UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF NEW YORK

13 CV 6608

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

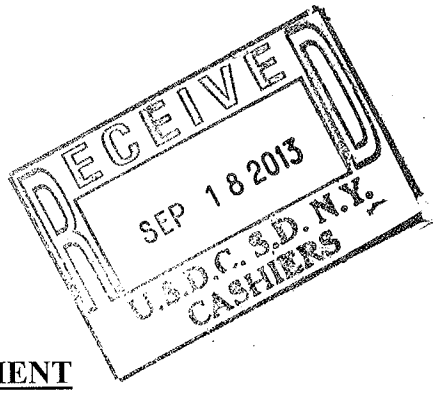
Plaintiffs,

v.

SANDOZ 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 Sandoz Inc. ("Sandoz") 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 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 patents-in-suit in this litigation.

6. Upon information and belief, defendant Sandoz Inc. is a corporation organized and existing under the laws of Colorado, with a principal place of business at 506 Carnegie Center, Suite 400, Princeton, New Jersey 08540.

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, Sandoz is in the business of manufacturing, marketing, and selling pharmaceutical drug products, including generic drug products. On information and belief, Sandoz 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, Sandoz is subject to personal jurisdiction and venue in this Court by virtue of the facts alleged in this Complaint, including Sandoz'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 Sandoz is proper because, *inter alia* and upon information and belief, Sandoz 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 Sandoz is proper because, *inter alia* and upon information and belief, Sandoz transacts business throughout the United States, including in New York and this Judicial District, by distributing and selling drug products.

12. Personal jurisdiction over Sandoz is proper because, *inter alia* and upon information and belief, Sandoz has engaged in conduct intended to obtain FDA approval for the proposed generic product at issue in this litigation, and upon receiving FDA approval, Sandoz 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 Sandoz is proper because, *inter alia* and upon information and belief, Sandoz 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 Sandoz should reasonably expect to have consequences in the State of New York.

14. Personal jurisdiction over Sandoz is proper because, *inter alia* and upon information and belief, Sandoz 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 Sandoz is proper because, *inter alia* and upon information and belief, Sandoz has, as part of its ordinary business practice of engaging in U.S. patent litigation, regularly and routinely litigated cases in this District, previously admitting to jurisdiction in this Court and availing itself of this forum as a plaintiff and to assert counterclaims. For example, at least as recently as February 14, 2013, in *Endo Pharms. Inc. et al. v. Sandoz Inc.*, No. 1:12-cv-08318-TPG-GWG (S.D.N.Y.), Sandoz consented to personal jurisdiction in the Southern District of New York. By way of further example, on February 16, 2006, in *Sandoz Inc. v. Pfizer Inc.*, No. 1:06-cv-01222-LAP (S.D.N.Y.), Sandoz Inc. initiated a civil action in this jurisdiction.

16. Personal jurisdiction over Sandoz is proper because Sandoz has availed and continues to avail itself of the legal protections of the State of New York. Upon information and belief, Sandoz is registered as a foreign business corporation with the New York State Department of State, Division of Corporations (DOS ID # 2935375). The Registration has an active status. Upon information and belief, Sandoz is registered as a non-resident manufacturer in the State of New York by the New York State Department of Education, Office of the Professions (Registration No. 031428). The Registration has an active status and is valid through June 30, 2015.

17. Upon information and belief, consistent with their practice with respect to other generic products, Sandoz 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. 205200 by the FDA.

18. Upon information and belief, Sandoz 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

19. 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

20. 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.

21. 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.

22. 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%.

23. United States Patent No. 6,645,963 ("the '963 patent"), entitled "Prolonged-Action Eye Drop," was duly and legally issued by the United States Patent and Trademark Office on November 11, 2003. The named inventors are Masayo Higashiyama and Akira Ohtori. Senju is the assignee of the '963 patent. A true and correct copy of the '963 patent is attached to this Complaint as Exhibit B.

24. The '963 patent was indexed in the Orange Book on September 13, 2013 as covering ISTALOL™.

25. Upon information and belief, Sandoz submitted ANDA No. 205200 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 "Sandoz ANDA Product") as a generic version of ISTALOL™, before the expiration of the '335 patent and the '963 patent.

