

Receipt date: 03/02/2021

INFORMATION DISCLOSURE STATEMENT BY APPLICANT				Application Number	16/582,486
				Filing Date	2019-09-25
				First Named Inventor	Eric Furfine
				Art Unit	1647
				Examiner Name	Jon McClelland Lockard
Sheet	1	of	3	Attorney Docket Number	REGN-024CON9

U.S. PATENT DOCUMENTS					
Examiner Initial*	Cite No.	Patent Number	Issue Date YYYY-MM-DD	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
		Number-Kind Code (if known)			
	1	6,171,586 B1	01/09/2001	Lam <i>et al.</i>	
	2	8,110,546 B2	02/07/2012	Dix <i>et al.</i>	
	3	10,464,992 B2	11/05/2019	Furfine <i>et al.</i>	

U.S. PATENT APPLICATION PUBLICATIONS					
Examiner Initial*	Cite No.	Publication Number	Publication Date YYYY-MM-DD	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
		Number-Kind Code (if known)			
	1	2003/0113316 A1	06/19/2003	Kaisheva <i>et al.</i>	
	2	2003/0138417 A1	07/24/2003	Kaisheva <i>et al.</i>	
	3	2004/0197324 A1	10/07/2004	Liu <i>et al.</i>	
	4				

FOREIGN PATENT DOCUMENTS						
Examiner Initial*	Cite No.	Foreign Document Number	Publication Date YYYY-MM-DD	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear	T
		Country Code-Number-Kind Code (if known)				
	1	WO 97/04801	02/13/1997	Genetech, Inc.		
	2					

