IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

HOPEWELL PHARMA VENTURES, INC.,
Petitioner

v.

MERCK SERONO S.A.,
Patent Owner

Case IPR2023-00480
U.S. Patent No. 7,713,947

PETITIONER HOPEWELL PHARMA VENTURES, INC.'S MOTION FOR *PRO HAC VICE* ADMISSION OF JOHN CHRISTOPHER ROZENDAAL UNDER 37 C.F.R. § 42.10(c)

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PETITIONER'S UPDATED EXHIBIT LIST

Exhibit #	*Description*
1001	De Luca, G., et al., "Cladribine Regimen for Treating Multiple Sclerosis," U.S. Patent No. 7,713,947 B2 (filed June 18, 2007; issued May 11, 2010)
1002	Declaration of Aaron Miller, M.D.
1003	*Curriculum Vitae* for Aaron Miller, M.D.
1004	File History for U.S. Patent No. 7,713,947
1005	*Intentionally Left Blank*
1006	Noseworthy, J.H., et al., "Multiple Sclerosis," *The New England Journal of Medicine*, 343(13):938-952 (2000)
1007	Neuhaus, O., et al., "Immunomodulation in multiple sclerosis: from immunosuppression to neuroprotection," *TRENDS in Pharmaceutical Sciences*, 24(3):131-138 (2003)
1008	Weiner, H.L., et al., "Immunotherapy of Multiple Sclerosis," *Annals of Neurology*, 23(3):211-222 (1988)
1009	Wingerchuk, D.M., et al., "Biology of Disease, Multiple Sclerosis: Current Pathophysiological Concepts," *Laboratory Investigation*, 81(3):263-281 (2001)
1010	Kurtzke, J.F., "Rating neurologic impairment in multiple sclerosis: An expanded disability status scale (EDSS)," *Neurology*, 33:1444-1452 (1983)
1011	*Intentionally Left Blank*
1012	Whitaker, J.N., "Rationale for Immunotherapy in Multiple Sclerosis," *Annals of Neurology*, 36:S103-S107 (1994)
1013	Stelmasiak, Z., et al., "A pilot trial of cladribine (2-chlorodeoxyadenosine) in remitting-relapsing multiple sclerosis," *Medical Science Monitor*, 4(1):4-8 (1998)
1014	Beutler, E., et al., "The treatment of chronic progressive multiple sclerosis with cladribine," *Proceedings of the National Academy of Sciences*, USA 93:1716-1720 (1996)
1015	Tortorella, C., et al., "Cladribine Ortho Biotech Inc," *Current Opinion in Investigational Drugs*, 2(12):1751-1756 (2001)
1016	Langtry, H.D., et al., "Cladribine, A Review of its Use in Multiple Sclerosis," *BioDrugs*, 9(5):419-433 (1998)

Exhibit #	***Description***
1017	Rudick, R.A., et al., "Management of Multiple Sclerosis," *The New England Journal of Medicine*, 337(22):1604-1611 (1997)
1018	Rice, G.P.A., et al., "Cladribine and progressive MS, Clinical and MRI outcomes of a multicenter controlled trial," *Neurology*, 54:1145-1155 (2000)
1019	Barkhof, R., et al., "Limited duration of the effect of methylprednisolone on changes on MRI in multiple sclerosis," *Neuroradiology*, 36:382-387 (1994)
1020	Pirko, I. and Rodriguez, M., "Pulsed Intravenous Methylprednisolone Therapy in Progressive Multiple Sclerosis: Need for a Controlled Trial," *Archives of Neurology*, 61:1148-1149 (2004)
1021	Weiner, H.L., et al., "Intermittent cyclophosphamide pulse therapy in progressive multiple sclerosis: Final report of the Northeast Cooperative Multiple Sclerosis Treatment Group," *Neurology*, 43:910-918 (1993)
1022	Bodor, N. and Dandiker, Y., "Oral Formulations of Cladribine," International Publication No. WO 2004/087101 A2 (filed March 26, 2004; published October 14, 2004)
1023	Grieb, P., et al., "Effect of Repeated Treatments with Cladribine (2-Chlorodeoxyadenosine) on Blood Counts in Multiple Sclerosis Patients," *Archivum Immunologiae Experimentalis*, 43:323-327 (1995)
1024	Schultz, T.W., et al., "Cyclodextrine Cladribine Formulations," U.S. Patent No. 6,194,395 B1 (filed February 25, 1999; issued February 27, 2001)
1025	File History for U.S. Patent No. 8,377,903
1026	Beutler, E., "Use of Substituted Adenine Derivatives for Treating Multiple Sclerosis," U.S. Patent No. 5,506,214 B2 (filed February 18, 1993; issued April 9, 1996)
1027	Docket Report, *Merck KGaA et al. v. Hopewell Pharma Ventures, Inc.*, Case No. 1:22-cv-01365-GBW (D.Del.)
1028	Docket Report, *Merck KGaA et al. v. Accord Healthcare, Inc.*, Case No. 1:22-cv-00974-GBW (D.Del.)
1029	United States District Courts - National Judicial Caseload Profile, June 2022
1030	*Curriculum Vitae* for Nancy E. Adams, Ed.D.

