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 ADAM C. MYERS, PH.D.

SENJU EXHIBIT 2126

I, Adam C. Myers, Ph.D., under penalty of perjury, declare as follows:

I. INTRODUCTION

1. I submit this declaration at the request of Finnegan, Henderson, Farabow, Garrett & Dunner, LLP on behalf of Senju Pharmaceutical, Co., Ltd. ("Senju") as an expert in the field of the design, evaluation, and formulation of drug products. My qualifications in these areas, as well as other areas, are established below and by my *curriculum vitae*, which is EX2127.

II. BACKGROUND AND QUALIFICATIONS

2. I am currently a Senior Research Investigator at SSCI, a Division of Albany Molecular Research, Inc. ("AMRI") in West Lafayette, Indianapolis, which I have been working for over a year.

3. I received a B.S. with Honors degree in biochemistry from Purdue University in 2000 and a Ph.D. degree in organic chemistry from Purdue University in 2005.

4. Prior to joining SSCI, I worked in the pharmaceutical industry for Quadraspec, Inc. and BASi in West Lafayette. My employment at Qaudraspec, Inc. began in 2006 and continued until I moved to BASi in 2007. My roles at BASi increased over the years from a Senior Scientist/Team Leader to Assistant Director of Pharmaceutical Analysis, and eventually to Director of Pharmaceutical Scientific Operations in 2012. As a Senior Scientist/Team Leader, I was

responsible for developing protocols, method and techniques for various analytical testing. As Assistant Director of Pharmaceutical Analysis and Director of Pharmaceutical Scientific Operations, I was responsible for providing scientific directions to a laboratory conducting Current Good Manufacturing Practice ("cGMP") and Good Laboratory Practice ("GLP") projects.

5. My current expertise in design, evaluation, and formulation of drug products focuses on drug formulation analytics utilizing chromatography, mass spectrometry, UV-Vis, dissolution, in a cGMP laboratory setting. I have extensive research, development, and manufacturing experience and have coauthored publications and given presentations related to pharmaceutical drug products.

III. DOCUMENTS AND INFORMATION CONSIDERED IN FORMING OPINIONS

6. In forming my opinions, I had available the documents cited herein as well as the publications listed on my *curriculum vitae* at EX2127. I also based my opinions on my professional and academic experience in the area of drug formulation and analytics. I reserve the right to testify about these materials and experience.

IV. STATEMENT OF OPINIONS EXPRESSED AND BASES AND REASONS THEREFOR

A. Background

7. Samples of Bausch & Lomb Incorporated's ("B+L's") Prolensa® product samples were sourced from B+L. B+L shipped the samples to Finnegan,

Henderson, Farabow, Garrett & Dunner, LLP, who then shipped the samples to SSCI for testing. A portion of these samples were further shipped to BioScience Laboratories, Inc. These samples were analyzed for potency, *i.e.* chemical stability, at SSCI and for preservative efficacy at BioScience Laboratories, Inc. during the months of November 2015 and January 2016. Potency measures the amount of an analyte present in the testing sample. In other words, the chemical stability data indicate the percentage amount of bromfenac free acid in the Prolensa® product samples that were subject to stressed and unstressed conditions for four weeks. I was personally present during the chemical stability testing of these samples.

8. SSCI has provided a summary report of both the chemical stability testing and preservative efficacy testing, which is attached as Appendix A. The SSCI report correctly details the analytical testing that was performed and accurately reports the chemical stability test results, as well as the preservative efficacy test results. The report describes the analytical methodology to quantitate bromfenac free acid in the stressed and unstressed conditions. The chemical stability results are reported in the document for all of the samples tested.

9. SSCI is a cGMP facility providing contract product development services to the pharmaceutical industry. SSCI's service offerings include analytical testing (*e.g.*, chemical stability), product development, and

manufacturing. The chemical stability testing of the B+L's Prolensa® product samples was performed in SSCI's cGMP quality control laboratory.

10. B+L's Prolensa® product samples were received, stored, handled, and maintained according to SSCI's cGMP sample handling procedures. The samples were stored under ambient laboratory conditions in their original containers.

11. A portion of the samples received from B+L were stressed in an oven at 60° C, and the rest were maintained at unstressed (ambient) conditions. All of the samples were tested for potency after four weeks, and percent recovery was calculated based on the potency of the stressed samples relative to the unstressed samples. To prevent contamination of the samples and to maintain uniformity of analysis, all of the samples were kept in the original containers and were tested for potency after four weeks at either unstressed or stressed conditions. Performing the HPLC analyses all at once after the four-week duration guarantees the uniformity of analysis, by utilizing the same standard preparations, mobile phase, column and instrument, while performing at different time points may add variables that could potentially skew the results.

12. Using this method was further justified because all of the samples were storage stable in the containers as provided. B+L's Prolensa® product is a marketed product with sufficient stability [redacted] for ophthalmic use. (*See, e.g.*, [redacted] EX1049 at 1.) From these known stability

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