

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

MYLAN PHARMACEUTICALS INC.,
Petitioner

v.

REGENERON PHARMACEUTICALS, INC.,
Patent Owner

Case IPR2021-00881
Patent No. 9,254,338 B2

PATENT OWNER'S UPDATED EXHIBIT LIST

TABLE OF EXHIBITS

Ex. No.	Description
2001	Expert Declaration of Dr. Diana V. Do, M.D.
2002	Curriculum Vitae of Dr. Diana Do
2003	Lucentis (ranibzumab injection) label, revised June 2010
2004	Ex. (a)(1)(a) to Tender Offer Statement to Momenta, filed with SEC on September 2, 2020
2005	Press Release, Johnson & Johnson, <i>Johnson & Johnson to Acquire Momenta Pharmaceuticals, Inc., Expanding Janssen's Leadership in Novel Treatments for Autoimmune Diseases</i> , dated August 19, 2020
2006	Press Release, Johnson & Johnson, <i>Johnson & Johnson Completes Acquisition of Momenta Pharmaceuticals, Inc</i> , dated October 1, 2020
2007	Press Release, THOMAS REUTERS INTEGRITY "VEGF Trap-Eye final phase II results in age-related macular degeneration presented at 2008 Retina Society Meeting" (September 2008)
2008	Information from ClinicalTrials.gov archive on the VIEW 2 study (NCT00637377) "VEGF Trap-Eye: Investigation of Efficacy and Safety in Wet AMD (VIEW 2)" versions available and updated on 17 March 2008.
2009	U.S. Patent App. No. 2006/0058234
2010	Excerpts from J.M. Berg <i>et al.</i> , <i>Biochemistry</i> (5 th Ed. 2002)
2011	M.W. Stewart & P.J. Rosenfeld, <i>Predicted Biological Activity of Intravitreal VEGF Trap</i> , <i>Br. J. Ophthalmol</i> 92:667-68 (2008)
2012	P. Iacono <i>et al.</i> , <i>Antivascular Endothelial Growth Factor in Diabetic Retinopathy</i> , <i>Dev. Ophthalmol.</i> 46:39-53 (2010)
2013	D.V. Do <i>et al.</i> , <i>An Exploratory Study of the Safety, Tolerability and Bioactivity of a Single Intravitreal Injection of Vascular Endothelial Growth Factor Trap-Eye in Patients With Diabetic Macular Oedema</i> , <i>Br. J. Ophthalmol</i> 93:144-49 (2009)
2014	J.W. Moroney <i>et al.</i> , <i>Aflibercept in Epithelial Ovarian Carcinoma</i> , <i>Future Oncol</i> 5(5):591-600 (2009)
2015	U.S. Patent Publication 2010/0160233 A1 to Bissery <i>et al.</i> , published June 24, 2010
2016	T. Hachiya <i>et al.</i> , <i>Increase in respiratory cost at high growth temperature is attributed to high protein turnover cost in <i>Petunia x hybrida</i> petals</i> , <i>Plant, Cell, and Environment</i> , 30:1269-1283 (2007)

2017	M. Piques et al., <i>Ribosome and transcript copy numbers, polysome occupancy and enzyme dynamics in Arabidopsis</i> , <i>Molecular Systems Biology</i> 5: Article number 314 (2009)
2018	Jaffe et al., <i>Differential Response to Anti-VEGF Regimens in Age-Related Macular Degeneration Patients with Early Persistent Retinal Fluid</i> , <i>Ophthalmology</i> 2016;123:1856-1864 (2016)
2019	Eylea (aflibercept) Injection label, revised May 2016
2020	A Study Investigating the Safety and Efficacy of Lampalizumab Intravitreal Injections in Participants With Geographic Atrophy Secondary to Age-Related Macular Degeneration (SPECTRI), NCT02247531, ClinicalTrials.gov (August 2, 2021), https://clinicaltrials.gov/ct2/show/NCT02247531?term=lampalizumab&phase=2&draw=2&rank=2
2021	A Study Investigating the Efficacy and Safety of Lampalizumab Intravitreal Injections in Participants With Geographic Atrophy Secondary to Age-Related Macular Degeneration (CHROMA), NCT02247479, ClinicalTrials.gov (August 2, 2021), https://clinicaltrials.gov/ct2/show/NCT02247479?term=lampalizumab&phase=2&draw=2&rank=3
2022	Efficacy and Safety Trial of Conbercept Intravitreal Injection for Neovascular AMD(PANDA-2), NCT03630952, ClinicalTrials.gov (August 2, 2021), https://clinicaltrials.gov/ct2/show/NCT03630952?term=NCT03630952&draw=2&rank=1
2023	Efficacy and Safety Trial of Conbercept Intravitreal Injection for Neovascular AMD(PANDA-1), NCT03577899, ClinicalTrials.gov (August 2, 2021), https://clinicaltrials.gov/ct2/show/NCT03577899?term=NCT03577899&draw=2&rank=1
2024	A Phase 3 Safety and Efficacy Study of Fovista® (E10030) Intravitreal Administration in Combination With Lucentis® Compared to Lucentis® Monotherapy, NCT01944839, ClinicalTrials.gov (August 2, 2021), https://clinicaltrials.gov/ct2/show/NCT01944839?term=fovista&phase=2&draw=2&rank=1

