

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

HOPEWELL PHARMA VENTURES, INC.,
Petitioner

v.

ARES TRADING S.A.,
Patent Owner

Case IPR2023-00482
U.S. Patent No. 10,849,919

JOINT MOTION TO TERMINATE PROCEEDING

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

TABLE OF CONTENTS

I.	PRECISE RELIEF REQUESTED	1
II.	REASONS FOR GRANTING THE MOTION	1
	A. Brief Explanation of Why Termination is Appropriate	2
	B. Identification of All Parties in Any Pending Related Litigation Involving the Patent at Issue	2
	C. Related Proceedings Currently Before the Office.....	4
	D. Current Status of Each Such Related Litigation or Proceeding With Respect to Each Party in the Litigation or Proceeding	4
III.	AGREEMENT.....	4
IV.	CONCLUSION.....	5

PETITIONER’S UPDATED EXHIBIT LIST

Exhibit No.	Description
1001	U.S. Patent No. 10,849,919 B2 to Dangond et al., “Cladribine Regimen for Treating Progressive Forms of Multiple Sclerosis,” (filed November 23, 2018; issued December 1, 2020).
1002	Declaration of Aaron Miller, M.D.
1003	<i>Curriculum Vitae</i> for Aaron Miller, M.D.
1004	Prosecution History of U.S. Patent No. 10,849,919
1005	Archived Clinicaltrials.gov Pages for “A Phase 2 Study of Cladribine Add-on Interferon-beta (INF-beta) Therapy in Multiple Sclerosis (MS) Subjects With Active Disease (ONWARD),” ClinicalTrials.gov, captured by Wayback Machine on Jul. 3, 2013 (pp. 10-13); and “A Phase 2 Study of Cladribine Add-on Interferon-beta (INF-beta) Therapy in Multiple Sclerosis (MS) Subjects With Active Disease (ONWARD),” ClinicalTrials.gov, captured by Wayback Machine on Nov. 2, 2014 (pages 5-8), with Affidavit of Nathaniel E. Frank-White (pp. 1-2, 14)
1006	Montalban, X., et al., “Efficacy of Cladribine Tablets as Add-On to IFN-beta Therapy in Patients with Active Relapsing MS: Final Results from the Phase II ONWARD Study P3.029,” published Apr. 4, 2016. (“Montalban”)
1007	Giovannoni, G., et al., “A Placebo-Controlled Trial of Oral Cladribine for Relapsing Multiple Sclerosis,” <i>The New England Journal of Medicine</i> , 362 (5), (Feb. 4, 2010), with attached supplementary appendix. (“Giovannoni”)
1008	Schreiber, K., et al., “Cladribine in the Treatment of Multiple Sclerosis,” <i>Clinical Investigation</i> , 1 (2), (2011). (“Schreiber”)
1009	Alvarez-Gonzalez, C., et al., “Cladribine to Treat Disease Exacerbation after Fingolimod Discontinuation in Progressive Multiple Sclerosis,” <i>Annals of Clinical and Translational Neurology</i> , 4 (7), (March 17, 2017). (“Alvarez-Gonzalez”)
1010	U.S. Patent No. 8,377,903 to De Luca et al., “Cladribine Regimen for Treating Multiple Sclerosis,” (filed Apr. 23, 2010; issued Feb. 19, 2013).
1011	Lassman, H., et al., “Heterogeneity of Multiple Sclerosis Pathogenesis: Implications for Diagnosis and Therapy,” <i>TRENDS in Molecular Medicine</i> , 7 (3), (March 2001).
1012	<i>Intentionally Left Blank</i>

