

UNITED STATES PATENT AND TRADEMARK OFFICE

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BEFORE THE PATENT TRIAL AND APPEAL BOARD

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

v.

ALLERGAN, INC.  
Patent Owner

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Case IPR2016-01128<sup>1</sup>  
Patent 8,629,111

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

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<sup>1</sup> Cases IPR2017-00578 and IPR2017-00596 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 <sup>th</sup> 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, <a href="http://www.accessdata.fda.gov/scripts/cder/daf/index.cfm?event=overview.process&amp;ApplNo=021023">http://www.accessdata.fda.gov/scripts/cder/daf/index.cfm?event=overview.process&amp;ApplNo=021023</a> |
| EX. 2033 | Drugs@FDA: FDA Approved Drug Products, Restasis Approved, <a href="http://www.accessdata.fda.gov/drugsatfda_docs/nda/2003/21-023_Restasis_Approv.PDF">http://www.accessdata.fda.gov/drugsatfda_docs/nda/2003/21-023_Restasis_Approv.PDF</a>              |
| EX. 2034 | Drugs@FDA: FDA Approved Drug Products, <a href="http://www.accessdata.fda.gov/scripts/cder/daf/index.cfm?event=overview.process&amp;ApplNo=050790">http://www.accessdata.fda.gov/scripts/cder/daf/index.cfm?event=overview.process&amp;ApplNo=050790</a> |
| EX. 2035 | Facts About Dry Eye, <a href="https://nei.nih.gov/health/dryeye/dryeye">https://nei.nih.gov/health/dryeye/dryeye</a>   |
| 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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