Paper No. \_\_\_\_\_ Filed: July 29, 2016

## UNITED STATES PATENT AND TRADEMARK OFFICE

## BEFORE THE PATENT TRIAL AND APPEAL BOARD

LUPIN LTD. and LUPIN PHARMACEUTICALS INC., 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

Case IPR2015-01105 U.S. Patent 8,871,813<sup>1</sup>

## PATENT OWNER'S UPDATED EXHIBIT LIST

<sup>1</sup> Case IPR 2016-00091 has been joined with this proceeding.

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Case IPR2015-01105 U.S. Patent 8,871,813

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 Exhibits 2345, 2346, and 2347

were filed and served via email to counsel of record for the Petitioner. Public

versions of Exhibits 2082, 2096, 2105, 2114, 2130, 2220, 2226, 2258, 2267, 2286,

2296, and 2316 were filed and served via email to counsel of record for the

Petitioner. Confidential versions of Exhibits 2096, 2102, 2103, 2110, 2116, 2126,

2130, 2251, 2291, 2292, and 2293 were filed as "BOARD AND PARTIES

ONLY" and served on counsel that executed the Acknowledgment Form of the

Proposed Stipulated Protective Order.

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.

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Exhibit 2011	Consolidated scheduling order, <i>Senju Pharm. Co., Ltd. et al. v.</i> <i>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 <sup>™</sup> (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</i> <i>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, Senju Pharm. Co., Ltd. et al. v. Apotex Inc. et al., 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, Senju Pharm. Co., Ltd. et al. v. Metrics, Inc. et

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	<i>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%20S ODIUM.
Exhibit 2032	Sheryl Gay Stolberg, New Painkiller is Withdrawn After 4 Deaths, 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, Effect of inorganic additives on solutions of nonionic surfactants – XVI. Limiting cloud points of highly polyoxyethylated surfactants, 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., Ocular Therapeutics and Drug Delivery: A Multi-Disciplinary Approach, 42-43, 390 (1996).
Exhibit 2037	Declaration of Uday B. Kompella in Support of Plaintiffs' Proposed Claim Constructions, <i>Insite Vision Inc. et al.</i> v. <i>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</i> <i>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.

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<ul> <li>Exhibit 2043 D. Attwood and A. T. Florence, "Pharmaceutical Aspects of Solubilization," Surfactant Systems: Their Chemistry, Pharmacy, and Biology. (Chapman and Hall, 1983) 293-387.</li> <li>Exhibit 2044 Drugs@FDA, Voltaren<sup>®</sup>.</li> <li>Exhibit 2045 Ronald Breslow and Peter Cambell, "Selective Aromatic Substitution Within A Cyclodextrin Mixed Complex", Communications to the Editor. Received Feb. 14, 1969.</li> <li>Exhibit 2046 Masami Sawada et al., "Measurement of Chiral Amino Acid Discrimination by Cyclic Oligosaccharides: A Direct FAB Mass Spectrometric Approach," Chemical Communications, 1998, 1453-1454.</li> <li>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," Journal of Surfactants and Detergents Vol. 4 No. 3, 2001, 303-309.</li> <li>Exhibit 2048 Kyosuke Yamamoto et al., "In Vitro Effect of Triton WR-1339 on Canine Plasma High Density Lipoproteins," Journal of Lipid Research Vol. 25, 1984, 770-79.</li> <li>Exhibit 2050 List of Publications of Stephen G. Davies, D.Phil.</li> <li>Exhibit 2051 CV of William B. Trattler, MD</li> <li>Exhibit 2053 Ocufen<sup>®</sup> Product Label (2001)</li> <li>Exhibit 2054 Drugs@FDA, Ocufen<sup>®</sup></li> <li>Exhibit 2055 Drugs@FDA, Ocufen<sup>®</sup></li> <li>Exhibit 2056 Profenal<sup>®</sup> Product Label (1998)</li> <li>Exhibit 2057 Voltaren<sup>®</sup> Product Label (1998)</li> <li>Exhibit 2058 Allan J. Flach, "Corneal Melts Associated With Topically Applied Nonsteroidal Anti-inflammatory Drugs," Transactions of the American Ophthalmology Society Vol. 99, 2001, 205-212.</li> <li>Exhibit 2050 Drugs@FDA, Acular<sup>®</sup> PF</li> </ul>		
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