Exhibit #	***Description***
1031	Romine, J. S., et al., "A Double-Blind, Placebo-Controlled, Randomized Trial of Cladribine in Relapsing-Remitting Multiple Sclerosis," *Proceedings of the Association of American Physicians*, 111(1):35-44 (1999)
1032	Docket Report, *Merck KGaA et al. v. Aurobindo Pharma USA, Inc., et al.*, Case No. 1:23-cv-00039-GBW (D.Del.)
1033	Bloom, P.M., "Treatment of Multiple Sclerosis with Lymphocytapheresis and Chemo-Immunosuppression," U.S. Patent No. 4,964,848 (filed June 27, 1988; issued October 23, 1990)
1034	*Intentionally Left Blank*
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1036	Lassmann, H., et al., "Heterogeneity of multiple sclerosis pathogenesis: implications for diagnosis and therapy," *TRENDS in Molecular Medicine*, 7(3):115-121 (March 2001)
1037	Lublin, F. D., et al., "Defining the clinical course of multiple sclerosis: Results of an international survey," *Neurology*, 46:907-911 (1996)
1038	Casanova, B., et al., "High clinical inflammatory activity prior to the development of secondary progression: a prospective 5-year follow-up study," *Multiple Sclerosis*, 8:59-63 (2002)
1039	Publisher's Record for Stelmasiak (EX1013)
1040	Declaration of Nancy E. Adams, Ed.D.
1041	*Intentionally Left Blank*
1042	Shurkovich, S., et al., "Randomized study of antibodies to INF-γ and TNF-α in secondary progressive multiple sclerosis," *Multiple Sclerosis*, 7:277-84 (2001)
1043	Khoury, S. J., "Multiple Sclerosis: What Have We Learned From Magnetic Resonance Imaging Studies?," *Archives of Internal Medicine*, 158:565-73 (1998)
1044	Roitt, I. M., "Essential Immunology, Sixth Edition," Blackwell Scientific Publications, 1-29 (1988) (Excerpt)
1045	Filippi, M., et al., "The effect of cladribine on T1 'black hole' changes in progressive MS," *Journal of Neurological Sciences*, 176:42-44 (2000)
1046	Romine, J. S., et al., "Cladribine: Use in Therapy of Multiple Sclerosis," *Biodrugs*, 7(5):386-93 (1997)

Exhibit #	***Description***
1047	Selby, R., et al., "Safety and Tolerability of Subcutaneous Cladribine Therapy in Progressive Multiple Sclerosis," *Canadian Journal of Neurological Sciences*, 25:295-99 (1998)
1048	Liliemark, J., "The Clinical Pharmacokinetics of Cladribine," *Clinical Pharmacokinetics*, 32(2):120-31 (1997)
1049	Barkhof, F., et al., "Limited duration of the effect of methylprednisolone on changes on MRI in multiple sclerosis," *Neuroradiology*, 36:382-387 (1994)
1050	Chumlea, W.C., "Total body water data for white adults 18 to 64 years of age: The Fels Longitudinal Study," *Kidney International*, 56:244-252 (1999)
1051	U.S. Patent and Trademark Office, Memorandum, Interim Procedure for Discretionary Denials in AIA Post-Grant Proceedings with Parallel District Court Litigation (June 21, 2022)
1052	Supplemental Declaration of Aaron Miller, M.D. (*served not filed*)
1053	Declaration of Christina E. Dashe in Support of Motion for *Pro Hac Vice* Admission
1054	Declaration of John Christopher Rozendaal in Support of Motion for *Pro Hac Vice* Admission

I. INTRODUCTION

Pursuant to 37 C.F.R. § 42.10(c) and the Notice of Filing Date Accorded to Petition (Paper 7), Petitioner Hopewell Pharma Ventures, Inc. ("Petitioner"), respectfully requests that the Board recognize John Christopher Rozendaal as counsel *pro hac vice* in this proceeding. Petitioner is not seeking to replace either its current lead or back-up lead counsel with Mr. Rozendaal. Patent Owner does not oppose this motion.

Where the lead counsel is a registered practitioner, a non-registered practitioner may be permitted to appear *pro hac vice* "upon a showing that counsel is an experienced litigating attorney and has established familiarity with the subject matter at issue in the proceeding." 37 C.F.R. § 42.10(c); *Unified Patents, Inc. v. Parallel Iron, LLC*, Case IPR2013-00639 (P.T.A.B. Oct. 15, 2013) (Paper 7) (setting forth requirements for *pro hac vice* admission).

As set forth in the accompanying Declaration (EX1054), John Christopher Rozendaal is a Director and head of the Trial and Appellate Practice Group at Sterne, Kessler, Goldstein & Fox PLLC and an experienced patent litigation attorney with significant experience representing clients in patent matters before the courts, the Patent Trial and Appeal Board, and U.S. International Trade Commission. Based on the facts detailed below and in his declaration, John Christopher Rozendaal has significant familiarity with the particular subject matter

in this IPR proceeding.

This motion is authorized by the Notice of Filing Date Accorded that was mailed on March 27, 2023. *See* Paper 7, 2.

