

Filed: February 28, 2024

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

TWI PHARMACEUTICALS INC.,

Petitioner,

v.

MERCK SERONO SA,

Patent Owner.

IPR2023-00049 (Patent 7,713,947 B2)

IPR2023-00050 (Patent 8,377,903 B2)¹

Before ULRIKE W. JENKS, ZHENYU YANG and TINA HULSE,
Administrative Patent Judges.

JENKS, *Administrative Patent Judge.*

**PETITIONER'S UNOPPOSED MOTION FOR *PRO HAC VICE*
ADMISSION OF DON J. MIZERK UNDER 37 C.F.R. 42.10(c)**

¹ The identical paper is filed in each proceeding identified in the caption.

EXHIBIT LIST

EXHIBIT	DESCRIPTION	SHORT FORM
Ex. 1001	US 7,713,947 B2.	'947 Patent
Ex. 1002	US 8,377,903 B2.	'903 Patent
Ex. 1003	File History for Ser. No. 11/722,018, which issued as the '947 patent.	'018 File Wrapper
Ex. 1004	File History Ser. No. 12/766,173, which issued as the '903 patent.	'173 File Wrapper
Ex. 1005	Declaration of Dr. Benjamin M. Greenberg, M.D.	Greenberg Decl.
Ex. 1006	<i>Curriculum Vitae</i> of Dr. Benjamin M. Greenberg, M.D.	Greenberg CV
Ex. 1007	WO 2004/087101 A2.	Bodor 'WO 101
Ex. 1008	Rice, George P.A., Massimo Filippi, and Giancarlo Comi. "Cladribine and progressive MS: clinical and MRI outcomes of a multicenter controlled trial." <i>Neurology</i> Vol. 54, no. 5 (2000) pp. 1145–1155.	Rice 2000 or Rice
Ex. 1009	Liliemark, Jan. "The clinical pharmacokinetics of cladribine." <i>Clinical pharmacokinetics</i> Vol. 32, no. 2 (1997) pp. 120–131.	Liliemark 1997
Ex. 1010	<i>Merck KGaA et al v. Accord Healthcare, Inc. et al 1-22-cv-00974 (DDE) Complaint.</i>	Merck Complaint
Ex. 1011	EMD Serano Inc., Mavenclad® (Cladribine) Package Insert, Mar. 2019	Mavenclad Package Insert
Ex. 1012	Lublin FD, Reingold SC. Defining the clinical course of multiple sclerosis: results of an international survey. <i>Neurology</i> 1996;46:907–911.	Lublin 1996
Ex. 1013	National Multiple Sclerosis Society, <i>What is MS, Types of MS</i> , https://www.nationalmssociety.org/What-is-MS/Types-of-MS , retrieved Sept. 20, 2022.	
Ex. 1014	National Multiple Sclerosis Society, <i>What is MS, Types of MS, Secondary Progressive MS</i> , https://www.nationalmssociety.org/What-is-	

EXHIBIT	DESCRIPTION	SHORT FORM
	MS/Types-of-MS/Secondary-progressive-MS.	
Ex. 1015	Casanova, B., et al. "High clinical inflammatory activity prior to the development of secondary progression: a prospective 5-year follow-up study," <i>Multiple Sclerosis Journal</i> , Feb. 2002, pp. 59-63, vol. 8.	Casanova 2002
Ex. 1016	Romine, J. et al. "A Double-Blind, Placebo-Controlled, Randomized Trial of Cladribine in Relapsing-Remitting Multiple Sclerosis," <i>Proceedings of the Association of American Physicians</i> , Jan./Feb. 1999, pp. 35-44, vol. 111, No. 1.	Romine 1999
Ex. 1017	Immunex Corporation, Novantrone [®] (Moxantrone) Package Insert, Oct. 13, 2000 ("Novantrone [®] Package Insert").	Novantrone Package Insert
Ex. 1018	Langtry, H. et al. "Cladribine: A Review of its Use in Multiple Sclerosis," <i>Biodrugs</i> , May 1998, pp. 419-433, vol. 9, No. 3.	Langtry 1998
Ex. 1019	Biogen Idec Inc., Tysabri [®] (natalizumab) Package Insert, Nov. 2004.	Tysabri Package Insert
Ex. 1020	Chiron Corporation, Betaseron [®] (Interferon beta- 1b) Package Insert, 1993.	Betaseron Package Insert
Ex. 1021	Biogen, Inc., Avonex [™] (Interferon Beta-1a) Package Insert, Nov. 1996.	Avonex Package Insert
Ex. 1022	Teva Pharms USA, Copaxone [®] (glatiramer acetate for injection) Package Insert, 2001.	Copaxone Package Insert
Ex. 1023	Serano, Inc., Rebif [®] (Interferon Beta-1a) Package Insert, May 2003.	Rebif Package Insert
Ex. 1024	Cursiefen, Simone, <i>et al.</i> "Escalating immunotherapy with mitoxantrone in patients with very active relapsing-remitting or progressive multiple sclerosis," <i>European neurology</i> , Apr. 2000, pp. 186-187, vol. 43, No. 3.	Cursiefen 2000
Ex. 1025	Burt, Richard K., <i>et al.</i> "Treatment of autoimmune disease by intense immunosuppressive conditioning and autologous hematopoietic stem cell transplantation," <i>Blood, The Journal of the American Society of Hematology</i> , Nov. 1998, pp. 3505-3514, vol. 92, No. 10.	Burt 1998

