UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY

BAUSCH & LOMB, INC.; BAUSCH & LOMB IRELAND LIMITED; and EYE THERAPIES, LLC, Plaintiffs, v. SLAYBACK PHARMA LLC and SLAYBACK PHARMA INDIA LLP, Defendants.	Civil Action No. 21-16766 (MAS) (DEA) **Initial Scheduling Conference Date:** **February 10, 2022 at 10:00 AM**

JOINT DISCOVERY PLAN

Plaintiffs Bausch & Lomb, Inc., Bausch & Lomb Ireland Limited, and Eye Therapies, LLC (collectively, "Plaintiffs") and Defendants Slayback Pharma LLC and Slayback Pharma India LLP (collectively, "Slayback" or "Defendants") (Plaintiffs and Defendants, collectively the "Parties") have conferred and submit the following Joint Discovery Plan, including proposed deadlines for discovery.

1. A brief factual statement of the claims or defenses in the action, as well as a brief statement of the legal issues in the case.

This patent infringement case arises under 21 U.S.C. § 355 (commonly referred to as "the Hatch-Waxman Act") from Slayback's submission of Abbreviated New Drug Application ("ANDA") No. 216361 seeking U.S. Food and Drug Administration ("FDA") approval to market brimonidine tartrate ophthalmic solution, 0.025% ("Slayback's Proposed ANDA Product") prior to the expiration of United States Patent Nos. 8,293,742 ("the '742 patent") and 9,259,425 ("the '425 patent") (the '742 patent and the '425 patent collectively, "the patents-in-suit"). Bausch & Lomb, Inc. is the registered holder of New Drug Application ("NDA") No. 208144 for the drug

product Lumify®, which the FDA approved on December 22, 2017. In conjunction with NDA No. 208144, the '742 and '425 patents are listed in the FDA's Approved Drug Products with Therapeutic Equivalence Evaluations (the "Orange Book").

After Plaintiffs received a letter from Slayback notifying Plaintiffs of Slayback's ANDA ("Slayback's Notice Letter"), along with notices of certification under 21 U.S.C. § 355(j)(2)(A)(vii)(IV) challenging the '742 and '425 patents, Plaintiffs filed this action on September 10, 2021, alleging that Slayback infringed the '742 and '425 patents by submitting ANDA No. 216361 to the FDA seeking approval for the commercial marketing of Slayback's Proposed ANDA Product before the expiration of the '742 and '425 patents. (*See* ECF No. 1.) Plaintiffs further allege that Slayback will, through the manufacture, use, import, offer for sale and/or sale of Slayback's Proposed ANDA Product directly infringe, contributorily infringe, and/or induce infringement of at least one claim of each of the '742 and '425 patents. (*Id.*) Accordingly, Plaintiffs seek an order that the date for any approval by the FDA for Slayback's Proposed ANDA Product be a date no earlier than the expiration of the '742 and '425 patents and that the Court enjoin Slayback from the commercial manufacture, use, import, offer for sale and/or sale of its generic brimonidine ophthalmic solution until the expiration of the patents-in-suit. Plaintiffs also seek to have this case declared exceptional under 35 U.S.C. §§ 271(e)(4) and 285. (*Id.*)

Slayback waived service of summons and, on November 9, 2021, answered Plaintiffs' Complaint. Slayback asserted several defenses, including that Slayback will not infringe any valid claim of the patents-in-suit, that the claims of the patents-in-suit are invalid, and failure to state a claim upon which relief can be granted. (ECF No. 9). Among its Prayers for Relief, Slayback asked the Court to declare this case exceptional and award Slayback its reasonable attorney's fees. (ECF No. 9.)

2. A description of all discovery conducted by the parties to date.

The Parties conducted the Rule 26(f) Conference on December 29, 2021. The Parties served initial disclosures pursuant to Fed. R. Civ. P 26(a)(1)(A) on January 12, 2022. Pursuant to the Local Rules, Slayback produced a copy of its ANDA No. 216361 on November 9, 2021. Slayback served its First Set of Requests for Production of Documents, Nos. 1-2 on December 29, 2021 and Plaintiffs served a timely response on January 28, 2022. Plaintiffs served their First Set of Requests for Production of Documents, Nos. 1-2 on January 7, 2022 and Slayback intends to serve a timely Response on February 7, 2022.

