

JUDGE CROTTY,

**UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF NEW YORK**

SENJU PHARMACEUTICAL CO., LTD.,)

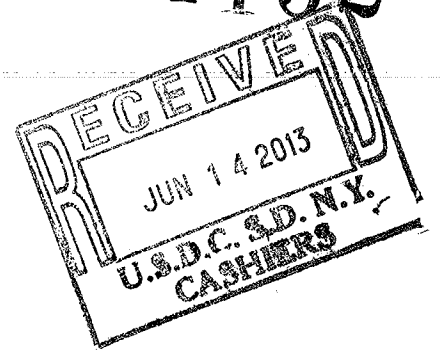
Plaintiff,)

v.)

APOTEX INC., APOTEX CORP., ISTA)
PHARMACEUTICALS, INC. and)
BAUSCH & LOMB INC.)

Defendants.)

Civil Action No. **13 CV 4132**



COMPLAINT FOR PATENT INFRINGEMENT

Plaintiff Senju Pharmaceutical Co., Ltd., by and through its undersigned counsel, brings this action for patent infringement and alleges 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 Apotex Inc. and Apotex Corp. (collectively, “Apotex”) 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. (“Plaintiff” or “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. Upon information and belief, defendant Apotex Corp. is a corporation organized and existing under the laws of Delaware, with a principal place of business at 2400 North Commerce Parkway, Suite 400, Weston, Florida 33326.

4. Upon information and belief, defendant Apotex Inc. is a corporation organized and existing under the laws of Canada, with a principal place of business at 150 Signet Drive, Toronto, Ontario, Canada M9L 1T9.

5. Upon information and belief, defendant 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%.

6. Upon information and belief, defendant ISTA Pharmaceuticals, Inc. (“ISTA”) is a corporation organized and existing under the laws of Delaware, with a principal place of business at 50 Technology Drive, Irvine, California 92618.

7. ISTA is the exclusive licensee of the patent-in-suit in this litigation. Upon information and belief, ISTA is a wholly-owned subsidiary of B+L.

8. Prior to commencing this action, Senju requested that ISTA and B+L join the litigation as plaintiffs, but ISTA and B+L have not done so.

9. Subject to being re-aligned by this Court as plaintiffs, ISTA and B+L are being joined to this action as defendants pursuant to Rule 19 of the Federal Rules of Civil Procedure. ISTA and B+L are proper parties who have an interest in the outcome of this litigation and are subject to personal jurisdiction in this Court.

JURISDICTION AND VENUE

10. 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).

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

12. Upon information and belief, Apotex Inc. and Apotex Corp. are subject to personal jurisdiction and venue in this Court by virtue of the facts alleged in this Complaint, including Apotex Inc.'s and Apotex Corp.'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.

Apotex Corp.

13. Personal jurisdiction over Apotex Corp. is proper because, *inter alia* and upon information and belief, Apotex Corp. 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.

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

15. Personal jurisdiction over Apotex Corp. is proper because, *inter alia* and upon information and belief, Apotex Corp. has engaged in conduct intended to obtain FDA approval

for the proposed generic product at issue in this litigation, and upon receiving FDA approval, Apotex Corp. 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.

16. Personal jurisdiction over Apotex Corp. is proper because, *inter alia* and upon information and belief, Apotex Corp. 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 Apotex Corp. should reasonably expect to have consequences in the State of New York.

17. Personal jurisdiction over Apotex Corp. is proper because, *inter alia* and upon information and belief, Apotex Corp. 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.

18. Personal jurisdiction over Apotex Corp. is proper because, *inter alia* and upon information and belief, Apotex Corp. 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 January 18, 2011, in *Pfizer Inc. et al. v. Actavis Inc. et al.*, No. 1:10-cv-08197 (S.D.N.Y.), Apotex Corp. consented to personal jurisdiction in the Southern District of New York. By way of further example, at least as recently as December 2, 2011, in *Apotex Inc. et al. v. Acorda Therapeutics, Inc.*, No. 1:11-cv-08803 (S.D.N.Y.), Apotex Corp. initiated a civil action in this jurisdiction.

