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 OPPOSITION TO PATENT OWNER'S CONTINGENT MOTION TO AMEND

DOCKET

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I.	THE SUBSTITUTE CLAIMS INTRODUCE NEW MATTER AND LACK WRITTEN DESCRIPTION SUPPORT			
	A.	The Original Disclosure Does Not Convey Possession of a Syringe Having 1-25 μ g or 3-25 μ g of Silicone Oil, a Break Loose Force of Less Than 11N, and a Shelf Life of at Least 12 Months		
	B.	The Original Disclosure Does Not Convey Possession of a 1 mL Syringe Having 1-25 µg or 3-25 µg of Silicone Oil and a Break Loose Force of Less Than 11N		
II.		SUBSTITUTE CLAIMS ARE UNPATENTABLE UNDER 35 U.S.C. 2(F)10		
	A.	The Numerical Ranges of Silicone Oil to Yield the Claimed Forces Are a Significant Aspect of the Claimed Invention		
	В.	Vetter Employees Made Significant Contributions to the Conception of the Numerical Ranges of Silicone Oil		
		1. The Novartis Inventors Did Not Possess a Concept before Working with Vetter		
		2. and Made Significant Contributions to the Conception of the Silicone Oil Ranges15		
	C.	Post-Conception Documents Confirm That Vetter Employees Made Significant Contributions to the Conception of the Silicone Oil Ranges		
III.	THE	SUBSTITUTE CLAIMS ARE NOT ENABLED		
	A.	The Specification Does Not Enable the Open-Ended "Shelf Life" Limitation		
	В.	The Specification Does Not Enable a Syringe Having about 1 µg or about 3 µg of Silicone Oil		
IV.	THE	SUBSTITUTE CLAIMS ARE INDEFINITE		
V.		SUBSTITUTE CLAIMS ARE UNPATENTABLE UNDER 35 U.S.C.		
	A.	Disclosure of New Limitations and Motivation to Combine		
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	C.	Claim Chart	
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PETITIONER'S 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, available at</i> https://web.archive.org/web/20110307065238/http://www.drugs.c om: 80/pro/macugen.html ("2008 Macugen Label")
Ex. 1010	ITC Investigation No. 337-TA-1207, Initial Determination Terminating the Investigation
Ex. 1011	Bhavnesh D. Shah & Bhupendra G. Prajapati, <i>Pre-Filled</i> <i>Syringes: A New Concept</i> , PHARMA BIO WORLD 51 (2009) ("Shah")
Ex. 1012	Arno Fries, Drug Delivery of Sensitive Biopharmaceuticals With Prefilled Syringes, 9(5) DRUG DELIVERY TECH. 22 (2009) ("Fries")
Ex. 1013	Thomas Schoenknecht, Prefilled Syringes: Why New Developments Are Important In Injectable Delivery Today, 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</i> <i>Forms: Parenteral Medications, Volume 1: Formulation and</i> <i>Packaging</i> (3rd ed. 2010) ("Nema Vol. 1")
Ex. 1016	Sandeep Nema & John D. Ludwig, <i>Pharmaceutical Dosage</i> <i>Forms: Parenteral Medications, Volume 2: Facility Design,</i> <i>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, USP 789, Particulate Matter in Ophthalmic Solutions, USP 34 NF 29 (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, Antiseptics and Disinfectants: Activities, Action, and Resistance, Clinical Microbiology Review, (Jan. 1999) ("McDonnel").
Ex. 1025	Lu Liu et al., Silicone Oil Microdroplets and Protein Aggregates in Repackaged Bevacizumab and Ranibizumab: Effects of Long- term Storage and Product Mishandling, 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")

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