

Filed: April 22, 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	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 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-Relapsing Multiple Sclerosis (July 1, 2013)
2023	Omar Khan et al., <i>Three Times Weekly Glatiramer Acetate in Relapsing-Relapsing Multiple Sclerosis</i> , 73 Annals Neurology 705 (2013)
2024	Teva Press Release, Teva Reports First Quarter 2015 Results (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-relapsing 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-Relapsing 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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2030	Cinthia 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).
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2032	Opinion, <i>Endo Pharmaceuticals, Inc. v. Mylan Pharmaceuticals, Inc.</i> , No. 11-cv-00717, Document 226 (D. Del. Jan. 28, 2014) (Peroutka Dep. Ex. 6).
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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).
2036	Masha Fridkis-Hareli et al., <i>Binding Motifs of Copolymer 1 to Multiple Sclerosis- and Rheumatoid Arthritis-Associated HLA-DR Molecules</i> , 162 <i>J. Immunology</i> 4697 (1999).
2037	Notice of Abandonment, APN 11/651,212, USPTO (Mar. 9, 2010).
2038	Bernd Meibohm & Hartmut Derendorf, <i>Basic Concepts of Pharmacokinetic/Pharmacodynamic (PK/PD) Modelling</i> , 35 <i>Int'l J. Clinical Pharmacology & Therapeutics</i> 401 (1997).
2039	Paul Henri Lambert & Philippe E. Laurent, <i>Intradermal Vaccine Delivery: Will New Delivery Systems Transform Vaccine Administration?</i> , 26 <i>Vaccine</i> 3197 (2008).
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2041	C.D. Partidos et al., <i>Immunity Under the Skin: Potential Application for Topical Delivery of Vaccines</i> , 21 <i>Vaccine</i> 776 (2003).
2042	Chandrabali 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 <i>Infection & Immunity</i> 2826 (2007).

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2047	G. Comi & L. Moiola, <i>Glatiramer Acetate</i> , 17 Neurologia 244 (2002).
2048 (corrected)	S. Chabot et al., <i>Cytokine Production in T Lymphocyte-Microglia Interaction Is Attenuated by Glatiramer Acetate: A Mechanism for Therapeutic Efficacy in Multiple Sclerosis</i> , 8 Multiple Sclerosis 299 (2002).
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