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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., and INNOPHARMA,
LLC,

Defendants.

Civil Action No.:
1:14-cv-06893-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 Incorporated, 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 (“NDA”) No. 203168, which covers Prolensa[®].

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[®]. 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 700 Route 202/206, 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.

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.

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.

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.

NATURE OF THE ACTION

8. 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”), 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 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: 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

9. 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.

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 (sic), New Jersey 08854,

and has thereby purposefully and systematically conducted and continues to conduct business in this judicial district.

ANSWER: To conserve the resources of the parties and the Court, InnoPharma Licensing, Inc. does not contest personal jurisdiction in this judicial district for the limited purpose of this action only and for the limited purpose of the product covered by ANDA No. 206326 which is the subject of the Complaint. InnoPharma Licensing, Inc. denies the remaining allegations in Paragraph 10 of the Complaint.

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, LLC operates as a patent owner or lessor for InnoPharma, LLC, whose principal place of business is, on information and belief, at 10 Knightsbridge Road, Picastaway (sic), New Jersey 08854, and has thereby purposefully and systematically conducted and continues to conduct business in this judicial district.

ANSWER: To conserve the resources of the parties and the Court, InnoPharma Licensing, LLC does not contest personal jurisdiction in this judicial district for the limited purpose of this action only and for the limited purpose of the product covered by ANDA No. 206326 which is the subject of the Complaint. InnoPharma Licensing, LLC denies the remaining allegations in Paragraph 11 of the Complaint.

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