UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

SAMSUNG BIOEPIS CO., LTD.
Petitioner,

v.

REGENERON PHARMACEUTICALS, INC.
Patent Owner.

Patent No. 11,253,572

Inter Partes Review No. IPR2023-00884

DECLARATION OF KAREN CHU

IPR2023-00884

I, Karen Chu, declare as follows:

1. I have personal knowledge of the facts contained in this Declaration, and if called upon to do so, I could and would testify competently thereto.

2. As I explain in detail below, I am an employee of Regeneron Pharmaceuticals ("Regeneron"). I have not been compensated separately for my efforts in connection with the preparation of this Declaration, but have instead continued to receive my usual salary, including with respect to periods of time during which I worked on this Declaration. My regular Regeneron compensation is in no way contingent on the results of these or any other proceedings.

3. I have personal knowledge of Exhibits 2004, 2008, 2013, 2020, 2036, 2043, 2047, 2048, 2068, and 2076 cited in this declaration, which are true and correct copies or excerpts of documents I received, sent, or reviewed. They also are business records created during the ordinary course of Regeneron's business operations and documenting various activities and product development, as is and was our practice at Regeneron.

I. BACKGROUND

4. I am the Vice President, Global Program Head for Ophthalmology at Regeneron and have held this position since October 2023. In this role, I am responsible for the overall strategy and cross-functional alignment for

ophthalmology clinical development. My duties include advancing candidates from preclinical development to clinical trials and developing the overall program strategy for all phases of clinical development. I have worked at Regeneron since 2003, and I have held various positions in the clinical development group, which I discuss further below.

5. I earned my Bachelor of Science in biology from California Polytechnic State University San Luis Obispo and my Master of Science in human nutrition from Columbia University. I have more than 25 years of direct experience in developing therapies for various diseases, including more than 20 years of experience in developing therapies for ophthalmic diseases.

II. MY ROLE IN THE DEVELOPMENT OF EYLEA®

6. In 2003, I joined Regeneron as a Senior Clinical Trial Manager. My job was to help implement and execute clinical trials. At that time, Regeneron was still in the early stages of clinical development of aflibercept, the active ingredient in EYLEA®, for both oncology and ophthalmology indications, and my duties included overseeing a group of Clinical Trial Managers and other personnel involved in the operations of Regeneron's early phase clinical trials for that drug. During clinical trials, Regeneron sometimes referred to EYLEA® as "VEGF Trap-Eye" and I will also use that terminology in this Declaration.

7. Within my first year at Regeneron, VEGF Trap-Eye had advanced from preclinical research to clinical development. It was at that time that I became involved in the development of EYLEA® and my focus shifted exclusively to ophthalmology. Due to the small size of Regeneron at the time, and the clinical and regulatory group in particular, I became involved in the early discussions around development strategy and study designs for VEGF Trap-Eye against various indications, including neovascular age-related macular degeneration ("wet AMD" or "AMD") and diabetic macular edema ("DME").

III. DR. YANCOPOULOS'S ROLE IN THE DEVELOPMENT OF EYLEA®

8. When I joined Regeneron, Dr. Yancopoulos was the Chief Scientific Officer at the company, a position that he still holds today. Dr. Yancopoulos has always taken, and continues to take, a hands-on role in research and development, including the clinical development of VEGF Trap-Eye.

9. At that time (and still to this day), members of senior management, including Dr. Yancopoulos, were substantively involved in clinical development planning and strategy. Regeneron employed a cross-functional team structure, meaning that senior management made decisions based on the collective input of the various teams working on clinical development. The various teams would prepare and present data to members of senior management for discussion, who

then would use that data to make final decisions regarding clinical development planning and strategy.

10. As the Chief Scientific Officer, Dr. Yancopoulos was always substantively engaged in these discussions and data analysis. It was common for Dr. Yancopoulos to intensely scrutinize presentations and to request additional data or analysis. Due to his scientific expertise and extensive knowledge of the field, [redacted] as discussed below.

IV. REGENERON'S COLLABORATION WITH BAYER

11. In the latter part of 2006, Regeneron entered a collaboration with Bayer Schering Pharmaceuticals, now called Bayer, for the global development and commercialization of VEGF Trap-Eye. Exhibit 2068 is a true and correct copy of an October 18, 2006 joint press release announcing the collaboration of Bayer and Regeneron on the development of VEGF Trap-Eye for the treatment of angiogenic eye diseases.

12. As part of the collaboration, Regeneron and Bayer established joint committees, each of which comprised a co-chair and a collection of members from each company. Ex.2069. The Joint Steering Committee (JSC) included senior-

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