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*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<sup>®</sup>.

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 400 Somerset Corporate Blvd., 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 Nos. 8,129,431 (“the ’431 patent”), 8,669,290 (“the ’290 patent”), 8,754,131 (“the ’131 patent”), 8,871,813 (“the ’813 patent”), and 8,927,606 (“the ’606 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 ’431 patent on March 6, 2012. The ’431 patent claims, *inter alia*, formulations of bromfenac for ophthalmic administration. Plaintiffs hold all substantial rights in the ’431 patent and have the right to sue for infringement thereof. Senju is the assignee of the ’431 patent. A copy of the ’431 patent is attached hereto as Exhibit A.

14. The PTO issued the ’290 patent on March 11, 2014. The ’290 patent claims, *inter alia*, formulations of bromfenac for ophthalmic administration. Plaintiffs hold all substantial rights in the ’290 patent and have the right to sue for infringement thereof. Senju is the assignee of the ’290 patent. A copy of the ’290 patent is attached hereto as Exhibit B.

15. The PTO issued the ’131 patent on June 17, 2014. The ’131 patent claims, *inter alia*, formulations of bromfenac for ophthalmic administration. Plaintiffs hold all substantial rights in the ’131 patent and have the right to sue for infringement thereof. Senju is the assignee of the ’131 patent. A copy of the ’131 patent is attached hereto as Exhibit C.

16. The PTO issued the '813 patent on October 28, 2014. The '813 patent claims, *inter alia*, formulations of bromfenac for ophthalmic administration. Plaintiffs hold all substantial rights in the '813 patent and have the right to sue for infringement thereof. Senju is the assignee of the '813 patent. A copy of the '813 patent is attached hereto as Exhibit D.

17. The PTO issued the '606 patent on January 6, 2015. The '606 patent claims, *inter alia*, formulations of bromfenac for ophthalmic administration. Plaintiffs hold all substantial rights in the '606 patent and have the right to sue for infringement thereof. Senju is the assignee of the '606 patent. A copy of the '606 patent is attached hereto as Exhibit E.

18. B+L is the holder of New Drug Application (“NDA”) No. 203168 for Prolensa<sup>®</sup>, which the FDA approved on April 5, 2013. In conjunction with NDA No. 203168, the '606 patent is listed in the FDA’s Approved Drug Products with Therapeutic Equivalence Evaluations (“the Orange Book”).

19. Bromfenac Ophthalmic Solution 0.07% is sold in the United States under the trademark Prolensa<sup>®</sup>.

#### **WATSON LABS.’ INFRINGING ANDA SUBMISSION**

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

21. 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<sup>®</sup>.

22. Bausch & Lomb received a letter from Watson Labs. dated June 1, 2015, 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).

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