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 IPR2023-00998
U.S. Patent No. 9,718,880 B2

PETITIONER'S UPDATED EXHIBIT LIST

Exhibit No.	Description of Document
1001	U.S. Patent No. 9,718,880 B2 issued to Leonard Bell et al. (filed May 6, 2016, issued Aug. 1, 2018) ("'880 patent")
1002	Prosecution History for U.S. Patent No. 9,718,880 B2
1003	Declaration of Jeffrey V. Ravetch, M.D., Ph.D.
1004	U.S. Patent Application Publication No. 2003/0232972 A1 issued to Katherine S. Bowdish et al. (filed Dec. 2, 2002, published Dec. 18, 2003) ("Bowdish")
1005	U.S. Patent No. 6,355,245 B1 issued to Mark J. Evans et al. (filed June 7, 1995, issued Mar. 12, 2002) ("Evans")
1006	John P. Mueller et al., *Humanized Porcine VCAM-Specific Monoclonal Antibodies with Chimeric IgG2/G4 Constant Regions Block Human Leukocyte Binding to Porcine Endothelial Cells*, 34 Molecular Immunology 441 (1997) ("Mueller 1997")
1007	U.S. Patent Application Publication No. 2005/0191298 A1 issued to Leonard Bell et al. (filed Feb. 3, 2005, published Sept. 1, 2005) ("Bell")
1008	Paul J. Tacken et al., *Effective induction of naive and recall T-Cell responses by targeting antigen to human dendritic cells via a humanized anti–DC-SIGN antibody*, 106 Blood 1278 (2005) ("Tacken")
1009	World Intellectual Property Organization International Publication No. WO 97/11971 issued to John P. Mueller et al. (filed Sept. 27, 1996, published Apr. 3, 1997) ("Mueller PCT")
1010	Thomas C. Thomas et al., *Inhibition of Complement Activity By Humanized Anti-C5 Antibody and Single-Chain Fv*, 33 Molecular Immunology 1389 (1996) ("Thomas")

Exhibit No.	Description of Document
1011	Peter Hillmen et al., *Effect of Eculizumab on Hemolysis and Transfusion Requirements in Patients with Paroxysmal Nocturnal Hemoglobinuria*, 350 N. Engl. J. Med. 552 (2004) ("Hillmen 2004")
1012	Anita Hill et al., *Abstract# 2823: Sustained Control of Hemolysis and Symptoms and Reduced Transfusion Requirements over a Period of 2 Years in Paroxysmal Nocturnal Hemoglobinuria (PNH) with Eculizumab Therapy*, 104 Blood 772a (2004) ("Hill 2004")
1013	Anita Hill et al., *Sustained response and long-term safety of eculizumab in paroxysmal nocturnal hemoglobinuria*, 106 Blood 2559 (2005) ("Hill 2005")
1014	Peter Hillmen et al., *The Complement Inhibitor Eculizumab in Paroxysmal Nocturnal Hemoglobinuria*, 355 N. Engl. J. Med. 1233 (2006) ("Hillmen 2006")
1015	Neal S. Young et al., *Abstract# 971: Safety and Efficacy of the Terminal Complement Inhibitor Eculizumab in Patients with Paroxysmal Nocturnal Hemoglobinuria: Interim Shepherd Phase III Clinical Study*, 108 Blood 290a (2006) ("Young")
1016	Peter Hillmen et al., *Abstract# 154: Eculizumab, a C5 Complement-Blocking Antibody, Abolishes Hemolysis and Renders Hemolytic Patients with Paroxysmal Nocturnal Hemoglobinuria (PNH) Transfusion Independent*, 100 Blood 44a (2002) ("Hillmen 2002")
1017	Peter Hillmen et al., *Abstract# 1858: Eculizumab, a C5 Complement-Blocking Antibody, Controls Hemolysis in Paroxysmal Nocturnal Hemoglobinuria (PNH) with Responses Maintained Over a Prolonged Period of Therapy*, 102 Blood 509a (2003) ("Hillmen 2003")
1018	Excerpts from *Recommended INN List 49, International Nonproprietary Names for Pharmaceutical Substances*, 17 WHO Drug Information 115, World Health Organization (2003)
1019	*Guidelines on the Use of International Nonproprietary Names (INNs) for Pharmaceutical Substances*, Programme on International