Exhibit No.	Description
1013	Lublin, F.D., et al., “Defining the Clinical Course of Multiple Sclerosis: The 2013 Revisions,” <i>Neurology</i> , 83 (2014).
1014	Lublin, F.D., et al., “Defining the Clinical Course of Multiple Sclerosis: Results of an International Survey,” <i>Neurology</i> , 46 (1996).
1015	Simsek, D., et al., “Understanding the characteristics of secondary progressive multiple sclerosis to facilitate early identification,” <i>Multiple Sclerosis Journal</i> , 21(11):77 (2015)
1016	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 (2002).
1017	Skurkovich, S., et al., “Randomized study of antibodies to IFN- γ and TNF- α in secondary progressive multiple sclerosis,” <i>Multiple Sclerosis</i> , 7 (2001).
1018	Sand, I.K., et al., “Diagnostic uncertainty during the transition to secondary progressive multiple sclerosis,” <i>Multiple Sclerosis Journal</i> , 20(12), (2014).
1019	Willis, M.A., et al., “Progressive Multiple Sclerosis,” <i>Continuum</i> , 22(3), (2016).
1020	Lassmann, H., “Targets of therapy in progressive MS,” <i>Multiple Sclerosis Journal</i> , 23(12), (2017).
1021	Clinicaltrials.gov for NCT00313976 “Study to Compare Double-Dose Betaferon to the Approved Dose, for Patients with Early Secondary Progressive Multiple Sclerosis”
1022	Khoury, S. J., “Multiple Sclerosis: What Have We Learned From Magnetic Resonance Imaging Studies?,” <i>Archives of Internal Medicine</i> , 158:565-73 (1998)
1023	Mavenclad European Public Assessment Report (EPAR), European Medicines Agency
1024	Langtry, H.D., et al., “Cladribine, A Review of its Use in Multiple Sclerosis,” <i>BioDrugs</i> 9(5):419-433 (1998)
1025	Sipe, J.C., et al., “Cladribine in treatment of chronic progressive multiple sclerosis,” <i>The Lancet</i> , 344(8914):9-13 (1994).
1026	International Publication No. WO 2004/087101 A2 to Bodor, N., et al., filed March 26, 2004; published October 14, 2004

Exhibit No.	Description
1027	Leist, T.P., et al., “Effect of oral cladribine on time to conversion to clinically definite multiple sclerosis in patients with a first demyelinating event (ORACLE MS): a phase 3 randomised trial,” <i>Lancet Neurology</i> , 13:257-67 (Feb 2014)
1028	<i>Intentionally Left Blank</i>
1029	Rudick, R.A., et al., “Management of Multiple Sclerosis,” <i>The New England Journal of Medicine</i> , 337(22):1604-1611 (1997)
1030	Noseworthy, J.H., et al., “Multiple Sclerosis,” <i>The New England Journal of Medicine</i> , 343(13):938-952 (2000)
1031	Tortorella, C., et al., “Cladribine Ortho Biotech Inc,” <i>Current Opinion in Investigational Drugs</i> , 2(12):1751-1756 (2001)
1032	Romine, J. S., et al., “Cladribine: Use in Therapy of Multiple Sclerosis,” <i>Biodrugs</i> , 7(5):386-93 (1997)
1033	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)
1034	Beutler, E., “Use of Substituted Adenine Derivatives for Treating Multiple Sclerosis,” U.S. Patent No. 5,506,214 (filed February 18, 1993; issued April 9, 1996)
1035	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)
1036	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)
1037	<i>Intentionally Left Blank</i>
1038	Schultz, T.W., et al., “Cyclodextrine Cladribine Formulations,” U.S. Patent No. 6,194,395 B1 (filed February 25, 1999; issued February 27, 2001)
1039	Andrade, C., “Bioequivalence of Generic Drugs: A Simple Explanation for a US Food and Drug Administration Requirement,” <i>J Clin Psychiatry</i> 76(6):742-744 (2015)
1040	Polman, C.H., et al., “Diagnostic Criteria for Multiple Sclerosis: 2005 Revisions to the ‘McDonald Criteria,’” <i>Annals of Neurology</i> , 58:840-46 (2005)
1041	<i>Intentionally Left Blank</i>

