APOTEX
ADVANCING GENERICS

December 10, 2014

VIA FEDERAL EXPRESS

Senju Pharmaceutical Co., Inc.
Attention: Chief Executive Officer
2-5-8 Hirano-machi
Chuo-ku
Osaka, 541-0046 Japan

Bausch & Lomb, Inc.
Attention: Chief Executive Officer
1400 North Goodman Street
Rochester, New York 14609

Senju USA Inc.
Attention: Chief Executive Officer
21700 Oxnard Street, #940
Woodland Hills, California 91367

Bausch & Lomb Pharma Holdings Corp.
Attention: Chief Executive Officer
700 Route 202/206
Bridgewater, New Jersey 08807

Confidential Notice: This Letter contains Apotex's proprietary information. Apotex considers this information a trade secret. You are not authorized to append this Letter to any court pleading (unless under seal) or any other public disclosure. *See In Re Gabapentin Patent Litigation*, 312 F.Supp.2d 653, 667 (D.N.J. 2004); 21 C.F.R. 314.430(b)-(d); *Southwestern Energy v. Eickenhorst*, 955 F.Supp. 1078, 1085 (W.D. Ark. 1997), *aff'd*, 175 F.3d 1025 (8th Cir. 1999) (regarding the penalties for public disclosure of proprietary information); 18 U.S.C.A. 1832 (Federal Economic Espionage Act.)

Dear Sir / Madam:

Re: Notice of Certification Under 21 U.S.C. § 355(j)(2)(B)(ii) (§ 505(j)(2)(B)(ii) of the Federal Food, Drug and Cosmetic Act) and 21 C.F.R. § 314.95

Pursuant to subsection 505(j)(2)(B) of the *Federal Food, Drug and Cosmetic Act*, ("the Act"), Apotex Inc. (hereinafter "Apotex") is providing Notice of the following information to you, as the holder of New Drug Application (NDA) number N203168 for PROLENSA® (bromfenac sodium) 0.07% ophthalmic solution/drops, or as the patent owner and/or assignee thereof of the listed patents, U.S. 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") listed in the FDA's *Approved Drug Products With Therapeutic Equivalence Evaluations* ("the FDA's Orange Book") associated with PROLENSA®.

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 the FDA has received an Abbreviated New Drug Application ("ANDA") from Apotex for Apotex's Bromfenac sodium 0.07% ophthalmic solution/drops ("the Apotex Product"). 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 a paragraph IV certification to obtain approval to engage in the commercial manufacture, use or sale of the Apotex Product, before the expirations of the '431, '290, '131, and '813 patents which are listed in the Patent and Exclusivity Information Addendum of the FDA's Orange Book.

Pursuant to 21 C.F.R. § 314.95(c)(2), we advise you that the ANDA submitted by Apotex has been assigned the number 20-7334 by the FDA.

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 Apotex's ANDA is Bromfenac ophthalmic solution (0.07%).

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

Pursuant to 21 C.F.R. § 314.95(c)(5), we advise you that the patents alleged to be invalid and/or not infringed in the paragraph IV certification are the '431, '290, '131, and '813 patents, which are listed in the FDA's Orange Book in connection with NDA N203168 for PROLENSA® (bromfenac) 0.07% ophthalmic solution/drops.

According to the electronic records of the FDA's Orange Book, the '431 patent will expire on or about September 11, 2025; the '290, '131 and '813 patents will expire on or about January 16, 2024.

Apotex alleges, and has certified to the FDA, that in Apotex's opinion and to the best of its knowledge, the '431, '290, '131 and '813 patents are each invalid, unenforceable and/or will not be infringed by the commercial manufacture, use or sale of the drug product described in Apotex's ANDA. Therefore, pursuant to 21 U.S.C. § 355(j)(2)(B)(iv)(II) and 21 C.F.R. § 314.95(c)(6), Apotex's detailed statement of the legal and factual basis for the paragraph IV certification set forth in Apotex's ANDA is attached hereto and made a part hereof.

A detailed statement of the factual and legal bases of our opinion that the claims of the '431, '290, '131, and '813 patents are invalid, unenforceable and/or will not be infringed follows and is made part hereof. In addition, Apotex reserves the right to demonstrate additional factual and legal bases concerning non-infringement, invalidity, or unenforceability should future information so warrant.

Service of Process and Courtesy Copies:

The following person is authorized to accept service of process for any patent infringement complaint that may result from this notification (and limited to such a complaint only):

Mr. Kiran Krishnan
Vice-President, U.S. Regulatory Affairs
Apotex Corp.
2400 N. Commerce Parkway
Weston, FL 33326
Tel: (954) 384-8007

As a professional courtesy, please send a copy of any such complaint:

Mr. Robert Shapiro, Esq.
Senior Global Lead Patent Attorney
Global Intellectual Property Dept.
Apotex Inc.
150 Signet Drive
Toronto, Ontario, Canada M9L 1T9
Tel: (416) 401-7311

Reservation of Legal Right

Apotex reserves the right to assert the same, similar, different or new theories of non-infringement, invalidity and/or unenforceability and nothing in this Notice Letter or Detailed Statement shall be construed as to limit Apotex's right to make any allegation in any subsequent litigation regarding any issue.

Yours very truly,
Apotex Inc.

