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

V.

SENJU PHARMACEUTICAL CO., LTD. Patent Owner

U.S. Patent No. 8,129,431 to Sawa *et al*.

Issue Date: March 6, 2012

Title: Aqueous Liquid Preparation Containing 2-Amino-3-(4-bromobenzoyl) Phenylacetic Acid

Inter Partes Review No.: 2015-00903

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Exhibit #	Description
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 Translation of: Hara, Yoshiyuki , "Bromfenac sodium hydrate," <i>Clinics & Drug Therapy</i> 19:1014-1015 (2002)
1003	Declaration of Dr. 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, et al., 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</i> : 27-29, Yakuji Nippo Limited (2001)
1008	FDA approved "BROMDAYTM (bromfenac ophthalmic solution, .09%) Product Label," U.S. Approval: March 24, 2005, ISTA Pharmaceuticals, Inc.
1009	Sallmann et al., 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 50</i> : 305-307 (1961)
1011	Fu <i>et al.</i> , Australian Patent No. AU-B-22042/88, "Preservative System For Ophthalmic Formulations"



Exhibit #	Description
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∏_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?A ppl_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 19:</i> 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"



Exhibit #	Description
1020	Wong, Michelle, International Patent No. WO 94/15597, "Ophthalmic Compositions Comprising Benzyllauryldimethylammonium 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 205:</i> 496-502 (1998)
1025	Regev, O., et al., "Aggregation Behavior of Tyloxapol, a Nonionic Surfactant Oligomer, in Aqueous Solution," <i>Journal of Colloid and Interface Science 210:</i> 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 20:</i> 1041, University of Sciences, United States (2000)
1028	Wade, A., and Weller, P., "Edetic Acid," and "Sodium Metabisulfite," <i>Handbook of Pharmaceutical Excipients 2:</i> 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.



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