

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

MYLAN PHARMACEUTICALS INC.,
Petitioner

v.

ALLERGAN, INC.
Patent Owner

Case IPR2016-01132¹
Patent 9,248,191

PATENT OWNER'S SURREPLY

¹ Cases IPR2017-00586 and IPR2017-00601 have been joined with this proceeding.

EXHIBIT LIST

| 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) |

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| EX. 2016 | Power et al., “Effect of Topical Cyclosporin A on Conjunctival T Cells in Patients with Secondary Sjögren’s Syndrome,” <i>Cornea</i> 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,” <i>Cornea</i> 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,” <i>Brit. F. Ophthalmol</i> /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,” <i>CLAO Journal</i> , 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,” <i>Clinical Pharmacology and Therapeutics</i> , 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, |

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| | 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 |
| 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 |

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| 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 |
| EX. 2059 | RESERVED |
| EX. 2060 | “Allergan Inc. (AGN) - Q4 2002 Financial Release Conference Call Wednesday, January 29, 2003 11:00 am” Fair Disclosure Financial Network |
| EX. 2061 | Restasis Launch Marketing Plan, dated February 12-13, 2003 |
| EX. 2062 | Allergan Dry Eye, “Dry Eye Franchise 2014 Business Plan,” 2014 U.S. Eye Care Sales & Marketing Plan, September 9, 2013 |
| EX. 2063 | Allergan Eye Care, “US Dry Eye Strat Plan Narrative: Summary Version,” April 16, 2011 |
| EX. 2064 | Kline, Kate, “Restasis Professional Critical Issues,” Allergan Dry Eye, 2010 |
| EX. 2065 | Allergan Dry Eye, “Restasis Business Update,” August 16, 2010 |
| EX. 2066 | “Sales-Units_2011-2016_AllData_NSP_Feb-19-2017_RESTASIS.xlsx” |

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