

UNITED STATES PATENT AND TRADEMARK OFFICE

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BEFORE THE PATENT TRIAL AND APPEAL BOARD

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MYLAN PHARMACEUTICALS INC.,  
Petitioner

v.

REGENERON PHARMACEUTICALS, INC.,  
Patent Owner

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Case IPR2021-00881  
Patent 9,254,338 B2

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**PETITIONER'S UPDATED EXHIBIT LIST**

Petitioner submits this Updated Exhibit List to accompany submission of Exhibit 1100, the Transcript of the Teleconference before the United States Patent Trial and Appeal Board on February 23, 2022.

**PETITIONER'S UPDATED EXHIBIT LIST**

<b>Exhibit</b>	<b>Description</b>
1001	U.S. Patent No. 9,254,338 B2 (“‘338 patent”)
1002	Expert Declaration of Dr. Thomas A. Albini in Support of Petition for <i>Inter Partes</i> Review of Patent No. 9,254,338 B2, dated May 4, 2021 (“Albini”)
1003	Expert Declaration of Mary Gerritsen, Ph.D. in Support of Petition for <i>Inter Partes</i> Review of U.S. Patent No. 9,254,338 B2, dated Apr. 26, 2021 (“Gerritsen”)
1004	Jocelyn Holash et al., <i>VEGF-Trap: A VEGF Blocker with Potent Antitumor Effects</i> , 99 PROC. NAT’L ACAD. SCI. 11393 (2002) (“Holash”)
1005	Quan Dong Nguyen et al., <i>A Phase I Study of Intravitreal Vascular Endothelial Growth Factor Trap-Eye in Patients with Neovascular Age-Related Macular Degeneration</i> , 116 OPHTHALMOLOGY 2141 (2009) (“Nguyen-2009”)
1006	James A Dixon et al., <i>VEGF Trap-Eye for the Treatment of Neovascular Age-Related Macular Degeneration</i> , 18 EXPERT OPINION ON INVESTIGATIONAL DRUGS 1573 (2009) (“Dixon”)
1007	Adis R&D Profile, <i>Aflibercept: AVE 0005, AVE 005, AVE0005, VEGF Trap – Regeneron, VEGF Trap (R1R2), VEGF Trap-Eye</i> , 9 DRUGS R&D 261 (2008) (“Adis”)
1008	U.S. Patent No. 7,531,173 B2 (“‘173 patent”)
1009	U.S. Patent No. 7,396,664 B2 (“‘664 patent”)
1010	U.S. Patent No. 7,374,758 B2 (“‘758 patent”)
1011	F Semeraro et al., <i>Aflibercept in Wet AMD: Specific Role and Optimal Use</i> , 7 DRUG DESIGN, DEV. & THERAPY 711 (2013) (“Semeraro”)
1012	Press Release, Regeneron, Regeneron and Bayer Health Care Announce Encouraging 32-Week Follow-Up Results from a Phase 2 Study of VEGF Trap-Eye in Age-Related Macular Degeneration

