

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. 8,685,930

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**APOTEX'S EXHIBIT LIST**

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

Petition for Inter Partes Review of USPN 8,685,930

| <b>APOTEX<br/>Exhibit #</b> | <b>Description</b>   |
|-----------------------------|--|
| 1001                        | Acheampong, A., <i>et al.</i> , "Methods of Providing Therapeutic Effects Using Cyclosporin Components," U.S. Patent No. 8,685,930 (filed on August 7, 2013; issued on April 1, 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<br/>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," <i>in 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 8,685,930 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  |
| 1026                        | "Certain Steroid Preparations for Ophthalmic and/or Otic Use," in <i>Federal Register</i> 41: 34340-34342 (1976)   |
| 1027                        | <i>Intentionally Left Blank</i>  |
| 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<br>Exhibit # | Description   |
|---------------------|---|
| 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)   |
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| 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)   |
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| 1040                | Taban, M. <i>et al.</i> , "Update on Punctal Plugs," <i>Comp. Ophthalmology 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 <a href="https://www.restasisprofessional.com/RestasisProfessional/FullPrescribingInformation">https://www.restasisprofessional.com/RestasisProfessional/FullPrescribingInformation</a> , last accessed January 28, 2015 |

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| 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), available at: <a href="http://www.aao.org/ppp">www.aao.org/ppp</a> (last accessed December 31, 2014) |
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| 1046                        | Autry, J.C., "Mix It Up: When to Call a Compounding Pharmacist," <i>Review of Optometry</i> 149: 30-37 (July 15, 2012)   |
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