

Paper No. _____
Filed: September 23, 2016

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

LUPIN LTD. and LUPIN PHARMACEUTICALS INC.
Petitioner

v.

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

Case IPR2015-01099
U.S. Patent 8,669,290

PATENT OWNER'S UPDATED EXHIBIT LIST

Further to 37 C.F.R. § 42.63(e), Patent Owner Senju Pharmaceutical Co., Ltd., hereby submits a current listing of Senju Exhibits to counsel for Petitioner Lupin Ltd. and Lupin Pharmaceuticals Inc. New Exhibit 2348 was filed and served via email to counsel of record for the Petitioner.

Exhibits	Description
Exhibit 2001	U.S. Patent No. 8,129,431 to Sawa <i>et al.</i> , “Aqueous Liquid Preparation Containing 2-amino-3-(4-bromobenzoyl)phenylacetic acid.”
Exhibit 2002	Lupin’s Paragraph IV Notice Letter dated December 19, 2013.
Exhibit 2003	Lupin’s Paragraph IV Notice Letter dated May 13, 2014.
Exhibit 2004	Lupin’s Paragraph IV Notice Letter dated July 3, 2014.
Exhibit 2005	Lupin’s Paragraph IV Notice Letter dated December 17, 2014.
Exhibit 2006	Lupin’s Paragraph IV Notice Letter dated February 19, 2015.
Exhibit 2007	Complaint, <i>Senju Pharm. Co., Ltd. et al. v. Lupin, Ltd. et al.</i> , No. 14-cv-00667 (D.N.J. Jan. 31, 2014), ECF No. 1.
Exhibit 2008	Complaint, <i>Senju Pharm. Co., Ltd. et al. v. Lupin, Ltd. et al.</i> , No. 14-cv-04149 (D.N.J. June 26, 2014), ECF No. 1.
Exhibit 2009	Complaint, <i>Senju Pharm. Co., Ltd. et al. v. Lupin, Ltd. et al.</i> , No. 14-cv-05144 (D.N.J. Aug. 15, 2014), ECF No. 1.
Exhibit 2010	Complaint, <i>Senju Pharm. Co., Ltd. et al. v. Lupin, Ltd. et al.</i> , No. 15-cv-00335 (D.N.J. Jan. 16, 2015), ECF No. 1.
Exhibit 2011	Consolidated scheduling order, <i>Senju Pharm. Co., Ltd. et al. v. InnoPharma Licensing, Inc. et al.</i> , No. 14-cv-06893 (D.N.J. April 16, 2015), ECF No. 30.
Exhibit 2012	Amended scheduling order, <i>Senju Pharm. Co., Ltd. et al. v. Lupin, Ltd. et al.</i> , No. 14-cv-00667 (D.N.J. Feb. 27, 2015), ECF No. 63.
Exhibit 2013	U.S. Patent No. 5,630,793 to Rowe, “Aqueous Ophthalmic Sprays.”
Exhibit 2014	Press Release by Bausch + Lomb, dated April 8, 2013, entitled “Bausch + Lomb Receives FDA Approval for Prolensa™ (bromfenac ophthalmic solution) 0.07%.”

Exhibit 2015	InnoPharma's Paragraph IV Notice Letter dated September 19, 2014.
Exhibit 2016	InnoPharma's Paragraph IV Notice Letter dated October 30, 2014.
Exhibit 2017	InnoPharma's Paragraph IV Notice Letter dated March 27, 2015.
Exhibit 2018	InnoPharma's Paragraph IV Notice Letter dated June 12, 2015.
Exhibit 2019	Metrics' Paragraph IV Notice Letter dated June 26, 2014.
Exhibit 2020	Paddock's Paragraph IV Notice Letter dated December 15, 2014.
Exhibit 2021	Paddock's Paragraph IV Notice Letter dated January 20, 2015.
Exhibit 2022	Apotex's Paragraph IV Notice Letter dated December 10, 2014.
Exhibit 2023	Watson's Paragraph IV Notice Letter dated June 1, 2015.
Exhibit 2024	Masson et al., <i>Stabilisation of ionic drugs through complexation with non-ionic and ionic cyclodextrins</i> , 164 INT'L J. PHARMACEUTICS 45 (1998).
Exhibit 2025	Loftsson et al., <i>Pharmaceutical Applications of Cyclodextrins</i> , 85 J. PHARMACEUTICAL SCIENCES 1017 (1996).
Exhibit 2026	HSBC Global Research Lupin Company Report, Feb. 3, 2014, http://www.lupin.com/pdf/14/20140203%20-%20Lupin%203QFY14%20-%20HSBC.pdf
Exhibit 2027	Consent judgment, <i>Senju Pharm. Co., Ltd. et al. v. Apotex Inc. et al.</i> , No. 15-cv-00336 (D.N.J. May 18, 2015), ECF No. 26.
Exhibit 2028	Consent judgment, <i>Senju Pharm. Co., Ltd. et al. v. Paddock Labs., LLC et al.</i> , No. 15-cv-00337 (D.N.J. June 5, 2015), ECF No. 33.
Exhibit 2029	Consent judgment, <i>Senju Pharm. Co., Ltd. et al. v. Metrics, Inc. et al.</i> , No. 14-cv-03962 (D.N.J. July 1, 2015), ECF No. 108.
Exhibit 2030	U.S. Patent No. 5,856,345 to Doi et al., "Method for Stabilizing Pranoprofen and Stable Liquid Preparation of Pranoprofen."
Exhibit 2031	Drugs@FDA, Listing of FDA-approved bromfenac ophthalmic solution 0.09% products, http://www.accessdata.fda.gov/scripts/cder/drugsatfda/index.cfm?fuseaction=Search.Overview&DrugName=BROMFENAC%20SODIUM .
Exhibit 2032	Sheryl Gay Stolberg, <i>New Painkiller is Withdrawn After 4 Deaths</i> , N.Y. TIMES, Jun. 23, 1998.
Exhibit 2033	Baklayan et al., <i>The ocular distribution of 14C-labeled bromfenac</i>

