

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

SANDOZ INC.,
Petitioner,

v.

PHARMACYCLICS LLC,
Patent Owner.

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

PATENT OWNER'S UPDATED EXHIBIT LIST AS OF JANUARY 6, 2020

Further to 37 C.F.R. § 42.63(e), Patent Owner Pharmacyclics LLC hereby submits a current listing of Pharmacyclics exhibits.

EXHIBIT	DESCRIPTION
2001	Dignan FL, et al., <i>Diagnosis and management of chronic graft-versus-host disease</i> . BRIT J HAEMATOL, 158:46-61 (2012).
2002	Choi SW, Levine JE & Ferrara JL, <i>Pathogenesis and management of graft-versus-host disease</i> . IMMUNOL ALLERGY CLIN N AM, 30:75-101 (2010).
2003	Min CK, <i>The pathophysiology of chronic graft-versus-host disease: the unveiling of an enigma</i> . KOREAN J HEMATOL, 46(2):80-87 (2011).
2004	Pavletic SZ & Fowler DH, <i>Are we making progress in GVHD prophylaxis and treatment?</i> HEMATOLOGY AM SOC HEMATOL EDUC PROGRAM, 2012(1):251-64 (2012).
2005	Ferrara JLM & Reddy P, <i>Cellular Therapy for Hematology Malignancies: Allogeneic Hematopoietic Stem Transplantation, Graft-Versus-Host Disease, and Graft Versus Leukemia Effects</i> , in ADVANCES IN STEM CELL RESEARCH. STEM CELL BIOLOGY AND REGENERATIVE MEDICINE, 303-66 (Baharvand H & Aghdami N eds, 2012).
2006	Martin PJ et al., <i>Treatment of chronic graft-versus-host disease: past, present and future</i> . KOREAN J HEMATOL, 46(3):153-63 (2011).
2007	Ferrara JL et al., <i>Graft-versus-host disease</i> . LANCET, 373:1550-61 (2009).
2008	Ferrara JL & Yanik G, <i>Acute graft versus host disease: Pathophysiology, risk factors, and prevention strategies</i> . CLIN ADV HEMATOL ONCOL, 3(5):415-19 (2005).
2009	Rota M et al., <i>Impact of Recipient Statin Treatment on Graft-Versus-Host disease after Allogeneic Hematopoietic Cell Transplantation</i> , BIOL BLOOD MARROW TRANSPLANT, 16:1463-66 (2010).
2010	Lee SJ, <i>New approaches for preventing and treating chronic graft-versus-host disease</i> . BLOOD, 105(11):4200-06 (2005).
2011	Kobbe G, et al., <i>Treatment of severe steroid refractory acute graft-versus-host disease with infliximab, a chimeric human/mouse anti TNFα antibody</i> . BONE MARROW TRANSPLANT, 28:47-49 (2001).

EXHIBIT	DESCRIPTION
2012	Levine JE, et al., <i>Etanercept plus methylprednisolone as initial therapy for acute graft-versus-host disease</i> . BLOOD, 111(4):2470-75 (2008).
2013	Davis JE & Ritchie DS. <i>B cells in GVHD: friend or foe?</i> BLOOD, 115(12):2558-59, author reply (2010).
2014	McIver Z, et al., <i>Rituximab administration within 6 months of T cell-depleted allogeneic SCT is associated with prolonged life-threatening cytopenias</i> . BIOL BLOOD MARROW TRANSPLANT, 16:1549-56 (2010).
2015	MacMillan ML, et al., <i>A phase 2/3 multicenter randomized clinical trial of ABX-CBL versus ATG as secondary therapy for steroid-resistant acute graft-versus-host disease</i> . BLOOD, 109(6):2657-62 (2007).
2016	Kitko CL, et al., <i>Combination therapy for graft-versus-host disease prophylaxis with etanercept and extracorporeal photopheresis: Results of a Phase II clinical trial</i> . BIOL BLOOD MARROW TRANSPLANT, 22:862-68 (2016).
2017	Betts BC, et al. <i>Anti-IL-6 receptor alpha (tocilizumab) does not inhibit human monocyte-derived dendritic cell maturation or alloreactive T-cell responses</i> . BLOOD, 118(19):5340-43 (2011).
2018	Henden AS & Hill GR, <i>Cytokines in graft-versus-host disease</i> . J IMMUNOL, 194:4604-12 (2015).
2019	Martin PJ, et al., <i>Evaluation of mycophenolate mofetil for initial treatment of chronic graft-versus-host disease</i> . BLOOD, 113(21):5074-82 (2009).
2020	Reserved
2021	Kitko CL, et al., <i>Plasma CXCL9 elevations correlate with chronic GVHD diagnosis</i> . BLOOD, 123(5):786-93 (2014).
2022	<i>FDA expands ibrutinib indications to chronic GVHD</i> , U.S. Food & Drug Administration, https://www.fda.gov/drugs/resources-information-approved-drugs/fda-expands-ibrutinib-indications-chronic-gvhd , (last visited May 24, 2019).
2023	Miklos D, et al., <i>Ibrutinib for chronic graft-versus-host disease after failure of prior therapy</i> . BLOOD, 130(21):2243-50 (2017).
2024	Dubovsky JA, et al., <i>Ibrutinib is an irreversible molecular inhibitor of ITK driving a Th1-selective pressure in T lymphocytes</i> . BLOOD, 122(15):2539-49 (2013).

