

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. 8,642,556

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Petition for Inter Partes Review of USPN 8,642,556

| APOTEX Exhibit # | Description |
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| 1001 | Acheampong, A., <i>et al.</i> , "Methods of Providing Therapeutic Effects Using Cyclosporin Components," U.S. Patent No. 8,642,556 (filed on August 14, 2013; issued on February 4, 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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| 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 8,642,556 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) |
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| 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) |

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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 & Exp. Optometry</i> 84: 4-18 (2001) |
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| 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) |
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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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| 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) |
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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) |
| 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) |
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