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50 Technology Drive
Irvine, CA 92618

General Counsel
Senju Pharmaceutical Co., Ltd.
2-5-8, Hiranomachi 2-Chome, Chuo-Ku
Osaka-Shi, Osaka 541-0046, Japan

Warren M. Cheek, Jr., Esq.
Wenderoth, Lind & Ponack, L.L.P.
1030 15th St., NW, Suite 400 East
Washington, DC 20005

HIGHLY CONFIDENTIAL

Re: Notification of Certification for U.S. Patent Nos. 8,129,431, 8,669,290, 8,754,131, 8,871,813 and 8,927,606 Pursuant to § 505(j)(2)(B)(iv) of the Federal Food, Drug, and Cosmetic Act

Dear Madam or Sir:

Pursuant to § 505(j)(2)(B)(iv) of the Federal Food, Drug, and Cosmetic Act and 21 C.F.R. § 314.95, Watson Laboratories, Inc. ("Watson") hereby provides notice of the following information to: (i) Bausch & Lomb ("Bausch & Lomb"), as the apparent holder of approved New Drug Application ("NDA") No. 203168 for Prolensa™ (bromfenac sodium) Ophthalmic Solution, Eq. 0.07% Acid according to the records of the U.S. Food and Drug Administration ("FDA") and Senju Pharmaceutical Co., Ltd ("Senju"), as the record owner of U.S. Patent Nos. 8,129,431, 8,669,290, 8,754,131, 8,871,813, and 8,927,606 according to the records of the U.S. Patent and Trademark Office ("PTO") and/or the face of the patent.

As a courtesy, Watson provides a copy of this Notice Letter and Detailed Statement to Warren M. Cheek, Jr., Esq. of Wenderoth, Lind & Ponack, L.L.P. as the correspondent for U.S. Patent Nos. 8,129,431; 8,669,290; 8,754,131; 8,871,813; and 8,927,606 according to the records

I. Pursuant to 21 U.S.C. § 355(j)(2)(B)(iv)(I) and 21 C.F.R. § 314.95(c)(1), we advise you that FDA has received an Abbreviated New Drug Application ("ANDA") from Watson for Bromfenac Ophthalmic Solution, 0.07%. The ANDA contains the required bioavailability and/or bioequivalence data and/or bioequivalence waiver. The ANDA was submitted under 21 U.S.C. § 355(j)(1) and (2)(A), and contains Paragraph IV certifications to obtain approval to engage in the commercial manufacture, use or sale of Bromfenac Ophthalmic Solution, 0.07%, before the expiration of U.S. Patent Nos. 8,129,431; 8,669,290; 8,754,131; 8,871,813; and 8,927,606 which are listed in the Patent and Exclusivity Information Addendum of FDA's publication, *Approved Drug Products with Therapeutic Equivalence Evaluations* (commonly known as the "Orange Book").

II. Pursuant to 21 C.F.R. § 314.95(c)(2), we advise you that FDA has assigned Watson's ANDA the number 206085.

III. Pursuant to 21 C.F.R. § 314.95(c)(3), we advise you that the established name of the drug product that is the subject of Watson's ANDA is Bromfenac Ophthalmic Solution, 0.07%.

IV. Pursuant to 21 C.F.R. § 314.95(c)(4), we advise you that the active ingredient in the proposed drug product is bromfenac sodium; the strength of the proposed drug product is 0.07% of bromfenac; and the dosage form of the proposed drug product is ophthalmic solution.

V. Pursuant to 21 C.F.R. § 314.95(c)(5), we advise you that the patents alleged to be invalid, unenforceable, and/or not infringed in the Paragraph IV certifications are U.S. Patent Nos. 8,129,431; 8,669,290; 8,754,131; 8,871,813; and 8,927,606 which are listed in the Orange Book in connection with Bausch & Lomb's approved NDA No. 203168 for Prolensa™. According to information published in the Orange Book, the patents will expire as follows:

U.S. PATENT NO.	EXPIRATION DATE
8,129,431	September 11, 2025
8,669,290	January 16, 2024
8,754,131	January 16, 2024
8,871,813	January 16, 2024

8,927,606 are invalid, unenforceable, and/or will not be infringed by the commercial manufacture, use or sale of the drug product described in Watson's ANDA. Therefore, pursuant to 21 U.S.C. § 355(j)(2)(B)(iv)(II) and 21 C.F.R. § 314.95(c)(6), Watson's detailed statement of the legal and factual basis for the Paragraph IV certifications set forth in Watson's ANDA is attached hereto and made a part hereof.

