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May 13, 2014

Via FedEx® Priority Overnight Service

Bausch & Lomb, Inc.
50 Technology Drive
Irvine, CA 92618

Valeant Pharmaceuticals International, Inc.
2150 St. Elzéar Blvd. West
Laval, Quebec H7L 4A8
Canada

HIGHLY CONFIDENTIAL[1]

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

Re: Notification of Certification of Invalidity, Unenforceability, and/or Noninfringement for U.S. Patent No. 8,669,290 Pursuant to § 505(j)(2)(B)(ii) and (iv) of the Federal Food, Drug, and Cosmetic Act[2]

Dear Madam or Sir:

Pursuant to § 505(j)(2)(B)(ii) and (iv) of the Federal Food, Drug, and Cosmetic Act and 21 C.F.R. § 314.95, we hereby provide notice on behalf of Lupin Limited ("Lupin") of the following information to Bausch & Lomb, Inc. ("Bausch & Lomb"), as the purported holder of approved New Drug Application ("NDA") No. 203168 for Prolensa® Bromfenac Ophthalmic Solution 0.07%, according to the records of the U.S. Food and Drug Administration ("FDA"). In addition, Lupin provides notice to Senju Pharmaceutical Co., Ltd. ("Senju") as the purported assignee of U.S. Patent No. 8,669,290, according to the electronic records of the United States Patent and Trademark Office ("PTO").

As a courtesy, Lupin also provides a copy of this Notice Letter and detailed statement to

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1 You are not authorized to attach this Notice Letter and detailed statement to any court pleading (unless filed under seal) or to attach this Notice Letter and detailed statement to any other document that is publicly disclosed.

2 Lupin Limited previously provided its notice letter and detailed statement regarding its Paragraph IV certification that U.S. Patent No. 8,129,431 is invalid, unenforceable and/or not infringed.

Valeant Pharmaceuticals International, Inc., which reportedly acquired Bausch & Lomb in 2013.

Pursuant to 21 C.F.R. § 314.95(e), permission from FDA to send this Notice Letter by means other than registered or certified mail was requested and received. Specifically, permission to send this notice by FedEx® was requested. FDA granted this request prior to this notice being sent. Consequently, the operative date for determining the start of the 45-day clock under 21 U.S.C. § 355(j)(5)(B)(iii) begins from the receipt of this Notice Letter sent via FedEx®.

I. Pursuant to 21 U.S.C. § 355(j)(2)(B)(iv)(I) and 21 C.F.R. § 314.95(c)(1), Lupin advises that FDA has received an Amendment to an Abbreviated New Drug Application ("ANDA") from Lupin for Bromfenac Ophthalmic Solution 0.07%. The ANDA contains the required bioavailability and/or bioequivalence data and/or bioequivalence waiver. The Amendment to the ANDA was submitted under 21 U.S.C. §§ 355(j)(1) and (2)(A), and contains a Paragraph IV certification 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 No. 8,669,290, which is 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 the ANDA submitted by Lupin is assigned the number 206027 by FDA.

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

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

V. Pursuant to 21 C.F.R. § 314.95(c)(5), Lupin advises that the patent alleged to be invalid, unenforceable and/or not infringed in the Paragraph IV certification is Senju's U.S. Patent No. 8,669,290, which is now listed in the Orange Book in connection with Bausch & Lomb's approved NDA No. 203168 for Prolensa® (Bromfenac Ophthalmic Solution 0.07%).

According to information submitted for listing in the Orange Book, U.S. Patent No. 8,669,290 will purportedly expire on or about January 16, 2024.

VI. Lupin alleges, and has certified to FDA, that in Lupin's opinion and to the best of its knowledge, U.S. Patent No. 8,669,290 is invalid, unenforceable and/or will not be infringed by the commercial manufacture, use or sale of the drug products described in Lupin's ANDA. Therefore, pursuant to 21 U.S.C. § 355(j)(2)(B)(iv)(II) and 21 C.F.R. § 314.95(c)(6), Lupin's detailed statement of the legal and factual basis for the Paragraph IV certification set forth in Lupin's ANDA is attached hereto and made part hereof. Lupin reserves the right to demonstrate

additional grounds, reasons and authorities that the claims of the '290 patent are invalid, unenforceable, and/or not infringed.

