UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

MYLAN PHARMACEUTICALS INC.,
Petitioner

v.

REGENERON PHARMACEUTICALS, INC.,
Patent Owner

Inter Partes Review No.: IPR2021-00881

U.S. Patent No. 9,254,338 B2
Filed: July 12, 2013
Issued: February 9, 2016
Inventor: George D. Yancopoulos

Title: USE OF A VEGF ANTAGONIST TO TREAT ANGIOGENIC EYE DISORDERS

**DECLARATION OF MARY GERRITSEN, PH.D.
IN SUPPORT OF PETITION FOR *INTER PARTES* REVIEW OF
U.S. PATENT NO. 9,254,338 B2**

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I, Mary Gerritsen, Ph.D., declare as follows:

I. INTRODUCTION.

1. I submit this declaration on behalf of Mylan Pharmaceuticals Inc. ("Petitioner"). I understand that Petitioner is filing a petition with the United States Patent and Trademark Office ("USPTO") for *inter partes* review of U.S. Patent No. 9,254,338 B2 (the "'338 patent") (Ex.1001).

2. This Declaration contains my qualifications; my opinions based on my expertise, and my review of the '338 patent and other documents cited within this Declaration; the factual basis for those opinions; and data or other information I considered in forming my opinions. The opinions and facts set forth in this Declaration are based upon information and my analysis of documents related to the '338 patent, as well as my knowledge and experience in the pharmaceutical and biotechnology industries.

II. QUALIFICATIONS.

3. I am a pharmacologist with over thirty years of experience in the pharmaceutical and biotechnology industries.

4. In 2010, I founded Gerritsen Consulting, and I have been a consultant for the biotechnology industry on topics related to biotherapeutics and drug discovery in the therapeutic areas of oncology, immuno-oncology, ophthalmology, autoimmune diseases/inflammation, cardiovascular disease, and angiogenesis-

related diseases. Specifically, I have collaborated with companies in numerous areas of product development, including research strategy, target selection and assessment, preclinical pharmacology and mechanism of action studies, preparation of Investigational New Drug applications, procedures for clinical trials, and evaluation of pipeline portfolio strategies.

5. Prior to my consulting work, I was the Vice President of Molecular and Cellular Pharmacology at Exelixis, Inc. from 2004-2010. Exelixis is a biotechnology company focused on the development of small molecular therapeutics for the treatment of oncology and metabolic disease. I supervised many of the processes involved in preclinical to early clinical development, including target identification and validation, early lead discovery and validation, lead optimization, cellular and molecular pharmacology studies, pharmacodynamic assays, and early translational medicine studies. I also collaborated with the clinical groups in the early stages of Phase I clinical trials.

6. From 2003-2004, I was a consultant with Frazier Health Care Ventures in which I was involved in the founding of MacuSight, Inc., a pharmaceutical company focused on angiogenesis disorders, specifically focused on age-related macular degeneration and diabetic macular edema. I was an inventor on several of the patents that were the basis for the foundation of the company which included U.S. Patent Nos. 8,222,271, 8,486,960, and 9,452,156.

7. From 2002-2003, I was the Senior Director, Vascular Biology with Millennium Pharmaceuticals (formerly COR Therapeutics) where I was responsible for development of the strategic plan for vascular biology and oversaw numerous small molecule development programs in the therapeutic indications of atherosclerosis, peripheral vascular disease, and fibrosis.

8. Prior to the above, I was Associate Director of the Department of Cardiovascular Research at Genentech, Inc. from 1997-2001. Separately, I was a senior investigator in the angiogenesis group whose focus was the identification of novel targets for protein-based therapeutics. Throughout my time at Genentech, I was involved in the drafting and filing of over 1,000 patent applications in which over forty such applications issued as patents.

9. Before joining Genentech, I was a Principal Staff Scientist and Group Leader, Institute for Inflammation and Autoimmunity at Bayer Pharmaceuticals (formerly Miles Pharmaceuticals) from 1990-1997. During this time, I led the screening efforts for small molecule inhibitors of leukocyte adhesion, cyclo-oxygenase, and cytokine release/action while also supervising six laboratories within the Institute. Additionally, I developed collaborations with other industrial development laboratories as well as academic laboratories in order to promote advances in target discovery and assay development.

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