UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

SAMSUNG BIOEPIS CO., LTD.,
Petitioner,

v.

ALEXION PHARMACEUTICALS, INC.
Patent Owner.

Case No. IPR2023-00933
Patent: 9,732,149

PATENT OWNER'S UPDATED EXHIBIT LIST

Exhibit No.	Description of Document
2000 to 2004	*Intentionally left blank*
2005	SOLIRIS® Label
2006	Dmytrijuk et al., FDA Report: Eculizumab (SOLIRIS®) for the Treatment of Patients with Paroxysmal Nocturnal Hemoglobinuria, THE ONCOLOGIST, 13:993 -1000 (2008)
2007	Janeway and Travers, *Immunobiology:* The Immune System in Health and Disease (Garland Science, 6thed. (2005))
2008	McCloskey *et al.,* Human Constant Regions Influence the Antibody Binding Characteristics of Mouse-Human Chimeric IgG Subclasses, IMMUNOLOGY, 88: 169-173 (1996)
2009	Torres *et al.,* The Immunoglobulin Heavy Chain Constant Region Affects Kinetic and Thermodynamic Parameters of Antibody Variable Region Interactions with Antigen, J. OF BIOL. CHEM., 282(18): 13917–27 (2007)
2010	Janda *et al.,* Ig Constant Region Effects on Variable Region Structure and Function, FRONT. MICROBIOL., 7(22): 1-10 (2016)
2011	Pritsch *et al.,* Can Immunoglobulin CH1 Constant Region Domain Modulate Antigen Binding Affinity of Antibodies?, J. CLIN. INVEST., 98(10): 2235-43 (1996)
2012	Pritsch *et al.,* Can Isotype Switch Modulate Antigen-Binding Affinity and Influence Clonal Selection?, EUR. J. IMMUNOL., 30: 3387-95 (2000)
2013	McLean *et al.,* Isotype Can Affect the Fine Specificity of an Antibody for a Polysaccharide Antigen, J. OF IMMUNOLOGY, 169: 1379–86 (2002)

2014	Greenspan et al., Complementarity, Specificity and the Nature of Epitopes and Paratopes in Multivalent Interactions, IMMUNOL. TODAY, 16(5): 226-30 (1995)
2015	Radbruch, *et al.,* Drastic Change in Idiotypic but Not Antigen-Binding Specificity of an Antibody by a Single Amino-Acid Substitution, NATURE, 315(6): 506-508 (1985)
2016	U.S. Patent No. 7,482,435, issued to Bowdish *et al.*
2017	Hawkins *et al.,* The Contribution of Contact and Non-contact Residues of Antibody in the Affinity of Biding to Antigen: The Interaction of Mutant D1.3 Antibodies with Lysozyme, J. MOL. BIO., 234: 958-964 (1993)
2018	Hawkins *et al.,* The Contribution of Contact and Non-contact Residues of Antibody in the Affinity of Biding to Antigen: The Interaction of Mutant D1.3 Antibodies with Lysozyme, J. MOL. BIO., 234: 958-964 (1993)
2019	Ricklin & Lambris, Complement-Targeted Therapeutics, NATURE BIOTECHNOLOGY, 25(11); 1265-1275 (2007)
2020	Alexion Press Release, Alexion's Soliris® Receives 2008 Prix Galien USA Award for Best Biotechnology Product, September 25, 2008, available at https://news.alexion.com/press-release/company-news/alexions-soliris-receives-2008-prix-galien-usa-award-best-biotechnology-p (last visited May 15, 2019)
2021	BusinessWire, Alexion's Soliris® Receives 2009 Prix Galien France for Most Innovative Drug for Rare Disease, June 10, 2009, available at https://www.businesswire.com/news/home/20090610005826/en/Alexions-Soliris®-Receives-2009-Prix-Galien-France (last visited May 15, 2019)
2022	Declaration of Arturo Casadevall, M.D., Ph.D. in IPR No. 2019-00741
2023	Curriculum Vitae of Arturo Casadevall, M.D., Ph.D. in IPR No. 2019-00741

2024 to 2025	*Intentionally left blank/Reserved*
2026	Declaration of Michel C. Nussenzweig, M.D., Ph.D.
2027	*Intentionally left blank/Reserved*
2028	Hill, et al., Erythropoietin treatment during complement inhibition with eculizumab in a patient with paroxysmal nocturnal hemoglobinuria, THE HEMATOLOGY JOURNAL, 31-33, 2007
2029	Points to Consider in the Manufacture and Testing of Monclonal Antibody Products for Human Use, U.S. Dept. of Health and Human Services, Food and Drug Admin., 1997
2030	3/16/2007 FDA Approves Alexion's Soliris™ for all Patients with PNH
2031	Janeway, et al., Immunobiology, The Immunse System in Health and Disease, Appendix I: Immunologists' Toolbox, 6th ed. 2005
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2036	Lo, Benny K., Antibody Engineering Methods and Protocols, METHODS IN MOLECULAR BIOLOGY, Vol. 248 2004
2037	Welt, et al., Phase I Study of Anticolon Cancer Humanized Antibody A33, CLINICAL CANCER RESEARCH, 2003
2038	Haller, et al., Safety Issues Specific to Clinical Development of Protein Therapeutics, NATURE PUBLISHING GROUP, 2008

