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 MICHAEL W. STEWART, M.D.



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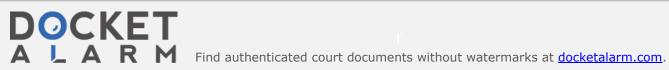


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A.	The prior art does not disclose or suggest the required benefits to visual acuity for angiogenic eye disorders, in general, or for AMD, specifically							
	1.	In general, partial results from Phase I and II clinical trials do not predict a Phase III clinical trial's outcome						
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		a.	Claim 1					
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	2.	Neither Dixon nor Hecht renders obvious a non-ionic surfactant						
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	1.	The 2009 Press Release does not teach or suggest the dosing regimen of claim 25						
	2.	The 2009 Press Release in combination with Shams does not teach or suggest the dosing regimen of claim 25						
		a.	Shams does not teach or suggest more loading doses					



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I, Michael W. Stewart, M.D., make this declaration in connection with the proceeding identified above.

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's Response in connection with the *Inter Partes* Review of United States Patent No. 11,253,572 ("the '572 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 '572 Patent are nonobvious and patentable. The following is a summary of my opinions:
 - The results of the recited dosing regimens for angiogenic eye disorders, in general, and for age related macular degeneration, specifically, were not obvious over Dixon, either alone or in view of the 2006 Press Release.

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