

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 EXHIBIT LIST

Pursuant to 37 C.F.R. § 42.63(e), Patent Owner Pharmacyclics LLC hereby submits a current listing of 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 | Yoon HK, et al., <i>Effects of Pravastatin on Murine Chronic Graft-Versus-Host Disease</i> . TRANSPLANTATION, 90(8):853–60 (2010). |
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| 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). |
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| 2013 | Shimabukuro-Vornhagen A & von Bergwelt-Baildon MS. <i>Response: Friend or foe in GVHD: a matter of targeting the right B-cell subset.</i> BLOOD, 115(12):2559–60 (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 an 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). |
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| EXHIBIT | DESCRIPTION |
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| 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 et al. |
| 2028 | Magenau J, et al., <i>Advances in understanding the pathogenesis of graft-versus-host disease</i> . BR J HAEMATOL, 173:190–205 (2016). |
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| 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</i> in HEMATOLOGY, 1650–68 (Hoffman R et al. eds, 2018). |
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| 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). |
| 2039 | Reserved. |

| EXHIBIT | DESCRIPTION |
|---------|---|
| 2040 | <i>Pharmacyclics LLC v. Fresenius Kabi USA, LLC</i> , Docket Sheet, Case 1:18-cv-00192-CFC Consolidated (accessed Jun. 26, 2019). |
| 2041 | <i>Pharmacyclics LLC v. Fresenius Kabi USA, LLC</i> , Notice of Service, Case 1:18-cv-00192-CFC Consolidated, D.I. 130 (Mar. 15, 2019). |
| 2042 | <i>Pharmacyclics LLC v. Fresenius Kabi USA, LLC</i> , 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). |

Respectfully submitted,

Date: June 28, 2019

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