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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of:

Diane D. Harrison, et al.

Group Art Unit: TBD

Application No.: Not yet assigned

Examiner: TBD

Filed: Herewith

Attorney Docket No.
206389-0003-02US

Title: ANTI-TNF ANTIBODIES, COMPOSITIONS, AND METHODS FOR THE
TREATMENT OF ACTIVE PSORIATIC ARTHRITIS

PRELIMINARY AMENDMENT

Prior to examination on the merits of the above-identified application and prior to the calculation of the fees, kindly amend the application without prejudice, as follows. If any additional fees are due, please charge deposit account number 50-5366.

REMARKS

This application is a continuation application of US Serial No. 16/517,594, filed July 20, 2019, which is a continuation application of US Serial No. 15/818,063, filed November 20, 2017, which claims priority to US Serial No. 62/452,079, filed January 30, 2017.

Amendment to the Specification

The Specification has been amended to include the priority to related applications. No new matter has been added by way of this amendment.

Amendment to the Claims

Claims 1-10 have been cancelled herein without prejudice or disclaimer to the inclusion of any cancelled subject matter in this application or in any continuing application(s).

Claims 11-20 are new and are directed to methods comprising administering an anti-TNF antibody comprising: (a.) a heavy chain (HC) complementary determining region (CDR) 1 comprising an amino acid sequence of SEQ ID NO: 1; (b.) a HC CDR2 comprising an amino acid sequence of SEQ ID NO: 2; wherein position 1 of SEQ ID NO: 2 is phenylalanine, position 2 of SEQ ID NO: 2 is methionine, position 3 of SEQ ID NO: 2 is serine, position 4 of SEQ ID NO: 2 is tyrosine, position 10 of SEQ ID NO: 2 is lysine, position 11 of SEQ ID NO: 2 is tyrosine, and position 17 of SEQ ID NO: 2 is glycine; (c.) a HC CDR3 comprising an amino acid sequence of SEQ ID NO: 3; wherein position 4 of SEQ ID NO: 3 is isoleucine, position 5 of SEQ ID NO: 3 is alanine, and position 9 of SEQ ID NO: 3 is asparagine; (d.) a light chain (LC) CDR1 comprising an amino acid sequence of SEQ ID NO: 4; wherein position 7 of SEQ ID NO: 4 is tyrosine; (e.) a LC CDR2 comprising an amino acid sequence of SEQ ID NO: 5; and (f.) a LC CDR3 comprising an amino acid sequence of SEQ ID NO: 6. Support for this amendment can be found at least in paragraph [44], of the originally filed Specification and in the originally filed sequence listing. No new matter has been added by way of these amendments.

Summary

Applicants respectfully submit that the pending claims are fully supported in the Specification as filed, and that no new matter has been added by way of the present Preliminary Amendment.

Favorable examination and allowance of the claims is hereby requested.

Respectfully submitted,

Diane D. Harrison, et al.

May 14, 2021

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U.S. PATENT/PUBLICATION DOCUMENTS					
Initials	Cite No.	Document Number	Issue/Publication Date	First Named Inventor	Relevant Pages, Columns, etc.
	1	3773919	11/20/1973	BOSWELL G	
	2	4239754	12/16/1980	BERTRAND HENRI	
	3	4309989	01/12/1982	FAHIM MOSTAFA S	
	4	4399216	08/16/1983	AXEL RICHARD	
	5	4603106	07/29/1986	CERAMI ANTHONY	
	6	4634665	01/06/1987	AXEL RICHARD	
	7	4656134	04/07/1987	RINGOLD GORDON M	
	8	4668218	05/26/1987	VIRTANEN RISTO	
	9	4676980	06/30/1987	SEGAL DAVID M	
	10	4683195	07/28/1987	MULLIS KARY B	
	11	4683202	07/28/1987	MULLIS KARY B	
	12	4704692	11/03/1987	LADNER ROBERT C	
	13	4766067	08/23/1988	BISWAS DEBAJIT K	
	14	4767402	08/30/1988	KOST JOSEPH	
	15	4795699	01/03/1989	TABOR STANLEY	
	16	4800159	01/24/1989	MULLIS KARY B	
	17	4816567	03/28/1989	CABILLY SHMUEL	
	18	4822776	04/18/1989	CERAMI ANTHONY	
	19	4873316	10/10/1989	MEADE HARRY	
	20	4889818	12/26/1989	GELFAND DAVID H	
	21	4921794	05/01/1990	TABOR STANLEY	
	22	4925673	05/15/1990	STEINER SOLOMON	
	23	4939666	07/03/1990	HARDMAN KARL D	
	24	4946778	08/07/1990	LADNER ROBERT C	
	25	4956288	09/11/1990	BARSOUM JAMES G	
	26	4965188	10/23/1990	MULLIS KARY B	
	27	4994370	02/19/1991	SILVER JONATHAN	
	28	5066584	11/19/1991	GYLLENSTEN ULF B	
	29	5091310	02/25/1992	INNIS MICHAEL A	

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U.S. PATENT/PUBLICATION DOCUMENTS					
Initials	Cite No.	Document Number	Issue/Publication Date	First Named Inventor	Relevant Pages, Columns, etc.
	30	5116964	05/26/1992	CAPON DANIEL J	
	31	5122464	06/16/1992	WILSON RICHARD H	
	32	5130238	07/14/1992	MALEK LAWRENCE T	
	33	5142033	08/25/1992	INNIS MICHAEL A	
	34	5149636	09/22/1992	AXEL RICHARD	
	35	5168062	12/01/1992	STINSKI MARK F	
	36	5179017	01/12/1993	AXEL RICHARD	
	37	5223409	06/29/1993	LADNER ROBERT C	
	38	5225538	07/06/1993	CAPON DANIEL J	
	39	5225539	07/06/1993	WINTER GREGORY P	
	40	5231024	07/27/1993	MOELLER ACHIM	
	41	5260203	11/09/1993	LADNER ROBERT C	
	42	5266491	11/30/1993	NAGATA SHIGEKAZU	
	43	5304489	04/19/1994	ROSEN JEFFREY M	
	44	5342613	08/30/1994	CREAVEN PATRICK J	
	45	5385839	01/31/1995	STINSKI MARK F	
	46	5403484	04/04/1995	LADNER ROBERT C	
	47	5404871	04/11/1995	GOODMAN DAVID E	
	48	5427908	06/27/1995	DOWER WILLIAM J	
	49	5447851	09/05/1995	BEUTLER BRUCE A	
	50	5455030	10/03/1995	LADNER ROBERT C	
	51	5458135	10/17/1995	PATTON JOHN S	
	52	5496549	03/05/1996	YAMAZAKI HIROH	
	53	5514670	05/07/1996	FRIEDMAN DORON	
	54	5518889	05/21/1996	LADNER ROBERT C	
	55	5530101	06/25/1996	QUEEN CARY L	
	56	5534621	07/09/1996	LADNER ROBERT C	
	57	5545806	08/13/1996	LONBERG NILS	
	58	5545807	08/13/1996	SURANI AZIM M	

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Initials	Cite No.	Document Number	Issue/Publication Date	First Named Inventor	Relevant Pages, Columns, etc.
	59	5565362	10/15/1996	ROSEN JEFFREY M	
	60	5569825	10/29/1996	LONBERG NILS	
	61	5571698	11/05/1996	LADNER ROBERT C	
	62	5576195	11/19/1996	ROBINSON RANDY R	
	63	5580717	12/03/1996	DOWER WILLIAM J	
	64	5580734	12/03/1996	TRECO DOUGLAS A	
	65	5582996	12/10/1996	CURTIS PETER J	
	66	5585089	12/17/1996	QUEEN CARY L	
	67	5595898	01/21/1997	ROBINSON RANDY R	
	68	5601819	02/11/1997	WONG JOHNSON T	
	69	5618920	04/08/1997	ROBINSON RANDY R	
	70	5625126	04/29/1997	LONBERG NILS	
	71	5625825	04/29/1997	ROSTOKER MICHAEL D	
	72	5633425	05/27/1997	LONBERG NILS	
	73	5637052	06/10/1997	HIROTA TOSHIKI	
	74	5641670	06/24/1997	TRECO DOUGLAS A	
	75	5643759	07/01/1997	PFREUNDSCUHL MICHAEL	
	76	5643768	07/01/1997	KAWASAKI GLENN H	
	77	5654407	08/05/1997	BOYLE PETRA	
	78	5656272	08/12/1997	LE JUNMING	
	79	5656730	08/12/1997	LEE LIHSYNG STANFORD	
	80	5658570	08/19/1997	NEWMAN ROLAND A	
	81	5658754	08/19/1997	KAWASAKI GLENN H	
	82	5661016	08/26/1997	LONBERG NILS	
	83	5693493	12/02/1997	ROBINSON RANDY R	
	84	5693762	12/02/1997	QUEEN CARY L	
	85	5698195	12/16/1997	LE JUNMING	
	86	5698417	12/16/1997	ROBINSON RANDY R	
	87	5698419	12/16/1997	WOLPE STEPHEN D	

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Initials	Cite No.	Document Number	Issue/Publication Date	First Named Inventor	Relevant Pages, Columns, etc.
	88	5698435	12/16/1997	ROBINSON RANDY R	
	89	5714352	02/03/1998	JAKOBOBITS AYA	
	90	5723323	03/03/1998	KAUFFMAN STUART ALAN	
	91	5733746	03/31/1998	TRECO DOUGLAS A	
	92	5733761	03/31/1998	TRECO DOUGLAS	
	93	5750105	05/12/1998	NEWMAN ROLAND A	
	94	5750373	05/12/1998	GARRARD LISA J	
	95	5763192	06/09/1998	KAUFFMAN STUART ALAN	
	96	5763733	06/09/1998	WHITLOW MARC	
	97	5766886	06/16/1998	STUDNICKA GARY M	
	98	5767260	06/16/1998	WHITLOW MARC	
	99	5770198	06/23/1998	COLLER BARRY S	
	100	5770222	06/23/1998	UNGER EVAN C	
	101	5770359	06/23/1998	WILSON RICHARD HARRIS	
	102	5770428	06/23/1998	BORIS-LAWRIE KATHLEEN A	
	103	5789650	08/04/1998	LONBERG NILS	
	104	5807706	09/15/1998	CARTER PAUL J	
	105	5814476	09/29/1998	KAUFFMAN STUART ALAN	
	106	5814599	09/29/1998	MITRAGOTRI SAMIR S	
	107	5817483	10/06/1998	KAUFFMAN STUART ALAN	
	108	5821333	10/13/1998	CARTER PAUL J	
	109	5824514	10/20/1998	KAUFFMAN STUART ALAN	
	110	5827690	10/27/1998	MEADE HARRY	
	111	5827739	10/27/1998	WILSON RICHARD HARRIS	
	112	5833985	11/10/1998	BALL EDWARD D	
	113	5837500	11/17/1998	LADNER ROBERT CHARLES	
	114	5839446	11/24/1998	WANER MILTON	
	115	5849695	12/15/1998	COHEN FRED E	

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Initials	Cite No.	Document Number	Issue/Publication Date	First Named Inventor	Relevant Pages, Columns, etc.
	116	5849992	12/15/1998	MEADE HARRY	
	117	5851198	12/22/1998	CASTELLANO THOMAS P	
	118	5856456	01/05/1999	WHITLOW MARC D	
	119	5871753	02/16/1999	CRABTREE GERALD R	
	120	5879681	03/09/1999	LEONE-BAY ANDREA	
	121	5885793	03/23/1999	GRIFFITHS ANDREW DAVID	
	122	5888511	03/30/1999	SKURKOVICH BORIS	
	123	5919452	07/06/1999	LE JUNMING	
	124	5932448	08/03/1999	TSO J YUN	
	125	5958413	09/28/1999	ANAGNOSTOPULOS HIRISTO	
	126	5959083	09/28/1999	BOSSLET KLAUS	
	127	5959084	09/28/1999	RING DAVID	
	128	5976862	11/02/1999	KAUFFMAN STUART ALAN	
	129	5989530	11/23/1999	LORENZ HERIBERT	
	130	5993833	11/30/1999	DE LACHARRIERE OLIVIER	
	131	5994616	11/30/1999	ROSEN JEFFREY M	
	132	6010902	01/04/2000	LEDBETTER JEFFREY A	
	133	6017732	01/25/2000	JESPER LAURENT STEPHANE ANNE	
	134	6037453	03/14/2000	JARDIEU PAULA M	
	135	6060285	05/09/2000	LENZ HELMUT	
	136	6106833	08/22/2000	RING DAVID	
	137	6132992	10/17/2000	LEDBETTER JEFFREY A	
	138	6180370	01/30/2001	QUEEN CARY L	
	139	6190691	02/20/2001	MAK VIVIEN	
	140	6193967	02/27/2001	MORGANELLI PETER M	
	141	6204023	03/20/2001	ROBINSON RANDY R	
	142	6210668	04/03/2001	LINDHOFER HORST	
	143	6277969	08/21/2001	LE JUNMING	

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Initials	Cite No.	Document Number	Issue/Publication Date	First Named Inventor	Relevant Pages, Columns, etc.
	144	6284471	09/04/2001	LE JUNMING	
	145	7521206	04/21/2009	HEAVNER GEORGE	
	146	7691378	04/06/2010	HEAVNER GEORGE	
	147	8241899	08/14/2012	HEAVNER GEORGE	
	148	9512065	12/06/2016	NORTEN JULIAN SCOTT	
	149	20020168360	11/14/2002	DINGIVAN CHRISTINE	
	150	20080311043	12/18/2008	HOFFMAN REBECCA S	
	151	20090028794	01/29/2009	MEDICH JOHN R	
	152	20090214528	08/27/2009	DORAI HAIMANTI	
	153	20100266590	10/21/2010	DEMETRI GEORGE D	

FOREIGN PATENT DOCUMENTS						
Initials	Cite No.	Document Number	Publication Date	Country	Relevant Pages, Columns, etc.	T
	154	1764992A	10/21/1992	AU		X
	155	0212489B1	11/30/1994	EP		X
	156	0218868A2	04/22/1987	EP		
	157	0229046B1	05/04/1994	EP		X
	158	0229246B1	08/04/1993	EP		X
	159	0237507B1	12/27/1991	EP		
	160	0260610B1	09/01/1993	EP		X
	161	0288088B1	03/09/1994	EP		X
	162	0308378B1	11/30/1994	EP		X
	163	0350690A2	01/17/1990	EP		X
	164	0351789B1	11/25/1998	EP		X
	165	0368684B1	03/09/1994	EP		X
	166	0371998B1	03/02/1994	EP		X
	167	0380068A1	08/01/1990	EP		X
	168	0393438A2	10/24/1990	EP		X
	169	0398327B1	03/15/1995	EP		X

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	170	0412486B1	11/30/1994	EP		X
	171	0433900A1	06/26/1991	EP		X
	172	0438474B1	05/15/1996	EP		X
	173	0463151B1	06/12/1996	EP		X
	174	0486526B2	03/07/2001	EP		X
	175	0525570A2	02/03/1993	EP		X
	176	0526905A3	05/05/1993	EP		X
	177	0550400B1	07/10/1996	EP		X
	178	0590689A2	04/06/1994	EP		X
	179	0610201B1	05/16/2001	EP		X
	180	614989A1	09/14/1994	EP		X
	181	0710719B1	03/14/2007	EP		X
	182	2870137B1	05/16/2018	EP		X
	183	2272440A	05/18/1994	GB		
	184	11127855A	05/18/1999	JP		X
	185	0212500A2	02/14/2001	WO		X
	186	0212502A2	02/14/2002	WO		X
	187	8605803A1	10/09/1986	WO		
	188	8806630A1	09/07/1988	WO		X
	189	8906283A1	07/13/1989	WO		X
	190	9000902A1	02/08/1990	WO		X
	191	9003809A1	04/19/1990	WO		X
	192	9004036A1	04/19/1990	WO		
	193	9005370A1	05/17/1990	WO		
	194	9014424A1	11/29/1990	WO		X
	195	9014430A1	11/29/1990	WO		X
	196	9014443A1	11/29/1990	WO		X
	197	9100360A1	01/10/1991	WO		X
	198	9102078A1	02/21/1991	WO		X

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	199	9109967A1	07/11/1991	WO		X
	200	9117271A1	11/14/1991	WO		
	201	9118980A1	12/12/1991	WO		X
	202	9119818A1	12/26/1991	WO		X
	203	9200373A1	01/09/1992	WO		X
	204	9203461A1	03/05/1992	WO		
	205	9205258A1	04/02/1992	WO		X
	206	9206204A1	04/16/1992	WO		
	207	9207076A1	04/30/1992	WO		X
	208	9211272A1	07/09/1992	WO		
	209	9211383A1	07/09/1992	WO		X
	210	9213095A1	08/06/1992	WO		X
	211	9214843A1	09/03/1992	WO		X
	212	9216221A1	10/01/1992	WO		X
	213	9216553A1	10/01/1992	WO		X
	214	9218619A1	10/29/1992	WO		X
	215	9302108A1	02/04/1993	WO		X
	216	9308278A1	04/29/1993	WO		X
	217	9308829A1	05/13/1993	WO		X
	218	9311383A1	06/10/1993	WO		X
	219	9406498A1	03/31/1994	WO		X
	220	9408552A2	04/28/1994	WO		X
	221	9416970A1	08/04/1994	WO		X
	222	9418219A1	08/18/1994	WO		X
	223	9425585A1	11/10/1994	WO		X
	224	9501538A1	01/12/1995	WO		
	225	9516027A1	06/15/1995	WO		X
	226	9607754A1	03/14/1996	WO		X
	227	9619256A1	06/27/1996	WO		X

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	228	9633735	10/31/1996	WO		X
	229	9634096A1	10/31/1996	WO		X
	230	9713852A1	04/17/1997	WO		X
	231	9720032A1	06/05/1997	WO		
	232	9722376A1	06/26/1997	WO		X
	233	9725086	07/17/1997	WO		
	234	9729131A1	08/14/1997	WO		X
	235	9801757A1	01/15/1998	WO		
	236	9824884A1	06/11/1998	WO		X
	237	9824893A1	06/11/1998	WO		
	238	9835888A1	08/20/1998	WO		X
	239	9850433A2	11/12/1998	WO		X
	240	9853847A1	12/03/1998	WO		X
	241	9906834A2	02/11/1999	WO		
	242	1992001047A1	01/23/1992	WO		X
	243	1992020791A1	11/26/1992	WO		X
	244	1993006213A1	04/01/1993	WO		X
	245	1993011236A1	06/10/1993	WO		X
	246	1993019172A1	09/30/1993	WO		X
	247	2008016633	02/07/2008	WO		X
	248	2010056399A1	05/20/2010	WO		
	249	2014006414A1	01/09/2014	WO		X
	250	2014140509A1	09/18/2014	WO		

OTHER DOCUMENTS			
Initials	Cite No.	Author, Title, Date, Pages, etc.	T
	251	ACOSTA FELQUER et al., "Drug therapies for peripheral joint disease in psoriatic arthritis: a systematic review", Journal of Rheumatology, (20141130), vol. 41, no. 11, doi:10.3899/jrheum.140876, ISSN 0315-162X, pages 2277 - 2285, XP055622320	
	252	ADERKA, Dan et al., "IL-6 Inhibits Lipopolysaccharide-Induced tumor Necrosis Factor Production in Cultured Human Monocytes, U937 Cells, and in Mice," J Immunol, 143:3517-3523(1989).	

Examiner Signature	Date Considered
Examiner: Please initial if citation considered, whether or not citation is in conformance with MPEP Section 609. Please draw a line through the citation if it is not in conformance and it is not considered. Please include a copy of this form with the next communication to the applicant.	

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OTHER DOCUMENTS			
Initials	Cite No.	Author, Title, Date, Pages, etc.	T
	253	ADERKA, Dan et al., "The Possible Role of Tumor Necrosis Factor (TNF) and Its Natural Inhibitors, The Soluble-TNF Receptors, In Autoimmune Diseases," Israel J. Med. Sci., 28(2):126-130 (1992).	
	254	ADERKA, Dan, "Role of Tumor Necrosis Factor in the Pathogenesis of Intravascular Coagulopathy of Sepsis: Potential New Therapeutic Implications," IsrJ Med Sci, 27:52-60 (1991).	
	255	AGGARWAL, Bharat B. et al., "Human Tumor Necrosis Factor Production, Purification and Characterization," J. of Biol. Chem., 260(4):2345-2354 (1985).	
	256	AKAMA, Hideto et al., "Mononuclear Cells Enhance Prostaglandin E2 Production of Polymorphonuclear Leukocytes via Tumor Necrosis Factor α ," Biochemical and Biophysical Research Comm., 168(2):857-862 (1990).	
	257	ALT, et al., "Selective Multiplication of Dihydrofolate Reductase Genes in Methotrexate-resistant Variants of Cultured Murine Cells", J. Biol. Chem. 253:1357-1370 (1978)	
	258	Anonymous, "History of Changes for Study NCT02181673", submitted January 23, 2017, https://clinicaltrials.gov/ct2/history/NCT02181673?V_30=View#StudyPageTop	
	259	ASHKENAZI et al., "Protection against endotoxic shock by a tumor necrosis factor receptor immunoadhesin", Proc. Natl. Acad. Sci. USA 88:10535-10539 (1991);	
	260	BABCOOK et al., "A novel strategy for generating monoclonal antibodies from single, isolated lymphocytes producing antibodies of defined specificities", Proc. Natl. Acad. Sci. USA 93:7843-7848(1996));	
	261	BAKER et al., "Control of established experimental allergic encephalomyelitis by inhibition of tumor necrosis factor (TNF) activity within the central nervous system using monoclonal antibodies and TNF receptor-immunoglobulin fusion proteins", Eur. J. Immunol. 24:2040-2048 (1994)	
	262	Basra MKA, Fenech R, Gatt RM, Salek MS, Finlay AY. The Dermatology Life Quality Index 1994-2007: a comprehensive review of validation data and clinical results. Br J Rheumatol. 2008;159:997-1035.	
	263	BEBBINGTON, et al., "High-Level Expression of a Recombinant Antibody from Myeloma Cells Using a Glutamine Synthetase Gene as an Amplifiable Selectable Marker", Bio/Technology 10:169-175(1992))	
	264	BERKOW et al., Eds, The Merck Manual of Diagnosis and Therapy, Sixteenth Edition, Merck Research Laboratories, Rahway, NJ 1992 pg. 1263-1287	
	265	BEUTLER, B. et al., "Identity of tumour necrosis factor and the macrophage-secreted factor cachectin," Nature, 316:552-554 (1985).	
	266	BEUTLER, B. et al., "Passive Immunization Against Cachectin/Tumor Necrosis Factor Protects Mice from Lethal Effect of Endotoxin," Science, 229:869-871 (1985).	
	267	BEUTLER, B. et al., "Purification of Cachectin, A Lipoprotein Lipase-Suppressing Hormone Secreted by Endotoxin-induced RAW 264.7 Cells," J. Exp. Med., 161:984-995 (1985).	
	268	BODMER, Mark, "Humanized Antibodies for Anti-TNF Therapy," Abstract, Endotoxemia & Sepsis Conference (1991).	
	269	BOSHART, et al., "A Very Strong Enhancer Is Located Upstream of an Immediate Early Gene of Human Cytomegalovirus", Cell 41:521-530 (1985))	
	270	BRINGMAN, Timothy S. and Aggarwal, Bharat B., "Monoclonal Antibodies to Human Tumor Necrosis Factors Alpha and Beta: Applications for Affinity Purification, Immunoassays, and as Structural Probes," Hybridoma, 6(5):489-507 (1987).	

Examiner Signature		Date Considered	
Examiner: Please initial if citation considered, whether or not citation is in conformance with MPEP Section 609. Please draw a line through the citation if it is not in conformance and it is not considered. Please include a copy of this form with the next communication to the applicant.			

