

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

SAWAI USA, INC. AND
SAWAI PHARMACEUTICAL CO., LTD.
Petitioners,

v.

BIOGEN MA, INC.
Patent Owner.

Patent No. 8,399,514

Inter Partes Review IPR2019-00789

PETITIONERS' EXHIBIT LIST AS OF MAY 6, 2019

EXHIBIT NO.	DESCRIPTION
1001	U.S. Patent No. 8,399,514, <i>Treatment for Multiple Sclerosis</i> (filed Feb. 13, 2012) (issued Mar. 19, 2013)
1002	Declaration of John R. Corboy, M.D.
1003	Declaration of Leslie Benet, Ph.D.
1004	Declaration of Ian McKeague, Ph.D.
1005	Biogen News Release, <i>Phase II Study of Oral Compound BG-12 Meets Primary Endpoint in Multiple Sclerosis</i> (Jan. 9, 2006)
1006	S. Schimrigk et al., <i>A Prospective, Open-Label, Phase II Study of Oral Fumarate Therapy for the Treatment of Relapsing-Remitting Multiple Sclerosis</i> , 10 (Suppl. 2) MULTIPLE SCLEROSIS CLIN. & LAB. RES. S258, Abstract P642 (2004)
1007	L. Kappos et al., <i>Efficacy of a Novel Oral Single-Agent Fumarate, BG00012, in Patients with Relapsing-Remitting Multiple Sclerosis: Results of a Phase 2 Study</i> , 253 (Suppl. 2) J. NEUROL. II27, O108 (2006)
1008	International Publication No. WO 2006/0037342 A2 (published Apr. 13, 2006)
1009	U.S. Patent No. 7,320,999, <i>Dimethyl Fumarate for the Treatment of Multiple Sclerosis</i> (filed July 17, 2002) (issued Jan. 22, 2008)
1010	NCT00168701, CLINICALTRIALS.GOV, https://clinicaltrials.gov/archive/NCT00168701/2005_09_14
1011	ICH HARMOISED TRIPARITE GUIDELINE – DOSE-RESPONSE INFORMATION TO SUPPORT DRUG REGISTRATION E4 (Mar. 10, 1994)

EXHIBIT NO.	DESCRIPTION
1012	S. Schimrigk et al., <i>A Prospective, Open-Label, Phase II Study of Oral Fumarate Therapy for the Treatment of Relapsing-Remitting Multiple Sclerosis</i> (2004), available at http://web.archive.org/web/20041021033354/http://www.fumapharm.ch:80/pdf/BG-12_Schimrigk_Poster_Final.pdf (“Schimrigk 2004 Poster”)
1013	N. Brune et al., <i>Oral Fumarate Therapy Alters Cytokine Production in Patients with Relapsing-Remitting Multiple Sclerosis</i> , 10 (suppl. 2) <i>MULTIPLE SCLEROSIS CLIN & LAB. RES.</i> S259, ABSTRACT P643 (2004)
1014	S. Schimrigk et al., <i>An Open-Label, Prospective Study of Oral Fumaric Acid Therapy for the Treatment Relapsing-Remitting Multiple Sclerosis (RRMS)</i> , 64(6)(Suppl. 1) <i>NEUROLOGY</i> A392, S46.003 (2005)
1015	L. Kappos et al., <i>A Randomised, Placebo-controlled Phase II Trial of a Novel Oral Single-Agent Fumarate Therapy, BG0012, in Patients with Relapsing-Remitting Multiple Sclerosis</i> , 252 (Suppl. 2) <i>J. NEUROL.</i> II/148, P574 (2005)
1016	Biogen News Release, <i>Oral Compound BG-12 Achieves Primary Endpoint in Phase II Study of Relapsing-Remitting Multiple Sclerosis; Treatment with BG-12 Led to Statistically Significant Reductions in MRI Measures</i> (May 30, 2006)
1017	C. Nieboer et al., <i>Fumaric Acid Therapy in Psoriasis: A Double-Blind Comparison between Fumaric Acid Compound Therapy and Monotherapy with Dimethylfumaric Acid Ester</i> , 181 <i>DERMATOLOGICA</i> 33 (1990)
1018	S. Schimrigk et al., <i>Oral Fumaric Acid Esters for the Treatment of Active Multiple Sclerosis: An Open-Label, Baseline-Controlled Pilot Study</i> , 13 <i>EUR. J. NEUOL.</i> 604 (2006)

