

Filed: November 20, 2015

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 IPR2015-00644

Patent No. 8,399,413

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	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 Mclerosis</i> , 1 J. Autoimmun. & Cell Responses 3 (2014)
2008	Copaxone, Physicians Desk Reference 3231 (62 ed. 2008)
2009	Wiebke Schremppf 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 S3-9 (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. 27-37 (2007)

2013	Oded Abramsky <i>et al.</i> , <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 <i>et al.</i> , <i>Treatment of Multiple Sclerosis with a Synthetic Polypeptide: Preliminary Results</i> , 105 Tran. Am. Neurol. Assoc. 348 (1980)
2015	Murry B. Bornstein <i>et al.</i> , <i>Multiple Sclerosis: Trial of a Synthetic Polypeptide</i> , 11 Annals Neurol. 317 (1982)
2016	Murry B. Bornstein <i>et al.</i> , <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 <i>et al.</i> , <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 <i>et al.</i> , <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 <i>et al.</i> , <i>Risk-benefit assessment of glatiramer acetate in multiple sclerosis</i> , 24(13) Drug Safety 979 (2001)
2022	Teva News Release, <i>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-Relapsing Multiple Sclerosis</i> (July 1, 2013)
2023	Omar Khan <i>et al.</i> , <i>Three Times Weekly Glatiramer Acetate in Relapsing-Relapsing Multiple Sclerosis</i> , 73 Annals Neurol. 705 (2013)
2024	Teva Press Release, <i>Teva Reports First Quarter 2015 Results</i> (April 30, 2015)
2025	Kate McKeage, <i>Glatiramer Acetate 40 mg/mL in Relapsing-Relapsing 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 a phase III multicenter, double-blind, placebo-controlled trial</i> , 45 <i>Neurology</i> 1268 (1995)
2027	Intentionally left Blank
2028	G. 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)
2029	Jerry S. Wolinsky et al., <i>GLACIER: An open-label, randomized, multicenter study to assess the safety and tolerability of glatiramer acetate 40 mg three times weekly versus 20 mg daily in patients with relapsing-remitting multiple sclerosis</i> , 4 <i>Multiple Sclerosis and Related Disorders</i> 370 (2015)
2030	C. Farina et al., <i>Treatment of multiple sclerosis with Copaxone (COP): Elispot assay detects COP-induced interleukin-4 and interferon-gamma response in blood cells</i> . 124 <i>Brain</i> 705 (2001).
2031	PRA, <i>Multiple Sclerosis: Transform Your Clinical Trial with PRA</i> (2012) (Peroutka Dep. Ex. 4)
2032	Opinion, <i>Endo Pharmaceuticals, Inc. v. Mylan Pharmaceuticals, Inc.</i> , No. 11-cv-00717, Document 226 (Jan. 28, 2014) (Peroutka Dep. Ex. 6)
2033	Donna Oksenberg et al., <i>A single amino acid difference confers major pharmacological variation between human and rodent 5-HT-1B receptors</i> , 360 <i>Nature</i> 161 (1992) (Peroutka Dep. Ex. 9)
2034	Shalit et al., <i>Copolymer-1 (Copaxone®) induces in non-immunologic activation of connective tissue type mast cells</i> , 97(1) <i>J. Allergy And Clinical Immunology</i> 345 (1996) (Peroutka Dep. Ex. 12)

2035	Order, <i>Endo Pharmaceuticals, Inc. v. Mylan Pharmaceuticals, Inc.</i> , No. 11-cv-00717, Document 310 (Apr. 8, 2014) (Peroutka Dep. Ex. 15)
2036	M. Fridkis-Hareli et al., <i>Binding motifs of copolymer 1 to multiple sclerosis- and rheumatoid arthritis-associated HLA-DR molecules.</i> . 15;162(8):4697-704. (Apr. 1999)
2037	Notice of Abandonment APN 11/651,212 (03-09-10)
2038	B. Meibohm & H. Derendorf, <i>Basic concepts of pharmacokinetic/pharmacodynamic (PK/PD) modelling.</i> 35(10) , 401-413 (1997)
2039	P.H. Lambert & P.E. Laurent, <i>Intradermal vaccine delivery: will new delivery systems transform vaccine administration?</i> 26(26) Vaccine, 3197-208 (2008)
2040	G. Glenn et al., <i>Transcutaneous immunization and immunostimulant strategies</i> , 23(4) Immunology And Allergy Clinics Of N. Am., 787-813 (2003)
2041	C.D. Partidos et al., <i>Immunity under the skin: potential application for topical delivery of vaccines</i> , 21Vaccine 776 (2003)
2042	C. Ghose et al., <i>Transcutaneous immunization with Clostridium difficile toxoid A induces systemic and mucosal immune responses and toxin A-neutralizing antibodies in mice</i> , 75 Infection & Immunity 2326 (2007)
2043	G. Glenn et al., <i>Transcutaneous immunization with cholera toxin protects mice against lethal mucosal toxin challenge</i> , 161(7) J. Immunology 3211 (1998)
2044	R. Aharoni et al., <i>Specific Th2 cells accumulate in the central nervous system of mice protected against experimental autoimmune encephalomyelitis by copolymer 1</i> , 97 Proc. Nat'l Acad. Sci. U.S.A., 11472 (2000)

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