

Filed: April 12, 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 & DEVELOPMENT CO. LTD.

Patent Owner.

Case IPR2015-00644  
Patent No. 8,399,413

**FIFTH UPDATED LIST OF PETITIONERS' EXHIBITS**

Pursuant to 37 C.F.R. § 42.63(e), Petitioners submit the following current exhibit list.

<b><u>Exhibit No.</u></b>	<b><u>Description</u></b>
1001	U.S. Patent No. 8,399,413, <i>Low Frequency Glatiramer Acetate Therapy</i> (filed Aug. 19, 2010) (issued May 19, 2013)
1002	File History for U.S. Patent No. 8,399,413
1003	[Corrected] Declaration of Stephen J. Peroutka, M.D., Ph.D.
1003A	<i>Curriculum Vitae</i> of Stephen J. Peroutka, M.D., Ph.D.
1003B	Materials Reviewed by Stephen J. Peroutka, M.D., Ph.D.
1004	Expert Declaration of Ari Green, M.D.
1004A	<i>Curriculum Vitae</i> of Ari Green, M.D.

<b><u>Exhibit No.</u></b>	<b><u>Description</u></b>
1004B	Materials Reviewed by Ari Green, M.D.
1005	Irit Pinchasi: International Publication No. WO 2007/081975 (published July 19, 2007)
1006	J.A. Cohen et al., <i>Randomized, double-blind, dose-comparison study of glatiramer acetate in relapsing-remitting MS</i> , 68:12 NEUROLOGY, 939-44 (2007)
1007	Affidavit of Marlene S. Bobka dated December 9, 2014
1007A	John J. Jessop, <i>Review and Evaluation of Pharmacology Toxicology Data Original NDA Review (1996) (the 1996 FDA SBOA)</i> (attached as Exhibit A to Exh. 1007)
1008	Shlomo Flechter et al., <i>Copolymer 1 (Glatiramer Acetate) in Relapsing Forms of Multiple Sclerosis: Open Multicenter Study of Alternate-Day Administration</i> . 25:1 CLINICAL NEUROPHARMACOLOGY, 11-15 (2002) (Flechter 2002A)
1009	Zeev Meiner et al., <i>Copolymer 1 in relapsing-remitting multiple sclerosis: a multi-centre trial</i> , in FRONTIERS IN MULTIPLE SCLEROSIS: CLINICAL RESEARCH AND THERAPY (Oded Abramsky and Haim Ovadia, eds., 1997)
1010	Omar Khan et al., <i>Randomized, prospective, rater-blinded, four-year, pilot study to compare the effect of daily versus every-other-day glatiramer acetate 20 mg subcutaneous injections in relapsing-remitting multiple sclerosis</i> , 14 MULTIPLE SCLEROSIS, S296 (2008)
1011	Christina Caon et al., <i>Randomized, Prospective, Rater-Blinded, Four Year Pilot Study to Compare the Effect of Daily Versus Every Other Day Glatiramer Acetate 20 mg Subcutaneous Injections in RRMS</i> , 72:11(3) NEUROLOGY, A317 (2009)

<u>Exhibit No.</u>	<u>Description</u>
1012	Shlomo Flechter et al., <i>Comparison of glatiramer acetate (Copaxone) and interferon <math>\beta</math>-1b (Betaferon) in multiple sclerosis patients: an open-label 2-year follow up</i> , 197 JOURNAL OF THE NEUROLOGICAL SCIENCES, 51-55 (2002). (“Flechter 2002B”)
1013	James R Miller, <i>The importance of early diagnosis of multiple sclerosis</i> , 10(3) (Suppl. S-b) J. MANAG. CARE PHARM., S4-11 (2004)
1014	M.B. Bornstein, <i>Multiple Sclerosis: Trial of a Synthetic Polypeptide</i> , 11:3 ANNALS OF NEUROLOGY, 317-19 (1982)
1015	M.B. Bornstein et al., <i>Clinical Trial of Copolymer I in Multiple Sclerosis</i> , 436 ANNALS NEW YORK ACADEMY OF SCIENCES, 366-372 (1984)
1016	M.B. Bornstein et al., <i>A Pilot Trial of COP 1 in Exacerbating-Relapsing Multiple Sclerosis</i> , 317:7 THE NEW ENGLAND JOURNAL OF MEDICINE, 408-14 (1987)
1017	FDA, GUIDELINE FOR INDUSTRY: Dose-Response Information to Support Drug Registration (1994)
1018	K.P. Johnson, et al., <i>Copolymer 1 reduces relapse rate and improves disability in relapsing-relapsing multiple sclerosis</i> , 43 NEUROLOGY, 1268-1276 (1995)
1019	Affidavit of Marlene S. Bobka dated January 5, 2015
1019A	1996 FDA Meeting Agenda minutes from the Peripheral and Central Nervous System Drug Advisory Committee (dated September 19, 1996) (Exhibit A to Exhibit 1019)
1020	Ruth Arnon, <i>The development of Cop 1 (Copaxone<sup>®</sup>), an innovative drug for the treatment of multiple sclerosis: personal reflections</i> , 50 IMMUNOLOGY LETTERS 1-15 (1996)

