UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

HOPEWELL PHARMA VENTURES, INC.,
Petitioner,

v.

MERCK SERONO SA,
Patent Owner.

Case IPR2023-00481
U.S. Patent No. 8,377,903

PATENT OWNER'S MOTION FOR ADMISSION *PRO HAC VICE* OF DAVID MLAVER

I. Statement of Precise Relief Requested

Pursuant to 37 C.F.R. § 42.10(c) and Paper No. 7 authorizing the parties to file motions for *pro hac vice* admissions under 37 C.F.R. § 42.10(c), Patent Owner Merck Serono SA requests that the Patent Trial and Appeal Board (the "Board") admit David Mlaver *pro hac vice* in this proceeding, IPR2023-00481. The parties have met and conferred, and Petitioner does not oppose this motion.

II. Statement of Facts Showing Good Cause for the Board to Recognize Counsel *Pro Hac Vice* During the Proceeding

In accordance with 37 C.F.R. § 42.10(c), the 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. Section 42.10(c) indicates that "where 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 a showing that counsel is an experienced litigating attorney and has an established familiarity with the subject matter at issue in the proceeding." The facts here establish good cause for the Board to recognize Mr. Mlaver *pro hac vice* in this proceeding.

Lead counsel, Emily R. Whelan, is a registered practitioner. Backup

counsel, Deric Geng and Cindy Kan, are also registered practitioners. Mr. Mlaver is an experienced litigator and has established familiarity with the subject matter at issue in the proceeding. Accompanying this motion as Exhibit 2075 is the February 7, 2024, Declaration of David Mlaver in Support of this Motion for Admission *Pro Hac Vice* ("Mlaver Decl."). In his declaration, Mr. Mlaver asserts: "I am a member in good standing of the Bars of the District of Columbia, Maryland, and Massachusetts." Mlaver Decl. ¶ 2 (Ex. 2075).

Mr. Mlaver demonstrates that he has a detailed working knowledge of the relevant subject matter through his participation in the *inter partes review* matters challenging U.S. Patent No. 8,377,903 and U.S. Patent No. 7,713,947 and in consolidated district court litigations. *Id*. ¶ 10 (Ex. 2075). Mr. Mlaver also has significant experience with litigation involving pharmaceuticals, methods of treatment, and small molecule therapeutics. *Id*. ¶ 11 (Ex. 2075)

In his declaration, Mr. Mlaver also attests to each of the listed items required by the "Order – Authorizing Motion for *Pro Hac Vice* Admission" in Case IPR2013-00639, Paper 7. *See* Mlaver Decl. ¶¶ 1-12 (Ex. 2075). Mr. Mlaver attests that he has read and will comply with the Office Patent Trial

Practice Guide and the Board's Rules of Practice for Trials set forth in 37 C.F.R. § 42. *See id*. ¶ 7 (Ex. 2075). Mr. Mlaver further attests that he agrees to be subject to the United States Patent and Trademark Office's Rules of Professional Conduct as set forth in 37 C.F.R. §§ 11.101 *et seq.* and disciplinary jurisdiction under 37 C.F.R. § 11.19(a). *See id*. ¶ 8 (Ex. 2075).

III. Conclusion

For the foregoing reasons, Patent Owner respectfully requests that the Board admit Mr. Mlaver *pro hac vice* in this proceeding. The undersigned authorizes the Office to charge $250 to Deposit Account No.08-0219 for the fees set forth in 37 C.F.R. § 42.15(e) for this *pro hac vi*ce motion. Please charge any shortage of fees or credit any overpayments to the above Deposit Account.