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	Client Number	206389
Page 11 of 20	Matter Number	0003-02-US

OTHER DOCUMENTS			
Initials	Cite No.	Author, Title, Date, Pages, etc.	T
	271	BUTLER et al., "TNF Receptor Fusion Proteins Are Effective Inhibitors of TNF-Mediated Cytotoxicity on Human KYM-1D4 Rhabdomyosarcoma Cells", Cytokine 6(6):616-623 (1994);	
	272	Capellas, et al., "Enzymatic Condensation of Cholecystokinin CCK-8 (4-6) and CCK-8 (7-8) Peptide Fragments in Organic Media," Biotechnology and Bioengineering, 56(4): 456-463 (1997).	
	273	CAPON et al., "Designing CD4 immunoadhesins for AIDS therapy", Nature 337:525-531 (1989),	
	274	CARTER et al., "Humanization of an anti-p185HER2 antibody for human cancer therapy", Proc. Natl. Acad. Sci. U.S.A. 89:4285 (1992)	
	275	Cassell SE, Bieber JD, Rich P, Tutuncu ZN, Lee SJ, Kalunian KC, Wu CW, Kavanaugh A. The modified Nail Psoriasis Severity Index: validation of an instrument to assess psoriatic nail involvement in patients with psoriatic arthritis. J Rheumatol. 2007;34(1):123-129.	
	276	Cella D, Yount S, Sorensen M, Chartash E, Sengupta N, Grober J. Validation of the Functional Assessment of Chronic Illness Therapy Fatigue Scale relative to other instrumentation in patients with rheumatoid arthritis. J Rheumatol. 2005;32(5):811-819	
	277	Chandran V, Bhella S, Schentag C, Gladman D. Functional Assessment of Chronic Illness Therapy-Fatigue Scale is valid in patients with psoriatic arthritis. Ann Rheum Dis. 2007;66:936-939.	
	278	Chothia, et al., "Canonical Structures for the Hypervariable Regions of Immunoglobulins," Journal of Molecular Biology, 196: 901-917 (1987).	
	279	Coates LC, Helliwell PS. Validation of minimal disease activity criteria for psoriatic arthritis using interventional trial data. Arthritis Care Res (Hoboken). 2010; 62(7):965-969.	
	280	COHEN et al., "Intravenous golimumab in rheumatoid arthritis", Expert Review of Clinical Immunology, (20140515), vol. 10, no. 7, doi:10.1586/1744666X.2014.918847, pages 823 - 830, XP009516813	
	281	COLLINS, M.S. et al., "Immunoprophylaxis of Polymicrobial Cellulitis with a Human Monoclonal Antibody Against Lipopolysaccharide Antigen of Pseudomonas aeruginosa," Abstract E-63, Abstracts of Annual Meeting 1989.	
	282	CONRAD et al., "Compartment-specific accumulation of recombinant immunoglobulins in plant cells: an essential tool for antibody production and immunomodulation of physiological functions and pathogen activity", Plant Mol. Biol. 38:101-109 (1998)	
	283	Copy of Canadian Examination Report for CA2878319 dated 11 December 2019	
	284	CORCORAN et al., "Characterization of ligand binding by the human p55 tumour-necrosis-factor receptor", Eur. J. Biochem. 223:831-840 (1994)),	
	285	Costello P, FitzGerald O. Disease mechanisms in psoriasis and psoriatic arthritis. Curr Rheumatol Rep. 2001 ;3(5):419-427.	
	286	CRAMER et al., "Transgenic Plants for Therapeutic Proteins: Linking Upstream and Downstream Strategies", Curr. Top. Microbol. Immunol. 240:95-118 (1999)	
	287	CROSS, A.S. et al., "Pretreatment with Recombinant Murine Tumor Necrosis Factor a Cachectin and Murine Interleukin 1 a Protects Mice from Lethal Bacterial Infection," J of Exp Med., 169:2021 -2027 (1989).	
	288	CULLEN, et al., "Functional Analysis of the Transcription Control Region Located Within the Avian Retroviral Long Terminal Repeat", Molec. Cell. Biol. 5:438-447 (1985))	
	289	CUNNINGHAM AND WELLS, "High-Resolution Epitope Mapping of hGH-Receptor Interactions by Alanine-Scanning Mutagenesis", Science Ausubel, supra, Chapters 8, 15; 244:1081-1085 (1989)).	

Examiner Signature	Date Considered
Examiner: Please initial if citation considered, whether or not citation is in conformance with MPEP Section 609. Please draw a line through the citation if it is not in conformance and it is not considered. Please include a copy of this form with the next communication to the applicant.	

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	Client Number	206389
Page 12 of 20	Matter Number	0003-02-US

OTHER DOCUMENTS			
Initials	Cite No.	Author, Title, Date, Pages, etc.	T
	290	D. SHEALY et al., "Characterization of golimumab, a human monoclonal antibody specific for human tumor necrosis factor alpha", MABS, Vol. 2, No. 4, pgs. 428-439 (2010)	
	291	DE VOS, et al., "Human Growth Hormone and Extracellular Domain of Its Receptor: Crystal Structure of the Complex", Science 255:306-312 (1992)).	
	292	DI GIOVINE, Francesco, S. et al., "Tumour necrosis factor in synovial exudates," Annals of the Rheumatic Diseases, 47:768-772 (1988).	
	293	DUNCOMBE, Andrew S. et al., "Tumor Necrosis Factor Mediates Autocrine Growth Inhibition in a Chronic Leukemia," J Immunol, 143:3828-3834 (1989).	
	294	DUPONT et al., "Escherichia coli Diarrhea" Bacterial Infections of Humans:Epidemiology and Control, A.S. Evans et al., 2nd Edition, Spring Science & Business Media, New York, pgs. 239-254(1991)	
	295	E. RANKIN et al., "The therapeutic effects of an engineered human anti-tumour necrosis factor alpha antibody (CDP571) in rheumatoid arthritis", British Journal of Rheumatology, Vol. 34, No. 4, pgs. 334-342, XP000674590 (April 1995)	
	296	ECHTENACHER, Bernd et al., "Requirement of Endogenous Tumor Necrosis Factor/Cachectin for Recovery from Experimental Peritonitis," J. of Immunology, 145(11):3762-3766 (1990).	
	297	ECK, Michael J. and Sprang, Stephen R., "The Structure of Tumor Necrosis Factor-L at 2.6 L Resolution," J Biol Chem, 264:17595-17605 (1989).	
	298	ELLIOTT, M.J. et al., "A Repeated Therapy with Monoclonal Antibody to Tumour Necrosis Factor a (cA2) in Patients with Rheumatoid Arthritis", The Lancet, 344:1125-1127, 1994	
	299	ENGELMANN, Hartmut et al., "A Tumor Necrosis Factor-binding Protein Purified to Homogeneity from Human Urine Protects Cells from Tumor Necrosis Factor Toxicity," J. of Bio. Chem., 264(20): 1974-11980 (1989).	
	300	ENGELMANN, Hartmut et al., "Two Tumor Necrosis Factor-binding Proteins Purified from Human Urine," J. of Bio. Chem., 265(3):1531 -1536 (1990).	
	301	EREN et al. "Human monoclonal antibodies specific to hepatitis B virus generated in a human/mouse radiation chimera: the Trimer system", Immunol. 93: 154-161 (1998)	
	302	EUROQOL GROUP. EUROQOL - a new facility for the measurement of health-related quality of life. Health Policy. 1990;16:199-208.	
	303	EXLEY, A.R. et al., "Monoclonal Antibody (Mab) to Recombinant Human Tumour Necrosis Factor (rhTNF) in the Prophylaxis and Treatment of Endotoxic Shock in Cynomolgus Monkeys," Medical Research Society, Abstract 184, p. 50 (1989).	
	304	EXLEY, A.R. et al., "Monoclonal antibody to TNF in severe septic shock," The Lancet, 335:1275-1277(1990).	
	305	Faraawi et al., 2016, "Comparison of Baseline Characteristics of Rheumatoid Arthritis Patients Initiating Therapy with Subcutaneous Golimumab and Infliximab and Intravenous Golimumab: An Analysis from the Prospective, Observational Registry, BioTRAC." The Journal of Rheumatology, 43(6), Number 87, p.1186	
	306	Feldman SR, Gordon KB, Bala M, et al. Infliximab treatment results in significant improvement in the quality of life of patients with severe psoriasis: a double-blind placebo-controlled trial. British Journal of Dermatology. 2005;152:954-960.	
	307	Felson, et al., "American College of Rheumatology Preliminary Definition of Improvement in Rheumatoid Arthritis," Arthritis & Rheumatism, 38 (6): 727-735 (1995).	

Examiner Signature	Date Considered
Examiner: Please initial if citation considered, whether or not citation is in conformance with MPEP Section 609. Please draw a line through the citation if it is not in conformance and it is not considered. Please include a copy of this form with the next communication to the applicant.	

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	Client Number	206389
Page 13 of 20	Matter Number	0003-02-US

OTHER DOCUMENTS			
Initials	Cite No.	Author, Title, Date, Pages, etc.	T
	308	FENDLY, Brian M. et al., "Murine Monoclonal Antibodies Defining Neutralizing Epitopes on Tumor Necrosis Factor," Hybridoma, 6(4):359-370 (1987).	
	309	Finlay AY, Khan GK. Dermatology Life Quality Index (DLQI)-a simple practical measure for routine clinical use. Clin Exp Dermatol. 1994;19(3):210-216.	
	310	FISCH et al., "Site-Specific Modification of a Fragment of a Chimeric Monoclonal Antibody Using Reverse Proteolysis", Bioconjugate Chem., 3:147-153 (1992);	
	311	FISCHER et al., "Towards molecular farming in the future: moving from diagnostic protein and antibody production in microbes to plants", Biotechnol. Appl. Biochem. 30:101-108 (Oct., 1999),	
	312	FISHWALD et al., "High-avidity human IgGk monoclonal antibodies from a novel strain of minilocus transgenic mice", Nat Biotechnol 14(7):845-851 (1996).	
	313	FONG, Yuman and Lowry, Stephen F., "Tumor Necrosis Factor in the Pathophysiology of Infection and Sepsis," Clin Immunol Immunopathol, 55:157-170 (1990).	
	314	FONG, Yuman et al., "Antibodies to Cachectin/Tumor Necrosis Factor Reduce Interleukin 1 β and Interleukin 6 Appearance During Lethal Bacteremia," J. Exp. Med., 170:1627-1633 (1989).	
	315	FOOTE et al., "Antibody Framework Residues Affecting the Conformation of the Hypervariable Loops", Journal of Molecular Biology, 224(2), pgs. 487-499 (1992)	
	316	Fredriksson T, Pettersson U. Severe psoriasis - oral therapy with a new retinoid. Dermatologica. 1978;157(4):238-244.	
	317	Fries JF, Spitz P, Kraines RG, Holman HR. Measurement of patient outcomes in arthritis. Arthritis Rheum. 1980;23(2):137-145.	
	318	GALLOWAY, Cynthia J. et al., "Monoclonal anti-tumor necrosis factor (TNF) antibodies protect mouse and human cells from TNF cytotoxicity," J. of Immunological Methods, 140:37-43 (1991).	
	319	GARRETT S, JENKINSON T, KENNEDY LG, WHITELOCK H, GAISFORD P, CALIN A. A new approach to defining disease status in ankylosing spondylitis: the Bath Ankylosing Spondylitis Disease Activity Index. J Rheumatol. 1994;21(12):2286-2291.	
	320	GENEBANK ACCESSION, No. M32046 (1990, June 15).	
	321	Genebank Accession, No. N90300 (Nov. 1, 1989).	
	322	GILLIES, Stephen D. et al., "High-level expression of chimeric antibodies using adapted cDNA variable region cassettes," J Immunol Methods, 125:191-202 (1989).	
	323	Gladman DD, Inman RD, Cook RJ, et al. International spondylarthritis interobserver reliability exercise-the INSPIRE study: II. Assessment of peripheral joints, enthesitis, and dactylitis. J Rheumatol. 2007;34(8):1740-1745	
	324	Gladman DD, Ziouzina O, Thavaneswaran A, Chandran V. Dactylitis in psoriatic arthritis: prevalence and response to therapy in the biologic era. J Rheumatol. 2013;40(8):1357-1359.	
	325	Goedkoop AY, Kraan MC, Teunissen MB, et al. Early effects of tumour necrosis factor alpha blockade on skin and synovial tissue in patients with active psoriasis and psoriatic arthritis. Ann Rheum Dis. 2004;63(7):769-773.	
	326	GORMAN, S.D. and Clark, M.R., "Humanisation of monoclonal antibodies for therapy," Sem Immunol, 2:457-466 (1990).	
	327	GOSSEN, AND H. BUJARD, "Tight control of gene expression in mammalian cells by tetracycline-responsive promoters", Proc. Natl. Acad. Sci. USA 89: 5547-5551 (1992)	

Examiner Signature	Date Considered
Examiner: Please initial if citation considered, whether or not citation is in conformance with MPEP Section 609. Please draw a line through the citation if it is not in conformance and it is not considered. Please include a copy of this form with the next communication to the applicant.	

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	Client Number	206389
Page 14 of 20	Matter Number	0003-02-US

OTHER DOCUMENTS			
Initials	Cite No.	Author, Title, Date, Pages, etc.	T
	328	GRAY et al., "Secretion capture and report web: use of affinity derivatized agarose microdroplets for the selection of hybridoma cells", J. Imm. Meth. 182:155-163 (1995);	
	329	GREEN et al, "Antigen-specific human monoclonal antibodies from mice engineered with human Ig heavy and light chain YACs", Nature Genetics 7:13-21 (1994)	
	330	GREEN, L. "Antibody Engineered via Genetic Engineering of the Mouse: Xenomouse Strains Are a Vehicle for the Facile Generation of Therapeutic Human Monoclonal Antibodies", Journal of Immunological Methods, 231, pgs. 11-23 (1999)	
	331	H. HOOGENBOOM et al., "By-passing immunization. Human antibodies from synthetic repertoires of germline VH gene segments rearranged in vitro", JOURNAL OF MOLECULAR BIOLOGY, Vol. 227, No. 2, XP024020530; page 386 (September 10, 1992)	
	332	HANES et al. "Ribosome display efficiently selects and evolves high-affinity antibodies in vitro from immune libraries", Proc Natl. Aca. Sci USA 95 14130-14135 (Nov. 1998)	
	333	HANES et al., "In vitro selection and evolution of functional proteins by using ribosome display", Proc. Natl. Acad. Sci. USA 94:4937-4942 (May 1997)	
	334	HARRIS, "Anklosing Spondylitis", Chapter 6, Spondyloarthropathies, Kelley's Textbook of Rheumatology, 6th Edition, Sledge CB, pas. 1039-1053 (2001)	
	335	HAYASHI, H. et al., "An Enzyme-linked Immunosorbent Assay for Recombinant Human Tumor Necrosis Factor Using Monoclonal Antibody," Recent Adv. Chemother, 820-821 (1985).	
	336	Healy PJ, Helliwell PS. Measuring clinical enthesitis in psoriatic arthritis: assessment of existing measures and development of an instrument specific to psoriatic arthritis. Arthritis Rheum. 2008;59(5):686-691	
	337	HERVE, P. et al., "Monoclonal Anti TNF a Antibody for the Treatment of Severe Acute GvHD in Humans," Abstract 3.25, Lymphoma Res. 9:591 (1990).	
	338	HINSHAW, L.B. et al., "Survival of Primates in LD100 Septic Shock Following Therapy with Antibody to Tumor Necrosis Factor (TNFa)," Circulatory Shock, 30:279-292 (1990).	
	339	HIRAI, Makoto et al., "Production and characterization of monoclonal antibodies to human tumor necrosis factor," J. of Immun. Methods, 96:57-62 (1987).	
	340	HOOD et al., "Molecular Farming of Industrial Proteins from Transgenic Maize", Adv. Exp. Med. Biol. 464:127-147(1999)	
	341	Husted JA, Gladman DD, Cook RJ, Farewell VT. Responsiveness of health status instruments to changes in articular status and perceived health in patients with psoriatic arthritis. J Rheumatol. 1998;25(11):2146-2155.	
	342	ITOH et al., "Application of Inverse Substrates to Trypsin-Catalyzed Peptide Synthesis", Bioorg. Chem., 24(1): 59-68 (1996).	
	343	J. L. HAMLIN AND C. MA, "The mammalian dihydrofolate reductase locus", Biochem. et Biophys. Acta 1097:107-143 (1990)	
	344	Jones, et al., "Replacing the complementarity-determining regions in a human antibody with those from a mouse," Nature, 321: 522-525 (1986).	
	345	JUNGINGER, et al. "Visualization of Drug Transport Across Human Skin and the Influence of Penetration Enhancers", In Drug Permeation Enhancement, Hsieh, D. S., Eds., pp. 59-90 (Marcel Dekker, Inc. New York 1994	

Examiner Signature	Date Considered
Examiner: Please initial if citation considered, whether or not citation is in conformance with MPEP Section 609. Please draw a line through the citation if it is not in conformance and it is not considered. Please include a copy of this form with the next communication to the applicant.	

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Page 15 of 20	Matter Number	0003-02-US

OTHER DOCUMENTS			
Initials	Cite No.	Author, Title, Date, Pages, etc.	T
	346	KAMEYAMA, Koh-zoh, et al., "Convenient plasmid vectors for construction of chimeric mouse/human antibodies," FEBS Lett, 244:301-306 (1989).	
	347	KATSUBE, Y., et al., "Analysis of k light chain contribution to anti-DNA antibody activity of a human VH4-21-encoded monoclonal antibody (NE-1) by antibody-phage display technique", Int J Mol. Med, 1(5):863-868 (1998))	
	348	Kavanaugh et al., 2014, "Clinical efficacy, radiographic and safety findings through 5 years of subcutaneous golimumab treatment in patients with active psoriatic arthritis: results from a long-term extension of a randomised, placebo-controlled trial (the GO-REVEAL study)", Ann Rheum Dis, 73(9): 1689-1694	
	349	KAWASAKI, Hajime et al., "Analysis of Endotoxin Fever in Rabbits by Using a Monoclonal Antibody to Tumor Necrosis Factor (Cachectin)," Infection and Immunity, 57(10):3131-3135 (1989).	
	350	KENNY et al., "Production of Monoclonal Antibodies Using a Secretion Capture Report Web", Bio/ Technol. 13:787-790 (1995).	
	351	Khilji FA, Gonzalez M, Finlay AY. Clinical meaning of change in dermatology life quality index scores. Br J Dermatol. 2002;147(suppl 62): 25-54. SIMPONI IV (golimumab) Clinical Protocol CNT0148PSA3001 Amendment 2 98 Approved, 29 June 2016	
	352	KNIGHT, D. M. et al., "A Construction and Initial Characterization of a Mouse-Human Chimeric Anti-TNF Antibody", Mol. Immunol. 30 (16): 1443-1453, 1993	
	353	KOLLS et al., "Prolonged and effective blockade of tumor necrosis factor activity through adeno virus-mediated gene transfer", Proc. Natl. Acad. Sci. USA 91:215-219 (1994);	
	354	KOZBOR et al., "The production of monoclonal antibodies from human lymphocytes", Immunol. Today, 4:72-79(1983);	
	355	KUMARAN et al., "Conformationally driven protease-catalyzed splicing of peptide segments: V8 protease-mediated synthesis of fragments derived from thermolysin and ribonuclease A", Protein Sci. 6(10):2233-2241 (1997);	
	356	LARMONIER et al., "The inhibition of TNF-alpha anti-tumoral properties by blocking antibodies promotes tumor growth in rat model" Exp. Cell Res. 2007 Mar 30; Epub ahead of print; Abstract only	
	357	LASSALLE, Ph., et al., "Potential Implication of Endothelial Cells in Bronchial Asthma," Int Arch Allergy Appl Immunol, 94:233-238 (1991).	
	358	LESSLAUER et al., "Recombinant soluble tumor necrosis factor receptor proteins protect mice from lipopolysaccharide-induced lethality", Eur. J. Immunol. 21:2883-2886 (1991)	
	359	LIANG, Chi-Ming et al., "Production and Characterization of Monoclonal Antibodies Against Recombinant Human Tumor Necrosis Factor/Cachectin," Biochem. & Biophys. Res. Comm., 137(2):847-854(1986).	
	360	LOETSCHER et al., "Molecular Cloning and Expression of the Human 55 kd Tumor Necrosis Factor Receptor", Cell 61: pgs. 351-359 (1990)	
	361	LONBERG et al. "Antigen-specific human antibodies from mice comprising four distinct genetic modifications", Nature 368:856-859 (1994)	
	362	LONBERG et al., "Human Antibodies from Transgenic Mice", Int Rev Immunol 13(1):65-93 (1995)	
	363	LUCAS, R. et al., "Generation and characterization of a neutralizing rat anti-rm TNF-a monoclonal antibody," Immunology, 71:218-223 (1990).	

Examiner Signature		Date Considered	
Examiner: Please initial if citation considered, whether or not citation is in conformance with MPEP Section 609. Please draw a line through the citation if it is not in conformance and it is not considered. Please include a copy of this form with the next communication to the applicant.			

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Page 16 of 20	Matter Number	0003-02-US

OTHER DOCUMENTS			
Initials	Cite No.	Author, Title, Date, Pages, etc.	T
	364	M. J. PAGE AND M. A. SYDENHAM, "High Level Expression of the Humanized Monoclonal Antibody Campath-1H in Chinese Hamster Ovary Cells", Biotechnology 9:64-68 (1991)).	
	365	MA et al., "Immunotherapeutic potential of antibodies produced in plants", Trends Biotechnol. 13:522-7(1995)	
	366	MA et al., "Plant Antibodies for Immunotherapy", Plant Physiol. 109:341-6 (1995).	
	367	MARRACK et al, "The Staphylococcal Enterotoxins and Their Relatives", Science, 248:705-711 (1990),	
	368	MEAGER, Anthony et al., "Preparation and Characterization of Monoclonal Antibodies Directed Against Antigenic Determinants of Recombinant Human Tumour Necrosis Factor (rTNF)," Hybridoma, 6(3):305-311 (1987).	
	369	Mease PJ, Antoni CE, Gladman DD, Taylor WJ. Psoriatic arthritis assessment tools in clinical trials. Ann Rheum Dis. 2005;64(Suppl II):ii49-ii54.	
	370	Mease PJ, Kivitz AJ, Burch FX, et al. Etanercept treatment of psoriatic arthritis: safety, efficacy, and effect on disease progression. Arthritis Rheum. 2004;50(7):2264-2272	
	371	Mease PJ. Measures of psoriatic arthritis: Tender and Swollen Joint Assessment, Psoriasis Area and Severity Index (PASI), Nail Psoriasis Severity Index (NAPSI), Modified Nail Psoriasis Severity Index (mNAPSI), Mander/Newcastle Enthesitis Index (MEI), Leeds Enthesitis Index (LEI), Spondylarthritis Research Consortium of Canada (SPARCC), Maastricht Ankylosing Spondylitis Enthesis Score (MASES), Leeds Dactylitis Index (LDI), Patient Global for Psoriatic Arthritis, Dermatology Life Quality Index (DLQI), Psoriatic Arthritis Quality of Life (PsAQOL), Functional Assessment of Chronic Illness Therapy-Fatigue (FACIT-F), Psoriatic Arthritis Response Criteria (PsARC), Psoriatic Arthritis Joint Activity Index (PsAJAI), Disease Activity in Psoriatic Arthritis (DAPSA), and Composite Psoriatic Disease Activity Index (CPDAI). Arthritis Care Res (Hoboken). 2011;63 Suppl 11:S64-S85.	
	372	Mendez, et al., "Functional transplant of megabase human immunoglobulin loci recapitulates human antibody response in mice," Nature Genetics, 15(2): 146-156 (1997).	
	373	Milstein, et al., "Hybrid hybridomas and their Use in Immunohistochemistry," Nature, 305: 537-540 (1983).	
	374	MOCELLIN et al., "Tumor necrosis factor, cancer and anticancer therapy", Cytokine Growth Factor Rev. 2005 Feb; 16(1) 35-53, Epub 2004 Dec 19	
	375	MOLLER, Achim et al., "Monoclonal Antibodies to Human Tumor Necrosis Factor a: In Vitro and In Vivo Application," Cytokine, 2(3):162-169 (1990).	
	376	MORRISON, Sherie L., "Transfectomas Provide Novel Chimeric Antibodies," Science, 229:1202-1207(1985).	
	377	MULLER, "Determination of Affinity and Specificity of Anti-Hapten Antibodies by Competitive Radioimmunoassay", Meth. Enzymol., 92:589-601 (1983),	
	378	MURPHY, et al., "Matrix metalloproteinase degradation of elastin, type IV collagen and proteoglycan", Biochem. J. 227:277-279 (1991)	
	379	NAGAI, M. et al., "Antibody to tumor necrosis factor (TNF) reduces endotoxin fever," Experientia, 44:606-607 (1988).	
	380	NEUBERGER, M., "Generating high-avidity human Mabs in mince", Nature Biotech. 14:826 (1996)	
	381	NGUYEN et al., "Production of Human Monoclonal Antibodies in SCID Mouse", Microbiol. Immunol. 41:901-907(1997)	

Examiner Signature	Date Considered
Examiner: Please initial if citation considered, whether or not citation is in conformance with MPEP Section 609. Please draw a line through the citation if it is not in conformance and it is not considered. Please include a copy of this form with the next communication to the applicant.	

