

UNITED STATES PATENT AND TRADEMARK OFFICE

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BEFORE THE PATENT TRIAL AND APPEAL BOARD

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REGENERON PHARMACEUTICALS, INC.,  
Petitioner,

v.

NOVARTIS PHARMA AG,  
NOVARTIS TECHNOLOGY LLC,  
NOVARTIS PHARMACEUTICALS CORPORATION,  
Patent Owners.

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Case IPR2021-00816  
Patent 9,220,631

PETITIONER'S REPLY TO PATENT OWNER'S PRELIMINARY RESPONSE

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## PETITIONER'S EXHIBIT LIST

Ex. 1001	U.S. Patent No. 9,220,631 (“the ’631 Patent”)
Ex. 1002	Prosecution File History of U.S. Patent No. 9,220,631
Ex. 1003	Declaration of Horst Koller under 37 C.F.R. § 1.68.
Ex. 1004	Curriculum Vitae of Horst Koller
Ex. 1005	ITC Investigation No. 337-TA-1207, Staff’s Pre-Hearing Brief (public version)
Ex. 1006	ITC Investigation No. 337-TA-1207, Complainant’s Unopposed Motion to Terminate
Ex. 1007	PCT Patent Publication No. WO 2011/006877 to Sigg <i>et al.</i> (“Sigg”)
Ex. 1008	PCT Patent Publication No. WO 2009/030976 to Boulange <i>et al.</i> (“Boulange”)
Ex. 1009	Internet Archive WayBack Machine, March 7, 2011 Record of Drugs.com, <i>Macugen Prescribing Information</i> , available at <a href="https://web.archive.org/web/20110307065238/http://www.drugs.com:80/pro/macugen.html">https://web.archive.org/web/20110307065238/http://www.drugs.com:80/pro/macugen.html</a> (“2008 Macugen Label”)
Ex. 1010	ITC Investigation No. 337-TA-1207, Initial Determination Terminating the Investigation
Ex. 1011	Bhavnes D. Shah & Bhupendra G. Prajapati, <i>Pre-Filled Syringes: A New Concept</i> , PHARMA BIO WORLD 51 (2009) (“Shah”)
Ex. 1012	Arno Fries, <i>Drug Delivery of Sensitive Biopharmaceuticals With Prefilled Syringes</i> , 9(5) DRUG DELIVERY TECH. 22 (2009) (“Fries”)

Ex. 1013	Thomas Schoenknecht, <i>Prefilled Syringes: Why New Developments Are Important In Injectable Delivery Today</i> , in PREFILLED SYRINGES INNOVATIONS THAT MEET THE GROWING DEMAND (OnDrugDelivery 2005) (“Schoenknecht”)
Ex. 1014	U.S. Patent Publication No. 2012/0091026 to Chacornac <i>et al.</i> (“Chacornac”)
Ex. 1015	Sandeep Nema & John D. Ludwig, <i>Pharmaceutical Dosage Forms: Parenteral Medications, Volume 1: Formulation and Packaging</i> (3rd ed. 2010) (“Nema Vol. 1”)
Ex. 1016	Sandeep Nema & John D. Ludwig, <i>Pharmaceutical Dosage Forms: Parenteral Medications, Volume 2: Facility Design, Sterilization and Processing</i> (3rd ed. 2010) (“Nema Vol. 2”)
Ex. 1017	PCT Patent Publication No. WO 2007/035621 to Scypinski <i>et al.</i> (“Scypinski”)
Ex. 1018	U.S. Patent Publication No. 2003/0003014 to Metzner <i>et al.</i> (“Metzner”)
Ex. 1019	U.S. Pharmacopeia, <i>USP 789, Particulate Matter in Ophthalmic Solutions, USP 34 NF 29</i> (2011)
Ex. 1020	U.S. Patent Publication No. 2011/276005 to Hioki <i>et al.</i> (“Hioki”)
Ex. 1021	PCT Patent Publication No. WO 2007/149334 to Furfine <i>et al.</i> (“Furfine”)
Ex. 1022	Michael W. Stewart <i>et al.</i> , <i>Fresh From the Pipeline Aflibercept</i> , 11 NAT. REV. DRUG DISCOV. 269 (2012) (“Stewart”)
Ex. 1023	U.S. Patent No. 7,060,269 to Baca <i>et al.</i> (“Baca”)
Ex. 1024	Gerald McDonnel and Denver Russell, <i>Antiseptics and Disinfectants: Activities, Action, and Resistance</i> , Clinical Microbiology Review, (Jan. 1999) (“McDonnel”).

Ex. 1025	Lu Liu <i>et al.</i> , <i>Silicone Oil Microdroplets and Protein Aggregates in Repackaged Bevacizumab and Ranibizumab: Effects of Long-term Storage and Product Mishandling</i> , 52(2) INVESTIGATIVE OPHTHALMOLOGY & VISUAL SCIENCE 1023 (2011) (“Liu”)
Ex. 1026	U.S. Patent No. 7,404,278 to Wittland <i>et al.</i> (“Wittland”)
Ex. 1027	U.S. Food and Drug Administration, Lucentis® Highlights of the Prescribing Information, (June 2010) (“Lucentis Label”)
Ex. 1028	International Organization for Standardization, <i>ISO 11040-4 Prefilled Syringes – Part 4: Glass Barrels for Injectables</i> (2nd ed. 2007) (“ISO 11040-4”)
Ex. 1029	PCT Patent Publication No. WO 2008/077155 to Lam <i>et al.</i> (“Lam”)
Ex. 1030	James A. Dixon, et al. "VEGF Trap-Eye for the treatment of neovascular age-related macular degeneration." <i>Expert opinion on investigational drugs</i> 18.10 (2009): 1573-1580. (“Dixon”)
Ex. 1031	Declaration of Dr. Szilard Kiss under 37 C.F.R. § 1.68.
Ex. 1032	Curriculum Vitae of Dr. Szilard Kiss
Ex. 1033	Declaration of James L. Mullins, Ph.D.
Ex. 1034	Dow Corning® 365 35% Dimethicone NF Emulsion – Frequently Asked Questions (2002) (“DC365 FAQ”)
Ex. 1035	European Patent Application No. 12174860 to Novartis AG
Ex. 1036	U.S. Food and Drug Administration, Guidance for Industry: Sterile Drug Products Produced by Aseptic Processing—Current Good Manufacturing Practice (September 2004)

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