Exhibit No.	Description of Document
	Nonproprietary Names (INN), Division of Drug Management & Policies, World Health Organization, Geneva (1997)
1020	Alexion Press Release, *Alexion Issued Key C5 Complement Inhibitor Patent for Inflammatory Diseases* (Mar. 15, 2002), https://web.archive.org/web/20030621141230/http://www.alxn.com/products/index.cfm
1021	World Intellectual Property Organization International Patent Publication No. WO 2005/007809 A2 issued to Russell P. Rother et al. (filed May 28, 2004, published Jan. 27, 2005)
1022	World Intellectual Property Organization International Patent Publication No. WO 2005/110481 A2 issued to Russell P. Rother et al. (filed May 16, 2005, published Nov. 24, 2005)
1023	Mariana Kaplan, *Eculizumab Alexion*, 3 Curr. Opin. Investig. Drugs 1017 (2002)
1024	*Amgen Inc. v. Alexion Pharmaceuticals, Inc.*, IPR2019-00740, Paper 15, Decision – Institution of *Inter Partes* Review (PTAB Aug. 30, 2019)
1025	*Amgen Inc. v. Alexion Pharmaceuticals, Inc.*, IPR2019-00740, Paper 22, Patent Owner Response Pursuant to 37 C.F.R. § 42.120 (PTAB Nov. 22, 2019)
1026	*Amgen Inc. v. Alexion Pharmaceuticals*, IPR2019-00740, Paper 48, Termination – Due to Settlement After Institution of Trial (PTAB June 1, 2020)
1027	Opposition File History for European Patent No. 1 720 571 B1
1028	File History for European Patent No. 3 167 888
1029	Excerpt from the File History for U.S. Patent Application No. 11/127,438, Amendment in Response to Non-Final Office Action (Aug. 2, 2011)

Exhibit No.	Description of Document
1030	Application for Extension of Patent Term under 35 U.S.C. § 156 and 37 CFR § 1.740, U.S. Patent No. 6,355,245, Alexion Pharmaceuticals (May 11, 2007)
1031	Certificate Extending Patent Term, U.S. Patent No. 6,355,245 (June 11, 2010)
1032	Excerpt from the File History of U.S. Patent No. 10,590,189, Information Disclosure Statement by Applicant, considered by Examiner James L Rogers, May 31, 2019
1033	Esther M. Yoo et al., *Human IgG2 Can Form Covalent Dimers*, 170 J. Immunol. 3134 (2003) ("Yoo 2003")
1034	Excerpt from the File History of U.S. Patent No. 10,590,189, Non-Final Rejection, mailed June 11, 2019
1035	Excerpt from the File History of U.S. Patent No. 10,590,189, Notice of Allowance, mailed Jan. 22, 2020
1036	Excerpt from the File History of U.S. Patent No. 10,590,189, Amendment in Response to Non-Final Office Action Under 37 C.F.R. § 1.111, mailed Dec. 11, 2019
1037	Jette Wypych et al., *Human IgG2 Antibodies Display Disulfide-mediated Structural Isoforms*, 283 J. Biol. Chem. 16194 (2008) ("Wypych")
1038	Stylianos Bournazos et al., *Fc-optimized* antibodies *elicit CD8 immunity to viral respiratory infection*, 588 Nature 485 (2020) ("Bournazos 2020")
1039	Stylianos Bournazos et al., *Human IgG Fc domain engineering enhances antitoxin neutralizing antibody activity*, 124 J. Clinical Investigation 725 (2014) ("Bournazos 2014")

