

**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. 10,888,601

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*Inter Partes* Review No. IPR2023-00739

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**DECLARATION OF MICHAEL W. STEWART, M.D.**

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I, Michael W. Stewart, M.D., declare as follows:

## **I. INTRODUCTION**

1. I have been retained by counsel for Patent Owner, Regeneron Pharmaceuticals, Inc. (“Regeneron”), as a technical expert in connection with the proceeding identified above. I submit this declaration in support of Patent Owner Regeneron’s Responses in connection with the *Inter Partes* Review of United States Patent No. 10,888,601 (“the ’601 Patent”).

2. I am being paid at 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. SUMMARY OF OPINIONS**

3. It is my opinion that the challenged claims of the ’601 Patent are patentable and nonobvious. The following is a summary of my opinions:

- The plain and ordinary meaning of the challenged claims requires a predetermined dosing regimen.
- The plain and ordinary meaning of the challenged claims requires both (1) an intent to treat a specific angiogenic disorder and (2) treating the angiogenic eye disorder with a level of efficacy comparable to monthly Lucentis or Avastin.

- The dosing regimen recited in the challenged claims of the '601 Patent is not obvious over the 2009 Press Release either alone or in combination with Shams.
- The recited dosing regimen is not obvious over the 2009 Press Release in view of Elman 2010.
- The prior art does not disclose the level of efficacy required by the challenged claims.
- The prior art does not disclose intent to treat diabetic retinopathy.
- Eylea embodies the claims of the '601 Patent such that there is a nexus between the '601 Patent and the commercial success of Eylea.

### III. QUALIFICATIONS

4. I am the Chair of the Department of Ophthalmology at Mayo Clinic in Jacksonville, Florida, where I have been Chair since 2005 and Consultant since 2002. I have been a Professor of Ophthalmology at the Mayo Clinic College of Medicine and Science since 2014 and am currently the Knights Templar Eye Foundation, Inc. Professor of Ophthalmology Research.

5. I graduated from Harvard University with a degree in Chemistry cum laude in 1979. I received my M.D. at McGill University School of Medicine in

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