

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 IPR2016-01127¹
Patent 8,685,930

**PATENT OWNER ALLERGAN, INC.'S
MOTION FOR *PRO HAC VICE* ADMISSION
UNDER 37 C.F.R. § 42.10(c)**

¹ Cases IPR2017-00576 and IPR2017-00594 have been joined with this proceeding.

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) |

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| 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 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, 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 |

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| 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 |

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| 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 |
| EX. 2046 | Restasis Strategic Plan Forecast 2009-2013 |
| EX. 2047 | Allergan Inc., Credit Suisse First Boston Equity Research Report, Jan 30, 2003 |
| EX. 2048 | Allergan Inc., Buckingham Research Group Equity Research Report, Feb 5, 2003 |
| EX. 2049 | Allergan Inc., SalomonSmithBarney Equity Research Report, Feb 12, 2003 |
| EX. 2050 | Allergan Inc., Morgan Stanley Equity Research Report, Jan 30, 2003 |
| EX. 2051 | Restasis P&L (US Only excl. Canada and Puerto Rico) |
| EX. 2052 | Allergan Inc., Morgan Stanley Equity Research Report, Apr 30, 2004 |
| EX. 2053 | Allergan Inc., JP Morgan Equity Research Report, Nov 1, 2005 |
| EX. 2054 | RESERVED |
| EX. 2055 | "commercial Restasis Formulary June 2006.xls" |
| EX. 2056 | "NOVEMBER 2006 input MHC Report Restasis Playbook data.ppt" |
| EX. 2057 | Restasis® 2013 Managed Markets Tactics & Preliminary Budget, August 8, 2012 |
| EX. 2058 | RESERVED |

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