

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

ONCUSP THERAPEUTICS SUB, INC.,
Petitioner,

v.

DAIICHI SANKYO CO LTD,
Patent Owner.

Case No. PGR2023-00037
Patent No. 11,446,386

**JOINT REQUEST TO FILE SETTLEMENT AGREEMENT AS BUSINESS
CONFIDENTIAL INFORMATION PURSUANT TO 35 U.S.C. § 327(b)**

LIST OF EXHIBITS

Exhibit No.	Description
1001	US Patent No. 11,446,386 to Atsuko Saito, et al., issued September 20, 2022 (“the ’386 Patent”)
1002	Prosecution History of the ’386 Patent
1003	Declaration of Stylianos Bournazos, Ph.D.
1004	<i>Curriculum Vitae</i> of Stylianos Bournazos, Ph.D.
1005	International PCT Application WO2016/024195A1 to Carl Bialucha, et al., published February 18, 2016
1006	U.S. Application Publication No. 2016/0317656A1 to Atsushi Urano et al., published November 3, 2016
1007	U.S. Application Publication No. 2016/0046720A1 to Hiromu Sato, et al., published February 18, 2016
1008	Mark L. Chiu, et al., <i>Antibody Structure and Function: The Basis for Engineering Therapeutics</i> , 8 ANTIBODIES 55 (2019)
1009	Inbal Sela-Culang, et al., <i>The Structural Basis of Antibody-Antigen Recognition</i> , 4 FRONTIERS IN IMMUNOLOGY, Oct. 8, 2013, at 1
1010	Charles A. Janeway et al., IMMUNOBIOLOGY: THE IMMUNE SYSTEM IN HEALTH AND DISEASE (Garland Publishing, 5th ed. 2001)
1011	Cristina Caldas, et al., <i>Humanization of the Anti-CD18 Antibody 6.7: An Unexpected Effect of a Framework Residue in Binding to Antigen</i> , 39 MOLECULAR IMMUNOLOGY 941 (2003)
1012	Vered Kunik, et al., <i>Structural Consensus Among Antibodies Defines the Antigen Binding Site</i> , 8 PLOS COMPUTATIONAL BIOLOGY, Feb. 2012, at 1
1013	Sanjib Bhattacharyya, et al., <i>Nanoconjugation Modulates the Trafficking and Mechanism of Antibody Induced Receptor Endocytosis</i> , 107 PROC. NAT. ACAD. SCI. USA 14541 (2010)
1014	Cecile Chalouni & Sophia Doll, <i>Fate of Antibody-Drug Conjugates in Cancer Cells</i> , 37 J. EXP. & CLINICAL CANCER RESEARCH, no. 20, 2018, at 1
1015	Christina Peters & Stuart Brown, <i>Antibody-Drug Candidates as Novel Anti-Cancer Chemotherapeutics</i> , 35 BIOSCIENCE REP. 4 (2015)

Exhibit No.	Description
1016	Madeleine K. Ramos, et al., <i>Valency of HER2 Targeting Antibodies Influences Tumor Cell Internalization and Penetration</i> , 20 MOLECULAR CANCER THERAPEUTICS 1956 (2021)
1017	Stephen A. Beers, et al., <i>Antigenic Modulation Limits the Efficacy of Anti-CD20 Antibodies: Implications for Antibody Selection</i> , 115 BLOOD 5191 (2010)
1018	Hilal A. Parray, et al., <i>Hybridoma Technology a Versatile Method for Isolation of Monoclonal Antibodies, its Applicability Across Species, Limitations, Advancement, and Future Perspectives</i> , 85 INT'L IMMUNOPHARMACOLOGY, May 27, 2020, at 1
1019	Phei Er Saw & Er-Wei Song, <i>Phage Display Screening of Therapeutic Peptide for Cancer Targeting and Therapy</i> , 10 PROTEIN & CELL 787 (2019)
1020	Thilo Riedl, et al., <i>High-Throughput Screening for Internalizing Antibodies by Homogeneous Fluorescence Imaging of a pH-Activated Probe</i> , 21 J. BIOMOLECULAR. SCREENING 12 (2016)
1021	Yutaka Shimoyama, et al., <i>Isolation and Sequence Analysis of Human Cadherin-6 Complementary DNA for the Full coding Sequence and Its Expression in Human Carcinoma Cells</i> , 55 CANCER RESEARCH 2206 (1995)
1022	Fabian Sievers, et al., <i>Fast, Scalable Generation of High-Quality Protein Multiple Sequence Alignments Using Clustal Omega</i> , 7 MOLECULAR SYSTEMS BIOLOGY, Oct. 11, 2011, at 1
1023	Veronique Giudicelli, et al., <i>IMGT/V-QUEST: IMGT Standardized Analysis of the Immunoglobulin (IG) and T Cell Receptor (TR) Nucleotide Sequences</i> , 6 COLD SPRING HARBOR PROTOCOLS, June 1, 2011, at 1
1024	Carien M. Niessen, et al., <i>Tissue Organization by Cadherin Adhesion Molecules: Dynamic Molecular and Cellular Mechanisms of Morphogenetic Regulation</i> , 91 PHYSIOLOGY REV. 691 (2011)
1025	Roger Paul, et al., <i>Cadherin-6: A New Prognostic Marker for Renal Cell Carcinoma</i> , 171 J. UROLOGY 97 (2004)
1026	Toru Shimazui, et al., <i>Expression of Cadherin-6 as a Novel Diagnostic Tool to Predict Prognosis of Patients with E-Cadherin-Absent Renal Cell Carcinoma</i> , 4 CLINICAL CANCER RESEARCH 2419 (1998)

