

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.: IPR2021-00880

U.S. Patent No. 9,669,069 B2
Filed: December 17, 2015
Issued: June 6, 2017
Inventor: George D. Yancopoulos

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

**EXPERT DECLARATION OF MARY GERRITSEN, PH.D.
IN SUPPORT OF PETITION FOR *INTER PARTES* REVIEW OF
U.S. PATENT NO. 9,669,069 B2**

Mylan Exhibit 1003
Mylan v. Regeneron, IPR2021-00880

TABLE OF CONTENTS

I.	INTRODUCTION.....	1
II.	QUALIFICATIONS.....	1
III.	SCOPE OF ENGAGEMENT.....	4
IV.	THE PERSON OF ORDINARY SKILL IN THE ART.....	7
V.	LEGAL STANDARDS.....	9
VI.	U.S. PATENT NO. 9,669,069.....	9
VII.	PROSECUTION HISTORIES OF THE '069 PATENT AND ITS EUROPEAN EQUIVALENT, EP-325.....	10
VIII.	DISCLOSURES, KNOWLEDGE, & INFORMATION AVAILABLE IN THE ART BEFORE JANUARY 13, 2011.....	23
	A. JOURNAL ARTICLES.....	23
	B. REGENERON PRESS RELEASES.....	25
	1. May 2008 Press Release.....	27
	2. September 2008 Press Release.....	30
	3. April 2009 Press Release.....	33
	4. February 2010 Press Release.....	35
	5. Additional Regeneron Press Releases.....	37
	C. CLINICALTRIALS.GOV.....	42
	D. SEC FILINGS.....	53
IX.	CONCLUDING STATEMENTS.....	56

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 1000 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, cyclooxygenase, 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.

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.