

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

REGENERON PHARMACEUTICALS, INC.,
Petitioner,

v.

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

Case No. IPR2021-00816

U.S. Patent No. 9,220,631

PETITIONER'S FIRST SUPPLEMENTAL EXHIBIT LIST

Petitioner Regeneron Pharmaceuticals, Inc. submits this First Supplemental Exhibit List with Petitioner's Notice of Supplemental Evidence pursuant to 37

C.F.R. § 42.63(e):

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 https://web.archive.org/web/20110307065238/http://www.drugs.com:80/pro/macugen.html ("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)
Ex. 1037	Affidavit of Internet Archive Office Manager
Ex. 1038	Internet Archive WayBack Machine, March 8, 2011 Record of Drugs.com, <i>Welcome to Drugs.com</i> , available at https://web.archive.org/web/20110308203650/http://www.drugs.com:80/
Ex. 1039	Internet Archive WayBack Machine, February 25, 2011 Record of Drugs.com, <i>FDA Professional Drug Information</i> , available at https://web.archive.org/web/20110225193929/http://www.drugs.com:80/pro/
Ex. 1040	U.S. Food and Drug Administration, Eylea [®] Highlights of the Prescribing Information, (November 2011) (“Eylea label”)
Ex. 1041	U.S. Food and Drug Administration, Guidance for Industry: Container Closure Systems for Packaging Human and Biologics – Chemistry, Manufacturing, and Controls Documentation (May 1999), available at https://www.fda.gov/downloads/drugs/guidances/ucm070551.pdf
Ex. 1042	International Standard ISO-7864, <i>Sterile hypodermic needles for single use</i> , ISO 7864:1993(E) (“ISO-7864”)
Ex. 1043	International Standard ISO-9626, <i>Stainless steel needle tubing for the manufacture of medical devices – Amendment 1</i> , ISO 9626:1991/Amd.1:2001(E) (“ISO-9626”)
Ex. 1044	Advait Badkar, <i>et al. Development of Biotechnology Products in Pre-filled Syringes: Technical Considerations and Approaches</i> , American Association of Pharmaceutical Sciences, June 2011, 12(2): 564-572 (“Badkar”)
Ex. 1045	William Leventon, “Medical Device Sterilization: What Manufacturers Need to Know” (MDDI online, Sept. 1, 2002), available at https://www.mddionline.com/medical-device-sterilization-what-manufacturers-need-know (“Leventon”)

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