NON PATENT LITERATURE DOCUMENTS						
Examiner Initials*	Cite No.	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.				T
	1	Petition for <i>Inter Partes</i> Review of U.S. Patent No. 10,464,992, as submitted to the USPTO on January 7, 2021, in <i>Inter Partes</i> Review No. IPR2021-00402, 59 pgs.				
	2	File History of U.S. Patent No. 10,464,992, as submitted to the USPTO on January 7, 2021, in <i>Inter Partes</i> Review No. IPR2021-00402, 124 pgs.				
	3	Declaration of Dr. Reiner Gentz, as submitted to the USPTO on January 7, 2021, in <i>Inter Partes</i> Review No. IPR2021-00402, 76 pgs.				
	4	Fraser <i>et al.</i> , "Single Injections of Vascular Endothelial Growth Factor Trap Block Ovulation in the Macaque and Produce a Prolonged, Dose-Related Suppression of Ovarian Function," <i>J. Clin. Endocrinol. & Metab.</i> , 90(2):1114-1122 (2004)				
	5	Wulff <i>et al.</i> , "Prevention of Thecal Angiogenesis, Antral Follicular Growth, and Ovulation in the Primate by Treatment with Vascular Endothelial Growth Factor Trap R1R2," <i>Endocrinology</i> , 143(7):2797-2807 (2002)				
	6	Certificate of Correction dated March 3, 2020, in U.S. Patent No. 10,464,992, 1 pg.				
	7	Holash <i>et al.</i> , "VEGF-Trap: A VEGF blocker with potent antitumor effects," <i>PNAS</i> , 99(17):11393-11398 (2002)				
	8	Response to Office Action in U.S. Patent Application No. 12/835,065 filed November 22, 2011, as submitted to the USPTO on January 7, 2021, in <i>Inter Partes</i> Review No. IPR2021-00402, 4 pgs.				
	9	Declaration Pursuant to 37 C.F.R. § 1.131 of Daniel B. Dix, Kelly Frye, and Susan Kautz in Support of Response to Office Action in U.S. Patent Application No. 12/835,065 filed November 22, 2011, as submitted to the USPTO on January 7, 2021, in <i>Inter Partes</i> Review No. IPR2021-00402, 11 pgs.				
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	10	Resume of Reiner Gentz, Ph.D., as submitted to the USPTO on January 7, 2021, in <i>Inter Partes</i> Review No. IPR2021-00402, 3 pgs.		
	11	Rudge <i>et al.</i> , "VEGF Trap as a Novel Antiangiogenic Treatment Currently in Clinical Trials for Cancer and Eye Diseases, and VelociGene®-based Discovery of the Next Generation of Angiogenesis Targets," <i>Cold Spring Harbor Symposia on Quantitative Biology</i> , 70:411-418 (2004)		
	12	Chi <i>et al.</i> , "Physical Stability of Proteins in Aqueous Solution: Mechanism and Driving Forces in Nonnative Protein Aggregation," <i>Pharmaceutical Research</i> , 20(9):1325-1336 (2003)		
	13	Bontempo, "Preformulation Development of Parenteral Biopharmaceuticals," <i>Drugs and the Pharmaceutical Sciences</i> , 85:91-108 (1997)		
	14	"Guidance for Industry Q1A(R2) Stability Testing of New Drug Substances and Products," U.S. Department of Health and Human Services, Food and Drug Administration, Rockville, MD, as submitted to the USPTO on January 7, 2021, in <i>Inter Partes</i> Review No. IPR2021-00402, 25 pgs.		
	15	Parkins <i>et al.</i> , "The formulation of biopharmaceutical products," <i>Pharmaceutical Science & Technology Today</i> , 3(4):129-137 (2000)		
	16	Randolph <i>et al.</i> , "Surfactant-Protein Interactions," <i>Rational Design of Stable Protein Formulations</i> , pp. 159-175, Springer, Boston, MA (2002)		
	17	"Phosphate buffer," Cold Spring Harbor Protocols, 2006.pdb.rec8543, as submitted to the USPTO on January 7, 2021, in <i>Inter Partes</i> Review No. IPR2021-00402, 1 pg.		
	18	LUCENTIS® label, as submitted to the USPTO on January 7, 2021, in <i>Inter Partes</i> Review No. IPR2021-00402, 14 pgs.		
	19	AVASTIN® label, as submitted to the USPTO on January 7, 2021, in <i>Inter Partes</i> Review No. IPR2021-00402, 37 pgs.		
	20	REMICADE® label, as submitted to the USPTO on January 7, 2021, in <i>Inter Partes</i> Review No. IPR2021-00402, 58 pgs.		
	21	XOLAIR® label, as submitted to the USPTO on January 7, 2021, in <i>Inter Partes</i> Review No. IPR2021-00402, 17 pgs.		
	22	RAPTIVA® label, as submitted to the USPTO on January 7, 2021, in <i>Inter Partes</i> Review No. IPR2021-00402, 36 pgs.		
	23	SIMULECT® label, as submitted to the USPTO on January 7, 2021, in <i>Inter Partes</i> Review No. IPR2021-00402, 7 pgs.		
	24	HERCEPTIN® label, as submitted to the USPTO on January 7, 2021, in <i>Inter Partes</i> Review No. IPR2021-00402, 2 pgs.		
	25	Andersen <i>et al.</i> , "Recombinant protein expression for therapeutic applications," <i>Current Opinion in Biotechnology</i> , 13:117-123 (2002)		
	26	Janeway <i>et al.</i> , "The structure of a typical antibody molecule," <i>Immunobiology: The Immune System in Health and Disease</i> , 5th edition, New York: Garland Science, 6 pgs. (2001)		
	27	Drug Vehicle (Code C927), National Cancer Institute (NCI), retrieved January 6, 2021, from < https://ncithesaurus.nci.nih.gov/ncitbrowser/ConceptReport.jsp?dictionary=NCI_Thesaurus&ns=ncit&code=C927 >, as submitted to the USPTO on January 7, 2021, in <i>Inter Partes</i> Review No. IPR2021-00402, 2 pgs.		

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	28	Controls in SCI experiments, RegenBase, retrieved January 6, 2021, from < http://regenbase.org/control-groups.html >, as submitted to the USPTO on January 7, 2021, in <i>Inter Partes</i> Review No. IPR2021-00402, 2 pgs.			
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Examiner Signature	/JON M LOCKARD/	Date Considered	04/12/2021
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