of the Akorn ANDA Product.

26. The Notice Letter alleges that the '335 patent is invalid and/or will not be infringed by "the manufacture, use, or sale" of the Akorn ANDA Product, but does not provide any valid basis for these allegations.

COUNT I
(INFRINGEMENT OF U.S. PATENT 6,335,335 BY AKORN)

27. Plaintiffs expressly incorporate by reference paragraphs 1 through 26, inclusive, as if fully set forth herein.

28. Upon information and belief, the Akorn ANDA Product, together with Akorn's package insert, and their use are the subject of one or more claims of the '335 patent.

29. Upon information and belief, when Akorn filed ANDA No. 204912, it was aware of the '335 patent and that the filing of its ANDA with the request for its approval prior to the expiration of the '335 patent was an act of infringement. Akorn was aware of the existence of the '335 patent at least as of the date it sent the July 12, 2013 Notice Letter.

30. Upon information and belief, Akorn's submission of ANDA No. 204912 for the purposes of obtaining approval to engage in the commercial manufacture, use and sale of the Akorn ANDA Product, prior to the expiration of the '335 patent, is an act of infringement of one or more claims of the '335 patent under 35 U.S.C. § 271(e)(2)(A). Moreover, any commercial manufacture, use, offer to sell, sale, and/or importation of the Akorn ANDA Product into the United States would infringe the '335 patent under 35 U.S.C. §§ 271(a), 271(b) and/or 271(c).

31. Unless enjoined by this Court, upon FDA approval of ANDA No. 204912, Akorn will infringe, induce infringement of and/or contributorily infringe the '335 patent under 35 U.S.C. §§ 271(a), 271(b) and/or 271(c) by making, using, offering to sell, importing, and/or selling the Akorn ANDA Product in the United States.

32. Upon information and belief, upon FDA approval of ANDA No. 204912, Akorn will intentionally encourage acts of direct infringement with knowledge of the '335 patent and knowledge that its acts are encouraging infringement. Upon further information and belief, Akorn has the specific intent to induce direct infringement of one or more claims of the '335 patent at least by resellers, pharmacies, health care professionals and end users of the Akorn ANDA Product.

33. Defendant has been aware of the existence of the '335 patent, and has no reasonable basis for believing that the commercial sale, offer for sale, use, importation and/or manufacture of the Akorn ANDA product will not infringe, induce the infringement of and/or contributorily infringe the '335 patent, thus rendering the case "exceptional," as that term is used in 35 U.S.C. § 285.

34. The acts of infringement by Akorn set forth above will cause Plaintiffs irreparable harm for which they have no adequate remedy at law, and will continue unless enjoined by this Court.

PRAYER FOR RELIEF

WHEREFORE, Plaintiffs request the Court to enter judgment in their favor and grant the following relief:

(a) A judgment that Akorn, Inc. has infringed the '335 patent, and finding that the commercial sale, offer for sale, use, and/or manufacture of the Akorn ANDA product described in ANDA No. 204912 would infringe, induce infringement of and/or contributorily infringe the '335 patent;

(b) A judgment, pursuant to 35 U.S.C. § 271(e)(4)(A), that the effective date of any approval of ANDA No. 204912, under § 505(j) of the Federal Food, Drug and Cosmetic Act (21

U.S.C. § 355(j)), is to be a date not earlier than the date of expiration of the '335 patent plus any additional periods of exclusivity;

(c) A judgment and order permanently restraining and enjoining Akorn, Inc. and all of its respective present and future directors, officers, agents, servants, employees, attorneys, parents, subsidiaries, divisions, affiliate corporations, parent entities, equity holders, other related business entities, and all persons in active concert or privity with any of them, and their respective successors and assigns, from infringing any claims of the '335 patent by making, offering for sale and/or importing the Akorn ANDA Product in the United States;

(d) A finding that this case is exceptional under 35 U.S.C. § 285, warranting an award to Plaintiffs of their costs, including attorneys' fees and other expenses incurred in connection with this action; and

(e) Such further relief in favor of Plaintiffs as this Court deems just and proper, not inconsistent with the terms hereof.

Dated: August 28, 2013

ROPES & GRAY LLP

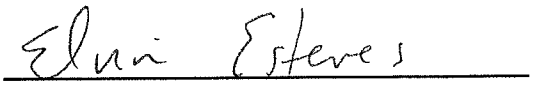
Christopher J. Harnett
Pablo D. Hendler
Sona De
Hassen A. Sayeed
1211 Avenue of the Americas
New York, New York 10036
Phone: (212) 596-9000
christopher.harnett@ropesgray.com
pablo.hendler@ropesgray.com
sona.de@ropesgray.com
hassen.sayeed@ropesgray.com

Hiroyuki Hagiwara
Yusen Building 2F
3-2 Marunouchi 2-Chome
Chiyoda-ku, Tokyo 100-0005
Japan
Phone: +81-3-6259-3500
hiroyuki.hagiwara@ropesgray.com

Attorneys for Plaintiff
Senju Pharmaceutical Co., Ltd.

Dated: August 28, 2013

GIBBONS P.C.



Elvin Esteves
William Deni
One Gateway Center
Newark, New Jersey 07102-5310
Phone: (973) 596-4500
eesteves@gibbonslaw.com
WDeni@gibbonslaw.com

Of Counsel:

FINNEGAN, HENDERSON, FARABOW, GARRETT & DUNNER, LLP

Bryan C. Diner
Justin J. Hasford
Jessica Lebeis
901 New York Avenue, NW
Washington, DC 20001-4413
Phone: (202) 408-4000
bryan.diner@finnegan.com
justin.hasford@finnegan.com
jessica.lebeis@finnegan.com

Attorneys for Plaintiffs
Bausch & Lomb Incorporated and
Bausch & Lomb Pharma Holdings Corp.