

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

METRICS, 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.: IPR2014-01041

PETITIONER'S UPDATED EXHIBIT LIST

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PETITIONER'S UPDATED EXHIBIT LIST

<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	Hara, Yoshiyuki , "Bromfenac sodium hydrate," <i>Clinics & Drug Therapy</i> 19:1014-1015 (2002)
1003	Second Corrected Declaration of Uday B. Kompella, 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</i> : 27-29, 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)

Petitioner's Updated Exhibit List
January 21, 2015

<i>Exhibit #</i>	<i>Description</i>
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?Appl_No=203168&TABLE1=OB_Rx , last accessed on February 14, 2014
1015	"ophthalmic" Webster's Deluxe Unabridged Dictionary: 1254, Webster's New Twentieth Century Dictionary, Simon and Schuster (1979)
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"

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January 21, 2015*

<i>Exhibit #</i>	<i>Description</i>
1020	Wong, Michelle, International Patent No. WO 94/15597, "Ophthalmic Compositions Comprising Benzylauryltrimethylammonium 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.

<i>Exhibit #</i>	<i>Description</i>
1030	"Duract™," Physician's Desk Reference 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?Appl_No=020037&TABLE1=OB_Rx
1033	Yanni et al., 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™," Physician's Desk Reference 54: 486-487, 491-492 (2000).
1036	Doughty, M., "Medicines Update for optical practitioners- Part 11.," Optician 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," Journal of Pharmaceutical Sciences 82 (11): 1172-1174, American Pharmaceutical Association, United States (1993).
1038	Guy et al., 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).

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