June 26, 2014

**VIA FEDERAL EXPRESS**

Chief Executive Officer
Bausch & Lomb Incorporated
1400 North Goodman St.
Rochester, NY 14609

**Re: Notification Pursuant to § 505(j)(2)(B)(ii) of the Federal Food, Drug, and Cosmetic Act for U.S. Patent Nos. 8,129,431 and 8,669,290**

Dear Sir/Madam:

We represent Coastal Pharmaceuticals, Inc. ("Coastal"). Coastal is providing notice of the following information pursuant to Section 505(j)(2)(B)(ii) of the Federal Food, Drug, and Cosmetic Act ("the Act"):

1. In order to obtain approval to engage in the commercial manufacture, use, importation, offer for sale or sale of bromfenac sodium ophthalmic solution, 0.07%, Coastal submitted to the Food and Drug Administration ("FDA") an Abbreviated New Drug Application ("ANDA''), which contains the required bioavailability or bioequivalence data or information.

2. The ANDA number is 206257.

3. The established name of the proposed drug product that is the subject of Coastal's ANDA is bromfenac sodium ophthalmic solution, 0.07%, marketed by Bausch & Lomb Incorporated ("B&L") under the name PROLENSA®.

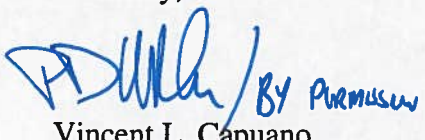
4. The active ingredient in the proposed drug product that is the subject of Coastal's ANDA No. 206257 is bromfenac sodium; the strength of the proposed drug

and listed in the publication entitled *Approved Drug Products with Therapeutic Equivalence Evaluation* ("Orange Book"). According to the Orange Book, the '431 patent expires on September 11, 2025 and the '290 patent expires on January 16, 2024.

Coastal contends, as provided in its certifications to FDA, that the claims of the '431 patent and the '290 patent are invalid, unenforceable, and/or will not be infringed by the commercial manufacture, use, importation, offer for sale, or sale of the proposed drug product that is the subject of Coastal's ANDA. Pursuant to 21 U.S.C. § 355(j)(2)(B)(iv)(II) and 21 C.F.R. § 314.95(c)(6), a detailed statement of the factual and legal bases for the Paragraph IV certifications contained in Coastal's ANDA No. 206257 with respect to the Orange Book Patents is attached hereto as Appendix A. This information is supplied for the sole purpose of complying with the above-referenced statutes and regulations. Coastal reserves the right to challenge the infringement, validity and/or enforceability of the Orange Book Patents on other and further grounds, should such grounds appear during any ensuing litigation.

Pursuant to 21 C.F.R. § 314.95(e), Coastal requested and received from FDA permission to send this notice by means other than registered or certified mail. Specifically, Coastal requested that it be allowed to send this notice by FedEx®. FDA granted Coastal's 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) began from the receipt of this notice, as sent via FedEx®.

Sincerely,



Vincent L. Capuano

This document is the detailed factual and legal basis for Coastal's certification that, in its opinion and to the best of its knowledge, U.S. Patent Nos. 8,129,431 ("the '431 patent") and 8,669,290 ("the '290 patent") (collectively, the "Orange Book Patents") are invalid, unenforceable, and/or will not be infringed by the commercial manufacture, use, or sale of the drug product described in Coastal's ANDA. The right to raise additional noninfringement, invalidity, and unenforceability defenses is expressly reserved.

## II. COASTAL'S ANDA PRODUCT

Coastal's ANDA Product consists of an ophthalmic solution containing bromfenac sodium as the active pharmaceutical ingredient (0.07%). Coastal seeks approval for the use of its ANDA Product for the treatment of postoperative inflammation and reduction of ocular pain in patients who have undergone cataract surgery.

The composition of Coastal's ANDA Product may be disclosed pursuant to the terms set forth in the Offer of Confidential Access attached hereto as **APPENDIX B**.

## III. THE ORANGE BOOK LISTED PATENTS

The Orange Book listing for PROLENSA® (Bromfenac Sodium Ophthalmic Solution, 0.07%) contains the following patents:

| U.S. Patent No. | Expiration Date |
|---|---|
| 8,129,431 | September 11, 2025 |
| 8,669,290 | January 16, 2024 |

## IV. GOVERNING LAW

### A. Claim Construction

A court must first construe claims before determining whether they are valid or infringed. *Amazon.com, Inc. v. Barnesandnoble.com, Inc.*, 239 F.3d 1343, 1351 (Fed. Cir. 2001); *Markman v. Westview Instruments, Inc.*, 52 F.3d 967, 976, 996 n. 7 (Fed. Cir. 1995) (*en banc*). Claims must be construed the same way for determining validity and infringement. *Id.*

The claim construction inquiry begins in all cases with the actual words of the claims. *Phillips v. AWH Corp.*, 415 F.3d 1303, 1312 (Fed. Cir. 2005) (*en banc*). Claim terms are to be given their ordinary and customary meanings as they would have been understood by a person of

### B. Infringement

To literally infringe a United States Letters Patent, an accused product or process must meet each and every limitation of the patent claim exactly, including any functional limitations. *See Corning Glass Works v. Sumitomo Elec.*, 868 F.2d 1251, 1258 (Fed. Cir. 1989). Any deviation from the claim precludes a finding of literal infringement. *See*, *e.g.*, *Cole v. Kimberly-Clark Corp.*, 102 F.3d 524, 532 (Fed. Cir. 1996).

An analysis of literal infringement requires two inquiries: first, the claims must be construed to resolve their proper scope and meaning; and second, it must be determined whether the accused product or process falls exactly within the scope of the properly construed claims. *See Markman*, 52 F.3d at 976; *see also Novo Nordisk of N. Am., Inc. v. Genentech, Inc.*, 77 F.3d 1364, 1368 (Fed. Cir. 1997). The first inquiry is a legal question for the court; the second inquiry is a factual determination for the fact-finder. *See Markman*, 52 F.3d at 976–80.

Infringement may also be found under the doctrine of equivalents if the accused product or method includes features that are identical or equivalent to each claimed element. *Warner-Jenkinson Co., Inc. v. Hilton Davis Chem. Co.*, 520 U.S. 17, 21, 40 (1997). The determination of equivalency, which is evaluated as of the time of infringement, is an objective inquiry applied on an element-by-element basis taking into account the role of each claim element in the context of the claim. *Id.* at 18, 29, 37, 40.

The Supreme Court has not mandated any specific approach to evaluate equivalency. *Id.* at 39–40. Among the recognized approaches that may be applied, including the function-way-result test and the insubstantial differences test. *Id.* at 19–20, 25, 36, 39–40.

There are a number of limitations on the application of the doctrine of equivalents. For example, the doctrine of equivalents cannot be applied so as to effectively eliminate a claim limitation in its entirety. *Id.* at 29. Moreover, limitations may not be afforded a scope of equivalency that effectively results in a claim that does not patentably distinguish the prior art. *See*, *e.g.*, *Wilson Sporting Goods Co. v. David Geoffrey & Assocs.*, 904 F.2d 677, 683 (Fed. Cir. 1990), overruled on other grounds by *Cardinal Chem. Co. v. Morton Int'l*, 508 U.S. 83 (1993). Additionally, prosecution history estoppel operates to prevent recapture, through the doctrine of equivalents, of coverage of subject matter that was relinquished by amendment or argument during prosecution. *Festo Corp. v. Shoketsu Kinzoku Kogyo Kabushiki Co.*, 535 U.S. 722, 733–34 (2002).

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