

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.
Petitioners

v.

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

Case IPR2015-00902
Patent 8,669,290

DECLARATION OF WILLIAM B. TRATTLER, M.D.

I, William B. Trattler, M.D., under penalty of perjury, declare as follows:

I. INTRODUCTION

1. I have been retained by Finnegan, Henderson, Farabow, Garrett & Dunner, LLP on behalf of Patent Owner Senju Pharmaceutical, Co., Ltd. (“Senju”), Bausch + Lomb Incorporated and Bausch + Lomb Pharma Holdings Corp. in connection with two *inter partes* review (“IPR”) proceedings (IPR2015-00902 and IPR2015-00903) before the United States Patent and Trademark Office Patent Trial and Appeal Board as a medical expert in the field of ophthalmology, including cataract, corneal and refractive surgery.

A. Qualifications

2. I am an ophthalmologist specializing in refractive, corneal and cataract eye surgery at the Center for Excellence in Eye Care in Miami, FL, where I have practiced since July 1997. I perform a wide variety of cataract and refractive surgeries, including photorefractive keratectomy (“PRK”), all laser LASIK, and no-injection sutureless cataract surgery as well as laser cataract surgery. In connection with these surgeries, I administer various medications, including Prolensa[®] (bromfenac ophthalmic solution 0.07%), to patients to treat post-operative inflammation and pain.

3. I received my Bachelor of Arts degree in biology from Dartmouth College in 1988 and my M.D. degree, with research distinction, from the University of Miami School of Medicine in 1992. I completed an internal medicine internship at Mount Sinai Medical Center in June 1993, an ophthalmology residency at the University of Pennsylvania Scheie Eye Institute in July 1996, and a cornea and external disease fellowship from the University of Texas-Southwestern Medical Center in 1997. I received board certification in ophthalmology in October 1998, and in January 2009 I was recertified through 2018.

4. While practicing at the Center for Excellence in Eye Care, I also served on the surgical staff of the V.A. Hospital in Miami from July 1997 through July 2001, supervising University of Miami ophthalmology residents in surgery and in the clinic. I additionally assisted at the Bascom Palmer Eye Institute on a part-time basis from July 2002 through July 2006, supervising residents in the eye emergency department and instructing residents in cataract and corneal surgery. From 2002 to the present, I also have worked as a volunteer for the Good News Care Center in Miami, which provides free medical services to uninsured low-income patients regardless of race, occupation, national origin or immigrant status. In this role, I have provided between 50 and 100 free examinations and 5 to 10 free surgeries to low-income patients each year.

5. I also have held two academic appointments during my career as an ophthalmologist. From July 2000 through the present, I have been a Volunteer Assistant Professor of Ophthalmology at the Bascom Palmer Eye Institute. From January 2012 through the present, I have been a volunteer faculty member in the Department of Ophthalmology at the Herbert Wertheim College of Medicine at Florida International University.

6. I have received numerous awards and honors over the course of my professional career, including an Achievement Award and Senior Achievement Award from the American Academy of Ophthalmology, the Curtis D. Benton, Jr., M.D. Outstanding Young Ophthalmologist Leadership Award presented by the Florida Society of Ophthalmology, and the Scheie Eye Institute Teaching Award on two separate occasions. I have been qualified and listed as a Trusted LASIK Surgeon, a LASIK directory service that screens surgeons based on experience, premier patient care and professional credentials. I also have been voted by readers of the publication *Cataract and Refractive Surgery Today* as a top 50 opinion leader in the field

of cataract and refractive surgery. I have received a Patient Choice Award and, for the past several years, have been elected to Best Doctors in America. I also have been selected by my peers as a Florida Super Doctor for South Florida, a distinction bestowed upon the top 5% of South Florida doctors, based on peer nominations as well as a panel review process and independent research on candidates. A full list of awards and honors I have received can be found in my curriculum vitae. (EX2051 at 1-2.)

7. I have conducted research in the field of ophthalmology for over 30 years and have been an investigator on nearly 70 clinical trials for ophthalmic products, a full list of which can be found in my curriculum vitae. (EX2051 at 2-6.) I have conducted clinical trials for bromfenac formulations, including clinical trials for Xibrom[®] and Bromday[®] that led to their approval by the U.S. Food and Drug Administration (“FDA”).

8. I have authored scores of publications in both peer-reviewed and non-peer reviewed journals, and I have co-authored four textbooks and two chapters in textbooks. I also have co-authored chapters in four different online textbooks. A full list of my publications can be found in my curriculum vitae. (EX2051 at 6-8.)

9. I regularly attend a variety of scientific meetings in the field of ophthalmology and have given hundreds of presentations at these meetings. I also have served on a number of scientific panels, as both a panelist and moderator. I have given numerous lectures to local ophthalmology and medical groups. A full list of these activities can be found in my curriculum vitae. (EX2051 at 8-11, 19-34.)

10. I have served as a reviewer for the American Academy of Ophthalmology, and I currently serve as a peer reviewer for five journals: *Ophthalmology*, *Journal of Cataract and Refractive Surgery*, *Cornea*, *American Journal of Ophthalmology*, and *Ophthalmic Research*. I

also have served on the editorial boards for several publications, which are listed in my curriculum vitae. (EX2051 at 34.)

11. I have been a member of several professional associations for many years. I have been a member of the American Academy of Ophthalmology since 1996 and have served in various capacities, including on the Annual Meeting Program Committee for Refractive Surgery, on the Ophthalmic Technology Assessment Committee Refractive Surgery Panel, and as Chairperson of the Refractive Management/Intervention Panel. Since 1997 I have been a member of the American Society of Cataract and Refractive Surgery, as well as the Miami Ophthalmology Society, for which I served as Secretary in 2004, Treasurer in 2005 and President in 2006. Since 2000 I have been a member of the Florida Society of Ophthalmology, and since 2007 I have been a member of The Cornea Society. I also have been a member of the International Society of Refractive Surgery since 2007 and was appointed to the Executive Board in 2011. I am a founding board member of the American-European Congress of Ophthalmic Surgery and a founding member of CEDARS, which stands for Cornea, External Disease and Refractive Surgeons. A full list of these activities can be found in my curriculum vitae. (EX2051 at 34-35.)

12. I have consulted for numerous pharmaceutical companies over the years. I also have served as an expert witness in the field of ophthalmology, and my testimony has been credited in court.

13. On the basis of my education and experience, I believe I am qualified to express the opinions provided below.

B. Materials Considered

14. In forming my opinions, I had available the documents cited herein as well as the publications listed on my curriculum vitae. (EX2051 at 6-8.) I have also reviewed Dr. Paul

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