

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

MYLAN PHARMACEUTICALS INC.

Petitioner

v.

YEDA RESEARCH AND DEVELOPMENT CO. LTD.

Patent Owner

Case No. IPR2015-00644

Patent No. 8,399,413

**PETITIONER'S OBJECTIONS UNDER 37 C.F.R. § 42.62
TO EVIDENCE SUBMITTED BY PATENT OWNER**

Pursuant to 37 C.F.R. § 42.64(b)(1), Petitioner Mylan Pharmaceuticals Inc. (“Petitioner”) objects to the admissibility of the following exhibits filed by Patent Owner Yeda Research and Development Co. Ltd.

In this paper, a reference to “FRE” means the Federal Rules of Evidence, a reference to “CFR” means the Code of Federal Regulations, and “413 patent” means U.S. Patent No. 8,399,413. All objections under FRE 802 (hearsay) apply to the extent Patent Owner relies on the exhibits identified in connection with that objection for the truth of the matter asserted therein.

Exhibit descriptions provided in this table are Patent Owner’s exhibit list and are used for identification purposes only. The use of the description does not indicate that Petitioner agrees with the descriptions or characterizations of the documents.

Exhibit	Description	Objection
2001	Teva Provides Update on Forte Trial (July 7, 2008)	A, B, D, F, G, H, I, J, N, O, K, T
2002	Francisco J. Quintana, <i>et al.</i> , <i>Systems Biology Approaches for the Study of Multiple Sclerosis</i> , J. CELL. MOL. MED. Vol 12, No 4, 1087-93 (2008)	A, D, F, G, H, M, N, O
2003	David J. Virley, <i>Developing Therapeutics for the treatment of multiple sclerosis</i> , 2 J. AM. SOC. EXP. NEUROTHERAPEUTICS, 638-49 (Oct. 2005)	A, D, F, G, H, M, N, O

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2004	Manuel A. Friese, <i>The value of animal models for drug development in multiple sclerosis</i> , 129 BRAIN, 1940-52 (2006)	A, D, F, G, H, M, N, O
2005	Copaxone Prescribing Information (January 2014)	A, C, D, E, F, G, H, M, N, O
2006	Dvora Teitelbaum <i>et al.</i> , <i>Suppression of experimental allergic encephalomyelitis by a synthetic polypeptide</i> , 1 EUR. J. IMMUNOL., 242-248 (Aug. 1971)	A, B, D, F, G, H, I, K, M, N, O
2007	Jill Conner, <i>Glatiramer acetate and therapeutic peptide vaccines for multiple sclerosis</i> , 1 J. Autoimmunity and Cell Responses 3 (2014)	A, D, F, G, H, M, N, O
2008	Copaxone, Physicians Desk Reference 62ed. (2008)	A, D, F, G, H, I, M, N, O
2009	Wiebke Schrempf and Tjalf Ziemssen, <i>Glatiramer acetate: Mechanisms of action in multiple sclerosis</i> , 6 AUTOIMMUN. REV., 469-475 (2007)	A, D, F, G, H, M, N, O
2010	V.Wee Yong, <i>Differential mechanisms of action of interferon-β and glatiramer acetate in MS</i> , 59 NEUROLOGY, 802-8 (April 2002)	A, D, F, G, H, M, N, O
2011	Suhayl Dhib-Jalbut, <i>Mechanisms of action of interferons and glatiramer acetate in multiple sclerosis</i> , 58 NEUROLOGY (8 Suppl 4) S3-9 (2002)	A, D, F, G, H, M, N, O

Exhibit	Description	Objection
2012	Oliver Neuhaus <i>et al.</i> , <i>Pharmacokinetics and pharmacodynamics of the interferon-betas, glatiramer acetate, and mitoxantrone in multiple sclerosis</i> , 259 J. NEUROL. SCI., 27–37 (2007)	A, D, F, G, H, M, N, O
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. Preliminary Report</i> , 31 J. NEUROL. SCI., 433-38 (1977)	A, D, F, G, H, M, N, O
2014	Murray B. Bornstein <i>et al.</i> , <i>Treatment of Multiple Sclerosis with a Synthetic Polypeptide: Preliminary Results</i> , 105 TRAN. AM. NEUROL. ASSOC., 348-50 (1980)	A, D, F, G, H, I, M, N, O
2015	Murray B. Bornstein <i>et al.</i> , <i>Multiple Sclerosis: Trial of a Synthetic Polypeptide</i> , 11 ANN. NEUROL., 317-19 (Mar. 1982)	A, D, F, G, H, M, N, O
2016	Murray B. Bornstein <i>et al.</i> , <i>A Pilot Trial of COP 1 in Exacerbating-Relmitting Multiple Sclerosis</i> , 13 N. ENGL. J. MED., 408-14 (Aug. 13, 1987)	A, D, F, G, H, M, N, O
2017	Sage Journals, http://msj.sagepub.com/content/14/1_suppl.toc (Sept. 2008)	A, B, C, D, E, F, G, H, I, K, L, N, O
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)	A, D, F, G, H, M, N, O

Exhibit	Description	Objection
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. PATH., 40-54 (2012)	A, D, F, G, H, K, M, N, O
2020	U.S. Patent Application No. 2007/0161566 A1 (“Pinchasi”)	A, D, F, G, H, K, M, N, O
2021	Tjalf Ziemssen <i>et al.</i> , <i>Risk-Benefit Assessment of Glatiramer Acetate in Multiple Sclerosis</i> , 24 DRUG SAFETY, 13, 979-90 (2001)	A, D, F, G, H, M, N, O
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-Remitting Multiple Sclerosis</i> (July 1, 2013)	A, B, C, D, E, F, G, H, M, N, O, T
2023	Omar Khan <i>et al.</i> , <i>Three Times Weekly Glatiramer Acetate in Relapsing-Remitting Multiple Sclerosis</i> , 73 ANN. NEUROL., 705-13 (2013)	A, C, D, E, F, G, H, M, N, O
2024	Teva Press Release, <i>Teva Reports First Quarter 2015 Results</i> (April 30, 2015)	A, B, C, D, E, F, G, H, L, M, N, O, T
2025	Kate McKeage, <i>Glatiramer Acetate 40 mg/mL in Relapsing-Remitting Multiple Sclerosis: A Review</i> , CNS DRUGS (April 24, 2015)	A, C, D, E, F, G, H, I, M, N, O

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