

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

**PETITIONER HOPEWELL PHARMA VENTURES, INC.'S
UPDATED EXHIBIT LIST**

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Patent Trial and Appeal Board
U.S. Patent and Trademark Office
P.O. Box 1450
Alexandria, VA 22313-1450

Petitioner Hopewell Pharma Ventures, Inc. (“Petitioner”) files this Updated Exhibit List to accompany filing of Exhibit 1092, Petitioner’s Demonstratives for Oral Argument.

Exhibit No.	Description
1001	De Luca, G., et al., “Cladribine Regimen for Treating Multiple Sclerosis,” U.S. Patent No. 8,377,903 B2 (filed April 23, 2010; issued February 19, 2013)
1002	Declaration of Aaron Miller, M.D.
1003	<i>Curriculum Vitae</i> for Aaron Miller, M.D.
1004	File History for U.S. Patent No. 8,377,903
1005	<i>Intentionally Left Blank</i>
1006	Noseworthy, J.H., et al., “Multiple Sclerosis,” <i>The New England Journal of Medicine</i> , 343(13):938-952 (2000)
1007	Neuhaus, O., et al., “Immunomodulation in multiple sclerosis: from immunosuppression to neuroprotection,” <i>TRENDS in Pharmaceutical Sciences</i> , 24(3):131-138 (2003)
1008	Weiner, H.L., et al., “Immunotherapy of Multiple Sclerosis,” <i>Annals of Neurology</i> , 23(3):211-222 (1988)
1009	Wingerchuk, D.M., et al., “Biology of Disease, Multiple Sclerosis: Current Pathophysiological Concepts,” <i>Laboratory Investigation</i> , 81(3):263-281 (2001)
1010	Kurtzke, J.F., “Rating neurologic impairment in multiple sclerosis: An expanded disability status scale (EDSS),” <i>Neurology</i> , 33:1444-1452 (1983)
1011	<i>Intentionally Left Blank</i>
1012	Whitaker, J.N., “Rationale for Immunotherapy in Multiple Sclerosis,” <i>Annals of Neurology</i> , 36:S103-S107 (1994)
1013	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)
1014	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)
1015	Tortorella, C., et al., “Cladribine Ortho Biotech Inc.,” <i>Current Opinion in Investigational Drugs</i> , 2(12):1751-1756 (2001)

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1016	Langtry, H.D., et al., “Cladribine, A Review of its Use in Multiple Sclerosis,” <i>BioDrugs</i> , 9(5):419-433 (1998)
1017	Rudick, R.A., et al., “Management of Multiple Sclerosis,” <i>The New England Journal of Medicine</i> , 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,” <i>Neurology</i> , 54:1145-1155 (2000)
1019	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)
1020	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)
1021	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)
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,” <i>Archivum Immunologiae Experimentalis</i> , 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. 7,713,947
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, <i>Merck KGaA et al. v. Hopewell Pharma Ventures, Inc.</i> , Case No. 1:22-cv-01365-GBW (D.Del.)
1028	Docket Report, <i>Merck KGaA et al. v. Accord Healthcare, Inc.</i> , Case No. 1:22-cv-00974-GBW (D.Del.)
1029	United States District Courts - National Judicial Caseload Profile, June 2022

Exhibit No.	Description
1030	<i>Curriculum Vitae</i> for Nancy E. Adams, Ed.D.
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 Lymphocyapheresis and Chemo-Immunosuppression,” U.S. Patent No. 4,964,848 (filed June 27, 1988; issued October 23, 1990)
1034	Order Regarding Motion to Stay, <i>Merck KGaA et al. v. Accord Healthcare, Inc. et al.</i> , Case No. 1:22-cv-00974 (D. Del.), December 15, 2022
1035	Stipulation and [Proposed] Order Staying Litigation with Respect to Accord Healthcare, Inc., <i>Merck KGaA et al. v. Accord Healthcare, Inc. et al.</i> , Case No. 1:22-cv-00974 (D. Del.), December 14, 2022
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- γ and TNF- α 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)

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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)
1047	Selby, R., et al., “Safety and Tolerability of Subcutaneous Cladribine Therapy in Progressive Multiple Sclerosis,” <i>Canadian Journal of Neurological Sciences</i> , 25:295-99 (1998)
1048	Liliemark, J., “The Clinical Pharmacokinetics of Cladribine,” <i>Clinical Pharmacokinetics</i> , 32(2):120-31 (1997)
1049	<i>Intentionally Left Blank</i>
1050	<i>Intentionally Left Blank</i>
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. (<i>served not filed</i>)
1053	Declaration of Christina E. Dashe in Support of Motion for <i>Pro Hac Vice</i> Admission
1054	Declaration of John Christopher Rozendaal in Support of Motion for <i>Pro Hac Vice</i> Admission
1055	IVAX Corporation Form 10-K for Fiscal Year 2003
1056	IVAX Corporation Form 10-K for Fiscal Year 2004
1057	File History for U.S. Patent No. 7,888,328 to Bodor et al.
1058	File History for U.S. Patent No. 8,785,415 to Bodor et al.
1059	Transcript of the Deposition of Nicholas S. Bodor. Ph.D. (CONFIDENTIAL – PROTECTIVE ORDER MATERIAL)
1060	Transcript of the Deposition of Yogesh Dandiker, Ph.D. (CONFIDENTIAL – PROTECTIVE ORDER MATERIAL)
1061	Transcript of the Deposition of Fred D. Lublin, M.D.
1062	Transcript of the Deposition of Dr. Bernd Meibohm
1063	Transcript of the Deposition of Alain Munafo, Ph.D. (CONFIDENTIAL – PROTECTIVE ORDER MATERIAL)
1064	Albertioni, F., et al., “On the bioavailability of 2-chloro-2'-deoxyadenosine (CdA),” <i>European Journal of Clinical Pharmacology</i> , 44:579-582 (1993)

