

Filed: February 4, 2016

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

MYLAN PHARMACEUTICALS INC.

Petitioner,

v.

YEDA RESEARCH & DEVELOPMENT CO. LTD.

Patent Owner.

Case IPR2015-00643

Patent No. 8,232,250

UPDATED LIST OF PATENT OWNER'S EXHIBITS

Pursuant to 37 C.F.R. § 42.63(e), Patent Owner submits the following current exhibit list.

Exhibit No.	Description
2001	Teva Provides Update on Forte Trial (July 7, 2008)
2002	Francisco J. Quintana et al., <i>Systems Biology Approaches for the Study of Multiple Sclerosis</i> , 12 J. Cellular & Molecular Med. 1087 (2008)
2003	David Virley, <i>Developing Therapeutics for the Treatment of Multiple Sclerosis</i> , 2 J. Am. Soc. Experimental Neurotherapeutics 638 (Oct. 2005)
2004 (corrected)	Manuel A. Friese et al., <i>The Value of Animal Models for Drug Development in Multiple Sclerosis</i> , 129 Brain 1940 (2006)
2005	Copaxone Prescribing Information (Jan. 2014)
2006	Dvora Teitelbaum et al., <i>Suppression of Experimental Allergic Encephalomyelitis by a Synthetic Polypeptide</i> , 1 Eur. J. Immunology 242 (1971)
2007	Jill Conner, <i>Glatiramer Acetate and Therapeutic Peptide Vaccines for Multiple Sclerosis</i> , 1 J. Autoimmun. & Cell Responses 3 (2014)
2008	Copaxone, Physicians Desk Reference 3231 (62 ed. 2008)
2009	Wiebke Schrempf and Tjalf Ziemssen, <i>Glatiramer Acetate: Mechanisms of Action In Multiple Sclerosis</i> , 6 Autoimmun. Rev. 469 (2007)
2010	V. Wee Yong, <i>Differential Mechanisms of Action of Interferon-β and Glatiramer Acetate in MS</i> , 59 Neurology 802 (2002)
2011	Suhayl Dhib-Jalbut, <i>Mechanisms of Action of Interferons and Glatiramer Acetate in Multiple Sclerosis</i> , 58 Neurology S3 (Supp. 4 2002)
2012	O. Neuhaus et al., <i>Pharmacokinetics and Pharmacodynamics of the Interferon-Betas, Glatiramer Acetate, and Mitoxantrone in Multiple Sclerosis</i> , 259 (1-2) J. Neurol. Sci. 27 (2007)
2013	Oded Abramsky et al., <i>Effect of A Synthetic Polypeptide (COP 1) on Patients with Multiple Sclerosis and with Acute Disseminated Encephalomyelitis</i> , 31 J. Neurol. Sci. 433 (1977)
2014	Murry B. Bornstein et al., <i>Treatment of Multiple Sclerosis with a Synthetic Polypeptide: Preliminary Results</i> , 105 Tran. Am. Neurol. Assoc. 348 (1980)
2015	Murry B. Bornstein et al., <i>Multiple Sclerosis: Trial of a Synthetic Polypeptide</i> , 11 Annals Neurology 317 (1982)
2016	Murry B. Bornstein et al., <i>A Pilot Trial of COP 1 in Exacerbating-Relapsing Multiple Sclerosis</i> , 13 New Engl. J. Med. 408 (1987)