Exhibit No.	Description
1042	Supplementary Appendix to Leist, T.P., et al., “Effect of oral cladribine on time to conversion to clinically definite multiple sclerosis in patients with a first demyelinating event (ORACLE MS): a phase 3 randomised trial,” <i>Lancet Neurology</i> (Feb 2014)
1043	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)
1044	Docket Report, <i>Merck KGaA et al. v. Aurobindo Pharma USA, Inc., et al.</i> , Case No. 1:23-cv-00039-GBW (D.Del.)
1045	Docket Report, <i>Merck KGaA et al. v. Hopewell Pharma Ventures, Inc.</i> , Case No. 1:22-cv-01365-GBW (D.Del.)
1046	Docket Report, <i>Merck KGaA et al. v. Accord Healthcare, Inc.</i> , Case No. 1:22-cv-00974-GBW (D.Del.)
1047	United States District Courts - National Judicial Caseload Profile, June 2022
1048	Publisher’s Record of Alvarez-Gonzalez (EX1009)
1049	PubMed’s Record of Alvarez-Gonzalez (EX1009)
1050	Publisher’s Record of Giovannoni (EX1007)
1051	PubMed’s Record of Giovannoni (EX1007)
1052	Publisher’s Record of Montalban (EX1006)
1053	Clarivate Analytics Web of Science's Record of Montalban (EX1006)
1054	Citation History of Montalban (EX1006)
1055	Publisher’s Record of Schreiber (EX1008)
1056	National Library of Medicine’s Record of Schreiber (EX1008)
1057	National Library of Medicine’s Copy of Schreiber (EX1008)
1058	Beutler, E., et al., “The treatment of chronic progressive multiple sclerosis with cladribine,” <i>Proceedings of the National Academy of Sciences</i> , USA 93:1716-1720 (1996)
1059	Kurtzke, J.F., “Rating neurologic impairment in multiple sclerosis: An expanded disability status scale (EDSS),” <i>Neurology</i> , 33:1444-1452 (1983)
1060	“ClinicalTrials.gov Background,” ClinicalTrials.gov, accessible at https://www.clinicaltrials.gov/ct2/about-site/background
1061	Wingerchuk, D.M., et al., “Biology of Disease, Multiple Sclerosis: Current Pathophysiological Concepts,” <i>Laboratory Investigation</i> , 81(3):263-281 (2001)

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1062	Neuhaus, O., et al., “Immunomodulation in multiple sclerosis: from immunosuppression to neuroprotection,” <i>TRENDS in Pharmaceutical Sciences</i> , 24(3):131-138 (2003)
1063	<i>Intentionally Left Blank</i>
1064	<i>Curriculum Vitae</i> for Nancy E. Adams, Ed.D.
1065	Declaration of Nancy E. Adams, Ed.D.
1066	Archived Clinicaltrials.gov Pages for NCT00213135 “CLARITY - Safety and Efficacy of Oral Cladribine in Subjects With Relapsing-remitting Multiple Sclerosis (MS),” ClinicalTrials.gov, captured by Wayback Machine on Jul. 3, 2013 (pp. 6-8), with Affidavit of Nathaniel E. Frank-White (pp. 1-3, 9)
1067	Hernandez, A., et al., “The Definition of Placebo in the Informed Consent Forms of Clinical Trials,” PLoS ONE 9(11):e113654 (2014)
1068	Weiten, W., <i>Psychology: Themes and Variations</i> , Third Ed., “Chapter 3: The Biological Bases of Behavior,” Brooks/Cole Publishing Company, 1995
1069	Mavenclad FDA Approval Letter, March 29, 2019
1070	Confidential settlement agreement between Hopewell Pharma Ventures, Inc. and Merck KGaA, Merck Serono SA, and Ares Trading S.A.

I. PRECISE RELIEF REQUESTED

Pursuant to 35 U.S.C. § 317(a), Petitioner Hopewell Pharma Ventures, Inc. (“Petitioner”) and Patent Owner Ares Trading S.A. (“Patent Owner”) jointly request that this *inter partes* review proceeding involving U.S. Patent No. 10,849,919 (“the ’919 patent”) be terminated based on an agreement between Petitioner and Patent Owner (“the Parties”).

Petitioner and Patent Owner have settled their dispute regarding the ’919 patent, including both this proceeding and Patent Owner’s assertion of the ’919 Patent in the related district court litigation, *Merck KGaA et al. v. Hopewell Pharma Ventures, Inc., et al.*, Case No. 1:22-cv-01365 (D. Del.). The Parties do not anticipate any further litigation between them concerning the ’919 patent.

II. REASONS FOR GRANTING THE MOTION

Generally, the Board expects that a proceeding will terminate after the filing of a settlement agreement between parties made in connection with, or in contemplation of, the termination of the proceeding, unless the Board has already decided the merits of the proceeding. *See, e.g.*, Patent Trial and Appeal Board Consolidated Trial Practice Guide (Nov. 2019) at 86. The Board authorized filing of the instant motion on August 9, 2023. Guidance as to the content of a motion to terminate is provided in IPR2013-00428, Paper No. 56. There, the Board indicated that a joint motion, such as this one, should (a) include a brief explanation as to why

termination is appropriate; (b) identify all parties in any related litigation involving the patent at issue; (c) identify any related proceedings currently before the Office; and (d) discuss specifically the current status of each such related litigation or proceeding with respect to each party to the litigation or proceeding. *Id.* at 2. This motion satisfies each of the above requirements.

