

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

INNOPHARMA LICENSING, INC., INNOPHARMA LICENSING LLC,
INNOPHARMA INC., INNOPHARMA LLC,
MYLAN PHARMACEUTICALS INC., and MYLAN INC.,
Petitioner

v.

SENJU PHARMACEUTICAL CO., LTD., BAUSCH & LOMB, INC., and
BAUSCH & LOMB PHARMA HOLDINGS CORP.,
Patent Owner.

U.S. Patent No. 8,754,131 to Sawa *et al.*
Issue Date: June 17, 2014
Title: Aqueous Liquid Preparation Containing
2-Amino-3-(4-
bromobenzoyl) Phenylacetic Acid

Inter Partes Review No.: IPR2016-00089

Petitioner's Exhibit List

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Petitioner's Exhibit List

<i>InnoPharma Exhibit #</i>	<i>Description</i>
1001	Sawa <i>et al.</i> , U.S. Patent No. 8,754,131, "Aqueous Liquid Preparation Containing 2-Amino-3-(4-Bromobenzoyl) Phenylacetic Acid"
1002	Certified English translation of: Hara, Yoshiyuki, "Bromfenac sodium hydrate," <i>Clinics & Drug Therapy</i> 19:1014-1015 (2002)
1003	Declaration of Paul A. Laskar, Ph.D.
1004	Ogawa <i>et al.</i> , U.S. Patent No. 4,910,225, "Locally Administrable Therapeutic Composition for Inflammatory Disease"
1005	Desai <i>et al.</i> , U.S. Patent No. 5,603,929, "Preserved Ophthalmic Drug Compositions Containing Polymeric Quaternary Ammonium Compounds"
1006	Desai, <i>et al.</i> , U.S. Patent No. 5,558,876, "Topical Ophthalmic Acidic Drug Formulations"
1007	Certified English translation of "Bromfenac sodium hydrate" in the <i>Japanese Pharmacopoeia 2001 Edition: 27-29</i> , Yakuji Nippo Limited (2001)
1008	FDA approved "BROMDAY™ (bromfenac ophthalmic solution, .09%) Product Label," U.S. Approval: March 24, 2005, ISTA Pharmaceuticals, Inc.
1009	Sallmann <i>et al.</i> , U.S. Patent No. 6,107,343, "Ophthalmic And Aural Compositions Containing Diclofenac Potassium"
1010	Guttman <i>et al.</i> , "Solubilization of Anti-inflammatory steroids by Aqueous Solutions of Triton-WR-1339," <i>Journal of Pharmaceutical Sciences</i> 50: 305-307 (1961)
1011	Fu <i>et al.</i> , Australian Patent No. AU-B-22042/88, "Preservative System For Ophthalmic Formulations"
1012	Yasueda <i>et al.</i> , U.S. Patent No. 6,274,609, "Aqueous Liquid Pharmaceutical Composition Containing as Main Component Benzopyran Derivative"

<i>InnoPharma Exhibit #</i>	<i>Description</i>
1013	U.S. Patent Application No. 13/687,242, Office Action of August 1, 2013
1014	U.S. Patent Application No. 10/525,006, Applicant Remarks in support of amendment March 26, 2008
1015	U.S. Patent Application No. 10/525,006, Applicant Remarks in support of amendment, September 6, 2011
1016	<i>The Pharmacopeia of the United States of America</i> , Thirty-Eighth Revision and the National Formulary, Thirty-Third Edition
1017	Kapin, <i>et al.</i> , International Patent No. WO 2002/13804, "Method for Treating Angiogenesis-Related Disorders Using Benzoyl Phenylacetic Acid"
1018	Flach, Allan., "Topical Nonsteroidal Antiinflammatory Drugs for Ophthalmic Uses," <i>Ophthalmic NSAIDs: 77-83</i> (1996)
1019	Schott, H., "Comparing the Surface Chemical Properties and the Effect of Salts on the Cloud Point of a Conventional Nonionic Surfactant, Octoxynol 9 (Triton X-100), and of Its Oligomer, Tyloxapol (Triton WR-1339)," <i>Journal of Colloid and Interface Science</i> 205: 496-502 (1998)
1020	Regev, O., <i>et al.</i> , "Aggregation Behavior of Tyloxapol, a Nonionic Surfactant Oligomer, in Aqueous Solution," <i>Journal of Colloid and Interface Science</i> 210: 8-17 (1999)
1021	Aviv, H., International Patent No. WO 94/05298, "Submicron Emulsions as Ocular Drug Delivery Vehicles"
1022	Bergamini <i>et al.</i> , U.S. Patent No. 5,597,560, "Diclofenac And Tobramycin Formulations For Ophthalmic And Otis Topical Use"
1023	U.S. Patent Application No. 13/687,242, Applicant Remarks in support of amendment, November 28, 2012
1024	Excerpt of Plaintiffs' Opening Markman Brief filed in <i>Senju Pharm. Co., Ltd. et al. v. InnoPharma Licensing, Inc. et al.</i> , C.A. No. 1:15-cv-03240-JBA-KMW (D.N.J.) D.I. 16 (Aug. 10, 2015).

