

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

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BEFORE THE PATENT TRIAL AND APPEAL BOARD

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HOPEWELL PHARMA VENTURES, INC.,  
Petitioner

v.

MERCK SERONO S.A.,  
Patent Owner

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

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**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**

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

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

| <i>Exhibit #</i> | <i>Description</i>  |
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| 1031             | Romine, J. S., 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> , 111(1):35-44 (1999) |
| 1032             | Docket Report, <i>Merck KGaA et al. v. Aurobindo Pharma USA, Inc., et al.</i> , Case No. 1:23-cv-00039-GBW (D.Del.)   |
| 1033             | Bloom, P.M., "Treatment of Multiple Sclerosis with Lymphocytapheresis and Chemo-Immunsuppression," U.S. Patent No. 4,964,848 (filed June 27, 1988; issued October 23, 1990)   |
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| 1036             | Lassmann, H., et al., "Heterogeneity of multiple sclerosis pathogenesis: implications for diagnosis and therapy," <i>TRENDS in Molecular Medicine</i> , 7(3):115-121 (March 2001)   |
| 1037             | Lublin, F. D., et al., "Defining the clinical course of multiple sclerosis: Results of an international survey," <i>Neurology</i> , 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," <i>Multiple Sclerosis</i> , 8:59-63 (2002)                           |
| 1039             | Publisher's Record for Stelmasiak (EX1013)  |
| 1040             | Declaration of Nancy E. Adams, Ed.D.  |
| 1041             | <i>Intentionally Left Blank</i>   |
| 1042             | Shurkovich, S., et al., "Randomized study of antibodies to INF- $\gamma$ and TNF- $\alpha$ in secondary progressive multiple sclerosis," <i>Multiple Sclerosis</i> , 7:277-84 (2001)                                      |
| 1043             | Khoury, S. J., "Multiple Sclerosis: What Have We Learned From Magnetic Resonance Imaging Studies?," <i>Archives of Internal Medicine</i> , 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," <i>Journal of Neurological Sciences</i> , 176:42-44 (2000)  |
| 1046             | Romine, J. S., et al., "Cladribine: Use in Therapy of Multiple Sclerosis," <i>Biodrugs</i> , 7(5):386-93 (1997)   |

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