

Paper No. _____
Filed: May 5, 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 IPR2015-01100
U.S. Patent 8,927,606¹

PATENT OWNER'S UPDATED EXHIBIT LIST

¹ Case IPR 2016-00091 has been joined with this proceeding.

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. Public Exhibit 2323 was filed on the PRPS and served via email to counsel of record for the Petitioner. Confidential Exhibit 2323 was filed on the PRPS as “BOARD AND PARTIES ONLY” and served on Petitioner Counsel Deborah Yellin , Jonathan Lindsay, Jitendra Malik, Lance Soderstrom, and Hidetada James Abe, who were the only counsel that executed the Acknowledgment Form of the Proposed Stipulation Order.

| Exhibits | Description |
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| 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.</i> |

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| | <i>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.” |

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| 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 ophthalmic solution 0.07% in a rabbit model</i> , CLINICAL 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 WL8667473 (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. |

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| 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 [®] |

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