	<i>ophthalmic solution 0.07% in a rabbit model</i> , CLINICAL 2014:8 OPHTHALMOLOGY 1717 (2014).
Exhibit 2034	Schott, <i>Effect of inorganic additives on solutions of nonionic surfactants – XVI. Limiting cloud points of highly polyoxyethylated surfactants</i> , 186 COLLOIDS AND SURFACES A: PHYSICOCHEMICAL AND ENGINEERING ASPECTS 129 (2001).
Exhibit 2035	European Patent No. 0274870 to Story, M., et al., “Micelles containing a non-steroidal antiinflammatory compound” (filed December 12, 1987; issued July 7, 1988).
Exhibit 2036	Reddy, Indra K., <i>Ocular Therapeutics and Drug Delivery: A Multi-Disciplinary Approach</i> , 42-43, 390 (1996).
Exhibit 2037	Declaration of Uday B. Kompella in Support of Plaintiffs’ Proposed Claim Constructions, <i>Insite Vision Inc. et al. v. Sandoz Inc. et al.</i> , No. 11-cv-03080, 2012 WL 8667473 (D.N.J. April 12, 2012).
Exhibit 2038	Transcript of Teleconference with the Board, dated December 11, 2015
Exhibit 2039	Reserved.
Exhibit 2040	Christopher A. Lipinski <i>et al.</i> , "Experimental and Computational Approaches to Estimate Solubility and Permeability in Drug Discovery and Development Settings," <i>Advanced Drug Delivery Reviews</i> Vol. 23, 1997, 3-25.
Exhibit 2041	Andrew Streitwieser and Clayton H. Heathcock, <i>Introduction to Organic Chemistry</i> , 3rd ed. (Macmillan, 1985) 696-697.
Exhibit 2042	Andrew Streitwieser and Clayton H. Heathcock, <i>Introduction to Organic Chemistry</i> , 3rd ed. (Macmillan, 1985) 456-458.
Exhibit 2043	D. Attwood and A. T. Florence, "Pharmaceutical Aspects of Solubilization," <i>Surfactant Systems: Their Chemistry, Pharmacy, and Biology</i> . (Chapman and Hall, 1983) 293-387.
Exhibit 2044	Drugs@FDA, Voltaren [®] .
Exhibit 2045	Ronald Breslow and Peter Cambell, “Selective Aromatic Substitution Within A Cyclodextrin Mixed Complex”, <i>Communications to the Editor</i> . Received Feb. 14, 1969.
Exhibit 2046	Masami Sawada <i>et al.</i> , "Measurement of Chiral Amino Acid Discrimination by Cyclic Oligosaccharides: A Direct FAB Mass Spectrometric Approach," <i>Chemical Communications</i> , 1998, 1453-1454.

Exhibit 2047	Samik K. Hait and Satya P. Moulik, "Determination of Critical Micelle Concentration (CMC) of Nonionic Surfactants by Donor-Acceptor Interaction with Iodine and Correlation of CMC with Hydrophile-Lipophile Balance and Other Parameters of the Surfactants," <i>Journal of Surfactants and Detergents</i> Vol. 4 No. 3, 2001, 303-309.
Exhibit 2048	Kyosuke Yamamoto <i>et al.</i> , "In Vitro Effect of Triton WR-1339 on Canine Plasma High Density Lipoproteins," <i>Journal of Lipid Research</i> Vol. 25, 1984, 770-79.
Exhibit 2049	CV of Stephen G. Davies, D.Phil.
Exhibit 2050	List of Publications of Stephen G. Davies, D.Phil.
Exhibit 2051	CV of William B. Trattler, MD
Exhibit 2052	Majed Alkharashi <i>et al.</i> , "Advances in Cataract Surgery," <i>Expert Review of Ophthalmology</i> Vol. 8 No. 5, 2013, 447-456.
Exhibit 2053	Ocufen [®] Product Label (2001)
Exhibit 2054	Drugs@FDA, Ocufen [®]
Exhibit 2055	Drugs@FDA, Profenal [®]
Exhibit 2056	Profenal [®] Product Label (1998)
Exhibit 2057	Voltaren [®] Product Label
Exhibit 2058	Allan J. Flach, "Corneal Melts Associated With Topically Applied Nonsteroidal Anti-inflammatory Drugs," <i>Transactions of the American Ophthalmology Society</i> Vol. 99, 2001, 205-212.
Exhibit 2059	Drugs@FDA, Acular [®]
Exhibit 2060	Acular [®] / Acular [®] PF Product Label (2002)
Exhibit 2061	Drugs@FDA, Acular [®] PF
Exhibit 2062	Drugs@FDA, Xibrom [®]
Exhibit 2063	Drugs@FDA, Bromday [®]
Exhibit 2064	Caroline Debbasch <i>et al.</i> , "Evaluation of the Toxicity of Benzalkonium Chloride on the Ocular Surface," <i>Journal of Toxicology: Cutaneous and Ocular Toxicology</i> Vol. 19 No. 2-3, 2000, 105-115.
Exhibit 2065	Markman Opinion, <i>Senju Pharm. Co., Ltd. v. Lupin Ltd.</i> , No. 1:14-CV-00667-JBS-KMW (D.N.J., dated November 18, 2015) (No. 107).
Exhibit 2066	Lara C. Pullen, "FDA Approves Prolensa for Cataract Surgery Postop Pain," <i>Medscape</i> , April 8, 2013 (published at

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