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 Owners

_____

Case IPR2020-1318
Patent 9,220,631

_____

DECLARATION OF MARIE PICCI IN SUPPORT OF NOVARTIS'S PATENT OWNER PRELIMINARY RESPONSE

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I. INTRODUCTION

1. I, Marie Picci, have personal knowledge of the facts set forth in this Declaration and am competent to testify concerning the same.

2. I joined Novartis AG, the owner of United States Patent No. 9,220,631 (the "'631 patent"), in 2006. I work at Novartis AG's Basel, Switzerland location. From 2006–2014, I held the title of Senior Project Leader/Principal Device Engineer/ Team Lead for Device Development. In 2014, I became the Group Head of Portfolio Management for Device Development. I started working on the Lucentis® pre-filled syringe ("PFS") project around April 2011. As Device Team Leader, I was responsible for the device constituent of the PFS, which includes the syringe components. My work focused on the development of the integral parts of the device, including siliconization and sterilization of the PFS. I worked on the PFS project until late 2018, when I transitioned to my current role as the Delivery Systems Strategy Director for Device Development & Life Cycle Management ("LCM").

3. I am familiar with the subject matter claimed in the '631 patent. I am a named inventor of the '631 patent.

4. I have been asked to provide this declaration to explain the facts and circumstances surrounding the invention described in the '631 patent.

5. The documents cited in this document were generated as part of the IPR2020-01318

ordinary course of business at Novartis AG ("Novartis"). Through my employment with Novartis, I am familiar with Novartis's practices regarding the creation and maintenance of such documents. The documents cited were made at or near the time referenced in the document by someone with knowledge of the subject matter relevant to the document. The documents were kept in the course of Novartis's regularly conducted research and development activities, and making these documents was a regular practice of these activities.

II. INVENTION OF THE CLAIMED SUBJECT MATTER

6. I, along with my co-inventors, Juergen Sigg, Christophe Royer, Andrew Mark Bryant, and Heinrich Martin Buettgen conceived of the invention claimed in the '631 patent by no later than July 2012. Specifically, no later than October 2011, we had conceived of, *e.g.*, a terminally sterilized PFS for intravitreal injection, the syringe components comprising a glass barrel, a stopper and a plunger rod, and containing a solution comprising a VEGF antagonist. The PFS we conceived of also had, *e.g.*, a maximum fill volume of either 0.5 mL or 1 mL, the syringe barrel included from about 1 µg to 100 µg silicone oil, the VEGF antagonist had no more than two particles greater than 50 µm in diameter per mL, and the syringe had a stopper break loose force of less than about 11 N.

7. Our conception is corroborated by, for example, a PowerPoint presentation we presented to the Technical Development Review Committee in

October 2011, entitled RFB002 (Lucentis) Pharmaceutical Development Technical Review ("Development Technical Review" or "DTR"). Ex. 2031. Ex. 2031 is a true and correct copy of the Development Technical Review PowerPoint slide deck. The Development Technical Review was authored by Juergen Sigg, and summarizes our work to that point on the development of an intravitreal PFS for Novartis's Lucentis® product, which includes ranibizumab as an active ingredient, and provides details concerning the properties and features we intended the PFS to have. *Id*.

8. The Development Technical Review describes [redacted] Ranibizumab, the active ingredient in Lucentis®, is a VEGF antagonist administered by intravitreal injection. *See* Ex. 1027.001 and .004 (then-current Lucentis® prescribing information identifying Lucentis® (ranibizumab) as a monoclonal antibody fragment that binds to and inhibits VEGF and administered via intravitreal injection). [redacted]

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