

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

SANDOZ INC.,
Petitioner,

v.

PHARMACYCLICS LLC,
Patent Owner.

Case No. IPR2019-00865
Patent 9,795,604

MOTION FOR ADMISSION *PRO HAC VICE*
OF CHRISTOPHER L. MCARDLE

AMENDED EXHIBIT LIST

Ex #	Exhibit
1001	U.S. Patent No. 9,795,604 B2 (“the ’604 Patent”)
1002	U.S. Patent Pub. No. 2015/0140085 A1 (“the ’085 Publication ”)
1003	Shimabukuro-Vornhagen <i>et al.</i> , “The role of B cells in the pathogenesis of graft-versus-host disease,” BLOOD, Volume 114, No. 24, pp. 4919–4927, December 3, 2009 (“Shimabukuro-Vornhagen”)
1004	Herman <i>et al.</i> , “Bruton tyrosine kinase represents a promising therapeutic target for treatment of chronic lymphocytic leukemia and is effectively targeted by PCI-32765,” BLOOD, Volume 117, No. 23, pp. 6287–6296, June 9, 2011 (“Herman”)
1005	Uckun <i>et al.</i> , “Bruton’s tyrosine kinase as a molecular target in treatment of leukemias and lymphomas as well as inflammatory disorders and autoimmunity,” EXPERT OPINION ON THERAPEUTIC PATENTS, Volume 20, No. 11, pp. 1457–1470, November 2010 (“Uckun”)
1006	Declaration of James L. M. Ferrara M.D., D.Sc.
1007	Goldstein <i>et al.</i> , “Induction of Costimulatory Molecules B7-1 and B7-2 in Murine B Cells: the CBA/N Mouse Reveals a Role for Bruton’s Tyrosine Kinase in CD4- Mediated B7 Induction,” MOLECULAR IMMUNOLOGY, Volume 33, No. 6, pp. 541–551, 1996 (“Goldstein”)
1008	Declaration of Sylvia D. Hall-Ellis, Ph.D.
1009	July 22, 2016 Amendment and Response in Appl. No. 14/523,650
1010	Barak <i>et al.</i> , “Cytokine Dysregulation in Chronic Graft Versus Host Disease,” LEUKEMIA AND LYMPHOMA, Volume 17, pp. 169–173, 1995 (“Barak”)
1011	PCT No. PCT/US2013/047958
1012	Cetkovic-Cvrlje, “Dual targeting of Bruton’s tyrosine kinase and Janus kinase 3 with rationally designed inhibitors prevents graft-versus-host disease (GVHD) in a murine allogeneic bone marrow transplantation model,” BRITISH JOURNAL OF HAEMATOLOGY, Volume 126, pp. 821–827, 2004
1013	U.S. Patent No. 7,514,444 B2
1014	Provisional Patent Application No. 61/666,562 and filing receipt
1015	Honigberg <i>et al.</i> , “The Bruton tyrosine kinase inhibitor PCI-32765 blocks B-cell activation and is efficacious in models of autoimmune disease and B-cell malignancy,” PROCEEDINGS OF THE NATIONAL ACADEMY OF SCIENCES OF THE USA, Volume 107, No. 29, pp. 13075–13080, July 20, 2010

1016	Advani <i>et al.</i> , “Bruton Tyrosine Kinase Inhibitor Ibrutinib (PCI-32765) Has Significant Activity in Patients With Relapsed/Refractory B-Cell Malignancies,” JOURNAL OF CLINICAL ONCOLOGY, Volume 31, No. 1, pp. 88–94, January 1, 2013
1017	Dolgin, “Precision therapies take aim at non-Hodgkin’s lymphoma” NATURE, Volume 563, S46–S47, November 14, 2018
1018	U.S. Patent No. 8,476,284 B2
1019	U.S. Patent No. 8,497,277 B2
1020	Orange Book Listing for Ibrutinib 420 mg Capsules
1021	April 22, 2016 Office Action in Appl. No. 14/523,650
1022	Auphan <i>et al.</i> , “Immunosuppression by Glucocorticoids: Inhibition of NF- κ B Activity Through Induction of I κ B Synthesis,” SCIENCE, Volume 270, pp. 286–290, October 13, 1995
1023	Curriculum Vitae of Dr. James L. M. Ferrara M.D., D.Sc.
1024	Koreth <i>et al.</i> , “Current and Future Approaches for Control of Graft-Versus-Host Disease,” EXPERT REVIEWS IN HEMATOLOGY, Volume 1, No. 1, pp. 111–128, 2008
1025	Sarantopoulous <i>et al.</i> , “Altered B-cell Homeostasis and Excess BAFF in Human Chronic Graft-Versus-Host Disease,” BLOOD, Volume 113, No. 16, pp. 3865–3874, April 16, 2009
1026	Cutler <i>et al.</i> , “Rituximab Prophylaxis Prevents Corticosteroid-Requiring Chronic GVHD After Allogeneic Peripheral Blood Stem Cell Transplantation: Results of a Phase 2 Trial,” BLOOD, Volume 122, No. 8, pp. 1510–1517, August 22, 2013
1027	NCCN Clinical Practice Guidelines in Oncology, Hematopoietic Cell Transplantation (HCT): Pre-Transplant Recipient Evaluation and Management of Graft Versus Host Disease, Version 1.2020, October 30, 2019
1028	April 27, 2017 Response and Amendment in Appl. No. 14/523,650
1029	October 14, 2014 Specification Filed in Appl. No. 14/523,650
1030	March 13, 2020 Deposition Transcript of John Koreth M.B.B.S., D. Phil.
1031	Declaration of Christopher L. McArdle in Support of Motion <i>pro hac vice</i>

Pursuant to 37 C.F.R. §§ 42.10(b) and (c), Petitioner, Sandoz Inc., hereby moves for the admission of Christopher L. McArdle, a member of the Bar of the State of New York, as co-counsel for Petitioner in this *inter partes* review (“IPR”) proceeding. An appropriate power of attorney from Petitioner so appointing Mr. McArdle was filed with the Petition. *See* Paper 1.

Mr. McArdle holds a B.A. degree in Chemistry from Washington University in St. Louis and a J.D. degree from Tulane University. Exhibit 1023 ¶ 1. Mr. McArdle is a member in good standing with the Bar of the State of New York. Exhibit 1023 ¶ 2. He has never been suspended, disbarred, sanctioned, denied admission to practice, or cited for contempt by any court or administrative body. *Id.* at ¶¶ 3–5.

Mr. McArdle has become intimately familiar with the patent at issue in this proceeding and the prior art, including Petitioner’s arguments as to why the claims at issue are invalid in view of Petitioner’s prior art. Mr. McArdle’s technical experience will aid Petitioner in this proceeding. He also satisfies the remaining conditions for admissibility identified by the Board. Exhibit 1023 ¶¶ 6–9.

Petitioner moves for the admission of Mr. McArdle to designate him as back-up counsel in this IPR, in view of his knowledge, familiarity, and experience with the subject matter of this IPR. Although Mr. McArdle is not a registered USPTO

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practitioner, Petitioner's undersigned lead counsel is registered and remains on this case.

Dated: May 29, 2020

Respectfully submitted,

/ Kirk T. Bradley /
Kirk. T. Bradley
Reg. No. 46,571

Counsel for Petitioner Sandoz Inc.

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