

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.

SAINT REGIS MOHAWK TRIBE and ALLERGAN, INC.<sup>1</sup>  
Patent Owners.

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Case IPR2016-01127 (U.S. Patent No. 8,685,930)  
Case IPR2016-01128 (U.S. Patent No. 8,629,111)  
Case IPR2016-01129 (U.S. Patent No. 8,642,556)  
Case IPR2016-01130 (U.S. Patent No. 8,633,162)  
Case IPR2106-01131 (U.S. Patent No. 8,648,048)  
Case IPR2016-01132 (U.S. Patent No. 9,248,191)<sup>2</sup>

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**PATENT OWNER'S SUPPLEMENTAL BRIEFING ON COLLATERAL  
ESTOPEL AUTHORIZED BY PAPER 142**

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<sup>1</sup> The caption used in this Notice of Appeal was intended only to comply with the Board's Order that the "caption for these proceedings shall reflect both Allergan's and the Tribe's status as 'Patent Owners.'" Saint Regis Mohawk Tribe is the Patent Owner. By using this caption, neither Saint Regis Mohawk Tribe nor Allergan concede that Allergan is a "Patent Owner."

<sup>2</sup> Cases IPR2017-00576 and IPR2017-00594, IPR2017-00578 and IPR2017-00596, IPR2017-00579 and IPR2017-00598, IPR2017-00583 and IPR2017-00599, IPR2017-00585 and IPR2017-00600, and IPR2017-00586 and IPR2017-00601, have respectively been joined with the captioned proceedings. have been joined with this proceeding. The identical brief is being filed in each proceeding in the caption.

## 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	Lallemant 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,” <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 <sup>th</sup> 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, <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
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
EX. 2066	“Sales-Units_2011-2016_AllData_NSP_Feb-19-2017_RESTASIS.xlsx”

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