<b>Exhibit No.</b>	<b>Description</b>
1021	Leslie Z. Benet et al., <i>Pharmacokinetics: The Dynamics of Drug Absorption, Distribution, and Elimination</i> , in THE PHARMACOLOGICAL BASIS OF THERAPEUTICS, 3 (Alfred Goodman Gilman ed. 1996)
1022	E. Lobel, et al., <i>Copolymer-1</i> , 21(2) DRUGS OF THE FUTURE, 131-134 (1996)
1023	Haines et al., <i>Linkage of the MHC to familial multiple sclerosis suggests genetic heterogeneity. The multiple sclerosis genetics group</i> , HUM. MOL. GENET. 7:1229-34 (Aug 1998)
1024	U.S. Patent No. 6,342,476, <i>Copolymer-1 Improvements in Compositions of Copolymers</i> (2002).
1025	Y. Ge et al., <i>Glatiramer acetate (Copaxone) treatment in relapsing-remitting MS: Quantitative MR assessment</i> , 54 NEUROLOGY, 813-17 (2000)
1026	Giancarlo Comi et al., <i>European/Canadian multicenter, double-blind, randomized, placebo-controlled study of the effects of glatiramer acetate on magnetic resonance imaging-measured disease activity and burden in patients with relapsing multiple sclerosis: European/Canadian Glatiramer Acetate Study Group</i> , 49:3 ANN. NEUROL., 290-97 (2001)
1027	Boissel and Nony, <i>Using pharmacokinetic-pharmacodynamic relationships to predict the effect of poor compliance</i> , CLIN. PHARMACOL. 41:1-6 (2002)
1028	McBride, INT'L J. MS CARE 4:85 (2002)
1029	Dene Simpson, <i>Adis Drug Evaluation Glatiramer Acetate – A Review of its use in Relapsing-Remitting Multiple Sclerosis</i> , 16:12 CNS DRUGS, 825-50, 834 (2002)
1030	Catherine M. Edgar, et al., <i>Lipoatrophy in Patients with Multiple Sclerosis on Glatiramer Acetate</i> , 31 CAN. J. NEUROL. SCI., 58-63 (2004)

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1031	Rich et al., <i>Stepped-care approach to treating MS: A managed care treatment algorithm</i> , J. MANAGED CARE PHARM. 10:S26-S32 (June 2004)
1032	Stuart, <i>Clinical management of multiple sclerosis: The treatment paradigm and issues of patient management</i> , J. MANAGED CARE PHARMACY 10:S19-S25 (June 2004)
1033	Rohit Bakshi et al., <i>Imaging of Multiple Sclerosis: Role in Neurotherapeutics</i> , 2(2) NEURORX, 277–303 (2005)
1034	Paul Beringer et al., <i>Clinical Pharmacokinetics and Pharmacodynamics</i> , in REMINGTON: THE SCIENCE AND PRACTICE OF PHARMACY, 1191-1205, 1197, 1201 (Paul Beringer ed., 2005)
1035	Michael Franklin et al., <i>Drug Absorption, Action, and Disposition</i> , in REMINGTON: THE SCIENCE AND PRACTICE OF PHARMACY, 1142-1170, 1167 (Paul Beringer ed., 2005)
1036	James Rasmussen: International Patent Publication No. WO 2005/120542 A2 (published December 22, 2005)
1037	Devonshire et al., <i>The Global Adherence Project – A multicentre observational study on adherence to disease-modifying therapies in patients suffering from relapsing-remitting multiple sclerosis</i> , MULTIPLE SCLEROSIS 12:S1 (P316) (2006)
1038	C.C. Ford et al., <i>A prospective open-label study of glatiramer acetate: over a decade of continuous use in multiple sclerosis patients</i> , 12 MULTIPLE SCLEROSIS, 309-320 (2006)
1039	Frohman, <i>Multiple Sclerosis – The Plaque and its Pathogenesis</i> , NEW ENGLAND J. MED. 354:942-55 (2006)
1040	J.J. Kragt et al., <i>How similar are commonly combined criteria for EDSS progression in multiple sclerosis?</i> , 12(6) MULTIPLE SCLEROSIS 782-786 (2006)

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