INFORMATION DISCLOSURE STATEMENT BY APPLICANT	Application Number	17320490
	Filing Date	05/14/2021
	First Named Inventor	Harrison
	Art Unit	OPAP
	Client Number	206389
Page 17 of 20	Matter Number	0003-02-US

OTHER DOCUMENTS			
Initials	Cite No.	Author, Title, Date, Pages, etc.	T
	382	NOPHAR, YARON et al., "Soluble forms of tumor necrosis factor receptors (TNF-Rs). The cDNA for the type 1 TNF-R, cloned using amino acid sequence data of its soluble form, encodes both the cell surface and a soluble form of the receptor," The EMBO Journal, 9(10):3269-3278(1990).	
	383	OPAL, Steven M. et al., "Efficacy of a Monoclonal Antibody Directed Against Tumor Necrosis Factor in Protecting Neutropenic Rats from Lethal Infection with Pseudomonas aeruginosa," J. of Infectious Diseases, 161:1148-1152 (1990).	
	384	PARRILLO, Joseph E., "Pathogenetic Mechanisms of Septic Shock," N.E. Journal of Medicine, 328(20):1471-1477 (1993).	
	385	Partsch G, Steiner G, Leeb BF, Dunky A, Broil H, Smolen JS. Highly increased levels of tumor necrosis factor-alpha and other proinflammatory cytokines in psoriatic arthritis synovial fluid. J Rheumatol. 1997;24(3):518-523.	
	386	PAULUS, H., A Preparation and Biomedical Applications of Bispecific Antibodies®, Behring Inst. Mitt, No.78:118-132 (1985).	
	387	PENNINGTON, James, "TNF: Therapeutic Target in Patients with Sepsis," ASM News, 58(9):479-482(1992).	
	388	PEPPEL et al., "A Tumor Necrosis Factor (TNF) Receptor-IgG Heavy ChainChimeric Protein as a Bivalent Antagonist of TNF Activity", J. Exp. Med. 174:1483-1489 (1991);	
	389	Pham et al., 2006, "TNFa antagonist therapy in ankylosing spondylitis and psoriatic arthritis: recommendations of the French Society for Rheumatology." JOINT BONE SPINE, ELSEVIER, Amsterdam, NL , 73(5), pages 547-553	
	390	Pham T, Guillemin F, Claudepierre P, et al. TNFa antagonist therapy in ankylosing spondylitis and psoriatic arthritis: recommendations of the French Society for Rheumatology. Joint Bone Spine. 2006;73:547- 553.	
	391	PIGUET, Pierre-Francois et al., "Tumor Necrosis Factor/Cachectin is an Effector of Skin and Gut Lesions of the Acute Phase of Graft-vs.-Host Disease," J. Exp. Med., 166:1280-1289 (1987).	
	392	POWELL et al., "Gel Microdroplets and Flow Cytometry: Rapid Determination of Antibody Secretion by Individual Cells Within a Cell Population", Biotechnol. 8:333-337 (1990)	
	393	PRESTA et al., "Humanization of an Antibody Directed Against IgE", J. Immunol. 151:2623 (1993),	
	394	Reichmann, et al., "Reshaping human antibodies for therapy," Nature, 332: 323-327 (1988).	
	395	Ritchlin C, Haas-Smith SA, Hicks D, Cappuccio J, Osterland CK, Looney RJ. Patterns of cytokine production in psoriatic synovium. J Rheumatol. 1998;25(8):1544-1552.	
	396	RUDDLE, Nancy H. et al., "An Antibody to Lymphotoxin and Tumor Necrosis Factor Prevents Transfer of Experimental Allergic Encephalomyelitis," J. Exp. Med., 172:1193-1200 (1990).	
	397	RUDIHOFF et al., Single amino acid substitution altering antigen-binding specificity", PNAS, March 1982, Vol 79, p. 1979-83	
	398	S. SIEGAL et al., "The mouse/human chimeric momoclonia antibody cA2 neutralizes TNF in vitro and protects transgenic mice from cachexia and TNF lethality in vivo", Cytokine, Vol. 7, No. 1 pgs. 15-25 XP000990566 (January 1995)	
	399	S. STEPHENS et al., "Comprehensive pharmacokinetic of a humanized antibody and analysis of residual anti-idiotypic responses", Immunology, Vol. 85, No. 4, pgs. 668-674 XP000881488 (August 1995)	

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Page 18 of 20	Matter Number	0003-02-US

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Initials	Cite No.	Author, Title, Date, Pages, etc.	T
	400	SANDHU et al., "The Use of SCID Mice in Biotechnology and as a Model for Human Disease", Crit. Rev. Biotechnol. 16:95-118 (1996)	
	401	SCALLON, et al., Functional Comparisons of Different Tumour Necrosis Factor Receptor/IgG Fusion Proteins", Cytokine 7:759-770 (1995)	
	402	SCHALL, Thomas J. et al., "Molecular Cloning and Expression of a Receptor for Human Tumor Necrosis Factor," Cell, 61:361-370 (1990).	
	403	SCOTT et al., "An Anti-Tumor Necrosis Factor- α Antibody Inhibits the Development of Experimental Skin Tumors", Mol. Can Therapy, 2003 May, 2:445-451	
	404	SHIMAMOTO, Yoshinori et al., "Monoclonal antibodies against human recombinant tumor necrosis factor: prevention of endotoxic shock," Immunology Letters, 77:311-318 (1988).	
	405	SILVA, Ayona T. et al., "Prophylactic and Therapeutic Effects of a Monoclonal Antibody to Tumor Necrosis Factor- α in Experimental Gram-Negative Shock," J. of Infectious Diseases, 162:421-427(1990).	
	406	SIMS et al., "A Humanized CD18 Antibody Can Block Function without Cell Destruction", J. Immunol. 151:2296(1993)	
	407	SMITH, Craig R., "Human and Chimeric Antibodies to LPS and TNF," 4Abstract, Endotoxemia & Sepsis Conference (1991).	
	408	SMITH, et al., "Human Interleukin 4: The Solution Structure of a Four-helix Bundle Protein", J. Mol. Biol. 224:899-904 (1992)	
	409	SPRAGUE, et al., "Expression of a Recombinant DNA Gene Coding for the Vesicular Stomatitis Virus Nucleocapsid Protein", J. Virol. 45:773-781 (1983)).	
	410	STARNES, H. Fletcher, Jr., et al., "ANTI-IL-6 Monoclonal Antibodies Protect Against Lethal Escherichia Coll Infection and Lethal Tumor Necrosis FactorL Challenge in Mice," J Immunol, 145:4185-4191 (1990).	
	411	STEADMAN' Medical Dictionary, 27th Ed. 2000 Lippincott Williams & Wilkins - "Carcinoma"	
	412	STEENBAKKERS et al., "Efficient generation of monoclonal antibodies from preselected antigen-specific B", Molec. Biol. Reports 19:125-134 (1994).	
	413	STEIN et al., "Diseases of the Hearth and Blood Vessels", Internal Medicine, 3rd 3d., pg.1-13, Little Brown and Co. Boston (1990)	
	414	STONE et al., "Solid malignancies among patients in the Wegener's Granulomatosis Etanercept Trial", Arthritis Rheum. 2006 May; 54(5) 1608-18 abstract only	
	415	SUNAHARA, N. et al., "Simple enzyme immunoassay methods for recombinant human tumor necrosis factor L and its antibodies using a bacterial cell wall carrier," J Immunol Methods, 109:203-214(1988).	
	416	SURESH et al., "Bispecific Monoclonal Antibodies from Hybrid Hybridomas", Methods in Enzymology 121:210 (1986)	
	417	TAVERNIER et al., "Analysis of the Structure-Function Relationship of Tumour Necrosis Factor. Human/Mouse Chimeric TNF Proteins: General Properties and Epitope Analysis", Journal Molecular Biology, 211, pg. 493-501 (1990)	
	418	TAYLOR et al., "A transgenic mouse that expresses a diversity of human sequence heavy and light chain immunoglobulins", Nucleic Acids Research 20(23):6287-6295 (1992),	

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OTHER DOCUMENTS			
Initials	Cite No.	Author, Title, Date, Pages, etc.	T
	419	Taylor W, Gladman D, Helliwell P, Marchesoni A, Mease P, Mielants H; CASPAR Study Group. Classification criteria for psoriatic arthritis: development of new criteria from a large international study. Arthritis Rheum. 2006;54(8):2665-2673.	
	420	Taylor, et al., "Human immunoglobulin transgenes undergo rearrangement, somatic mutation and class switching in mice that lack endogenous IgM," International Immunology, 6(4): 579-591 (1994).	
	421	TRACEY, Kevin J. et al., "Anti-cachectin/TNF monoclonal antibodies prevent septic shock during lethal bacteraemia," Nature, 330:662-664 (1987).	
	422	Traunecker, et al., "Bispecific Single chain molecules (Janusins) target cytotoxic lymphocytes on HIV infected cells," EMBO Journal, 10(12): 3655-3659 (1991).	
	423	TUAILLON et al., "Human immunoglobulin heavy-chain minilocus recombination in transgenic mice: Gene-segment use in u and y transcripts", Proc Natl Acad Sci USA 90(8)3720-3724 (1993)	
	424	Van der Heijde DM, van Leeuwen MA, van Riel PL, et al. Biannual radiographic assessments of hands and feet in a three-year prospective followup of patients with early rheumatoid arthritis. Arthritis Rheum. 1992;35(1):26-34.	
	425	Van der Linden MA. Disease Activity Scores using C-reactive protein. April 5, 2004. Available at: www.umcn.nl/scientist/afdelingen/reumatologie/the_das/the_das_crp . Accessed 19 August 2005	
	426	Van Riel P, Fransen J, Scott DL. EULAR handbook of clinical assessments in rheumatoid arthritis. Third ed. Alphen Aan Den Rijn, The Netherlands: Van Zuiden Communications B.V. 2004.	
	427	Van Riel PL, van Gestel AM, Scott DL, for the EULAR Standing Committee for International Clinical Studies Including Therapeutic Trials - ESCISIT. EULAR Handbook of Clinical Assessments in Rheumatoid Arthritis. Alphen Aan Den Rijn, The Netherlands: Van Zuiden Communications B.V.; 2000:40.	
	428	Veale DJ, Markham T, Fearon U, et al. St Vincents University Hospital, Dublin, Ireland. Therapy in psoriasis and psoriatic arthritis: anti-TNF-alpha clinical and angiogenic responses. Arthritis Rheum. 2003;48(suppl):S168-S169.	
	429	VERHOEF, J. and Torensma, R., "Prospects for Monoclonal Antibodies in the Diagnosis and Treatment of Bacterial Infections," Eur. J. Clin. Microbiol. Dis., 9(4):247-250 (1990).	
	430	VERHOEYEN et al., "Reshaping Human Antibodies:Grafting an Antilysozyme Activity", Science 239:1534(1988).	
	431	VON ASMUTH, E.J.U. et al., "Tumour Necrosis Factor Alpha (TNF-a) and Interleukin 6 in a Zymosan-Induced Shock Model," Scand. J. Immunol., 32:313-319 (1990).	
	432	WALDMANN, Thomas A., "Monoclonal Antibodies in Diagnosis and Therapy," Science, 252:1657-1662(1991).	
	433	WARE JE JR, SHERBOURNE CD. The MOS 36 item short form health survey (SF 36), I. Conceptual framework and item selection. Med Care. 1992;30(6):473-483.	
	434	WARE JE, KOSINSKI M, KELLER SD. Interpretation: NormBased. In: SF-36 Physical and Mental Health Summary Scales: A User's Manual. Boston, MA: The Health Institute; 1994:8:1-8:42.	
	435	WEN et al., "Limiting dilution assay for human B cells based on their activation by mutant EL4 thymoma cells:total and antimalaria responder B cell frequencies" J. Immunol. 17:887-892 (1987)	
	436	WERLEN et al., "Site-Specific Conjugation of an Enzyme and an Antibody Fragment", Bioconjugate Chem., 5:411-417 (1994)	

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OTHER DOCUMENTS			
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	437	Whitelam, et al., "Antibody production in transgenic plants," Biochemical Society Transactions, Transgenic Plants and Plan Biochemistry, 22: 940-944 (1994).	
	438	WHITTLE, Nigel, et al., "Construction and Expression of a CDR-Grafted Anti-TNF Antibody," J. Cell Blochem, Supl. 13A:96 (1989).	
	439	WINTER et al., "Antibody-based Therapy", Immunology Today, 14(6), pgs. 243-246 (1993)	
	440	WOOD et al, "Staphylococcal enterotoxins and the immune system", FEMS Microbiology Immunology, 76:121-134 (1991)	
	441	Zhuang et al., 2010, Pharmacokinetics of Golimumab, an Anti-TNFalpha Human Monoclonal Antibody After Multiple Subcutaneous or Intravenous Injections in Subjects with Rheumatoid Arthritis" Clinical Pharmacology & Therapeutics, Vol. 87, Supplement 1, PI-80, p. S34-S35	
	442	Zochling J, van der Heijde D, Burgos-Vargas R, et al. ASAS/EULAR recommendations for the management of ankylosing spondylitis. Ann Rheum Dis. 2006;65(4):442-452.	

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GENERAL

Pursuant to 37 C.F.R. 1.97 and 1.98 and to the duty of disclosure set forth in 37 C.F.R. 1.56, the Examiner in charge of the above-identified application is requested to consider and make of record the references listed herewith. A copy of each listed reference, other than U.S. patents/applications and references cited in a parent application, is enclosed.

Although the information submitted herewith may be "material" to the Examiner's consideration of the subject application, this submission is not intended to constitute an admission that such information is "prior art" as to the claimed invention.

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TIMING

In accordance with 37 CFR 1.97(b), this Information Disclosure Statement is being filed within three months of the filing of a national application other than a continued prosecution application under 37 CFR 1.53(d); within three months of the date of entry of the national stage as set forth in 37 CFR 1.491 in an international application; before the mailing of a first Office Action on the merits; or before the mailing of a first Office Action after the filing of a request for continued examination under 37 CFR 1.114.

CERTIFICATION STATEMENT

No certification statement is required. This Information Disclosure Statement is being filed in accordance with 37 CFR 1.97(b).

FEE

No fee is required. This Information Disclosure Statement is being filed in accordance with 37 CFR 1.97(b).

If necessary, the Director is hereby authorized to charge or credit Deposit Account No. 50-5366 for any additional fees, or any underpayment or credit for overpayment in connection herewith. Please reference attorney docket number 206389-0003-02-US for any such charge or credit.

ADDITIONAL COMMENTS

SIGNATURE

Signature	/ Pallab Singh /	Date	2022-01-24
Name	Pallab Singh	Registration Number	70731

INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Not for submission under 37 CFR 1.99)

Application Number	17320490
Filing Date	2021-05-14
First Named Inventor	Diane D. Harrison
Art Unit	1646
Examiner Name	CHANDRA
Attorney Docket Number	206389-0003-02-US

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**INFORMATION DISCLOSURE
STATEMENT BY APPLICANT**
(Not for submission under 37 CFR 1.99)

Application Number	17320490
Filing Date	2021-05-14
First Named Inventor	Diane D. Harrison
Art Unit	1646
Examiner Name	CHANDRA
Attorney Docket Number	206389-0003-02-US

1	DEODHAR, A. A. et al, "Safety and Efficacy of Intravenous Golimumab in Adult Patients with Active Ankylosing Spondylitis: Results through Week 28", Arthritis Rheumatol, 68, Suppl. 10, abstract no. 1043, 28 September 2016, 3 pages.
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STATEMENT BY APPLICANT**
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Application Number	17320490
Filing Date	2021-05-14
First Named Inventor	Diane D. Harrison
Art Unit	1646
Examiner Name	CHANDRA
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CERTIFICATION STATEMENT

Please see 37 CFR 1.97 and 1.98 to make the appropriate selection(s):

That each item of information contained in the information disclosure statement was first cited in any communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing of the information disclosure statement. See 37 CFR 1.97(e)(1).

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See attached certification statement.

The fee set forth in 37 CFR 1.17 (p) has been submitted herewith.

☒ A certification statement is not submitted herewith.

SIGNATURE

A signature of the applicant or representative is required in accordance with CFR 1.33, 10.18. Please see CFR 1.4(d) for the form of the signature.

Signature	/Pallab Singh/	Date (YYYY-MM-DD)	2022-11-16
Name/Print	Pallab Singh	Registration Number	70731

This collection of information is required by 37 CFR 1.97 and 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 1 hour to complete, including gathering, preparing and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. **SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.**

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INFORMATION DISCLOSURE STATEMENT BY APPLICANT	Application Number	17320490
	Filing Date	05/14/2021
	First Named Inventor	Diane D. Harrison
	Art Unit	1646
	Client Number	206389
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ADDITIONAL COMMENTS

SIGNATURE			
Signature	/ Pallab Singh /	Date	2022-11-16
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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
17/320,490	05/14/2021	Diane D. Harrison	206389-0003-02US	5386
171672	7590	04/26/2023	EXAMINER	
Riverside Law LLP/J&J			CHANDRA, GYAN	
175 Strafford Avenue				
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			ART UNIT	PAPER NUMBER
			1646	
			NOTIFICATION DATE	DELIVERY MODE
			04/26/2023	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

LMorozin@ITS.JNJ.COM
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DETAILED ACTION

Notice of Pre-AIA or AIA Status

The present application, filed on or after March 16, 2013, is being examined under the first inventor to file provisions of the AIA.

Claims 11-20 are pending and under examination.

Information Disclosure Statement

The Information Disclosure Statement filed on 1/24/2022 and 11/16/2022 have been considered.

Specification

The disclosure is objected to because it contains an embedded hyperlink and/or other form of browser-executable code see pages 25-26. Applicant is required to delete the embedded hyperlink and/or other form of browser-executable code; references to websites should be limited to the top-level domain name without any prefix such as http:// or other browser-executable code. See MPEP § 608.01.

The lengthy specification has not been checked to the extent necessary to determine the presence of all possible minor errors. Applicant's cooperation is requested in correcting any errors of which applicant may become aware in the specification.

Drawings

New corrected drawings in compliance with 37 CFR 1.121(d) are required in this application because Figures 10 and 11A-11C showing charts or bars are too light to read or print by the office. Applicant is advised to employ the services of a competent patent draftsman outside the Office, as the U.S. Patent and Trademark Office no

longer prepares new drawings. The corrected drawings are required in reply to the Office action to avoid abandonment of the application. The requirement for corrected drawings will not be held in abeyance.

Claim Rejections - 35 USC § 112

The following is a quotation of 35 U.S.C. 112(b):

(b) CONCLUSION.—The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the inventor or a joint inventor regards as the invention.

The following is a quotation of 35 U.S.C. 112 (pre-AIA), second paragraph:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 12 and 15 are rejected under 35 U.S.C. 112(b) or 35 U.S.C. 112 (pre-AIA), second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which the inventor or a joint inventor (or for applications subject to pre-AIA 35 U.S.C. 112, the applicant), regards as the invention.

Regarding claims 12 and 15, the phrase "such that" renders the claim indefinite because it is unclear whether the limitations following the phrase are part of the claimed invention. See MPEP § 2173.05(d).

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(a)(1) the claimed invention was patented, described in a printed publication, or in public use, on sale, or otherwise available to the public before the effective filing date of the claimed invention.

Claim(s) 11, 13, 14, 16, 17, 18 and 20 are rejected under 35 U.S.C. 102(a)(1) as being anticipated by Hoffman et al (US Pub. No. 20080311043).

The instant claims are broadly drawn to a method for treating a tumor necrosis factor alpha (TNF- α) related condition, wherein the TNF- α related condition is active psoriatic arthritis, the method comprising: administering to a subject having active psoriatic arthritis a composition comprising a safe and effective amount of at least one isolated mammalian anti-TNF- α antibody comprising: a. a heavy chain (HC) complementary determining region (CDR) 1 comprising an amino acid sequence of SEQ ID NO: 1; b. a HC CDR2 comprising an amino acid sequence of SEQ ID NO: 2; wherein position 1 of SEQ ID NO: 2 is phenylalanine, position 2 of SEQ ID NO: 2 is methionine, position 3 of SEQ ID NO: 2 is serine, position 4 of SEQ ID NO: 2 is tyrosine, position 10 of SEQ ID NO: 2 is lysine, position 11 of SEQ ID NO: 2 is tyrosine, and position 17 of SEQ ID NO: 2 is glycine; c. a HC CDR3 comprising an amino acid sequence of SEQ ID NO: 3; wherein position 4 of SEQ ID NO: 3 is isoleucine, position 5 of SEQ ID NO: 3 is alanine, and position 9 of SEQ ID NO: 3 is asparagine; d. a light chain (LC) CDR1 comprising an amino acid sequence of SEQ ID NO: 4; wherein position 7 of SEQ ID NO: 4 is tyrosine; e. a LC CDR2 comprising an amino acid sequence of SEQ ID NO: 5; and f. a LC CDR3 comprising an amino acid sequence of SEQ ID NO: 6, and at least one pharmaceutically acceptable carrier or diluent, wherein said composition is administered via intravenous (IV) infusion, and wherein at week 14 of treatment patients treated with the anti-TNF- α antibody achieve a mean change from baseline in one or more criteria selected from the group consisting of: Health Assessment Questionnaire Disability Index score (HAQ-DI) = -0.60 ± 0.53 SD, enthesitis = -1.87 ± 1.75 SD, dactylitis = -7.8 ± 8.57 SD, Short-Form Health Survey Physical Summary score (SF-36 PCS) = 8.65 ± 7.60 SD, and Short-Form Health Survey

Mental Component Summary score (SF-36 MCS) = 5.33 9.95 SD and wherein the method further comprises administering said composition with or without methotrexate (MTX).

It is noted that the search results of 4/14/2023 in PE2E show that HC CDR1-3 of SEQ ID NO: 1-3 and LC CDR1-3 of SEQ ID NO:4-6 are six CDRs of golimumab against TNF- α . Therefore, administration of golimumab intravenously would anticipate the instantly claimed invention.

Hoffman et al teach treating psoriatic arthritis using antagonist to TNF- α [0005]. They teach a method of determining the efficacy of TNF- α inhibitor for treating psoriatic arthritis in a subject comprising determining an ACR20 response in patients who have been administered with TNF- α inhibitor, wherein response is about 39%-61% or 64% [0006-0010, 0223] or ACR50 is about 25%-46% [0011]. They teach that efficacy of TNF- α inhibitor can also be determined by measuring a decrease in Health Assessment Questionnaire (HAQ) on an average of 0.3, 0.4 or 0.5 [0024]. They teach that TNF- α inhibitor is TNF- α antibody, or antigen-binding portion thereof which is infliximab or golimumab (or CNTO 148) see paragraphs [0051 or 0079] or claim 85. They teach dosing for treating psoriatic arthritis using TNF- α inhibitor starting at 0 week and followed by bi-weekly dosing regimen [0096-0099]. They teach that the administration of TNF- α inhibitor antibody can be bi-weekly or at 4 weeks, 8 weeks, 16 weeks, 16 weeks, 24 weeks, 26, 36, 42, 48, 52, 56 weeks etc. [0099]. They teach the administration of TNF- α antibody is preferably administered by intravenous injection or infusion [0155, 0159]. They teach stratified subject population based on methotrexate treatment [0293]. They teach the effect of TNF- α antibody effect with or without

methotrexate (MTX) (see Table 33). Therefore, the instantly claimed invention is implicitly or explicitly anticipated by the prior art of record.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103 which forms the basis for all obviousness rejections set forth in this Office action:

A patent for a claimed invention may not be obtained, notwithstanding that the claimed invention is not identically disclosed as set forth in section 102, if the differences between the claimed invention and the prior art are such that the claimed invention as a whole would have been obvious before the effective filing date of the claimed invention to a person having ordinary skill in the art to which the claimed invention pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries for establishing a background for determining obviousness under 35 U.S.C. 103 are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating

obviousness or nonobviousness.

Claim(s) 11-20 are rejected under 35 U.S.C. 103 as being unpatentable over Hoffman et al (US Pub. No. 20080311043) in view of Doyle et al. (Rheumatology 52: 1214-1219, 2013).

