

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

SAMSUNG BIOEPIS CO., LTD., CELLTRION INC,
and BIOCON BIOLOGICS INC.

Petitioners,

v.

REGENERON PHARMACEUTICALS, INC.

Patent Owner.

Patent No. 11,253,572

Inter Partes Review No. IPR2023-00884¹

PATENT OWNER'S UPDATED EXHIBIT LIST

¹ IPR2024-00260 and IPR2024-00298 are joined with IPR2023-00884.

Updated Exhibit List for *Inter Partes* Review of U.S. Patent No. 11,253,572

Exhibit No.	Exhibit Description
2001	Expert Declaration of Richard Manning, Ph.D., <i>Mylan Pharms. Inc. v. Regeneron Pharms., Inc.</i> , IPR2021-00881, Ex. No. 2052 (Feb. 11, 2022)
2002	EYLEA® Label (rev. Oct. 2014)
2003	Trial Transcript (unsealed portions), <i>Regeneron Pharms., Inc. v. Mylan Pharms. Inc.</i> , No. 1:22-cv-00061-TSK-JPM (N.D.W. Va.)
2004	Press Release, <i>Positive Interim Phase 2 Data Reported for VEGF Trap-Eye in Age-Related Macular Degeneration</i> , Regeneron Pharmaceuticals, Inc. (Mar. 27, 2007)
2005	Email from George Yancopoulos to Murray Goldberg re Top Line sum for PR (Mar. 22, 2007)
2006	Interim Analysis of Phase 2 Study of VEGF Trap in AMD patients (Mar. 22, 2007) (Attachment to Ex.2005)
2007	George D. Yancopoulos, VEGF Trap : Scientific Background, BSP / REGN Kick-Off (Feb. 16, 2007)
2008	Email from Kathleen Lawrence re Decisions & Actions: AMD Ph3 Program Mtg – 4/2/07 (Apr. 2, 2007)
2009	Email from George Yancopoulos to Darlene Jody re Summary of issues for call: AMD P3 Planning with enclosed outline attached (Apr. 4, 2007)
2010	Email from Robert Terifay to George Yancopoulos re VGTeye VIEW 430 presentation (Nov. 19, 2010)
2011	Vascular Endothelial Growth Factor (VEGF) Trap-Eye: Investigation of Efficacy and Safety in Wet Age-Related Macular Degeneration (AMD) - VIEW 1 and VIEW 2 – 1-Year Results (Attachment to Ex.2010)
2012	Regeneron Pharmaceuticals, <i>Phase 1 Study of VEFT Trap in Patients With Diabetic Macular Edema</i> , https://clinicaltrials.gov/study/NCT00320814 (last updated Jun. 10, 2011)
2013	Regeneron, <i>Clinical Study Concept - Ophthalmology-Diabetic Macular Edema-Phase 2-IVT-VGFT-OD-0706</i> (updated May 19, 2008)
2014	Diana V. Do et al., <i>One-Year Outcomes of the DA VINCI Study of VEGF Trap-Eye in Eyes with Diabetic Macular Edema</i> , 119 OPTHALMOLOGY 1658-1665 (Aug. 2012).

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Exhibit No.	Exhibit Description
2015	DA VINCI – DME And VEGF Trap-Eye: Investigation of Clinical Impact: One Year Data (Dec. 8, 2010) (attachment to Ex.2024)
2016	Regeneron Pharmaceuticals, <i>DME And VEGF Trap-Eye [Intravitreal Aflibercept Injection (IAI; EYLEA®; BAY86-5321)] Investigation of Clinical Impact (DA VINCI)</i> , https://clinicaltrials.gov/study/NCT00789477 (last updated Sep. 9, 2014)
2017	Email from Caroline Saxton re Data Review (Feb. 1, 2010)
2018	Regeneron Pharmaceuticals, Inc., <i>VGFT-OD-0706 Week 24 Topline Results</i> (Feb. 1, 2010) (attachment to Ex.2017)
2019	DRAFT – DA VINCI – 6-Month Primary Endpoint (Feb. 1, 2010) (attachment to Ex.2017)
2020	Regeneron Pharmaceuticals, Inc., <i>VEGF Trap-Eye Shows Positive Results in a Phase 2 Study in Patients With Diabetic Macular Edema</i> (Feb. 18, 2010)
2021	Email from Alyson Berliner to Dave Brown re ARVO late breakers (Mar. 1, 2010)
2022	<i>DA VINCI: DME And VEGF Trap-Eye: Investigation of Clinical Impact: Phase 2 study in patients with Diabetic Macular Edema (DME)</i> (Mar. 1, 2010) (Attachment to Ex.2021)
2023	Email from Dave Brown to Alyson Berliner and James Major re ARVO abstract (Mar. 3, 2010)
2024	Email from Caroline Saxton re Slides and tables – DaVinci (Dec. 8, 2010)
2025	U.S. Provisional Patent Application No. 61/434,836 (Jan. 21, 2011)
2026	Mylan Pharmaceuticals Inc.’s Answer, Defenses, and Counterclaims to Plaintiff’s Complaint, <i>Regeneron Pharms., Inc. v. Mylan Pharms. Inc.</i> , No. 1:22-cv-00061-TSK-JPM (N.D.W. Va.), ECF No. 47 (filed Aug. 25, 2022)
2027	Stipulation and Order Joining Biocon Biologics Inc. as Defendant, <i>Regeneron Pharms., Inc. v. Mylan Pharms. Inc.</i> , No. 1:22-cv-00061-TSK-JPM (N.D.W. Va.), ECF No. 523 (filed Jun. 5, 2023)
2028	Complaint for Patent Infringement, <i>Regeneron Pharms., Inc. v. Mylan Pharms. Inc.</i> , No. 1:22-cv-00061-TSK-JPM (N.D.W. Va.), ECF No. 1 (filed Aug. 2, 2022)

