

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 IPR2021-00816
Patent 9,220,631

PATENT OWNER'S UPDATED EXHIBIT LIST

Pursuant to 37 C.F.R. § 42.63(e), Patent Owner Concert Pharmaceuticals

hereby submits a current listing of Patent Owner's Exhibits.

Exhibit	Description
Ex. 2001	Declaration of Karl R. Leinsing, PE
Ex. 2002	Declaration of Marie Picci [Filed Under Seal]
Ex. 2003	October 29, 2020 Telephonic Hearing Transcript, <i>Regeneron Pharmaceuticals, Inc. v. Novartis Pharma AG et al.</i> , IPR2020-01317
Ex. 2004	Redline comparison of Koller Declarations submitted in IPR2020-01317 and IPR2021-00816
Ex. 2005	Court Notice setting Rule 16 Scheduling Conference (DI45), <i>Novartis Pharma AG, et al. v. Regeneron Pharmaceuticals, Inc.</i> , 1:20-cv-00690-TJM-CFH (N.D.N.Y. June 22, 2021)
Ex. 2006	Regeneron Pharmaceuticals, Inc.'s Partial Answer to Complaint (DI55), <i>Novartis Pharma AG, et al. v. Regeneron Pharmaceuticals, Inc.</i> , 1:20-cv-00690-TJM-CFH (N.D.N.Y. July 11, 2021)
Ex. 2007	Regeneron Pharmaceuticals, Inc.'s Complaint (DI01), <i>Regeneron Pharmaceuticals, Inc. v. Novartis Pharma AG et al.</i> , 1:20-cv-005502 (S.D.N.Y. July 17, 2020)
Ex. 2008	9220631 File History (Examiner's Search)
Ex. 2009	WO 2007/084765 (Deschatelets)
Ex. 2010	WO 1997/44068 (Tack)
Ex. 2011	English Translation of WO 1997/44068 (Tack)
Ex. 2012	IDS with Deschatelets (9220631 File History)
Ex. 2013	IDS with Tack (9220631 File History)
Ex. 2014	European Patent Application No. EP 12189649 (EP '649)

Exhibit	Description
Ex. 2015	Screen capture of Genentech Press Release, “FDA Approves Genentech’s Lucentis (Ranibizumab Injection) Prefilled Syringe” (Oct. 14, 2016)
Ex. 2016	Roche Finance Report 2018
Ex. 2017	Eric Souied, <i>Ranibizumab prefilled syringes: benefits of reduced syringe preparation times and less complex preparation procedures</i> , EUR. J. OPHTHALMOL. 25(6): 529-34 (2015) (“Souied”)
Ex. 2018	Thérèse M Sassalos and Yannis M Paulus, <i>Prefilled syringes for intravitreal drug delivery</i> , CLINICAL OPHTHALMOLOGY 13:701-06 (2019) (“Sassalos”)
Ex. 2019	Gholam A. Peyman, Eleonora M. Lad and Darius M. Moshfeghi, <i>Intravitreal Injection Of Therapeutic Agents</i> , RETINA 29:875–912 (2009) (“Peyman”)
Ex. 2020	Lloyd Aiello, et al., <i>Evolving guidelines for intravitreal injections</i> , RETINA (2004) (“Aiello”)
Ex. 2021	Bruno Reuter and Claudia Petersen, <i>Syringe Siliconisation Trends , Methods, Analysis Procedures.</i> ” (2012) (“Reuter”)
Ex. 2022	Edwin Chan, et al., <i>Syringe Siliconization Process Investigation and Optimization</i> , PDA JOURNAL OF PHARMACEUTICAL SCIENCE AND TECHNOLOGY, 136-158 (2012) (“Chan”)
Ex. 2023	Anita Leys, et al., <i>Neovascular growth following photodynamic therapy for choroidal hemangioma and neovascular regression after intravitreal injection of triamcinolone</i> , RETINA (2006) ul-Aug;
Ex. 2024	Joseph Remington and Paul Beringer, Remington: <i>The Science and Practice of Pharmacy</i> , Philadelphia: Lippincott Williams & Wilkins, 776-801 (21 st Ed. 2006) (“Remington”)
Ex. 2025	Pearse Keane and Srinivas Satta, <i>Development of Anti-VEGF Therapies for Intraocular Use: A Guide for Clinicians</i> , J OPTHAMOL. (2012) (“Keane”)