The instant invention is broadly drawn to a method for treating a tumor necrosis factor alpha (TNF-a) related condition, wherein the TNF-a related condition is active psoriatic arthritis, the method comprising: administering to a subject having active psoriatic arthritis a composition comprising a safe and effective amount of at least one isolated mammalian anti-TNF-a antibody comprising: a. a heavy chain (HC)

complementary determining region (CDR) 1 comprising an amino acid sequence of SEQ ID NO: 1; b. a HC CDR2 comprising an amino acid sequence of SEQ ID NO: 2; wherein position 1 of SEQ ID NO: 2 is phenylalanine, position 2 of SEQ ID NO: 2 is methionine, position 3 of SEQ ID NO: 2 is serine, position 4 of SEQ ID NO: 2 is tyrosine, position 10 of SEQ ID NO: 2 is lysine, position 11 of SEQ ID NO: 2 is tyrosine, and position 17 of SEQ ID NO: 2 is glycine; c. a HC CDR3 comprising an amino acid sequence of SEQ ID NO: 3; wherein position 4 of SEQ ID NO: 3 is isoleucine, position 5 of SEQ ID NO: 3 is alanine, and position 9 of SEQ ID NO: 3 is asparagine; d. a light chain (LC) CDR1 comprising an amino acid sequence of SEQ ID NO: 4; wherein position 7 of SEQ ID NO: 4 is tyrosine; e. a LC CDR2 comprising an amino acid sequence of SEQ ID NO: 5; and f. a LC CDR3 comprising an amino acid sequence of SEQ ID NO: 6, and at least one pharmaceutically acceptable carrier or diluent, wherein said composition is administered via intravenous (IV) infusion, and wherein at week 14 of treatment patients treated with the anti-TNF- α antibody achieve a mean change from baseline in one or more criteria selected from the group consisting of: Health Assessment Questionnaire Disability Index score (HAQ-DI) = -0.60 ± 0.53 SD, enthesitis = -1.87 ± 1.75 SD, dactylitis = -7.8 ± 8.57 SD, Short-Form Health Survey Physical Summary score (SF-36 PCS) = 8.65 ± 7.60 SD, and Short-Form Health Survey Mental Component Summary score (SF-36 MCS) = 5.33 ± 9.95 SD, wherein the composition is administered at 2 mg/kg to said subject and wherein the method further comprises administering said composition with or without methotrexate (MTX).

The teachings of Hoffman et al is set forth above. Hoffman et al do not teach administering golimumab to subject comprising 2 mg/kg to a subject in need thereof.

Doyle et al teach that the administration of golimumab by subcutaneous as well as intravenous route (see the title). They teach that administration by intravenous route is superior to subcutaneous in reducing anti-TNF α markers (see Fig. 1), pg. 1216. They teach administering 2 mg/kg golimumab iv infusion vs. subcutaneous for 4 weeks and 12 weeks (pg. 1215, Patients and Methods).

Therefore, it would have been prima facie obvious to one of ordinary skill in the art at the time of invention to administer the anti-TNF- α antibody golimumab as taught by Doyle et al for treating psoriatic arthritis as taught by Hoffman et al. Further, one of ordinary skill of the art would have been motivated to administer golimumab by an intravenous infusion because Doyle et al teach that golimumab when administered through intravenous it reduces TNF- α markers better than when administered subcutaneously. One would have a reasonable expectation of success in administering golimumab at 2 mg/kg intravenously to a subject in need thereof because Doyle et al. teach administering golimumab intravenously. Therefore, the invention is obvious over the combined teachings of the prior art.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the “right to exclude” granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have

been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on nonstatutory double patenting provided the reference application or patent either is shown to be commonly owned with the examined application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement. See MPEP § 717.02 for applications subject to examination under the first inventor to file provisions of the AIA as explained in MPEP § 2159. See MPEP § 2146 *et seq.* for applications not subject to examination under the first inventor to file provisions of the AIA. A terminal disclaimer must be signed in compliance with 37 CFR 1.321(b).

The USPTO Internet website contains terminal disclaimer forms which may be used. Please visit www.uspto.gov/patent/patents-forms. The filing date of the application in which the form is filed determines what form (e.g., PTO/SB/25, PTO/SB/26, PTO/AIA/25, or PTO/AIA/26) should be used. A web-based eTerminal Disclaimer may be filled out completely online using web-screens. An eTerminal Disclaimer that meets all requirements is auto-processed and approved immediately upon submission. For more information about eTerminal Disclaimers, refer to www.uspto.gov/patents/process/file/efs/guidance/eTD-info-I.jsp.

Claims 11-20 are rejected on the ground of nonstatutory double patenting as being unpatentable over claims 1-10 of U.S. Patent No. 11,041,020. Although the claims at issue are not identical, they are not patentably distinct from each other because a method for treating a tumor necrosis factor alpha (TNF-a) related condition, wherein the TNF-a related condition is active psoriatic arthritis, the method comprising: administering to a subject having active psoriatic arthritis a composition comprising a safe and effective amount of at least one isolated mammalian anti-TNF-a antibody comprising: a. a heavy chain (HC) complementary determining region (CDR) 1 comprising an amino acid sequence of SEQ ID NO: 1; b. a HC CDR2 comprising an amino acid sequence of SEQ ID NO: 2; wherein position 1 of SEQ ID NO: 2 is phenylalanine, position 2 of SEQ ID NO: 2 is methionine, position 3 of SEQ ID NO: 2 is serine, position 4 of SEQ ID NO: 2 is tyrosine, position 10 of SEQ ID NO: 2 is lysine, position 11 of SEQ ID NO: 2 is tyrosine, and position 17 of SEQ ID NO: 2 is glycine; c. a HC CDR3 comprising an amino acid sequence of SEQ ID NO: 3; wherein position 4 of SEQ ID NO: 3 is isoleucine, position 5 of SEQ ID NO: 3 is alanine, and position 9 of SEQ ID NO: 3 is asparagine; d. a light chain (LC) CDR1 comprising an amino acid sequence of SEQ ID NO: 4; wherein position 7 of SEQ ID NO: 4 is tyrosine; e. a LC CDR2 comprising an amino acid sequence of SEQ ID NO: 5; and f. a LC CDR3 comprising an amino acid sequence of SEQ ID NO: 6, and at least one pharmaceutically acceptable carrier or diluent, wherein said composition is administered via intravenous (IV) infusion, and wherein at week 14 of treatment patients treated with the anti-TNF-a antibody achieve a mean change from baseline in one or more criteria selected from the group consisting of: Health Assessment Questionnaire Disability

Index score (HAQ-DI) = -0.60 ± 0.53 SD, enthesitis = -1.87 ± 1.75 SD, dactylitis = -7.8 ± 8.57 SD, Short-Form Health Survey Physical Summary score (SF-36 PCS) = 8.65 ± 7.60 SD, and Short-Form Health Survey Mental Component Summary score (SF-36 MCS) = 5.33 ± 9.95 SD, wherein the composition is administered at 2 mg/kg to said subject and wherein the method further comprises administering said composition with or without methotrexate (MTX) are taught in claims 1-10 of US Pat. No. 11,041,020.

It is noted that the examiner has carefully reviewed the amino acid sequences of heavy chain (HC) SEQ ID NO: 36 which comprises HC CDR1-3 of SEQ ID NO: 1-3 and the amino acid sequence of light chain (LC) SEQ ID NO: 37 which comprises LC CDR1-3 of SEQ ID NO: 4-6 as being instantly claimed.

Claims 11-20 are provisionally rejected on the ground of nonstatutory double patenting as being unpatentable over claims 8-13 of copending Application No. 17/423,512 (reference application). Although the claims at issue are not identical, they are not patentably distinct from each other because a method for treating a tumor necrosis factor alpha (TNF- α) related condition, wherein the TNF- α related condition is active psoriatic arthritis, the method comprising: administering to a subject having active psoriatic arthritis a composition comprising a safe and effective amount of at least one isolated mammalian anti-TNF- α antibody comprising: a. a heavy chain (HC) complementary determining region (CDR) 1 comprising an amino acid sequence of SEQ ID NO: 1; b. a HC CDR2 comprising an amino acid sequence of SEQ ID NO: 2; wherein position 1 of SEQ ID NO: 2 is phenylalanine, position 2 of SEQ ID NO: 2 is methionine, position 3 of SEQ ID NO: 2 is serine, position 4 of SEQ ID NO: 2 is tyrosine, position 10 of SEQ ID NO: 2 is lysine, position 11 of SEQ ID NO: 2 is tyrosine, and

position 17 of SEQ ID NO: 2 is glycine; c. a HC CDR3 comprising an amino acid sequence of SEQ ID NO: 3; wherein position 4 of SEQ ID NO: 3 is isoleucine, position 5 of SEQ ID NO: 3 is alanine, and position 9 of SEQ ID NO: 3 is asparagine; d. a light chain (LC) CDR1 comprising an amino acid sequence of SEQ ID NO: 4; wherein position 7 of SEQ ID NO: 4 is tyrosine; e. a LC CDR2 comprising an amino acid sequence of SEQ ID NO: 5; and f. a LC CDR3 comprising an amino acid sequence of SEQ ID NO: 6, and at least one pharmaceutically acceptable carrier or diluent, wherein said composition is administered via intravenous (IV) infusion, and wherein at week 14 of treatment patients treated with the anti-TNF- α antibody achieve a mean change from baseline in one or more criteria selected from the group consisting of: Health Assessment Questionnaire Disability Index score (HAQ-DI) = -0.60 ± 0.53 SD, enthesitis = -1.87 ± 1.75 SD, dactylitis = -7.8 ± 8.57 SD, Short-Form Health Survey Physical Summary score (SF-36 PCS) = 8.65 ± 7.60 SD, and Short-Form Health Survey Mental Component Summary score (SF-36 MCS) = 5.33 ± 9.95 SD, wherein the composition is administered at 2 mg/kg to said subject and wherein the method further comprises administering said composition with or without methotrexate (MTX) are taught in claims 8-13 of US Application No. 17/423,512.

This is a provisional nonstatutory double patenting rejection because the patentably indistinct claims have not in fact been patented.

Claims 11-20 are provisionally rejected on the ground of nonstatutory double patenting as being unpatentable over claims 1-19 of copending Application No. 17/615,949 (reference application). Although the claims at issue are not identical, they are not patentably distinct from each other because a method for treating a tumor

necrosis factor alpha (TNF-a) related condition, wherein the TNF-a related condition is active psoriatic arthritis, the method comprising: administering to a subject having active psoriatic arthritis a composition comprising a safe and effective amount of at least one isolated mammalian anti-TNF-a antibody comprising: a. a heavy chain (HC) complementary determining region (CDR) 1 comprising an amino acid sequence of SEQ ID NO: 1; b. a HC CDR2 comprising an amino acid sequence of SEQ ID NO: 2; wherein position 1 of SEQ ID NO: 2 is phenylalanine, position 2 of SEQ ID NO: 2 is methionine, position 3 of SEQ ID NO: 2 is serine, position 4 of SEQ ID NO: 2 is tyrosine, position 10 of SEQ ID NO: 2 is lysine, position 11 of SEQ ID NO: 2 is tyrosine, and position 17 of SEQ ID NO: 2 is glycine; c. a HC CDR3 comprising an amino acid sequence of SEQ ID NO: 3; wherein position 4 of SEQ ID NO: 3 is isoleucine, position 5 of SEQ ID NO: 3 is alanine, and position 9 of SEQ ID NO: 3 is asparagine; d. a light chain (LC) CDR1 comprising an amino acid sequence of SEQ ID NO: 4; wherein position 7 of SEQ ID NO: 4 is tyrosine; e. a LC CDR2 comprising an amino acid sequence of SEQ ID NO: 5; and f. a LC CDR3 comprising an amino acid sequence of SEQ ID NO: 6, and at least one pharmaceutically acceptable carrier or diluent, wherein said composition is administered via intravenous (IV) infusion, and wherein at week 14 of treatment patients treated with the anti-TNF-a antibody achieve a mean change from baseline in one or more criteria selected from the group consisting of: Health Assessment Questionnaire Disability Index score (HAQ-DI) = -0.60 ± 0.53 SD, enthesitis = -1.87 ± 1.75 SD, dactylitis = -7.8 ± 8.57 SD, Short-Form Health Survey Physical Summary score (SF-36 PCS) = 8.65 ± 7.60 SD, and Short-Form Health Survey Mental Component Summary score (SF-36 MCS) = 5.33 ± 9.95 SD, wherein the

composition is administered at 2 mg/kg to said subject and wherein the method further comprises administering said composition with or without methotrexate (MTX) are taught in claims 1-19 of US Application No. 17/615,949.

This is a provisional nonstatutory double patenting rejection because the patentably indistinct claims have not in fact been patented.

Conclusion

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to GYAN CHANDRA whose telephone number is (571)272-2922. The examiner can normally be reached Mon-Friday 8:30AM-5:00P.

Examiner interviews are available via telephone, in-person, and video conferencing using a USPTO supplied web-based collaboration tool. To schedule an interview, applicant is encouraged to use the USPTO Automated Interview Request (AIR) at <http://www.uspto.gov/interviewpractice>.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Vanessa Ford can be reached on 571-272-0857. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of published or unpublished applications may be obtained from Patent Center. Unpublished application information in Patent Center is available to registered users. To file and manage patent submissions in Patent Center, visit: <https://patentcenter.uspto.gov>. Visit <https://www.uspto.gov/patents/apply/patent-center> for more information about Patent Center and <https://www.uspto.gov/patents/docx> for information about filing in DOCX format. For

additional questions, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/GYAN CHANDRA/
Primary Examiner, Art Unit 1646

Notice of References Cited	Application/Control No. 17/320,490		Applicant(s)/Patent Under Reexamination Harrison et al.	
	Examiner GYAN CHANDRA		Art Unit 1646	Page 1 of 1

U.S. PATENT DOCUMENTS

*		Document Number Country Code-Number-Kind Code	Date MM-YYYY	Name	CPC Classification	US Classification
*	A	US-20080311043-A1	12-2008	Hoffman; Rebecca S.	C07K16/241	424/9.2
	B					
	C					
	D					
	E					
	F					
	G					
	H					
	I					
	J					
	K					
	L					
	M					

FOREIGN PATENT DOCUMENTS

*		Document Number Country Code-Number-Kind Code	Date MM-YYYY	Country	Name	CPC Classification
	N					
	O					
	P					
	Q					
	R					
	S					
	T					

NON-PATENT DOCUMENTS

*		Include as applicable: Author, Title Date, Publisher, Edition or Volume, Pertinent Pages)
	U	Doyle et al., Rheumatology 52: 1214-1219, (2013).
	V	
	W	
	X	

*A copy of this reference is not being furnished with this Office action. (See MPEP § 707.05(a).)
Dates in MM-YYYY format are publication dates. Classifications may be US or foreign.

<i>Search Notes</i> 	Application/Control No. 17/320,490	Applicant(s)/Patent Under Reexamination Harrison et al.
	Examiner GYAN CHANDRA	Art Unit 1646

CPC - Searched*		
Symbol	Date	Examiner
C07K16/241	04/18/2023	gc
A61K2039/505	04/19/2023	gc
a61k9/0019	04/19/2023	gc

CPC Combination Sets - Searched*		
Symbol	Date	Examiner

US Classification - Searched*			
Class	Subclass	Date	Examiner
None	None	04/19/2023	gc

* See search history printout included with this form or the SEARCH NOTES box below to determine the scope of the search.

Search Notes		
Search Notes	Date	Examiner
STIC search for SEQ ID NOs: 1-6 (see search results in PE2E)	04/14/2023	gc
Claims searched in PE2E (see enclosed doc)	04/18/2023	gc
claims searched in Caplus, Biosis, Medline (see enclosed transcript)	04/18/2023	gc
Inventorship search in Caplus, Biosis medline (see enclosed transcript)	04/18/2023	gc
Inventorship search in PE2E	04/18/2023	gc

/GYAN CHANDRA/ Primary Examiner, Art Unit 1646	
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<i>Search Notes</i> 	Application/Control No. 17/320,490	Applicant(s)/Patent Under Reexamination Harrison et al.
	Examiner GYAN CHANDRA	Art Unit 1646

Interference Search			
US Class/CPC Symbol	US Subclass/CPC Group	Date	Examiner

/GYAN CHANDRA/ Primary Examiner, Art Unit 1646	
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PE2E SEARCH - Search History (Prior Art)

Ref #	Hits	Search Query	DBs	Default Operator	Plurals	British Equivalents	Time Stamp
L1	1	17/320490	(US-PGPUB; USPAT; USOCR; FIT (AP, AT, AU, BE, BG, BR, BY, CA, CH, CN, CS, CU, CZ, DD, DE, DK, EA, EE, EP, ES, FI, FR, GB, HR, HU, ID, IE, IL, IS, IT, JP, KR, LT, LU, LV, MA, MC, MD, MY, NL, NO, NZ, OA, PH, PL, PT, RO, RS, RU, SE, SG, SI, SK, SU, TH, TN, TR, TW, UA, VN, WO); FPRS; EPO; JPO; DERWENT)	OR	ON	ON	2023/04/17 06:06 PM
L2	132	Harrison Diane D.in.	(US-PGPUB; USPAT; USOCR; FIT (AP, AT, AU, BE, BG, BR, BY, CA, CH, CN, CS, CU, CZ, DD, DE, DK, EA, EE, EP, ES, FI, FR, GB, HR, HU, ID, IE, IL, IS, IT, JP, KR, LT, LU, LV, MA, MC, MD, MY, NL, NO, NZ, OA, PH, PL, PT, RO, RS, RU, SE, SG, SI, SK, SU, TH, TN, TR, TW, UA, VN, WO); FPRS; EPO; JPO; DERWENT)	ADJ	ON	ON	2023/04/18 08:15 AM
L3	132	Harrison Diane D.inv.	(US-PGPUB; USPAT; USOCR; FIT (AP, AT, AU, BE, BG, BR, BY, CA, CH, CN, CS, CU, CZ, DD, DE, DK, EA, EE, EP, ES, FI, FR, GB, HR, HU, ID, IE, IL, IS, IT, JP, KR, LT, LU, LV, MA, MC, MD, MY, NL, NO, NZ, OA, PH, PL, PT, RO, RS, RU, SE, SG, SI, SK, SU, TH, TN, TR, TW, UA, VN, WO); FPRS; EPO; JPO; DERWENT)	ADJ	ON	ON	2023/04/18 08:16 AM
L4	66	Hsia Elizabeth C.in.	(US-PGPUB; USPAT; USOCR; FIT (AP, AT, AU, BE, BG, BR, BY, CA, CH, CN, CS, CU, CZ, DD, DE, DK, EA, EE, EP, ES, FI, FR, GB, HR, HU, ID, IE, IL, IS,	ADJ	ON	ON	2023/04/18 08:16 AM

L5	68	Kim Lee Lian.in.	IT, JP, KR, LT, LU, LV, MA, MC, MD, MY, NL, NO, NZ, OA, PH, PL, PT, RO, RS, RU, SE, SG, SI, SK, SU, TH, TN, TR, TW, UA, VN, WO); FPRS; EPO; JPO; DERWENT) (US-PGPUB; USPAT; USOCR; FIT (AP, AT, AU, BE, BG, BR, BY, CA, CH, CN, CS, CU, CZ, DD, DE, DK, EA, EE, EP, ES, FI, FR, GB, HR, HU, ID, IE, IL, IS, IT, JP, KR, LT, LU, LV, MA, MC, MD, MY, NL, NO, NZ, OA, PH, PL, PT, RO, RS, RU, SE, SG, SI, SK, SU, TH, TN, TR, TW, UA, VN, WO); FPRS; EPO; JPO; DERWENT)	ADJ	ON	ON	2023/04/18 08:17 AM
L6	67	Lo kim hung.in.	(US-PGPUB; USPAT; USOCR; FIT (AP, AT, AU, BE, BG, BR, BY, CA, CH, CN, CS, CU, CZ, DD, DE, DK, EA, EE, EP, ES, FI, FR, GB, HR, HU, ID, IE, IL, IS, IT, JP, KR, LT, LU, LV, MA, MC, MD, MY, NL, NO, NZ, OA, PH, PL, PT, RO, RS, RU, SE, SG, SI, SK, SU, TH, TN, TR, TW, UA, VN, WO); FPRS; EPO; JPO; DERWENT)	ADJ	ON	ON	2023/04/18 08:18 AM
L7	166	L2 OR L3 OR L4 OR L5 OR L6	(US-PGPUB; USPAT; USOCR; FIT (AP, AT, AU, BE, BG, BR, BY, CA, CH, CN, CS, CU, CZ, DD, DE, DK, EA, EE, EP, ES, FI, FR, GB, HR, HU, ID, IE, IL, IS, IT, JP, KR, LT, LU, LV, MA, MC, MD, MY, NL, NO, NZ, OA, PH, PL, PT, RO, RS, RU, SE, SG, SI, SK, SU, TH, TN, TR, TW, UA, VN, WO); FPRS; EPO; JPO; DERWENT)	ADJ	ON	ON	2023/04/18 08:18 AM
L8	49	L7 AND golimumab AND psoriat\$2 AND arthritis	(US-PGPUB; USPAT; USOCR; FIT (AP, AT, AU, BE, BG, BR, BY, CA, CH, CN, CS, CU,	ADJ	ON	ON	2023/04/18 08:19 AM

			CZ, DD, DE, DK, EA, EE, EP, ES, FI, FR, GB, HR, HU, ID, IE, IL, IS, IT, JP, KR, LT, LU, LV, MA, MC, MD, MY, NL, NO, NZ, OA, PH, PL, PT, RO, RS, RU, SE, SG, SI, SK, SU, TH, TN, TR, TW, UA, VN, WO); FPRS; EPO; JPO; DERWENT)				
L9	48	L7 AND golimumab AND psoriatic\$2 AND arthritis AND intravenous	(US-PGPUB; USPAT; USOCR; FIT (AP, AT, AU, BE, BG, BR, BY, CA, CH, CN, CS, CU, CZ, DD, DE, DK, EA, EE, EP, ES, FI, FR, GB, HR, HU, ID, IE, IL, IS, IT, JP, KR, LT, LU, LV, MA, MC, MD, MY, NL, NO, NZ, OA, PH, PL, PT, RO, RS, RU, SE, SG, SI, SK, SU, TH, TN, TR, TW, UA, VN, WO); FPRS; EPO; JPO; DERWENT)	ADJ	ON	ON	2023/04/18 08:34 AM
L10	9605	golimumab AND psoriatic\$2 AND arthritis AND intravenous	(US-PGPUB; USPAT; USOCR; FIT (AP, AT, AU, BE, BG, BR, BY, CA, CH, CN, CS, CU, CZ, DD, DE, DK, EA, EE, EP, ES, FI, FR, GB, HR, HU, ID, IE, IL, IS, IT, JP, KR, LT, LU, LV, MA, MC, MD, MY, NL, NO, NZ, OA, PH, PL, PT, RO, RS, RU, SE, SG, SI, SK, SU, TH, TN, TR, TW, UA, VN, WO); FPRS; EPO; JPO; DERWENT)	ADJ	ON	ON	2023/04/18 10:37 AM
L11	1018	golimumab AND psoriatic\$2 AND arthritis AND intravenous.clm.	(US-PGPUB; USPAT; USOCR; FIT (AP, AT, AU, BE, BG, BR, BY, CA, CH, CN, CS, CU, CZ, DD, DE, DK, EA, EE, EP, ES, FI, FR, GB, HR, HU, ID, IE, IL, IS, IT, JP, KR, LT, LU, LV, MA, MC, MD, MY, NL, NO, NZ, OA, PH, PL, PT, RO, RS, RU, SE, SG, SI, SK, SU, TH, TN, TR, TW, UA, VN, WO); FPRS; EPO; JPO; DERWENT)	ADJ	ON	ON	2023/04/18 10:37 AM
L12	253	golimumab.clm. AND	(US-PGPUB; USPAT; USOCR; FIT (AP, AT, AU, BE, BG, BR, BY, CA, CH, CN, CS, CU, CZ, DD, DE, DK, EA, EE, EP, ES, FI, FR, GB, HR, HU, ID, IE, IL, IS, IT, JP, KR, LT, LU, LV, MA, MC, MD, MY, NL, NO, NZ, OA, PH, PL, PT, RO, RS, RU, SE, SG, SI, SK, SU, TH, TN, TR, TW, UA, VN, WO); FPRS; EPO; JPO; DERWENT)	ADJ	ON	ON	2023/04/18

		psoriat\$2 AND arthritis AND intravenous.clm.	USOCR; FIT (AP, AT, AU, BE, BG, BR, BY, CA, CH, CN, CS, CU, CZ, DD, DE, DK, EA, EE, EP, ES, FI, FR, GB, HR, HU, ID, IE, IL, IS, IT, JP, KR, LT, LU, LV, MA, MC, MD, MY, NL, NO, NZ, OA, PH, PL, PT, RO, RS, RU, SE, SG, SI, SK, SU, TH, TN, TR, TW, UA, VN, WO); FPRS; EPO; JPO; DERWENT)				10:37 AM
L13	167	golimumab.clm. AND psoriat\$2 AND arthritis.clm. AND intravenous.clm.	(US-PGPUB; USPAT; USOCR; FIT (AP, AT, AU, BE, BG, BR, BY, CA, CH, CN, CS, CU, CZ, DD, DE, DK, EA, EE, EP, ES, FI, FR, GB, HR, HU, ID, IE, IL, IS, IT, JP, KR, LT, LU, LV, MA, MC, MD, MY, NL, NO, NZ, OA, PH, PL, PT, RO, RS, RU, SE, SG, SI, SK, SU, TH, TN, TR, TW, UA, VN, WO); FPRS; EPO; JPO; DERWENT)	ADJ	ON	ON	2023/04/18 10:38 AM
L14	4	L13 AND SEQ ADJ ID ADJ No ADJ "37"	(US-PGPUB; USPAT; USOCR; FIT (AP, AT, AU, BE, BG, BR, BY, CA, CH, CN, CS, CU, CZ, DD, DE, DK, EA, EE, EP, ES, FI, FR, GB, HR, HU, ID, IE, IL, IS, IT, JP, KR, LT, LU, LV, MA, MC, MD, MY, NL, NO, NZ, OA, PH, PL, PT, RO, RS, RU, SE, SG, SI, SK, SU, TH, TN, TR, TW, UA, VN, WO); FPRS; EPO; JPO; DERWENT)	ADJ	ON	ON	2023/04/18 11:07 AM
L15	23037	C07K16/241.cpc.	(US-PGPUB; USPAT; USOCR; FIT (AP, AT, AU, BE, BG, BR, BY, CA, CH, CN, CS, CU, CZ, DD, DE, DK, EA, EE, EP, ES, FI, FR, GB, HR, HU, ID, IE, IL, IS, IT, JP, KR, LT, LU, LV, MA, MC, MD, MY, NL, NO, NZ, OA, PH, PL, PT, RO, RS, RU, SE, SG, SI, SK, SU, TH, TN, TR, TW, UA, VN, WO); FPRS; EPO; JPO; DERWENT)	ADJ	ON	ON	2023/04/18 11:14 AM

