UNITED STATES PATENT AND TRADEMARK OFFICE

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BEFORE THE PATENT TRIAL AND APPEAL BOARD

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SAMSUNG BIOEPIS CO., LTD.
Petitioner,

v.

REGENERON PHARMACEUTICALS, INC.
Patent Owner.

Patent No. 11,253,572

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Inter Partes Review No. IPR2023-00884

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DECLARATION OF DAVID M. BROWN, M.D.

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I, David M. Brown, M.D., declare as follows:

I.   INTRODUCTION

1.   I have been retained by counsel for Patent Owner, Regeneron Pharmaceuticals, Inc., as a technical expert in connection with the *Inter Partes* Review proceeding identified above. I submit this declaration in support of Regeneron's Response in this proceeding.

2.   I understand that Petitioner Samsung Bioepis Co., Ltd. challenges a number of claims of United States Patent No. 11,253,572 ("the '572 Patent") in this proceeding.

3.   I understand that Petitioner has asserted Shams (Ex.1017), a Genentech patent application filed in 2004, as one of its prior art references. The Shams reference focuses on the protocol for Genentech's PIER trial. I was a principal investigator on PIER, and so I have been asked to opine on aspects of PIER that could color a POSA's understanding of the Shams reference.

4.   I understand that Petitioner has asserted the 2010 ARVO Abstract (Ex.1010) reporting certain top-line results of the DA VINCI trial. I was a clinical investigator on the DA VINCI trial, so I have been asked to explain my and the other clinical investigators' role on the DA VINCI trial. I am also listed with Dr. James Major as one of the authors on the 2010 ARVO Abstract, so I have been asked to explain my and Dr. Major's roles in preparing the abstract.

5.   I have personal knowledge of Exhibits 2022–2023 and 2077–2080 cited in this declaration, which are true and correct copies of documents I received, sent, or reviewed.

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

II.   QUALIFICATIONS

7.   I am the Director of the Greater Houston Retina Research Center, where I have been a Physician Partner and Researcher since 1995. I also have a series of academic appointments: Clinical Professor of Ophthalmology, Cullen Eye Institute at Baylor College of Medicine; Vice-Chair of Ophthalmology for Research and Associate Clinical Professor of Ophthalmology at the Methodist Hospital, Weill Cornell College of Medicine in Houston, Texas; and the NASA Research and Clinical Advisory Panel—Space Associated Neuro-Ophthalmic Syndrome at NASA Johnson Space Center in Houston, Texas.

8.   I graduated from Baylor College of Medicine with highest honors in 1988. I completed a medical/surgical internship at Baylor College of Medicine from 1989 to 1990. From 1990 to 1995, I completed ophthalmology and retina training at the University of Iowa, where I was a Thomas Heed Fellow and a Hermann Knapp Fellow, and was awarded the Ron Michels Fellowship award presented to the top retinal surgery fellow in the United States in 1994.

9.   I have served on the Board of Directors of the American Society of Retina Specialists since 2014; the Macula Society Credentials Committee since 2013; and the Retina Society Finance Committee since 2018. I have served in numerous additional leadership roles in professional organizations and societies in the retina and ophthalmology field over the past three decades. I have also been a peer reviewer for the journals in these fields, including *Ophthalmology*, *Retina*, and the *New England Journal of Medicine*.

10.   I maintain an active medical and surgical practice focused on treatment of retinal diseases and have continuously been elected as one of the "Best Doctors in America" from 2007 to 2024 and "Texas Super Docs" from 2009 to 2024. I am also an elected member of the Macula Society, the Retina Society, and the Club Jules Gonin. My honors include the American Academy of Ophthalmology Honor Award (2000), the American Society of Retina Specialists Honor Award (2008), the ASRS Senior Honor Award (2010), the AAO Senior Honor Award (2014), and Retina Hall of Fame inaugural inductee (2017).

11.   My research and clinical trial experience has led to my recognition as an international thought leader on treatments and current standards of care for age-related macular degeneration, retinal vein occlusion, and diabetic retinopathy. I have written and published over 400 national meeting presentations, abstracts, and scientific papers, including many of the primary papers establishing the safety and

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