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 9,254,338 B2

PETITIONER'S OBJECTIONS TO ADMISSIBILITY OF EVIDENCE SUBMITTED BY PATENT OWNER

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Pursuant to 37 C.F.R. § 42.64(b), Petitioner Mylan Pharmaceuticals Inc. ("Petitioner"), hereby objects as follows to the admissibility of evidence filed by Patent Owner Regeneron Pharmaceuticals, Inc. ("Regeneron" or "Patent Owner"), in conjunction with the Patent Owner Preliminary Response, filed on August 16, 2021, and Patent Owner Consolidated Sur-Reply, filed on October 6, 2021.

In this paper, a reference to "FRE" means the Federal Rules of Evidence, a reference to "CFR" means the Code of Federal Regulations, and "'338 patent" means U.S. Patent No. 9,254,338. All objections under FRE 802 (hearsay) apply to the extent Patent Owner relies on the exhibits identified in connection with that objection for the truth of the matter asserted therein.

Exhibit descriptions provided in this table are Patent Owner's exhibit list and are used for identification purposes only. The use of the description does not indicate that Petitioner agrees with the descriptions or characterizations of the documents.

Ex. No.	Description	Objections
2001	Expert Declaration of Dr. Diana V. Do, M.D.	A, C, D, E, F, G, H, M, N, O, Q, S, T
2002	Curriculum Vitae of Dr. Diana Do	A, B, C, D, E, F, G, H, I, M, N, O, T
2003	Lucentis (ranibzumab injection) label, revised June 2010	A, C, D, E, F, G, H, M, N, O
2004	Ex. (a)(1)(a) to Tender Offer Statement to Momenta, filed with SEC on September 2, 2020	A, B, C, D, E, F, G, H, I, M, N, O, T
2005	Press Release, Johnson & Johnson, *Johnson &*	A, B, C, D, E, F, G,

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Ex. No.	Description	Objections
	Johnson to Acquire Momenta Pharmaceuticals, Inc., Expanding Janssen's Leadership in Novel Treatments for Autoimmune Diseases, dated August 19, 2020	H, M, N, O, T
2006	Press Release, Johnson & Johnson, *Johnson & Johnson Completes Acquisition of Momenta Pharmaceuticals, Inc*, dated October 1, 2020	A, B, C, D, E, F, G, H, M, N, O, T
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)	A, B, C, D, E, F, G, H, M, N, O, T
2010	Excerpts from J.M. Berg *et al*., Biochemistry (5th Ed. 2002)	A, C, D, E, F, G, H, I, M, N, O
2012	P. Iacono *et al*., *Antivascular Endothelial Growth Factor in Diabetic Retinopathy*, Dev. Opthamol. 46:39-53 (2010)	A, C, D, E, F, G, H, M, N, O
2014	J.W. Moroney *et al*., *Aflibercept in Epithelial Ovarian Carcinoma*, Future Oncol 5(5):591-600 (2009)	A, C, D, E, F, G, H, M, N, O
2015	U.S. Patent Publication 2010/0160233 A1 to Bissery *et al*., published June 24, 2010	A, C, D, E, F, G, H, K, M, N, O
2016	T. Hachiya et al., *Increase in respiratory cost at high growth temperature is attributed to high protein turnover cost in Petunia x hybrida petals*, Plant, Cell, and Environment, 30:1269-1283 (2007)	A, C, D, E, F, G, H, M, N, O
2017	M. Piques et al., *Ribosome and transcript copy numbers, polysome occupancy and enzyme dynamics in Arabidoposis*, Molecular Systems Biology 5: Article number 314 (2009)	A, C, D, E, F, G, H, M, N, O

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Ex. No.	Description	Objections
2018	Jaffe et al., *Differential Response to Anti-VEGF Regimens in Age- Related Macular Degeneration Patients with Early Persistent Retinal Fluid*, Ophthalmology 2016;123:1856-1864 (2016)	A, C, D, E, F, G, H, M, N, O
2019	Eylea (aflibercept) Injection label, revised May 2016	A, C, D, E, F, G, H, M, N, O
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	A, B, C, D, E, F, G, H, M, N, O, T
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	A, B, C, D, E, F, G, H, M, N, O, T
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	A, B, C, D, E, F, G, H, M, N, O, T
2023	Efficacy and Safety Trial of Conbercept Intravitreal Injection for Neovascular	A, B, C, D, E, F, G, H, M, N, O, T

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Ex. No.	Description	Objections
	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) Intravitreous 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	A, B, C, D, E, F, G, H, M, N, O, T
2025	A Phase 3 Safety and Efficacy Study of Fovista® (E10030) Intravitreous 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	A, B, C, D, E, F, G, H, M, N, O, T
2026	S. Elvidge, *Opthotech's Fovista crashes out in wet AMD*, BIOPHARMADIVE (Aug. 14, 2017), *available at*, https://www.biopharmadive.com/news/opthotech-fovista-phase-3-failure-setback-novartis/449248/	A, B, C, D, E, F, G, H, M, N, O
2027	X. Li et al., *Safety and Efficacy of Conbercept in Neovascular Age- Related Macular Degeneration: Results from a 12-Month Randomized Phase 2 Study: AURORA Study*, Ophthalmology 2014:121:1740-1747 (2014)	A, C, D, E, F, G, H, M, N, O
2029	Bhisitkul, Robert B. and Stewart, Jay M., *Alternative anti-VEGF treatment regimens in exudative age-related macular degeneration*,	A, C, D, E, F, G, H, M, N, O

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