19. Personal jurisdiction over Apotex Corp. is proper because Apotex Corp. has availed and continues to avail itself of the legal protections of the State of New York. Upon

information and belief, Apotex Corp. 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. 025806). The Registration has an active status and is valid through January 31, 2015.

Apotex Inc.

20. Personal jurisdiction over Apotex Inc. is proper because, *inter alia* and upon information and belief, Apotex Inc. regularly does and solicits business in New York and this Judicial District by manufacturing drug products which it distributes, sells or offers to sell, including through Apotex Corp.

21. Personal jurisdiction over Apotex Inc. is proper because, *inter alia* and upon information and belief, Apotex Inc. transacts business throughout the United States, including in New York and this Judicial District, by manufacturing drug products which it distributes, sells or offers to sell, including through Apotex Corp.

22. Personal jurisdiction over Apotex Inc. is proper because, *inter alia* and upon information and belief, Apotex Inc. has, directly or through an agent, filed an ANDA, and/or been actively involved in the preparation and submission of an ANDA, for the purpose of seeking approval to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of the Apotex ANDA Product in the United States, including in New York and this Judicial District.

23. Personal jurisdiction over Apotex Inc. is proper because, *inter alia* and upon information and belief, upon receiving FDA approval, Apotex Inc. 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.

24. Personal jurisdiction over Apotex Inc. is proper because, *inter alia* and upon information and belief, Apotex Inc. 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 Apotex Inc. should reasonably expect to have consequences in the State of New York.

25. Personal jurisdiction over Apotex Inc. is proper because, *inter alia* and upon information and belief, Apotex Inc. 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 drug products and ophthalmic products, and transacts business either directly or through its agents and/or affiliates with companies located and/or headquartered in New York and this Judicial District.

26. Personal jurisdiction over Apotex Inc. is proper because, *inter alia* and upon information and belief, Apotex Corp., acting as Apotex Inc.'s agent and/or alter ego, regularly does and solicits business in New York and is engaged in a persistent, continuous and systematic course of conduct in New York in which it distributes, sells, and offers to sell Apotex Inc.'s drug products in New York and derives substantial revenue from services or things used or consumed in the State of New York on behalf of Apotex Inc.

27. Personal jurisdiction over Apotex Inc. is proper because, *inter alia* and upon information and belief, Apotex Inc. 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 January 18, 2011, in *Pfizer Inc. et al. v. Actavis Inc. et al.*, No. 1:10-cv-08197 (S.D.N.Y.), Apotex Inc. consented to personal jurisdiction

in the Southern District of New York. By way of further example, at least as recently as December 2, 2011, in *Apotex Inc. et al. v. Acorda Therapeutics, Inc.*, No. 1:11-cv-08803 (S.D.N.Y.), Apotex Inc. initiated a civil action in this jurisdiction.

Apotex Corp. and Apotex Inc.

28. Upon information and belief, consistent with their practice with respect to other generic products, Apotex Corp. and Apotex Inc. have acted and will act in concert to distribute and sell the proposed generic product at issue in this litigation throughout the United States and within New York following approval ANDA No. 204936 by the FDA.

29. Upon information and belief, Apotex Corp. and Apotex Inc. know and intend that the proposed generic product at issue in this litigation will be distributed in the United States and within New York.

B+L

30. This Court has personal jurisdiction over B+L because, upon information and belief, B+L is registered as a Domestic Business Corporation by the New York State Department of State, Division of Corporations, and has a registered agent in this Judicial District.

31. This Court has personal jurisdiction over B+L because, upon information and belief, B+L transacts business with companies located and/or headquartered in New York and this Judicial District, including business relating to the sale of ISTALOL™ (timolol maleate ophthalmic solution), 0.5%.

32. This Court has personal jurisdiction over B+L because, upon information and belief, B+L derives substantial revenue from services or things used or consumed in the State of New York and this Judicial District, including revenue relating to the sale of ISTALOL™ (timolol maleate ophthalmic solution), 0.5%.

33. This Court has personal jurisdiction over B+L because, upon information and belief, B+L has availed and continues to avail itself of the legal protections of the State of New York. B+L is registered as a wholesaler and manufacturer in the State of New York by the New York State Department of Education, Office of the Professions (Registration Nos. 028311, 028324, 028330, and 031099).