Exhibit	Description
	(Apr. 28, 2008), <a href="http://investor.regeneron.com/releasedetail.cfm?releaseid=394066">http://investor.regeneron.com/releasedetail.cfm?releaseid=394066</a> ("Regeneron (28-April-2008)")
1013	Press Release, Regeneron, Bayer and Regeneron Dose First Patient in Second Phase 3 Study for VEGF Trap-Eye in Wet Age-Related Macular Degeneration (May 8, 2008), <a href="http://investor.regeneron.com/releasedetail.cfm?ReleaseID=394065">http://investor.regeneron.com/releasedetail.cfm?ReleaseID=394065</a> ("Regeneron (8-May-2008)")
1014	Vascular Endothelial Growth Factor (VEGF) Trap-Eye: Investigation of Efficacy and Safety in Wet Age-Related Macular Degeneration (AMD) (VIEW1), NCT00509795, ClinicalTrials.gov (Apr. 28, 2009), <a href="https://clinicaltrials.gov/ct2/show/NCT00509795">https://clinicaltrials.gov/ct2/show/NCT00509795</a> ("NCT-795")
1015	VEGF Trap-Eye: Investigation of Efficacy and Safety in Wet AMD (VIEW 2), NCT00637377, ClinicalTrials.gov (Mar. 17, 2008), <a href="https://clinicaltrials.gov/ct2/show/NCT00637377">https://clinicaltrials.gov/ct2/show/NCT00637377</a> ("NCT-377")
1016	U.S. Patent Nos. 7,303,746 B2; 7,303,747 B2; 7,306,799 B2; and 7,521,049 B2 ("Monthly-Dosing-Patents")
1017	File History of U.S. Patent No. 9,254,338 B2 ("338 FH")
1018	Jeffrey S. Heier et al., <i>Intravitreal Aflibercept (VEGF Trap-Eye) in Wet Age-Related Macular Degeneration</i> , 119 OPTHALMOLOGY 2537 (2012) ("Heier-2012")
1019	U.S. Patent No. 9,669,069 B2 ("069 patent")
1020	Jeffrey S. Heier, <i>Intravitreal VEGF Trap for AMD: An Update</i> , RETINA TODAY, Oct. 2009, 44 ("Heier-2009")
1021	Regeneron Pharm., Inc., Quarterly Report (Form 10-Q) (Sept. 30, 2009) ("2009 10-Q")
1022	U.S. Patent No. 7,374,757 B2 ("757 patent")
1023	U.S. Patent No. 7,070,959 B1 ("959 patent")
1024	File History of U.S. Patent No. 7,374,758 B2, 12/22/2011 Patent Term Extension Application ("758 FH, 12/22/2011 PTE")
1025	Michael Engelbert et al., <i>Long-Term Follow-Up For Type 1 (Subretinal Pigment Epithelium) Neovascularization Using A Modified "Treat And Extend" Dosing Regimen of Intravitreal Antivascular Endothelial Growth Factor Therapy</i> , 30 RETINA, J. RETINAL & VITREOUS DISEASES 1368 (2010) ("Engelbert-2010")

Exhibit	Description
1026	Michael Engelbert et al., <i>“Treat and Extend” Dosing of Intravitreal Antivascular Endothelial Growth Factor Therapy For Type 3 Neovascularization/Retinal Angiomatous Proliferation</i> , 29 J. RETINAL & VITREOUS DISEASES 1424 (2009) (“Engelbert-2009”)
1027	Richard F. Spaide et al., <i>Prospective Study of Intravitreal Ranibizumab as a Treatment for Decreased Visual Acuity Secondary to Central Retinal Vein Occlusion</i> , 147 AM. J. OPHTHALMOLOGY 298 (2009) (“Spaide”)
1028	Press Release, Regeneron, Bayer and Regeneron Extend Development Program for VEGF Trap-Eye to Include Central Retinal Vein Occlusion (Apr. 30, 2009), <a href="https://investor.regeneron.com/news-releases/news-release-details/bayer-and-regeneron-extend-development-program-vegf-trap-eye">https://investor.regeneron.com/news-releases/news-release-details/bayer-and-regeneron-extend-development-program-vegf-trap-eye</a> (“Regeneron (30-April-2009)”)
1029	Vascular Endothelial Growth Factor (VEGF) Trap-Eye: Investigation of Efficacy and Safety in Central Retinal Vein Occlusion (CRVO), NCT01012973, ClinicalTrials.gov (Nov. 12, 2009), <a href="https://clinicaltrials.gov/ct2/show/NCT01012973">https://clinicaltrials.gov/ct2/show/NCT01012973</a> (“NCT-973”)
1030	P Mitchell et al., <i>Ranibizumab (Lucentis) in Neovascular Age-Related Macular Degeneration: Evidence from Clinical Trials</i> , 94 BRIT. J. OPHTHALMOLOGY 2 (2009) (date of online publication) (“Mitchell”)
1031	Pascale G. Massin, <i>Anti-VEGF Therapy for Diabetic Macular Edema: An Update</i> , RETINA TODAY, SEPT./Oct. 2008, 54 (“Massin”)
1032	Press Release, Bayer AG, Bayer and Regeneron Start Additional Phase 3 Study for VEGF Trap-Eye in Wet Age-Related Macular Degeneration (May 8, 2008) (“Bayer (8-May-2008)”)
1033	U.S. Patent Application Publication No. 2006/0217311 A1 (“Dix”)
1034	Anne E. Fung et al., <i>An Optical Coherence Tomography-Guided, Variable Dosing Regimen with Intravitreal Ranibizumab (Lucentis) for Neovascular Age-related Macular Degeneration</i> , 143 AM. J. OPHTHALMOLOGY 566 (2007) (“Fung”)
1035	Geeta A. Lalwani et al., <i>A Variable-dosing Regimen with Intravitreal Ranibizumab for Neovascular Age-Related Macular Degeneration: Year 2 of the PrONTO Study</i> , 148 AM. J. OPHTHALMOLOGY 43 (2009) (“Lalwani”)