A. Brief Explanation of Why Termination is Appropriate

Good cause exists to terminate this proceeding under 37 C.F.R. § 42.74 and 37 C.F.R. § 42.72, because the parties are jointly requesting termination and the Office has not yet instituted trial nor “decided the merits of the proceeding before the request for termination is filed.” *See* 35 U.S.C. § 317(a). The parties have resolved their disputes regarding the ’919 patent and executed an agreement that contemplates requesting termination of this proceeding and terminating or dismissing the Parties’ related proceeding regarding the ’919 patent in *Merck KGaA et al v. Hopewell Pharma Ventures, Inc., et al.*, Case No. 1:22-cv-01365 (D. Del.). Terminating this proceeding thus serves the interests of judicial economy as well as the mutual interests of the parties.

B. Identification of All Parties in Any Pending Related Litigation Involving the Patent at Issue

- The following litigation is related to the ’919 patent and the Parties:
Merck KGaA et al v. Hopewell Pharma Ventures, Inc., et al., Case No. 1:22-cv-01365 (D. Del.), filed October 17, 2022, and currently

pending (the “Hopewell Action”). The Plaintiffs are Merck KGaA, Merck Serono SA, and Ares Trading SA, and the Defendant is Hopewell Pharma Ventures, Inc.

- The '919 patent has also been asserted in the following three cases. These cases are currently pending and do not involve Hopewell Pharma Ventures, Inc.:

(1) *Merck KGaA et al. v. Accord Healthcare, Inc. et al.*, Case No. 1:22-cv-00974 (D. Del.). The Plaintiffs are Merck KGaA, Merck Serono SA, and Ares Trading SA, and the Defendants are Accord Healthcare, Inc., and Intas Pharmaceuticals Ltd.

(2) *Merck KGaA et al. v. Aurobindo Pharma USA, Inc. et al.*, Case No. 1:23-cv-00039 (D. Del.). The Plaintiffs are Merck KGaA, Merck Serono SA, and Ares Trading SA, and the Defendants are Aurobindo Pharma USA, Inc., and Aurobindo Pharma Limited. This action has been consolidated with the Hopewell Action.

(3) *Merck KGaA et al. v. Apotex Inc. et al.*, Case No. 1:23-cv-00655 (D. Del.). The Plaintiffs are Merck KGaA, Merck Serono SA, and Ares Trading SA, and the Defendants are Apotex Inc., and Apotex Corp.

C. Related Proceedings Currently Before the Office

The following pending patent applications are related to the '919 patent.

U.S. Patent Application No. 17/932,796 is a continuation application of U.S. Patent Application No. 16/949,278, which is a divisional application of U.S. Patent Application No. 16/199,119, which issued as the '919 patent and claims the benefit of expired U.S. Provisional Application No. 62/590,442.

There are no other *inter partes* review proceedings involving the '919 patent. Petitioner has also filed IPR2023-00480 against Patent No. 7,713,947 and IPR2023-00481 against Patent No. 8,377,903, owned by Merck Serono S.A., an affiliate of Ares; both IPRs are pending and also are directed to treating Multiple Sclerosis with cladribine.

D. Current Status of Each Such Related Litigation or Proceeding With Respect to Each Party in the Litigation or Proceeding

Sections II.B and II.C above indicate the status of the related litigations and proceedings with respect to each party to the litigation.

III. AGREEMENT

Pursuant to 35 U.S.C. § 317(b) and 37 C.F.R. § 42.74(b), the Parties' agreement made in connection with, or in contemplation of, the termination of the proceeding is in writing, and a true and correct copy is being filed concurrently herewith as Exhibit 1070.¹ There are no other agreements, oral or written, between

¹ The agreement is being filed via the Patent Trial and Appeal Board

the parties made in connection with, or in contemplation of, the termination of this proceeding. The parties are also filing concurrently herewith a joint request under 35 U.S.C. § 317(b) and 37 C.F.R. § 42.74(c) to treat this agreement as business confidential information and keep it separate from the files of the '919 patent.

IV. CONCLUSION

For all of these reasons, the Parties respectfully request termination of this proceeding.

Respectfully submitted,

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P-TACTS system with access to the "Parties and Board only."

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

I certify that the above-captioned **JOINT MOTION TO TERMINATE PROCEEDING** and Exhibit 1070 were served in their entireties on August 15, 2023, upon the following parties via electronic mail:

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