

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

SENJU PHARMACEUTICAL CO., LTD.,	)	
BAUSCH & LOMB, INC. and BAUSCH &	)	
LOMB PHARMA HOLDINGS CORP.	)	
	)	
Plaintiffs,	)	Civil Action No.:
	)	
v.	)	
	)	
INNOPHARMA LICENSING, INC.,	)	
INNOPHARMA LICENSING, LLC,	)	
INNOPHARMA, INC., AND	)	
INNOPHARMA, LLC,	)	
	)	
Defendants.	)	

**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 Innopharma Licensing, Inc., InnoPharma Licensing, LLC, InnoPharma, Inc., and InnoPharma, LLC (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 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 Innopharma Licensing, Inc. is a corporation organized and existing under the laws of Delaware, having a principal place of business at 10 Knightsbridge Road, Picastaway, New Jersey 08854.

5. Upon information and belief, defendant InnoPharma Licensing, LLC is a limited liability company organized and existing under the laws of Delaware, having a principal place of business at 10 Knightsbridge Road, Picastaway, New Jersey 08854.

6. Upon information and belief, defendant InnoPharma Inc. is a corporation organized and existing under the laws of Delaware, having a principal place of business at 10 Knightsbridge Road, Picastaway, New Jersey 08854.

7. Upon information and belief, defendant InnoPharma, LLC is a limited liability company organized and existing under the laws of Delaware, having a principal place of business at 10 Knightsbridge Road, Picastaway, New Jersey 08854.

#### **NATURE OF THE ACTION**

8. 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”), and 8,871,813 (“the 813 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 Innopharma Licensing, Inc.’s

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% (“Innopharma Licensing, Inc.’s generic bromfenac ophthalmic solution”).

### **JURISDICTION AND VENUE**

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

10. Upon information and belief, this Court has jurisdiction over Innopharma Licensing, Inc. Upon information and belief, Innopharma Licensing, Inc. is in the business of licensing, manufacturing, distributing and selling pharmaceutical products, including generic drug products. Upon information and belief, Innopharma Licensing, Inc. 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 Innopharma Licensing, Inc.’s generic bromfenac ophthalmic solution. Upon information and belief, Innopharma Licensing, Inc. operates as a patent owner or lessor for InnoPharma, Inc., whose principal place of business is, on information and belief, at 10 Knightsbridge Road, Picastaway, New Jersey 08854, and has thereby purposefully and systematically conducted and continues to conduct business in this judicial district.

11. Upon information and belief, this Court has jurisdiction over InnoPharma Licensing, LLC. Upon information and belief, InnoPharma Licensing, LLC is in the business of licensing, manufacturing, distributing and selling pharmaceutical products, including generic drug products. Upon information and belief, InnoPharma Licensing, LLC 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 InnoPharma Licensing, LLC’s generic bromfenac ophthalmic solution. Upon information and belief, InnoPharma Licensing,

business is, on information and belief, at 10 Knightsbridge Road, Picastaway, New Jersey 08854, and has thereby purposefully and systematically conducted and continues to conduct business in this judicial district.

12. Upon information and belief, this court has jurisdiction over InnoPharma, Inc. Upon information and belief, InnoPharma, Inc. directly, or indirectly, manufactures, markets and sells generic drug products, including generic drug products manufactured by Innopharma Licensing, Inc. and InnoPharma Licensing, LLC, throughout the United States and in this judicial district. Upon information and belief, InnoPharma, Inc. purposefully has conducted and continues to conduct business in this judicial district.

13. Upon information and belief, this court has jurisdiction over InnoPharma, LLC. Upon information and belief, InnoPharma, LLC directly, or indirectly, manufactures, markets and sells generic drug products, including generic drug products manufactured by Innopharma Licensing, Inc. and InnoPharma Licensing, LLC, throughout the United States and in this judicial district. Upon information and belief, InnoPharma, LLC purposefully has conducted and continues to conduct business in this judicial district.

14. 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**

15. 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.

16. The U.S. Patent and Trademark Office (“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.

17. The U.S. Patent and Trademark Office (“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.

18. The U.S. Patent and Trademark Office (“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.

19. 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 ’431, the ’290, the ’131, and the ’813 patents are listed in the FDA’s Approved Drug Products with Therapeutic Equivalence Evaluations (“the Orange Book”).<sup>1</sup>

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

<sup>1</sup> Due to an error by the FDA, the information in the Orange Book for the ’813 patent incorrectly identifies the patent’s expiration date as January 16, 2016. Plaintiffs are in the process of notifying the FDA of this error and requesting that the FDA correct it.

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