UNITED STATES PATENT AND TRADEMARK OFFICE

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BEFORE THE PATENT TRIAL AND APPEAL BOARD

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MYLAN PHARMACEUTICALS INC., CELLTRION, INC.,
and APOTEX INC.,
Petitioners,

v.

REGENERON PHARMACEUTICAL, INC.,
Patent Owner

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Inter Partes Review No. 2021-00881[1]
U.S. Patent No. 9,254,338 B2

DECLARATION OF DIANA V. DO, M.D.

[1] IPR2022-00258 and IPR2022-00298 have been joined with this proceeding.

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I, Dr. Diana Do, declare:

I. INTRODUCTION

1. I have been retained by counsel for Regeneron Pharmaceuticals, Inc. ("Regeneron") as a technical expert in connection with the above-captioned proceeding. I have been asked to provide my opinions and views on the materials I have reviewed in relation to the Petition for *Inter Partes* review ("IPR") of U.S. Patent No. 9,254,338 (the "'338 patent") (Ex. 1001) and, in particular, how the person of skill in the art as of the filing date of the '338 patent would have understood certain terms of the '338 patent claims. I have also been asked to provide my opinions and views about whether the dosage and administration criteria set forth in the FDA label for Eylea practice one or more of the claims of the '338 patent and whether physicians in clinical practice treat patients with Eylea using the methods recited in one or more claims of the '338 patent. I have been further asked to respond to the opinions and views of Petitioner's declarant, Dr. Thomas A. Albini. I submit this declaration in support of Regeneron's Patent Owner Response ("POR"). I reserve the right to provide further and additional opinions in the event that IPR is instituted.

2. I am being paid at an hourly rate for my work on this matter. I have no personal or financial stake in the outcome of the present proceeding.

II. QUALIFICATIONS AND EXPERIENCE

3. I am a Professor of Ophthalmology and the Vice Chair for Clinical Affairs at the Byers Eye Institute at Stanford University School of Medicine and have been since 2017. I also serve as a Physician Improvement Leader at Byers Eye Institute, a position I have held since 2018. I have an active clinical and surgical practice and I work as a clinical investigator to study novel treatments for retinal diseases. In addition, I teach students, residents, and retina fellows at Stanford and am a member of the Stanford Ophthalmology Education Committee.

4. I graduated from the University of California Berkeley (summa cum laude) with a B.A. degree in Molecular and Cellular Biology in 1995 and earned my M.D. (Alpha Omega Alpha) from the University of California San Francisco School of Medicine in 1999. Following medical school, I completed an internship in internal medicine at Massachusetts General Hospital at Harvard Medical School. From 2000-2003, I completed my residency in Ophthalmology at the Wilmer Eye Institute at Johns Hopkins University School of Medicine, and then remained at the Wilmer Eye Institute for a Retina Fellowship in surgical and medical retina from 2003-2005.

5. From 2005 through 2010, I served as Assistant Professor of Ophthalmology and Assistant Head of the Retina Fellowship Training Program at the Wilmer Eye Institute. In 2011, I was promoted to Associate Professor and Head of the Retina Fellowship Training Program, positions I held through 2013.

6. In 2013, I joined the faculty at the Truhlsen Eye Institute at the University of Nebraska College of Medicine, where I became a full Professor of Ophthalmology in 2015. At the Truhlsen Eye Institute, I was Head of the Retina Fellowship Training Program and Program Director for the Ophthalmology Residency. In my leadership roles at the Truhlsen Eye Institute, I also served as Vice Chair of Education. I was recruited by Stanford University's Ophthalmology Department (the Byers Eye Institute) at Stanford in the beginning of 2017.

7. As a physician-scientist, I am an international leader in the treatment of diabetic retinopathy and wet AMD ("wAMD"). My research has led to more than 140 peer-reviewed publications. My research interest focuses on evaluating the efficacy and safety of novel pharmacologic therapies for diabetic macular edema, diabetic retinopathy, wAMD, retinal vein occlusion, and ocular inflammation. I have led national and global clinical trials investigating intravitreal VEGF inhibitors (aflibercept and ranibizumab) for diabetic eye disease and wet AMD. Our research developed a greater understanding of how intraocular inhibition of VEGF reduces vascular permeability and angiogenesis in diabetic eye disease, thereby reducing diabetic macular edema and improving visual acuity. Before the onset of pharmacologic therapies, thermal laser photocoagulation was the only treatment option for diabetic macular edema and laser was not effective in improving vision. Our research led to new treatment paradigms and better vision outcomes for patients

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