Filed: March 7, 2016

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

MYLAN PHARMACEUTICALS INC. and AMNEAL PHARMACEUTICALS LLC

Petitioners

v.

YEDA RESEARCH AND DEVELOPMENT CO. LTD.

Patent Owner

Case IPR2015-00644 (Patent 8,399,413 B2)[1]

UPDATED LIST OF PATENT OWNER'S EXHIBITS

[1] Case IPR2015-01080 has been joined with this proceeding.

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	Franscisco J. Quintana et al., *Systems Biology Approaches for the Study of Multiple Sclerosis*, 12 J. Cellular & Molecular Med. 1087 (2008)
2003	David Virley, *Developing Therapeutics for the Treatment of Multiple Sclerosis*, 2 J. Am. Soc. Experimental Neurotherapeutics 638 (Oct. 2005)
2004	Manuel A. Friese et al., *The Value of Animal Models for Drug Development in Multiple Sclerosis*, 129 Brain 1940 (2006)
2005	Copaxone Prescribing Information (Jan. 2014)
2006	Dvora Teitelbaum et al., *Suppression of Experimental Allergic Encephalomyelitis by a Synthetic Polypeptide*, 1Eur. J. Immunology 242 (1971)
2007	Jill Conner, *Glatiramer Acetate and Therapeutic Peptide Vaccines for Multiple Mclerosis*,1 J. Autoimmun. & Cell Responses 3 (2014)
2008	Copaxone, Physicians Desk Reference 3231 (62 ed. 2008)
2009	Wiebke Schrempf and Tjalf Ziemssen, *Glatiramer Acetate: Mechanisms of Action In Multiple Sclerosis*, 6 Autoimmun. Rev. 469 (2007)
2010	V. Wee Yong, *Differential Mechanisms of Action of Interferon-β and Glatiramer Acetate in MS*, 59 Neurology 802 (2002)
2011	Suhayl Dhib-Jalbut, *Mechanisms of Action of Interferons and Glatiramer Acetate in Multiple Sclerosis*, 58 Neurology S3 (Supp. 4 2002)
2012	O. Neuhaus et al., *Pharmacokinetics and Pharmacodynamics of the Interferon-Betas, Glatiramer Acetate, and Mitoxantrone in Multiple Sclerosis*, 259 (1-2) J. Neurol. Sci. 27 (2007)
2013	Oded Abramsky et al., *Effect of A Synthetic Polypeptide (COP 1) on Patients with Multiple Sclerosis and with Acute Disseminated Encephalomyelitis*, 31 J. Neurol. Sci. 433 (1977)
2014	Murry B. Bornstein et al., *Treatment of Multiple Sclerosis with a Synthetic Polypeptide: Preliminary Results*, 105 Tran. Am. Neurol. Assoc. 348 (1980)
2015	Murry B. Bornstein et al., *Multiple Sclerosis: Trial of a Synthetic Polypeptide*, 11 Annals Neurology 317 (1982)

2016	Murry B. Bornstein et al., *A Pilot Trial of COP 1 in Exacerbating-Remitting Multiple Sclerosis*, 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., *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*, http://neurology.thelancet.com (Jan. 20, 2006)
2019	Yuval Ramot et al., *Comparative Long-Term Preclinical Safety Evaluation of Two Glatiramoid Compounds (Glatiramer Acetate, Copaxone1, and TV-5010, Protiramer) in Rats and Monkeys*, 40 Toxicol. Pathways 40 (2012)
2020	U.S. Patent Application No. 2007/0161566 A1
2021	T. Ziemssen et al., *Risk-benefit Assessment of Glatiramer Acetate in Multiple Sclerosis*, 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., *Three Times Weekly Glatiramer Acetate in Relapsing–Remitting Multiple Sclerosis*, 73 Annals Neurology 705 (2013)
2024	Teva Press Release, Teva Reports First Quarter 2015 Results (April 30, 2015)
2025	Kate McKeage, *Glatiramer Acetate 40 mg/mL in Relapsing-Remitting Multiple Sclerosis: A Review*, CNS Drugs (April 24, 2015)
2026	K.P. Johnson et al., *Copolymer 1 reduces relapse rate and improves disability in relapsing-remitting multiple sclerosis: Results of Phase III Multicenter, Double-Blind, Placebo-Controlled Trial*, 45 Neurology 1268 (1995)
2027	Intentionally left Blank
2028	Giancarlo Comi, *Forte: Results from a phase II, 1-year, Randomized, Double-blind, Parallel-Group, Dose-Comparison Study with Glatiramer Acetate in Relapsing-Remitting Multiple Sclerosis*, 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., *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*, 4 Multiple Sclerosis & Related Disorders 370 (2015).
2030	Cinthia Farina et al., *Treatment of Multiple Sclerosis with Copaxone (COP): Elispot Assay Detects COP-Induced Interleukin-4 and Interferon-Gamma Response in Blood Cells*, 124 Brain 705 (2001).
2031	Marketing Materials, PRA, Multiple Sclerosis: Transform Your Clinical Trial with PRA (2012) (on file with author) (Peroutka Dep. Ex. 4).
2032	Opinion, *Endo Pharmaceuticals, Inc. v. Mylan Pharmaceuticals, Inc.*, No. 11-cv-00717, Document 226 (D. Del. Jan. 28, 2014) (Peroutka Dep. Ex. 6).
2033	Donna Oksenberg et al., *A Single Amino-Acid Difference Confers Major Pharmacological Variation Between Human and Rodent 5-HT1B Receptors*, 360 Nature 161 (1992) (Peroutka Dep. Ex. 9).
2034	M. Shalit et al., Abstract, *Copolymer-1 (Copaxone®) Induces a Non-Immunologic Activation of Connective Tissue Type Mast Cells*, 97 J. Allergy & Clinical Immunology 345 (1996) (Peroutka Dep. Ex. 12).
2035	Order, *Endo Pharmaceuticals, Inc. v. Mylan Pharmaceuticals, Inc.*, No. 11-cv-00717, Document 310 (D. Del. Apr. 8, 2014) (Peroutka Dep. Ex.15).
2036	Masha Fridkis-Hareli et al., *Binding Motifs of Copolymer 1 to Multiple Sclerosis- and Rheumatoid Arthritis-Associated HLA-DR Molecules*, 162 J. Immunology 4697 (1999).
2037	Notice of Abandonment, APN 11/651,212, USPTO (Mar. 9, 2010).
2038	Bernd Meibohm & Hartmut Derendorf, *Basic Concepts of Pharmacokinetic/Pharmacodynamic (PK/PD) Modelling*, 35 Int'l J. Clinical Pharmacology & Therapeutics 401 (1997).
2039	Paul Henri Lambert & Philippe E. Laurent, *Intradermal Vaccine Delivery: Will New Delivery Systems Transform Vaccine Administration?*, 26 Vaccine 3197 (2008).
2040	Gregory M. Glenn et al., *Transcutaneous Immunization and Immunostimulant Strategies: Capitalizing on the Immunocompetence of the Skin*, 2 Expert Rev. Vaccines 253 (2003).
2041	C.D. Partidos et al., *Immunity Under the Skin: Potential Application for Topical Delivery of Vaccines*, 21 Vaccine 776 (2003).
2042	Chandrabali Ghose et al., *Transcutaneous Immunization with Clostridium difficile Toxoid A Induces Systemic and Mucosal Immune Responses and Toxin A-Neutralizing Antibodies in Mice*, 75 Infection & Immunity 2826 (2007).