II. STATEMENT OF FACTS

As detailed in his declaration, Mr. Rozendaal serves as head of the Trial and Appellate Practice Group at Sterne, Kessler, Goldstein & Fox PLLC, which is the nation's fourth-largest firm specializing in intellectual property matters. He has focused his practice on patent litigation throughout his nearly 25-year-long career as an attorney and has extensive experience representing clients before courts and agencies, including the Board, in patent matters. EX1054, ¶¶8-9. He has been granted *pro hac vice* admission by the Board in post-grant proceedings and interference proceedings (*id.*, ¶9) and has represented clients in numerous appeals involving patents before the U.S. Court of Appeals for the Federal Circuit (*id.*, ¶8).

Mr. Rozendaal has significant knowledge and experience in patent litigation, including through litigating invalidity defenses, defending and deposing witnesses, handling evidentiary issues, and arguing issues of claim construction. *Id.*, ¶¶8-9.

Mr. Rozendaal has been involved in numerous proceedings before the Board, and has worked on such matters since 2019. *Id.*, ¶9. This experience includes: preparing petitions, motions, and other submissions; deposing, defending, and preparing witnesses; and seeking relief from the Board in accordance with

Board procedures. *Id*.

Based on his involvement to date, Mr. Rozendaal has developed an established familiarity with the subject matter of this proceeding, including a close familiarity with the arguments and evidence in the petition. *Id.*, ¶10. He has gained this familiarity through review and analysis of the challenged patent, the prosecution history of the challenged patent, technical literature, the expert declaration, and other sources of information. *Id*.

Mr. Rozendaal has been granted *pro hac vice* admission in post-grant proceedings and interference proceedings, as identified in his declaration. *Id.*, ¶9. Petitioner is concurrently filing a motion for *pro hac vice* admission of Mr. Rozendaal in related proceeding IPR2023-00481.

Mr. Rozendaal is a member in good standing of the bars of District of Columbia since 1999, State of Virginia since 1997, the Supreme Court of the United States (since 2001), and numerous other federal courts of appeal and district courts. *Id.*, ¶2.

Mr. Rozendaal has never been suspended or disbarred from practice before any court or administrative body (*id.*, ¶3), has never been denied admission to practice before any court or administrative body (*id.*, ¶4), and has never received sanctions or contempt citations from any court or administrative body (*id.*, ¶5).

Mr. Rozendaal certifies 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 part 42 of 37 C.F.R. EX1054, ¶6. Mr. Rozendaal certifies that he understands that he will be subject to the Rules of Professional Conduct under 37 C.F.R. §§ 11.101 *et seq*. and disciplinary jurisdiction under 37 C.F.R. § 11.19(a). EX1054, ¶7.

Mr. Rozendaal certifies that in this proceeding he will work in coordination with lead counsel Eldora L. Ellison, who is a registered practitioner. *Id.*, ¶11.

III. GOOD CAUSE EXISTS FOR THIS MOTION

The Board may recognize counsel *pro hac vice* during a proceeding upon a showing of good cause. Based on the facts above, as supported by Mr. Rozendaal's declaration (EX1054), there is good cause to admit Mr. Rozendaal *pro hac vice* in this proceeding given his extensive experience and qualifications (*id.*, ¶¶2, 8-9) and established familiarity with the subject matter at issue in this proceeding (*id.*, ¶10).

In addition, Mr. Rozendaal has significant knowledge and experience in patent litigation, including defending and deposing witnesses, handling evidentiary issues, and arguing issues of claim construction. *Id.*, ¶¶8-9. These skills are readily applicable to post-grant proceedings and favor admitting Mr. Rozendaal to represent Petitioner.

Petitioner will maintain a registered practitioner as lead counsel for at least as long as Mr. Rozendaal is admitted *pro hac vice*. Mr. Rozendaal certifies that he will coordinate and associate with the designated lead counsel for Petitioner,

Eldora L. Ellison, who is a registered practitioner, for the duration of his involvement. *Id.*, ¶11.

IV. DECLARATION OF INDIVIDUAL SEEKING TO APPEAR

This motion is accompanied by the declaration required by *Unified Patents, Inc. v. Parallel Iron, LLC*, Case IPR2013-00639 (P.T.A.B. Oct. 15, 2013) (Paper 7).

V. CONCLUSION

Petitioner submits that there is good cause under 37 C.F.R. § 42.10(c) for the Board to recognize John Christopher Rozendaal as counsel *pro hac vice* during this proceeding.

Respectfully submitted,

STERNE, KESSLER, GOLDSTEIN & FOX PLLC

/Eldora L. Ellison/

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CERTIFICATE OF SERVICE (37 C.F.R. § 42.6(e))

I certify that the above-captioned **PETITIONER HOPEWELL PHARMA VENTURES, INC.'S MOTION FOR *PRO HAC VICE* ADMISSION OF JOHN CHRISTOPHER ROZENDAAL UNDER 37 C.F.R. § 42.10(c)** and Exhibit 1054 was served in its entirety on January 5, 2024, upon the following parties via electronic mail:

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Respectfully submitted,

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