

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

MYLAN PHARMACEUTICALS INC.,
Petitioner

v.

ALLERGAN, INC.
Patent Owner

Case IPR2016-01128¹
Patent 8,629,111

**PATENT OWNER ALLERGAN'S MOTION
FOR OBSERVATIONS ON THE CROSS-EXAMINATION
TESTIMONY OF IVAN T. HOFMANN**

¹ Cases IPR2017-00578 and IPR2017-00596 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)
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”
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
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
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

Explore Litigation Insights

Docket Alarm provides insights to develop a more informed litigation strategy and the peace of mind of knowing you're on top of things.

Real-Time Litigation Alerts



Keep your litigation team up-to-date with **real-time alerts** and advanced team management tools built for the enterprise, all while greatly reducing PACER spend.

Our comprehensive service means we can handle Federal, State, and Administrative courts across the country.

Advanced Docket Research



With over 230 million records, Docket Alarm's cloud-native docket research platform finds what other services can't. Coverage includes Federal, State, plus PTAB, TTAB, ITC and NLRB decisions, all in one place.

Identify arguments that have been successful in the past with full text, pinpoint searching. Link to case law cited within any court document via Fastcase.

Analytics At Your Fingertips



Learn what happened the last time a particular judge, opposing counsel or company faced cases similar to yours.

Advanced out-of-the-box PTAB and TTAB analytics are always at your fingertips.

API

Docket Alarm offers a powerful API (application programming interface) to developers that want to integrate case filings into their apps.

LAW FIRMS

Build custom dashboards for your attorneys and clients with live data direct from the court.

Automate many repetitive legal tasks like conflict checks, document management, and marketing.

FINANCIAL INSTITUTIONS

Litigation and bankruptcy checks for companies and debtors.

E-DISCOVERY AND LEGAL VENDORS

Sync your system to PACER to automate legal marketing.