

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

SANDOZ INC.,
Petitioner,

v.

ACERTA PHARMA B.V.,
Patent Owner.

Case IPR2023-00478
Patent 10,272,083 B2

PETITIONER'S UPDATED EXHIBIT LIST
(as of June 8, 2023)

LIST OF EXHIBITS

No.	Description
1001	U.S. Patent No. 10,272,083 to Hamdy et al. (the “’083 patent”)
1002	Declaration of John P. Fruehauf, M.D., Ph.D.
1003	Declaration of Sylvia Hall-Ellis, Ph.D.
1004	Prosecution History of U.S. Patent No. 10,272,083 (Application No. 15/112,968)
1005	U.S. Patent No. 9,758,524 to Barf, et al. (“Barf”)
1006	PCT International Publication No. WO2013/010868 to Barf, et al. (“Barf-PCT”)
1007	U.S. Provisional Application No. 61/509,397 to Barf, et al. (“Barf Provisional”)
1008	Bruce D. Cheson, et al., <i>Advancements in the Treatment of B-Cell Malignancies</i> (International Conference on Malignant Lymphoma), CLINICAL ADVANCES IN HEMATOLOGY & ONCOLOGY, Vol. 11, Issue 9, Supplement 12 (Sept. 2013) (“Cheson”)
1009	Ranjana H. Advani, et al., <i>Bruton Tyrosine Kinase Inhibitor Ibrutinib (PCI-32765) Has Significant Activity in Patients With Relapsed/Refractory B-Cell Malignancies</i> , J. CLINICAL ONCOLOGY, 31(1):88-94 (Jan. 2013) (“Advani”)
1010	John C. Byrd, et al., <i>Acalabrutinib (ACP-196) in Relapsed Chronic Lymphomatic Leukemia</i> , N. ENGL. J. MED. 374(4):323-32 (Jan. 2016) (“Byrd”)
1011	U.S. Provisional Application No. 61/929,742
1012	U.S. Provisional Application No. 61/974,665
1013	U.S. Provisional Application No. 62/035,777
1014	Stefano A. Pileri, et al., <i>Mantle cell lymphoma</i> , HAEMATOLGICA 94(11):1488-92 (2009) (“Pileri”)
1015	M. Dreyling, et al., <i>How to manage mantle cell lymphoma</i> , LEUKEMIA 28:2117-31 (2014) (“Dreyling”)
1016	IMBRUVICA™ (ibrutinib) Prescribing Information (2014)
1017	U.S. Food and Drug Administration Office of Clinical Pharmacology Review of IMBRUVICA™ (ibrutinib), Application No. NDA 205552 (Jan. 2014)

No.	Description
1018	Akintunde Akinleye, et al., <i>Ibrutinib and novel BTK inhibitors in clinical development</i> , J. OF HEMATOLOGY & ONCOLOGY 6:59 (2013) (“Akinleye”)
1019	Claire V. Hutchinson, et al., <i>Breaking good: the inexorable rise of BTK inhibitors in the treatment of chronic lymphocytic leukaemia</i> , BRITISH J. OF HAEMATOLOGY 166:12-22 (2014) (“Hutchinson”)
1020	Jennifer R. Brown, et al., <i>Phase I Study Of Single Agent CC-292, a Highly Selective Bruton’s Tyrosine Kinase (BTK) Inhibitor, In Relapsed/Refractory Chronic Lymphocytic Leukemia (CLL)</i> , BLOOD 122(21):1630 (2013) (“Brown”)
1021	Daniel W. Pierce, et al., <i>Target Engagement, Pathway Inhibition, and Efficacy Of The Bruton’s Tyrosine Kinase (Btk) Inhibitor CC-292</i> , BLOOD 122(21):4169 (2013) (“Pierce”)
1022	Simon Rule, et al., <i>A Phase I Study Of The Oral Btk Inhibitor ONO-4059 In Patients With Relapsed/Refractory B-Cell Lymphoma</i> , BLOOD 122(21):4397 (2013) (“Rule”)
1023	Prosecution History of U.S. Patent No. 9,758,524
1024	U.S. Food and Drug Administration, <i>Good Review Practice: Clinical Review of Investigational New Drug Applications</i> (Dec. 2013) (“FDA 2013 Good Review Practice”)
1025	U.S. Patent No. 7,732,454 (“Verner”)
1026	International Conference on Harmonisation; Dose-Response Information to Support Drug Registration; Guideline; Availability, 59 Fed. Reg. 55,972 (Nov. 9, 1994)
1027	U.S. Food and Drug Administration, <i>Guidance for Industry - S9 Nonclinical Evaluation for Anticancer Pharmaceuticals</i> (March 2010) (“S9 Guidance”)
1028	U.S. Food and Drug Administration, <i>Guidance for Industry - Estimating the Maximum Safe Starting Dose in Initial Clinical Trials for Therapeutics in Adult Healthy Volunteers</i> (July 2005) (“MSSD Guidance”)
1029	Erica K. Evans, et al., <i>Inhibition of Btk with CC-292 Provides Early Pharmacodynamic Assessment of Activity in Mice and Humans</i> , J. PHARMACOLOGY AND EXPERIMENTAL THERAPEUTICS 346:219-228 (Aug. 2013) (“Evans”)

