

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

APOTEX CORP.
APOTEX, INC.
Petitioner

v.

ALLERGAN, INC.
Patent Owner

Case IPR: Unassigned
U.S. Patent No. 8,633,162

APOTEX'S EXHIBIT LIST

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U.S. Patent and Trademark Office
P.O. Box 1450
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APOTEX Exhibit #	Description
1001	Acheampong, A., <i>et al.</i> , "Methods of Providing Therapeutic Effects Using Cyclosporin Components," U.S. Patent No. 8,633,162 (filed on August 14, 2013; issued on January 21, 2014)
1002	Ding, S., <i>et al.</i> , "Emulsion Eye Drop For Alleviation of Dry Eye Related Symptoms in Dry Eye Patients and/or Contact Lens Wearers," U.S. Patent No. 5,981,607 (filed on January 20, 1998; issued on November 9, 1999)
1003	Ding, S., <i>et al.</i> "Nonirritating Emulsions For Sensitive Tissue," U.S. Patent No. 5,474,979 (filed on May 17, 1994; issued December 12, 1995)
1004	Sall, K., <i>et al.</i> , "Two Multicenter, Randomized Studies of the Efficacy and Safety of Cyclosporine Ophthalmic Emulsion in Moderate to Severe Dry Eye Disease," <i>Ophthalmology</i> 107: 631-639 (2000)
1005	Declaration of Erning Xia, Ph.D.
1006	<i>Curriculum Vitae</i> of Erning Xia, Ph.D.
1007	Declaration of Christopher N. Ta, Ph.D.
1008	<i>Curriculum Vitae</i> of Christopher N. Ta, Ph.D.
1009	Coles, W.H. and Jaros, P.A., "Dynamics of ocular surface pH," <i>Brit. J. Ophthalmol.</i> 68: 549-552 (1984)
1010	Declaration of Harry C. Boghigian
1011	<i>Curriculum Vitae</i> of Harry C. Boghigian
1012	"Ophthalmic Drug Products for Over-the-Counter Human Use; Final Monograph," <i>Federal Register</i> 53: 7076-93 (1988), available at http://www.fda.gov/Drugs/DevelopmentApprovalProcess/DevelopmentResources/Over-theCounterOTCDrugs/StatusofOTCRulemakings/ucm071941.htm , last accessed March 24, 2015
1013	"CTFA Becomes the Personal Care Products Council," available at http://www.personalcarecouncil.org/ctfa-becomes-personal-care-products-council (last accessed Jan. 29, 2015)
1014	Freeman, J.M., "The Punctum Plug: Evaluation of a New Treatment for the Dry Eye," <i>Transactions American Academy of Ophthalmology and Otolaryngology</i> 79: 874-879 (1975)
1015	Kunert, K., <i>et al.</i> , "Analysis of Topical Cyclosporine Treatment of Patients With Dry Eye Syndrome," <i>Arch Ophthalmol</i> 118: 1489-1496 (2000)

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APOTEX Exhibit #	Description
1016	Turner, K., <i>et al.</i> , "Interleukin-6 Levels in the Conjunctival Epithelium of Patients with Dry Eye Disease Treated with Cyclosporine Ophthalmic Emulsion," <i>Cornea</i> 19: 492-496 (2000)
1017	Acheampong, A., <i>et al.</i> , "Cyclosporine Distribution Into The Conjunctiva, Cornea, Lacrimal Gland, And Systemic Blood Following Topical Dosing Of Cyclosporine To Rabbit, Dog, And Human Eyes," in <i>Lacrimal Gland, Tear Film, And Dry Eye Syndromes 2 - Basic Science and Clinical Relevance</i> , Plenum Press, New York New York, Chapter 144, pp. 1001-1004 (1998)
1018	Small, D., <i>et al.</i> , "Blood Concentrations of Cyclosporin A During Long-Term Treatment With Cyclosporin A Ophthalmic Emulsions in Patients With Moderate to Severe Dry Eye Disease," <i>Journal of Ocular Pharmacology and Therapeutics</i> 18: 411-418 (2002)
1019	USPN 8,633,162 complete File History
1020	Murphy, R., "The Once and Future Treatment Of Dry Eye," <i>Review of Optometry January 2000 Cover Focus</i> , available at http://legacy.revoptom.com/archive/FEATURES/ro0200f6.htm 6 (last accessed October 21, 2014)
1021	Inatomi, T., <i>et al.</i> , "Expression of Secretory Mucin Genes by Human Conjunctival Epithelia," <i>Invest Ophthalmol</i> 37: 1684-1692 (1996)
1022	Solomon, A., <i>et al.</i> , "Doxycycline Inhibition of Interleukin-1 in the Corneal Epithelium," <i>Invest Ophthalmol Vis Sci</i> 41: 2544-2557 (2000)
1023	Stevenson, D., <i>et al.</i> , "Efficacy and Safety of Cyclosporin A Ophthalmic Emulsion in the Treatment of Moderate-to-Severe Dry Eye Disease," <i>Ophthalmology</i> 107: 967-974 (2000)
1024	Personal Care Production Council available at http://www.personalcarecouncil.org/ (last accessed Jan. 29, 2015)
1025	Allergan Dry Eye Product Portfolio Fact Sheet, downloaded from http://www.allergan.com/assets/pdf/dry_eye_product_portfolio_fact_sheet.pdf , last accessed January 26, 2015
1026	"Certain Steroid Preparations for Ophthalmic and/or Otic Use," in <i>Federal Register</i> 41: 34340-34342 (1976)
1027	Chidambaram, N. and Burgess, D.J., "Effect of Nonionic Surfactant on Transport of Surface-Active and Non-Surface-Active Model Drugs and Emulsion Stability in Triphasic Systems," <i>AAP Pharmsci</i> 2: 1-11 (2000)
1028	Pflugfelder, S.C., <i>et al.</i> , "The Diagnosis and Management of Dry Eye-A Twenty-five-Year Review," <i>Cornea</i> 19: 644-649 (2000)

