

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., MYLAN INC., LUPIN LTD., and LUPIN
PHARMACEUTICALS, INC.

Petitioner,

v.

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

Patent Owner.

Case IPR2015-00903¹
Patent 8,129,431

Filed: March 18, 2016

Petitioner's Updated Exhibit List

¹ IPR2015-01871 has been joined with IPR2015-00903.

I. INTRODUCTION

Pursuant to 37 C.F.R. § 42.63(e), Petitioners InnoPharma Licensing, Inc., InnoPharma Licensing LLC, InnoPharma Inc., InnoPharma LLC, Mylan Pharmaceuticals Inc., Mylan Inc., Lupin Ltd., and Lupin Pharmaceuticals, Inc. (collectively “Petitioners”) hereby submits a current listing of Petitioner Exhibits to counsel for Patent Owner Senju Pharmaceutical Co., Ltd., Bauch & Lomb, Inc., and Bausch & Lomb Pharma Holdings Corp. (collectively “Patent Owner”).

<i>Exhibit #</i>	<i>Description</i>
1001	Sawa <i>et al.</i> , U.S. Patent No. 8,129,431 B2, “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”
1013	“Orange Book: Approved Drug Products with Therapeutic Equivalence Evaluations,” Appl. No. N203168, U.S. FDA, accessed at http://www.accessdata.fda.gov/scripts/cder/ob/docs/patexclnew.cfm?Appl_No=203168&Product_No=001&table1=OB_Rx
1014	“Orange Book: Approved Drug Products with Therapeutic Equivalence Evaluations,” Appl. No. N203168, Active Ingredient Bromfenac Sodium, accessed at http://www.accessdata.fda.gov/scripts/cder/ob/docs/obdetail.cfm?App1_No=203168&TABLE1=OB_Rx , last accessed on February 14, 2014
1015	Reserved
1016	Kapin, <i>et al.</i> , International Patent No. WO 2002/13804, “Method For Treating Angiogenesis-Related Disorders Using Benzoyl Phenylacetic Acid”
1017	Flach, Allan., “Topical Nonsteroidal Antiinflammatory Drugs for Ophthalmic Uses,” <i>Ophthalmic NSAIDS</i> : 77-83 (1996)
1018	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)
1019	Bergamini <i>et al.</i> , U.S. Patent No. 5,597,560, “Diclofenac And Tobramycin Formulations For Ophthalmic And Otis Topical use”
1020	Wong, Michelle, International Patent No. WO 94/15597, “Ophthalmic Compositions Comprising Benzyl lauryldimethylammonium Chloride” (filed January 11, 1993); issued July 21, 1994)
1021	Reddy, Indra K., <i>Ocular Therapeutics and Drug Delivery: A Multi-Disciplinary Approach</i> : 42-43, 390 (1996)
1022	Story, M., <i>et al.</i> , European Patent No. 0274870, “Micelles containing a non-steroidal antiinflammatory compound” (filed December 12, 1987; issued July 7, 1988)

1023	“Borax (Sodium tetraborate),” <i>Biochemicals and Reagents</i> : 175, Sigma-Aldrich (2000-2001)
1024	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)
1025	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)
1026	Aviv, H., International Patent No. WO 94/05298, “Submicron Emulsions as Ocular Drug Delivery Vehicles”
1027	Gennaro, A., “Boric Acid,” <i>Remington: The Science and Practice of Pharmacy</i> 20: 1041, University of Sciences, United States (2000)
1028	Wade, A., and Weller, P., “Edetic Acid,” and “Sodium Metabisulfite,” <i>Handbook of Pharmaceutical Excipients</i> 2: 176-179, 451-453, American Pharmaceutical Association, United States (1994)
1029	Selected pages from the file history of U.S. Patent No. 8,129,431, March 28, 2005 Amendment.
1030	"Duract™," <i>Physician's Desk Reference</i> 52:3035-3037 (1998)
1031	"monohydrate," Webster's New World Dictionary of the American Language: 920, New World Dictionaries / Simon and Schuster (1980)
1032	"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?App1No=020037&TABLE1=OB Rx
1033	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"
1034	"ISTA Pharmaceuticals Submits New Drug Application for Xibrom™ QD (once-daily), News Release, ISTA Pharmaceuticals (December 20, 2007)
1035	"Acular®" and "Azopt™," <i>Physician's Desk Reference</i> 54: 486-487, 491-492 (2000)
1036	Doughty, M., "Medicines Update for optical practitioners- Part 11.," <i>Optician</i> 5853 (223), (2002)

1037	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)
1038	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)
1039	FDA approved "ALREX™ (loteprednol etabonate ophthalmic suspension) 0.2% Product Label," U.S. Approval: 1998, Bausch & Lomb Pharmaceuticals
1040	FDA approved "LOTEMAX™ (loteprednol etabonate ophthalmic suspension) 0.5% Product Label," U.S. Approval: 1998, Bausch & Lomb Pharmaceuticals
1041	"TOBRADEX®" Physician's Desk Reference 54: 490 (2000)
1042	"Alomide® 0.1%" Physician's Desk Reference 50: 469 (1996)
1043	Kawabata <i>et al.</i> , Canadian Patent No. CA 2 383 971 A1, "Prophylactic and Therapeutic Medicaments for Ophthalmic Uses"
1044	Johnson, R., <i>et al.</i> , U.S. Patent No. 2,880,130, "Anti-Inflammatory Steroid Solutions"
1045	Johnson, R., <i>et al.</i> , U.S. Patent No. 2,880,138, "Anti-Inflammatory Steroid Solutions"
1046	Patani, G., <i>et al.</i> , "Bioisoterism: A Rational Approach in Drug Design," <i>Chem. Rev.</i> 96: 3147-3176 (1996)
1047	Ostrovskii, V.A., <i>et al.</i> , "Acid-base properties of 5-substituted tetrazoles," <i>Chemistry of Heterocyclic Compounds</i> 17: 412-416 (1981)
1048	FDA approved "XIBROM™ (bromfenac ophthalmic solution, .09%) Product Label," ISTA Pharmaceuticals, Inc.
1049	Senju Pharmaceutical Co., Ltd. Press Releases, "The approval of BRONUCK® (bromfenac sodium hydrate ophthalmic solution) as an import drug in China," http://www.senju.co.jp/ , accessed at http://www.senju.co.jp/english/news/_icsFiles/afieldfile/2009/11/18/2009111814br.pdf , published November 17, 2009, 1 page
1050	FDA approved "PROLENSA™ (bromfenac ophthalmic solution, 0.07%) Product Label," U.S. Approval: April 5, 2013, Bausch & Lomb Incorporated

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