VII. Pursuant to 21 U.S.C. § 355(j)(5)(C), this notice letter includes an Offer of Confidential Access to Application. As required by § 355(j)(5)(C)(i)(III), Watson offers to provide confidential access to certain information from its ANDA No. 206085 for the sole and exclusive purpose of determining whether an infringement action referred to in § 355(j)(5)(B)(iii) can be brought.

Section 355(j)(5)(C)(i)(III) allows Watson to impose restrictions "as to persons entitled to access, and on the use and disposition of any information accessed, as would apply had a protective order been entered for the purpose of protecting trade secrets and other confidential business information." That provision also grants Watson the right to redact its ANDA in response to a request for Confidential Access under this offer.

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

(1) Watson will permit confidential access to certain information from its proprietary ANDA No. 206085 to attorneys from one outside law firm representing Bausch & Lomb and one outside law firm representing Senju, provided however that such attorneys do not engage, formally or informally, in any patent prosecution for Bausch & Lomb or Senju or any FDA counseling, litigation or other work before or involving FDA. Such information (hereinafter, "Confidential Watson Information") shall be marked with the legend "CONFIDENTIAL."

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

(3) As provided by § 355(j)(5)(C)(i)(III), the outside law firms representing Bausch & Lomb or Senju shall make use of the Confidential Watson Information for the sole and exclusive purpose of determining whether an action referred to in § 355(j)(5)(B)(iii) can be brought — and for no other purpose. By way of

Watson Information, and that all Confidential Watson Information shall be kept confidential and not disclosed in any manner inconsistent with this Offer of Confidential Access.

(4) The Confidential Watson Information disclosed is, and remains, the property of Watson. By providing the Confidential Watson Information, Watson does not grant Bausch & Lomb or Senju and/or their outside law firms any interest in or license for the Confidential Watson Information.

(5) The outside law firms representing Bausch & Lomb or Senju shall, within thirty-five (35) days from the date that it first receives the Confidential Watson Information, return to Watson all Confidential Watson Information and any copies thereof. Said outside law firm shall return all Confidential Watson Information before any infringement suit is filed by Bausch & Lomb and/or Senju, if suit is commenced before this 35-day period expires. In the event that Bausch & Lomb and/or Senju opts to file suit, none of the information contained in or obtained from any Confidential Watson Information that Watson provides 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 Watson regarding the validity, enforceability, and/or infringement of any U.S. patent. Further, nothing herein shall be construed as an agreement or admission by Watson with respect to the competency, relevance, or materiality of any such Confidential Watson Information, document, or thing. The fact that Watson provides Confidential Watson Information upon request of Bausch & Lomb or Senju shall not be construed as an admission by Watson that such Confidential Watson Information is relevant to the disposition of any issue relating to any alleged infringement of or to the validity or enforceability of U.S. Patent Nos. 8,129,431; 8,669,290; 8,754,131; 8,871,813; and 8,927,606.

(7) The attorneys from the outside law firms representing Bausch & Lomb or Senju shall acknowledge in writing their receipt of a copy of these terms and restrictions prior to production of any Confidential Watson Information. Such written acknowledgement shall be provided to Watson.

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

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

Brian Anderson, Esq.
Morris Corporate Center III
400 Interpace Parkway
Parsippany, NJ 07054
(862) 261-8406
brian.anderson@actavis.com

By providing this Offer of Confidential Access to Application, Watson 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).

Very truly yours,

Watson Laboratories, Inc.

By: Joyce Anne Delgaudio
Executive Director, Regulatory Affairs

Enclosure: *Watson's Detailed Factual and Legal Basis for Its Paragraph IV Certifications that U.S. Patent Nos. 8,129,431, 8,669,290, 8,754,131, 8,871,813, and 8,927,606 are Invalid, Unenforceable and/or Not Infringed by the Bromfenac Product Described in Watson's ANDA No. 206085*

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