Dr. Ross Maclean
Senior Vice-President, Scientific & Regulatory Affairs
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I. Detailed Statement For ANDA 20-7334

A. Introduction

Pursuant to 21 U.S.C. § 355(j)(2)(B)(iv)(II) and 21 C.F.R. § 314.95(c)(6), this document is the detailed factual and legal bases for the paragraph IV certification of Apotex that, in its opinion and to the best of its knowledge, the claims of the '431, '290, '131, and '813 patents are invalid, unenforceable and/or will not be infringed by the commercial manufacture, use or sale of the drug product described in Apotex's ANDA 20-7334. Apotex reserves the right to raise additional factual and legal bases concerning non-infringement, invalidity, and/or unenforceability in any litigation or other proceeding.

A.1 The Apotex ANDA Product

The Apotex ANDA Product is an ophthalmic solution/drops containing as active ingredient bromfenac. The strength of the proposed ANDA product is 0.07%.

B. Legal Standards

B.1 Claim Construction

It is a "bedrock principle" of patent law that "the claims of a patent define the invention to which the patentee is entitled the right to exclude." *Phillips v. AWH Corp.*, 415 F.3d 1303, 1312 (Fed. Cir. 2005). The first step, claim construction, "is simply a way of elaborating the normally terse claim language in order to understand and explain, but not to change, the scope of the claims." *DeMarini Sports, Inc. v. Worth, Inc.*, 239 F.3d 1314, 1322 (Fed. Cir. 2001) (citation omitted).

The words of a claim "are generally given their ordinary and customary meaning," *i.e.*, the meaning that the term would have to a person of ordinary skill in the art in question as of the effective filing date of the patent application. *Phillips*, 415 F.3d at 1312-13 (citations omitted). Because the meaning of a claim term as understood by persons of skill in the art is often not immediately apparent, and because patentees frequently use terms idiosyncratically, courts look to "those sources available to the public that show what a person of skill in the art would have understood disputed claim language to mean," which include "the words of the claims themselves, the remainder of the specification, the prosecution history, and extrinsic evidence concerning relevant scientific principles, the meaning of technical terms, and the state of the art." *Phillips*, 415 F.3d at 1314 (citations omitted).

When construing a patent claim, a court first analyzes the intrinsic evidence of record—the claims, the specification, and the prosecution history, as such evidence is the most significant source of the legally operative meaning of a claim. *Phillips*, 415 F.3d at 1314-17; *Markman v. Westview Instruments Inc.*, 52 F.3d 967, 980 (Fed. Cir. 1995) (en banc), *aff'd* 517 U.S. 370 (1996). While "words in a claim are generally given their ordinary and customary meaning, a[n] applicant may choose to be his own lexicographer and use terms in a manner other than their ordinary meaning, as long as the special definition is

clearly stated in the patent specification or file history." *Vitronics Corp. v. Conceptronic, Inc.*, 90 F.3d 1576, 1582 (Fed. Cir. 1996); *Phillips*, 415 F.3d at 1316.

The Federal Circuit has recognized that a court construing a patent claim may also utilize extrinsic evidence, such as expert testimony and technical dictionaries. *Phillips*, 415 F.3d at 1317. While extrinsic evidence on the issue of claim construction may be referenced, the Federal Circuit has held that it is "less significant than the intrinsic record in determining 'the legally operative meaning of claim language.'" *Id.* On several occasions, the Federal Circuit has admonished courts construing patent claims for relying on extrinsic evidence because it "poses the risk that [the extrinsic evidence] will be used to change the meaning of claims in derogation of the 'indisputable public records consisting of the claims, the specification and the prosecution history,' thereby undermining the public notice function of patents." *Id.* at 1319 (citation omitted). Likewise, extrinsic evidence may not correct errors, erase limitations, or otherwise diverge from the description of the invention as contained in the patent documents. *Aqua-Aerobic Sys., Inc. v. Aerators, Inc.*, 211 F.3d 1241, 1245 (Fed. Cir. 2000).

A patentee cannot recapture in litigation claim scope surrendered, either by amendment or argument, during the prosecution of the patent. *Pharmacia & Upjohn Co. v. Mylan Pharms., Inc.*, 170 F.3d 1373, 1376-77 (Fed. Cir. 1999). Because "[c]laims may not be construed one way in order to obtain their allowance and in a different way against accused infringers," *Southwall Techs., Inc. v. Cardinal IG Co.*, 54 F.3d 1570, 1576 (Fed. Cir. 1995), if a claim must be construed in a particular way to make the claimed subject matter patentable, it cannot be construed differently to cover an accused device if that construction would simultaneously include the prior art. This principle prevents a patentee from claiming that its patent claims cover subject matter for which the PTO was unwilling to issue a patent. It also gives courts guidance as to what claims or claim elements warrant a narrow scope. When a patentee urges a court to broadly construe or effectively "read out" claim limitations which, if so broadly construed or eliminated, would fail to differentiate a claim from the prior art, courts have a basis for rejecting such claim constructions. *Id.* at 1580-82; *DeMarini*, 239 F.3d at 1332.

B.2. Infringement Analysis

The first step to determining whether infringement exists is to construe the patent claim language. Second, the properly construed claims are compared to the accused product or process to determine whether it falls within the scope of the claims. *Markman v. Westview Instruments, Inc.*, 52 F.3d 967, 976 (Fed. Cir. 1995), *aff'd*, 517 U.S. 370 (1996).

Literal infringement of a patent claim requires that the accused product contain each limitation of the claim. *Litton Sys., Inc. v. Honeywell, Inc.*, 140 F.3d 1149, 1454 (Fed. Cir. 1998). Each limitation of the claim is essential; if one or more limitations or its equivalent cannot be found in the accused product or process, the claim is not infringed. *London v. Carson Pirie Scott & Co.*, 946 F.2d 1534, 1538-39 (Fed. Cir. 1991).

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