UNITED STATES PATENT AND TRADEMARK OFFICE

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BEFORE THE PATENT TRIAL AND APPEAL BOARD

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REGENERON PHARMACEUTICALS, INC.,
Petitioner

v.

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

_____

Case IPR2021-00816
Patent 9,220,631

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DECLARATION OF ANDREW F. CALMAN, M.D., PH.D., IN SUPPORT OF PATENT OWNER RESPONSE

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I. INTRODUCTION

1. I, Andrew F. Calman, M.D., Ph.D., have been retained by Novartis Pharma AG, Novartis Technology LLC, and Novartis Pharmaceuticals Corp. (collectively, "Patent Owner" or "Novartis") as an independent expert witness in the above-captioned *inter partes* review ("IPR"), in which Petitioner Regeneron Pharmaceuticals, Inc. ("Petitioner" or "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 opinions based on the materials I have considered and my knowledge, education, skills, training, and experience.

2. I provide this declaration to provide medical and ophthalmological context for the '631 patent and the claims contained therein, including a description of age-related macular degeneration and its treatments, injection of drugs directed against vascular endothelial growth factor (VEGF), and the factors and considerations that a clinician would have found important as of the priority date of the '631 patent with regard to drug injection devices, particularly pre-filled syringes (PFS).

II. QUALIFICATIONS AND COMPENSATION

3. I graduated in 1982 from Yale University, having earned both my B.S. (*summa cum laude*, with Distinction in the Major) and my M.S. in Molecular

Biophysics and Biochemistry in four years. I then spent seven years at the University of California, San Francisco ("UCSF"), earning an M.D. and a Ph.D. in Microbiology and Immunology. While in medical and graduate school, I earned the Dean's Prize for Student Research, the Chancellor's Fellowship, and received the E.E. Osgood Award from the American Federation for Clinical Research, awarded for the best student research in the Western United States. My published research (including two papers in *Nature* and two in the *Proceedings of the National Academy of Sciences*) included identification of a human T-cell antigen receptor gene, an *in vitro* model of immune deficiency, and mechanisms of HIV gene activation.

4. I went on to pursue a year of medical internship, during which time I oversaw a UCSF laboratory team responsible for isolating a human galactokinase gene, followed by ophthalmology residency training at UCSF. During the eleven years that I spent working in research laboratories, from undergraduate to internship, I was exposed to a variety of methods in biochemistry, microbiology, immunology, and molecular genetics, including gene splicing, manipulation of DNA, RNA, and proteins, production and use of antibodies including monoclonal antibodies, growth of bacterial and viral cultures, and various types of sterilization.

5. Since completing my ophthalmology residency training in 1993, I have served on the UCSF clinical faculty, currently as Associate Clinical Professor

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