UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

LUPIN, LTD. and LUPIN PHARMACEUTICALS INC.,

Petitioner

v.

SENJU PHARMACEUTICAL CO., LTD.
Patent Owner

Case IPR2015-01097
Patent 8,754,131 B2

DECLARATION OF DARYL S. PAULSON, PH.D., M.A., M.S., M.B.A.

SENJU EXHIBIT 2128

I, Daryl S. Paulson, Ph.D., M.A., M.S., M.B.A., under penalty of perjury, declare as follows:

I. QUALIFICATIONS

1. I submit this declaration at the request of Finnegan, Henderson, Farabow, Garrett & Dunner, LLP on behalf of Senju Pharmaceutical, Co., Ltd. ("Senju") in connection with IPR2015-01097 *inter partes* review ("IPR") proceeding before the United States Patent and Trademark Office ("PTO") Patent Trial and Appeal Board ("Board") as an expert in the field of the evaluation of drug products. My qualifications in these areas, as well as other areas, are established below and by my *curriculum vitae*, which is EX2129.

2. I am currently the President and CEO of BioScience Laboratories, Inc. in Bozeman, Montana, which I founded in 1991.

3. In the field of microbiology, I received a B.S. degree in medical microbiology from College of Great Falls in 1979 and a M.S. degree in medical microbiology/biostatistics from University of Montana in 1981. I have also received a M.A. degree in psychology from Pacifica Graduate Institute – Santa Barbra, California, in 1988, a Ph.D. degree in Psychology from Sierra University in 1989, and a Ph.D. degree in Human Science from SayBrook Research Institute and Graduate School. I have also received an M.B.A. degree from University of Montana in 2002, a Ph.D. degree in Asian art history from Warnborough

University, UK, and a Ph.D. degree in Psychology from the Institute of Transpersonal Psychology in 2008.

4. I have an extensive experience in the fields of management science, research and development, clinical trials, biostatistics, and clinical microbiology and have authored publications and given presentations related to pharmaceutical drug products. Among my numerous publications, I have authored *Topical Antimicrobial Testing and Evaluation*, Taylor & Francis, 2014, and I have also edited the *Handbook of Topical Antimicrobials*, Marcel Dekker, 2002.

II. DOCUMENTS AND INFORMATION CONSIDERED IN FORMING OPINIONS

5. 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 as well as the publications listed on my *curriculum vitae* at EX2129. 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.

III. STATEMENT OF OPINIONS EXPRESSED AND BASES AND REASONS THEREFOR

A. Background

6. BioScience Laboratories, Inc. received from SSCI samples of Bausch & Lomb Incorporated's ("B+L's") Prolensa® product 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 and January 2016. BioScience Laboratories Study Director, Dan M. Dragotoiu, was personally present during the preservative efficacy testing of these samples.

7. A summary report of the preservative efficacy testing conducted by BioScience Laboratories, Inc. on these samples is 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. The preservative efficacy results are reported in the document for all of the samples tested.

8. 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 the B+L's Prolensa® product samples was performed in BioScience Laboratories, Inc.'s GLP/GMP In-Vitro laboratory.

9. 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 report (Appendix A).

B. Preservative Efficacy Testing of B+L's Prolensa® product

10. As discussed above, samples of B+L's Prolensa® product were analyzed for preservative efficacy. Consistent with the '131 patent, the preservative effectiveness tests were conducted based on the methods described in the European Pharmacopoeia, using the two bacterial species *Pseudomonas aeruginosa* (ATCC #9027) and *Staphylococcus aureus* (ATCC #6538), and the two fungal species *Candida albicans* (ATCC #10231) and *Aspergillus brasiliensis* (ATCC #16404). [redacted]

As indicated in the '131 patent, the preservative effectiveness of the vials were evaluated at the following times: 24 hours, 7 days, 14 days and 28 days following inoculation with the two bacterial species, and 14 days, 21 days and 28 days

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