EXHIBIT NO.	DESCRIPTION
1019	U. Mrowietz et al., <i>Dimethylfumarate for Psoriasis: More than a Dietary Curiosity</i> , 11(1) TRENDS MOL. MED. 43 (2005)
1020	Fumaderm® prescribing information
1021	H.M. Ockenfels et al., <i>The Antipsoriatic Agent Dimethylfumarate Immunomodulates T-Cell Cytokine Secretion and Inhibits Cytokines of the Psoriatic Cytokine Network</i> , 139 BR. J. DERM. 390 (1998)
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1023	R. de Jong et al., <i>Selective Stimulation of T Helper 2 Cytokine Responses by the Anti-Psoriasis Agent Monomethylfumarate</i> , 26 EUR. J. IMMUNOL. 2067 (1996)
1024	P. Nibbering et al., <i>Effects of Monomethylfumarate on Human Granulocytes</i> , 101 J. INVEST. DERMATOL. 37 (1993)
1025	U.S. Patent No. 6,509,376, <i>Utilization of Dialkylfumarates</i> (filed Oct. 29, 1999) (issued Jan 21, 2003)
1026	Biogen News Release, <i>BG-12 Psoriasis Study Meets Primary Endpoint; Oral Compound Also Being Studied for MS in Phase II Trial</i> (Apr. 7, 2005)
1027	A.D. Ormerod et al., <i>Fumaric Acid Esters, Their Place in the Treatment of Psoriasis</i> , 150 Br. J. Dermatol. 630 (2004)
1028	U. Mrowietz et al., <i>Treatment of Psoriasis with Fumaric Acid Esters: Results of a Prospective Multicentre Study</i> , 138(3) BR. J. DERMATOL. 456 (1998)
1029	W. Nugteren-Huying et al., <i>Fumaric Acid Therapy for Psoriasis: A Randomized, Double-Blind, Placebo-Controlled Study</i> , 22(2) J. AM. ACAD. DERMATOL. 311 (1990)

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1030	P. Altmeyer et al., <i>Antipsoriatic Effect of Fumaric Acid Derivatives: Results of a Multicenter Double-Blind Study in 100 Patients</i> , 30 J. AM. ACAD. DERMATOL. 977 (1994)
1031	C. Nieboer et al., <i>Systemic Therapy with Fumaric Acid Derivatives: New Possibilities in the Treatment of Psoriasis</i> , 20 J. AM. ACAD. DERM. 601 (1989)
1032	N. Brune et al., <i>Detection of Altered Intracellular TH₁- and TH₂-Type Cytokine Production of Peripheral Blood Mononuclear cells (PBMCs) in Patients with Relapsing-Remitting Multiple Sclerosis (RRMS) Undergoing an Oral Fumaric-Acid Ester Therapy</i> , 4(4) MULTIPLE SCLEROSIS: CLINICAL AND LABORATORY RESEARCH P3038 (1998) (ECTRIMS 98:14th Congress of the European Committee for Treatment and Research in Multiple Sclerosis, Sept. 9-12, 1998, Stockholm, Sweden)
1033	S. Schimrigk et al., <i>Oral Fumaric Acid Ester (FAE) in Relapsing-Remitting Multiple Sclerosis (RRMS). A Short Term, Open, clinical, Immunological and Magnetic Resonance Imaging (MRI) Controlled Phase II Trial</i> , 246 (Suppl. 1) J. NEUROL. I/36, 144 (1999) (Ninth Meeting of the European Neurological Society, June 5-9, 1999, Milan, Italy)
1034	L. Kappos et al., <i>A Randomized, Placebo-Controlled Phase 2 Trial of a Novel Oral Fumarate, BG00012, in Patients with Relapsing-Remitting Multiple Sclerosis</i> (15th Meeting of the European Neurological Society, June 18-22, 2005), and Declaration of Gilmore O'Neill, M.D.
1035	A. Wierinckx et al., <i>Detoxication Enzyme Inducers Modify Cytokine Production in Rat Mixed Glial Cells</i> , 166 J. NEUROIMMUNOL. 132 (2005)
1036	R. Fox et al., <i>Dimethyl Fumarate to Treat Multiple Sclerosis</i> , in MULTIPLE SCLEROSIS THERAPEUTICS 387 (Jeffrey A. Cohen et al. eds., 4th ed. 2011)

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