

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

---

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

***Mail Stop “PATENT BOARD”***  
Patent Trial and Appeal Board  
U.S. Patent and Trademark Office  
P.O. Box 1450  
Alexandria, VA 22313-1450

**TABLE OF CONTENTS**

I. INTRODUCTION ..... 1  
II. STATEMENT OF FACTS ..... 2  
III. GOOD CAUSE EXISTS FOR THIS MOTION ..... 4  
IV. DECLARATION OF INDIVIDUAL SEEKING TO APPEAR..... 5  
V. CONCLUSION..... 6

**PETITIONER'S UPDATED EXHIBIT LIST**

<b><i>Exhibit #</i></b>	<b><i>Description</i></b>
<b>1001</b>	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)
<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. 8,377,903
<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>
<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. 7,713,947
<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>
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-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- $\gamma$ 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)

# Explore Litigation Insights

Docket Alarm provides insights to develop a more informed litigation strategy and the peace of mind of knowing you're on top of things.

## Real-Time Litigation Alerts



Keep your litigation team up-to-date with **real-time alerts** and advanced team management tools built for the enterprise, all while greatly reducing PACER spend.

Our comprehensive service means we can handle Federal, State, and Administrative courts across the country.

## Advanced Docket Research



With over 230 million records, Docket Alarm's cloud-native docket research platform finds what other services can't. Coverage includes Federal, State, plus PTAB, TTAB, ITC and NLRB decisions, all in one place.

Identify arguments that have been successful in the past with full text, pinpoint searching. Link to case law cited within any court document via Fastcase.

## Analytics At Your Fingertips



Learn what happened the last time a particular judge, opposing counsel or company faced cases similar to yours.

Advanced out-of-the-box PTAB and TTAB analytics are always at your fingertips.

## API

Docket Alarm offers a powerful API (application programming interface) to developers that want to integrate case filings into their apps.

## LAW FIRMS

Build custom dashboards for your attorneys and clients with live data direct from the court.

Automate many repetitive legal tasks like conflict checks, document management, and marketing.

## FINANCIAL INSTITUTIONS

Litigation and bankruptcy checks for companies and debtors.

## E-DISCOVERY AND LEGAL VENDORS

Sync your system to PACER to automate legal marketing.