### 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: <u>Unassigned</u> U.S. Patent No. 8,629,111

#### **APOTEX'S EXHIBIT LIST**

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Patent Trial and Appeal Board U.S. Patent and Trademark Office P.O. Box 1450 Alexandria, VA 22313-1450

APOTEX Exhibit #	Description
1001	Acheampong, A., <i>et al.</i> , "Methods of Providing Therapeutic Effects Using Cyclosporin Components," U.S. Patent No. 8,629,111 (filed on August 14, 2013; issued on January 14, 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	Curriculum Vitae of Erning Xia, Ph.D.
1007	Declaration of Christopher N. Ta, Ph.D.
1008	Curriculum Vitae 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	Curriculum Vitae 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/DevelopmentR esources/Over- theCounterOTCDrugs/StatusofOTCRulemakings/ucm071941.htm, ( <i>last</i> <i>accessed</i> March 24, 2015)
1013	"CTFA Becomes the Personal Care Products Council," available at <u>http://www.personalcarecouncil.org/ctfa-becomes-personal-care-products-council</u> ( <i>last accessed</i> Jan. 29, 2015)
1014	Freeman, J.M., "The Punctum Plug: Evaluation of a New Treatment for the Dry Eye," Transactions American Academy of Ophthalmology and Otolaryngology 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)

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 Opthalmic 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," <i>in Lacrimal Gland,</i> <i>Tear Film, And Dry Eye Syndromes 2 - Basic Science and Clinical</i> <i>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</i> <i>Pharmacology and Therapeutics</i> 18: 411-418 (2002)
1019	USPN 8,629,111 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 ( <i>last accessed</i> 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_shee t.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)
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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)
1029	Albietz, J.M., "Dry eye: An Update On Clinical Diagnosis, Management and Promising New Treatments," <i>Clin &amp; Exp. Optometry</i> 84: 4-18 (2001)

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1030	Liu, K. <i>et al.</i> , "Synthetic Approaches to the 2010 New Drugs," <i>Bioorganic &amp; Medicinal Chemistry</i> 20: 1155-1174 (2012)
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1032	Intentionally Left Blank
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 &amp; Visual Sci.</i> 44:124-129 (2003)
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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. et al., "Ocular therapeutics," Clin. & Exp. Optometry 86: 414-415 (2003)
1039	Allergan, Inc. 2002 Annual Report, downloaded from http://agn.client.shareholder.com/financials.cfm, ( <i>last accessed</i> Jan. 16, 2015)
1040	Taban, M. <i>et al.</i> , "Update on Punctal Plugs," <i>Comp. Ophthalmology</i> <i>Update</i> 7: 205-2012 (2006)
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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)
1043	RESTASIS <sup>®</sup> Approved Label, downloaded from the Allergan website https://www.restasisprofessional.com/RestasisProfessional/FullPrescribin gInformation, last accessed January 28, 2015

APOTEX Exhibit #	Description
1044	American Academy of Ophthalmology Cornea/External Disease Panel. Preferred Practice Pattern <sup>®</sup> Guidelines. Dry Eye Syndrome. San Francisco, CA: American Academy of Ophthalmology (2013), <i>available</i> <i>at</i> : <u>www.aao.org/ppp</u> ( <i>last accessed</i> 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</i> & <i>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
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1050	Allergan, Inc. 2004 Annual Report, downloaded from http://agn.client.shareholder.com/financials.cfm, last accessed January 1, 2015
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