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. IPR2023-01069
Patent: 10,590,189

PATENT OWNER'S UPDATED EXHIBIT LIST

Exhibit No.	Description of Document
2001 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	*Intentionally left blank*
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 IPR2019-00739
2023	Curriculum Vitae of Arturo Casadevall, M.D., Ph.D. in IPR2019-00739

2024	Declaration of Bernhardt L. Trout, Ph.D. in IPR2019-00739
2025	Curriculum Vitae of Bernhardt L. Trout, Ph.D. in IPR2019-00739
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
2032	Deposition Transcript of Joseph P. Balthasar, Ph.D., Amgen, Inc. v. Alexion Pharmaceuticals, Inc., IPR No. 2019-00740 (Oct. 23, 2019)
2033	Kim, et al., Antibody Engineering for the Development of Therapeutic Antibodies, MOLECULES AND CELLS, Vol. 20, No. 1, pp. 17-29, 2005
2034	Hwang, et al., Immunogenicity of engineered antibodies, SCIENCE DIRECT, 17 Jan. 2005
2035	Shephered, et al., Monoclonal Antibodies, Oxford University Press, pp. 58-5 (Appendix) 2000
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
2043	Andersen, et al., Production technologies for monoclonal antibodies and their fragments, SCIENCE DIRECT, 2004
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
2047	McClean, et al., A point mutation in the CH3 domain of huan IgG3 inhibits antibody secretion without affecting antigen specificity, MOLECULAR IMMUNOLOGY, 2005
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 Coformation 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)
2076 to 2078	*Intentionally left blank/Reserved*
2079	Chang, Byeong S. and Hershenson, Susan, "Practical Approaches to Protein Formulation Development," Pharmaceutical Biotechnology Vol. 13, 1-25 (2002)
2080	Wang, Wei, "Instability, stabilization, and formulation of liquid protein pharmaceuticals," International Journal of Pharmaceutics, 185:129-188 (April 28, 1999)
2081	Hermeling, S. et al., "Structure-Immunogenicity Relationships of Therapeutic Proteins, " Pharmaceutical Research, 12:6, 897-903 (June 2004)

2082	Frokjaer, Sven and Otzen, Daniel E., "Protein Drug Stability: A Formulation Challenge," Nature Reviews, Drug Discovery, 4:298-306 (April 2005)
2083	Rosenberg, Amy S., "Effects of Protein Aggregates: An Immunologic Perspective," AAPS Journal 8, Article 59, pp. E501-E507 (Aug. 4, 2006)
2084	ICH Topic Q5C, "Quality of Biotechnological Products: Stability Testing of Biotechnological/Biological Products," European Medicines Agency (July 1996)
2085	U.S. Depart of Health and Human Services, FDA, "Guidance for Industry Q1A(R2) Stability Testing of New Drug Substances and Products," ICH Rev. 2 (Nov. 2003)
2086	Stebbings, R., et al., “After TGN1412: Recent developments in cytokine release assays,” J. of Immunotoxicology, 10(1): 75-82 (2013)
2087	*Intentionally left blank/Reserved*
2088	Amgen Biosimilar Pipeline Approved Products (2019)
2089	Generium Pharmaceutical, “Elizaria” Product (2019)
2090	Samsung Bioepis – Biosimilar candidates and Novel biologic (2019)
2091	Harlow and Lane, Chapter 15: Antibody Molecules, in Antibodies, A Laboratory Manual, 622-25 (1988)
2092 to 2097	*Intentionally left blank/Reserved*
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	Deposition Transcript of Cindy Ippoliti, Pharm.D. (Feb. 20, 2024)
2107	Declaration of Bernhardt L. Trout, Ph.D., 2024
2108	Deposition Transcript of Jeffrey V. Ravetch, M.D., Ph.D. (July 16, 2024)

Respectfully submitted,

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CERTIFICATION OF SERVICE

The undersigned hereby certifies that the foregoing **PATENT OWNER'S UPDATED EXHIBIT LIST** were served via electronic mail on July 29, 2024, in their entirety on the following:

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