

**Regeneron's Initial Invalidity Contentions
in Inv. No. 337-TA-1207**

**Exhibit A: Invalidity of U.S. Patent
No. 9,220,631 Under 35 U.S.C. §§ 102-103**

Regeneron contends that each of the references set forth below, either alone or in combination with other prior art, invalidates the claims of the 631 Patent under 35 U.S.C. §§ 102-103:

Prior Art Reference	Date of Publication or Other Prior Art Date	Statutory Provision of Prior Art ¹	Bates Number
A. Fries, Drug Delivery of Sensitive Biopharmaceuticals with Prefilled Syringes, Drug Delivery Technology, Vol. 9, No. 5 (May 2009) ("Fries")	2009	102(b)	REGITC00140895- REGITC00140901
Bruno Reuter and Claudia Petersen. "Die Silikonisierung von Spritzen: Trends, Methoden, Analyseverfahren," TechnoPharm 2, Nr. 4 (2012): 238-244. ("Reuter")	2012	102(a)	REGITC00138492- REGITC00138499 (German); REGITC00140881- REGITC00140887 (English translation)
Bryon Lambert, et al. Radiation and Ethylene Oxide Terminal Sterilization Experiences with Drug Eluting Stent Products, American Association of Pharmaceutical Sciences, December 2011, 12(4):1116-1126 ("Lambert")	December 2011	102(a); 102(b)	REGITC00143623- REGITC00143633
Carl Hultman, et al. The Physical Chemistry of Decontamination with Gaseous Hydrogen Peroxide, Pharmaceutical Engineering, January/February 2007, 27(1):1-6 ("Hultman")	2007	102(b)	REGITC00148651- REGITC00148656
Dow Corning® 365 35% Dimethicone NF Emulsion – Frequently Asked Questions (2002) ("DC365 FAQ")	2002	102(b)	REGITC00143381- REGITC00143385
European Patent Application No. EP2371406 to Hioki et al. ("Hioki")	2011	102(a); 102(b); 102(e)	REGITC00131496- REGITC00131518

¹ In light of Novartis' failure to provide any basis to support its effective filing date and conception contentions with respect to the 631 Patent, Regeneron reserves the right to identify different statutory provisions under which each reference qualifies as prior art.

Prior Art Reference	Date of Publication or Other Prior Art Date	Statutory Provision of Prior Art ¹	Bates Number
Macugen PFS: <i>see e.g.</i> , Internet Archive WayBack Machine, March 7, 2011 Record of Drugs.com, Macugen Prescribing Information, available at https://web.archive.org/web/20110307065238/http://www.drugs.com:80/pro/macugen.html (“Macugen® Label”)	2011	102(a); 102(b)	REGITC00140870- REGITC00140880
John R. Gillis & Gregg Mosley, Validation of Pharmaceutical Processes, Chapter 16 – Validation of Ethylene Oxide Sterilization Processes (2011), pp.241-262. (“Gillis”)	2011	102(a); 102(b)	REGITC00143647- REGITC00143670
K. Kereluk, et al. Microbiological Aspects of Ethylene Oxide Sterilization: I. Experimental Apparatus & Methods, Applied Microbiology 1970, 19(1):146-151. (“Kereluk”)	1970	102(b)	REGITC00143640- REGITC00143646
Pamela Carter, et al. The lowdown on low temperature sterilization for packaged devices, Healthcare Purchasing News, July 2008, 42-45. (“Carter”)	2008	102(b)	REGITC00143602- REGITC00143605
PCT Patent Publication No. WO 2007/035621 to Scypinski et al. (“Scypinski”)	2007	102(b)	REGITC00141757- REGITC00141801
PCT Patent Publication No. WO 2007/149334 to Furfine et al. (“Furfine”)	2007	102(b)	REGITC00141830- REGITC00141844
PCT Patent Publication No. WO 2008/077155 to Lam et al. (“Lam”)	2008	102(b)	REGITC00143159- REGITC00143181
PCT Patent Publication No. WO 2009/030976 to Boulange et al. (“Boulange”)	2009	102(b)	REGITC00140838- REGITC00140869
PCT Patent Publication No. WO 2011/006877 to Sigg et al. (“Sigg”)	2011	102(b)	REGITC00140803- REGITC00140837
PCT Patent Publication No. WO 2011/159975 to D’Souza et al. (“D’Souza”)	December 2011	102(a); 102(b); 102(e)	REGITC00136157- REGITC00136195

