William P. Deni, Jr.
J. Brugh Lower
GIBBONS P.C.
One Gateway Center
Newark, New Jersey 07102
Tel: (973) 596-4500
Fax: (973) 596-0545

Attorneys for Plaintiffs

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 *Document Electronically Filed*

COMPLAINT FOR PATENT INFRINGEMENT

Plaintiffs Bausch & Lomb, Inc., Bausch & Lomb Ireland Limited, and Eye Therapies, LLC (collectively, "Plaintiffs") by way of Complaint against Defendants Slayback Pharma LLC and Slayback Pharma India LLP (collectively, "Defendants") allege as follows:

NATURE OF THE ACTION

1. This is an action for infringement of United States Patent Nos. 8,293,742 ("the '742 patent") and 9,259,425 ("the '425 patent"), arising under the United States patent laws, Title 35, United States Code, § 100 et seq., including 35 U.S.C. §§ 271 and 281, and for declaratory judgment of infringement under 28 U.S.C. §§ 2201 and 2202. This action relates to Slayback Pharma LLC's filing of an Abbreviated New Drug Application ("ANDA") under Section 505(j)

of the Federal Food, Drug, and Cosmetic Act ("the Act"), 21 U.S.C. § 355(j), seeking U.S. Food and Drug Administration ("FDA") approval to market its generic Brimonidine Tartrate Ophthalmic Solution, 0.025% ("Slayback's generic brimonidine ophthalmic solution") prior to the expiration of the '742 patent and the '425 patent.

THE PARTIES

2. Plaintiff Bausch & Lomb, Inc. ("Bausch") is a corporation organized and existing under the laws of New York with a place of business at 1400 N. Goodman St. Rochester, NY 14609. Bausch is the registered holder of approved New Drug Application ("NDA") No. 208144, which covers Lumify® ophthalmic solution/drops (brimonidine tartrate, 0.025%).

3. Plaintiff Bausch & Lomb Ireland Limited ("Bausch Ireland") is a company organized and existing under the laws of Ireland, having its registered office at 3013 Lake Drive, Citywest Business Park, Dublin, Ireland. Bausch Ireland exclusively licenses the '742 patent and the '425 patent.

4. Plaintiff Eye Therapies, LLC ("Eye Therapies") is a limited liability company organized and existing under the laws of Delaware, having its principal place of business at 26933 Camino De Estrella, 2nd Fl., Dana Point, California 92624. Eye Therapies is the owner of the '742 patent and the '425 patent.

5. Upon information and belief, Slayback Pharma, LLC ("Slayback") is a Delaware limited liability company having a principal place of business at 301 Carnegie Center, Suite 303, Princeton, NJ 08540, within this judicial district.

6. Upon information and belief, Slayback Pharma India LLP ("Slayback India") is a limited liability partnership organized under the laws of India, having a principal place of business

at 310, 3rd Floor, Manjeera Trinity Corporate, JNTU - Hitech City Road, KPHB Phase 3, Kukutpally Hyderabad, Telangana 500072, India.

7. Upon information and belief, Slayback is the parent corporation of Slayback India, and the acts of Slayback complained of herein were done with the cooperation, participation and assistance of Slayback India.

JURISDICTION AND VENUE

8. This Court has subject matter jurisdiction under 28 U.S.C. §§ 1331, 1338(a), 2201 and 2202.

9. Upon information and belief, this court has jurisdiction over Slayback. Upon information and belief, Slayback is in the business of, *inter alia*, developing, manufacturing, marketing, importing and selling pharmaceutical products, including generic drug products. Upon information and belief, Slayback directly, or indirectly, develops, manufactures, markets, and sells generic drug products throughout the United States and in this judicial district, and this judicial district is a likely destination for Slayback's generic brimonidine ophthalmic solution. Upon information and belief, Slayback purposefully has conducted and continues to conduct business in this judicial district. Upon information and belief, Slayback has its principal place of business at 301 Carnegie Center, Suite 303, Princeton, New Jersey 08540. Upon information and belief, Slayback has previously submitted to the jurisdiction of this Court and has further previously availed itself of this Court by asserting counterclaims in other civil actions initiated in this jurisdiction.