No.	Description
1030	Tjeerd Barf, et al., <i>Irreversible Protein Kinase Inhibitors: Balancing the Benefits and Risks</i> , J. MED. CHEM. 55:6243-62 (2012) (“Barf 2012”)
1031	Amit Mahipal, et al., <i>Risks and Benefits of Phase I Clinical Trial Participation</i> , CANCER CONTROL 21:193-99 (July 2014) (“Mahipal”)
1032	Sarah Brumskill, et al., <i>Conference Scene: Recent developments in the understanding and treatment of hematological malignancies</i> , INT’L J. HEMATOLOGIC ONCOLOGY, Vol. 2, No. 5, published online at https://doi.org/10.2217/ijh.13.52 (Oct. 8, 2013) (“Brumskill”)
1033	Toshio Yoshizawa, et al., <i>ONO-4059—a Potent and Selective Reversible Bruton’s Tyrosine Kinase (Btk) Inhibitor: Single Agent, Twice Daily (BD) Dosing and Dosing with Food Results in Sustained, High Trough Levels of ONO-4059, Translating into 100% Tumour Remission in a TMD-8 Xenograft Model</i> , BLOOD, 124(21):4502 (2014) (“Yoshizawa”)
1034	Plaintiffs’ Initial Infringement Contentions to Defendant Sandoz Inc., C.A. No. 22-154-GBW-SRF (Consolidated) (D. Del. Sept. 26, 2022)
1035	CALQUENCE® (acalabrutinib) Prescribing Information (2017)
1036	Jan de Jong, et al., <i>Effect of CYP3A perpetrators on ibrutinib exposure in healthy participants</i> , PHARMACOLOGY RESEARCH & PERSPECTIVES, Vol. 3, Issue 4 (2015) (“de Jong”)
1037	Dominique Levêque, <i>Evaluation of Fixed Dosing of New Anticancer Agents in Phase I Studies</i> , ANTICANCER RESEARCH 28:3075-78 (2008) (“Levêque”)
1038	ZYDELIG® (idelalisib) Prescribing Information (2014)
1039	TASIGNA® (nilotinib) Prescribing Information (2007)
1040	JAKAFI™ (ruxolitinib) Prescribing Information (2011)
1041	LYNPARZA™ (olaparib) Prescribing Information (2014)
1042	Betty Y. Chang, et al., <i>Egress of CD191CD51 cells into peripheral blood following treatment with the Bruton tyrosine kinase inhibitor ibrutinib in mantle cell lymphoma patients</i> , BLOOD 122(14):2142 (2013) (“Chang”)
1043	Yan Bao, et al., <i>Tyrosine Kinase Btk Is Required for NK Cell Activation</i> , J. Biological Chemistry 287(28):23769 (2012)

No.	Description
1044	Declaration Of Charles B. Klein In Support Of Motion For PHV Admission
1045	Declaration Of Eimeric Reig-Plessis In Support Of Motion For PHV Admission
1046	Complaint in <i>Acerta Pharma B.V. et al. v. Sandoz Inc.</i> , Case No. 1:22-cv-00164-GBW, Dkt. 1 (D. Del. Feb. 4, 2022)

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Respectfully submitted,

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