L16	336388	A61K2039/505.cpc.	WO); FPRS; EPO; JPO; DERWENT) (US-PGPUB; USPAT; USOCR; FIT (AP, AT, AU, BE, BG, BR, BY, CA, CH, CN, CS, CU, CZ, DD, DE, DK, EA, EE, EP, ES, FI, FR, GB, HR, HU, ID, IE, IL, IS, IT, JP, KR, LT, LU, LV, MA, MC, MD, MY, NL, NO, NZ, OA, PH, PL, PT, RO, RS, RU, SE, SG, SI, SK, SU, TH, TN, TR, TW, UA, VN, WO); FPRS; EPO; JPO; DERWENT)	ADJ	ON	ON	2023/04/18 11:15 AM
L17	268955	a61k9/0019.cpc.	(US-PGPUB; USPAT; USOCR; FIT (AP, AT, AU, BE, BG, BR, BY, CA, CH, CN, CS, CU, CZ, DD, DE, DK, EA, EE, EP, ES, FI, FR, GB, HR, HU, ID, IE, IL, IS, IT, JP, KR, LT, LU, LV, MA, MC, MD, MY, NL, NO, NZ, OA, PH, PL, PT, RO, RS, RU, SE, SG, SI, SK, SU, TH, TN, TR, TW, UA, VN, WO); FPRS; EPO; JPO; DERWENT)	ADJ	ON	ON	2023/04/18 11:15 AM
L18	10610	L15 AND L16	(US-PGPUB; USPAT; USOCR; FIT (AP, AT, AU, BE, BG, BR, BY, CA, CH, CN, CS, CU, CZ, DD, DE, DK, EA, EE, EP, ES, FI, FR, GB, HR, HU, ID, IE, IL, IS, IT, JP, KR, LT, LU, LV, MA, MC, MD, MY, NL, NO, NZ, OA, PH, PL, PT, RO, RS, RU, SE, SG, SI, SK, SU, TH, TN, TR, TW, UA, VN, WO); FPRS; EPO; JPO; DERWENT)	ADJ	ON	ON	2023/04/18 11:17 AM
L19	2792	L18 AND psoriatis\$2 AND arthritis	(US-PGPUB; USPAT; USOCR; FIT (AP, AT, AU, BE, BG, BR, BY, CA, CH, CN, CS, CU, CZ, DD, DE, DK, EA, EE, EP, ES, FI, FR, GB, HR, HU, ID, IE, IL, IS, IT, JP, KR, LT, LU, LV, MA, MC, MD, MY, NL, NO, NZ, OA, PH, PL, NO, NZ, OA, PH, PL,	ADJ	ON	ON	2023/04/18 11:17 AM

L20	2680	L18 AND psoriatis\$2 ADJ arthritis	PT, RO, RS, RU, SE, SG, SI, SK, SU, TH, TN, TR, TW, UA, VN, WO); FPRS; EPO; JPO; DERWENT) (US-PGPUB; USPAT; USOCR; FIT (AP, AT, AU, BE, BG, BR, BY, CA, CH, CN, CS, CU, CZ, DD, DE, DK, EA, EE, EP, ES, FI, FR, GB, HR, HU, ID, IE, IL, IS, IT, JP, KR, LT, LU, LV, MA, MC, MD, MY, NL, NO, NZ, OA, PH, PL, PT, RO, RS, RU, SE, SG, SI, SK, SU, TH, TN, TR, TW, UA, VN, WO); FPRS; EPO; JPO; DERWENT)	ADJ	ON	ON	2023/04/18 11:18 AM
L21	178	L18 AND psoriatis\$2 ADJ arthritis SAME intravenous AND antibod\$3	(US-PGPUB; USPAT; USOCR; FIT (AP, AT, AU, BE, BG, BR, BY, CA, CH, CN, CS, CU, CZ, DD, DE, DK, EA, EE, EP, ES, FI, FR, GB, HR, HU, ID, IE, IL, IS, IT, JP, KR, LT, LU, LV, MA, MC, MD, MY, NL, NO, NZ, OA, PH, PL, PT, RO, RS, RU, SE, SG, SI, SK, SU, TH, TN, TR, TW, UA, VN, WO); FPRS; EPO; JPO; DERWENT)	ADJ	ON	ON	2023/04/18 11:19 AM
L22	174	L21 AND TNF	(US-PGPUB; USPAT; USOCR; FIT (AP, AT, AU, BE, BG, BR, BY, CA, CH, CN, CS, CU, CZ, DD, DE, DK, EA, EE, EP, ES, FI, FR, GB, HR, HU, ID, IE, IL, IS, IT, JP, KR, LT, LU, LV, MA, MC, MD, MY, NL, NO, NZ, OA, PH, PL, PT, RO, RS, RU, SE, SG, SI, SK, SU, TH, TN, TR, TW, UA, VN, WO); FPRS; EPO; JPO; DERWENT)	ADJ	ON	ON	2023/04/18 11:20 AM
L23	0	L21 AND TNF AND SEQ ADJ ID ADJ No ADJ "37"	(US-PGPUB; USPAT; USOCR; FIT (AP, AT, AU, BE, BG, BR, BY, CA, CH, CN, CS, CU, CZ, DD, DE, DK, EA, EE, EP, ES, FI, FR, GB, HR, HU, ID, IE, IL, IS,	ADJ	ON	ON	2023/04/18 11:21 AM

L24	53	L21 AND TNF AND SEQ ADJ ID NEAR "37"	IT, JP, KR, LT, LU, LV, MA, MC, MD, MY, NL, NO, NZ, OA, PH, PL, PT, RO, RS, RU, SE, SG, SI, SK, SU, TH, TN, TR, TW, UA, VN, WO); FPRS; EPO; JPO; DERWENT) (US-PGPUB; USPAT; USOCR; FIT (AP, AT, AU, BE, BG, BR, BY, CA, CH, CN, CS, CU, CZ, DD, DE, DK, EA, EE, EP, ES, FI, FR, GB, HR, HU, ID, IE, IL, IS, IT, JP, KR, LT, LU, LV, MA, MC, MD, MY, NL, NO, NZ, OA, PH, PL, PT, RO, RS, RU, SE, SG, SI, SK, SU, TH, TN, TR, TW, UA, VN, WO); FPRS; EPO; JPO; DERWENT)	ADJ	ON	ON	2023/04/18 11:21 AM
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		golimumab AND					
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		"6277969" OR					
		"7521206" OR					
		"7691378" OR					
		"8241899" OR					

L29	3	"9512065").pn. AND golimumab AND psoriatic ADJ arthritis ("0000030" OR "0000059" OR "0000088" OR "0000116" OR "0000144" OR "20020168360" OR "20080311043" OR "20090028794" OR "20090214528" OR "20100266590" OR "3773919" OR "4239754" OR "4309989" OR "4399216" OR "4603106" OR "4634665" OR "4656134" OR "4668218" OR "4676980" OR "4683195" OR "4683202" OR "4704692" OR "4766067" OR "4767402" OR "4795699" OR "4800159" OR "4816567" OR "4822776" OR "4873316" OR "4889818" OR "4921794" OR "4925673" OR "4939666" OR "4946778" OR "4956288" OR "4965188" OR "4994370" OR "5066584" OR "5091310" OR "5122464" OR "5130238" OR "5142033" OR "5149636" OR "5168062" OR "5179017" OR "5223409" OR "5225538" OR "5225539" OR "5231024" OR "5260203" OR "5266491" OR "5304489" OR "5342613" OR "5385839" OR "5403484" OR	(US-PGPUB; USPAT)	ADJ	ON	ON	2023/04/18 02:15 PM
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		psoriatic ADJ arthritis					
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L31	3	("0000030" OR "0000059" OR "0000088" OR "0000116" OR "0000144" OR "20020168360" OR "20080311043" OR "20090028794" OR "20090214528" OR "20100266590" OR "3773919" OR "4239754" OR "4309989" OR "4399216" OR "4603106" OR "4634665" OR "4656134" OR "4668218" OR "4676980" OR "4683195" OR "4683202" OR "4704692" OR "4766067" OR "4767402" OR "4795699" OR "4800159" OR "4816567" OR "4822776" OR "4873316" OR "4889818" OR "4921794" OR "4925673" OR	(US-PGPUB; USPAT)	ADJ	ON	ON	2023/04/18 02:34 PM

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L32	2	"6277969" OR "7521206" OR "7691378" OR "8241899" OR "9512065").pn. AND golimumab AND psoriatic ADJ arthritis AND intravenous AND methotrexate AND week\$1 ("0000030" OR "0000059" OR "0000088" OR "0000116" OR "0000144" OR "20020168360" OR "20080311043" OR "20090028794" OR "20090214528" OR "20100266590" OR "3773919" OR "4239754" OR "4309989" OR "4399216" OR "4603106" OR "4634665" OR "4656134" OR "4668218" OR "4676980" OR "4683195" OR "4683202" OR "4704692" OR "4766067" OR "4767402" OR "4795699" OR "4800159" OR "4816567" OR "4822776" OR "4873316" OR "4889818" OR "4921794" OR "4925673" OR "4939666" OR "4946778" OR "4956288" OR "4965188" OR "4994370" OR "5066584" OR "5091310" OR "5122464" OR "5130238" OR "5142033" OR "5149636" OR "5168062" OR "5179017" OR "5223409" OR "5225538" OR "5225539" OR	(US-PGPUB; USPAT)	ADJ	ON	ON	2023/04/18 02:36 PM
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PE2E SEARCH - Search History (Interference)

There are no Interference searches to show.

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Searching Capabilities
NEWS 15 NOV 10 PS (Pharmaceutical Substances) Database Reloaded
NEWS 16 DEC 05 Expanded access to Taiwanese patent information provided
by new full text database TWFULL and claims coverage
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NEWS 17 DEC 05 New Implementation of Derwent Drug File (DRUGU/DDFU)
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NEWS 19 DEC 30 2023 MeSH now available in MEDLINE on STNext
NEWS 20 FEB 03 January 2023 Update to Emtree(R) Now Available in Embase(R)
NEWS 21 FEB 17 Identification of Substances from Claims Simplified in
CAS PatentPak - UPDATE
NEWS 22 FEB 23 Derwent World Patents Index - Manual Code revision 2023
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E4	9	HARRISON DIANE DEBORAH/AU
E5	1	HARRISON DIANE J/AU
E6	6	HARRISON DIANNE/AU
E7	2	HARRISON DIANNE F/AU
E8	5	HARRISON DIANNE M/AU
E9	1	HARRISON DICK/AU
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E22	27	HSIA FENG CHUN/AU
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L1 66 "HARRISON DIANE D"/AU

=> s e15

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E36 1 KIM LEE S U/AU

=> s e27

L3 18 "KIM LEE LIAN"/AU

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E47 2 LO KIN/AU
E48 27 LO KIN CHEUNG/AU

=> s e39

L4 105 "LO KIM HUNG"/AU

=> s l1-4

L5 313 (L1 OR L2 OR L3 OR L4)

=> s golimumab

L6 5758 GOLIMUMAB

=> s psoriatic arthritis

L7 33750 PSORIATIC ARTHRITIS

=> s l6 (1) l7

L8 644 L6 (L) L7

=> s l8 and intravenous

L9 47 L8 AND INTRAVENOUS

=> s l9 and py<2017

L10 8 L9 AND PY<2017

=> s l10 and <2016

MISSING TERM 'AND <2016'

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=> s l10 and py<2016

L11 8 L10 AND PY<2016

=> dup rem l11

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L12 7 DUP REM L11 (1 DUPLICATE REMOVED)

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L12 ANSWER 1 OF 7 BIOSIS COPYRIGHT (c) 2023 Clarivate Analytics on STN
TI LACK OF CORRELATION BETWEEN GOLIMUMAB EXPOSURE AND SELECTED SAFETY
EVENTS FOLLOWING INTRAVENOUS OR SUBCUTANEOUS ADMINISTRATION IN AN

INTEGRATED ANALYSIS OF PHASE 3 DATA IN RHEUMATOID ARTHRITIS, PSORIATIC ARTHRITIS, OR ANKYLOSING SPONDYLITIS.

SO Annals of the Rheumatic Diseases, (JUN 2013) Vol. 72, No. Suppl. 3, pp. 868. <http://ard.bmj.com/>.
Meeting Info.: Annual European Congress of Rheumatology (EULAR). Madrid, SPAIN. June 12 -15, 2013.
CODEN: ARDIAO. ISSN: 0003-4967. E-ISSN: 1468-2060.

PY 2013

TI LACK OF CORRELATION BETWEEN GOLIMUMAB EXPOSURE AND SELECTED SAFETY EVENTS FOLLOWING INTRAVENOUS OR SUBCUTANEOUS ADMINISTRATION IN AN INTEGRATED ANALYSIS OF PHASE 3 DATA IN RHEUMATOID ARTHRITIS, PSORIATIC ARTHRITIS, OR ANKYLOSING SPONDYLITIS.

SO Annals of the Rheumatic Diseases, (JUN 2013) Vol. 72, No. Suppl. 3, pp. 868. <http://ard.bmj.com/>.
Meeting Info.: Annual European Congress of Rheumatology (EULAR). Madrid, SPAIN. June. . . .

IT
disease, joint disease, integumentary system disease, drug therapy
Arthritis, Psoriatic (MeSH)

IT Chemicals & Biochemicals
MTX: immunologic-drug, antiarthritic-drug; golimumab: immunologic-drug, antiarthritic-drug, intravenous administration, subcutaneous administration, safety, pharmacokinetics, dosage, phase III clinical trial

ACCESSION NUMBER: 2014:264899 BIOSIS Full-text
DOCUMENT NUMBER: PREV201400264899
TITLE: LACK OF CORRELATION BETWEEN GOLIMUMAB EXPOSURE AND SELECTED SAFETY EVENTS FOLLOWING INTRAVENOUS OR SUBCUTANEOUS ADMINISTRATION IN AN INTEGRATED ANALYSIS OF PHASE 3 DATA IN RHEUMATOID ARTHRITIS, PSORIATIC ARTHRITIS, OR ANKYLOSING SPONDYLITIS.

AUTHOR(S): Leu, J. H. [Reprint Author]; Beutler, A.; Mendelsohn, A.; Liao, S.; Davis, H.; Zhou, H.; Xu, Z.

CORPORATE SOURCE: Janssen R and D LLC, Spring House, PA USA

SOURCE: Annals of the Rheumatic Diseases, (JUN 2013) Vol. 72, No. Suppl. 3, pp. 868. <http://ard.bmj.com/>.
Meeting Info.: Annual European Congress of Rheumatology (EULAR). Madrid, SPAIN. June 12 -15, 2013.
CODEN: ARDIAO. ISSN: 0003-4967. E-ISSN: 1468-2060.

DOCUMENT TYPE: Conference; (Meeting)
Conference; Abstract; (Meeting Abstract)

LANGUAGE: English

ENTRY DATE: Entered STN: 26 Mar 2014
Last Updated on STN: 26 Mar 2014

L12 ANSWER 2 OF 7 BIOSIS COPYRIGHT (c) 2023 Clarivate Analytics on STN

TI Lack Of Correlation Between Golimumab Exposure and Selected Safety Events Following Intravenous Or Subcutaneous Administration In An Integrated Analysis Of Phase 3 Data Of Patients With Rheumatoid Arthritis, Psoriatic Arthritis, Or Ankylosing Spondylitis.

SO Arthritis & Rheumatism, (OCT 2013) Vol. 65, No. Suppl. 10, Sp. Iss. SI, pp. S599. [http://onlinelibrary.wiley.com/journal/10.1002/\(ISSN\)1529-0131](http://onlinelibrary.wiley.com/journal/10.1002/(ISSN)1529-0131).
Meeting Info.: 77th Annual Meeting of the American-College-of-Rheumatology / 48th Annual Meeting of the Association-of-Rheumatology-Health-Professionals. San Diego, CA, USA. October 25 -30, 2013. Amer Coll Rheumatol; Assoc Rheumatol Hlth Profess.
CODEN: ARHEAW. ISSN: 0004-3591. E-ISSN: 1529-0131.

PY 2013

TI Lack Of Correlation Between Golimumab Exposure and Selected Safety Events Following Intravenous Or Subcutaneous Administration In An Integrated Analysis Of Phase 3 Data Of Patients With Rheumatoid Arthritis, Psoriatic Arthritis, Or Ankylosing Spondylitis.

SO Arthritis & Rheumatism, (OCT 2013) Vol. 65, No. Suppl. 10, Sp. Iss. SI, pp. S599. [http://onlinelibrary.wiley.com/journal/10.1002/\(ISSN\)1529-0131](http://onlinelibrary.wiley.com/journal/10.1002/(ISSN)1529-0131).
Meeting Info.: 77th Annual Meeting of the American-College-of-Rheumatology. . . .

ACCESSION NUMBER: 2013:782346 BIOSIS Full-text
DOCUMENT NUMBER: PREV201300782346
TITLE: Lack Of Correlation Between Golimumab Exposure and Selected Safety Events Following Intravenous Or Subcutaneous Administration In An Integrated Analysis Of

Phase 3 Data Of Patients With Rheumatoid Arthritis,
 Psoriatic Arthritis, Or Ankylosing Spondylitis.
 AUTHOR(S): Leu, Jocelyn H. [Reprint Author]; Beutler, Anna;
 Mendelsohn, Alan M.; Liao, Sam; Davis, Hugh M.; Zhou,
 Honghui; Xu, Zhenhua
 CORPORATE SOURCE: Janssen Res and Dev LLC, Spring House, PA USA
 SOURCE: Arthritis & Rheumatism, (OCT 2013) Vol. 65, No. Suppl.
 10, Sp. Iss. SI, pp. S599.
[http://onlinelibrary.wiley.com/journal/10.1002/\(ISSN\)1529-0131](http://onlinelibrary.wiley.com/journal/10.1002/(ISSN)1529-0131).
 Meeting Info.: 77th Annual Meeting of the
 American-College-of-Rheumatology / 48th Annual Meeting of
 the Association-of-Rheumatology-Health-Professionals. San
 Diego, CA, USA. October 25 -30, 2013. Amer Coll Rheumatol;
 Assoc Rheumatol Hlth Profess.
 CODEN: ARHEAW. ISSN: 0004-3591. E-ISSN: 1529-0131.
 DOCUMENT TYPE: Conference; (Meeting)
 Conference; (Meeting Poster)
 LANGUAGE: English
 ENTRY DATE: Entered STN: 27 Nov 2013
 Last Updated on STN: 27 Nov 2013

L12 ANSWER 3 OF 7 BIOSIS COPYRIGHT (c) 2023 Clarivate Analytics on STN
 TI Patient Satisfaction and Experience with Golimumab, Adalimumab, and
 Etanercept for the Treatment of Rheumatoid Arthritis, Psoriatic
 Arthritis, and Ankylosing Spondylitis.
 SO Arthritis & Rheumatism, (OCT 2012) Vol. 64, No. 10, Suppl. S, pp. S817.
[http://onlinelibrary.wiley.com/journal/10.1002/\(ISSN\)1529-0131](http://onlinelibrary.wiley.com/journal/10.1002/(ISSN)1529-0131).
 Meeting Info.: Annual Scientific Meeting of the
 American-College-of-Rheumatology (ACR) and
 Association-of-Rheumatology-Health-Professionals (ARHP). Washington, DC,
 USA. November 09 -14, 2012. Amer Coll Rheumatol (ACR); Assoc Rheumatol
 Hlth Profess (ARHP).
 CODEN: ARHEAW. ISSN: 0004-3591. E-ISSN: 1529-0131.
 PY 2012
 TI Patient Satisfaction and Experience with Golimumab, Adalimumab, and
 Etanercept for the Treatment of Rheumatoid Arthritis, Psoriatic
 Arthritis, and Ankylosing Spondylitis.
 SO Arthritis & Rheumatism, (OCT 2012) Vol. 64, No. 10, Suppl. S, pp. S817.
[http://onlinelibrary.wiley.com/journal/10.1002/\(ISSN\)1529-0131](http://onlinelibrary.wiley.com/journal/10.1002/(ISSN)1529-0131).
 Meeting Info.: Annual Scientific Meeting of the
 American-College-of-Rheumatology (ACR) and. . .
 IT . . .
 psoriatic arthritis: bone disease, joint disease, integumentary system
 disease, drug therapy
 Arthritis, Psoriatic (MeSH)
 IT Chemicals & Biochemicals
 etanercept: immunologic-drug, antiarthritic-drug, intravenous
 administration, subcutaneous administration; golimumab:
 immunologic-drug, antiarthritic-drug, intravenous administration,
 subcutaneous administration; adalimumab: immunologic-drug,
 antiarthritic-drug, intravenous administration, subcutaneous
 administration
 ACCESSION NUMBER: 2013:2966 BIOSIS Full-text
 DOCUMENT NUMBER: PREV201300002966
 TITLE: Patient Satisfaction and Experience with Golimumab,
 Adalimumab, and Etanercept for the Treatment of Rheumatoid
 Arthritis, Psoriatic Arthritis, and Ankylosing
 Spondylitis.
 AUTHOR(S): Bolge, Susan [Reprint Author]; Eldridge, Helen; Doshi,
 Dilesh; Ellis, Lorie; Roland, Barbara; Woelfel, John
 CORPORATE SOURCE: Janssen Sci Affairs LLC, Horsham, PA USA
 SOURCE: Arthritis & Rheumatism, (OCT 2012) Vol. 64, No. 10,
 Suppl. S, pp. S817.
[http://onlinelibrary.wiley.com/journal/10.1002/\(ISSN\)1529-0131](http://onlinelibrary.wiley.com/journal/10.1002/(ISSN)1529-0131).
 Meeting Info.: Annual Scientific Meeting of the
 American-College-of-Rheumatology (ACR) and
 Association-of-Rheumatology-Health-Professionals (ARHP).
 Washington, DC, USA. November 09 -14, 2012. Amer Coll
 Rheumatol (ACR); Assoc Rheumatol Hlth Profess (ARHP).