10. Upon information and belief, Slayback has taken the costly, significant step of applying to the FDA for approval to engage in future activities—including the marketing of its generic drugs—that will be purposefully directed at, upon information and belief, the State of New

Jersey and elsewhere. Slayback's ANDA filings constitute formal acts that reliably indicate plans to engage in marketing of the proposed generic drugs. Upon information and belief, Slayback intends to direct sales of its drugs into New Jersey, among other places, once it has the requested FDA approval to market them. Upon information and belief, Slayback will engage in marketing of its generic brimonidine ophthalmic solution in New Jersey upon approval of its ANDA.

11. Upon information and belief, this court has jurisdiction over Slayback India. Upon information and belief, Slayback India is in the business of, *inter alia*, developing, manufacturing, marketing, importing and selling pharmaceutical products, including generic drug products. Upon information and belief, Slayback India directly, or indirectly, develops, manufactures, markets, and sells generic drug products throughout the United States and in this judicial district, and this judicial district is a likely destination for Slayback's generic brimonidine ophthalmic solution. Upon information and belief, Slayback India purposefully has conducted and continues to conduct business in this judicial district in concert with Slayback.

12. Upon information and belief, Slayback and Slayback India operate as interrelated corporate entities. Upon information and belief, Slayback is the parent corporation of Slayback India. Upon information and belief, Slayback and Slayback India each act as an agent of the other and work together to, *inter alia*, develop, manufacture, obtain regulatory approval, market, sell and distribute generic copies of branded pharmaceutical products throughout the United States, including in this judicial district.

13. Defendants know or should know that Lumify® is manufactured for Bausch, at least because that information is included in the label for Lumify® and is publicly available.

14. Upon information and belief, venue is proper in this judicial district under 28 U.S.C. §§ 1391(c) and (d), and § 1400(b).

15. Venue is proper against Slayback Pharma, LLC, which maintains a regular and established place of business in this judicial district.

16. Venue is proper against Slayback India, a foreign corporation, in any judicial district that has personal jurisdiction, including this judicial district.

THE PATENTS IN SUIT

17. The PTO issued the '742 patent on October 23, 2012. The '742 patent claims, *inter alia*, methods of reducing eye redness consisting essentially of administering brimonidine into ocular tissue. Plaintiffs hold all substantial rights in the '742 patent and have the right to sue for infringement thereof. A copy of the '742 patent is attached hereto as Exhibit 1.

18. The U.S. Patent and Trademark Office ("PTO") issued the '425 patent on February 16, 2016. The '425 patent claims, *inter alia*, methods of reducing redness of an eye and/or increasing whiteness of an eye comprising administering compositions comprising brimonidine. Plaintiffs hold all substantial rights in the '425 patent and have the right to sue for infringement thereof. A copy of the '425 patent is attached hereto as Exhibit 2.

19. Bausch is the holder of NDA No. 208144 for 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").

20. Brimonidine tartrate ophthalmic solution, 0.025%, is sold in the United States under the trademark Lumify®.

SLAYBACK'S INFRINGING ANDA SUBMISSION

21. Upon information and belief, Slayback filed or caused to be filed with the FDA ANDA No. 216361, under Section 505(j) of the Act and 21 U.S.C. § 355(j).

DOCKET ALARM

Explore Litigation Insights

Docket Alarm provides insights to develop a more informed litigation strategy and the peace of mind of knowing you're on top of things.

Real-Time Litigation Alerts

Keep your litigation team up-to-date with **real-time alerts** and advanced team management tools built for the enterprise, all while greatly reducing PACER spend.

Our comprehensive service means we can handle Federal, State, and Administrative courts across the country.

Advanced Docket Research

With over 230 million records, Docket Alarm's cloud-native docket research platform finds what other services can't. Coverage includes Federal, State, plus PTAB, TTAB, ITC and NLRB decisions, all in one place.

Identify arguments that have been successful in the past with full text, pinpoint searching. Link to case law cited within any court document via Fastcase.

Analytics At Your Fingertips

Learn what happened the last time a particular judge, opposing counsel or company faced cases similar to yours.

Advanced out-of-the-box PTAB and TTAB analytics are always at your fingertips.

API

Docket Alarm offers a powerful API (application programming interface) to developers that want to integrate case filings into their apps.

LAW FIRMS
Build custom dashboards for your attorneys and clients with live data direct from the court.

Automate many repetitive legal tasks like conflict checks, document management, and marketing.

FINANCIAL INSTITUTIONS
Litigation and bankruptcy checks for companies and debtors.

E-DISCOVERY AND LEGAL VENDORS
Sync your system to PACER to automate legal marketing.