Dated: February 9, 2024

Respectfully Submitted,

/Emily R. Whelan/
Emily R. Whelan, Reg. No. 50,391
Counsel for Patent Owner

PATENT OWNER'S UPDATED EXHIBIT LIST

Exhibit No.	Description
2001	MAVENCLAD® (cladribine) Package Insert (2022)
2002	Declaration of David B. Bassett in Support of Motion for Admission *Pro Hac Vice*
2003	Declaration of Vinita Ferrera in Support of Motion for Admission *Pro Hac Vice*
2004	H. El-Moslimany et al., *Escape Therapies and Management of Multiple Sclerosis* in C. S. Raine MULTIPLE SCLEROSIS A COMPREHENSIVE TEXT 333 (2008) (Excerpt)
2005	A. E. Miller et al., *Treatment Issues* in R. C. Kalb MULTIPLE SCLEROSIS: THE QUESTION YOU HAVE – THE ANSWERS YOU NEED 43 (2d ed. 2000) (Excerpt)
2006	M. J. Tullman et al., *Immunotherapy of Multiple Sclerosis – Current Practice and Future Directions*, 39 J. REHAB. RES. DEV. 273 (2002)
2007	Video: A. Miller, *What You Need to Know About Mavenclad®* (https://www.nationalmssociety.org/Treating-MS/Medications/Mavenclad) (2019); image of USB Drive containing video
2008	Transcript of Video, A. Miller, *What You Need to Know About Mavenclad®* (2019)
2009	Deposition Transcript of Dr. Aaron Miller (December 12, 2023)
2010	J. E. Joy et al., Multiple Sclerosis: Current Status and Strategies for the Future, 17 (2001) (Excerpt)

Exhibit No.	Description
2011	F. Lublin, *History of Modern Multiple Sclerosis Therapy*, 252 (SUPPL 3) J. NEUROL. III/3 (2005)
2012	*Reserved*
2013	D. S. Goodin et al., *Disease Modifying Therapies in Multiple Sclerosis*, 58 NEUROLOGY 169 (2002)
2014	Betaseron® (Interferon beta-1b) Package Insert (1993)
2015	Avonex™ (Interferon beta-1a) Package Insert (1996)
2016	Rebif® (Interferon beta-1a) Package Insert (2003)
2017	Copaxone® (glatiramer acetate) Package Insert (2001)
2018	Novantrone® (mitoxantrone) Package Insert (2000)
2019	Tysabri® (natalizumab) Package Insert (2004)
2020	R. A. Rudick et al., *Natalizumab: α_4-Integrin Antagonist Selective Adhesion Molecule Inhibitors for MS*, 4 EXPERT REV. NEUROTHER. 571 (2004)
2021	R. A. Rudick et al., *Natalizumab plus Interferon Beta-1a for Relapsing Multiple Sclerosis*, 354 NEW ENG. J. MED. 911 (2006)
2022	*Reserved*
2023	*Reserved*
2024	L. Durelli, *Dose and Frequency of Interferon Treatment Matter*, 250 J. NEUROL. (SUPPL 4) IV/9 (2003)

Exhibit No.	Description
2025	D. S. Alberts et al., *Disposition of Mitoxantrone in Cancer Patients*, 45 CANCER RES. 1879 (1985)
2026	M. Caporro et al., *Two Decades of Subcutaneous Glatiramer Acetate Injection: Current Role of the Standard Dose, and New High-Dose Low-Frequency Glatiramer Acetate in Relapsing-Remitting Multiple Sclerosis Treatment*, 8 PATIENT PREFER. ADHERENCE 1123 (2014)
2027	*Reserved*
2028	*Reserved*
2029	U.S. Patent No. 8,785,415
2030	J. C. Sipe et al., *Development of Cladribine Treatment in Multiple Sclerosis*, 1 MULT. SCLER. 343 (1996)
2031	J. Noseworthy et al., *Disease-Modifying Treatments in Multiple Sclerosis* in A. Compston MCALPINE'S MULTIPLE SCLEROSIS 729 (4th ed. 2005) (Excerpt)
2032	K. Rammohan et al., *The Development of Cladribine Tablets for the Treatment of Multiple Sclerosis: A Comprehensive Review*, 80 DRUGS 1901 (2020)
2033	G. Giovannoni et al., *A Placebo-Controlled Trial of Oral Cladribine for Relapsing Multiple Sclerosis*, 362 NEW ENG. J. MED. 416 (2010)
2034	G. Giovannoni et al., Supplementary Appendix to *A Placebo-Controlled Trial of Oral Cladribine for Relapsing Multiple Sclerosis*, 362 NEW ENG. J. MED. 416 (2010)

