Melissa A. Chuderewicz
PEPPER HAMILTON LLP
(A Pennsylvania Limited Liability Partnership)
Suite 400
301 Carnegie Center
Princeton, NJ 08543
Tel: (609) 951-4118
Fax: (609) 452-1147
chuderem@pepperlaw.com

Attorneys for Plaintiffs
SENJU PHARMACEUTICAL CO., LTD.
BAUSCH & LOMB INCORPORATED, and
BAUSCH & LOMB PHARMA HOLDINGS CORP.

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY

SENJU PHARMACEUTICAL CO., LTD., BAUSCH & LOMB INCORPORATED and BAUSCH & LOMB PHARMA HOLDINGS CORP. Plaintiffs, v. WATSON LABORATORIES, INC., ACTAVIS, INC., and ACTAVIS PHARMA, INC. Defendants.	)	Civil Action No.:

COMPLAINT FOR PATENT INFRINGEMENT

Plaintiffs Senju Pharmaceutical Co., Ltd., Bausch & Lomb Incorporated and Bausch & Lomb Pharma Holdings Corp. (collectively "Plaintiffs") by way of Complaint against Defendants Watson Laboratories, Inc. ("Watson Labs."), Actavis, Inc. ("Actavis"), and Actavis Pharma, Inc. ("Actavis Pharma") (collectively, "Defendants") allege as follows:

THE PARTIES

1. 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.

2. Plaintiff Bausch & Lomb Incorporated ("B+L") is a corporation organized and existing under the laws of New York, with a place of business at 1400 North Goodman St., Rochester, New York 14609. B+L is the registered holder of approved New Drug Application No. 203168, which covers Prolensa®.

3. Plaintiff Bausch & Lomb Pharma Holdings Corp. ("B+L Pharma Holdings") is a corporation organized and existing under the laws of Delaware, with a place of business at 700 Route 202/206, Bridgewater, New Jersey 08807. B+L Pharma Holdings is a wholly-owned subsidiary of B+L.

4. Upon information and belief, defendant Watson Labs. is a corporation organized and existing under the laws of Nevada, having a principal place of business at 132 Business Center Drive Corona, CA 92880. Upon information and belief, Watson Labs. is a wholly-owned subsidiary of Actavis.

5. Upon information and belief, defendant Actavis is a corporation organized and existing under the laws of Nevada, having a principal place of business at Morris Corporate Center III, 400 Interpace Parkway, Parsippany, New Jersey 07054.

6. Upon information and belief, defendant Actavis Pharma is a corporation organized and existing under the laws of Delaware, having a principal place of business at Morris Corporate Center III, 400 Interpace Parkway, Parsippany, New Jersey 07054. Upon information and belief, Actavis Pharma is a wholly-owned subsidiary of Actavis.

NATURE OF THE ACTION

7. This is an action for infringement of United States Patent No. 9,144,609 ("the '609 patent"), arising under the United States patent laws, Title 35, United States Code, § 100 et seq., including 35 U.S.C. §§ 271 and 281. This action relates to Watson Labs.' filing of an Abbreviated New Drug Application ("ANDA") under Section 505(j) of the Federal Food, Drug, and Cosmetic Act ("the Act"), 21 U.S.C. § 355(j), seeking U.S. Food and Drug Administration ("FDA") approval to market generic Bromfenac Ophthalmic Solution 0.07% ("Watson Labs.' generic bromfenac ophthalmic solution").

JURISDICTION AND VENUE

8. This Court has subject matter jurisdiction under 28 U.S.C. §§ 1331 and 1338(a).

9. Upon information and belief, this Court has jurisdiction over Watson Labs. Upon information and belief, Watson Labs. is in the business of licensing, manufacturing, distributing and selling pharmaceutical products, including generic drug products. Upon information and belief, Watson Labs. directly licenses, 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 the Watson Labs.' generic bromfenac ophthalmic solution. Upon information and belief, Watson Labs. purposefully has conducted and continues to conduct business in this judicial district.

10. Upon information and belief, this Court has jurisdiction over Actavis. Upon information and belief, Actavis is in the business of licensing, manufacturing, distributing and selling pharmaceutical products, including generic drug products. Upon information and belief, Actavis directly licenses, 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

Watson Labs.' generic bromfenac ophthalmic solution. Upon information and belief, Actavis purposefully has conducted and continues to conduct business in this judicial district.

11. Upon information and belief, this court has jurisdiction over Actavis Pharma. Upon information and belief, Actavis Pharma directly, or indirectly, manufactures, markets and sells generic drug products, including generic drug products manufactured by Watson Labs. and/or Actavis, throughout the United States and in this judicial district. Upon information and belief, Actavis Pharma purposefully has conducted and continues to conduct business in this judicial district.

12. Upon information and belief, venue is proper in this judicial district under 28 U.S.C. §§ 1391(c) and (d), and § 1400(b).

THE PATENTS IN SUIT

13. The U.S. Patent and Trademark Office ("PTO") issued the '609 patent on September 29, 2015. The '609 patent claims, *inter alia*, formulations of bromfenac for ophthalmic administration. Plaintiffs hold all substantial rights in the '609 patent and have the right to sue for infringement thereof. Senju is the assignee of the '609 patent. A copy of the '609 patent is attached hereto as Exhibit A.

14. B+L is the holder of New Drug Application ("NDA") No. 203168 for Prolensa®, which the FDA approved on April 5, 2013. In conjunction with NDA No. 203168, the '609 patent is listed in the FDA's Approved Drug Products with Therapeutic Equivalence Evaluations ("the Orange Book").