2017	Sage Journals, Table of Contents, http://msj.sagepub.com/content/14/1_suppl.toc (Sept. 2008)
2018	Massimo Filippi et al., <i>Effects of Oral Glatiramer Acetate on Clinical and MRI Monitored Disease Activity in Patients with Relapsing Multiple Sclerosis: A Multicentre, Double-Blind, Randomised, Placebo-Controlled Study</i> , http://neurology.thelancet.com (Jan. 20, 2006)
2019	Yuval Ramot et al., <i>Comparative Long-Term Preclinical Safety Evaluation of Two Glatiramoid Compounds (Glatiramer Acetate, Copaxone1, and TV-5010, Protiramer) in Rats and Monkeys</i> , 40 Toxicol. Pathways 40 (2012)
2020	U.S. Patent Application No. 2007/0161566 A1
2021	T. Ziemssen et al., <i>Risk-benefit Assessment of Glatiramer Acetate in Multiple Sclerosis</i> , 24(13) Drug Safety 979 (2001)
2022	Teva News Release, Phase III Data Published in Annals of Neurology Show That a Higher Concentration Dose of Glatiramer Acetate Given Three Times a Week Reduced Annualized Relapse Rates in the Treatment of Relapsing-Remitting Multiple Sclerosis (July 1, 2013)
2023	Omar Khan et al., <i>Three Times Weekly Glatiramer Acetate in Relapsing-Remitting Multiple Sclerosis</i> , 73 Annals Neurology 705 (2013)
2024	Teva Press Release, Teva Reports First Quarter 2015 Results (April 30, 2015)
2025 (corrected)	Kate McKeage, <i>Glatiramer Acetate 40 mg/mL in Relapsing-Remitting Multiple Sclerosis: A Review</i> , CNS Drugs (April 24, 2015)
2026	K.P. Johnson et al., <i>Copolymer 1 reduces relapse rate and improves disability in relapsing-remitting multiple sclerosis: Results of Phase III Multicenter, Double-Blind, Placebo-Controlled Trial</i> , 45 Neurology 1268 (1995)
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2028	Giancarlo Comi, <i>Forte: Results from a phase II, 1-year, Randomized, Double-blind, Parallel-Group, Dose-Comparison Study with Glatiramer Acetate in Relapsing-Remitting Multiple Sclerosis</i> , Presented at World Congress on Treatment and Research in Multiple Sclerosis: 2008 Joint Meeting of the American, European, and Latin America Committees on Treatment and Research in Multiple Sclerosis, San Raffaele, Italy (ACTRIMS,ECTRIMS, LACTRIMS) (2008)
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2035	Order, <i>Endo Pharmaceuticals, Inc. v. Mylan Pharmaceuticals, Inc.</i> , No. 11-cv-00717, Document 310 (D. Del. Apr. 8, 2014) (Peroutka Dep. Ex.15).
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2037	Notice of Abandonment, APN 11/651,212, USPTO (Mar. 9, 2010).
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2100	Curriculum Vitae of Edward J. Fox. MD., PhD., FAAN
2101	Per Soelberg Sorensen et al., <i>Clinical Importance of Neutralizing Antibodies Against Interferon Beta in Patients with Relapsing-Remitting Multiple Sclerosis</i> , 362 <i>Lancet</i> 1184 (2003).

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2104	Curriculum Vitae of Dr. Henry George Grabowski
2105	List of Testimony of Henry G. Grabowski
2106	Documents Relied Upon (Grabowski)
2107	Table: Approval Timeline, Multiple Sclerosis Drugs
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2123 (corrected)	G. Comi et al., <i>Effect of Glatiramer Acetate on Conversion to Clinically Definite Multiple Sclerosis in Patients with Clinically Isolated Syndrome (PreCISe study): A Randomised, Double-Blind, Placebo-Controlled Trial</i> , 374 Lancet 1503 (2009).
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2129	Declaration of Edward J. Fox, MD., PhD
2130	Curriculum Vitae of Robert William Gristwood PhD
2131	Curriculum Vitae of Tjalf Ziemssen
2132	Ziemssen's MS clinical trials
2133 (corrected)	Corrected Declaration of Henry G. Grabowski, Ph.D.
2134	Declaration of Robert William Gristwood, Ph.D.
2135	Declaration of Tjalf Ziemssen, M.D., Ph.D
2136	Declaration of John T. Bennett in support of Patent Owner's Motion for <i>Pro Hac Vice</i> Admission of John T. Bennett Under 37 C.F.R. § 42.10(c)
2137	Declaration of Daryl L. Wiesen in support of Patent Owner's Motion for <i>Pro Hac Vice</i> Admission of Daryl L. Wiesen Under 37 C.F.R. § 42.10(c)
2138	Declaration of Nicholas K. Mitrokostas in support of Patent Owner's Motion for <i>Pro Hac Vice</i> Admission of Nicholas K. Mitrokostas Under 37 C.F.R. § 42.10(c)
2139	Patent Owner's Proposed Supplemental Exhibits
2140	Letter from Brandon M. White to Eleanor M. Yost, re: Mylan Pharmaceuticals Inc. v. Yeda Research & Development Co. Ltd. Case Nos. IPR2105-00643, IPR2015-00644 and IPR2015-00830 (Jan. 12, 2016).
2141	Analyst Report: "Spec Pharmaceuticals," Morgan Stanley (Mar. 3, 2014)
2142	U.S. Patent No. 8,377,885
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2144	Analyst Report: "Multiple Sclerosis: It's a Revolution! (vs. Evolution)," Credit Suisse (Dec. 12, 2013)

Pursuant to the Board's Order dated February 1, 2016 (Paper 48), Patent Owner Yeda Research and Development Co. Ltd. hereby files Exhibits 2141, 2142, 2143, and 2144. Also filed herewith, pursuant to the same, is Corrected Exhibit 2133.

Respectfully submitted,

Dated: February 4, 2016

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CERTIFICATION OF SERVICE

The undersigned hereby certifies that the foregoing **UPDATED LIST OF PATENT OWNER'S EXHIBITS** and accompanying Exhibits 2133 and 2141-2144 were served electronically via e-mail on February 4, 2016 on the following:

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