

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

MYLAN PHARMACEUTICALS INC.,
Petitioner

v.

ALLERGAN, INC.
Patent Owner

Case IPR2016-01131
Patent 8,648,048

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

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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,” Elsevier/North-Holland Biomedical Press (1970)
EX. 2020	Williamson et al., “Histology of 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 Human Services, 37 th 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”

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