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1065	Kottke, M.K., et al., “Tablet Dosage Forms,” Chapter 10 of <i>Modern Pharmaceutics</i> , 4th Ed., Banker, G.S., et al., eds. (2002)
1066	“Biopharmaceutical Drug Delivery,” BioPharm International (August 1, 2004), accessible at https://www.biopharminternational.com/view/biopharmaceutical-drug-delivery-0 (last accessed February 26, 2024)
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1068	Davis, M.E., et al., “Cyclodextrin-Based Pharmaceutics: Past, Present, and Future,” <i>Nature Reviews</i> , 3:1023-1035 (December 2004)
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1070	Leuner, C., et al., “Improving drug solubility for oral delivery using solid dispersions,” <i>European Journal of Pharmaceutics and Biopharmaceutics</i> , 50:47-60 (2000)
1071	Martinez, M.N., et al., “A Mechanistic Approach to Understanding the Factors Affecting Drug Absorption: A Review of Fundamentals,” <i>Journal of Clinical Pharmacology</i> , 42:620-643 (2002)
1072	Munafo, A., Tran, D., Marcus, S., Ammoury, N., “Pharmacokinetics of oral cladribine (Mylinax) after administration in patients with multiple sclerosis,” <i>Serono International S.A., Geneva, Switzerland, Bourn Hall Clinic, Cambridge, UK, Ivax Corp Inc., Miami, USA.</i>
1073	Rajewski, R.A., et al., “Pharmaceutical Applications of Cyclodextrins,” <i>Journal of Pharmaceutical Sciences</i> , 85(11):1142-1169 (November 1996)
1074	Saven, A., et al., “Pharmacokinetic Study of Oral and Bolus Intravenous 2-Chlorodeoxyadenosine in Patients With Malignancy,” <i>Journal of Clinical Oncology</i> , 14(3):978-983 (March 1996)

Exhibit No.	Description
1075	Schultz, T.W., et al., “Cyclodextrin Cladribine Formulations,” U.S. Patent No. 6,194,395 B1 (filed February 25, 1999; issued February 27, 2001)
1076	Chapters 2, 5, 6, 10 from Shargel, L., et al., <i>Applied Biopharmaceutics & Pharmacokinetics</i> , 4th Ed. (1999)
1077	Loftsson, T., et al., “2-Hydroxypropyl- β -cyclodextrin: Properties and Usage in Pharmaceutical Formulations,” <i>PZ Wissenschaft</i> , 136(1):5-10 (January 1991)
1078	Sietsema, W.K., “The absolute oral bioavailability of selected drugs,” <i>International Journal of Clinical Pharmacology, Therapy, and Toxicology</i> , 27(4):179-211 (1989)
1079	Hermann, R., “The Clinical Pharmacology of Cladribine Tablets for the Treatment of Relapsing Multiple Sclerosis,” <i>Clinical Pharmacokinetics</i> , 58:283-297 (2019)
1080	Declaration of Rodolfo Pinal, Ph.D. (CONFIDENTIAL – PROTECTIVE ORDER MATERIAL)
1081	<i>Curriculum Vitae</i> of Rodolfo Pinal, Ph.D.
1082	Chumlea, W.C., “Total body water data for white adults 18 to 64 years of age: The Fels Longitudinal Study,” <i>Kidney International</i> , 56:244-252 (1999)
1083	Sipe, J.C., et al., “A neurologic rating scale (NRS) for use in multiple sclerosis,” <i>Neurology</i> , 34:1368-1372 (October 1984).
1084	Second Declaration of Aaron Miller, M.D. (CONFIDENTIAL – PROTECTIVE ORDER MATERIAL)
1085	Second Supplemental Declaration of Aaron Miller, M.D. (<i>served not filed</i>)
1086	Supplemental Declaration of Rodolfo Pinal, Ph.D. (<i>served not filed</i>)
1087	Errata and Acknowledgement for the Transcript of the Deposition of Nicholas S. Bodor. Ph.D. (CONFIDENTIAL – PROTECTIVE ORDER MATERIAL) (<i>served not filed</i>)
1088	Errata and Acknowledgement for the Transcript of the Deposition of Yogesh Dandiker, Ph.D. (CONFIDENTIAL – PROTECTIVE ORDER MATERIAL) (<i>served not filed</i>)
1089	Errata and Acknowledgement for the Transcript of the Deposition of Fred D. Lublin, M.D. (<i>served not filed</i>)
1090	Errata and Acknowledgement for the Transcript of the Deposition of Dr. Bernd Meibohm (<i>served not filed</i>)

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1092	Petitioner's Demonstratives for Oral Argument (CONFIDENTIAL – PROTECTIVE ORDER MATERIAL)

Respectfully submitted,

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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 UPDATED EXHIBIT LIST** and **EXHIBIT 1092** were served in their entireties on June 20, 2024, upon the following parties via electronic mail:

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