<i>InnoPharma Exhibit #</i>	<i>Description</i>
1025	U.S. Patent Application No. 13/687,242, Applicant Remarks in support of amendment, October 22, 2013
1026	"monohydrate," Webster's New World Dictionary of the American Language: 920, New World Dictionaries / Simon and Schuster (1980).
1027	"Voltaren," Orange Book: Approved Drug Products with Therapeutic Equivalence Evaluations, Appl. No. N020037, U.S. FDA, accessed at http://www.accessdata.fda.gov/scripts/cder/ob/docs/obdetail.cfm?A_ppl_No=020037&TABLE1=OB_Rx
1028	Yanni <i>et al.</i> , U.S. Patent No. 5,475,034, "Topically Administrable Compositions Containing 3-Benzoylphenylacetic Acid Derivatives for Treatment of Ophthalmic Inflammatory Disorders".
1029	"ISTA Pharmaceuticals Submits New Drug Application for Xibrom™ QD (once-daily), News Release, ISTA Pharmaceuticals (December 20, 2007)
1030	Prince, S., <i>et al.</i> , "Analysis of benzalkonium chloride and its homologs: HPLC versus HPCE," <i>Journal of Pharmaceutical and Biomedical Analysis</i> 19: 877-882, Elsevier Science B.V., Netherlands (1999)
1031	"Acular®" and "Azopt™," Physician's Desk Reference 54: 486- 487, 491-492 (2000).
1032	Doughty, M., "Medicines Update for optical practitioners- Part 11," <i>Optician</i> 5853 (223), (2002).
1033	Reddy, Indra K., Ocular Therapeutics and Drug Delivery: A Multi-Disciplinary Approach: 42-43, 390 (1996).

<i>InnoPharma Exhibit #</i>	<i>Description</i>
1034	Fan, T., "Determination of Benzalkonium Chloride in Ophthalmic Solutions Containing Tyloxapol by Solid-Phase Extraction and Reversed-Phase High-Performance Liquid Chromatography," <i>Journal of Pharmaceutical Sciences</i> 82 (11): 1172-1174, American Pharmaceutical Association, United States (1993).
1035	Wong, Michelle, International Patent No. WO 94/15597, "Ophthalmic Compositions Comprising Benzyllauryldimethylammonium Chloride" (filed January 11, 1993; issued July 21, 1994).
1036	Guy <i>et al.</i> , U.S. Patent No. 5,540,930, "Suspension of Loteprednol Etabonate for Ear, Eye, or Nose Treatment" (filed October 25, 1993; issued July 30, 1996).
1037	FDA approved "ALREXTM (loteprednol etabonate ophthalmic suspension) 0.2% Product Label," U.S. Approval: 1998, Bausch & Lomb Pharmaceuticals.
1038	FDA approved "LOTEMAXTM (loteprednol etabonate ophthalmic suspension) 0.5% Product Label," U.S. Approval: 1998, Bausch & Lomb Pharmaceuticals.
1039	"TOBRADEX®" Physician's Desk Reference 54: 490 (2000).
1040	"Alomide® 0.1%" Physician's Desk Reference 50: 469 (1996).
1041	Johnson, R., <i>et al.</i> , U.S. Patent No. 2,880,130, "Anti-Inflammatory Steroid Solutions."
1042	Johnson, R., <i>et al.</i> , U.S. Patent No. 2,880,138, "Anti-Inflammatory Steroid Solutions."
1043	Kawabata <i>et al.</i> , Canadian Patent No. CA 2 383 971 A1, "Prophylactic and Therapeutic Medicaments for Ophthalmic Uses."
1044	Patani, G., <i>et al.</i> , "Bioisoterism: A Rational Approach in Drug Design," <i>Chem. Rev.</i> 96: 3147-3176 (1996).
1045	FDA approved "XIBROMTM (bromfenac ophthalmic solution, .09%) Product Label," ISTA Pharmaceuticals, Inc.

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