APOTEX Exhibit #	Description
1029	Albietz, J.M., "Dry eye: An Update On Clinical Diagnosis, Management and Promising New Treatments," <i>Clin & Exp. Optometry</i> 84: 4-18 (2001)
1030	Liu, K., <i>et al.</i> , "Synthetic Approaches to the 2010 New Drugs," <i>Bioorganic & Medicinal Chemistry</i> 20: 1155-1174 (2012)
1031	Glonek, T., <i>et al.</i> , "Dry Eye Treatment Process And Solution," U.S. Patent No. 5,578,586 (filed on February 4, 1994; issued on November 26, 1996)
1032	Rowe, E.L., "Effect of Emulsifer Concentration and Type on the Particle Size Distribution of Emulsions," <i>Journal of Pharmaceutical Science</i> 54: 260-264 (1965)
1033	Goto, E. <i>et al.</i> , "Low-concentration Homogenized Castor Oil Eye Drops for Noninflamed Obstructive Meibomian Gland Dysfunction," <i>Ophthalmology</i> 109: 2030-2035 (2002)
1034	Certain Ophthalmic Combination Drugs Containing a Steroid and Anti-Infective(s) for Human Use; Drug Efficacy Study Implementation; Amendment," <i>Federal Register</i> 47: 21296-21301 (1982)
1035	Yeh, S. <i>et al.</i> , "Apoptosis of Ocular Surface Cells in Experimentally Induced Dry Eye," <i>Invest. Ophthalmology & Visual Sci.</i> 44:124-129 (2003)
1036	Lemp, M.A., "Report of the National Eye Institute/Industry Workshop on Clinical Trials in Dry Eyes," <i>CLAO</i> 21: 221-232 (1995)
1037	Gilbard, J.P., "Dry Eye, Blepharitis, and Chronic Eye Irritation: Divide and Conquer," <i>J. Ophthalmic Nurs. Technol.</i> 18: 109-115 (1999)
1038	Napper, G. <i>et al.</i> , "Ocular therapeutics," <i>Clin. & Exp. Optometry</i> 86: 414-415 (2003)
1039	Allergan, Inc. 2002 Annual Report, downloaded from http://agn.client.shareholder.com/financials.cfm , (last accessed Jan. 16, 2015)
1040	Taban, M. <i>et al.</i> , "Update on Punctal Plugs," <i>Comp. Ophthalmology Update</i> 7: 205-2012 (2006)
1041	Chanana, G., and Sheth, B., "Particle Size Reduction of Emulsions by Formulation Design-II: Effect of Oil and Surfactant Concentration," <i>PDA J. Pharm. Sci. & Tech.</i> , 49: 71-76 (1995)
1042	Chung, H. <i>et al.</i> , "Oil components modulate physical characteristics and function of the natural oil emulsions as drug or gene delivery system," <i>J. Controlled Release</i> 71:339- 350 (2001)

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<i>APOTEX Exhibit #</i>	<i>Description</i>
1043	RESTASIS® Approved Label, downloaded from the Allergan website https://www.restasisprofessional.com/RestasisProfessional/FullPrescribingInformation , last accessed January 28, 2015
1044	American Academy of Ophthalmology Cornea/External Disease Panel. Preferred Practice Pattern® Guidelines. Dry Eye Syndrome. San Francisco, CA: American Academy of Ophthalmology (2013), available at: www.aao.org/ppp (last accessed December 31, 2014)
1045	De Paiva, C.S., and Pflugfelder, S.C., "Rationale for Anti-Inflammatory Therapy in Dry Eye Syndrome," <i>Arq. Bras. Oftalmol.</i> 71: 89-95 (2008)
1046	Autry, J.C., "Mix It Up: When to Call a Compounding Pharmacist," <i>Review of Optometry</i> 149: 30-37 (July 15, 2012)
1047	Mann, E., "Drugs Used in the Treatment of Dry Eye Syndrome, Anti-Inflammatory Drugs and Topical Anti-Allergy Drugs," <i>Continuing Education & Training</i> pp. 30-40 (2007)
1048	Allergan, Inc. 2001 Annual Report, downloaded from http://agn.client.shareholder.com/financials.cfm , last accessed January 1, 2015
1049	Allergan, Inc. 2003 Annual Report, downloaded from http://agn.client.shareholder.com/financials.cfm , last accessed January 1, 2015
1050	Allergan, Inc. 2004 Annual Report, downloaded from http://agn.client.shareholder.com/financials.cfm , last accessed January 1, 2015
1051	Allergan, Inc. 2005 Annual Report, downloaded from http://agn.client.shareholder.com/financials.cfm , last accessed January 1, 2015
1052	Allergan, Inc. 2006 Annual Report, downloaded from http://agn.client.shareholder.com/financials.cfm , last accessed January 1, 2015
1053	Allergan, Inc. 2009 Annual Report, downloaded from http://agn.client.shareholder.com/financials.cfm , last accessed January 1, 2015

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