

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 IPR2023-00884

U.S. Patent No. 11,253,572

PETITION FOR *INTER PARTES* REVIEW

OF U.S. PATENT NO. 11,253,572

RESPONSIVE DECLARATION OF DR. EDWARD CHAUM

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 A. A POSA Would Have Considered It Obvious That Some
 Patients Would Achieve and Maintain to Week 52 the Recited
 Gains Based on Pre-November 2010 Art.....3

 B. A POSA Would Have Considered It Obvious That Some DME
 Patients Would Achieve The Recited Gains Within 24 Weeks
 Based On Pre-November 2010 Art12

TABLE OF EXHIBITS

| Exhibit | Description |
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| 1001 | U.S. Patent No. 11,253,572 |
| 1002 | Expert Declaration of Dr. Edward Chaum in Support of Petition for <i>Inter Partes</i> Review of Patent No. 11,253,572, dated April 27, 2023 (“Chaum Decl.”) |
| 1003 | Edward Chaum <i>Curriculum Vitae</i> |
| 1004 | Institution Decision in <i>Apotex Inc. v. Regeneron Pharmaceuticals, Inc.</i> , IPR2022-01524. (“Apotex ’572 ID”) |
| 1005 | Press Release, “Enrollment Completed in Regeneron and Bayer Healthcare Phase 3 Studies of VEGF Trap-Eye in Neovascular Age-Related Macular Degeneration (Wet AMD) (September 14, 2009),” available at: https://newsroom.regeneron.com/news-releases/news-release-details/enrollment-completed-regeneron-and-bayer-healthcare-phase-3 (“2009 Press Release”) |
| 1006 | Press Release, “Regeneron and Bayer Report Positive Results for VEGF Trap-Eye in Phase 3 Study in Central Retinal Vein Occlusion (CRVO) and in Phase 2 Study in Diabetic Macular Edema (DME),” Exhibit 99.1 to Regeneron 8-K filed on December 20, 2010, available at: https://yahoo.brand.edgar-online.com/displayfilinginfo.aspx?FilingID=7617341-6436-23571&type=sect&TabIndex=2&companyid=5036&ppu=%252fdef%E2%80%A6 (“December 2010 Press Release”) |
| 1007 | Press Release, “Bayer and Regeneron Report Positive Top-Line Results of Two Phase 3 Studies with VEGF Trap-Eye in Wet Age-related Macular Degeneration,” Exhibit 99.1 to Regeneron 8-K filed on November 22, 2010, available at: https://yahoo.brand.edgar-online.com/displayfilinginfo.aspx?FilingID=7572010-8611-26486&type=sect&TabIndex=2&companyid=5036&ppu=%252fdef%E2%80%A6 (“November 2010 Press Release”) |
| 1008 | Apotex Petition for IPR filed in <i>Apotex Inc. v. Regeneron Pharmaceuticals, Inc.</i> , IPR2022-01524 (Paper 1) (“Apotex Petition”) |

| Exhibit | Description |
|---------|---|
| 1009 | 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”) |
| 1010 | Major JC et al., “DA VINCI: DME and VEGF Trap-Eye: INvestigation of Clinical Impact: Phase 2 Study in Patients With Diabetic Macular Edema (DME), ARVO Annual Meeting Abstract (April 2010), Vol. 51, Issue 13, available at: https://iovs.arvojournals.org/article.aspx?articleid=2375028 (“2010 ARVO Abstract”) |
| 1011 | Final Written Decision in <i>Mylan Pharmaceuticals Inc. v. Regeneron Pharmaceuticals, Inc.</i> , IPR2021-00881 (Paper 94) (“338 FWD”) |
| 1012 | Institution Decision in <i>Mylan Pharmaceuticals Inc. v. Regeneron Pharmaceuticals, Inc.</i> , IPR2022-01225 (Paper 21) (“681 ID”) |
| 1013 | Institution Decision in <i>Mylan Pharmaceuticals Inc. v. Regeneron Pharmaceuticals, Inc.</i> , IPR2022-01226 (Paper 22) (“601 ID”) |
| 1014 | Certified Prosecution History of U.S. Patent No. 11,253,572 (“572 patent PH) |
| 1015 | Adis R&D Profile, 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”) |
| 1016 | Hecht, “Ophthalmic Preparations,” Remington: The Science and Practice of Pharmacy, Volume II, 19th edition, Chapter 89 (1995). (“Hecht”) |
| 1017 | WO 2006/047325 A1 (“Shams”) |
| 1018 | Elman MJ, et al., Randomized trial evaluating ranibizumab plus prompt or deferred laser or triamcinolone plus prompt laser for diabetic macular edema. <i>Ophthalmology</i> . 2010 Jun;117(6):1064-1077.e35. (“Elman 2010”) |
| 1019 | Elman MJ, et al., Randomized trial evaluating ranibizumab plus prompt or deferred laser or triamcinolone plus prompt laser for diabetic macular edema. <i>Ophthalmology</i> . 2010 Jun;117(6):1064-1077.e35, published April 28 2010, available at https://www.aaojournal.org/article/S0161-6420(10)00243-5/fulltext (“Elman AAO Website) |

| Exhibit | Description |
|---------|---|
| 1020 | Authenticating Affidavit and the July 13, 2010 Web Archive of the CATT Patient Eligibility Criteria, available at https://web.archive.org/web/20100713035617/http://www.med.upenn.edu/cpob/studies/documents/CATTEligibilityCriteria_000.pdf , attached as Exhibit B (“CATT Study”). |
| 1021 | 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”). |
| 1022 | Comparison of Age-related Macular Degeneration Treatments Trials: Lucentis-Avastin Trial (NCT00593450), available at: https://clinicaltrials.gov/ct2/show/NCT00593450 (“NCT-450”) |
| 1023 | 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, published December 3, 2007, available at https://www.ajo.com/article/S0002-9394(07)00881-1/fulltext (“PIER AJO Website”) |
| 1024 | 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 . (“NCT-623”) |
| 1025 | ClinicalTrials.gov Background, available at: https://clinicaltrials.gov/ct2/about-site/background (“ClinicalTrials.gov Background”) |
| 1026 | ClinicalTrials.gov About the Results Database, available at: https://clinicaltrials.gov/ct2/about-site/results (“ClinicalTrials.gov About the Results Database”) |
| 1027 | Press Release, “Regeneron Reports Positive Phase 1 Data for the VEGF TRAP in Age-Related Macular Degeneration,” Exhibit 99(a) to Regeneron 8-K filed on May 2, 2006, available at: https://yahoo.brand.edgar- |

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