Exhibit No.	Description
2035	G. Giovannoni et al., *Safety and Efficacy of Cladribine Tablets in Patients with Relapsing-Remitting Multiple Sclerosis: Results from the Randomized Extension Trial of the CLARITY Study*, 24 MULT. SCLER. J. 1594 (2018)
2036	G. Giovannoni et al., *Long-Term Follow-Up of Patients with Relapsing Multiple Sclerosis from the CLARITY/CLARITY Extension Cohort of CLASSIC-MS: An Ambispective Study*, 29 MULT. SCLER. J. 719 (2023)
2037	A. Miller et al., *Current and Investigational Therapies Used to Alter the Course of Disease in Multiple Sclerosis*, 90 SOUTH. MED. J. 367 (1997)
2038	*Merck Receives Complete Response Letter From FDA on Cladribine Tablets New Drug Application*, FIERCEBIOTECH.COM (March 2, 2011) (https://www.fiercebiotech.com/biotech/merck-receives-complete-response-letter-from-fda-on-cladribine-tablets-new-drug-application), accessed on December 20, 2023
2039	*Reserved*
2040	FDA News Release: *FDA Approves New Oral Treatment For Multiple Sclerosis* (March 29, 2019) (https://www.fda.gov/news-events/press-announcements/fda-approves-new-oral-treatment-multiple-sclerosis), accessed on November 25, 2023
2041	ClinicalTrials.gov publication and Record History, NCT00213135 *A Safety and Efficacy Study of Oral Cladribine in Subjects With Relapsing-Remitting Multiple Sclerosis (RRMS) (CLARITY)* (2014) (https://clinicaltrials.gov/study/NCT00213135; https://clinicaltrials.gov/study/NCT00213135?tab=history&a=13), accessed on November 25, 2023

Exhibit No.	Description
2042	M. Hoffman, K. Rammohan Interview: *Short-Term Dosing Regimen Gives Cladribine an Advantage in MS*, NEUROLOGYLIVE (July 1, 2020) (https://www.neurologylive.com/view/shortcommitment-dosing-regimen-gives-cladribine-an-advantage-in-ms), accessed on November 10, 2023
2043	J. Liliemark et al., *On the Bioavailability of Oral and Subcutaneous 2-Chloro-2'-Deoxydenosine in Humans: Alternative Routes of Administration*, 10 J. CLIN. ONCOL. 1514 (1992)
2044	U.S. Provisional Patent Application No. 60/458,922
2045	U.S. Provisional Patent Application No. 60/484,756
2046	U.S. Provisional Patent Application No. 60/541,247
2047	U.S. Patent No. 8,785,415 File History, Response to Rule 312 Communication Post Allowance, filed on June 12, 2014
2048	The 2002 Product Development and License Agreement between IVAX International GMBH and Ares Trading S.A. (PROTECTIVE ORDER MATERIAL)
2049	December 17, 2003 email and Cladribine Briefing Document (PROTECTIVE ORDER MATERIAL)
2050	August 27, 2003 Meeting Minutes for the Oral Cladribine for MS Project Joint Meeting (PROTECTIVE ORDER MATERIAL)
2051	Declaration of Fred D. Lublin, M.D.
2052	Declaration of Bernd Meibohm, Dr.rer.nat.
2053	Declaration of Alain Munafo, Ph.D.

