Bausch Health Companies, Inc.
400 Somerset Corporate Blvd.
Bridgewater, NJ 08807

Wood, Phillips, Katz, Clark & Mortimer
Attn: Mark V. Polyakov
500 W. Madison Street
Suite 1130
Chicago, IL 60661-2562

Rochester, NY 14609

Robert D. Rowlett
Founder & Chief Executive
Eye Therapies, LLC
26933 Camino De Estrella, 2nd FL
Dana Point, CA 92624

FROM: Slayback Pharma LLC

DATED: August 13, 2021

RE: **NOTICE OF PARAGRAPH IV CERTIFICATION RE: SLAYBACK PHARMA LLC'S BRIMONIDINE TARTRATE OPHTHALMIC SOLUTION, 0.025%; U.S. PATENT NOS. 8,293,742 and 9,259,425**

Dear Sirs:

Pursuant to § 505(j)(2)(B)(ii) and § 505(j)(2)(B)(iv) of the Federal Food, Drug and Cosmetic Act ("the Act") and § 314.95 of Title 21 of the Code of Federal Regulations ("C.F.R."), please be advised that Slayback Pharma LLC ("Slayback") has filed a patent certification pursuant to § 505(j)(2)(A)(vii)(IV) of the Act and § 314.94(a)(12)(i)(A)(4) of Title 21 of the C.F.R in support of its Abbreviated New Drug Application ("ANDA") No. 216361 with respect to Slayback's proposed Brimonidine Tartrate Ophthalmic Solution, 0.025% ("Slayback's proposed product"). Slayback seeks to obtain approval to engage in the commercial manufacture, use, or sale of Slayback's proposed product before the expiration of U.S. Patent Nos. 8,293,742 ("the '742 patent") and 9,259,425 ("the '425 patent"). We understand that the holder of the application under § 505(b) of the Act ("New Drug Application" or "NDA") No. N208144 in connection with brimonidine tartrate ophthalmic solution/drops, 0.025%, (reference listed drug: LUMIFY®) is Bausch and Lomb Inc. ("Bausch and Lomb"). We further understand based on information available in the United States Patent and Trademark Office ("USPTO") patent assignments database that Eye Therapies, LLC ("Eye Therapies") is the assignee of the '742 and '425 patents and we understand from the USPTO Public Pair database that Wood, Phillips, Katz, Clark & Mortimer are the attorney correspondents.

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ophthalmic solution, 0.025%;

(2) The ANDA number is 216361;

(3) Slayback has received the Paragraph-IV acknowledgment letter for its ANDA No. 216361 from the FDA;

(4) The established name of the proposed drug product, as defined in § 502(e)(3) of the Act, is "brimonidine tartrate ophthalmic solution, 0.025%";

(5) The active ingredient of Slayback's proposed product is 5-bromo-N-(4,5-dihydro-1*H*-imidazol-2-yl)-6-quinoxalinamine L-tartrate, commonly known as brimonidine tartrate; the dosage strength is 0.025%; and the dosage form is an ophthalmic solution;

(6) The U.S. patent numbers and expiration dates of the patents listed in the electronic version of the FDA publication *Approved Drug Products with Therapeutic Equivalence Evaluations* ("Orange Book") for LUMIFY®, as known to Slayback, alleged to be invalid, unenforceable, or not infringed are:

Patent No.	Expiration Date
8,293,742	July 14, 2030
9,259,425	July 14, 2030

(7) Slayback certified with the FDA pursuant to § 505(j)(2)(A)(vii)(IV) of the Act and 21 C.F.R. § 314.94(a)(12)(i)(A)(4) ("Paragraph IV Certification") that the '742 and '425 patents are invalid, unenforceable, or will not be infringed by the manufacture, use, or sale of Slayback's proposed product for which Slayback has submitted its ANDA. Therefore, pursuant to 21 U.S.C § 355(j)(2)(B)(iv)(II) and 21 C.F.R. § 314.95(c)(7), a detailed statement of the legal and factual basis for the Paragraph IV Certification is enclosed herewith and is made a part hereof. The information detailed in this letter and the attached memorandum is supplied for the sole purpose of complying with the above-referenced statutes and regulations, and neither Slayback nor its attorneys waive any attorney-client privilege or attorney work product immunity concerning the subject matter of this communication; and

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contained in 21 U.S.C. § 355(j)(5)(C)(i)(III) (as amended December 8, 2003) and pursuant to 21 C.F.R. § 314.95(c)(8), Slayback hereby offers confidential access to only those portions of Slayback's ANDA that, in Slayback's judgment, are needed by Bausch and Lomb and/or Eye Therapies to determine whether an action under Section 355 should be filed within the statutory 45 days of the receipt of this letter. Access to the information is and shall be limited to only those attorneys acting as outside counsel for Bausch and Lomb and/or Eye Therapies that are needed to evaluate the information, and such persons who are to have access shall be identified to Slayback's outside counsel, Andrew J. Miller, Esq. at Windels Marx Lane & Mittendorf, LLP, One Giralda Farms, Madison, NJ 07940 (e-mail: amiller@windelsmarx.com) before access is granted. Such persons so identified shall agree in writing that the information can and only will be used to determine whether an action under Section 355 should be filed within the statutory 45 days of the receipt of this letter. Those persons receiving access to Slayback's ANDA materials shall not engage, formally or informally, directly or indirectly in any work (prosecution or post-issuance) before any patent office, including the USPTO, relating to brimonidine or its salts, or in any counseling, litigation or other work before or involving a regulatory agency, including the United States FDA, relating to brimonidine or its salts. Slayback's ANDA materials and any tangible form of information derived from a review of the ANDA materials shall be destroyed, with notice to Slayback's outside counsel, within the statutory 45 days of receipt of this letter or upon the filing of an action against Slayback, whichever is earlier. Pursuant to 21 C.F.R. § 314.95(c)(8), by providing this Offer of Confidential Access, Slayback 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).

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I. INTRODUCTION

Pursuant to § 505(j)(2)(B)(iv)(II) of the Federal Food, Drug, and Cosmetic Act ("the Act") (codified at 21 U.S.C. § 355(j)(2)(B)(iv)(II)) and 21 C.F.R. § 314.95(c)(7), given below is the detailed factual and legal basis for Slayback's Paragraph IV Certification alleging that U.S. Patent Nos. 8,293,742 ("the '742 patent") and 9,259,425 ("the '425 patent") are invalid, unenforceable, or will not be infringed by the manufacture, use or sale of Slayback's proposed product described in its ANDA No. 216361.

The defenses herein are stated in the alternative. Nothing herein is or should be construed to be an admission with respect to the claim construction of any claim of the '742 or '425 patents, that any claim of the '742 or '425 patents is valid or infringed, or that any claim of the '742 or '425 patents is enabled by, or has written description in, the respective application from which those patents issued or any application in their respective chain of claimed priority.

II. LEGAL PRINCIPLES

A. Law of Infringement

The test for infringement of a patent is set forth in 35 U.S.C. § 271(a):

> (a) [w]hoever without authority makes, uses, offers to sell or sells any patented invention, within the United States or imports into the United States any patented invention during the term of the patent therefor, infringes the patent.

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