VII. Pursuant to 21 C.F.R. § 314.95(c)(7), the name and address of an agent in the United States authorized to accept service of process for Lupin, limited to commencement of a patent infringement suit based on this notification of certification, is:

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VIII. 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), Lupin offers to provide confidential access to certain information from its ANDA No. 206027 for the sole and exclusive purpose of determining whether an infringement action referred to in §355(j)(5)(B)(iii) for a patent listed in the Orange Book for NDA No. 203168 can be brought.

Section 355(j)(5)(C)(i)(III) allows Lupin 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 Lupin the right to redact its ANDA in response to a request for Confidential Access under this offer.

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

(1) Lupin will permit confidential access to certain information from its proprietary ANDA No. 206027 to attorneys from one outside law firm representing Bausch & Lomb and/or 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 Lupin Information") shall be marked with the legend "CONFIDENTIAL."

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

(3) As provided by § 355(j)(5)(C)(i)(III), the designated outside law firm representing Bausch & Lomb and/or Senju shall make use of the Confidential Lupin 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 example only, the Confidential Lupin Information shall not be used to prepare or prosecute any future or pending

patent applications by Bausch & Lomb or Senju, or in connection with any filing to, or communication with, FDA or the United States Pharmacopeia or any similar or related organization relating to Lupin's ANDA No. 206027. The outside law firm for Bausch & Lomb and/or Senju agrees to take all measures necessary to prevent unauthorized disclosure or use of the Confidential Lupin Information, and that all Confidential Lupin Information shall be kept confidential and not disclosed in any manner inconsistent with this Offer of Confidential Access.

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

(5) The designated outside law firm representing Bausch & Lomb and/or Senju shall, within thirty-five (35) days from the date that it first receives the Confidential Lupin Information, return to Lupin all Confidential Lupin Information and any copies thereof. The outside law firm of Bausch & Lomb and/or Senju shall return all Confidential Lupin Information to Lupin 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 Lupin Information that Lupin 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 Lupin regarding the validity, enforceability, and/or infringement of any U.S. patent. Further, nothing herein shall be construed as an agreement or admission by Lupin with respect to the competency, relevance, or materiality of any such Confidential Lupin Information, document, or thing. The fact that Lupin provides Confidential Lupin Information upon request of Bausch & Lomb and/or Senju shall not be construed as an admission by Lupin that such Confidential Lupin Information is relevant to the disposition of any issue relating to any alleged infringement of U.S. Patent No. 8,669,290, or to the validity or enforceability of that patent.

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

(8) If Confidential Lupin Information is disclosed by the designated outside law firm representing Bausch & Lomb and/or Senju to any person not authorized to receive such Confidential Lupin Information pursuant to this Offer of Confidential Access, then the designated outside law firm representing Bausch & Lomb and/or Senju must immediately bring all pertinent facts relating to such disclosure to the attention of Lupin and, without prejudice to other rights and remedies of Lupin, make every effort to prevent further disclosure by it or by the person who was the recipient of such Confidential Lupin Information.

Section 355(j)(5)(C)(i)(III) provides that any request for access that Bausch & Lomb and/or Senju makes under this Offer of Confidential Access "shall be considered acceptance of the offer of confidential access with the 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 Bausch & Lomb and/or Senju requests access to Confidential Lupin Information, they necessarily accept the terms and restrictions outlined above. Written notice requesting access under this Offer of Confidential Access should be made to:

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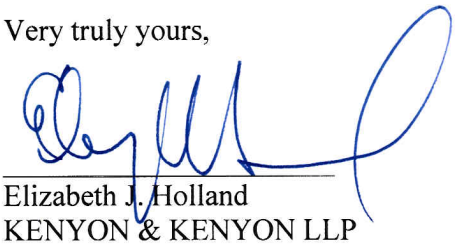
By providing this Offer of Confidential Access, Lupin maintains the right and ability to bring and maintain a Declaratory Judgment action under 28 U.S.C. §§ 2201 *et seq.*, pursuant to 21 U.S.C. § 355(j)(5)(C).

Very truly yours,



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Counsel for Lupin Limited

Enclosure: Lupin Limited's Detailed Factual and Legal Bases for Its Opinion That U.S. Patent No. 8,669,290 Is Invalid, Unenforceable and/or Not Infringed by the Manufacture, Use or Sale of Lupin Limited's Proposed Bromfenac Ophthalmic Solution 0.07%

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