Exhibit No.	Description
2054	Declaration of Nicholas Bodor, Ph.D., D.Sc., d.h.c.
2055	Declaration of Yogesh Dandiker, Ph.D.
2056	Serono Press Release, *Serono and IVAX to Develop Oral Therapy for Multiple Sclerosis* (October 30, 2002)
2057	Serono S.A. Form 20F (2003)
2058	C. Sargent, *Serono Purchases Rights to Experimental MS Drug*, Wall Street Journal (October 31, 2002) (https://www.wsj.com/articles/SB1035995148253461151), accessed on December 14, 2023
2059	Copaxone® (glatiramer acetate) Package Insert (2014)
2060	A. Liu, *Better 8 Years Late Than Never: Merck KGaA Nabs FDA Nod for MS Drug Mavenclad*, FIERCEPHARMA.COM (April 1, 2019) (https://www.fiercepharma.com/pharma/better-8-years-late-than-never-merck-kgaa-nabs-fda-nod-for-ms-drug-mavenclad), accessed on December 18, 2023
2061	The Canadian Cooperative Multiple Sclerosis Study Group, *The Canadian Cooperative Trial of Cyclophosphamide and Plasma Exchange in Progressive Multiple Sclerosis*, 337 LANCET 441 (1991)
2062	J. W. Hainer et al., *Dosing in Heavy-Weight/Obese Patients with the LMWH, Tinzaparin: A pharmacodynamic Study*, 87 THROMB HAEMOST. 817 (2002) (Excerpt)
2063	B. Meibohm et al., *Clinical Pharmacodynamics & Pharmacokinetics*, In: R. A. Helms, RA et al. TEXTBOOK OF THERAPEUTICS: DRUG AND DISEASE MANAGEMENT 1 (8th ed. 2006) (Excerpt)

Exhibit No.	Description
2064	*Reserved*
2065	*Reserved*
2066	*Reserved*
2067	Declaration of Asher S. McGuffin in Support of Exhibits 2056, 2057, and 2058
2068	Declaration of Cindy Kan in Support of Exhibits 2038, 2040, 2041, 2042, 2060, and 2070
2069	U.S. Patent No. 7,888,328
2070	SAFETY & SIDE EFFECTS Learn about the possible risks of MAVENCLAD (https://www.mavenclad.com/en/home/why-mavenclad/safety-and-side-effects.html#:~:text=It) (last updated November 2022), accessed on December 18, 2023
2071	Declaration of Willem de Weerd in Support of Exhibits 2048, 2049, and 2050
2072	Supplemental Declaration of Fred D. Lublin, M.D. (SERVICE ONLY)
2073	D. S. Goodin et al., *Disease Modifying Therapies in Multiple Sclerosis*, 58 NEUROLOGY 169, Supplementary Material (2002) (SERVICE ONLY)
2074	The 2002 Product Development and License Agreement between IVAX International GMBH and Ares Trading S.A. (SERVICE ONLY)
2075	Declaration of David Mlaver in Support of Motion for Admission *Pro Hac Vice*

Exhibit No.	**Description**
2076	Declaration of Mary Pheng in Support of Motion for Admission *Pro Hac Vice*

CERTIFICATE OF SERVICE

I hereby certify that on February 9, 2024, I caused a true and correct copy of the foregoing materials:

- Patent Owner's Motion for Admission *Pro Hac Vice* of David Mlaver
- Exhibit 2075
- Patent Owner's Updated Exhibit List

to be served via e-mail, as consented to by Petitioner, to:

eellison-PTAB@sternekessler.com
opartington-PTAB@sternekessler.com
cvira-PTAB@sternekessler.com
jcrozendaal-PTAB@sternekessler.com
cdashe-PTAB@sternekessler.com
PTAB@sternekessler.com

By: /Cindy Kan/
Cindy Kan (Reg. No. 76,385)
Wilmer Cutler Pickering Hale and Dorr LLP
7 World Trade Center
250 Greenwich Street
New York, NY 10007
Tel: (212) 295-6470
E-mail: cindy.kan@wilmerhale.com