Exhibit	Description
1036	Peter A Campochiaro et al., <i>Ranibizumab for Macular Edema Due to Retinal Vein Occlusions: Implication of VEGF as a Critical Stimulator</i> , 16 MOLECULAR THERAPY 791 (2008) (“Campochiaro”)
1037	Robert Steinbrook, <i>The Price of Sight — Ranibizumab, Bevacizumab, and the Treatment of Macular Degeneration</i> , 355 N. ENG. J. MED. 1409 (2006) (“Steinbrook”)
1038	Curriculum Vitae of Dr. Thomas Albini (“Albini CV”)
1039	U.S. Patent No. 7,378,095 B2 (“’095 patent”)
1040	<i>International Nonproprietary Names for Pharmaceutical Substances (INN)</i> , 20 WHO DRUG INFORMATION 115 (2006) (“WHO Drug Info”)
1041	Press Release, Regeneron, Regeneron Reports Full Year and Fourth Quarter 2008 Financial and Operating Results (Feb. 26, 2009), <a href="https://investor.regeneron.com/news-releases/news-release-details/regeneron-reports-full-year-and-fourth-quarter-2008-financial">https://investor.regeneron.com/news-releases/news-release-details/regeneron-reports-full-year-and-fourth-quarter-2008-financial</a> (“Regeneron (26-February-2009)”)
1042	U.S. DEP’T HEALTH & HUMAN SERVS., NAT’L INST. HEALTH, NAT’L EYE INST., <i>Age-Related Macular Degeneration: What You Should Know</i> (Sept. 2015), <a href="https://www.nei.nih.gov/sites/default/files/health-pdfs/WYSK_AMD_English_Sept2015_PRINT.pdf">https://www.nei.nih.gov/sites/default/files/health-pdfs/WYSK_AMD_English_Sept2015_PRINT.pdf</a> (“NIH AMD”)
1043	David M. Brown & Carl D. Regillo, <i>Anti-VEGF Agents in the Treatment of Neovascular Age-Related Macular Degeneration: Applying Clinical Trial Results to the Treatment of Everyday Patients</i> , 144 AM. J. OPHTHALMOLOGY 627 (2007) (“Brown”)
1044	U.S. DEP’T HEALTH & HUMAN SERVS., NAT’L INST. HEALTH, NAT’L EYE INST., <i>Diabetic Retinopathy: What You Should Know</i> (Sept. 2015), <a href="https://www.nei.nih.gov/sites/default/files/2019-06/Diabetic-Retinopathy-What-You-Should-Know-508.pdf">https://www.nei.nih.gov/sites/default/files/2019-06/Diabetic-Retinopathy-What-You-Should-Know-508.pdf</a> (“NIH DR”)
1045	Napoleone Ferrara & Kari Alitalo, <i>Clinical Applications of Angiogenic Growth Factors and Their Inhibitors</i> , 5 NATURE MED. 1359 (1999) (“Ferrara-1999”)
1046	Napoleone Ferrara & Robert S. Kerbel, <i>Angiogenesis as a Therapeutic Target</i> , 438 NATURE 967 (2005) (“Ferrara-2005”)
1047	Ziad F. Bashshur et al., <i>Intravitreal Bevacizumab for the Management of Choroidal Neovascularization in Age-Related</i>



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