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 Owner

Case No. IPR2021-00816
U.S. Patent No. 9,220,631

DECLARATION OF JAMES AGALLOCO

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I. INTRODUCTION

1. I have been retained by Petitioner Regeneron Pharmaceuticals, Inc. ("Petitioner" or "Regeneron"), as an independent expert witness in the above-captioned *inter partes* review ("IPR"), in which Regeneron has requested that the U.S. Patent and Trademark Office cancel as unpatentable all claims of U.S. Patent No. 9,220,631 ("the '631 patent") (Ex. 1001).

2. This declaration sets forth my analyses and opinions based on my knowledge, experience, and the materials I have considered.

II. QUALIFICATIONS AND COMPENSATION

3. I have a M.B.A. in Pharmaceutical Studies from Fairleigh Dickinson University, a M.S.Ch.E. from the Polytechnic Institute of New York, and a B.E.Ch.E. from Pratt Institute.

4. I have over fifty years of management experience in pharmaceutical manufacturing, pharmaceutical process, pharmaceutical process engineering, technical services and research and development. Since 1991, I have been the President of Agalloco & Associates, which provides to the pharmaceutical, biotechnology, and medical device industry a wide range of technical services such as process and product validation, sterilization, aseptic processing, processing, isolation technology, sterility assurance, compliance and facility design.

5. Prior to 1991, I was Director of Validation and Technology at Bristol-Myers Squibb; Director of Worldwide Validation and Automated Technology and Pharmaceutical Engineering; Department Manager at Bristol-Myers Squibb, and held a number of other positions, including Engineering Project Manager and Senior Production Supervisor at Pfizer Pharmaceuticals.

6. As Director of Validation and Technology at Bristol-Myers Squibb, I directed validation, automation and technical documentation activities and served as an important technical resource for worldwide pharmaceutical manufacturing. I was an active participant on product introduction and facility upgrade task forces. As Director of Worldwide Validation and Automated Technology at Bristol-Myers Squibb, I was responsible for facilities in 27 countries around the world and served as a major technical resource for facility design, facility start-up, sterilization, aseptic processing, validation and automation. I participated actively on major product, process, facility and equipment projects, directed the validation and automation phases of a $25 million expansion of existing parenteral facility in New Brunswick, and provided major support to sterile bulk manufacturing. As head of the Validation department at Squibb New Brunswick, I was responsible for validation of all processes at the site including various sterilization processes. I also led the validation effort for a $60 million parenteral facility.

7. In previous positions, I provided validation expertise for sterile facilities, acted as a spokesperson for validation to the Food and Drug Administration ("FDA") and other regulatory agencies, managed production operations for sterile and oral liquid and powder products, and had major areas of responsibility including cost control, cost reduction, Current Good Manufacturing Practice ("CGMP") compliance, scheduling, equipment selection, and process trouble shooting.

8. In addition to my work experience, I have many years of experience participating in professional organizations, and pharmacopoeias relating to sterilization and sterility assurance for pharmaceuticals and medical devices, including microbiology as it relates to sterilization. For example, I have been an active member of the United States Pharmacopoeia ("USP") Microbiology Expert Committee since 2005, and the lead author on the comprehensive revision of USP <1211> *Sterilization & Sterility Assurance of Compendial Items*. The new USP content (Chapters <1211> *Sterility Assurance* and <1229> *Sterilization*) includes substantially expanded content addressing the full range of sterilization processes and means for the aseptic processing for drugs and medical devices. In addition, I have led and participated in the development of numerous sterilization and aseptic processing industry guidance documents as a member of the Parenteral Drug Association. I have been a member of the Parenteral Drug Association since 1980

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