

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

SAMSUNG BIOEPIS CO., LTD.,
Petitioner,

v.

REGENERON PHARMACEUTICALS, INC.,
Patent Owner.

Case IPR2023-00442

U.S. Patent No. 10,130,681

PETITIONER'S UPDATED EXHIBIT LIST

TABLE OF EXHIBITS

Exhibit	Description
1001	U.S. Patent No. 10,130,681 B2 (“’681 patent”)
1002	Expert Declaration of Dr. Edward Chaum in Support of Petition for <i>Inter Partes</i> Review of Patent No. 10,130,681, dated January 5, 2023 (“Chaum Decl.”)
1003	Edward Chaum <i>Curriculum Vitae</i>
1004	Final Written Decision in <i>Mylan Pharmaceuticals Inc. v. Regeneron Pharmaceuticals, Inc.</i> , IPR2021-00881 (Paper 94) (“’338 FWD”)
1005	U.S. Dep’t Health & Human Servs., Nat’l Inst. Health, Nat’l Eye Inst., Age-Related Macular Degeneration: What You Should Know (Sept. 2015), https://www.nei.nih.gov/sites/default/files/health-pdfs/WYSK_AMD_English_Sept2015_PRINT.pdf (“NIH AMD”)
1006	Dixon JA, Oliver SC, Olson JL, Mandava N. VEGF Trap-Eye for the treatment of neovascular age-related macular degeneration. <i>Expert Opin Investig Drugs</i> . 2009;18(10):1573-1580. (“Dixon”)
1007	Press Release, Regeneron, Enrollment Completed in Regeneron and Bayer HealthCare Phase 3 Studies of VEGF Trap-Eye in Neovascular Age-Related Macular Degeneration (Wet AMD) (Sept. 14, 2009), https://newsroom.regeneron.com/node/10806/pdf (“Regeneron September 14, 2009 Press Release”)
1008	Halpern MT, Schmier JK, Covert D, Venkataraman K. Resource utilization and costs of age-related macular degeneration. <i>Health Care Financ Rev</i> . 2006;27(3):37-47. (“Halpern 2006”).
1009	Holash J, Davis S, Papadopoulos N, et al. VEGF-Trap: a VEGF blocker with potent antitumor effects. <i>Proc Natl Acad Sci U S A</i> . 2002;99(17):11393-11398. (“Holash”)
1010	Rudge JS, Thurston G, Davis S, et al. VEGF trap as a novel antiangiogenic treatment currently in clinical trials for cancer and eye diseases, and VelociGene- based discovery of the next generation of angiogenesis targets. <i>Cold Spring Harb Symp Quant Biol</i> . 2005;70:411-418 (“Rudge 2005”)
1011	Gomez-Manzano C, Holash J, Fueyo J, et al. VEGF Trap induces antiglioma effect at different stages of disease. <i>Neuro Oncol</i> . 2008;10(6):940-945. (“Gomez-Manzano”)
1012	Aflibercept: AVE 0005, AVE 005, AVE0005, VEGF Trap - Regeneron, VEGF Trap (R1R2), VEGF Trap-Eye. <i>Drugs R D</i> . 2008;9(4):261-269. (“Adis”)

1013	U.S. Patent No. 7,531,173 (“173 patent”)
1014	Rudge JS, Holash J, Hylton D, et al. VEGF Trap complex formation measures production rates of VEGF, providing a biomarker for predicting efficacious angiogenic blockade. <i>Proc Natl Acad Sci U S A</i> . 2007;104(47):18363-18370. (“Rudge 2007”)
1015	Li E, Donati S, Lindsley KB, Krzystolik MG, Virgili G. Treatment regimens for administration of anti-vascular endothelial growth factor agents for neovascular age-related macular degeneration. <i>Cochrane Database Syst Rev</i> . 2020;5(5):CD012208. (“Li 2020”)
1016	Heier JS, Brown DM, Chong V, et al. Intravitreal aflibercept (VEGF trap-eye) in wet age-related macular degeneration. <i>Ophthalmology</i> . 2012;119(12):2537-2548. (“Heier 2012”)
1017	Brown DM, Michels M, Kaiser PK, et al. Ranibizumab versus verteporfin photodynamic therapy for neovascular age-related macular degeneration: Two-year results of the ANCHOR study. <i>Ophthalmology</i> . 2009;116(1):57-65.e5. (“Brown 2009”)
1018	Martin DF, Maguire MG, Fine SL, Ying GS, Jaffe GJ, Grunwald JE, et al, Comparison of Age-Related Macular Degeneration Treatments Trial (CATT) Research Group. Ranibizumab and bevacizumab for treatment of neovascular age-related macular degeneration: two-year results. <i>Ophthalmology</i> 2012; 119(7):1388-98 (“Martin”)
1019	Heier JS, Boyer D, Nguyen QD, Marcus D, Roth DB, Yancopoulos G, et al. The 1-year results of CLEAR-IT 2, a phase 2 study of vascular endothelial growth factor trap-eye dosed as-needed after 12-week fixed dosing. <i>Ophthalmology</i> 2011; 118(6):1098-106 (“Heier 2011”)
1020	Chakravarthy U, Harding SP, Rogers CA, Downes SM, Lotery AJ, Wordsworth S, et al, Inhibition of VEGF in Age-related choroidal Neovascularization (IVAN) Study Investigators. Ranibizumab versus bevacizumab to treat neovascular age-related macular degeneration: one-year findings from the IVAN randomized trial. <i>Ophthalmology</i> 2012; 119(7):1399-411 (“Chakravarthy 2012”)
1021	Rosenfeld PJ, Brown DM, Heier JS, Boyer DS, Kaiser PK, Chung CY, et al. Ranibizumab for neovascular age-related macular degeneration. <i>New England Journal of Medicine</i> 2006; 355(14):1419-31 (“Rosenfeld”)
1022	Heimann, H. (2007). Chapter 5 Intravitreal Injections: Techniques and Sequelae. In: Holz, F.G., Spaide, R.F. (eds) <i>Medical Retina</i> .