2025	A Phase 3 Safety and Efficacy Study of Fovista® (E10030) Intravitreal Administration in Combination With Lucentis® Compared to Lucentis® Monotherapy, ClinicalTrials.gov (August 2, 2021), https://clinicaltrials.gov/ct2/show/NCT01940900?term=fovista&phase=2&draw=2&rank=2
2026	S. Elvidge, <i>Ophotech's Fovista crashes out in wet AMD</i> , BIOPHARMADIVE (Aug. 14, 2017), available at, https://www.biopharmadive.com/news/ophtotech-fovista-phase-3-failure-setback-novartis/449248/
2027	X. Li et al., <i>Safety and Efficacy of Conbercept in Neovascular Age-Related Macular Degeneration: Results from a 12-Month Randomized Phase 2 Study: AURORA Study</i> , <i>Ophthalmology</i> 2014;121:1740-1747 (2014)
2028	Regeneron Pharmaceuticals Inc., "VEGF Trap-Eye CLEAR-IT 2 Final Primary Endpoint Results" presented at the 2007 Retina Society Conference in Boston, Massachusetts (September 30, 2007)
2029	Bhisitkul, Robert B. and Stewart, Jay M., <i>Alternative anti-VEGF treatment regimens in exudative age-related macular degeneration</i> , <i>Expert Rev. Ophthalmol.</i> , Vol. 5, No. 6 (2010).
2030	Park, Young Gun et al., <i>New Approach to Anti-VEGF Agents for Age-Related Macular Degeneration</i> , <i>Journal of Ophthalmology</i> (2012).
2031	Spaide, Richard, <i>Ranibizumab According to Need: A Treatment for Age-related Macular Degeneration</i> , <i>American Journal of Ophthalmology</i> (April 2007)
2032	Boyer, David S., <i>A Phase IIIb Study to Evaluate the Safety of Ranibizumab in Subjects with Neovascular Age-related Macular Degeneration</i> , <i>Ophthalmology</i> , Vol. 116, No. 9 (Sept. 2009)
2033	Lucentis (ranibizumab injection) label, revised March 2018
2034	U.S. Patent No. 7,303,746
2035	U.S. Patent No. 7,521,049
2036	U.S. Patent No. 7,303,747
2037	U.S. Patent No. 7,306,799
2038	Macugen (pegaptanib sodium injection) label submitted with NDA 21-756
2039	Press Release, <i>Regeneron, Regeneron Reports Fourth Quarter and Full Year 2012 Financial and Operating Results</i> , dated February 14, 2013
2040	Press Release, <i>Regeneron, Regeneron Reports Fourth Quarter and Full Year 2019 Financial and Operating Results</i> , dated February 6, 2020

2041	Press Release, Regeneron, <i>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)</i> , dated December 20, 2010
2042	J.P. Levine <i>et al.</i> , <i>Macular Hemorrhage in Neovascular Age-related Macular Degeneration After Stabilization With Antiangiogenic Therapy</i> , <i>Retina</i> 29(8):1074-79 (2009)
2043	Press Release, <i>Thomson Reuters Links Discovery and Literature Citation Databases</i> , dated January 4, 2010
2044	Declaration of Victoria Reines
2045	Declaration of Daniel Reisner
2046	Declaration of Matthew M. Wilks
2047	Declaration of Jeremy Cobb

Dated: November 22, 2021

Respectfully Submitted,

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