UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

REGENERON PHARMACEUTICALS, INC.,
Petitioner

v.

NOVARTIS PHARMA AG,
NOVARTIS TECHNOLOGY LLC,
NOVARTIS PHARMACEUTICALS CORPORATION,
Patent Owners

Case IPR2021-00816
Patent 9,220,631

DECLARATION OF MICHAEL J. MILLER, PH.D., IN SUPPORT OF NOVARTIS'S PATENT OWNER RESPONSE

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I. Introduction

1. I, Michael J. Miller, have been retained to provide expert opinions in the above captioned proceeding, which I understand was initiated by Regeneron Pharmaceuticals, Inc. ("Petitioner") by filing a Petition seeking cancellation of all claims of U.S. Patent No. 9,220,631 ("the '631 patent"). I submit this declaration on behalf of Novartis Pharma AG, Novartis Technology LLC, and Novartis Pharmaceuticals Corporation (collectively, "Patent Owner" or "Novartis").

II. Qualifications

2. I am a microbiologist and an expert in, among other things, the sterilization of medical devices, pharmaceutical and ophthalmic preparations.

3. I have over 30 years of experience in the fields of microbiology, sterilization, manufacturing, regulatory and quality assurance for the pharmaceutical, biopharmaceutical, ophthalmic/contact lens care and medical device industries.

4. I received a Ph.D. in Microbiology and Biochemistry from Georgia State University (GSU) in 1988. My Ph.D. focused on the bacterial contamination of contact lenses, which was a significant clinical issue during the time of my studies. My studies resulted in the publication of my research in several peer-reviewed clinical microbiology and ophthalmology journals.

5. Concurrent with my Ph.D. work at GSU, I performed research studies associated with bacterial endophthalmitis (an inflammatory condition of the intraocular cavities, i.e., the aqueous and/or vitreous humor, usually caused by infection) at the Department of Ophthalmology at Emory University School of Medicine. My research was published in two peer-reviewed ophthalmology journals.

6. After receiving my degree, I was employed by Advanced Sterilization Products (ASP), a Johnson & Johnson company, and Johnson & Johnson Medical, Inc. in Arlington, Texas from July 1988–July 1991, where I held the position of Senior Microbiologist and Manager of Microbiology. While at ASP, I was personally responsible for developing all the microbiology developmental and validation strategies for the company's vaporized hydrogen peroxide ("VHP") technology. My work encompassed the development of the technology, demonstrating technical benefits to other sterilization methods, including ethylene oxide, performance of VHP residual studies and biological indicator challenges to demonstrate sterility assurance levels. I was also responsible for managing a laboratory that conducted many of the evaluations, focusing on the sterilization of surgical and ophthalmic instrumentation and implantable medical devices. During this time, I also worked on an American National Standard Institute (ANSI) sterilization technical committee, whose work was used to help create the

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