

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

Case IPR2021-00816
Patent 9,220,631

**DECLARATION OF DR. JEREMY WOLFE, IN SUPPORT OF
PATENT OWNERS' CONTINGENT MOTION TO AMEND**

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I. Introduction

1. I, Jeremy Wolfe M.D., submit this declaration on behalf of Novartis Pharma AG, Novartis Technology LLC, Novartis Pharmaceuticals Corporation, (collectively, “Patent Owners” or “Novartis”), as an independent expert witness regarding the proposed amended claims of U.S. Patent No. 9,220,631 (“the ’631 patent”).

2. I understand that Regeneron Pharmaceuticals, Inc. (“Petitioner” or “Regeneron”) filed a petition for *inter partes* review (“IPR”) in *Regeneron Pharmaceuticals, Inc. v. Novartis Pharma AG*, IPR2021-00816, seeking cancellation of all claims of the ’631 patent. I further understand that the Patent Trial and Appeal Board (“PTAB”) of the U.S. Patent and Trademark Office (“PTO”) issued a decision on October 26, 2021, granting institution of *inter partes* review of the ’631 patent. I understand that Novartis is submitting claim amendments in the alternative, if the current claims are found unpatentable.

3. I have been asked to opine on certain issues relating to the non-obviousness of the proposed substitute claims of the ’631 patent. This declaration provides my opinions and an explanation of certain practices and subject matter related to ophthalmology and intravitreal injections. My opinions and analyses are based on my knowledge and experience, in addition

to the materials I have considered from this IPR proceeding including the prior art referenced by Petitioner in its IPR petition.

II. Qualifications and Compensation

4. I attended Case Western Reserve University and graduated with my B.A. in biochemistry in 1999, magna cum laude. I earned my M.D. and a M.S. in Biomedical Science from the Medical College of Ohio in 2004. While in medical school, I was selected to be a Howard Hughes research scholar at the National Eye Institute in Bethesda, Maryland, where I conducted research on macular degeneration. I completed my internship and medical residency in Ophthalmology at Emory University, and then completed a two-year fellowship in Vitreoretinal Surgery at the Wills Eye Institute in Philadelphia, Pennsylvania.

5. I am a board certified ophthalmologist specializing in all aspects of vitreoretinal disease. I obtained my Board Certification in 2009. I have extensive experience in the medical and surgical treatment of all retinal diseases, and I regularly perform advanced retinal surgery for many vitreoretinal diseases. I completed my ophthalmology residency in 2008 and my vitreoretinal fellowship in 2010 and have been practicing continuously in this field since then. As an experienced ophthalmologist with an established practice, I treat more than 5,000 patients per year, and I conduct on average 25 injections/day to treat patients with retinal diseases such as Neovascular Age-

Related Macular Degeneration, Macular Edema Following Retinal Vein Occlusion, Diabetic Macular Edema, Myopic Choroidal Neovascularization, and Diabetic Retinopathy.

6. I have been a partner at my practice, Associated Retinal Consultants, since August 2010. I also have served as the co-Director of the Vitreoretinal Surgery Fellowship Program at the practice since September 2019. In September 2021, I became the co-President of the practice. In addition to working at my practice, I treat patients through medical staff appointments at William Beaumont Hospital, Truvista Surgery Center.

7. In addition to my medical practice, I am an Associate Professor of Ophthalmology at Oakland University William Beaumont School of Medicine in Rochester, Michigan, where I have taught since December 2010.

8. Additional information regarding my background, professional and research experience, and published works are listed on my curriculum vitae, attached as Ex. 2211.

9. I am being compensated at my standard rate of \$750/hour. My compensation is in no way contingent upon my opinions or the outcome of this proceeding.

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