Exhibit	Description
Ex. 2026	FDA Alerts Health Care Professionals of Injection Risk from Repackaged Avastin Intravitreal Injections, U.S. Food and Drug Administration (Sep. 1, 2011), https://web.archive.org/web/20110901180651/https://www.fda.gov/Drugs/DrugSafety/ucm270296.htm (last accessed Nov. 10, 2020) (“FDA Alert”)
Ex. 2027	FDA Guidance for Industry – Q1A (R2) Stability Testing of New Drug Substances and Products (2003)
Ex. 2028	Hultman, et al., <i>The Physical Chemistry of Decontamination with Gaseous Hydrogen Peroxide</i> , Pharmaceutical Engineering, January/February 2007, 27(1):1-6 (“Hultman”)
Ex. 2029	Nitin Rathore, et al., <i>Characterization of Protein Rheology and Delivery Forces for Combination Products</i> , JOURNAL OF PHARMACEUTICAL SCIENCES, 101(12):4472-80 (Dec. 2012) (“Rathore 2012”)
Ex. 2030	Tracy Chang, et al., <i>Cell and Protein Compatibility of Parylene-C Surfaces</i> , Langmuir (2007) (“Chang”)
Ex. 2031	Marta Kaminska, et al., <i>Interaction of parylene C with biological objects</i> , Acta Bioeng Biomech. (2009) (“Kaminska”)
Ex. 2032	United States Patent Publication 2014/0012227A1
Ex. 2033	Joseph Remington and Paul Beringer, Remington: <i>The Science and Practice of Pharmacy</i> , Philadelphia: Lippincott Williams & Wilkins, 1025-1036 (21st Ed. 2006) (“Remington”)
Ex. 2034	Sandeep Nema, et al., <i>Antibody Structure, Instability, and Formulation</i> , Wiley InterScience. (2006) (“Nema”)
Ex. 2035	Gregory Sacha, et al., <i>Practical fundamentals of glass, rubber, and plastic sterile packaging systems</i> , PHARM DEV TECHNOL. (2010) (“Sacha”)

Exhibit	Description
Ex. 2036	MiniVision, Eylea Pre-Filled Syringe PBS Listed, Indication Expanded (Dec. 1, 2020)
Ex. 2037	<i>Intentionally Omitted</i>
Ex. 2038	<i>Intentionally Omitted</i>
Ex. 2039	<i>Intentionally Omitted</i>
Ex. 2040	<i>Intentionally Omitted</i>
Ex. 2041	Ingrid Markovic, <i>Regulatory Perspective on Safety Qualification of Extractables and Leachables</i> , (2011)
Ex. 2042	International Standard, Biological Evolution of medical devices – Part 1: Evaluation and Testing Within a Risk Management Process, (2009)
Ex. 2043	<i>Intentionally Omitted</i>
Ex. 2044	U.S. Lucentis® PFS Administration Flashcard (dated April 2018)
Ex. 2045	IPR2020-01317, Petition for Inter Partes Review
Ex. 2046	IPR2020-01318, Petition for Inter Partes Review
Ex. 2047	IPR2020-01318 Novartis Pharma AG, Novartis Technology LLC, and Novartis Pharmaceuticals Corporation’s Patent Owner Preliminary Response
Ex. 2048	International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use, STABILITY TESTING OF NEW DRUG SUBSTANCES AND PRODUCTS Q1A(R2) GUIDELINE (Feb. 6, 2003)
Ex. 2049	Glen Petrie, <i>The Need for Specificity in Accelerated Aging</i> , Medical Device & Diagnostic Industry (2006) (“Petrie”)
Ex. 2050	2020-01318 IPR, Paper No. 16, Petitioner’s Unopposed Motion to

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