DOCUMENT TYPE: CODEN: ARHEAW. ISSN: 0004-3591. E-ISSN: 1529-0131.
Conference; (Meeting)
Conference; (Meeting Poster)
LANGUAGE: English
ENTRY DATE: Entered STN: 5 Dec 2012
Last Updated on STN: 5 Dec 2012

L12 ANSWER 4 OF 7 BIOSIS COPYRIGHT (c) 2023 Clarivate Analytics on STN
DUPLICATE 1
TI Golimumab: Review of the Efficacy and Tolerability of a Recently Approved
Tumor Necrosis Factor-alpha Inhibitor.
SO Clinical Therapeutics, (SEP 2010) Vol. 32, No. 10, pp. 1681-1703.
<http://www.journals.elsevierhealth.com/periodicals/clithe>.
CODEN: CLTHDG. ISSN: 0149-2918. E-ISSN: 1879-114X.
PY 2010
SO Clinical Therapeutics, (SEP 2010) Vol. 32, No. 10, pp. 1681-1703.
<http://www.journals.elsevierhealth.com/periodicals/clithe>.
CODEN: CLTHDG. ISSN: 0149-2918. E-ISSN: 1879-114X.
AB Background: Golimumab (GLM) is a tumor necrosis factor-alpha (TNF-alpha)
inhibitor that was approved in the United States in 2009 for use with .
. severe active rheumatoid arthritis (RA), and with or without MTX or
other non-biologic disease-modifying antirheumatic drugs in adults with
active psoriatic arthritis (PSA) or active ankylosing spondylitis
(AS). GLM is administered as a 50-mg subcutaneous injection once a
month.Objectives: The goals of. . . were searched for relevant articles
published in English between the inception of the databases through April
2010. Search terms included golimumab and CNTO 148. Pharmacologic,
pharmacokinetic, clinical, outcomes, and economic studies as well as
meta-analyses, case reports, and select abstracts were. . . and used to
evaluate the efficacy and tolerability of GLM: 5 in patients with RA (4
subcutaneous administration and 1 intravenous administration), 1 in
patients with PSA (subcutaneous), and 1 in patients with AS
(subcutaneous). In MTX-naive patients with RA, the. . .
ACCESSION NUMBER: 2010:595467 BIOSIS Full-text
DOCUMENT NUMBER: PREV201000595467
TITLE: Golimumab: Review of the Efficacy and Tolerability of a
Recently Approved Tumor Necrosis Factor-alpha Inhibitor.
AUTHOR(S): Boyce, Eric G. [Reprint Author]; Halilovic, Jenana;
Stan-Ugbene, Oby
CORPORATE SOURCE: Univ Pacific, Thomas J Long Sch Pharm and Hlth Sci, Dept
Pharm Practice, 3601 Pacific Ave, Stockton, CA 95211 USA
eboyce@pacific.edu
SOURCE: Clinical Therapeutics, (SEP 2010) Vol. 32, No. 10, pp.
1681-1703.
<http://www.journals.elsevierhealth.com/periodicals/clithe>.
CODEN: CLTHDG. ISSN: 0149-2918. E-ISSN: 1879-114X.
DIGITAL OBJECT ID: 10.1016/j.clinthera.2010.09.003
DOCUMENT TYPE: Article
General Review; (Literature Review)
LANGUAGE: English
ENTRY DATE: Entered STN: 3 Nov 2010
Last Updated on STN: 29 May 2019

L12 ANSWER 5 OF 7 MEDLINE @ on STN
TI Golimumab: A novel human anti-TNF-alpha monoclonal antibody for the
treatment of rheumatoid arthritis, ankylosing spondylitis, and psoriatic
arthritis.
SO Core evidence, (2010 Jun 15) Vol. 4, pp. 159-70. Electronic Publication
Date: 15 Jun 2010
Journal code: 101256593. E-ISSN: 1555-175X. L-ISSN: 1555-1741.
Report No.: PMC-PMC2899784.
PY 2010
TI Golimumab: A novel human anti-TNF-alpha monoclonal antibody for the
treatment of rheumatoid arthritis, ankylosing spondylitis, and psoriatic
arthritis.
SO Core evidence, (2010 Jun 15) Vol. 4, pp. 159-70. Electronic Publication
Date: 15 Jun 2010
Journal code: 101256593. E-ISSN: 1555-175X. L-ISSN: 1555-1741.
Report No.: . . .
AB . . . satisfactory clinical improvement with these therapeutic agents.

The mode of administration of these medications is inconvenient for some patients.

AIMS: Golimumab is a novel anti-TNF-alpha monoclonal antibody that is in clinical development for the treatment of RA, psoriatic arthritis (PsA), and ankylosing spondylitis (AS), either as a first-line biologic therapy or an alternative after other TNF-alpha inhibitors have been discontinued. This review summarizes the development of, and clinical evidence achieved with, golimumab.

EVIDENCE REVIEW: Golimumab has demonstrated significant efficacy in randomized, double-blind, placebo-controlled trials when administered subcutaneously once every four weeks. It has been generally well tolerated in clinical trials and demonstrates a safety profile comparable with currently available TNF-alpha inhibitors.

OUTCOMES SUMMARY: Golimumab has been confirmed to be an effective treatment for patients with RA, PsA, and AS in phase III clinical trials. . . as well as measures of physical function, patient reported outcomes, and health economic measures. The efficacy and safety profile of golimumab in RA, PsA, and AS appears to be similar to other anti-TNF agents. However, golimumab has the potential advantage of once monthly subcutaneous administration and the possibility of both subcutaneous and intravenous administration.

ST TNF- α inhibitors; ankylosing spondylitis; golimumab; psoriatic arthritis; rheumatoid arthritis

ACCESSION NUMBER: 2010732769 MEDLINE Full-text

DOCUMENT NUMBER: PubMed ID: 20694072

TITLE: Golimumab: A novel human anti-TNF-alpha monoclonal antibody for the treatment of rheumatoid arthritis, ankylosing spondylitis, and psoriatic arthritis.

AUTHOR: Kay Jonathan

CORPORATE SOURCE: Division of Rheumatology, UMass Memorial Medical Center, University of Massachusetts Medical School, Worcester, MA, USA.

AUTHOR: Rahman Mahboob U

SOURCE: Core evidence, (2010 Jun 15) Vol. 4, pp. 159-70.

Electronic Publication Date: 15 Jun 2010

Journal code: 101256593. E-ISSN: 1555-175X. L-ISSN: 1555-1741.

Report No.: PMC-PMC2899784.

DIGITAL OBJECT ID: <http://dx.doi.org/10.2147/ce.s6000>

PUB. COUNTRY: New Zealand

DOCUMENT TYPE: Journal; Article; (JOURNAL ARTICLE)

LANGUAGE: English

FILE SEGMENT: NONMEDLINE; PUBMED-NOT-MEDLINE

FILE SEGMENT: Electronic

ENTRY MONTH: 201107

ENTRY DATE: Entered STN: 10 Aug 2010

Last Updated on STN: 15 Jul 2011

Entered Medline: 14 Jul 2011

OS.CITING REF COUNT: 9 There are 9 MEDLINE records that cite this record

MEDLINE REFERENCE COUNT: 32 There are 32 cited references available in MEDLINE for this document.

L12 ANSWER 6 OF 7 BIOSIS COPYRIGHT (c) 2023 Clarivate Analytics on STN

TI GOLIMUMAB: A NOVEL ANTI-TNF-alpha HUMAN MONOCLONAL ANTIBODY FOR RHEUMATOID ARTHRITIS, PSORIATIC ARTHRITIS AND ANKYLOSING SPONDYLITIS.

SO Drugs of Today, (JAN 2010) Vol. 46, No. 1, pp. 13-22.

ISSN: 1699-3993. E-ISSN: 1699-4019.

PY 2010

TI GOLIMUMAB: A NOVEL ANTI-TNF-alpha HUMAN MONOCLONAL ANTIBODY FOR RHEUMATOID ARTHRITIS, PSORIATIC ARTHRITIS AND ANKYLOSING SPONDYLITIS.

SO Drugs of Today, (JAN 2010) Vol. 46, No. 1, pp. 13-22.

ISSN: 1699-3993. E-ISSN: 1699-4019.

AB. . . a proinflammatory cytokine, has been implicated in the pathology of a variety of chronic autoimmune diseases such as rheumatoid arthritis, psoriatic arthritis and ankylosing spondylitis. The introduction of TNF-alpha inhibitors represented a significant advance in the management of these diseases but the responses of individual patients to TNF-alpha inhibitors are not homogeneous and more therapeutic tools are needed.

Golimumab (CNTO-748) is a novel anti-TNF-alpha human monoclonal antibody that blocks both soluble and transmembrane TNF-alpha. It is indicated in the . . . treatment of adults with moderately to severely active rheumatoid arthritis in combination with methotrexate, in adults with active and progressive psoriatic arthritis either alone or in combination with methotrexate, and in adult patients with active ankylosing spondylitis who have had an inadequate response to conventional therapies. Golimumab has generally been well tolerated in clinical trials with a safety profile comparable to other currently available TNF-alpha inhibitors. Its . . . be administered s.c. once monthly, it is labeled for patient self-administration and is suitable for both s.c. and i.v. administration. Golimumab is currently being investigated in other chronic inflammatory diseases.

IT . . .
 pathology
 Arthritis, Psoriatic (MeSH)
 IT Chemicals & Biochemicals
 tumor necrosis factor-alpha [TNF-alpha]: proinflammatory cytokine;
 methotrexate: antiinflammatory-drug, immunosuppressant-drug,
 immunologic-drug; golimumab: immunologic-drug, immunostimulant-drug,
 intravenous administration, tolerability, subcutaneous
 administration, safety, pharmacodynamics, phase III clinical trial
 ACCESSION NUMBER: 2010:240145 BIOSIS Full-text
 DOCUMENT NUMBER: PREV201000240145
 TITLE: GOLIMUMAB: A NOVEL ANTI-TNF-alpha HUMAN MONOCLONAL
 ANTIBODY FOR RHEUMATOID ARTHRITIS, PSORIATIC ARTHRITIS
 AND ANKYLOSING SPONDYLITIS.
 AUTHOR(S): Campas-Moya, Clara [Reprint Author]
 CORPORATE SOURCE: Baldiri Reixac 10-12, Barcelona 08028, Spain
 claracampas@gmail.com
 SOURCE: Drugs of Today, (JAN 2010) Vol. 46, No. 1, pp. 13-22.
 ISSN: 1699-3993. E-ISSN: 1699-4019.
 DIGITAL OBJECT ID: 10.1358/dot.2010.46.1.1444434
 DOCUMENT TYPE: Article
 LANGUAGE: English
 ENTRY DATE: Entered STN: 5 May 2010
 Last Updated on STN: 5 Dec 2018

L12 ANSWER 7 OF 7 BIOSIS COPYRIGHT (c) 2023 Clarivate Analytics on STN
 TI Golimumab.
 SO mAbs, (SEP-OCT 2009) Vol. 1, No. 5, pp. 422-431.
<http://www.tandfonline.com/loi/kmab20>.
 ISSN: 1942-0862. E-ISSN: 1942-0870.
 PY 2009
 SO mAbs, (SEP-OCT 2009) Vol. 1, No. 5, pp. 422-431.
<http://www.tandfonline.com/loi/kmab20>.
 ISSN: 1942-0862. E-ISSN: 1942-0870.
 AB Golimumab, a human anti-TNFalpha IgG1 kappa monoclonal antibody, was approved in the US and Canada in April 2009 as a treatment for rheumatoid arthritis, psoriatic arthritis and ankylosing spondylitis, and is under-going regulatory review in the EU for these indications. The product was developed by Centocor and Janssen Pharmaceutical KK (Johnson & Johnson subsidiaries), in collaboration with Schering-Plough and Mitsubishi Tanabe Pharma. Golimumab faces numerous protein therapeutic competitors on the market, but as the first patient-administered, once-monthly dosed anti-TNF alpha drug, it will. . .
 IT . . .
 psoriatic arthritis: bone disease, joint disease, integumentary system disease, PsA
 Arthritis, Psoriatic (MeSH)
 IT Chemicals & Biochemicals
 golimumab: immunologic-drug, antigout-drug, dermatological-drug,
 intravenous administration, anti-TNF-alpha IgG1-kappa monoclonal
 antibody, pharmacokinetics, dosage, clinical trial
 ACCESSION NUMBER: 2010:34666 BIOSIS Full-text
 DOCUMENT NUMBER: PREV201000034666
 TITLE: Golimumab.
 AUTHOR(S): Mazumdar, Sohini [Reprint Author]; Greenwald, David
 CORPORATE SOURCE: Tufts Univ, Sch Med, Grad Program Genet, Dept Anat and Cell
 Biol, Sackler Sch Grad Biomed Sci, Boston, MA 02111 USA
 sohini.mazumdar@tufts.edu; dave.greenwald@gmail.com

SOURCE: mAbs, (SEP-OCT 2009) Vol. 1, No. 5, pp. 422-431.
http://www.tandfonline.com/loi/kmab20.
ISSN: 1942-0862. E-ISSN: 1942-0870.
DOCUMENT TYPE: Article
General Review; (Literature Review)
LANGUAGE: English
ENTRY DATE: Entered STN: 30 Dec 2009
Last Updated on STN: 11 Dec 2019

=> s 15 (1) golimumab and psoriatic

L13 0 L5 (L) GOLIMUMAB AND PSORIATIC

=> s 15 (1) psoriatic

L14 0 L5 (L) PSORIATIC

=> s 15 and psoriatic arthritis

L15 0 L5 AND PSORIATIC ARTHRITIS

=> s 15 and golimumab

L16 176 L5 AND GOLIMUMAB

=> s 116 and arthritis

L17 0 L16 AND ARTHRITIS

=> s 116 and arthritis

L18 145 L16 AND ARTHRITIS

=> s 118 psoriatic

MISSING OPERATOR L18 PSORIATIC

The search profile that was entered contains terms or nested terms that are not separated by a logical operator.

=> s 118 and psoriatic arthritis

L19 0 L18 AND PSORIATIC ARTHRITIS

=> s 118 and py<2016

L20 95 L18 AND PY<2016

=> s 120 and psoriasis

L21 0 L20 AND PSOROSIS

=> s 120 and rheumatoid

L22 0 L20 AND RHEMATOID

=> s 120 and antibody and tnf

L23 12 L20 AND ANTIBODY AND TNF

=> s 123 and treatment

L24 11 L23 AND TREATMENT

=> s 124 and active psoriatic

L25 0 L24 AND ACTIVE PSORIATIC

=> d his

(FILE 'HOME' ENTERED AT 13:42:59 ON 18 APR 2023)

FILE 'CAPLUS, BIOSIS, MEDLINE' ENTERED AT 13:45:11 ON 18 APR 2023

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      E HARRISON DIANE D/AU
      E HSIA ELIZABETH C/AU
L1      66 S E3
L2      222 S E15
      E KIM LEE LIAN/AU
L3      18 S E27
      E LO KIM HUNG/AU
L4      105 S E39
L5      313 S L1-4
L6      5758 S GOLIMUMAB
L7      33750 S PSORIATIC ARTHRITIS
L8      644 S L6 (L) L7
L9      47 S L8 AND INTRAVENOUS
L10     8 S L9 AND PY<2017
L11     8 S L10 AND PY<2016
L12     7 DUP REM L11 (1 DUPLICATE REMOVED)
L13     0 S L5 (L) GOLIMUMAB AND PSORIATIC
L14     0 S L5 (L) PSORTIATIC
L15     0 S L5 AND PSORITATIC ARTHRITIS
L16     176 S L5 AND GOLIMUMAB
L17     0 S L16 AND ARTHRITIIS
L18     145 S L16 AND ARTHRITIS
L19     0 S L18 AND PSORIATIC ARHRITIS
L20     95 S L18 AND PY<2016
L21     0 S L20 AND PSOROSIS
L22     0 S L20 AND RHEMATOID
L23     12 S L20 AND ANTIBODY AND TNF
L24     11 S L23 AND TREATMENT
L25     0 S L24 AND ACTIVE PSORIATIC
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=>

Doc code: IDS

Doc description: Information Disclosure Statement (IDS) Filed

PTO/SB/08a (02-18)

Approved for use through 11/30/2020. OMB 0651-0031

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INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Not for submission under 37 CFR 1.99)

Application Number	17320490
Filing Date	2021-05-14
First Named Inventor	Diane D. Harrison
Art Unit	1646
Examiner Name	CHANDRA
Attorney Docket Number	206389-0003-02-US

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**INFORMATION DISCLOSURE
STATEMENT BY APPLICANT**
(Not for submission under 37 CFR 1.99)

Application Number	17320490
Filing Date	2021-05-14
First Named Inventor	Diane D. Harrison
Art Unit	1646
Examiner Name	CHANDRA
Attorney Docket Number	206389-0003-02-US

/G.C/	1	DEODHAR, A. A. et al, "Safety and Efficacy of Intravenous Golimumab in Adult Patients with Active Ankylosing Spondylitis: Results through Week 28", Arthritis Rheumatol, 68, Suppl. 10, abstract no. 1043, 28 September 2016, 3 pages.
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Examiner Signature	/GYAN CHANDRA/	Date Considered	04/17/2023
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¹ See Kind Codes of USPTO Patent Documents at www.USPTO.GOV or MPEP 901.04. ² Enter office that issued the document, by the two-letter code (WIPO Standard ST.3). ³ For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. ⁴ Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST.16 if possible. ⁵ Applicant is to place a check mark here if English language translation is attached.

**INFORMATION DISCLOSURE
STATEMENT BY APPLICANT**
(Not for submission under 37 CFR 1.99)

Application Number	17320490
Filing Date	2021-05-14
First Named Inventor	Diane D. Harrison
Art Unit	1646
Examiner Name	CHANDRA
Attorney Docket Number	206389-0003-02-US

CERTIFICATION STATEMENT

Please see 37 CFR 1.97 and 1.98 to make the appropriate selection(s):

That each item of information contained in the information disclosure statement was first cited in any communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing of the information disclosure statement. See 37 CFR 1.97(e)(1).

OR

That no item of information contained in the information disclosure statement was cited in a communication from a foreign patent office in a counterpart foreign application, and, to the knowledge of the person signing the certification after making reasonable inquiry, no item of information contained in the information disclosure statement was known to any individual designated in 37 CFR 1.56(c) more than three months prior to the filing of the information disclosure statement. See 37 CFR 1.97(e)(2).

See attached certification statement.

The fee set forth in 37 CFR 1.17 (p) has been submitted herewith.

☒ A certification statement is not submitted herewith.

SIGNATURE

A signature of the applicant or representative is required in accordance with CFR 1.33, 10.18. Please see CFR 1.4(d) for the form of the signature.

Signature	/Pallab Singh/	Date (YYYY-MM-DD)	2022-11-16
Name/Print	Pallab Singh	Registration Number	70731

This collection of information is required by 37 CFR 1.97 and 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 1 hour to complete, including gathering, preparing and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. **SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.**

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7. A record from this system of records may be disclosed, as a routine use, to the Administrator, General Services, or his/her designee, during an inspection of records conducted by GSA as part of that agency's responsibility to recommend improvements in records management practices and programs, under authority of 44 U.S.C. 2904 and 2906. Such disclosure shall be made in accordance with the GSA regulations governing inspection of records for this purpose, and any other relevant (i.e., GSA or Commerce) directive. Such disclosure shall not be used to make determinations about individuals.
8. A record from this system of records may be disclosed, as a routine use, to the public after either publication of the application pursuant to 35 U.S.C. 122(b) or issuance of a patent pursuant to 35 U.S.C. 151. Further, a record may be disclosed, subject to the limitations of 37 CFR 1.14, as a routine use, to the public if the record was filed in an application which became abandoned or in which the proceedings were terminated and which application is referenced by either a published application, an application open to public inspections or an issued patent.
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INFORMATION DISCLOSURE STATEMENT BY APPLICANT	Application Number	17320490
	Filing Date	05/14/2021
	First Named Inventor	Harrison
	Art Unit	OPAP
	Client Number	206389
Page 1 of 20	Matter Number	0003-02-US

U.S. PATENT/PUBLICATION DOCUMENTS					
Initials	Cite No.	Document Number	Issue/Publication Date	First Named Inventor	Relevant Pages, Columns, etc.
	1	3773919	11/20/1973	BOSWELL G	
	2	4239754	12/16/1980	BERTRAND HENRI	
	3	4309989	01/12/1982	FAHIM MOSTAFA S	
	4	4399216	08/16/1983	AXEL RICHARD	
	5	4603106	07/29/1986	CERAMI ANTHONY	
	6	4634665	01/06/1987	AXEL RICHARD	
	7	4656134	04/07/1987	RINGOLD GORDON M	
	8	4668218	05/26/1987	VIRTANEN RISTO	
	9	4676980	06/30/1987	SEGAL DAVID M	
	10	4683195	07/28/1987	MULLIS KARY B	
	11	4683202	07/28/1987	MULLIS KARY B	
	12	4704692	11/03/1987	LADNER ROBERT C	
	13	4766067	08/23/1988	BISWAS DEBAJIT K	
	14	4767402	08/30/1988	KOST JOSEPH	
	15	4795699	01/03/1989	TABOR STANLEY	
	16	4800159	01/24/1989	MULLIS KARY B	
	17	4816567	03/28/1989	CABILLY SHMUEL	
	18	4822776	04/18/1989	CERAMI ANTHONY	
	19	4873316	10/10/1989	MEADE HARRY	
	20	4889818	12/26/1989	GELFAND DAVID H	
	21	4921794	05/01/1990	TABOR STANLEY	
	22	4925673	05/15/1990	STEINER SOLOMON	
	23	4939666	07/03/1990	HARDMAN KARL D	
	24	4946778	08/07/1990	LADNER ROBERT C	
	25	4956288	09/11/1990	BARSOUJ JAMES G	
	26	4965188	10/23/1990	MULLIS KARY B	
	27	4994370	02/19/1991	SILVER JONATHAN	
	28	5066584	11/19/1991	GYLLENSTEN ULF B	
	29	5091310	02/25/1992	INNIS MICHAEL A	

Examiner Signature		Date Considered	
Examiner: Please initial if citation considered, whether or not citation is in conformance with MPEP Section 609. Please draw a line through the citation if it is not in conformance and it is not considered. Please include a copy of this form with the next communication to the applicant.			

INFORMATION DISCLOSURE STATEMENT BY APPLICANT	Application Number	17320490
	Filing Date	05/14/2021
	First Named Inventor	Harrison
	Art Unit	OPAP
	Client Number	206389
Page 2 of 20	Matter Number	0003-02-US

U.S. PATENT/PUBLICATION DOCUMENTS					
Initials	Cite No.	Document Number	Issue/Publication Date	First Named Inventor	Relevant Pages, Columns, etc.
	30	5116964	05/26/1992	CAPON DANIEL J	
	31	5122464	06/16/1992	WILSON RICHARD H	
	32	5130238	07/14/1992	MALEK LAWRENCE T	
	33	5142033	08/25/1992	INNIS MICHAEL A	
	34	5149636	09/22/1992	AXEL RICHARD	
	35	5168062	12/01/1992	STINSKI MARK F	
	36	5179017	01/12/1993	AXEL RICHARD	
	37	5223409	06/29/1993	LADNER ROBERT C	
	38	5225538	07/06/1993	CAPON DANIEL J	
	39	5225539	07/06/1993	WINTER GREGORY P	
	40	5231024	07/27/1993	MOELLER ACHIM	
	41	5260203	11/09/1993	LADNER ROBERT C	
	42	5266491	11/30/1993	NAGATA SHIGEKAZU	
	43	5304489	04/19/1994	ROSEN JEFFREY M	
	44	5342613	08/30/1994	CREAVEN PATRICK J	
	45	5385839	01/31/1995	STINSKI MARK F	
	46	5403484	04/04/1995	LADNER ROBERT C	
	47	5404871	04/11/1995	GOODMAN DAVID E	
	48	5427908	06/27/1995	DOWER WILLIAM J	
	49	5447851	09/05/1995	BEUTLER BRUCE A	
	50	5455030	10/03/1995	LADNER ROBERT C	
	51	5458135	10/17/1995	PATTON JOHN S	
	52	5496549	03/05/1996	YAMAZAKI HIROH	
	53	5514670	05/07/1996	FRIEDMAN DORON	
	54	5518889	05/21/1996	LADNER ROBERT C	
	55	5530101	06/25/1996	QUEEN CARY L	
	56	5534621	07/09/1996	LADNER ROBERT C	
	57	5545806	08/13/1996	LONBERG NILS	
	58	5545807	08/13/1996	SURANI AZIM M	

Examiner Signature		Date Considered	
Examiner: Please initial if citation considered, whether or not citation is in conformance with MPEP Section 609. Please draw a line through the citation if it is not in conformance and it is not considered. Please include a copy of this form with the next communication to the applicant.			

