

**UNITED STATES PATENT AND TRADEMARK OFFICE**

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**BEFORE THE PATENT TRIAL AND APPEAL BOARD**

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**REGENERON PHARMACEUTICALS, INC.,**  
Petitioner

v.

**NOVARTIS PHARMA AG,  
NOVARTIS TECHNOLOGY LLC,  
NOVARTIS PHARMACEUTICALS CORPORATION,**  
Patent Owner

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**Case IPR2021-00816**  
Patent 9,220,631

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**DECLARATION OF JUERGEN SIGG, PH.D., IN SUPPORT OF  
NOVARTIS'S  
PATENT OWNER RESPONSE**

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I, Juergen Sigg, declare and state as follows:

**I. INTRODUCTION**

1. I am an Executive Director of Science and Technology in Biologics Drug Product Development at Novartis Pharma AG (“Novartis”). As part of my duties at Novartis, I serve as the lead scientist for formulation and process development of assigned biologic drug products.

2. I have a degree in pharmaceutical science and a Ph.D. in pharmaceutical technology. Over the course of my career at Novartis, I have been the lead formulation and process development scientist on several prefilled syringe (“PFS”) products. My work in this area began in 1995, and continues to this day. Several of the PFS products I worked on, including Xolair® and Extavia®, made it to the market. Relevant here, I served as the technical lead in the development of the Lucentis® PFS.

3. I am a named inventor on several patents and patent applications, including U.S. Patent No. 9,220,631 (“’631 patent”) and the abandoned patent application WO 2011/006877 (“WO ’877”).

4. I have personal knowledge of the facts set forth below.

**II. GENENTECH TRIED TO DEVELOP A TERMINALLY STERILIZED PFS FOR INTRAVITREAL INJECTION OF A VEGF ANTAGONIST BUT FAILED**

5. Lucentis is the brand name for a compound discovered by Genentech called ranibizumab. Ranibizumab functions as a VEGF antagonist and is used to

treat degenerative eye diseases. Lucentis is administered through intravitreal injection into the eye.

6. [REDACTED]  
[REDACTED]  
[REDACTED]  
[REDACTED]  
[REDACTED].

7. [REDACTED]  
[REDACTED]  
[REDACTED]  
[REDACTED]  
[REDACTED]  
[REDACTED].

8. [REDACTED]  
[REDACTED]  
[REDACTED]  
[REDACTED]  
[REDACTED]

9. [REDACTED] [REDACTED]  
[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

10. [REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED].

11. [REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED].

12. [REDACTED] [REDACTED]

[REDACTED]

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