	Essentials in Ophthalmology. Springer, Berlin, Heidelberg. (“Heimann”)
1023	Uveitis Fact Sheet by Prevent Blindness available at: https://preventblindness.org/wp-content/uploads/2021/06/FS119-Uveitisshort.pdf
1024	Hashmi MF, Gurnani B, Benson S. Conjunctivitis. [Updated 2022 Dec 6]. In: StatPearls [Internet]. Treasure Island (FL): StatPearls Publishing; 2022 Jan-. Available at: https://www.ncbi.nlm.nih.gov/books/NBK541034/
1025	Certified Prosecution History of U.S. Patent No. 10,130,681 B2 (“’681 patent PH”)
1026	Lucentis ® Original Approved Labeling (2006), available at: https://www.accessdata.fda.gov/drugsatfda_docs/nda/2006/125156s0000_Lucentis_Prntlbl.pdf
1027	Prosecution History of U.S. Patent No. 9,254,338 (“’338 patent PH”)
1028	U.S. Patent No. 9,254,338 (“’338 patent”)
1029	U.S. Patent No. 9,669,069 (“’069 patent”).
1030	Joint Claim Construction Chart (Dkt. 102) filed in <i>Regeneron Pharmaceuticals, Inc. v. Mylan Pharmaceuticals Inc.</i> , NDWV-1-22-cv-00061 (“Mylan Litigation CC Chart”)
1031	CATT Patient Eligibility Criteria (July 13, 2010), available at: https://web.archive.org/web/20100713035617/http://www.med.upenn.edu/cpob/studies/documents/CATTeligibilityCriteria_000.pdf (“CATT Study”)
1032	Ranibizumab Injections to Treat Macular Telangiectasia Without New Blood Vessel Growth (NCT00685854) (May 24, 2008), available at: https://clinicaltrials.gov/ct2/history/NCT00685854?V1=View#StudyPageTop (“MACTEL Study”)
1033	Ranibizumab Injections to Treat Macular Telangiectasia Without New Blood Vessel Growth (NCT00685854) (November 7, 2008), available at: https://web.archive.org/web/20081107014243/https://clinicaltrials.gov/ct2/show/NCT00685854 (“MACTEL Study Wayback Machine”)
1034	Regillo CD, Brown DM, Abraham P, et al. Randomized, double-masked, sham-controlled trial of ranibizumab for neovascular age-

