

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 CORRECTED
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)¹:

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| 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") |

¹ Exhibits 1091-1094 were served on the Patent Owner on November 23, 2021 pursuant to 37 C.F.R. § 42.64(b)(2). Exhibits 1091-1094 were not filed with the Board.

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| 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) |

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| 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. |

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| 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”) |

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