Anandita Vyakarnam Louis H. Weinstein WINDELS MARX LANE & MITTENDORF, LLP One Giralda Farms Madison, NJ 07940 (973) 966-3200 Attorneys for Defendants Slayback Pharma LLC and Slayback Pharma India LLP

IN THE UNITED STATES DISTRICT COURT FOR THE DISTRICT OF NEW JERSEY

BAUSCH & LOMB, INC.; BAUSCH & LOMB IRELAND LIMITED; and EYE THERAPIES, LLC,

Plaintiffs,

C.A. No. 3:21-16766-MAS-DEA

V.

SLAYBACK PHARMA LLC and SLAYBACK PHARMA INDIA LLP,

Defendants.

DEFENDANTS' FIRST SET OF REQUESTS FOR PRODUCTION TO PLAINTIFFS NOS. 1-2

Pursuant to Rules 26 and 34 of the Federal Rules of Civil Procedure, Defendants Slayback Pharma LLC and Slayback Pharma India LLP (collectively, "Slayback" or "Defendants") request that Plaintiffs Bausch & Lomb, Inc. ("Bausch"), Bausch & Lomb Ireland Limited ("Bausch Ireland"), and Eye Therapies, LLC ("Eye Therapies") (collectively, "Plaintiffs") respond to each Request set forth below and produce for inspection and copying the documents and things described below, within thirty (30) days of service of these Requests for Production. The



production shall be made at the offices of Defendants' counsel, or at some other place or in some other manner agreed upon by the Parties.

To the extent any Response or production pursuant to any of these Requests may at any time become incomplete or incorrect, Defendants request that Plaintiffs promptly supplement their Response and production pursuant to Rule 26 of the Federal Rules of Civil Procedure.

DEFINITIONS

- 1. "Plaintiffs" and "you" mean individually and collectively, Plaintiff Bausch & Lomb, Inc., Plaintiff Bausch & Lomb Ireland Limited, and Plaintiff Eye Therapies, LLC ("Eye Therapies") and includes Plaintiffs' current and former officers, directors, employees, consultants, attorneys, experts, agents, partners, corporate parents, subsidiaries, subdivisions, predecessors, or affiliates.
- 2. "Defendants" means, Defendant Slayback Pharma LLC and Defendant Slayback Pharma India LLP.
- 3. "Patents-in-Suit" means U.S. Patent Nos. 8,293,742 ("the '742 patent") and 9,259,425 ("the '425 patent");
 - 4. "U.S. FDA" means the United States Food & Drug Administration.
- 5. "U.S. PTO" or "Patent Office" means the United States Patent & Trademark Office.
 - 5. "PTAB" means the Patent Trial and Appeal Board of the U.S. PTO.
- 6 "U.S. FDA Review" means any review by the U.S. FDA, of an IND Application or NDA, including without limitation any review that falls under the heading "Summary Review", "Medical Review", "Chemistry Review", "Pharmacology Review", "Statistical Review", "Clinical Pharmacology Biopharmaceutics Review", "Proprietary Name Review", "Other Review", or "Administrative Document(s) & Correspondence".



- 7. "NDA" means New Drug Application.
- 8. "IND Application" means Investigational New Drug Application.
- 9. "Communication" means any transmission of information between two or more persons, including information transmitted by way of telephone conversations, letters, faxes, email, computer links, written memorandums or other documents, bulletin board posting, and face-to-face conversations.
- 10. "Concerning" means relating to, referring to, describing, evidencing, embodying, comprising, or constituting and is construed in the broadest sense to require the production of all documents which contain or comprise any communication (including representations, requests, demands and the like) referred to and documents that discuss, mention, or pertain to the subject matter of the request.
- 11. "Document" is defined to be synonymous in meaning and equal in scope to the usage of the term "documents or electronically stored information" in Federal Rule of Civil Procedure 34(a)(1)(A). A draft or non-identical copy is a separate document within the meaning of this term.

INSTRUCTIONS

1. IND Application and NDA materials submitted to U.S. FDA as electronic modules should be produced to Defendants as electronic modules in addition to being produced as individually Bates numbered pages.



REQUESTS FOR PRODUCTION

REQUEST NO. 1: A complete and unredacted copy of: IND Application No.

108524; any supplements or amendments to IND Application No. 108524; and all other

Documents filed with or received from the U.S. FDA concerning IND Application No. 108524,

including without limitation all Briefing Packages, Meeting Comments or Summaries,

Investigator Brochures and U.S. FDA Reviews.

REQUEST NO. 2: A complete and unredacted copy of: NDA No. 208144; any

supplements or amendments to NDA No. 208144; and all other Documents filed with or received

from the U.S. FDA concerning NDA No. 208144, including without limitation all Briefing

Packages, Meeting Comments or Summaries, Investigator Brochures and U.S. FDA Reviews.

Dated: December 29, 2021

/s/ Louis H. Weinstein

Anandita Vyakarnam

Louis H. Weinstein

WINDELS MARX LANE &

MITTENDORF, LLP

One Giralda Farms

Madison, NJ 07940

(973) 966-3200

avyakarnam@windelsmarx.com

lweinstein@windelsmarx.com

Attorneys for Defendants Slayback Pharma

LLC and Slayback Pharma India LLP

CERTIFICATE OF SERVICE

The undersigned attorney certifies that a true and accurate copy of the foregoing DEFENDANTS' FIRST SET OF REQUESTS FOR PRODUCTION TO PLAINTIFFS NOS.

1-2 was served on counsel for Plaintiffs by electronic mail on December 29, 2021.

Dated: December 29, 2021

<u>s/Louis H. Weinstein</u> Louis H. Weinstein

WINDELS MARX LANE & MITTENDORF, LLP One Giralda Farms Madison, NJ 07940 (973) 966-3200 avyakarnam@windelsmarx.com

Attorneys for Defendants Slayback Pharma LLC and Slayback Pharma India LLP

