UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

LUPIN LTD., and LUPIN PHARMACEUTICALS INC.,

Petitioners,

v.

SENJU PHARMACEUTICAL CO., LTD., BAUSCH & LOMB, INC., and BAUSCH & LOMB PHARMA HOLDINGS CORP.,

Patent Owners.

IPR2015-01097 (Patent 8,754,131)
IPR2015-01099 (Patent 8,669,290)
IPR2015-01100 (Patent 8,927,606)
IPR2015-01105 (Patent 8,871,813)

DECLARATION OF IVAN T. HOFMANN, CPA/CFF, CLP[1]

[1] A word-for-word identical paper has been filed in each proceeding identified in the heading. IPR2016-00089 has been joined with IPR2015-01097; IPR2016-00091 has been joined with IPR2015-01100; and IPR2016-00090 has been joined with IPR2015-01105. Each of these joined proceedings includes Petitioners InnoPharma Licensing, Inc., InnoPharma Licensing LLC, InnoPharma Inc., Mylan Pharmaceuticals Inc., and Mylan Inc. (collectively, "InnoPharma") in addition to the parties identified above.

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I. Introduction

1. I am over the age of eighteen (18) and otherwise competent to make this declaration.

2. I am a Managing Director at Gleason IP, a division of Gleason & Associates, P.C. ("Gleason"). Gleason is an economic, accounting, and financial consulting firm which provides services primarily in the areas of Valuation, Litigation Support, Intellectual Property, Forensic Accounting and Financial Reorganization. I am the leader of the Intellectual Property Practice. Prior to joining Gleason, I worked for the global firm of Deloitte & Touche, LLP.

3. I have been retained as an expert witness on behalf of Petitioner for the above captioned *inter partes* review ("IPR"). Gleason is being compensated for the work performed on this engagement based on the time incurred by me at a rate of $435 per hour and by other Gleason personnel working under my direct supervision at rates ranging from $95 to $275 per hour. Our compensation is in no way dependent on the outcome of this IPR.

4. I have been jointly retained by Lupin Ltd. and Lupin Pharmaceuticals Inc. (collectively, "Lupin" or "Petitioners") to analyze objective indicia of nonobviousness, specifically commercial success and nexus related to U.S. Patent No. 8,754,131 ("the '131 Patent"), U.S. Patent No. 8,669,290 ("the '290 Patent"), U.S. Patent No. 8,927,606 ("the '606 Patent"), and U.S. Patent No. 8,871,813 ("the

'813 Patent") (collectively, "the patents at issue"). I have also been asked to respond to the Declaration of John C. Jarosz on objective indicia of nonobviousness, dated February 23, 2016 (the "Jarosz Declaration") (EX2130[2]).

5. To accomplish the objective of this engagement, to date, I have performed the following tasks:

a. Researched and reviewed information regarding Prolensa®, Bromday®, Xibrom®, and other prescription ophthalmic nonsteroidal anti-inflammatory drug ("NSAID") pharmaceutical products.

b. Reviewed and analyzed documents, correspondence, pleadings, and other information produced in this matter.

c. Reviewed the following expert declarations:

i. The Jarosz Declaration (EX2130);

ii. The Declaration of William B. Trattler, M.D., dated February 23, 2016 (EX2116);

iii. The Declaration of Robert O. Williams, III Ph.D., dated February 22, 2016 (EX2082).

[2] Unless otherwise noted, exhibit numbers referenced herein are the same in each of IPR2015-01097, IPR2015-01099, IPR2015-01100, and IPR2015-01105.

d. Performed independent research on various topics and issues.

e. Summarized my analysis and findings to date in this declaration.

6. This declaration is based on information known to me as of the date I signed this declaration. I may obtain additional documents, information, and testimony which may cause me to amend and/or supplement my opinions at a later date. I also reserve the right to rebut any additional opinions offered by any expert for Senju Pharmaceutical Co., Ltd. ("Senju") and Bausch & Lomb Incorporated and Bausch & Lomb Pharma Holdings Corp. (collectively, "B&L") (collectively, the "Patent Owner").

7. As I explain more fully below, Prolensa® is not a commercial success and the performance of Prolensa® is attributable to various extrinsic factors unrelated to the patents at issue. Specifically, the performance of Prolensa® is explained by the execution of a coordinated life-cycle management strategy for the bromfenac franchise which involved the following components: (1) the systematic migration to new bromfenac products and the discontinuation of legacy bromfenac products; (2) substantial marketing and promotional efforts; and (3) tactical pricing of Prolensa®. As a result, the performance of Prolensa® does not provide objective indicia of nonobviousness of the patents at issue.

8. The sections below explain the details of my analysis in the following areas:

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