	related macular degeneration: PIER Study year 1. Am J Ophthalmol. 2008;145(2):239-248. (“PIER Study”).
1035	Comparison of Age-related Macular Degeneration Treatments Trials: Lucentis-Avastin Trial (NCT00593450), available at: https://clinicaltrials.gov/ct2/show/NCT00593450
1036	U.S. Patent No. 7,374,758 (“758 patent”)
1037	U.S. Patent Application Publication No. 2006/0217311 A1 (“Dix”)
1038	W.H. Brown et al., Polypeptides and Proteins, Chapter 27.3, 1075–96, in ORGANIC CHEMISTRY (Fourth Ed.) (2005) (“Brown”)
1039	American Academy of Ophthalmology, “What is a Slit Lamp”, available at: https://www.aao.org/eye-health/treatments/what-is-slit-lamp
1040	Glenn J. Jaffe, Paul Ashton, P. Andrew Pearson, Intraocular Drug Delivery (2006) (“Jaffe”).
1041	Steps for a Safe Intravitreal Injection Technique (2009), available at: https://www.retinalphysician.com/issues/2009/july-aug/steps-for-a-safe-intravitreal-injection-technique
1042	Press Release, Regeneron and Bayer HealthCare Announce Encouraging 32-Week Follow-Up Results from a Phase 2 Study of VEGF Trap-Eye in Age-Related Macular Degeneration (April 28, 2008), https://newsroom.regeneron.com/node/10566/pdf (“Regeneron April 28, 2008 Press Release”)
1043	Using the Wayback Machine, available at: https://help.archive.org/help/using-the-wayback-machine/
1044	Ranibizumab Injections to Treat macular Telangiectasia Without New Blood Vessel Growth (NCT00685854) and Glossary, available at: https://clinicaltrials.gov/ct2/show/NCT00685854 (“NCT00685854”).
1045	History of Changes for Study: NCT00685854, available at: https://clinicaltrials.gov/ct2/history/NCT00685854
1046	Final Written Decision in <i>Mylan Pharmaceuticals Inc. v. Regeneron Pharmaceuticals, Inc.</i> , IPR2021-00880 (Paper 89) (“’069 FWD”)
1047	Institution Decision in <i>Mylan Pharmaceuticals Inc. v. Regeneron Pharmaceuticals, Inc.</i> , IPR2021-00880 (Paper 21) (“’069 Institution Decision”)
1048	The Expert Opinion on Investigational Drugs journal page listing an online publication date of August 20, 2009 for Dixon, available at: https://www.tandfonline.com/doi/abs/10.1517/13543780903201684?journalCode=ieid20 .

1049	ClinicalTrials.gov Background, available at: https://clinicaltrials.gov/ct2/about-site/background
1050	ClinicalTrials.gov About the Results Database, available at: https://clinicaltrials.gov/ct2/about-site/results
1051	ClinicalTrials.gov How to Read a Study Record, available at: https://clinicaltrials.gov/ct2/help/how-read-study
1052	American Journal of Ophthalmology entry for the PIER Study showing a publication date of December 3, 2007, available at: https://www.ajo.com/article/S0002-9394(07)00881-1/fulltext
1053	History of Changes for Study: A Study of rhuFab V2 (Ranibizumab) in Subjects With Subfoveal Choroidal Neovascularization Secondary to Age-Related Macular Degeneration (AMD) (NCT00090623), available at: https://clinicaltrials.gov/ct2/history/NCT00090623?V_1=View#StudyPageTop .
1054	Expert Declaration of Lucian V. Del Priore, M.D., Ph.D. submitted in <i>Mylan Pharmaceuticals Inc. v. Regeneron Pharmaceuticals, Inc.</i> , IPR2021-00881 as Exhibit 2048.
1055	August 10, 2022 Record of Oral Hearing in <i>Mylan Pharmaceuticals Inc. v. Regeneron Pharmaceuticals, Inc.</i> , IPR2021-00880, 00881
1056	File History of U.S. Patent No. 7,374,758 B2, 12/22/2011 Patent Term Extension Application (“758 FH, 12/22/2011 PTE”)
1057	Regeneron Pharm., Inc., Quarterly Report (Form 10-Q) (Sept. 30, 2009) (“Regeneron 10-Q (2009)”)
1058	<i>Inter Partes</i> Review Petition by Mylan Pharmaceuticals Inc. filed in <i>Mylan Pharmaceuticals Inc. v. Regeneron Pharmaceuticals, Inc.</i> , IPR2022-01225.
1059	Jager RD, Aiello LP, Patel SC, Cunningham ET Jr. Risks of intravitreal injection: a comprehensive review. <i>Retina</i> . 2004;24(5):676-698. (“Jager”)
1060	Complaint by Regeneron Pharmaceuticals, Inc. filed in <i>Regeneron Pharmaceuticals, Inc. v. Mylan Pharmaceuticals Inc.</i> , NDWV-1-22-cv-00061, dated August 2, 2022.
1061	Purple Book Patent List for Eylea, available at: https://purplebooksearch.fda.gov/patent-list
1062	Eylea Label 2011 available at: https://www.accessdata.fda.gov/drugsatfda_docs/nda/2011/125387Orig1s000Lbl.pdf

