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June 12, 2015

CONFIDENTIAL

VIA FEDEX OVERNIGHT DELIVERY[1]

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SENJU PHARMACEUTICAL CO., LTD.
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President & CEO
BAUSCH & LOMB PHARMA HOLDINGS CORP.
700 Route 202/206 North
Bridgewater, NJ 08807

President & CEO
BAUSCH & LOMB INCORPORATED
1400 North Goodman Street
Rochester, NY 14609

Re: ANDA No. 206326 (Bromfenac) Notification of Certification of Noninfringement and/or Invalidity for U.S. Patent No. 8,871,813 Pursuant to § 505(j)(2)(B)(ii) of the U.S. Federal Food, Drug and Cosmetic Act

To whom it may concern:

We represent Innopharma Licensing, Inc. ("Innopharma") in connection with this letter and in connection with any litigation that ensues therefrom. Pursuant to Section 505(j)(2)(B)(ii) of the Federal Food, Drug and Cosmetic Act and 21 C.F.R. § 314.95, Innopharma hereby provides notice that today it has amended Abbreviated New Drug Application No. 206326 ("ANDA") certifying, as described in 21 C.F.R.

is invalid, unenforceable, and/or will not be infringed by the manufacture, use, sale, offer for sale, or importation of Innopharma's Bromfenac Product as defined by Innopharma's ANDA No. 206326.

Innopharma's ANDA is for a generic drug product having the established name PROLENSA™. The active ingredient in the proposed drug product is bromfenac, which is present in the PROLENSA™ ophthalmic solution product in the form of bromfenac sodium sesquihydrate. PROLENSA™ is supplied as a sterile, aqueous 0.07% solution with a pH of 7.8.

The United States Food and Drug Administration ("FDA") has accepted Innopharma's ANDA for filing and has assigned the application No. 206326. The ANDA contains the required bioavailability and/or bioequivalence data from studies on Innopharma's Bromfenac Product that is the subject of the ANDA.

Innopharma originally submitted its ANDA under 21 U.S.C. § 355(j)(1) and (2)(A) with Paragraph IV certifications to U.S. Patent Nos. 8,129,431 ("the '431 patent") and the 8,669,290 ("the '290 patent"). On September 19, 2014, Innopharma sent to Senju Pharmaceuticals and Bausch & Lomb written notification of its Paragraph IV certification and a detailed statement of its then-existing factual and legal bases of Innopharma's belief that each of the '431 and '290 patents is invalid, unenforceable, or will not be infringed by the manufacture, use, sale, offer for sale, or importation of the drug product described in Innopharma's ANDA. On October 30, 2014, Innopharma sent to Senju Pharmaceuticals and Bausch & Lomb written notification of its amendment to Innopharma's ANDA to further include a Paragraph IV certification to U.S. Patent No. 8,754,131 ("the '131 patent") and a detailed statement of its then-existing factual and legal bases of Innopharma's belief that the '131 patent is invalid, unenforceable, or will not be infringed by the manufacture, use, sale, offer for sale, or importation of the drug product described in Innopharma's ANDA. On March 25, 2015, Innopharma sent to Senju Pharmaceuticals and Bausch & Lomb, written notification of its amendment to Innopharma's ANDA to further include a Paragraph IV certification to U.S. Patent No. 8,927,606 ("the '606 patent") and a detailed statement of its then-existing factual and legal bases of Innopharma's belief that the '606 patent is invalid, unenforceable, or will not be infringed by the manufacture, use, sale, offer for sale, or importation of the drug product described in Innopharma's ANDA. Innopharma has amended its ANDA under 21 C.F.R. § 314.94(a)(12)(vi) to further include a Paragraph IV certification to the '813 patent, which lists as an issuance date on its face of October 28, 2014. Each of the '431, '290, '131, '606, and '813 patents is listed in Approved Drug Products with Therapeutic Equivalence Evaluations ("the Orange Book") in connection with

additionally alleges and has certified to the FDA that, to the best of Innopharma's knowledge, the '131 and '606 patents are invalid, unenforceable, and/or will not be infringed by the manufacture, use, sale, offer for sale, or importation of the drug product described in Innopharma's ANDA. Further, Innopharma additionally alleges and has certified to the FDA that, to the best of Innopharma's knowledge, the '813 patent is invalid, unenforceable, and/or will not be infringed by the manufacture, use, sale, offer for sale, or importation of the drug product described in Innopharma's ANDA. With regard to the '813 patent, according to the FDA's Orange Book:

- the '813 patent will expire on January 16, 2024.