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1027	Valentina Sancisi, et al., <i>Cadherin 6 is a New RUNX2 Target in TGF-β Signalling Pathway</i> , 8 PLoS ONE, Sept. 12, 2013, at 1
1028	Martin Kobel, et al., <i>Ovarian Carcinoma Subtypes are Different Diseases: Implications for Biomarker Studies</i> , 5 PLoS MEDICINE, Dec. 2, 2008, at 1
1029	Ming Meng, et al., <i>CDH6 as a Prognostic Indicator and Marker for Chemotherapy in Gliomas</i> , 13 FRONTIERS IN GENETICS, July. 22, 2022, at 1
1030	Brent A. Kochert, et al., <i>Hydrogen-Deuterium Exchange Mass Spectrometry to Study Protein Complexes</i> , in METHODS IN MOLECULAR BIOLOGY 1764 (Joseph A. Marsh ed., 2018)
1031	Jeffrey G. Mandell, et al., <i>Identification of Protein-Protein Interfaces by Decreased Amide Proton Solvent Accessibility</i> , 95 PROC. NAT. ACAD. SCI. USA 14705 (1998)
1032	Carl U. Bialucha, et al., <i>Discovery and Optimization of HKT288, a Cadherin-6-Targeting ADC for the Treatment of Ovarian and Renal Cancers</i> , 7 CANCER DISCOVERY 1030 (2017)
1033	Ruth Muchekeh, et al., <i>The Effect of Molecular Weight, PK, and Valency on Tumor Biodistribution and Efficacy of Antibody-Based Drugs</i> , 6 TRANSLATIONAL ONCOLOGY 562 (2013)
1034	Ben T. Ruddle, et al., <i>Characterization of Disulfide Bond Rebridged Fab-Drug Conjugates Prepared Using a Dual Maleimide Pyrrol benzodiazepine Cytotoxic Payload</i> , 14 CHEMMEDCHEM 1185 (2019)
1035	Lutz Riechmann, et al., <i>Reshaping Human Antibodies for Therapy</i> , 332 NATURE 323 (1988)
1036	Josee Golay, et al., <i>Role of Fc Core Fucosylation in the Effector Function of IgG1 Antibodies</i> , 13 FRONTIERS IN IMMUNOLOGY, June 30, 2022, at 1
1037	Christian Klein, et al., <i>Epitope Interactions of Monoclonal Antibodies Targeting CD20 and Their Relationship to Functional Properties</i> , 5 MABS 22 (2013)
1038	Prosecution History of U.S. Application No. 17/010,162
1039	Settlement Agreement FILED CONFIDENTIALLY
1040	Collateral Letter Agreement FILED CONFIDENTIALLY

Pursuant to 35 U.S.C. § 327(b) and 37 C.F.R. § 42.74(c), Petitioner OnCusp Therapeutics Sub, Inc. (“Petitioner”) and Daiichi Sankyo Co. LTD. (“Patent Owner”) (collectively “the Parties”) jointly request to file and treat the settlement agreement between the parties and the collateral letter agreement (the “Settlement Agreement”), as referenced in the Joint Motion to Terminate Proceedings Pursuant to 35 U.S.C. §327(a), as business confidential information. The Parties further jointly request that the confidential Settlement Agreement be kept separate from the file of the subject patent in the captioned proceeding and be made available only to Federal Government agencies on written request or to persons showing good cause. *See* 35 U.S.C. §327(b); 37 C.F.R. §42.74(c).

A true copy of the Settlement Agreement entered into between the Parties on December 15, 2023 has been submitted as Exhibits 1039 and 1040 with the Parties’ Joint Motion to Terminate. That Settlement Agreement contains business confidential information of both Parties. Additionally, the Parties have agreed to not disclose the terms of the Settlement Agreement. *See* Exhibit 1039 at §4.3(a).

Dated: December 20, 2023

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CERTIFICATE OF SERVICE

The undersigned hereby certifies that on December 20, 2023, the foregoing Joint Request to File Settlement Agreement as Business Confidential Information Pursuant to 35 U.S.C. § 327(b) was served by e-mail at the following email address:

Daiichi.OnCusp.PGR@weil.com

Dated: December 20, 2023

/s/ Ryan N. Miller

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Counsel for OnCusp Therapeutics Sub, LLC