EXHIBIT	DESCRIPTION
2025	Buggy JJ & Elias L, <i>Bruton Tyrosine Kinase (BTK) and Its Role in B-cell Malignancy</i> . INT REV IMMUNOL, 31:119-32 (2012).
2026	<i>FDA Approves Ibrutinib to Treat Chronic Graft Versus Host Disease</i> , Lymphoma Research Foundation, Aug. 3, 2017, https://www.lymphoma.org/newsarchive/fda-approves-ibrutinib-cgvhd/ (last visited June 24, 2019).
2027	U.S. Patent Application Publication No. 2015/0086507 to Izumi.
2028	Magenau J, et al., <i>Advances in understanding the pathogenesis of graft-versus-host disease</i> . BR J HAEMATOL, 173:190-205 (2016).
2029	Notice of Allowance in U.S. Patent Application No. 14/523,650 (Aug. 16, 2017).
2030	Final Office Action in U.S. Patent Application No. 14/523,650 (Nov. 3, 2016).
2031	Reddy P & Ferrara JLM, <i>Graft-Versus-Host Disease and Graft-Versus-Leukemia Responses in HEMATOLOGY</i> , 1650-68 (Hoffman R et al. eds, 2018).
2032	Aalipour A & Advani RH, <i>Bruton tyrosine kinase inhibitors: a promising novel targeted treatment for B cell lymphomas</i> . BR J HAEMATOL, 163:436-43 (2013).
2033	van den Akker E, et al., <i>The BTK inhibitor LFM-A13 is a potent inhibitor of Jak2 kinase activity</i> . BIOL CHEM, 385:409-13 (2004).
2034	Zorn CN, et al., <i>Bruton's tyrosine kinase is dispensable for the Toll-like receptor-mediated activation of mast cells</i> . CELL SIGNAL, 21:79-86 (2008).
2035	Reserved
2036	Prescribing Information for Imbruvica [®] dated January 2019.
2037	Stewart J, <i>Health Canada OKs Imbruvica for Treating Chronic Graft-Versus-Host Disease</i> , Lymphoma News Today, Oct. 31, 2017, https://lymphomanewstoday.com/2017/10/31/janssen-inc-announces-imbruvica-ibrutinib-as-the-first-approved-treatment-for-chronic-graft-versus-host-disease-cgvhd-granted-by-health-canada-priority-review/ (last visited May 24, 2019).
2038	NCI Staff, <i>Ibrutinib Relieves Chronic Graft-Versus-Host Disease Symptoms</i> , NIH National Cancer Institute, Jan. 11, 2017, https://www.cancer.gov/news-events/cancer-currents-blog/2017/ibrutinib-stem-cell-transplant-gvhd (last visited June 24, 2019).

EXHIBIT	DESCRIPTION
2039	<i>Pharmacyclics LLC v. Fresenius Kabi USA, LLC</i> , Scheduling Order, Case 1:18-cv-00192-CFC Consolidated, D.I. 85 (Jan. 28, 2019).
2040	<i>Pharmacyclics LLC v. Fresenius Kabi USA, LLC</i> , Docket Sheet, Case 1:18-cv-00192-CFC Consolidated (accessed May 31, 2019).
2041	Pharmacyclics LLC v. Fresenius Kabi USA, LLC, Notice of Service, Case 1:18-cv-00192-CFC Consolidated, D.I. 130 (Mar. 15, 2019).
2042	Pharmacyclics LLC v. Fresenius Kabi USA, LLC, Excerpts from Plaintiffs' First Supplemental Responses to Defendants' First Set of Joint Interrogatories (Nos. 1-4), Case 1:18-cv-00192-CFC Consolidated (Mar. 15, 2019).
2043	The Mount Sinai Hospital, <i>Test predicts response to treatment for complication of leukemia stem cell treatment</i> . Medical Xpress, Dec. 22, 2014, https://medicalxpress.com/news/2014-12-response-treatment-complication-leukemia-stem.html (last visited Dec. 4, 2019).
2044	Lawrence L, <i>Ibrutinib Approval Expanded to Include Chronic GVHD</i> . CancerNetwork, Aug. 4, 2017, https://www.cancernetwork.com/cancer-complications/ibrutinib-approval-expanded-include-chronic-gvhd (last visited Dec. 2, 2019).
2045	<i>FDA approves Imbruvica as first therapy for chronic graft-versus-host disease</i> . Healio, Aug. 2, 2017, https://www.healio.com/hematology-oncology/bone-marrow-transplantation/news/online/%7B9e5cb76a-cd54-4f5f-ae24-fa1284d83a41%7D/fda-approves-imbruvica-as-first-therapy-for-chronic-graft-versus-host-disease (last visited Nov. 25, 2019).
2046	<i>GVHD management improves, but questions remain about risk stratification, prophylaxis</i> . Healio, June 10, 2018, https://www.healio.com/hematology-oncology/bone-marrow-transplantation/news/print/hemonc-today/%7B5c381d14-ccc4-426d-8012-2250dc78319a%7D/gvhd-management-improves-but-questions-remain-about-risk-stratification-prophylaxis (last visited Dec. 3, 2019).
2047	Filipovich AH, et al. <i>National Institutes of Health consensus development project on criteria for clinical trials in chronic graft-versus-host disease: I. Diagnosis and staging working group report</i> . BIOL BLOOD MARROW TRANSPLANT, 11:945-56 (2005).

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