3. A description of all discovery problems encountered to date, the efforts undertaken by the parties to remedy these problems, and the parties' suggested resolution of the problems.

The Parties have not encountered any discovery problems to date.

4. A description of the parties' further discovery needs.

The Parties expect to take discovery concerning the subject matter of the claims set forth in Plaintiffs' Complaint and the defenses set forth in Defendants' Answer. The Parties contemplate serving additional written discovery, including requests for the production of documents and things, interrogatories, and requests for admission. The Parties also anticipate taking depositions of party and non-party witnesses. The Parties also anticipate conducting expert discovery.

5. The parties' estimate of the time needed to complete discovery.

The Parties estimate that they will need at least 18 months to complete fact and expert discovery.

6. A statement regarding whether expert testimony will be necessary, and the parties anticipated schedule for retention of experts and submission of their reports.

The Parties expect that expert testimony will be necessary given the highly technical nature of the subject matter of this lawsuit. The Parties expect expert discovery to commence after

completion of claim construction discovery, entry of the Court's claim construction order, and completion of fact discovery.

The Parties proposed schedule for expert discovery is identified in Appendix A.

7. A statement regarding whether there should be any limitation placed upon use of any discovery device, and if so, the reasons the limitation is sought.

If the Parties determine that privilege logs are necessary, then the Parties agree that the cutoff date for logging privileged documents in this case shall be the date on the face of Slayback's Notice Letter. In other words, no document dated after August 13, 2021, would need to be logged on a privilege log in this case, to the extent the Parties deem that a privilege log is necessary.

The Parties agree to be reasonable and cooperative with respect to the number and timing of discovery requests. The Parties agree to serve all discovery requests, objections and responses thereto, and all other papers in this case, by e-mail on counsel of record.

The Parties agree to cooperate to avoid unnecessary duplication of deposition testimony.

The Parties shall cooperate and use reasonable efforts to arrange for the attendance of any witness in their employment for depositions to take place remotely via videoconference, without the need for service of process.

The Parties agree that each Rule 30(b)(6) notice shall count as one deposition, regardless of the number of individuals designated by the party receiving the Rule 30(b)(6) notice and deposed by the party that noticed the Rule 30(b)(6) deposition.

The Parties agree to produce documents in single-page TIFF format accompanied by an image load file. The production will be placed on appropriate media based on the volume of information to be produced. Documents that are kept in OCR format will be produced in OCR format. The Parties will cooperate to agree on the precise format and fields of documents produced in single page TIFF format.

The Parties disagree on the format for the production of electronic documents submitted to the U.S. FDA and have set forth their positions on this issue below.

DEFENDANTS' POSITION: Defendants served a Request for Production asking Plaintiffs to produce the documents that Plaintiffs submitted to the U.S. FDA with respect to Plaintiffs' IND and NDA for Lumify®, the branded drug at issue in this case. Defendants requested that to the extent these documents were submitted to the U.S. FDA as electronic modules, Plaintiffs must produce these documents in the same form, *i.e.*, as electronic modules. Plaintiffs refused. The Parties conducted a meet and confer on this issue on February 1, 2022, and this issue is ripe for discussion at the February 10, 2022 Scheduling Conference.

To accommodate Plaintiffs' concern that it is not feasible to redact patient confidential information from an electronic module, Defendants agreed that any discreet submodule that contained patient confidential information need not be produced in native electronic form. To accommodate Plaintiffs' concern about redacting irrelevant information from electronic modules, Defendants agreed that production of an electronic module or submodule would not be deemed an admission of relevance or admissibility. At the meet and confer Plaintiffs were unable to identify any Court Order or Confidentiality Agreement that would prevent the production of the electronic modules.

Defendants' request that Plaintiffs produce these electronic modules in the same form that these electronic modules are kept in the ordinary course of business is consistent with Fed.R.Civ.P. 34(b)(2)(E)(i). Moreover, electronic modules are easy to use by a reviewer with basic computer skills, well organized, typically contain a hyperlinked index, and documents that reference other documents typically contain hyperlinks leading the reviewer directly to those other documents. The electronic module format makes it efficient for the U.S. FDA to review IND and NDA submissions and their production to Defendants as electronic modules is consistent with the goals

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