UNITED STATES PATENT AND TRADEMARK OFFICE

---

BEFORE THE PATENT TRIAL AND APPEAL BOARD

---

MYLAN PHARMACEUTICALS INC.,
Petitioner
v.

ALLERGAN, INC.
Patent Owner

---

Case IPR2016-01130
Patent 8,633,162

---

**PATENT OWNER ALLERGAN, INC.'S RESPONSE**

# TABLE OF CONTENTS

# LIST OF EXHIBITS

| Exhibit No. | Description |
|---|---|
| EX. 2001 | NDA 21-023 Cyclosporine Ophthalmic Emulsion 0.05%, Original NDA Filing, Vol. 1 (Feb. 24, 1999) |
| EX. 2002 | U.S. Pat. No. 4,839,342 |
| EX. 2003 | Said et al., Investigative Ophthalmology & Visual Science, vol. 48, No. 11 (Nov. 2007):5000-5006 |
| EX. 2004 | Alba et al., Folia Ophthalmol. Jpn. 40:902-908 (1989) |
| EX. 2005 | Stedman's Medical Dictionary, definition of therapeutic |
| EX. 2006 | Dorland's Illustrated Medical Dictionary, definition of therapeutic |
| EX. 2007 | Stedman's Medical Dictionary, definition of palliative |
| EX. 2008 | RESTASIS® label |
| EX. 2009 | Murphy, R., "The Once and Future Treatment of Dry Eye," Review of Optometry, pp. 73-75 (Feb. 15, 2000) |
| EX. 2010 | RESERVED |
| EX. 2011 | Agarwal, Priyanka and Ilva D. Rupenthal, "Modern Approaches to the Ocular Delivery of Cyclosporine A," Drug Discovery Today, vol. 21, no. 6 (June 2016) |
| EX. 2012 | Damato et al., "Senile Atrophy of the Human Lacrimal Gland: The Contribution of Chronic Inflammatory Disease," British Journal of Ophthalmology (1984) |
| EX. 2013 | Higuchi, "Physical Chemical Analysis of Percutaneous Absorption Process From Creams and Ointments," Seminar, New York City (1959) |
| EX. 2014 | Lallemand et al., "Cyclosporine a Delivery to the Eye: A Pharmaceutical Challenge," European Journal of Pharmaceutics and Biopharmaceutics (2003) |

| | |
|---|---|
| EX. 2015 | das Neves et al., " Mucosal Delivery of Biopharmaceuticals: Biology, Challenges and Strategies," Springer Science (2014) |
| EX. 2016 | Power et al., "Effect of Topical Cyclosporin A on Conjunctival T Cells in Patients with Secondary Sjögren's Syndrome," Cornea 12(6): 507-511 (1993) |
| EX. 2017 | Schaefer et al., "Skin Permeability," Springer-Verlag (1982) |
| EX. 2018 | Stern et al., "The Pathology of Dry Eye: The Interaction Between the Ocular Surface and Lacrimal Glands," Cornea 17(6): 584-589 (1998) |
| EX. 2019 | Wepierre, Jacques and Jean-Paul Marty, "Percutaneous Absorption of Drugs," Elsvier/North-Holland Biomedical Press (1970) |
| EX. 2020 | Williamson et al., "Histology f the Lacrimal Gland in Keratoconjunctivitis Sicca," Brit. F. Ophthal /91973) |
| EX. 2021 | "Approved Drug Products with Therapeutic Equivalence Evaluations," U.S. Department of Health and Huma Services, 37th Edition (2017) |
| EX. 2022 | Lemp, Michael A., " Report of the National Eye Institute/Industry Workshop on Clinical Trials in Dry Eyes," CLAO Journal, vol. 21, no. 4 (October 1995) |
| EX. 2023 | Deposition transcript of Mansoor Amiji, Ph.D |
| EX. 2024 | Declaration of John D. Sheppard, M.D., M.M.Sc. |
| EX. 2025 | Declaration of Dr. Thorsteinn Loftsson, Ph.D. |
| EX. 2026 | Declaration of Eric Rubinson |
| EX. 2027 | Allergan PK-98-074 Report |
| EX. 2028 | Declaration of Robert S. Maness, Ph.D. |
| EX. 2029 | DiMasi, "Risks in New Drug Development: Approval Success Rates for Investigational Drugs," Clinical Pharmacology and Therapeutics, May 2001 |
| EX. 2030 | FDA Review, "The Drug Development and Approval Process" |

DOCKET ALARM

# 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.