26. By letter dated August 7, 2013 (the "Notice Letter"), Sandoz informed Senju and B+L that Sandoz had submitted ANDA No. 205200 to the FDA seeking approval to engage in the commercial manufacture, use and sale of the Sandoz ANDA Product, which is a generic version of ISTALOL™ (timolol maleate ophthalmic solution), 0.5%, prior to the expiration of the '335 patent.

27. Senju did not receive the Notice Letter until August 9, 2013 by UPS.

28. Upon information and belief, Sandoz made, and included in ANDA No. 205200, 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 Sandoz ANDA Product.

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

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

30. Plaintiffs expressly incorporate by reference paragraphs 1 through 29, inclusive, as if fully set forth herein.

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

32. Upon information and belief, when Sandoz filed ANDA No. 205200, 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. Sandoz was aware of the existence of the '335 patent at least as of the date it sent the August 7, 2013 Notice Letter.

33. Upon information and belief, Sandoz's submission of ANDA No. 205200 for the purposes of obtaining approval to engage in the commercial manufacture, use and sale of the Sandoz 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 Sandoz ANDA Product into the United States would infringe the '335 patent under 35 U.S.C. §§ 271(a), 271(b) and/or 271(c).

34. Unless enjoined by this Court, upon FDA approval of ANDA No. 205200, Sandoz 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 Sandoz ANDA Product in the United States.

35. Upon information and belief, upon FDA approval of ANDA No. 205200, Sandoz 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, Sandoz 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 Sandoz ANDA Product.

36. Sandoz 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 Sandoz 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.

37. The acts of infringement by Sandoz 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.

COUNT II
(DECLARATORY JUDGMENT OF INFRINGEMENT OF U.S. PATENT 6,645,963 BY SANDOZ)

38. Plaintiffs expressly incorporate by reference paragraphs 1 through 37, inclusive, as if fully set forth herein.

39. Upon information and belief, Sandoz is seeking through its ANDA to obtain FDA approval to engage in the commercial manufacture, use, sale, offer for sale and/or importation of a generic copy of ISTALOL™ (timolol maleate ophthalmic solution), 0.5%, in the United States prior to the expiration of the '335 patent. The '963 patent expires after the '335 patent.

40. Upon information and belief, Sandoz will directly infringe, contributorily infringe and/or actively induce the infringement by others under 35 U.S.C. § 271 at least one claim of the '963 patent, either literally or under the doctrine of equivalents, by manufacturing, using, selling, offering for sale and/or importing the FDA-approved Sandoz ANDA product in the United States.

41. By virtue of the facts alleged in this Complaint, there is an actual and justiciable case or controversy between the parties that is ripe for adjudication under the Declaratory Judgment Act (28 U.S.C. §§ 2201 and 2202) as to whether Sandoz will infringe one or more claims of the '963 patent.

42. Plaintiffs are entitled to a declaration that Sandoz's manufacture, use, sale, offer for sale and/or importation of its FDA-approved ANDA product will infringe, contribute to the infringement of, and/or induce the infringement of one or more claims of the '963 patent.

43. These acts of infringement by Sandoz 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 Sandoz Inc. has infringed the '335 patent, and finding that the commercial sale, offer for sale, use, importation and/or manufacture of the Sandoz ANDA product described in ANDA No. 205200 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. 205200, 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, pursuant to 35 U.S.C. §§ 271(e)(4)(B) and 283, preliminarily and permanently enjoining Sandoz 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 manufacturing, using, selling, offering for sale and/or importing the Sandoz ANDA Product in the United States;

(d) A judgment that Sandoz Inc. will directly infringe, contribute to and/or actively induce the infringement of the '963 patent by manufacturing, using, selling, importing and/or offering to sell an FDA-approved Sandoz ANDA Product in the United States;

(e) A judgment and order, pursuant to 28 U.S.C. §§ 2201 and 2202 and 35 U.S.C. § 283, preliminarily and permanently enjoining Sandoz 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 '963 patent by manufacturing, using, selling, offering for sale and/or importing the Sandoz ANDA Product in the United States;

(f) 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

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

Dated: September 18, 2013

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