

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

MYLAN PHARMACEUTICALS, INC.
Petitioner,

v.

SENJU PHARMACEUTICAL CO., LTD.
Patent Owner.

U.S. Patent No. 8,877,168 to Higashiyama
Issue Date: November 4, 2014
Title: Aqueous Liquid Preparations and Light-Stabilized Aqueous Liquid
Preparations

Inter Partes Review No.: IPR2016-01163

Petitioner's Exhibit List

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Patent Trial and Appeal Board
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Alexandria, VA 22313-1450

Petitioner's Exhibit List

<i>Petitioner Exhibit #</i>	<i>Description</i>
1001	Higashiyama, U.S. Patent No. 8,784,789, "Aqueous Liquid Preparations and Light-Stabilized Aqueous Liquid Preparations" ("the '789 patent")
1002	Higashiyama, U.S. Patent No. 8,877,168 "Aqueous Liquid Preparations and Light-Stabilized Aqueous Liquid Preparations" ("the '168 patent")
1003	Declaration of Dr. Mansoor M. Amiji
1004	Yanni et al., U.S. Patent No. 6,174,914 "Method of Inhibiting Cytokine Release from Human Ocular Cells" ("Yanni")
1005	Remington: The Science and Practice of Pharmacy 20th Ed. ("Hecht")
1006	Lloyd V. Allen Jr. et al. "Compounding Ophthalmic Preparations," International Journal of Pharmaceutical Compounding 2(3) (1998) ("Allen")
1007	Tetsuya Araki et al., "Photochemical Behavior of Sitafloxacin, Fluoroquinolone Antibiotic, in an Aqueous Solution," Chemical and Pharmaceutical Bulletin 50(2) 229-234 (2002) ("Araki I")
1008	Press Release "Tanabe Seiyaku Granted Rights for Bepotastine Besilate for Ophtalmic [sic] Use to Senju Seiyaku (Japan)" ("Tanabe")
1009	Masanori Araki et al., PCT International Patent Publication No. WO 01/080858 "Stable Liquid Preparation" ("Araki II")
1010	R.J. Davies et al., Antihistamines: topical vs. oral administration, Clinical and Experimental Allergy 26(3):11-17 (1996) ("Davies")
1011	"Stability Testing: Photostability Testing of New Drug Substances and Products," ICH Harmonized Tripartite Guideline (1996) ("ICH Guideline")
1012	Dolores Kostecka et al., "Formulation of a Stable Parenteral Product; Clonidine Hydrochloride Injection," PDA Journal of Pharmaceutical Science & Technology 56(6):320-325 (1998) ("Kostecka")
1013	Gerold L. Mosher et al., "Photoreactivity of LY277359 Maleate, a 5- Hydroxytryptamine ₃ (5-HT ₃) Receptor Antagonist, in Solution," Pharmaceutical Research 8(10):1215-1222 (1991) ("Mosher")
1014	Reserved

1015	Press Release “Regarding Extended Indication for Selective Histamine H1 Receptor Antagonist/Anti-Allergic Agent Talion® Tablets 5 and Talion® Tablets 10 in Treating Pruritus/Itching Accompanying Urticaria and Other Skin Diseases” (“Talion Press Release”)
1016	Remington’s Pharmaceutical Sciences 16th Ed., pp. 1403-1419 (1980) (“Remington”).
1017	Jun-ichiro Kita et al., European Patent Publication No. EP 0 949 260 “Acid-Addition Salts of Optically Active Piperidine Compound and Process for Producing the Same” (“Kita”)
1018	CV of Dr. Mansoor M. Amiji
1019	Declaration of Higashiyama Under 37 CFR § 1.132 of Nov. 6, 2007
1020	Supplemental Amendment of Nov. 13, 2007
1021	Final Office Action of Feb. 8, 2008
1022	Declaration of Higashiyama of Dec. 22, 2008
1023	Amendment of Jan. 5, 2009
1024	Office Action of May 8, 2009
1025	Office Action of April 9, 2010
1026	Final Office Action of Dec. 20, 2010
1027	Declaration of Higashiyama of Sept., 11, 2012
1028	Supplemental Amendment of Sept. 14, 2012
1029	Office Action of Aug. 30, 2013
1030	Amendment of May 30, 2014
1031	Notice of Allowance of June 12, 2014
1032	Amendment of April 24, 2012
1033	Final Office Action of Apr. 30, 2014
1034	Examiner Interview Summary of August 11, 2018 in ’678 application

CERTIFICATION OF SERVICE ON PATENT OWNER

Pursuant to 37 C.F.R. §§ 42.6(e), 42.8(b)(4) and 42.105, the undersigned certifies that on the 8th day of June 2016, a complete copy of the foregoing Petition for *Inter Partes* Review of U.S. Patent No. 8,877,168, Power of Attorney, Exhibit List, and all supporting exhibits were served via UPS® to the Patent Owner by serving the correspondence address of record for the '168 patent:

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Courtesy copies of the foregoing were also served via UPS® on counsel of record for the Patent Owner in *Bausch & Lomb Inc. et al. v. Micro Labs Ltd. et al.*, No. 15-cv-03113-NLH-JS (D.N.J.) as follows:

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