

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

MYLAN PHARMACEUTICALS INC.,
Petitioner

v.

REGENERON PHARMACEUTICALS, INC.,
Patent Owner

Inter Partes Review No.: IPR2021-00881

U.S. Patent No. 9,254,338 B2
Filed: July 12, 2013
Issued: February 9, 2016
Inventor: George D. Yancopoulos

Title: USE OF A VEGF ANTAGONIST TO TREAT
ANGIOGENIC EYE DISORDERS

PETITIONER'S UPDATED EXHIBIT LIST

Petitioner submits this Updated Exhibit List to accompany submission of Exhibit 1101, the Declaration of Eric R. Hunt in support of Mylan Pharmaceuticals Inc.’s Unopposed Motion for Pro Hac Vice Admission, dated April 20, 2022.

PETITIONER’S UPDATED EXHIBIT LIST

Exhibit	Description
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), http://investor.regeneron.com/releasedetail.cfm?releaseid=394066 ("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), http://investor.regeneron.com/releasedetail.cfm?ReleaseID=394065 ("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), https://clinicaltrials.gov/ct2/show/NCT00509795 ("NCT-795")
1015	VEGF Trap-Eye: Investigation of Efficacy and Safety in Wet AMD (VIEW 2), NCT00637377, ClinicalTrials.gov (Mar. 17, 2008), https://clinicaltrials.gov/ct2/show/NCT00637377 ("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), https://investor.regeneron.com/news-releases/news-release-details/bayer-and-regeneron-extend-development-program-vegf-trap-eye (“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), https://clinicaltrials.gov/ct2/show/NCT01012973 (“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), https://investor.regeneron.com/news-releases/news-release-details/regeneron-reports-full-year-and-fourth-quarter-2008-financial (“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), https://www.nei.nih.gov/sites/default/files/health-pdfs/WYSK_AMD_English_Sept2015_PRINT.pdf (“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), https://www.nei.nih.gov/sites/default/files/2019-06/Diabetic-Retinopathy-What-You-Should-Know-508.pdf (“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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