EXHIBIT	DESCRIPTION	SHORT FORM
Ex. 1026	Tortorella, Carla, <i>et al.</i> “Cladribine. Ortho Biotech Inc.” <i>Current Opinion in Investigational Drugs</i> , Dec. 2001, pp. 1751–1756, vol. 2, no. 12.	Tortorella 2001
Ex. 1027	Beutler, E. <i>et al.</i> “The treatment of chronic progressive multiple sclerosis with cladribine,” <i>Proc. Natl. Acad. Sci. USA</i> , Feb. 1996, pp. 1716–1720, vol. 93.	Beutler 1996
Ex. 1028	Coles, Alasdair, <i>et al.</i> “Campath-1H treatment of multiple sclerosis: lessons from the bedside for the bench,” <i>Clinical neurology and neurosurgery</i> , June 2004, pp. 270–274, vol. 106, no. 3.	Coles 2004
Ex. 1029	U.S. Patent No. 7,888,328	Bodor '328
Ex. 1030	Center for Disease Control, Office of Enterprise Communication, Press Release, Oct. 27, 2004, https://www.cdc.gov/media/pressrel/r041027.htm .	CDC Press Release
Ex. 1031	Selby, R. <i>et al.</i> “Safety and Tolerability of Subcutaneous Cladribine Therapy in Progressive Multiple Sclerosis,” <i>Can. J. Neurol. Sci.</i> , 1998, pp. 295-299, vol. 25.	Selby 1998
Ex. 1032	Docket Navigator Printout of Case Activity for <i>Merck KGaA et al v. Accord Healthcare, Inc. et al</i>	
Ex. 1033	Food and Drug Administration, <i>Orange Book: Approved Drug Products with Therapeutic Equivalence Evaluations, Patent and Exclusivity for: N022561</i> , https://www.accessdata.fda.gov/scripts/cder/ob/patent_info.cfm?Product_No=001&Appl_No=022561&Appl_type=N , retrieved Oct. 5, 2022.	
Ex. 1034	<i>Merck KGaA et al v. Accord Healthcare, Inc. et al</i> 1-22-cv-00974 (DDE) Answer.	Accord Complaint
Ex. 1035	Declaration of A. Lauren Hitchens (<i>exhibit not filed</i>)	
Ex. 1036	Declaration of Don J. Mizerk	

Pursuant to 37 C.F.R. § 42.10(c), Petitioner TWi Pharmaceuticals Inc. (“Petitioner”) respectfully requests that the Patent Trial and Appeal Board admit Don J. Mizerk *pro hac vice* in this proceeding. Petitioner has conferred with Patent Owner Merck Serono SA (“Patent Owner”) and Patent Owner does not object to Petitioner’s request.

STATEMENT OF FACTS

In accordance with 37 C.F.R. § 42.10(c),

[t]he Board may recognize counsel *pro hac vice* during a proceeding upon a showing of good cause, subject to the condition that lead counsel be a registered practitioner and to any other conditions as the Board may impose. For example, where the lead counsel is a registered practitioner, a motion to appear *pro hac vice* by counsel who is not a registered practitioner may be granted upon showing that counsel is an experienced litigating attorney and has an established familiarity with the subject matter at issue in the proceeding.

Good cause exists for the Board to recognize Don J. Mizerk *pro hac vice* in this proceeding. Petitioner’s lead counsel in this proceeding, Philip D. Segrest, Jr., is a registered patent practitioner (Reg. No. 39,021). Accompanying the instant motion is the Declaration of Don J. Mizerk (Ex. 1036) attesting to the information required by “Order – Authorizing Motion for *Pro Hac Vice* Admission” in *Unified Patents, Inc. v. Parallel Iron, LLC*, Case No. IPR2013-00639, Paper No. 7 (October 15, 2013). Mr. Mizerk is an experienced litigation attorney (Ex. 1036 at ¶¶ 1-3),

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