Attached as Exhibit A is a detailed statement, made pursuant to 21 U.S.C. § 355(j)(2)(B)(iv)(II) and 21 C.F.R. § 314.95, of the present factual and legal bases for Innopharma's Paragraph IV certification to the '813 patent of the Orange Book Patents. The statements made therein are based on the information currently available to Innopharma. Innopharma reserves all rights to raise any additional defenses relating to invalidity, unenforceability, and/or noninfringement should additional information become known to Innopharma.

Offer of Confidential Access to ANDA

Pursuant to 21 U.S.C. § 355(j)(5)(C), this notice letter includes an Offer of Confidential ccess to Innopharma's ANDA and any supplement(s) thereto. As required by Section 55(j)(5)(C)(i)(III), Innopharma offers to provide confidential access to certain information om its ANDA No. 206326 for the sole and exclusive purpose of determining whether an ıfringement action referred to in Section 355(j)(5)(B)(iii) can be brought.

Section 355(j)(5)(C)(i)(III) allows Innopharma to impose restrictions "as to persons ıtitled to access, and on the use and disposition of any information accessed, as would apply ıd a protective order been entered for the purpose of protecting trade secrets and other ɔnfidential business information." That provision also grants Innopharma the right to redact s ANDA to exclude non-relevant information in response to a request for Confidential Access ıder this Offer.

As permitted by statute, Innopharma imposes the following terms and restrictions on its ffer of Confidential Access:

(1) Innopharma will permit confidential access to certain information from its

(2) The attorneys from the outside law firm representing B&L shall not disclose any Confidential Innopharma Information to any other person or entity, including B&L employees, outside scientific consultants, and/or other outside counsel retained by B&L, without the prior written consent of Innopharma.

(3) As provided by Section 355(j)(5)(C)(i)(III), B&L's outside law firm shall make use of the Confidential Innopharma Information for the sole and exclusive purpose of determining whether an action referred to in Section 355(j)(5)(B)(iii) can be brought and for no other purpose. By way of example only, the Confidential Innopharma Information shall not be used to prepare or prosecute any future or pending patent application by B&L in connection with any filing to, or communication with, the FDA relating to Innopharma's ANDA No. 206326. B&L's outside law firm agrees to take all measures necessary to prevent unauthorized disclosure or use of the Confidential Innopharma Information, and that all Confidential Innopharma Information shall be kept confidential and not disclosed in any manner inconsistent with this Offer of Confidential Access.

(4) The Confidential Innopharma Information disclosed is, and remains, the property of Innopharma. By providing said Confidential Innopharma Information, Innopharma does not grant B&L and/or its outside law firm any interest in or license for and to the Confidential Innopharma Information.

(5) B&L's outside law firm shall, within thirty-five (35) days from the date that it first receives the Confidential Innopharma Information, return to Innopharma all Confidential Innopharma Information and any copies thereof. B&L's outside law firm shall return all Confidential Innopharma Information to Innopharma before any infringement suit is filed by B&L, if suit is commenced before this 35-day period expires. In the event that B&L opts to file suit, none of the information contained in or obtained from any Confidential Innopharma Information that Innopharma provides, including Exhibit A to this letter, shall be included in any publicly-available complaint or other pleading.

(6) Nothing in this Offer of Confidential Access shall be construed as an admission by Innopharma regarding the validity, enforceability, and/or infringement of any U.S. patent. Further, nothing herein shall be construed as an agreement or admission by Innopharma with respect to the competency, relevance, or materiality of any such Confidential Innopharma Information, document, or

Confidential Innopharma Information. Such written acknowledgement shall be provided to the undersigned.

(8) This Offer of Confidential Access shall be governed by the laws of the State of New Jersey, USA.

Section 355(j)(5)(C)(i)(III) provides that any request for access that B&L makes under this Offer of Confidential Access "shall be considered acceptance of the offer of confidential access with restrictions as to persons entitled to access, and on the use and disposition of any information accessed, contained in [this] offer of confidential access" and that the "restrictions and other terms of [this] offer of confidential access shall be considered terms of an enforceable contract." Thus, to the extent that B&L requests access to Confidential Innopharma Information, it necessarily accepts the terms and restrictions outlined above.

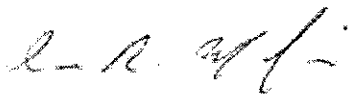
Written notice requesting access under this Offer of Confidential Access should be made to:

Deepro R. Mukerjee
Alston & Bird LLP
90 Park Avenue
New York, New York 10016
Tel: (212) 210-9400
Fax: (212) 210-9444
deepro.mukerjee@alston.com

By providing this Offer of Confidential Access, Innopharma maintains the right and ability to bring and maintain a Declaratory Judgment action under 28 U.S.C. § 2201 *et seq.*, pursuant to 21 U.S.C. § 355(j)(5)(C).

Copies of this letter and the attached exhibits are also being provided by U.S. Registered mail, return receipt requested.

Sincerely,



Deepro R. Mukerjee

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