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 Owners

_____

Case IPR2021-00816
Patent 9,220,631

_____

PATENT OWNER'S UPDATED EXHIBIT LIST

Pursuant to 37 C.F.R. § 42.63(e), Patent Owners Novartis Pharma AG, Novartis Technology LLC, and Novartis Pharmaceuticals Corporation (collectively. "Novartis") hereby submit a current listing of Patent Owners' 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, *Regeneron Pharmaceuticals, Inc. v. Novartis Pharma AG et al.*, 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), *Novartis Pharma AG, et al. v. Regeneron Pharmaceuticals, Inc.,* 1:20-cv-00690-TJM-CFH (N.D.N.Y. June 22, 2021)
Ex. 2006	Regeneron Pharmaceuticals, Inc.'s Partial Answer to Complaint (DI55), *Novartis Pharma AG, et al. v. Regeneron Pharmaceuticals, Inc.,* 1:20-cv-00690-TJM-CFH (N.D.N.Y. July 11, 2021)
Ex. 2007	Regeneron Pharmaceuticals, Inc.'s Complaint (DI01), *Regeneron Pharmaceuticals, Inc. v. Novartis Pharma AG et al.,* 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)

Exhibit	Description
Ex. 2013	IDS with Tack (9220631 File History)
Ex. 2014	European Patent Application No. EP 12189649 (EP '649)
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, *Ranibizumab prefilled syringes: benefits of reduced syringe preparation times and less complex preparation procedures*, EUR. J. OPHTHALMOL. 25(6): 529-34 (2015) ("Souied")
Ex. 2018	Thérèse M Sassalos and Yannis M Paulus, *Prefilled syringes for intravitreal drug delivery*, CLINICAL OPHTHALMOLOGY 13:701-06 (2019) ("Sassalos")
Ex. 2019	Gholam A. Peyman, Eleonora M. Lad and Darius M. Moshfeghi, *Intravitreal Injection Of Therapeutic Agent*s, RETINA 29:875–912 (2009) ("Peyman")
Ex. 2020	Lloyd Aiello, et al., *Evolving guidelines for intravitreous injections*, RETINA (2004) ("Aiello")
Ex. 2021	Bruno Reuter and Claudia Petersen, *Syringe Siliconisation Trends , Methods*, *Analysis Procedures*." (2012) ("Reuter")
Ex. 2022	Edwin Chan, et al., *Syringe Siliconization Process Investigation and Optimization*, PDA JOURNAL OF PHARMACEUTICAL SCIENCE AND TECHNOLOGY, 136-158 (2012) ("Chan")
Ex. 2023	Anita Leys, et al., *Neovascular growth following photodynamic therapy for choroidal hemangioma and neovascular regression after intravitreous injection of triamcinolone*, RETINA (2006) ul-Aug;
Ex. 2024	Joseph Remington and Paul Beringer, Remington: *The Science and Practice of Pharmacy*, Philadelphia: Lippincott Williams & Wilkins, 776-801 (21st Ed. 2006) ("Remington")

Exhibit	Description
Ex. 2025	Pearse Keane and Srinivas Sadda, *Development of Anti-VEGF Therapies for Intraocular Use: A Guide for Clinicians*, J OPTHAMOL. (2012) ("Keane")
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., *The Physical Chemistry of Decontamination with Gaseous Hydrogen Peroxide*, Pharmaceutical Engineering, January/February 2007, 27(1):1-6 ("Hultman")
Ex. 2029	Nitin Rathore, et al., *Characterization of Protein Rheology and Delivery Forces for Combination Products*, JOURNAL OF PHARMACEUTICAL SCIENCES, 101(12):4472-80 (Dec. 2012) ("Rathore 2012")
Ex. 2030	Tracy Chang, et al., *Cell and Protein Compatibility of Parylene-C Surfaces*, Langmuir (2007) ("Chang")
Ex. 2031	Marta Kaminska, et al., *Interaction of parylene C with biological objects*, Acta Bioeng Biomech. (2009) ("Kaminska")
Ex. 2032	United States Patent Publication 2014/0012227A1
Ex. 2033	Joseph Remington and Paul Beringer, Remington*: The Science and Practice of Pharmacy*, Philadelphia: Lippincott Williams & Wilkins, 1025-1036 (21st Ed. 2006) ("Remington")
Ex. 2034	Sandeep Nema, et al., *Antibody Structure, Instability, and Formulation*, Wiley InterScience. (2006) ("Nema")

Exhibit	Description
Ex. 2035	Gregory Sacha, et al., *Practical fundamentals of glass, rubber, and plastic sterile packaging systems*, PHARM DEV TECHNOL. (2010) ("Sacha")
Ex. 2036	MiniVision, Eylea Pre-Filled Syringe PBS Listed, Indication Expanded (Dec. 1, 2020)
Ex. 2037	*Intentionally Omitted*
Ex. 2038	*Intentionally Omitted*
Ex. 2039	*Intentionally Omitted*
Ex. 2040	*Intentionally Omitted*
Ex. 2041	Ingrid Markovic, *Regulatory Perspective on Safety Qualification of Extractables and Leachables,* (2011)
Ex. 2042	International Standard, Biological Evolution of medical devices – Part 1: Evaluation and Testing Within a Risk Management Process, (2009)
Ex. 2043	*Intentionally Omitted*
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)

DOCKET ALARM

Explore Litigation Insights

Docket Alarm provides insights to develop a more informed litigation strategy and the peace of mind of knowing you're on top of things.

Real-Time Litigation Alerts

Keep your litigation team up-to-date with **real-time alerts** and advanced team management tools built for the enterprise, all while greatly reducing PACER spend.

Our comprehensive service means we can handle Federal, State, and Administrative courts across the country.

Advanced Docket Research

With over 230 million records, Docket Alarm's cloud-native docket research platform finds what other services can't. Coverage includes Federal, State, plus PTAB, TTAB, ITC and NLRB decisions, all in one place.

Identify arguments that have been successful in the past with full text, pinpoint searching. Link to case law cited within any court document via Fastcase.

Analytics At Your Fingertips

Learn what happened the last time a particular judge, opposing counsel or company faced cases similar to yours.

Advanced out-of-the-box PTAB and TTAB analytics are always at your fingertips.

API

Docket Alarm offers a powerful API (application programming interface) to developers that want to integrate case filings into their apps.

LAW FIRMS
Build custom dashboards for your attorneys and clients with live data direct from the court.

Automate many repetitive legal tasks like conflict checks, document management, and marketing.

FINANCIAL INSTITUTIONS
Litigation and bankruptcy checks for companies and debtors.

E-DISCOVERY AND LEGAL VENDORS
Sync your system to PACER to automate legal marketing.