ISTA

34. This Court has personal jurisdiction over ISTA because, upon information and belief, ISTA is a wholly-owned subsidiary of B+L and is being wound down at the direction of B+L, such that ISTA is present where B+L is present, including in New York.

35. This Court has personal jurisdiction over ISTA because, upon information and belief, ISTA transacts business with companies located and/or headquartered in New York and this Judicial District, including business relating to the sale of ISTALOL™ (timolol maleate ophthalmic solution), 0.5%.

36. This Court has personal jurisdiction over ISTA because, upon information and belief, ISTA derives substantial revenue from services or things used or consumed in the State of New York and this Judicial District, including revenue relating to the sale of ISTALOL™ (timolol maleate ophthalmic solution), 0.5%.

37. This Court has personal jurisdiction over ISTA because, upon information and belief, ISTA markets, sells and/or distributes ISTALOL™ (timolol maleate ophthalmic solution), 0.5%, throughout the United States, including in New York and this Judicial District, as the exclusive licensee of the patent-in-suit.

Venue

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

BACKGROUND

39. 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. ISTA is the holder of NDA No. N021516.

40. 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.

41. 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%

42. Upon information and belief, Apotex submitted ANDA No. 204936 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 “Apotex ANDA Product”) as a generic version of ISTALOL™, before the expiration of the ‘335 patent.

43. By letter dated April 30, 2013 (the “Notice Letter”), Apotex informed Senju, ISTA and B+L that Apotex had submitted ANDA No. 204936 to the FDA seeking approval to

engage in the commercial manufacture, use and sale of the Apotex ANDA Product, which is a generic version of ISTALOL™ (timolol maleate ophthalmic solution), 0.5%, prior to the expiration of the '335 patent.

44. Senju did not receive the Notice Letter until May 7, 2013 by FedEx®.

45. Upon information and belief, Apotex made, and included in ANDA No. 204936, 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 Apotex ANDA Product.

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

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

47. Senju expressly incorporates by reference paragraphs 1 through 46, inclusive, as if fully set forth herein.

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

49. Upon information and belief, when Apotex filed ANDA No. 204936, 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. Apotex was aware of the existence of the '335 patent at least as of the date it sent the April 30, 2013 Notice Letter.

50. Upon information and belief, Apotex's submission of ANDA No. 204936 for the purposes of obtaining approval to engage in the commercial manufacture, use and sale of the Apotex 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 Apotex ANDA Product into the United States would infringe the '335 patent under 35 U.S.C. §§ 271(a), 271(b) and/or 271(c).

51. Unless enjoined by this Court, upon FDA approval of ANDA No. 204936, Apotex 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 Apotex ANDA Product in the United States.

52. Upon information and belief, upon FDA approval of ANDA No. 204936, Apotex 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, Apotex 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 Apotex ANDA Product.

53. Defendants have been aware of the existence of the '335 patent, and have no reasonable basis for believing that the commercial sale, offer for sale, use, importation and/or manufacture of the Apotex 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.

54. The acts of infringement by Apotex set forth above will cause Senju irreparable harm for which it has no adequate remedy at law, and will continue unless enjoined by this Court.

PRAYER FOR RELIEF

WHEREFORE, Senju requests the Court to enter judgment in its favor and grant the following relief:

(a) A judgment properly aligning each of B+L and ISTA in this action, finding that both Apotex Inc. and Apotex Corp. have infringed the '335 patent, and finding that the commercial sale, offer for sale, use, importation, and/or manufacture of the Apotex ANDA product described in ANDA No. 204936 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. 204936, 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;

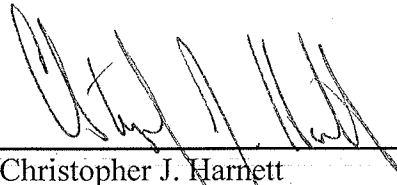
(c) A judgment and order permanently restraining and enjoining Apotex Inc. and Apotex Corp. and all of their respective present and future directors, officers, agents, servants, employees, attorneys, parents, subsidiaries, divisions, affiliate corporations, parent entities, equity holders, other related 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, using, selling, offering for sale and/or importing the Apotex ANDA Product in the United States;

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

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

Dated: June 14, 2013

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