

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. 10,888,601

Inter Partes Review No. IPR2023-00739

DECLARATION OF MICHAEL W. STEWART, M.D.

CONTENTS

I.	INTRODUCTION	3
II.	SUMMARY OF OPINIONS.....	3
III.	QUALIFICATIONS	4
IV.	MATERIALS CONSIDERED	6
V.	LEGAL STANDARDS	7
VI.	TECHNICAL BACKGROUND	10
	A. Diabetic retinopathy and diabetic macular edema.....	10
	B. Prior art therapies for angiogenic eye disorders	14
	C. Eylea	21
VII.	THE '601 PATENT.....	25
VIII.	PETITIONER'S PRIOR ART REFERENCES.....	26
	A. 2009 Press Release (Ex.1009)	26
	B. Shams (Ex.1010).....	27
	C. Elman 2010 (Ex.1006).....	28
IX.	PERSON OF ORDINARY SKILL IN THE ART	29
X.	CLAIM CONSTRUCTION	30
	A. "[E]very 4 weeks for the first 5 injections followed by . . . every 8 weeks" refers to a predetermined dosing regimen.....	30
	B. "[M]ethod for treating" / "effective amount"	37
	1. The claims require efficacy comparable to monthly ranibizumab or bevacizumab	37
	2. The claims require intent to treat a specific angiogenic eye disorder.....	41
XI.	THE FIVE LOADING-DOSE REGIMEN RECITED IN THE CHALLENGED CLAIMS IS NOT OBVIOUS.....	42
	A. The dosing regimen recited in the '601 claims is not obvious over the 2009 Press Release alone or in view of Shams	44
	1. The 2009 Press Release and Shams do not teach toward five loading doses.....	45

2. A POSA would not arrive at the claimed regimen with “routine optimization” or “routine adjustments.”	52
3. A POSA would not have a reasonable expectation of success in using a fixed extended dosing regimens in order to treat effectively while minimizing the number of loading doses.	56
B. The recited dosing regimen is not obvious over the 2009 Press Release in view of Elman 2010.	58
1. Elman 2010 does not teach toward five loading doses	59
2. There is no motivation to combine Elman 2010 with the 2009 Press Release	68
XII. The prior art does not disclose the required efficacy.	79
A. 2009 Press Release	80
B. Shams.....	81
C. Elman 2010	82
D. PIER.....	83
E. CATT	83
XIII. The prior art does not disclose intent to treat diabetic retinopathy.	83
A. DR and DME are defined and measured differently.....	84
B. The 2009 Press Release does not disclose any indication of intent to treat DR.....	87
C. Treating DME is not tantamount to treating DR.....	90
XIV. Commercial success.....	92
A. Nexus to Eylea.....	93
B. Commercial success of Eylea	96

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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