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	First Named Inventor	Harrison
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	Client Number	206389
Page 3 of 20	Matter Number	0003-02-US

U.S. PATENT/PUBLICATION DOCUMENTS					
Initials	Cite No.	Document Number	Issue/Publication Date	First Named Inventor	Relevant Pages, Columns, etc.
	59	5565362	10/15/1996	ROSEN JEFFREY M	
	60	5569825	10/29/1996	LONBERG NILS	
	61	5571698	11/05/1996	LADNER ROBERT C	
	62	5576195	11/19/1996	ROBINSON RANDY R	
	63	5580717	12/03/1996	DOWER WILLIAM J	
	64	5580734	12/03/1996	TRECO DOUGLAS A	
	65	5582996	12/10/1996	CURTIS PETER J	
	66	5585089	12/17/1996	QUEEN CARY L	
	67	5595898	01/21/1997	ROBINSON RANDY R	
	68	5601819	02/11/1997	WONG JOHNSON T	
	69	5618920	04/08/1997	ROBINSON RANDY R	
	70	5625126	04/29/1997	LONBERG NILS	
	71	5625825	04/29/1997	ROSTOKER MICHAEL D	
	72	5633425	05/27/1997	LONBERG NILS	
	73	5637052	06/10/1997	HIROTA TOSHIAKI	
	74	5641670	06/24/1997	TRECO DOUGLAS A	
	75	5643759	07/01/1997	PFREUNDSCHUH MICHAEL	
	76	5643768	07/01/1997	KAWASAKI GLENN H	
	77	5654407	08/05/1997	BOYLE PETRA	
	78	5656272	08/12/1997	LE JUNMING	
	79	5656730	08/12/1997	LEE LIHSYNG STANFORD	
	80	5658570	08/19/1997	NEWMAN ROLAND A	
	81	5658754	08/19/1997	KAWASAKI GLENN H	
	82	5661016	08/26/1997	LONBERG NILS	
	83	5693493	12/02/1997	ROBINSON RANDY R	
	84	5693762	12/02/1997	QUEEN CARY L	
	85	5698195	12/16/1997	LE JUNMING	
	86	5698417	12/16/1997	ROBINSON RANDY R	
	87	5698419	12/16/1997	WOLPE STEPHEN D	

Examiner Signature		Date Considered	
Examiner: Please initial if citation considered, whether or not citation is in conformance with MPEP Section 609. Please draw a line through the citation if it is not in conformance and it is not considered. Please include a copy of this form with the next communication to the applicant.			

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Initials	Cite No.	Document Number	Issue/Publication Date	First Named Inventor	Relevant Pages, Columns, etc.
	88	5698435	12/16/1997	ROBINSON RANDY R	
	89	5714352	02/03/1998	JAKOBOBITS AYA	
	90	5723323	03/03/1998	KAUFFMAN STUART ALAN	
	91	5733746	03/31/1998	TRECO DOUGLAS A	
	92	5733761	03/31/1998	TRECO DOUGLAS	
	93	5750105	05/12/1998	NEWMAN ROLAND A	
	94	5750373	05/12/1998	GARRARD LISA J	
	95	5763192	06/09/1998	KAUFFMAN STUART ALAN	
	96	5763733	06/09/1998	WHITLOW MARC	
	97	5766886	06/16/1998	STUDNICKA GARY M	
	98	5767260	06/16/1998	WHITLOW MARC	
	99	5770198	06/23/1998	COLLER BARRY S	
	100	5770222	06/23/1998	UNGER EVAN C	
	101	5770359	06/23/1998	WILSON RICHARD HARRIS	
	102	5770428	06/23/1998	BORIS-LAWRIE KATHLEEN A	
	103	5789650	08/04/1998	LONBERG NILS	
	104	5807706	09/15/1998	CARTER PAUL J	
	105	5814476	09/29/1998	KAUFFMAN STUART ALAN	
	106	5814599	09/29/1998	MITRAGOTRI SAMIR S	
	107	5817483	10/06/1998	KAUFFMAN STUART ALAN	
	108	5821333	10/13/1998	CARTER PAUL J	
	109	5824514	10/20/1998	KAUFFMAN STUART ALAN	
	110	5827690	10/27/1998	MEADE HARRY	
	111	5827739	10/27/1998	WILSON RICHARD HARRIS	
	112	5833985	11/10/1998	BALL EDWARD D	
	113	5837500	11/17/1998	LADNER ROBERT CHARLES	
	114	5839446	11/24/1998	WANER MILTON	
	115	5849695	12/15/1998	COHEN FRED E	

Examiner Signature		Date Considered	
Examiner: Please initial if citation considered, whether or not citation is in conformance with MPEP Section 609. Please draw a line through the citation if it is not in conformance and it is not considered. Please include a copy of this form with the next communication to the applicant.			

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U.S. PATENT/PUBLICATION DOCUMENTS					
Initials	Cite No.	Document Number	Issue/Publication Date	First Named Inventor	Relevant Pages, Columns, etc.
	116	5849992	12/15/1998	MEADE HARRY	
	117	5851198	12/22/1998	CASTELLANO THOMAS P	
	118	5856456	01/05/1999	WHITLOW MARC D	
	119	5871753	02/16/1999	CRABTREE GERALD R	
	120	5879681	03/09/1999	LEONE-BAY ANDREA	
	121	5885793	03/23/1999	GRIFFITHS ANDREW DAVID	
	122	5888511	03/30/1999	SKURKOVICH BORIS	
	123	5919452	07/06/1999	LE JUNMING	
	124	5932448	08/03/1999	TSO J YUN	
	125	5958413	09/28/1999	ANAGNOSTOPOULOS HIRISTO	
	126	5959083	09/28/1999	BOSSLET KLAUS	
	127	5959084	09/28/1999	RING DAVID	
	128	5976862	11/02/1999	KAUFFMAN STUART ALAN	
	129	5989530	11/23/1999	LORENZ HERIBERT	
	130	5993833	11/30/1999	DE LACHARRIERE OLIVIER	
	131	5994616	11/30/1999	ROSEN JEFFREY M	
	132	6010902	01/04/2000	LEDBETTER JEFFREY A	
	133	6017732	01/25/2000	JESPER LAURENT STEPHANE ANNE	
	134	6037453	03/14/2000	JARDIEU PAULA M	
	135	6060285	05/09/2000	LENZ HELMUT	
	136	6106833	08/22/2000	RING DAVID	
	137	6132992	10/17/2000	LEDBETTER JEFFREY A	
	138	6180370	01/30/2001	QUEEN CARY L	
	139	6190691	02/20/2001	MAK VIVIEN	
	140	6193967	02/27/2001	MORGANELLI PETER M	
	141	6204023	03/20/2001	ROBINSON RANDY R	
	142	6210668	04/03/2001	LINDHOFER HORST	
	143	6277969	08/21/2001	LE JUNMING	

Examiner Signature		Date Considered	
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U.S. PATENT/PUBLICATION DOCUMENTS					
Initials	Cite No.	Document Number	Issue/Publication Date	First Named Inventor	Relevant Pages, Columns, etc.
	144	6284471	09/04/2001	LE JUNMING	
	145	7521206	04/21/2009	HEAVNER GEORGE	
	146	7691378	04/06/2010	HEAVNER GEORGE	
	147	8241899	08/14/2012	HEAVNER GEORGE	
	148	9512065	12/06/2016	NORTHEN JULIAN SCOTT	
	149	20020168360	11/14/2002	DINGIVAN CHRISTINE	
	150	20080311043	12/18/2008	HOFFMAN REBECCA S	
	151	20090028794	01/29/2009	MEDICH JOHN R	
	152	20090214528	08/27/2009	DORAI HAIMANTI	
	153	20100266590	10/21/2010	DEMETRI GEORGE D	

FOREIGN PATENT DOCUMENTS						
Initials	Cite No.	Document Number	Publication Date	Country	Relevant Pages, Columns, etc.	T
	154	1764992A	10/21/1992	AU		X
	155	0212489B1	11/30/1994	EP		X
	156	0218868A2	04/22/1987	EP		
	157	0229046B1	05/04/1994	EP		X
	158	0229246B1	08/04/1993	EP		X
	159	0237507B1	12/27/1991	EP		
	160	0260610B1	09/01/1993	EP		X
	161	0288088B1	03/09/1994	EP		X
	162	0308378B1	11/30/1994	EP		X
	163	0350690A2	01/17/1990	EP		X
	164	0351789B1	11/25/1998	EP		X
	165	0368684B1	03/09/1994	EP		X
	166	0371998B1	03/02/1994	EP		X
	167	0380068A1	08/01/1990	EP		X
	168	0393438A2	10/24/1990	EP		X
	169	0398327B1	03/15/1995	EP		X

Examiner Signature		Date Considered	
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FOREIGN PATENT DOCUMENTS						
Initials	Cite No.	Document Number	Publication Date	Country	Relevant Pages, Columns, etc.	T
	170	0412486B1	11/30/1994	EP		X
	171	0433900A1	06/26/1991	EP		X
	172	0438474B1	05/15/1996	EP		X
	173	0463151B1	06/12/1996	EP		X
	174	0486526B2	03/07/2001	EP		X
	175	0525570A2	02/03/1993	EP		X
	176	0526905A3	05/05/1993	EP		X
	177	0550400B1	07/10/1996	EP		X
	178	0590689A2	04/06/1994	EP		X
	179	0610201B1	05/16/2001	EP		X
	180	614989A1	09/14/1994	EP		X
	181	0710719B1	03/14/2007	EP		X
	182	2870137B1	05/16/2018	EP		X
	183	2272440A	05/18/1994	GB		
	184	11127855A	05/18/1999	JP		X
	185	0212500A2	02/14/2001	WO		X
	186	0212502A2	02/14/2002	WO		X
	187	8605803A1	10/09/1986	WO		
	188	8806630A1	09/07/1988	WO		X
	189	8906283A1	07/13/1989	WO		X
	190	9000902A1	02/08/1990	WO		X
	191	9003809A1	04/19/1990	WO		X
	192	9004036A1	04/19/1990	WO		
	193	9005370A1	05/17/1990	WO		
	194	9014424A1	11/29/1990	WO		X
	195	9014430A1	11/29/1990	WO		X
	196	9014443A1	11/29/1990	WO		X
	197	9100360A1	01/10/1991	WO		X
	198	9102078A1	02/21/1991	WO		X

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FOREIGN PATENT DOCUMENTS						
Initials	Cite No.	Document Number	Publication Date	Country	Relevant Pages, Columns, etc.	T
	199	9109967A1	07/11/1991	WO		X
	200	9117271A1	11/14/1991	WO		
	201	9118980A1	12/12/1991	WO		X
	202	9119818A1	12/26/1991	WO		X
	203	9200373A1	01/09/1992	WO		X
	204	9203461A1	03/05/1992	WO		
	205	9205258A1	04/02/1992	WO		X
	206	9206204A1	04/16/1992	WO		
	207	9207076A1	04/30/1992	WO		X
	208	9211272A1	07/09/1992	WO		
	209	9211383A1	07/09/1992	WO		X
	210	9213095A1	08/06/1992	WO		X
	211	9214843A1	09/03/1992	WO		X
	212	9216221A1	10/01/1992	WO		X
	213	9216553A1	10/01/1992	WO		X
	214	9218619A1	10/29/1992	WO		X
	215	9302108A1	02/04/1993	WO		X
	216	9308278A1	04/29/1993	WO		X
	217	9308829A1	05/13/1993	WO		X
	218	9311383A1	06/10/1993	WO		X
	219	9406498A1	03/31/1994	WO		X
	220	9408552A2	04/28/1994	WO		X
	221	9416970A1	08/04/1994	WO		X
	222	9418219A1	08/18/1994	WO		X
	223	9425585A1	11/10/1994	WO		X
	224	9501538A1	01/12/1995	WO		
	225	9516027A1	06/15/1995	WO		X
	226	9607754A1	03/14/1996	WO		X
	227	9619256A1	06/27/1996	WO		X

Examiner Signature		Date Considered	
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FOREIGN PATENT DOCUMENTS						
Initials	Cite No.	Document Number	Publication Date	Country	Relevant Pages, Columns, etc.	T
	228	9633735	10/31/1996	WO		X
	229	9634096A1	10/31/1996	WO		X
	230	9713852A1	04/17/1997	WO		X
	231	9720032A1	06/05/1997	WO		
	232	9722376A1	06/26/1997	WO		X
	233	9725086	07/17/1997	WO		
	234	9729131A1	08/14/1997	WO		X
	235	9801757A1	01/15/1998	WO		
	236	9824884A1	06/11/1998	WO		X
	237	9824893A1	06/11/1998	WO		
	238	9835888A1	08/20/1998	WO		X
	239	9850433A2	11/12/1998	WO		X
	240	9853847A1	12/03/1998	WO		X
	241	9906834A2	02/11/1999	WO		
	242	1992001047A1	01/23/1992	WO		X
	243	1992020791A1	11/26/1992	WO		X
	244	1993006213A1	04/01/1993	WO		X
	245	1993011236A1	06/10/1993	WO		X
	246	1993019172A1	09/30/1993	WO		X
	247	2008016633	02/07/2008	WO		X
	248	2010056399A1	05/20/2010	WO		
	249	2014006414A1	01/09/2014	WO		X
	250	2014140509A1	09/18/2014	WO		

OTHER DOCUMENTS			
Initials	Cite No.	Author, Title, Date, Pages, etc.	T
	251	ACOSTA FELQUER et al., "Drug therapies for peripheral joint disease in psoriatic arthritis: a systematic review", Journal of Rheumatology, (20141130), vol. 41, no. 11, doi:10.3899/jrheum.140876, ISSN 0315-162X, pages 2277 - 2285, XP055622320	
	252	ADERKA, Dan et al., "IL-6 Inhibits Lipopolysaccharide-Induced tumor Necrosis Factor Production in Cultured Human Monocytes, U937 Cells, and in Mice," J Immunol, 143:3517-3523(1989).	

Examiner Signature		Date Considered	
Examiner: Please initial if citation considered, whether or not citation is in conformance with MPEP Section 609. Please draw a line through the citation if it is not in conformance and it is not considered. Please include a copy of this form with the next communication to the applicant.			

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	Client Number	206389
Page 10 of 20	Matter Number	0003-02-US

OTHER DOCUMENTS			
Initials	Cite No.	Author, Title, Date, Pages, etc.	T
	253	ADERKA, Dan et al., "The Possible Role of Tumor Necrosis Factor (TNF) and Its Natural Inhibitors, The Soluble-TNF Receptors, In Autoimmune Diseases," Israel J. Med. Sci., 28(2):126-130 (1992).	
	254	ADERKA, Dan, "Role of Tumor Necrosis Factor in the Pathogenesis of Intravascular Coagulopathy of Sepsis: Potential New Therapeutic Implications," IsrJ Med Sci, 27:52-60 (1991).	
	255	AGGARWAL, Bharat B. et al., "Human Tumor Necrosis Factor Production, Purification and Characterization," J. of Biol. Chem., 260(4):2345-2354 (1985).	
	256	AKAMA, Hideto et al., "Mononuclear Cells Enhance Prostaglandin E2 Production of Polymorphonuclear Leukocytes via Tumor Necrosis Factor α ," Biochemical and Biophysical Research Comm., 168(2):857-862 (1990).	
	257	ALT, et al., "Selective Multiplication of Dihydrofolate Reductase Genes in Methotrexate-resistant Variants of Cultured Murine Cells", J. Biol. Chem. 253:1357-1370 (1978)	
	258	Anonymous, "History of Changes for Study NCT02181673", submitted January 23, 2017, https://clinicaltrials.gov/ct2/history/NCT02181673?V_30=View#StudyPageTop	
	259	ASHKENAZI et al., "Protection against endotoxic shock by a tumor necrosis factor receptor immunoadhesin", Proc. Natl. Acad. Sci. USA 88:10535-10539 (1991);	
	260	BABCOOK et al., "A novel strategy for generating monoclonal antibodies from single, isolated lymphocytes producing antibodies of defined specificities", Proc. Natl. Acad. Sci. USA 93:7843-7848(1996);	
	261	BAKER et al., "Control of established experimental allergic encephalomyelitis by inhibition of tumor necrosis factor (TNF) activity within the central nervous system using monoclonal antibodies and TNF receptor-immunoglobulin fusion proteins", Eur. J. Immunol. 24:2040-2048 (1994)	
	262	Basra MKA, Fenech R, Gatt RM, Salek MS, Finlay AY. The Dermatology Life Quality Index 1994-2007: a comprehensive review of validation data and clinical results. Br J Rheumatol. 2008;159:997-1035.	
	263	BEBBINGTON, et al., "High-Level Expression of a Recombinant Antibody from Myeloma Cells Using a Glutamine Synthetase Gene as an Amplifiable Selectable Marker", Bio/Technology 10:169-175(1992)	
	264	BERKOW et al., Eds, The Merck Manual of Diagnosis and Therapy, Sixteenth Edition, Merck Research Laboratories, Rahway, NJ 1992 pg. 1263-1287	
	265	BEUTLER, B. et al., "Identity of tumour necrosis factor and the macrophage-secreted factor cachectin," Nature, 316:552-554 (1985).	
	266	BEUTLER, B. et al., "Passive Immunization Against Cachectin/Tumor Necrosis Factor Protects Mice from Lethal Effect of Endotoxin," Science, 229:869-871 (1985).	
	267	BEUTLER, B. et al., "Purification of Cachectin, A Lipoprotein Lipase-Suppressing Hormone Secreted by Endotoxin-induced RAW 264.7 Cells," J. Exp. Med., 161:984-995 (1985).	
	268	BODMER, Mark, "Humanized Antibodies for Anti-TNF Therapy," Abstract, Endotoxemia & Sepsis Conference (1991).	
	269	BOSHART, et al., "A Very Strong Enhancer Is Located Upstream of an Immediate Early Gene of Human Cytomegalovirus", Cell 41:521-530 (1985)	
	270	BRINGMAN, Timothy S. and Aggarwal, Bharat B., "Monoclonal Antibodies to Human Tumor Necrosis Factors Alpha and Beta: Applications for Affinity Purification, Immunoassays, and as Structural Probes," Hybridoma, 6(5):489-507 (1987).	

Examiner Signature	Date Considered
Examiner: Please initial if citation considered, whether or not citation is in conformance with MPEP Section 609. Please draw a line through the citation if it is not in conformance and it is not considered. Please include a copy of this form with the next communication to the applicant.	

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OTHER DOCUMENTS			
Initials	Cite No.	Author, Title, Date, Pages, etc.	T
	271	BUTLER et al., "TNF Receptor Fusion Proteins Are Effective Inhibitors of TNF-Mediated Cytotoxicity on Human KYM-1D4 Rhabdomyosarcoma Cells", Cytokine 6(6):616-623 (1994);	
	272	Capellas, et al., "Enzymatic Condensation of Cholecystokinin CCK-8 (4-6) and CCK-8 (7-8) Peptide Fragments in Organic Media," Biotechnology and Bioengineering, 56(4): 456-463 (1997).	
	273	CAPON et al., "Designing CD4 immunoadhesins for AIDS therapy", Nature 337:525-531 (1989),	
	274	CARTER et al., "Humanization of an anti-p185HER2 antibody for human cancer therapy", Proc. Natl. Acad. Sci. U.S.A. 89:4285 (1992)	
	275	Cassell SE, Bieber JD, Rich P, Tutuncu ZN, Lee SJ, Kalunian KC, Wu CW, Kavanaugh A. The modified Nail Psoriasis Severity Index: validation of an instrument to assess psoriatic nail involvement in patients with psoriatic arthritis. J Rheumatol. 2007;34(1):123-129.	
	276	Cella D, Yount S, Sorensen M, Chartash E, Sengupta N, Grober J. Validation of the Functional Assessment of Chronic Illness Therapy Fatigue Scale relative to other instrumentation in patients with rheumatoid arthritis. J Rheumatol. 2005;32(5):811-819	
	277	Chandran V, Bhella S, Schentag C, Gladman D. Functional Assessment of Chronic Illness Therapy-Fatigue Scale is valid in patients with psoriatic arthritis. Ann Rheum Dis. 2007;66:936-939.	
	278	Chothia, et al., "Canonical Structures for the Hypervariable Regions of Immunoglobulins," Journal of Molecular Biology, 196: 901-917 (1987).	
	279	Coates LC, Helliwell PS. Validation of minimal disease activity criteria for psoriatic arthritis using interventional trial data. Arthritis Care Res (Hoboken). 2010; 62(7):965-969.	
	280	COHEN et al., "Intravenous golimumab in rheumatoid arthritis", Expert Review of Clinical Immunology, (20140515), vol. 10, no. 7, doi:10.1586/1744666X.2014.918847, pages 823 - 830, XP009516813	
	281	COLLINS, M.S. et al., "Immunoprophylaxis of Polymicrobial Cellulitis with a Human Monoclonal Antibody Against Lipopolysaccharide Antigen of Pseudomonas aeruginosa," Abstract E-63, Abstracts of Annual Meeting 1989.	
	282	CONRAD et al., "Compartment-specific accumulation of recombinant immunoglobulins in plant cells: an essential tool for antibody production and immunomodulation of physiological functions and pathogen activity", Plant Mol. Biol. 38:101-109 (1998)	
	283	Copy of Canadian Examination Report for CA2878319 dated 11 December 2019	
	284	CORCORAN et al., "Characterization of ligand binding by the human p55 tumour-necrosis-factor receptor", Eur. J. Biochem. 223:831-840 (1994)),	
	285	Costello P, FitzGerald O. Disease mechanisms in psoriasis and psoriatic arthritis. Curr Rheumatol Rep. 2001 ;3(5):419-427.	
	286	CRAMER et al., "Transgenic Plants for Therapeutic Proteins: Linking Upstream and Downstream Strategies", Curr. Top. Microbiol. Immunol. 240:95-118 (1999)	
	287	CROSS, A.S. et al., "Pretreatment with Recombinant Murine Tumor Necrosis Factor a Cachectin and Murine Interleukin 1 a Protects Mice from Lethal Bacterial Infection," J of Exp Med., 169:2021 -2027 (1989).	
	288	CULLEN, et al., "Functional Analysis of the Transcription Control Region Located Within the Avian Retroviral Long Terminal Repeat", Molec. Cell. Biol. 5:438-447 (1985))	
	289	CUNNINGHAM AND WELLS, "High-Resolution Epitope Mapping of hGH-Receptor Interactions by Alanine-Scanning Mutagenesis", Science Ausubel, supra, Chapters 8, 15; 244:1081-1085 (1989)).	

Examiner Signature	Date Considered
Examiner: Please initial if citation considered, whether or not citation is in conformance with MPEP Section 609. Please draw a line through the citation if it is not in conformance and it is not considered. Please include a copy of this form with the next communication to the applicant.	

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OTHER DOCUMENTS			
Initials	Cite No.	Author, Title, Date, Pages, etc.	T
	290	D. SHEALY et al., "Characterization of golimumab, a human monoclonal antibody specific for human tumor necrosis factor alpha", MABS, Vol. 2, No. 4, pgs. 428-439 (2010)	
	291	DE VOS, et al., "Human Growth Hormone and Extracellular Domain of Its Receptor: Crystal Structure of the Complex", Science 255:306-312 (1992)).	
	292	DI GIOVINE, Francesco, S. et al., "Tumour necrosis factor in synovial exudates," Annals of the Rheumatic Diseases, 47:768-772 (1988).	
	293	DUNCOMBE, Andrew S. et al., "Tumor Necrosis Factor Mediates Autocrine Growth Inhibition in a Chronic Leukemia," J Immunol, 143:3828-3834 (1989).	
	294	DUPONT et al., "Escherichia coli Diarrhea" Bacterial Infections of Humans: Epidemiology and Control, A.S. Evans et al., 2nd Edition, Spring Science & Business Media, New York, pgs. 239-254(1991)	
	295	E. RANKIN et al., "The therapeutic effects of an engineered human anti-tumour necrosis factor alpha antibody (CDP571) in rheumatoid arthritis", British Journal of Rheumatology, Vol. 34, No. 4, pgs. 334-342, XP000674590 (April 1995)	
	296	ECHTENACHER, Bernd et al., "Requirement of Endogenous Tumor Necrosis Factor/Cachectin for Recovery from Experimental Peritonitis," J. of Immunology, 145(11):3762-3766 (1990).	
	297	ECK, Michael J. and Sprang, Stephen R., "The Structure of Tumor Necrosis Factor-L at 2.6 L Resolution," J Biol Chem, 264:17595-17605 (1989).	
	298	ELLIOTT, M.J. et al., "A Repeated Therapy with Monoclonal Antibody to Tumour Necrosis Factor a (α2) in Patients with Rheumatoid Arthritis", The Lancet, 344:1125-1127, 1994	
	299	ENGELMANN, Hartmut et al., "A Tumor Necrosis Factor-binding Protein Purified to Homogeneity from Human Urine Protects Cells from Tumor Necrosis Factor Toxicity," J. of Bio. Chem., 264(20): 1974-11980 (1989).	
	300	ENGELMANN, Hartmut et al., "Two Tumor Necrosis Factor-binding Proteins Purified from Human Urine," J. of Bio. Chem., 265(3):1531 -1536 (1990).	
	301	EREN et al. "Human monoclonal antibodies specific to hepatitis B virus generated in a human/mouse radiation chimera: the Trimer system", Immunol. 93: 154-161 (1998)	
	302	EUROQOL GROUP. EUROQOL - a new facility for the measurement of health-related quality of life. Health Policy. 1990;16:199-208.	
	303	EXLEY, A.R. et al., "Monoclonal Antibody (Mab) to Recombinant Human Tumour Necrosis Factor (rhTNF) in the Prophylaxis and Treatment of Endotoxic Shock in Cynomolgus Monkeys," Medical Research Society, Abstract 184, p. 50 (1989).	
	304	EXLEY, A.R. et al., "Monoclonal antibody to TNF in severe septic shock," The Lancet, 335:1275-1277(1990).	
	305	Faraawi et al., 2016, "Comparison of Baseline Characteristics of Rheumatoid Arthritis Patients Initiating Therapy with Subcutaneous Golimumab and Infliximab and Intravenous Golimumab: An Analysis from the Prospective, Observational Registry, BioTRAC." The Journal of Rheumatology, 43(6), Number 87, p.1186	
	306	Feldman SR, Gordon KB, Bala M, et al. Infliximab treatment results in significant improvement in the quality of life of patients with severe psoriasis: a double-blind placebo-controlled trial. British Journal of Dermatology. 2005;152:954-960.	
	307	Felson, et al., "American College of Rheumatology Preliminary Definition of Improvement in Rheumatoid Arthritis," Arthritis & Rheumatism, 38 (6): 727-735 (1995).	