2039	Torres, et al., Exchanging Murine and Human Immunoglobulin Constant Chains Affects the Kinetics and Thermodynamics of Antigen Binding and Chimeric Antibody Autoreactivity, PLOS ONE, 2007
2040	Torres, et al., Variable-Region-Identical Antibodies Different in Isotype Demonsrate Differences in Fine Specificity and Idiotype, JOURNAL OF IMMUNOLOGY, 2005
2041	*Intentionally left blank/Reserved*
2042	Mathieu, Barbara G., Clinical Testing of Biologically Derived Therapeutics, Biologics Development: A Regulatory Overview, 3d ed., 2004
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2044	Chadd, et al., Therapeutic antibody expression technology, 2001
2045	2007 USP Dictionary of USAN and International Drug Names
2046	Guidelines on the Use of International Nonproprietary Names (INNs) for Pharmaceutical Substances, 1997
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2048	*Intentionally left blank/Reserved*
2049	HemOnc Today, Eculizumab's triumph over PNH, https://www.healio.com/hematology-oncology/news/print/hemonc-today/%7B01f97d7b-36b4-4462-aab4-02918370caa1%7D/eculizumabs-triumph-over-pnh (Aug. 25, 2008)
2050	Fatimah Al-Ani et al., "Eculizumab in the management of paroxysmal nocturnal hemoglobinuria: patient selection and special considerations, Ther. Clin. Risk Manag., 12:1161-1170 (2016)
2051	Foote, Jefferson and Winter, Greg, "Antibody Framework Residues Affecting the Conformation of the Hypervariable Loops," J. Mol. Biol., 224:487-449 (1992)

2052	Xiang, Jim et al., Framework Residues 71 and 93 of the Chimeric B72.3 Antibody are Major Determinants of the Conformation of Heavy-chain Hypervariable Loops," J. Mol. Biol. 253:385-390 (1995)
2053	June 2019 Soliris® Label
2054	Alexion Press Release, "Alexion Pharmaceuticals Submits Biologics License Application for Soliris ™ (eculizumab)," (Sept. 20, 2006)
2055	Alexion Press Release, "Alexion Submits Market Authorization Application for Soliris ™ (eculizumab) in the Treatment of Paroxysmal Nocturnal Hemoglobinuria to the European Medicines Agency," (Sept. 26, 2006)
2056 to 2074	*Intentionally left blank/Reserved*
2075	GenScript, "Final Report- Antibody Full Length Sequencing of Hybridoma 5G1.1 T175," Order Number: U856UEK140-1 (Nov. 15, 2019)
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2086	Stebbings, R., et al., "After TGN1412: Recent developments in cytokine release assays," J. of Immunotoxicology, 10(1): 75-82 (2013)
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2091	Harlow and Lane, Chapter 15: Antibody Molecules, in Antibodies, A Laboratory Manual, 622-25 (1988)

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2098	Harlow and Lane, Chapter 2:Antibody Molecules, in *Antibodies, A Laboratory Manual* (1988)
2099	*Intentionally left blank*
2100	Rother, R., *et al.,* "Discovery and development of the complement inhibitor eculizumab for the treatment of paroxysmal nocturnal hemoglobinuria," *Nature Biotechnology* 25: 1256-1264 (2007)
2101	Prosecution History for U.S. Patent No. 9,718,880 B2, submitted by Petitioner Samsung BioEpis Co., Ltd. in IPR2023-00998 as EX1002
2102	Prosecution History for U.S. Patent No. 10,590,189 B2, submitted by Petitioner Samsung BioEpis Co., Ltd. in IPR2023-01069 as EX1002
2103	Prosecution History for U.S. Patent No. 9,725,504 B2, submitted by Petitioner Samsung BioEpis Co., Ltd. in IPR2023-00999 as EX1002
2104	Deposition Transcript of Jeffrey V. Ravetch, M.D., Ph.D. (Feb. 23, 2024)
2105	Declaration of Arturo Casadevall, M.D., Ph.D., 2024
2106 to 2107	*Intentionally left blank/Reserved*
2108	Deposition Transcript of Jeffrey V. Ravetch, M.D., Ph.D. (July 16, 2024)

Respectfully submitted,

CAHILL, GORDON & REINDEL LLP

/Gerald J. Flattmann, Jr./

Gerald J. Flattmann, Jr. (Reg. No. 37,324)
Attorneys for Patent Owner, Alexion Pharmaceuticals, Inc.

Date: July 26, 2024

32 Old Slip
New York, NY 10005
(212) 701-3645
gflattmann@cahill.com

CERTIFICATION OF SERVICE

The undersigned hereby certifies that the foregoing **PATENT OWNER'S UPDATED EXHIBIT LIST** were served via electronic mail on July 26, 2024, in their entirety on the following:

Michelle S. Rhyu (Reg. No. 41,268
rhyums@cooley.com
Daniel J. Knauss (Reg. No. 56,393)
dknauss@cooley.com
Cooley LLP
1299 Pennsylvania Ave. NW, Suite 700
Washington DC 20004

CAHILL GORDON & REINDEL LLP

/Gerald J. Flattmann, Jr./

Gerald J. Flattmann, Jr. (Reg. No. 37,324)
Attorneys for Patent Owner, Alexion Pharmaceuticals, Inc.

Date: July 26, 2024

32 Old Slip
New York, NY 10005
(212) 701-3645
gflattmann@cahill.com