

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

MYLAN PHARMACEUTICALS INC.,
Petitioner

v.

ALLERGAN, INC.,
Patent Owner

Case IPR2016-01131
Patent 8,648,048

DECLARATION OF JOHN D. SHEPPARD, M.D., M.M.Sc.

I, John D. Sheppard, M.D., M.M.Sc., declare as follows:

I. Experience and Qualifications

1. I graduated in 1974 with a S.B. in Biology from Brown University. I then earned the M.M.Sc. in Medicine from Brown University in 1976. I obtained my medical degree from Brown University in 1978. Following medical school, I completed a one-year internship in pediatric medicine at the University of Virginia (1978-1979). I was then on active duty in the Navy from 1979-1983. Following active duty, I completed my residency at the University of Pittsburgh in Ophthalmology (1983-1986) and a fellowship at the Proctor Foundation at the University of California, San Francisco where I conducted research involving the cornea and uveitis (1986-1988). I have been a board certified ophthalmologist since 1988, passing the oral examination with honors at the first sitting.

2. Following my studies, I joined Virginia Eye Consultants in Norfolk Virginia in 1989, where I am currently employed and serve as the President, Senior Partner and Managing Partner. In this role, I have a busy and comprehensive ophthalmology practice where I treat a diverse population for a variety of ophthalmic conditions, including corneal and external disease, glaucoma, retinal disease, dry eye disease, cataract and ophthalmic manifestations of systemic, neurological and immune diseases.

3. In addition to my medical and surgical practice, I have been involved in over 120 clinical studies, approximately 50 of which involved dry eye disease. For example, I was a clinical investigator involved in the Phase 3 clinical trials for RESTASIS® for the treatment of dry eye.

4. Over the course of my career, I have diagnosed and treated thousands of patients with dry eye disease. Among various treatments, I have used RESTASIS® in treating patients with dry eye disease since the FDA approved it in 2003. Through my training and in my practice over the years, including my interactions with scientists and representatives in the pharmaceutical industry I am familiar with the formulation of ophthalmic pharmaceutical preparations, including RESTASIS®.

5. Between 1989-2008, I served as the Ophthalmology Program Director at Eastern Virginia Medical School, overseeing the education of ophthalmology residents. In addition, I have served as a visiting professor at several universities including Duke University, Yale University, University of Texas, University of Florida, and the University of California San Diego where I taught courses to practicing physicians, residents and medical students covering ocular diseases, including ocular inflammation and dry eye disease, as well as treatments for ocular diseases with various ophthalmic formulations.

6. I have served or currently serve on a number of professional societies including the American Academy of Ophthalmology, the American Board of Ophthalmology, American Society for Cataract and Refractive Surgery, the American Uveitis Society, the Association of University Professors of Ophthalmology and the Association for Research in Vision and Ophthalmology.

7. I have authored numerous publications in the field of ophthalmology including articles, textbook chapters, and case reports. A significant portion of these publications focus on treatments for dry eye. In addition to actively publishing, I also serve on the editorial and advisory boards for several journals including Clinical Ophthalmology and Eye and Contact Lens, and also serve as Chief Medical Editor for Web MD Medscape Ophthalmology.

8. I also serve or have served on numerous medical and scientific advisory boards. For example, I currently serve or have previously served on boards for the following companies: Alcon, Novartis, Aldeyra, Allergan, Bausch & Lomb, Valeant, Ciba Vision Ophthalmics, EyeRx Research, Parion, Topivert, EyeGate, Shire, Santen Pharmaceuticals, Sun Pharma and Isis Pharmaceuticals.

9. I have received numerous honors and awards over the course of my professional career, including for example, Armed Forces Health Professions Scholarship, National Society to Prevent Blindness Burroughs-Wellcome Scholarship, National Research Service Award from the National Eye Institute,

Senior Honor Award from the American Academy of Ophthalmology, and Best Doctors in America Award.

10. A more thorough summary of my education, experience, publications, awards, honors, and presentations is provided in my CV, which is attached to this declaration as Exhibit A.

II. Scope of Work

11. I understand that the United States Patent Trial and Appeal Board (“PTAB”) has instituted *inter partes* review of U.S. Patent Nos. 8,629,111, 8,633,162, 8,642,556, 8,648,048, 8,685,930 and 9,248,191 (collectively “the patents-in-suit”). (IPR2016-01128, -01130, -01129, -01131, -01127 and -01132, respectively). I have been engaged in the present matter to provide my independent analysis of the issues raised in the petitions for *inter partes* review of the patents-in-suit.

12. I am compensated for my work at the rate of \$1000 per hour during normal business hours, and \$450 per hour for work conducted after 6:00 PM and over the weekend. For any part of the case that requires work away from my home and office, I am being compensated at \$9,000 per day. My compensation does not in any way depend on the outcome the litigation or the *inter partes* reviews.

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