Prior Art Reference	Date of Publication or Other Prior Art Date	Statutory Provision of Prior Art ¹	Bates Number
PCT Patent Publication No. WO1994/013328 to Hagen (“Hagen”)	1994	102(b)	REGITC00375964- REGITC00375981
Sandeep Nema & John D. Ludwig, Pharmaceutical Dosage Forms: Parenteral Medications, Volume 1: Formulation and Packaging (3rd ed. 2010) (“Nema Vol. 1”)	2010	102(b)	REGITC00154788- REGITC00155211
Sandeep Nema & John D. Ludwig, Pharmaceutical Dosage Forms: Parenteral Medications, Volume 2: Facility Design, Sterilization and Processing (3rd ed. 2010) (“Nema Vol. 2”)	2010	102(b)	REGITC00155212- REGITC0015631
Sandeep Nema & John D. Ludwig, Pharmaceutical Dosage Forms: Parenteral Medications, Volume 3: (3rd ed. 2010) (“Nema Vol. 3”)	2010	102(b)	REGITC00155632- REGITC00155959
U.S. Patent Application No. 2007/0253984 to Khandke et al. (“Khandke”)	2007	102(b)	REGITC00131887- REGITC00131915
U.S. Patent Publication No. 2012/0091026 to Chacornac et al. (“Chacornac”)	April 19, 2012	102(a); 102(e)	REGITC00140907- REGITC00140912
U.S. Department of Labor, Occupational Safety & Health Administration, Ethylene Oxide (EtO): Understanding OSHA’s Exposure monitoring Requirements, 2007 OSHA3325-01N (2007), available at https://www.osha.gov/Publications/ethylene_oxide.html (“OSHA Guidelines”)	2007	102(b)	REGITC00143613- REGITC00143622
U.S. Food and Drug Administration, Eylea® Highlights of the Prescribing Information (Nov. 2011) (“the Eylea® Label”)	November 2011	102(a); 102(b)	REGITC00143489- REGITC00143503

Prior Art Reference	Date of Publication or Other Prior Art Date	Statutory Provision of Prior Art ¹	Bates Number
U.S. Food and Drug Administration, Lucentis® Highlights of the Prescribing Information, (June 2010) (“the Lucentis® Label”)	June 2010	102(b)	REGITC00143152- REGITC00143158
U.S. Patent No. 6,790,410 to Metzner et al. (“Metzner”)	2004	102(b)	REGITC00133839- REGITC00133846
United States Patent No 8,221,353 to Cormier et al. (“Cormier”)	July 17, 2012	102(a); 102(b); 102(e)	REGITC00134039- REGITC00134061
United States Patent No. 7,404,278 to Wittland et al. (“Wittland”)	2008	102(b)	REGITC00143121- REGITC00143125
United States Patent Publication No. 2007/0190058 to Sharms (“Sharms”)	2007	102(b)	REGITC00131870- REGITC00131886
William Leventon, “Medical Device Sterilization: What Manufacturers Need to Know” (MDDI online, Sept. 1, 2002), available at https://www.mddionline.com/medical-devicesterilization-what-manufacturers-need-know (“Leventon”)	2002	102(b)	REGITC00143586- REGITC00143592
Bhavnes Shah, “Pre-filled Syringes: A New Concept,” Pharma Bio World (August 2009) (“Shah”)	2009	102(b)	REGITC00137084- REGITC00137090
EYLEA Vial	On sale no later than November 21, 2011	102(a); 102(b)	REGITC00148499- REGITC00148513; REGITC00143489- REGITC00143503; REGITC00130774- REGITC00130788; REGITC00130789- REGITC00130796
EYLEA PFS	See Exhibits C1 and C2 for conception and reduction to practice dates	102(g)	REGITC00117951- REGITC00117962

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