15. Bromfenac Ophthalmic Solution 0.07% is sold in the United States under the trademark Prolensa®.

DEFENDANTS' INFRINGING ANDA SUBMISSION

16. Upon information and belief, Waston Labs. filed with the FDA ANDA No. 206085, under Section 505(j) of the Act and 21 U.S.C. § 355(j).

17. Upon information and belief, Watson Labs.' ANDA No. 206085 seeks FDA approval to sell in the United States Watson Labs.' generic bromfenac ophthalmic solution, intended to be a generic version of Prolensa®.

18. Plaintiffs received a letter from Watson Labs. dated February 4, 2016, purporting to be a Notice of Certification for ANDA No. 206085 ("Watson Labs.' notice letter") under Section 505(j)(2)(B)(ii) of the Act, 21 U.S.C. § 355(j)(2)(B)(ii), and 21 § C.F.R. 314.95(c).

19. Watson Labs.' notice letter alleges that Watson Labs. has submitted to the FDA ANDA No. 206085 seeking FDA approval to sell generic bromfenac ophthalmic solution, intended to be a generic version of Prolensa®.

20. Upon information and belief, ANDA No. 206085 seeks approval of Watson Labs.' generic bromfenac ophthalmic solution that is the same, or substantially the same, as Prolensa®.

21. Upon information and belief, Watson Labs.' actions relating to ANDA No. 206085 complained of herein were done with the cooperation, the participation, the assistance of, and at least in part for the benefit of Actavis and Actavis Pharma.

COUNT I

Infringement of the '609 patent under § 271(e)(2)

22. Paragraphs 1-21 are incorporated herein as set forth above.

23. Under 35 U.S.C. § 271(e)(2), Defendants have infringed at least one claim of the '609 patent by Watson Labs.' submitting, or causing to be submitted to the FDA, ANDA No.

206085 seeking approval for the commercial marketing of Watson Labs.' generic bromfenac ophthalmic solution before the expiration date of the '609 patent.

24. Upon information and belief, Watson Labs.' generic bromfenac ophthalmic solution will, if approved and marketed, infringe at least one claim of the '609 patent.

25. Upon information and belief, Defendants will, through the manufacture, use import, offer for sale and/or sale of Watson Labs.' generic bromfenac ophthalmic solution, directly infringe, contributorily infringe and/or induce infringement of at least one claim of the '609 patent.

COUNT II

Declaratory Judgment of Infringement of the '609 Patent

26. Paragraphs 1-25 are incorporated herein as set forth above.

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

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

29. Defendants have made, and will continue to make, substantial preparation in the United States to manufacture, use, offer to sell, sell and/or import Watson Labs.' generic bromfenac ophthalmic solution before the expiration date of the '609 patent, including Watson Labs.' filing of ANDA No. 206085.

30. Upon information and belief, any commercial manufacture, use, offer for sale, sale, and/or importation of Watson Labs.' generic bromfenac ophthalmic solution will directly

infringe, contributorily infringe and/or induce infringement of at least one claim of the '609 patent.

31. Plaintiffs are entitled to a declaratory judgment that future commercial manufacture, use, offer for sale, sale, and/or importation of Watson Labs.' generic bromfenac ophthalmic solution will constitute infringement of at least one claim of the '609 patent.

PRAYER FOR RELIEF

WHEREFORE, Plaintiffs respectfully request that the Court enter judgment in their favor and against Defendants on the patent infringement claim set forth above and respectfully request that this Court:

1. enter judgment that, under 35 U.S.C. § 271(e)(2), Defendants have infringed at least one claim of the '609 patent through Watson Labs.' submission of ANDA No. 206085 to the FDA to obtain approval for the commercial manufacture, use, import, offer for sale and/or sale in the United States of Watson Labs.' generic bromfenac ophthalmic solution before the expiration of the '609 patent;

2. order that the effective date of any approval by the FDA of Watson Labs.' generic bromfenac ophthalmic solution be a date that is not earlier than the expiration of the '609 patent, or such later date as the Court may determine;

3. enjoin Defendants from the commercial manufacture, use, import, offer for sale and/or sale of Watson Labs.' generic bromfenac ophthalmic solution until expiration the '609 patent, or such later date as the Court may determine;

4. enjoin Defendants and all persons acting in concert with Defendants from seeking, obtaining or maintaining approval of Watson Labs.' ANDA No. 206085 until expiration of the '609 patent;

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

6. award Plaintiffs such further and additional relief as this Court deems just and proper.

Dated: March 18, 2016

Respectfully submitted,

s/ Melissa A. Chuderewicz

Melissa A. Chuderewicz
PEPPER HAMILTON, LLP
(A Pennsylvania Limited Liability Partnership)
301 Carnegie Center
Suite 400
Princeton, NJ, 08543-5276
(609) 951-4118
chuderem@pepperlaw.com

Attorneys for Plaintiffs
SENJU PHARMACEUTICAL CO., LTD.,
BAUSCH & LOMB INCORPORATED and
BAUSCH & LOMB PHARMA HOLDINGS CORP.

Of Counsel:
Bryan C. Diner
Justin J. Hasford
FINNEGAN, HENDERSON,
FARABOW, GARRETT & DUNNER, LLP
901 New York Avenue, NW
Washington, DC 20001-4413
(202) 408-4000