

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

DECLARATION OF JOHN P. FRUEHAUF, M.D., Ph.D.

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LIST OF CITED EXHIBITS

No.	Description
1001	U.S. Patent No. 10,272,083 to Hamdy et al. (the “’083 patent”)
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> , HAEMATOLOGICA 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)
1018	Akintunde Akinleye, et al., <i>Ibrutinib and novel BTK inhibitors in clinical development</i> , J. OF HEMATOLOGY & ONCOLOGY 6:59 (2013) (“Akinleye”)

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