

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

REGENERON PHARMACEUTICALS, INC.

Petitioner,

v.

NOVARTIS PHARMA AG,
NOVARTIS TECHNOLOGY LLC,
NOVARTIS PHARMACEUTICALS CORPORATION,

Patent Owners.

Patent Number: 9,220,631

DECLARATION OF DR. SZILÁRD KISS

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I. Introduction

1. I have been retained by Petitioner Regeneron Pharmaceuticals, Inc. (“Petitioner” or “Regeneron”), as an independent expert witness in the above-captioned *inter partes* review (“IPR”), in which Regeneron has requested that the U.S. Patent and Trademark Office cancel as unpatentable all claims of U.S. Patent No. 9,220,631 (“the ’631 patent”). This declaration sets forth my analyses and opinions based on my knowledge, experience, and the materials I have considered.

2. I provide this declaration to explain that certain ophthalmology-related subject matter disclosed and claimed in the ’631 patent was well-known prior to 2012, and also to specifically opine on the obviousness of claims 24-26.

3. For purposes of this declaration, I have assumed that claim 1 of the ’631 patent has separately been shown to be obvious based on the prior art and the Declarations of Horst Koller (Ex. 1003) and James Agalloco (Ex. 1005).

II. Qualifications and Compensation

4. I received my B.A. in Biology from Columbia College in 1997 and my M.D. from Columbia University College of Physicians & Surgeons in 2002. Following graduation from medical school, I was an Intern in the Department of Internal Medicine at St. Luke’s Roosevelt Hospital, Columbia University College of Physicians & Surgeons, from 2002 to 2003. I then became a Resident in the

Ophthalmology Department of the Massachusetts Eye and Ear Infirmary of Harvard Medical School from 2003 to 2006.

5. Including my residency at Harvard, I have over sixteen years of experience in treating patients with ophthalmological diseases. I was certified by the American Board of Ophthalmology in 2007. Following my Residency, I was appointed as a Fellow of the Vitreo-Retinal Service in the Ophthalmology Department of the Massachusetts Eye & Ear Infirmary at Harvard Medical School in 2006 and promoted to Chief Fellow in 2007. In 2008, I became an Assistant Professor of Ophthalmology at Weill Cornell Medical College, and I was promoted to Associate Professor in 2013. I was given the title of Associate Dean of Clinical Compliance in 2019. During this time, I also held a number of other clinical positions. I also hold the title of Vice Chair of Research, Vice Chair of Compliance, Director of Retina Service and Director of Tele-Ophthalmology at Weill Cornell Medical College. I also hold the positions of Associate Attending Physician and Associate Attending Surgeon. My clinical duties involve outpatient evaluation and management for complex vitreo-retinal pathologies such as age-related macular degeneration, diabetic retinopathy, retinal vascular disorders, inherited retinal degenerations, infectious and non-infectious uveitis, and inherited and acquired maculopathies. I also perform surgical management for patients with the above complex vitreo-retinal pathologies.

6. A recent copy of my curriculum vitae (“CV”) is attached as Exhibit 1032 hereto, and provides information about my experience, expertise, and presentations.

7. In addition to my work experience, I have many years of experience participating in professional organizations relating to ophthalmology. Specifically, I am a member of the American Academy of Ophthalmology, the Association for Research in Vision and Ophthalmology, the American Society of Retina Specialists, the Pan-American Association of Ophthalmology, and a number of other professional societies and organizations.

8. In addition to the above, I have given numerous presentations at industry meetings and medical conferences relating to ocular diseases, including wet macular degeneration. These include, for example, a presentation specifically regarding anti-VEGF agents in wet age-related macular degeneration (wet AMD), sustained delivery systems, keratoprosthesis, retinal vein occlusion, uveitis, macular edema secondary to diabetic retinopathy, retinal vein occlusion, and diseases of the vitreomacular interface. I have also performed research on novel drug delivery approaches such as gene therapy, and developed a number of imaging methods. I have authored or co-authored a number of papers, a substantial number of which are listed on the attached CV. I am also on the editorial board of several journals, and I am an *ad hoc* reviewer for other journals and grants.

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