2043	Gregory M. Glenn et al., *Cutting Edge: Transcutaneous Immunization with Cholera Toxin Protects Mice Against Lethal Mucosal Toxin Challenge*, 161 J. Immunology 3211 (1998).
2044	Rina Aharoni et al., *Specific Th2 Cells Accumulate in the Central Nervous System of Mice Protected Against Experimental Autoimmune Encephalomyelitis by Copolymer 1*, 97 Proc. Nat'l Acad. Sci. U.S.A. 11,472 (2000).
2045	Ruth Arnon & Rina Aharoni, *Mechanism of Action of Glatiramer Acetate in Multiple Sclerosis and Its Potential for the Development of New Applications*, 101 Proc. Nat'l Acad. Sci. U.S.A. 14,593 (2004).
2046	Haim Varkony et al., *The Glatiramoid Class of Immunomodulator Drugs*, 10 Expert Opinion Pharmacotherapy 657 (2009).
2047	G. Comi & L. Moiola, *Glatiramer Acetate*, 17 Neurologia 244 (2002).
2048 (corrected)	S. Chabot et al., *Cytokine Production in T Lymphocyte-Microglia Interaction Is Attenuated by Glatiramer Acetate: A Mechanism for Therapeutic Efficacy in Multiple Sclerosis*, 8 Multiple Sclerosis 299 (2002).
2049 (corrected)	Tjalf Ziemssen, *Neuroprotection and Glatiramer Acetate: The Possible Role in the Treatment of Multiple Sclerosis*, *in Frontiers in Clinical Neuroscience* 111 (2004).
2050 (corrected)	Hana Schmeisser et al., *Radioiodination of Human Interferon-α2 Interferes with Binding of C-Terminal Specific Antibodies*, 238 J. Immunological Methods 81 (2000).
2051 (corrected)	Y. M. Efimova et al., *Changes in the Secondary Structure of Proteins Labeled with ^{125}I: CD Spectroscopy and Enzymatic Activity Studies*, 264 J. Radioanalytical & Nuclear Chemistry 91 (2005).
2052 (corrected)	P. L. Toutain & A. Bousquet-Mélou, *Plasma Terminal Half-Life*, 27 J. Veterinary Pharmacology & Therapeutics 427 (2004).
2053 (corrected)	Graeme B. Ryan & Guido Majno, *Acute Inflammation: A Review*, 86 Am. J. Pathology 183 (1977).
2054 (corrected)	M. Shalit et al., Abstract, *Copolymer-1 (Copaxone®) Induces in Non-Immunologic Activation of Connective Tissue Type Mast Cells*, 97 J. Allergy & Clinical Immunology 345 (1996)
2055 (corrected)	Peter Imming et al., *Drugs, Their Targets and the Nature and Number of Drug Targets*, 5 Nature Revs. Drug Discovery 821 (2006) (Erratum in: 6 Nature Revs. Drug Discovery 126 (2007)).
2056 (corrected)	Candace B. Pert & Solomon H. Snyder, *Properties of Opiate-Receptor Binding in Rat Brain*,70 Proc. Nat'l Acad. Sci. U.S.A. 2243 (1973).

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