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Paper No. ___

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

COALITION FOR AFFORDABLE DRUGS V LLC;
HAYMAN CREDES MASTER FUND, L.P.;
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HAYMAN CAPITAL MASTER FUND, L.P.;
HAYMAN CAPITAL MANAGEMENT FUND, L.P.;
HAYMAN OFFSHORE MANAGEMENT, INC.;
HAYMAN INVESTMENTS, LLC;
NXN PARTNERS, LLC;
IP NAVIGATION GROUP, LLC;
J KYLE BASS, and ERICH SPANGENBERG,
Petitioners,
v.
BIOGEN MA INC.,
Patent Owner.

Case IPR2015-01993
Patent 8,399,514 B2

PETITIONER'S EXHIBIT LIST AS OF 28 SEPTEMBER 2016

EXHIBIT	DESCRIPTION
1001	U.S. Patent 8,399,514, "Treatment for Multiple Sclerosis," issued to Lukashev et al. (the '514 patent).
1002	Wakkee M. et al., "Drug evaluation: BG-12, an immunomodulatory dimethylfumarate," Curr. Opin. Investig. Drugs, 2007 Nov; 8(11):955-62.
1003A	Kappos et al., "Efficacy of a novel single-agent fumarate, BG00012, in patients with relapsing-remitting multiple sclerosis: results of a phase 2 study," J. Neurol. (2006) 253 [Supp 2]: II/I-II/170; p. II/27 O108.
1004	International Conference on Harmonization of Technical Requirements for Registration of Pharmaceuticals for Human Use, ICH Harmonized Tripartite Guideline, Dose-Response Information to Support Drug Registration E4, Current Step 4 version, dated 10 March 1994.
1005	Declaration of Steven E. Linberg, Ph.D.
1006	European Medicines Agency, Assessment Report, Tecfidera, 26 November 2013.
1007	"Preliminary Amendment Under 37 C.F.R. § 1.115, In re application of: LUKASHEV et al.," Application No. 13/372,426 that issued as U.S. Patent 8,399,514.
1008	"Amendment and Reply Under 37 C.F.R. § 1.111, In re application of: LUKASHEV et al., Application No. 13/372,426" that issued as U.S. Patent 8,399,514.
1009	Office Action with mail date of 05/03/2012 for Application No. 13/372,426 that issued as U.S. Patent 8,399,514.
1010	Paper 178, Interference 106,023.

1011	PCT Application No. PCT/US2008/001602.
1012	Certified copy of U.S. Provisional Application No. 60/888,921.
1013	Assignment Record for U.S. Patent 8,399,514 from USPTO's Assignments on the Web.
1014	Paper 179, Interference 106,023.
1015	Reserved.
1016	D. Werdenberg, et al., "Presystemic Metabolism and Intestinal Absorption of Antipsoriatic Fumaric Acid Esters," 2003, BIOPHARMACEUTICALS & DRUG DISPOSITION, Biopharm. Drug Dispos. 24:259-273 (2003), Published online in Wiley InterScience (www.interscience.wiley.com). DOI: 10.1002/bdd.364.
1017	CV of Steven E. Linberg, Ph.D.
1018	U.S. Application 13/372,426, filed on February 13, 2012.
1019	Nieboer et al., "Fumaric Acid Therapy in Psoriasis: A Double-Blind Comparison between Fumaric Acid Compound Therapy and Monotherapy with Dimethylfumaric Acid Ester," Dermatologica 1990; 181:33-37.
1020	Declaration of Scott Bennett.
1021	Reserved.
1022	"View of NCT00168701 on 2005_09_14," from URL https://clinicaltrials.gov/archive/NCT00168701/2005_09_14 .
1023	Reserved.
1024	Declaration of Robert Mihail.
1025	Reserved.

1026	Reserved.
1027	Begleiter et al., "Dietary induction of NQO1 increases the antitumour activity of mitomycin C in human colon tumours in vivo," 2004, British Journal of Cancer, 1624-1631.
1028	Reserved.
1029	Hartung et al., "The cost of multiple sclerosis drugs in the US and the pharmaceutical industry," American Academy of Neurology, 2015.
1030	U.S. Patent 7,320,999, "Dimethyl Fumarate For The Treatment of Multiple Sclerosis," issued to Joshi et al.
1031	U.S. Application 2003/0018072 to Joshi et al.
1032	Reserved.
1033	Reserved.
1034	Reserved.
1035	IPR2015-01136, Paper 23, Decision Denying Institution of <i>Inter Partes</i> Review.
1036	U.S. Patent 6,436,992, "Use of Fumaric Acid Derivatives," issued to Joshi et al.
1037	Reserved.
1038	Reserved.
1039	Reserved.
1040	Current view of ClinicalTrials NCT00168701 on URL https://clinicaltrials.gov/show/NCT00168701 .

1041	History of Changes and the ClinicalTrials.gov Archive Site on URL https://clinicaltrials.gov/ct2/archive/NCT00168701 .
1042	History of ClinicalTrials NCT00168701 on URL https://clinicaltrials.gov/archive/NCT00168701 .
1043	ClinicalTrials.gov Background on URL https://www.clinicaltrials.gov/ct2/about%ADsite/background .
1044	Hendricks, Steve, "The Rise of Bib Generic: Why Knockoff Prescriptions Now Cost \$1,200," 08/08/2015, on URL http://www.truth-out.org/news/item/32182-the-rise-of-big-generic-why-knockoff-prescriptions-now-cost-1-200 .
1045	Declaration of Samuel J. Pleasure, M.D., Ph.D.
1046	CV of Samuel J. Pleasure, M.D., Ph.D.
1047	Hauser et al., "Multiple Sclerosis and Other Demyelinating Diseases," Chapter 359 in HARRISON'S PRINCIPLES OF INTERNAL MEDICINE, 16 th ed. (2005), pp. 2461-2471.
1048	Friese et al., "The value of animal models for drug development in multiple sclerosis," Brain (2006); 129:1940-1952.
1049	Sriram et al., "Experimental Allergic Encephalomyelitis: A Misleading Model of Multiple Sclerosis," Ann. Neurol. (2005); 58:939-945.
1050	Daniel Wynn, M.D., FACNS FAASM, deposition transcript.
1051	Reserved.
1052	Gilmore O'Neill, M.D., deposition transcript.
1053	Richard A. Rudick, M.D., deposition transcript.
1054	Tammy Sarnelli deposition transcript.

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