

Arnold B. Calmann (abc@saiber.com)  
Jeffrey S. Soos (js@saiber.com)  
Katherine A. Escanlar (kae@saiber.com)

**SAIBER LLC**

One Gateway Center, 10<sup>th</sup> Floor  
Newark, New Jersey 07102  
Telephone: (973) 662-3333  
Facsimile: (973) 286-2465

Deepro R. Mukerjee (deepro.mukerjee@alston.com)  
Lance A. Soderstrom (lance.soderstrom@alston.com)  
Leah W. Feinman (leah.feinman@alston.com)

**ALSTON & BIRD LLP**

90 Park Avenue  
New York, NY 10016  
(212) 210-9400

*Attorneys for Defendants InnoPharma Licensing, Inc.,  
InnoPharma Licensing LLC, InnoPharma, Inc.,  
and InnoPharma, LLC*

**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,

v.

INNOPHARMA LICENSING, INC.,  
INNOPHARMA LICENSING LLC,  
INNOPHARMA, INC., INNOPHARMA,  
LLC, MYLAN PHARMACEUTICALS INC.,  
and MYLAN INC.,

Defendants.

Civil Action No.:  
1:15-cv-03240-JBS-KMW

**Document Filed Electronically**

**ANSWER, SEPARATE DEFENSES AND COUNTERCLAIMS OF  
DEFENDANTS INNOPHARMA LICENSING, INC., INNOPHARMA LICENSING LLC,  
INNOPHARMA, INC., AND INNOPHARMA LLC**

Defendants InnoPharma Licensing, Inc., InnoPharma Licensing LLC, InnoPharma, Inc., and InnoPharma, LLC (collectively “InnoPharma” or “Defendants”), by and through their counsel, hereby answer the Complaint of Plaintiffs Senju Pharmaceutical Co., Ltd., Bausch & Lomb Inc., and Bausch & Lomb Pharma Holdings Corp. (collectively, “Plaintiffs”) and assert their separate defenses and counterclaims 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.

**ANSWER:** Defendants lack knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraph 1 of the Complaint and therefore deny them.

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>.

**ANSWER:** Defendants aver that the Orange Book as of the date of this answer currently lists B+L as the purported registered holder of New Drug Application (“NDA”) No. 203168, which purportedly covers Prolensa<sup>®</sup>. Defendants lack knowledge or information sufficient to form a belief as to the truth of the remaining allegations in Paragraph 2 of the Complaint and therefore deny them.

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.

**ANSWER:** Defendants lack knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraph 3 of the Complaint and therefore deny them.

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 (*sic*), New Jersey 08854.

**ANSWER:** Admitted, with the proviso that the township in which InnoPharma Licensing, Inc.'s principle place of business is located is named "Piscataway," not "Picastaway."

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 (*sic*), New Jersey 08854.

**ANSWER:** Admitted, with the proviso that the township in which InnoPharma Licensing LLC's principle place of business is located is named "Piscataway," not "Picastaway."

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 (*sic*), New Jersey 08854.

**ANSWER:** Admitted, with the proviso that the township in which InnoPharma, Inc.'s principle place of business is located is named "Piscataway," not "Picastaway."

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 (*sic*), New Jersey 08854.

**ANSWER:** Admitted, with the proviso that the township in which InnoPharma, LLC's principle place of business is located is named "Piscataway," not "Picastaway."

8. Upon information and belief, defendant Mylan Pharmaceuticals, Inc. is a company organized and existing under the laws of West Virginia, having a principal place of business at 781 Chestnut Ridge Road, Morgantown, West Virginia 26505. Upon information and belief, Mylan Pharmaceuticals, Inc. is a wholly-owned subsidiary of Mylan Inc. Upon information and belief, Mylan Pharmaceuticals, Inc. is registered to do business in New Jersey and has appointed Corporation Service Company, 830 Bear Tavern Road, West Trenton, New Jersey, as its registered agent for the receipt of service of process.

**ANSWER:** As Mylan Pharmaceuticals Inc. has been dismissed from this litigation (ECF No. 13), no answer is required to this Paragraph.

9. Upon information and belief, defendant Mylan Inc. is a company organized and existing under the laws of the Commonwealth of Pennsylvania, having a principal place of business at 1500 Corporate Drive, Canonsburg, Pennsylvania 15317. Upon information and belief, Mylan Inc. is registered to do business in New Jersey and has appointed Corporation Service Company, 830 Bear Tavern Road, West Trenton, New Jersey, as its registered agent for the receipt of service of process.

**ANSWER:** As Mylan Inc. has been dismissed from this litigation (ECF No. 13), no answer is required to this Paragraph.

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

10. This is an action for infringement of United States Patent No. 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") against Mylan and for infringement of the '606 patent against InnoPharma, 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 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% (“InnoPharma Licensing, Inc.’s generic bromfenac ophthalmic solution”).

**ANSWER:** As Mylan Inc. and Mylan Pharmaceuticals Inc. (collectively, “Mylan”) have been dismissed from this litigation (ECF No. 13), no answer is required to the allegations in this Paragraph relating to Mylan. Defendants admit that Plaintiffs’ Complaint purports to state an action for patent infringement. Defendants further admit that the Complaint filed by Plaintiffs purports to state an action relating to an Abbreviated New Drug Application (“ANDA”) No. 206326 purportedly filed by InnoPharma Licensing, Inc. with the United States Food and Drug Administration (“FDA”). To the extent an answer to any factual allegation not otherwise addressed herein is required, Defendants deny said allegation.

#### **JURISDICTION AND VENUE**

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

**ANSWER:** For the purposes of this action only, Defendants do not contest subject matter jurisdiction pursuant to 28 U.S.C. §§ 1331 and 1338(a). To the extent an answer to any factual allegation not otherwise addressed herein is required, Defendants deny said allegation.

12. 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

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