### 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

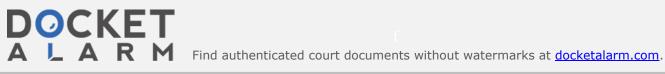


# TABLE OF CONTENTS

I.	Introduction
II.	Qualifications
III.	Scope of Study
IV.	Summary of Opinions
V.	Person of Ordinary Skill in the Art
VI.	Claim Construction
E	A. Development of a Sterilization Cycle
VIII	I. Sigg
A N V	Lam
O N	35. Lam Does Not Disclose an SAL of 10 <sup>-6</sup> as Required by Claim 21



Χ.	Macugen	37
XI.	Declaration	41



### 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.
- After receiving my degree, I was employed by Advanced Sterilization 6. 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



# DOCKET

# Explore Litigation Insights



Docket Alarm provides insights to develop a more informed litigation strategy and the peace of mind of knowing you're on top of things.

# **Real-Time Litigation Alerts**



Keep your litigation team up-to-date with **real-time** alerts and advanced team management tools built for the enterprise, all while greatly reducing PACER spend.

Our comprehensive service means we can handle Federal, State, and Administrative courts across the country.

# **Advanced Docket Research**



With over 230 million records, Docket Alarm's cloud-native docket research platform finds what other services can't. Coverage includes Federal, State, plus PTAB, TTAB, ITC and NLRB decisions, all in one place.

Identify arguments that have been successful in the past with full text, pinpoint searching. Link to case law cited within any court document via Fastcase.

# **Analytics At Your Fingertips**



Learn what happened the last time a particular judge, opposing counsel or company faced cases similar to yours.

Advanced out-of-the-box PTAB and TTAB analytics are always at your fingertips.

### API

Docket Alarm offers a powerful API (application programming interface) to developers that want to integrate case filings into their apps.

#### **LAW FIRMS**

Build custom dashboards for your attorneys and clients with live data direct from the court.

Automate many repetitive legal tasks like conflict checks, document management, and marketing.

#### **FINANCIAL INSTITUTIONS**

Litigation and bankruptcy checks for companies and debtors.

## **E-DISCOVERY AND LEGAL VENDORS**

Sync your system to PACER to automate legal marketing.

