UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

MYLAN PHARMACEUTICALS INC., TEVA PHARMACEUTICALS USA, INC., and AKORN INC.,
Petitioners

v.

ALLERGAN, INC.
Patent Owner

Case IPR2016-01129[1]
Patent 8,642,556

PATENT OWNER ALLERGAN, INC.'S
OPPOSITION TO MOTION FOR DISCOVERY

[1] Cases IPR2017-00579 and IPR2017-00598 have been joined with this proceeding.

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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"
EX. 2031	Allergan – NYSE: AGN – Company Profile
EX. 2032	Drugs@FDA: FDA Approved Drug Products, http://www.accessdata.fda.gov/scripts/cder/daf/index.cfm?event=overview.process&ApplNo=021023
EX. 2033	Drugs@FDA: FDA Approved Drug Products, Restasis Approved, http://www.accessdata.fda.gov/drugsatfda_docs/nda/2003/21-023_Restasis_Approv.PDF
EX. 2034	Drugs@FDA: FDA Approved Drug Products, http://www.accessdata.fda.gov/scripts/cder/daf/index.cfm?event=overview.process&ApplNo=050790
EX. 2035	Facts About Dry Eye, https://nei.nih.gov/health/dryeye/dryeye
EX. 2036	Christopher Glenn, "New Thinking Spurs New Products," Review of Ophthalmology, February 15, 2003
EX. 2037	Mark B. Abelson, MD and Jason Casavant, "Give Dry Eye a One-two Punch," Review of Ophthalmology, March 15, 2003
EX. 2038	Deposition of David LeCause, February 17, 2017
EX. 2039	Joan-Marie Stiglich ELS, "Restasis: the road to approval," Ocular Surgery News, March 1, 2003
EX. 2040	Lynda Charters, "Increased Tear Production," Ophthalmology Times, February 1, 2003
EX. 2041	RESERVED
EX. 2042	Jonathan R. Pirnazar, MD, "Taking a Custom Approach to Dry Eye Treatment," Ophthalmology Management, February 1, 2004
EX. 2043	RESERVED
EX. 2044	FDA label for Xiidra®
EX. 2045	RESERVED

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