

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

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BEFORE THE PATENT TRIAL AND APPEAL BOARD

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APOTEX CORP.  
APOTEX, INC.  
Petitioner

v.

ALLERGAN, INC.  
Patent Owner

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Case IPR: Unassigned  
U.S. Patent No. 8,648,048

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**APOTEX'S EXHIBIT LIST**

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P.O. Box 1450  
Alexandria, VA 22313-1450

<b>APOTEX Exhibit #</b>	<b>Description</b>
1001	Acheampong, A., <i>et al.</i> , "Methods of Providing Therapeutic Effects Using Cyclosporin Components," U.S. Patent No. 8,648,048 (filed on August 14, 2013; issued on February 11, 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," Federal Register 53: 7076-93 (1988), available at <a href="http://www.fda.gov/Drugs/DevelopmentApprovalProcess/DevelopmentResources/Over-theCounterOTCDrugs/StatusofOTCRulemakings/ucm071941.htm">http://www.fda.gov/Drugs/DevelopmentApprovalProcess/DevelopmentResources/Over-theCounterOTCDrugs/StatusofOTCRulemakings/ucm071941.htm</a> , last accessed March 24, 2015
1013	"CTFA Becomes the Personal Care Products Council," available at <a href="http://www.personalcarecouncil.org/ctfa-becomes-personal-care-products-council">http://www.personalcarecouncil.org/ctfa-becomes-personal-care-products-council</a> (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)

<b>APOTEX Exhibit #</b>	<b>Description</b>
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 8,648,048 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 <a href="http://legacy.revoptom.com/archive/FEATURES/ro0200f6.htm">http://legacy.revoptom.com/archive/FEATURES/ro0200f6.htm</a> 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 <a href="http://www.personalcarecouncil.org/">http://www.personalcarecouncil.org/</a> (last accessed Jan. 29, 2015)
1025	Allergan Dry Eye Product Portfolio Fact Sheet, downloaded from <a href="http://www.allergan.com/assets/pdf/dry_eye_product_portfolio_fact_sheet.pdf">http://www.allergan.com/assets/pdf/dry_eye_product_portfolio_fact_sheet.pdf</a> , last accessed January 26, 2015
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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)
1030	Liu, K., <i>et al.</i> , "Synthetic Approaches to the 2010 New Drugs," <i>Bioorganic &amp; 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)
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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)
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1039	Allergan, Inc. 2002 Annual Report, downloaded from <a href="http://agn.client.shareholder.com/financials.cfm">http://agn.client.shareholder.com/financials.cfm</a> , (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. &amp; Tech.</i> , 49: 71-76 (1995)
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<b>APOTEX Exhibit #</b>	<b>Description</b>
1043	RESTASIS <sup>®</sup> Approved Label, downloaded from the Allergan website <a href="https://www.restasisprofessional.com/RestasisProfessional/FullPrescribingInformation">https://www.restasisprofessional.com/RestasisProfessional/FullPrescribingInformation</a> , last accessed January 28, 2015
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 at: <a href="http://www.aao.org/ppp">www.aao.org/ppp</a></i> (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)
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1049	Allergan, Inc. 2003 Annual Report, downloaded from <a href="http://agn.client.shareholder.com/financials.cfm">http://agn.client.shareholder.com/financials.cfm</a> , last accessed January 1, 2015
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