1063	Overview of Uveitis published by National Health Service, available at: https://www.nhs.uk/conditions/uveitis/
1064	Board's May 11, 2023 Email
1065	Declaration of Zachariah Summers in Support of Motion for Admission <i>Pro Hac Vice</i>
1066	Declaration of Elliot Choi in Support of Motion for Admission <i>Pro Hac Vice</i>
1067	Declaration of Sarah M. Cork in Support of Motion for Admission <i>Pro Hac Vice</i>
1068	Final Written Decision in <i>Mylan Pharmaceuticals Inc. v. Regeneron Pharmaceuticals, Inc.</i> , IPR2022-01225 [Paper 96] (“’681 FWD”)
1069	Videotaped Deposition Transcript of Diana Do, M.D. dated June 2, 2023, submitted in IPR2022-01225 and IPR2022-01226 on June 28, 2023 [Ex. 1109]
1070	Videotaped Deposition Transcript of Diana V. Do, M.D. dated December 8, 2023
1071	Eligibility Criteria for ANCHOR Study, Appendix to Ex. 2108, available at: https://www.nejm.org/doi/suppl/10.1056/NEJMoa062655/suppl_file/nejm_brown_sa1.pdf
1072	Eligibility Criteria for MARINA Study, Appendix to Ex. 2109, available at: https://www.nejm.org/doi/suppl/10.1056/NEJMoa054481/suppl_file/nejm_rosenfeld_sa1.pdf
1073	Videotaped Deposition Transcript of Dr. David M. Brown dated December 13, 2023
1074	Videotaped Deposition Transcript of David Brown, M.D. dated May 17, 2023, submitted in IPR2022-01225 and IPR2022-01226 on June 28, 2023 [Ex. 1110]
1075	Videotaped Deposition Transcript of Richard Manning, Ph.D. dated June 1, 2023, submitted in IPR2022-01225 and IPR2022-01226 on June 28, 2023 [Ex. 1121]
1076	Videotaped Deposition Transcript of Richard Manning, Ph.D. dated December 12, 2023
1077	Videotaped Deposition Transcript of Richard Manning, Ph.D. dated May 4, 2022, submitted in IPR2021-00881 on May 27, 2022 [Ex. 1151]
1078	Eylea Label 2016 available at:

	https://www.accessdata.fda.gov/drugsatfda_docs/label/2016/125387s051lbl.pdf
1079	Regeneron 2022 Press Release, available at: https://investor.regeneron.com/news-releases/news-release-details/regeneron-receives-six-months-us-pediatric-exclusivity-eylearn#:~:text=(NASDAQ%3A%20REGN)%20today%20announced,months%20through%20May%2017%2C%202024%20.
1080	International Nonproprietary Names for Pharmaceutical Substances (INN), 20 WHO DRUG INFORMATION 118 (2006)
1081	Videotaped Deposition Transcript of Alexander Klibanov, dated December 20, 2023
1082	Standard Affidavit (unexecuted) filed as Exhibit 1014 in <i>ASM IP Holding BV et al v. Kokusai Electric Corporation a/k/a Kabushiki-Kaisha Kokusai Electric et al.</i> , IPR2019-00369
1083	Petitioner's Oral Hearing Presentation (DEMONSTRATIVE EXHIBIT – NOT EVIDENCE)

DATED: April 16, 2024

Respectfully submitted,

By /Raymond N. Nimrod/
Raymond N. Nimrod (Reg. No. 31,987)
raynimrod@quinnemanuel.com
QUINN EMANUEL URQUHART
& SULLIVAN LLP
51 Madison Avenue, 22nd Floor
New York, NY 10010
Tel: (212) 849-7000
Fax: (212) 849-7100

Lead Counsel for Petitioner Samsung Bioepis

CERTIFICATE OF SERVICE

In accordance with 37 C.F.R. § 42.6(e), I hereby certify that on April 16, 2024, true and correct copies of Petitioner's Updated Exhibit List was served via electronic mail to Patent Owner at the following email addresses of record:

Deborah.Fishman@arnoldporter.com
David.Caine@arnoldporter.com
David.Denuyl@arnoldporter.com
Alice.Ho@arnoldporter.com
Victoria.Reines@arnoldporter.com
Jeremy.Cobb@arnoldporter.com
Abigail.Struthers@arnoldporter.com
Daniel.Reisner@arnoldporter.com
Matthew.Wilk@arnoldporter.com
RegeneronEyleaIPRs@arnoldporter.com

DATED: April 16, 2024

Respectfully submitted,

By _____/Raymond N. Nimrod/

Raymond N. Nimrod (Reg. No. 31,987)
raynimrod@quinnemanuel.com
QUINN EMANUEL URQUHART
& SULLIVAN, LLP
51 Madison Ave., 22nd Floor
New York, NY 10010
Tel: (212) 849-7000
Fax: (212) 849-7100