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 UPDATED EXHIBIT LIST

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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. 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)
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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)
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1017	Rudick, R.A., et al., "Management of Multiple Sclerosis," *The New England Journal of Medicine*, 337(22):1604-1611 (1997)
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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

Exhibit No.	Description
1030	*Curriculum Vitae* 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," *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)
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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)
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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)

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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
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)," *European Journal of Clinical Pharmacology*, 44:579-582 (1993)
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Exhibit No.	Description
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)
1067	Brewster, M.E., et al., "Applications of chemically-modified cyclodextrins: use of hydroxypropyl-β-cyclodextrin as an enabling excipient for brain targeting, redox-based derivatives of estradiol, A review of preclinical and clinical findings," *Journal of Drug Delivery Science and Technology*, 14(1):21-34 (2004)
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1074	Saven, A., et al., "Pharmacokinetic Study of Oral and Bolus Intravenous 2-Chlorodeoxyadenosine in Patients With Malignancy," *Journal of Clinical Oncology*¸ 14(3):978-983 (March 1996)
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)

Exhibit No.	Description
1076	Chapters 2, 5, 6, 10 from Shargel, L., et al., *Applied Biopharmaceutics & Pharmacokinetics*¸4th Ed. (1999)
1077	Loftsson, T., et al., "2-Hydroxypropyl-β-cyclodextrin: Properties and Usage in Pharmaceutical Formulations," *PZ Wissenschaft*, 136(1):5-10 (January 1991)
1078	Sietsema, W.K., "The absolute oral bioavailability of selected drugs," *International Journal of Clinical Pharmacology, Therapy, and Toxicology*, 27(4):179-211 (1989)
1079	Hermann, R., "The Clinical Pharmacology of Cladribine Tablets for the Treatment of Relapsing Multiple Sclerosis," *Clinical Pharmacokinetics*, 58:283-297 (2019)
1080	Declaration of Rodolfo Pinal, Ph.D. (CONFIDENTIAL – PROTECTIVE ORDER MATERIAL)
1081	*Curriculum Vitae* of Rodolfo Pinal, Ph.D.
1082	*Intentionally Left Blank*
1083	Sipe, J.C., et al., "A neurologic rating scale (NRS) for use in multiple sclerosis," *Neurology*, 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. (*served not filed*)
1086	Supplemental Declaration of Rodolfo Pinal, Ph.D. (*served not filed*)
1087	Errata and Acknowledgement for the Transcript of the Deposition of Nicholas S. Bodor. Ph.D. (CONFIDENTIAL – PROTECTIVE ORDER MATERIAL) (*served not filed*)
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1089	Errata and Acknowledgement for the Transcript of the Deposition of Fred D. Lublin, M.D. (*served not filed*)
1090	Errata and Acknowledgement for the Transcript of the Deposition of Dr. Bernd Meibohm (*served not filed*)
1091	Errata and Acknowledgement for the Transcript of the Deposition of Alain Munafo, Ph.D. (CONFIDENTIAL – PROTECTIVE ORDER MATERIAL) (*served not filed*)
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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