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

SENJU PHARMACEUTICAL CO., LTD., BAUSCH & LOMB INCORPORATED and BAUSCH & LOMB PHARMA HOLDINGS CORP., Plaintiffs, v. INNOPHARMA LICENSING, INC., INNOPHARMA LICENSING, LLC, INNOPHARMA, INC. and INNOPHARMA, LLC, Defendants.	Civil Action No. 1:14-cv-00667 (JBS)(KMW) Civil Action No. 1:14-cv-04149 (JBS)(KMW) Civil Action No. 1:14-cv-05144 (JBS)(KMW) Civil Action No. 1:15-cv-00335 (JBS)(KMW) Civil Action No. 1:14-cv-06893 (JBS)(KMW) Civil Action No. 1:15-cv-03240 (JBS)(KMW) (Consolidated Actions) **CONTAINS CONFIDENTIAL MATERIAL PURSUANT TO STIPULATED DISCOVERY CONFIDENTIALITY ORDER**

SUPPLEMENTAL EXPERT REPORT OF DARYL S. PAULSON, PH.D., M.A., M.S., M.B.A.

I. QUALIFICATIONS

1. I, Daryl S. Paulson, Ph.D., M.A., M.S., M.B.A., submit this supplemental expert report at the request of Senju Pharmaceutical, Co., Ltd. ("Senju"), Bausch & Lomb Incorporated and Bausch & Lomb Pharma Holdings Corp. (collectively, "B+L") in connection with the above captioned actions as an expert in the field of the evaluation of drug products. My qualifications in these areas, as well as other areas, are summarized in my expert reports dated December 24, 2015, and established by my *curriculum vitae*, which was attached as Appendix A to my December 24, 2015, expert reports.

2. I am submitting this supplemental expert report to provide a complete set of experimental data in the SSCI reports dated January 5, 2016, attached as Appendix A of this report.

II. DOCUMENTS AND INFORMATION CONSIDERED IN FORMING OPINIONS

3. Under my direction and control, BioScience Laboratories, Inc. conducted a Preservative Effectiveness Test ("PET") to evaluate and determine the antimicrobial preservatives effectiveness of several samples challenged with resistant microorganisms. In reviewing the PET results, I had available to me the documents cited herein, the documents cited in my December 24, 2015, expert reports as well as the publications listed on my *curriculum vitae*. The data tables for the PET were created using the raw data collected by the Study Director, Dan M. Dragotoiu, who conducted this comparative study and who holds a B.S. degree and has over ten years of professional and academic experience in the area of microbiology. I reserve the right to testify about BioScience Laboratories, Inc. test results and scientific expertise. To the extent I am provided additional documents or information, including any expert reports produced by InnoPharma, I may offer further opinions. In addition to these materials, I may consider additional documents and information in forming any rebuttal opinions. Additionally, I may prepare demonstratives to illustrate any opinions I may present.

III. STATEMENT OF OPINIONS EXPRESSED AND BASES AND REASONS THEREFOR

4. BioScience Laboratories, Inc. received from SSCI samples of B+L's Prolensa® product [redacted] for PET. Upon receipt of these samples, BioScience Laboratories, Inc. stored, handled, and maintained according to BioScience Laboratories, Inc.'s current good manufacturing practice ("GMP") sample handling procedures as specifically outlined in their SOP L-0005. These samples were evaluated for preservative efficacy during the months of November 2015 through January 2016. BioScience Laboratories Study Director, Dan M. Dragotoiu, was personally present during the preservative efficacy testing of these samples.

5. Summary reports of the preservative efficacy testing conducted by BioScience Laboratories, Inc. on these samples are attached as Appendix A. The report describes the analytical methodology to evaluate preservative efficacy of stressed and unstressed samples of B+L's Prolensa® product [redacted] As set forth in the European Pharmacopoeia, the following organisms were tested: *Candida albicans* (AATCC# 10231), *Aspergillus niger* (AATCC# 16404), *Pseudomonas aeruginosa* (AATCC# 9027) and *Staphylococcus aureus* (AATCC# 6538). The preservative efficacy results are reported in the document for all of the samples tested.

6. BioScience Laboratories, Inc. is a Good Laboratory Practice ("GLP")/GMP facility providing contract product development services to the pharmaceutical industry. BioScience Laboratories, Inc.'s service offerings include, but are not limited to analytical testing (*e.g.*, preservative efficacy), product development, and manufactures label claims. The preservative efficacy testing of B+L's Prolensa® product [redacted] samples was performed in BioScience Laboratories, Inc.'s GLP/GMP In-Vitro laboratory.

7. The details of the analytical testing that was performed and the preservative efficacy test results obtained were provided to SSCI for incorporation in the SSCI reports (Appendix A).

IV. COMPENSATION

8. If called to testify to the facts stated herein, I will be compensated for my time preparing for and testifying in this matter at rate of $500.00 per. No part of my compensation is contingent upon the outcome of this matter or any issue in it.

V. PRIOR EXPERT TESTIMONY

9. During the past four years, I have not testified as an expert in any cases.

01-11-16
Date

Daryl S. Paulson, Ph.D., M.A., M.S., M.B.A.

Appendix A

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.