

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

INNOPHARMA LICENSING, INC., INNOPHARMA LICENSING LLC,
INNOPHARMA INC., INNOPHARMA LLC,
MYLAN PHARMACEUTICALS INC., and MYLAN INC.,
Petitioner

v.

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

Case IPR2015-00902 (Patent 8,669,290 B2)
Case IPR2015-00903 (Patent 8,129,431 B2)¹

DECLARATION OF IVAN T. HOFMANN, CPA/CFF, CLP

¹ A word-for-word identical paper has been filed in each proceeding identified in the heading. IPR2015-01871 has been joined with IPR2015-00903 and includes Petitioners Lupin Ltd. and Lupin Pharmaceuticals Inc. in addition to the parties identified above.

Petitioner InnoPharma EX 1150
IPR2015-00902

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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 InnoPharma Licensing, Inc., InnoPharma Licensing, LLC, InnoPharma, Inc., InnoPharma, LLC, Mylan Pharmaceuticals Inc., and Mylan Inc. (collectively, “InnoPharma” or “Petitioners”) to analyze objective indicia of nonobviousness, specifically commercial success and nexus related to U.S. Patent Nos. 8,669,290 (the “290 Patent”) and 8,129,431 (the

“431 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 December 24, 2015 (the “Jarosz Declaration”) (EX2130²).

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 December 23, 2015 (EX2116);
 - iii. The Declaration of Robert O. Williams, III Ph.D., dated December 22, 2015 (EX2082).

² Unless otherwise noted, exhibit numbers referenced herein are the same in both IPR2015-00902 and IPR2015-00903.

- 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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