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2029	Order on Claim Construction, <i>Regeneron Pharms., Inc. v. Mylan Pharms. Inc.</i> , No. 1:22-cv-00061-TSK-JPM (N.D.W. Va.), ECF No. 427 (filed Apr. 19, 2023)
2030	Scheduling Order, <i>Regeneron Pharms., Inc. v. Mylan Pharms. Inc.</i> , No. 1:22-cv-00061-TSK-JPM (N.D.W. Va.), ECF No. 87 (filed Oct. 25, 2022)
2031	Regeneron's Stipulation Regarding Summary Judgment and Case Narrowing, <i>Regeneron Pharms., Inc. v. Mylan Pharms. Inc.</i> , No. 1:22-cv-00061-TSK-JPM (N.D.W. Va.), ECF No. 433 (filed Apr. 27, 2023)
2032	Defendant's Opening Post Trial Brief - Issues Where Defendants Bear the Burden of Proof, <i>Regeneron Pharms., Inc. v. Mylan Pharms. Inc.</i> , No. 1:22-cv-00061-TSK-JPM (N.D.W. Va.), ECF No. 576 (filed July 7, 2023)
2033	Order Setting Briefing Schedule, <i>Regeneron Pharms., Inc. v. Mylan Pharms. Inc.</i> , No. 1:22-cv-00061-TSK-JPM (N.D.W. Va.), ECF No. 514 (filed May 30, 2023)
2034	Transcript of the Status Conference held on Sept. 28, 2022, <i>Regeneron Pharms., Inc. v. Mylan Pharms. Inc.</i> , No. 1:22-cv-00061-TSK-JPM (N.D.W. Va.), ECF No. 90 (filed Nov. 2, 2022)
2035	Email from George Yancopoulos re DME Phase 2 – ALL TABLES (Feb. 2, 2010)
2036	DME Target Product Profile - VEGF Trap-Eye (Sept. 26, 2007)
2037	Clinical Development & Regulatory Affairs Weekly Update (Oct. 29, 2010)
2038	Clinical Development & Regulatory Affairs Weekly Update (Dec. 3, 2010)
2039	Email from George Yancopoulos re DME PLANS & FDA meeting pre-discussion (Jan. 9, 2008)
2040	MEMO re Guidance From Bayer/ REGN Sr. Management Regarding Additional Indications in Ophthalmology from George Yancopoulos to Bayer/REGN Joint Development Group (Mar. 28, 2008)
2041	Action Items by GD Yancopoulos - Bayer/REGN JSC (Feb. 15, 2008)
2042	Email from Yuhwen Soo to George Yancopoulos re Can you send me that slide you made combining the VA curves for View1 & View2 (Nov. 20, 2010)

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2043	Vascular Endothelial Growth Factor (VEGF): Investigation of Efficacy and Safety in Wet Age-Related Macular Degeneration (AMD)—VIEW1 + VIEW 2: 1-Year Results (Nov. 20, 2010) (Attachment to Ex.2042)
2044	Email from Michael Aberman to George Yancopoulos and Leonard Schleifer re Press Release (Nov. 19, 2010)
2045	Regeneron, <i>Bayer and Regeneron Report Positive Top-Line Results of Two Phase 3 Studies with VEGF Trap-Eye in Wet Age-related Macular Degeneration</i> (Nov. 19, 2010) (Attachment to Ex.2044)
2046	U.S. Food & Drug Administration, <i>22 Case Studies Where Phase 2 and Phase 3 Trials Had Divergent Results</i> (Jan. 2017)
2047	VEGF Trap-Eye in Wet AMD - CLEAR-IT 2: Summary of One-Year Key Results, Presented at 2008 Retina Society Meeting, Scottsdale, Arizona (Sep. 28, 2008)
2048	Regeneron Pharmaceuticals, Inc., <i>A Double-Masked, Randomized, Controlled Study of the Safety, Tolerability and Biological Effect of Repeated Intravitreal Administration of VEGF Trap-Eye in Patients with Diabetic Macular Edema (DME)</i> (Issued Jan. 28, 2009)
2049	Appendix to Heier et al., <i>Intravitreal Aflibercept (VEGF Trap-Eye) in Wet Age-Related Macular Degeneration</i> , 119 OPTHALMOLOGY 2537 (2012)
2050	<i>Retinal Physician Symposium Covers Broad Range of Topics</i> , Retinal Physician (Sept. 1, 2006), https://www.retinalphysician.com/issues/2006/september2006/retinal-physician-symposium-covers-broad-range-of
2051	Prema Abraham et al., <i>Randomized, Double-Masked, Sham-Controlled Trial of Ranibizumab for Neovascular Age-Related Macular Degeneration: PIER Study Year 2</i> , 150 AM. J. OPTHALMOLOGY 315 (2010)
2052	FDA, <i>Step 3: Clinical Research</i> , https://www.fda.gov/patients/drug-development-process/step-3-clinical-research (last accessed Aug. 23, 2023)
2053	Prosecution History of U.S. Patent App. No. 16/159,282 B2
2054	Anant Pai et al., <i>Current concepts in intravitreal drug therapy for diabetic retinopathy</i> , 24 SAUDI J. OPTHALMOLOGY 143 (June 30, 2010)

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