

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

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

---

**PETITIONER'S UPDATED EXHIBIT LIST**

## PETITIONER'S UPDATED 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)

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 <a href="https://web.archive.org/web/20110308203650/http://www.drugs.com:80/">https://web.archive.org/web/20110308203650/http://www.drugs.com:80/</a>
Ex. 1039	Internet Archive WayBack Machine, February 25, 2011 Record of Drugs.com, <i>FDA Professional Drug Information</i> , available at <a href="https://web.archive.org/web/20110225193929/http://www.drugs.com:80/pro/">https://web.archive.org/web/20110225193929/http://www.drugs.com:80/pro/</a>
Ex. 1040	U.S. Food and Drug Administration, Eylea <sup>®</sup> 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 <a href="https://www.fda.gov/downloads/drugs/guidances/ucm070551.pdf">https://www.fda.gov/downloads/drugs/guidances/ucm070551.pdf</a>
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 <a href="https://www.mddionline.com/medical-device-sterilization-what-manufacturers-need-know">https://www.mddionline.com/medical-device-sterilization-what-manufacturers-need-know</a> (“Leventon”)
Ex. 1046	Pamela Carter, <i>et al. The lowdown on low temperature sterilization for packaged devices</i> , Healthcare Purchasing News, July 2008, 42-45. (“Carter”)
Ex. 1047	U.S. Patent Publication No. 2005/0182370 to Hato (“Hato”)

# 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.