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1040	Lucie Baudino et al., *Impact of a Three Amino Acid Deletion in the CH2 Domain of Murine IgG1 on Fc-Associated Effector Functions*, 181 J. Immunology 4107 (2008)
1041	Toshiyuki Takai et al., *FcR γ Chain Deletion Results in Pleiotropic Effector Cell Defects*, 76 Cell 519 (1994)
1042	Falk Nimmerjahn & Jeffrey V. Ravetch, *Fcγ receptors as regulators of immune responses*, 8 Nat. Rev. Immunol. 34 (2008)
1043	Jeffrey V. Ravetch & Jean-Pierre Kinet, *Fc Receptors*, 9 Annu. Rev. Immunol. 457 (1991)
1044	U.S. Patent Application Publication No. 2005/0271660 A1 issued to Yi Wang (filed May 11, 2005, published Dec. 8, 2005) ("Wang")
1045	Charles A. Janeway, Jr. et al., *Chapter 1: Basis Concepts in Immunology*, and *Chapter 3: Antigen Recognition by B-cell and T-cell Receptors*, Immunobiology: the immune system in health and disease, pp. 1-34, 93-122 (5th ed. 2001)
1046	Excerpts from Pei-Show Juo, Ph.D., Concise Dictionary of Biomedicine and Molecular Biology (2nd ed. 2001)
1047	Tina Völkel et al., *Optimized linker sequences for the expression of monomeric and dimeric bispecific single-chain diabodies*, 14 Protein Engineering 815 (2001) ("Völkel")
1048	Evelyn D. Lobo et al., *Antibody Pharmacokinetics and Pharmacodynamics*, 93 Journal of Pharmaceutical Sciences 2645 (2004) ("Lobo 2004")
1049	Neil S. Lipman et al., *Monoclonal Versus Polyclonal Antibodies: Distinguishing Characteristics, Applications, and Information Resources*, 46 ILAR Journal 258 (2005) ("Lipman 2005")

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1050	Benny K.C. Lo, *Chapter 7: Antibody Humanization by CDR Grafting*, Methods in Molecular Biology, Vol. 248: Antibody Engineering: Methods and Protocols, pp. 135-159 (2004) ("Lo 2004")
1051	Lutz Riechmann et al., *Reshaping human antibodies for therapy*, 332 Nature 323 (1988) ("Riechmann")
1052	Janice M. Reichert, *Marketed therapeutic antibodies compendium*, 4 mAbs 413 (2012) ("Reichert")
1053	Bruce Alberts et al., *Chapter 12: Intracellular Compartments and Protein Sorting*, Molecular Biology of the Cell, pp. 551-98 (1994)
1054	Elisabeth E. Adderson et al*., Immunoglobulin Light Chain Variable Region Gene Sequences for Human Antibodies to Haemophilus influenzae Type b Capsular Polysaccharide Are Dominated by a Limited Number of V_κ and V_λ Segments and VJ Combinations*, 89 J Clin. Invest. 729 (1992)
1055	Genentech, Inc., Avastin 2004 Package Insert, available at https://www.accessdata.fda.gov/drugsatfda_docs/label/2004/125085lbl.pdf
1056	Millennium, Campath 2001 Package Insert, available at https://www.accessdata.fda.gov/drugsatfda_docs/label/2001/alemmil050701LB.htm
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1060	Genentech, Inc., Rituxan 1997 Package Insert, available at https://www.accessdata.fda.gov/drugsatfda_docs/label/1997/ritugen112697-lab.pdf
1061	Ann L. Daugherty & Randall J. Mrsny, *Formulation and delivery issues for monoclonal antibody therapeutics*, 58 Advanced Drug Delivery Reviews 686 (2006)
1062	Declaration of Cindy Ippoliti, Pharm.D.
1063	Note for Guidance on Excipients, Antioxidants and Antimicrobial Preservatives in the Dossier for Application for Marketing Authorisation of a Medicinal Product, European Agency for the Evaluation of Medicinal Products (2003)
1064 - 1100	*Reserved*
1101	Deposition of Arturo Casadevall, Jan. 24, 2020
1102	*Reserved*
1103	Reply Declaration of Jeffrey V. Ravetch, M.D., Ph.D.

Dated: June 10, 2024

Respectfully submitted,

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CERTIFICATE OF SERVICE

I hereby certify, pursuant to 37 C.F.R. Section 42.6, that a complete copy of the attached **PETITIONER'S UPDATED EXHIBIT LIST** and related documents, are being served via electronic mail on June 10, 2024, upon Patent Owner by serving Patent Owner's counsel of record in this proceeding as follows:

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