# UNITED STATES PATENT AND TRADEMARK OFFICE BEFORE THE PATENT TRIAL AND APPEAL BOARD

MYLAN PHARMACEUTICALS INC., TEVA PHARMACEUTICALS USA, INC. and AKORN INC.,<sup>1</sup>
Petitioners,

v.

ALLERGAN, INC. Patent Owner.

\_\_\_\_\_

Case IPR2016-01127 (US 8,685,930 B2)

Case IPR2016-01128 (US 8,629,111 B2)

Case IPR2016-01129 (US 8,642,556 B2)

Case IPR2016-01130 (US 8,633,162 B2)

Case IPR2016-01131 (US 8,648,048 B2)

Case IPR2016-01132 (US 9,248,191 B2)

#### DECLARATION OF ANDREW F. CALMAN, M.D., PH.D.

<sup>1</sup> Cases IPR2017-00576 and IPR2017-00594, IPR2017-00578 and IPR2017-00596, IPR2017-00579 and IPR2017-00598, IPR2017-00583 and IPR2017-00599, IPR2017-00585 and IPR2017-00600, and IPR2017-00586 and IPR2017-00601, have respectively been joined with the captioned proceedings. The word-for-word identical paper is filed in each proceeding identified in the caption pursuant to the Board's Scheduling Order (Paper 10).

MYLAN - EXHIBIT 1039

Mulan Pharmacauticale Inc at al w Allargan Inc



### TABLE OF CONTENTS

I.	QUALIFICATIONS	1
II.	SCOPE OF WORK	4
III.	BRIEF OVERVIEW OF THE LEVEL OF SKILL	5
IV.	CLAIM CONSTRUCTION	6
V.	UNDERSTANDING AND DIAGNOSING DRY EYE DISEASE	7
VI.	TREATING DRY EYE DISEASE	12
VII.	SCHIRMER TEAR TESTS AND LACRIMAL GLAND TEARING	21
VIII.	THE PATENTED FEATURES OF RESTASIS® WERE DISCLOSED IN THE PRIOR ART	29
IX.	THE CLAIMED FORMULATION IS NOT CRITICALLY OR UNEXPECTEDLY DIFFERENT THAN THE FORMULATIONS DISCLOSED IN THE PRIOR ART	32
X.	THE CLAIMED FORMULATION'S PERFORMANCE RELATIVE TO THE 0.1% CSA/1.25% CASTOR OIL EMULSION WAS NOT UNEXPECTED	49
XI.	CONCLUDING STATEMENTS	55
VII	ADDENDIY LIST OF EVHIRITS	56



I, Andrew F. Calman, M.D., Ph.D., declare as follows:

#### I. QUALIFICATIONS

- I received my Bachelor of Science in Molecular Biophysics and Biochemistry, summa cum laude, from Yale University in 1982, with Distinction in the Major. I also received my Master of Science in Molecular Biophysics and Biochemistry from Yale University in 1982. I then attended medical school and graduate school at the University of California, San Francisco (UCSF) with a full scholarship from the Medical Scientist Training Program of the National Institutes of Health from 1982 to 1989. In 1989, I received my Doctor of Medicine (M.D.) and Doctor of Philosophy (Ph.D.) in Microbiology and Immunology from UCSF, earning the Dean's Prize for Student Research, Chancellor's Fellowship, membership in Alpha Omega Alpha, and the E. E. Osgood Award for best student biomedical research in the Western United States. My graduate research involved identification of the T-cell antigen receptor beta-chain gene, rearrangement and expression of T-cell antigen receptor genes in B-cells, activation of HIV gene expression in T-cells, and an in vitro model of Bare Lymphocyte Syndrome, a form of congenital immune deficiency involving deficient expression of class II major histocompatibility genes.
- From 1989-1990, I completed a one-year internship in Internal
   Medicine at Kaiser Foundation Hospital in San Francisco, followed by a three-year



residency in Ophthalmology at UCSF. During this time, I set up a molecular biology laboratory in the Department of Ophthalmology at UCSF, resulting in the cloning of a human cataract gene by genetic complementation of galactokinasedeficient yeast cells. During my clinical training, I was introduced to the use of compounded cyclosporin for ocular conditions. I have been on the clinical faculty of UCSF since 1993, with a current appointment as Associate Clinical Professor of Ophthalmology. For many years I also held a joint appointment in the Department of Family and Community Medicine at UCSF. I also hold a faculty appointment at California Pacific Medical Center. My teaching activities at these academic institutions include training residents and medical students in diagnosis and treatment of eye disease, and teaching cataract and other ophthalmic surgery. In addition, international medical students from the Netherlands, Thailand, Saudi Arabia, and Colombia have trained in my office, in preparation for residency training in ophthalmology.

3. I was board certified in ophthalmology in 1994, and recertified in 2004 and 2014. Since 1997, I have served as an Associate Examiner for the American Board of Ophthalmology, administering the Oral Board Examination for candidates for board certification. In this capacity I have examined candidates in multiple subspecialty areas within ophthalmology, most recently in Cornea, External Disease, and Pediatric Ophthalmology from June 3-5, 2016.



- 4. From 1996 to 2004, I served on the Medicare Carrier Advisory

  Committee for California and several other states, helping to formulate and review

  Medicare policies on various ophthalmic conditions and procedures, including
  those involving the cornea and conjunctiva. I held a similar position at the national
  level from 2004 to 2008, serving on the Health Policy Committee of the American

  Academy of Ophthalmology. In 2010, I served as President of the California

  Academy of Eye Physicians and Surgeons, which is the state professional society
  for California ophthalmologists. In addition to these and other leadership positions
  in professional societies at the local, state and national level, I am Past Chair of
  Prevent Blindness California, a non-profit dedicated to finding and treating cases
  of preventable vision loss in children.
- 5. Since 1993, I have had a busy comprehensive ophthalmology practice in the Mission District of San Francisco, treating a diverse, high-pathology population for a variety of ophthalmic conditions, including corneal and external disease, cataract, glaucoma, retinal disease, and ophthalmic manifestations of neurologic and systemic disease. Many of these patients over the years have had symptoms or clinical findings consistent with the group of clinical entities sometimes colloquially and/or collectively referred to as "dry eye," and have been diagnosed with various conditions and treated accordingly. Among various



# 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.