Examiner Signature	Date Considered
Examiner: Please initial if citation considered, whether or not citation is in conformance with MPEP Section 609. Please draw a line through the citation if it is not in conformance and it is not considered. Please include a copy of this form with the next communication to the applicant.	

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	Art Unit	OPAP
	Client Number	206389
Page 13 of 20	Matter Number	0003-02-US

OTHER DOCUMENTS			
Initials	Cite No.	Author, Title, Date, Pages, etc.	T
	308	FENDLY, Brian M. et al., "Murine Monoclonal Antibodies Defining Neutralizing Epitopes on Tumor Necrosis Factor," Hybridoma, 6(4):359-370 (1987).	
	309	Finlay AY, Khan GK. Dermatology Life Quality Index (DLQI)-a simple practical measure for routine clinical use. Clin Exp Dermatol. 1994;19(3):210-216.	
	310	FISCH et al., "Site-Specific Modification of a Fragment of a Chimeric Monoclonal Antibody Using Reverse Proteolysis", Bioconjugate Chem., 3:147-153 (1992);	
	311	FISCHER et al., "Towards molecular farming in the future: moving from diagnostic protein and antibody production in microbes to plants", Biotechnol. Appl. Biochem. 30:101-108 (Oct., 1999),	
	312	FISHWALD et al., "High-avidity human IgGk monoclonal antibodies from a novel strain of minilocus transgenic mice", Nat Biotechnol 14(7):845-851 (1996).	
	313	FONG, Yuman and Lowry, Stephen F., "Tumor Necrosis Factor in the Pathophysiology of Infection and Sepsis," Clin Immunol Immunopathol, 55:157-170 (1990).	
	314	FONG, Yuman et al., "Antibodies to Cachectin/Tumor Necrosis Factor Reduce Interleukin 1 β and Interleukin 6 Appearance During Lethal Bacteremia," J. Exp. Med., 170:1627-1633 (1989).	
	315	FOOTE et al., "Antibody Framework Residues Affecting the Conformation of the Hypervariable Loops", Journal of Molecular Biology, 224(2), pgs. 487-499 (1992)	
	316	Fredriksson T, Pettersson U. Severe psoriasis - oral therapy with a new retinoid. Dermatologica. 1978;157(4):238-244.	
	317	Fries JF, Spitz P, Kraines RG, Holman HR. Measurement of patient outcomes in arthritis. Arthritis Rheum. 1980;23(2):137-145.	
	318	GALLOWAY, Cynthia J. et al., "Monoclonal anti-tumor necrosis factor (TNF) antibodies protect mouse and human cells from TNF cytotoxicity," J. of Immunological Methods, 140:37-43 (1991).	
	319	GARRETT S, JENKINSON T, KENNEDY LG, WHITELOCK H, GAISFORD P, CALIN A. A new approach to defining disease status in ankylosing spondylitis: the Bath Ankylosing Spondylitis Disease Activity Index. J Rheumatol. 1994;21(12):2286-2291.	
	320	GENEBANK ACCESSION, No. M32046 (1990, June 15).	
	321	Genebank Accession, No. N90300 (Nov. 1, 1989).	
	322	GILLIES, Stephen D. et al., "High-level expression of chimeric antibodies using adapted cDNA variable region cassettes," J Immunol Methods, 125:191-202 (1989).	
	323	Gladman DD, Inman RD, Cook RJ, et al. International spondylarthritis interobserver reliability exercise-the INSPIRE study: II. Assessment of peripheral joints, enthesitis, and dactylitis. J Rheumatol. 2007;34(8):1740-1745	
	324	Gladman DD, Ziouzina O, Thavaneswaran A, Chandran V. Dactylitis in psoriatic arthritis: prevalence and response to therapy in the biologic era. J Rheumatol. 2013;40(8):1357-1359.	
	325	Goedkoop AY, Kraan MC, Teunissen MB, et al. Early effects of tumour necrosis factor alpha blockade on skin and synovial tissue in patients with active psoriasis and psoriatic arthritis. Ann Rheum Dis. 2004;63(7):769-773.	
	326	GORMAN, S.D. and Clark, M.R., "Humanisation of monoclonal antibodies for therapy," Sem Immunol, 2:457-466 (1990).	
	327	GOSSEN, AND H. BUJARD, "Tight control of gene expression in mammalian cells by tetracycline-responsive promoters", Proc. Natl. Acad. Sci. USA 89: 5547-5551 (1992)	

Examiner Signature	Date Considered
Examiner: Please initial if citation considered, whether or not citation is in conformance with MPEP Section 609. Please draw a line through the citation if it is not in conformance and it is not considered. Please include a copy of this form with the next communication to the applicant.	

INFORMATION DISCLOSURE STATEMENT BY APPLICANT	Application Number	17320490
	Filing Date	05/14/2021
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	Client Number	206389
Page 14 of 20	Matter Number	0003-02-US

OTHER DOCUMENTS			
Initials	Cite No.	Author, Title, Date, Pages, etc.	T
	328	GRAY et al., "Secretion capture and report web: use of affinity derivatized agarose microdroplets for the selection of hybridoma cells", J. Imm. Meth. 182:155-163 (1995);	
	329	GREEN et al, "Antigen-specific human monoclonal antibodies from mice engineered with human Ig heavy and light chain YACs", Nature Genetics 7:13-21 (1994)	
	330	GREEN, L. "Antibody Engineered via Genetic Engineering of the Mouse: Xenomouse Strains Are a Vehicle for the Facile Generation of Therapeutic Human Monoclonal Antibodies", Journal of Immunological Methods, 231, pgs. 11-23 (1999)	
	331	H. HOOGENBOOM et al., "By-passing immunization. Human antibodies from synthetic repertoires of germline VH gene segments rearranged in vitro", JOURNAL OF MOLECULAR BIOLOGY, Vol. 227, No. 2, XP024020530; page 386 (September 10, 1992)	
	332	HANES et al. "Ribosome display efficiently selects and evolves high-affinity antibodies in vitro from immune libraries", Proc Natl. Aca. Sci USA 95 14130-14135 (Nov. 1998)	
	333	HANES et al., "In vitro selection and evolution of functional proteins by using ribosome display", Proc. Natl. Acad. Sci. USA 94:4937-4942 (May 1997)	
	334	HARRIS, "Ankylizing Spondylitis", Chapter 6, Spondyloarthropathies, Kelley's Textbook of Rheumatology, 6th Edition, Sledge CB, pas. 1039-1053 (2001)	
	335	HAYASHI, H. et al., "An Enzyme-linked Immunosorbent Assay for Recombinant Human Tumor Necrosis Factor Using Monoclonal Antibody," Recent Adv. Chemother, 820-821 (1985).	
	336	Healy PJ, Helliwell PS. Measuring clinical enthesitis in psoriatic arthritis: assessment of existing measures and development of an instrument specific to psoriatic arthritis. Arthritis Rheum. 2008;59(5):686-691	
	337	HERVE, P. et al., "Monoclonal Anti TNF a Antibody for the Treatment of Severe Acute GvHD in Humans," Abstract 3.25, Lymphoma Res. 9:591 (1990).	
	338	HINSHAW, L.B. et al., "Survival of Primates in LD100 Septic Shock Following Therapy with Antibody to Tumor Necrosis Factor (TNFa)," Circulatory Shock, 30:279-292 (1990).	
	339	HIRAI, Makoto et al., "Production and characterization of monoclonal antibodies to human tumor necrosis factor," J. of Immun. Methods, 96:57-62 (1987).	
	340	HOOD et al., "Molecular Farming of Industrial Proteins from Transgenic Maize", Adv. Exp. Med. Biol. 464:127-147(1999)	
	341	Husted JA, Gladman DD, Cook RJ, Farewell VT. Responsiveness of health status instruments to changes in articular status and perceived health in patients with psoriatic arthritis. J Rheumatol. 1998;25(11):2146-2155.	
	342	ITOH et al., "Application of Inverse Substrates to Trypsin-Catalyzed Peptide Synthesis", Bioorg. Chem., 24(1): 59-68 (1996).	
	343	J. L. HAMLIN AND C. MA, "The mammalian dihydrofolate reductase locus", Biochem. et Biophys. Acta 1097:107-143 (1990)	
	344	Jones, et al., "Replacing the complementarity-determining regions in a human antibody with those from a mouse," Nature, 321: 522-525 (1986).	
	345	JUNGINGER, et al. "Visualization of Drug Transport Across Human Skin and the Influence of Penetration Enhancers", In Drug Permeation Enhancement, Hsieh, D. S., Eds., pp. 59-90 (Marcel Dekker, Inc. New York 1994	

Examiner Signature	Date Considered
Examiner: Please initial if citation considered, whether or not citation is in conformance with MPEP Section 609. Please draw a line through the citation if it is not in conformance and it is not considered. Please include a copy of this form with the next communication to the applicant.	

INFORMATION DISCLOSURE STATEMENT BY APPLICANT	Application Number	17320490
	Filing Date	05/14/2021
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	Client Number	206389
Page 15 of 20	Matter Number	0003-02-US

OTHER DOCUMENTS			
Initials	Cite No.	Author, Title, Date, Pages, etc.	T
	346	KAMEYAMA, Koh-zoh, et al., "Convenient plasmid vectors for construction of chimeric mouse/human antibodies," FEBS Lett, 244:301-306 (1989).	
	347	KATSUBE, Y., et al., "Analysis of k light chain contribution to anti-DNA antibody activity of a human VH4-21-encoded monoclonal antibody (NE-1) by antibody-phage display technique", Int J Mol. Med, 1(5):863-868 (1998))	
	348	Kavanaugh et al., 2014, "Clinical efficacy, radiographic and safety findings through 5 years of subcutaneous golimumab treatment in patients with active psoriatic arthritis: results from a long-term extension of a randomised, placebo-controlled trial (the GO-REVEAL study)", Ann Rheum Dis, 73(9): 1689-1694	
	349	KAWASAKI, Hajime et al., "Analysis of Endotoxin Fever in Rabbits by Using a Monoclonal Antibody to Tumor Necrosis Factor (Cachectin)," Infection and Immunity, 57(10):3131-3135 (1989).	
	350	KENNY et al., "Production of Monoclonal Antibodies Using a Secretion Capture Report Web", Bio/ Technol. 13:787-790 (1995).	
	351	Khilji FA, Gonzalez M, Finlay AY. Clinical meaning of change in dermatology life quality index scores. Br J Dermatol. 2002;147(suppl 62): 25-54. SIMPONI IV (golimumab) Clinical Protocol CNT0148PSA3001 Amendment 2 98 Approved, 29 June 2016	
	352	KNIGHT, D. M. et al., "A Construction and Initial Characterization of a Mouse-Human Chimeric Anti-TNF Antibody", Mol. Immunol. 30 (16): 1443-1453, 1993	
	353	KOLLS et al., "Prolonged and effective blockade of tumor necrosis factor activity through adeno virus-mediated gene transfer", Proc. Natl. Acad. Sci. USA 91:215-219 (1994);	
	354	KOZBOR et al., "The production of monoclonal antibodies from human lymphocytes", Immunol. Today, 4:72-79(1983);	
	355	KUMARAN et al., "Conformationally driven protease-catalyzed splicing of peptide segments: V8 protease-mediated synthesis of fragments derived from thermolysin and ribonuclease A", Protein Sci. 6(10):2233-2241 (1997);	
	356	LARMONIER et al., "The inhibition of TNF-alpha anti-tumoral properties by blocking antibodies promotes tumor growth in rat model" Exp. Cell Res. 2007 Mar 30; Epub ahead of print; Abstract only	
	357	LASSALLE, Ph., et al., "Potential Implication of Endothelial Cells in Bronchial Asthma," Int Arch Allergy Appl Immunol, 94:233-238 (1991).	
	358	LESSLAUER et al., "Recombinant soluble tumor necrosis factor receptor proteins protect mice from lipopolysaccharide-induced lethality", Eur. J. Immunol. 21:2883-2886 (1991)	
	359	LIANG, Chi-Ming et al., "Production and Characterization of Monoclonal Antibodies Against Recombinant Human Tumor Necrosis Factor/Cachectin," Biochem. & Biophys. Res. Comm., 137(2):847-854(1986).	
	360	LOETSCHER et al., "Molecular Cloning and Expression of the Human 55 kd Tumor Necrosis Factor Receptor", Cell 61: pgs. 351-359 (1990)	
	361	LONBERG et al. "Antigen-specific human antibodies from mice comprising four distinct genetic modifications", Nature 368:856-859 (1994)	
	362	LONBERG et al., "Human Antibodies from Transgenic Mice", Int Rev Immunol 13(1):65-93 (1995)	
	363	LUCAS, R. et al., "Generation and characterization of a neutralizing rat anti-rm TNF-a monoclonal antibody," Immunology, 71:218-223 (1990).	

Examiner Signature		Date Considered	
Examiner: Please initial if citation considered, whether or not citation is in conformance with MPEP Section 609. Please draw a line through the citation if it is not in conformance and it is not considered. Please include a copy of this form with the next communication to the applicant.			

INFORMATION DISCLOSURE STATEMENT BY APPLICANT	Application Number	17320490
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	Client Number	206389
Page 16 of 20	Matter Number	0003-02-US

OTHER DOCUMENTS			
Initials	Cite No.	Author, Title, Date, Pages, etc.	T
	364	M. J. PAGE AND M. A. SYDENHAM, "High Level Expression of the Humanized Monoclonal Antibody Campath-1H in Chinese Hamster Ovary Cells", Biotechnology 9:64-68 (1991)).	
	365	MA et al., "Immunotherapeutic potential of antibodies produced in plants", Trends Biotechnol. 13:522-7(1995)	
	366	MA et al., "Plant Antibodies for Immunotherapy", Plant Physiol. 109:341-6 (1995).	
	367	MARRACK et al, "The Staphylococcal Enterotoxins and Their Relatives", Science, 248:705-711 (1990),	
	368	MEAGER, Anthony et al., "Preparation and Characterization of Monoclonal Antibodies Directed Against Antigenic Determinants of Recombinant Human Tumour Necrosis Factor (rTNF)," Hybridoma, 6(3):305-311 (1987).	
	369	Mease PJ, Antoni CE, Gladman DD, Taylor WJ. Psoriatic arthritis assessment tools in clinical trials. Ann Rheum Dis. 2005;64(Suppl II):ii49-ii54.	
	370	Mease PJ, Kivitz AJ, Burch FX, et al. Etanercept treatment of psoriatic arthritis: safety, efficacy, and effect on disease progression. Arthritis Rheum. 2004;50(7):2264-2272	
	371	Mease PJ. Measures of psoriatic arthritis: Tender and Swollen Joint Assessment, Psoriasis Area and Severity Index (PASI), Nail Psoriasis Severity Index (NAPSI), Modified Nail Psoriasis Severity Index (mNAPSI), Mander/Newcastle Enthesitis Index (MEI), Leeds Enthesitis Index (LEI), Spondylarthritis Research Consortium of Canada (SPARCC), Maastricht Ankylosing Spondylitis Enthesis Score (MASES), Leeds Dactylitis Index (LDI), Patient Global for Psoriatic Arthritis, Dermatology Life Quality Index (DLQI), Psoriatic Arthritis Quality of Life (PsAQOL), Functional Assessment of Chronic Illness Therapy-Fatigue (FACIT-F), Psoriatic Arthritis Response Criteria (PsARC), Psoriatic Arthritis Joint Activity Index (PsAJAI), Disease Activity in Psoriatic Arthritis (DAPSA), and Composite Psoriatic Disease Activity Index (CPDAI). Arthritis Care Res (Hoboken). 2011;63 Suppl 11:S64-S85.	
	372	Mendez, et al., "Functional transplant of megabase human immunoglobulin loci recapitulates human antibody response in mice," Nature Genetics, 15(2): 146-156 (1997).	
	373	Milstein, et al., "Hybrid hybridomas and their Use in Immunohistochemistry," Nature, 305: 537-540 (1983).	
	374	MOCELLIN et al., "Tumor necrosis factor, cancer and anticancer therapy", Cytokine Growth Factor Rev. 2005 Feb; 16(1) 35-53, Epub 2004 Dec 19	
	375	MOLLER, Achim et al., "Monoclonal Antibodies to Human Tumor Necrosis Factor a: In Vitro and In Vivo Application," Cytokine, 2(3):162-169 (1990).	
	376	MORRISON, Sherie L., "Transfectomas Provide Novel Chimeric Antibodies," Science, 229:1202-1207(1985).	
	377	MULLER, "Determination of Affinity and Specificity of Anti-Hapten Antibodies by Competitive Radioimmunoassay", Meth. Enzymol., 92:589-601 (1983),	
	378	MURPHY, et al., "Matrix metalloproteinase degradation of elastin, type IV collagen and proteoglycan", Biochem. J. 227:277-279 (1991)	
	379	NAGAI, M. et al., "Antibody to tumor necrosis factor (TNF) reduces endotoxin fever," Experientia, 44:606-607 (1988).	
	380	NEUBERGER, M., "Generating high-avidity human Mabs in mince", Nature Biotech. 14:826 (1996)	
	381	NGUYEN et al., "Production of Human Monoclonal Antibodies in SCID Mouse", Microbiol. Immunol. 41:901-907(1997)	

Examiner Signature	Date Considered
Examiner: Please initial if citation considered, whether or not citation is in conformance with MPEP Section 609. Please draw a line through the citation if it is not in conformance and it is not considered. Please include a copy of this form with the next communication to the applicant.	

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	Client Number	206389
Page 17 of 20	Matter Number	0003-02-US

OTHER DOCUMENTS			
Initials	Cite No.	Author, Title, Date, Pages, etc.	T
	382	NOPHAR, YARON et al., "Soluble forms of tumor necrosis factor receptors (TNF-Rs). The cDNA for the type 1 TNF-R, cloned using amino acid sequence data of its soluble form, encodes both the cell surface and a soluble form of the receptor," The EMBO Journal, 9(10):3269-3278(1990).	
	383	OPAL, Steven M. et al., "Efficacy of a Monoclonal Antibody Directed Against Tumor Necrosis Factor in Protecting Neutropenic Rats from Lethal Infection with Pseudomonas aeruginosa," J. of Infectious Diseases, 161:1148-1152 (1990).	
	384	PARRILLO, Joseph E., "Pathogenetic Mechanisms of Septic Shock," N.E. Journal of Medicine, 328(20):1471-1477 (1993).	
	385	Partsch G, Steiner G, Leeb BF, Dunky A, Broil H, Smolen JS. Highly increased levels of tumor necrosis factor-alpha and other proinflammatory cytokines in psoriatic arthritis synovial fluid. J Rheumatol. 1997;24(3):518-523.	
	386	PAULUS, H., A Preparation and Biomedical Applications of Bispecific Antibodies®, Behring Inst. Mitt, No.78:118-132 (1985).	
	387	PENNINGTON, James, "TNF: Therapeutic Target in Patients with Sepsis," ASM News, 58(9):479-482(1992).	
	388	PEPPEL et al., "A Tumor Necrosis Factor (TNF) Receptor-IgG Heavy ChainChimeric Protein as a Bivalent Antagonist of TNF Activity", J. Exp. Med. 174:1483-1489 (1991);	
	389	Pham et al., 2006, "TNFa antagonist therapy in ankylosing spondylitis and psoriatic arthritis: recommendations of the French Society for Rheumatology." JOINT BONE SPINE, ELSEVIER, Amsterdam, NL , 73(5), pages 547-553	
	390	Pham T, Guillemin F, Claudepierre P, et al. TNFa antagonist therapy in ankylosing spondylitis and psoriatic arthritis: recommendations of the French Society for Rheumatology. Joint Bone Spine. 2006;73:547- 553.	
	391	PIQUET, Pierre-Francois et al., "Tumor Necrosis Factor/Cachectin is an Effector of Skin and Gut Lesions of the Acute Phase of Graft-vs.-Host Disease," J. Exp. Med., 166:1280-1289 (1987).	
	392	POWELL et al., "Gel Microdroplets and Flow Cytometry: Rapid Determination of Antibody Secretion by Individual Cells Within a Cell Population", Biotechnol. 8:333-337 (1990)	
	393	PRESTA et al., "Humanization of an Antibody Directed Against IgE", J. Immunol. 151:2623 (1993),	
	394	Reichmann, et al., "Reshaping human antibodies for therapy," Nature, 332: 323-327 (1988).	
	395	Ritchlin C, Haas-Smith SA, Hicks D, Cappuccio J, Osterland CK, Looney RJ. Patterns of cytokine production in psoriatic synovium. J Rheumatol. 1998;25(8):1544-1552.	
	396	RUDDLE, Nancy H. et al., "An Antibody to Lymphotoxin and Tumor Necrosis Factor Prevents Transfer of Experimental Allergic Encephalomyelitis," J. Exp. Med., 172:1193-1200 (1990).	
	397	RUDIHOFF et al., "Single amino acid substitution altering antigen-binding specificity", PNAS, March 1982, Vol 79, p. 1979-83	
	398	S. SIEGAL et al., "The mouse/human chimeric monoclonal antibody cA2 neutralizes TNF in vitro and protects transgenic mice from cachexia and TNF lethality in vivo", Cytokine, Vol. 7, No. 1 pgs. 15-25 XP000990566 (January 1995)	
	399	S. STEPHENS et al., "Comprehensive pharmacokinetic of a humanized antibody and analysis of residual anti-idiotypic responses", Immunology, Vol. 85, No. 4, pgs. 668-674 XP000881488 (August 1995)	

Examiner Signature	Date Considered
Examiner: Please initial if citation considered, whether or not citation is in conformance with MPEP Section 609. Please draw a line through the citation if it is not in conformance and it is not considered. Please include a copy of this form with the next communication to the applicant.	

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	Client Number	206389
Page 18 of 20	Matter Number	0003-02-US

OTHER DOCUMENTS			
Initials	Cite No.	Author, Title, Date, Pages, etc.	T
	400	SANDHU et al., "The Use of SCID Mice in Biotechnology and as a Model for Human Disease", Crit. Rev. Biotechnol. 16:95-118 (1996)	
	401	SCALLON, et al., Functional Comparisons of Different Tumour Necrosis Factor Receptor/IgG Fusion Proteins", Cytokine 7:759-770 (1995)	
	402	SCHALL, Thomas J. et al., "Molecular Cloning and Expression of a Receptor for Human Tumor Necrosis Factor," Cell, 61:361-370 (1990).	
	403	SCOTT et al., "An Anti-Tumor Necrosis Factor- α Antibody Inhibits the Development of Experimental Skin Tumors", Mol. Can Therapy, 2003 May, 2:445-451	
	404	SHIMAMOTO, Yoshinori et al., "Monoclonal antibodies against human recombinant tumor necrosis factor: prevention of endotoxic shock," Immunology Letters, 77:311-318 (1988).	
	405	SILVA, Ayona T. et al., "Prophylactic and Therapeutic Effects of a Monoclonal Antibody to Tumor Necrosis Factor- α in Experimental Gram-Negative Shock," J. of Infectious Diseases, 162:421-427(1990).	
	406	SIMS et al., "A Humanized CD18 Antibody Can Block Function without Cell Destruction", J. Immunol. 151:2296(1993)	
	407	SMITH, Craig R., "Human and Chimeric Antibodies to LPS and TNF," 4Abstract, Endotoxemia & Sepsis Conference (1991).	
	408	SMITH, et al., "Human Interleukin 4: The Solution Structure of a Four-helix Bundle Protein", J. Mol. Biol. 224:899-904 (1992)	
	409	SPRAGUE, et al., "Expression of a Recombinant DNA Gene Coding for the Vesicular Stomatitis Virus Nucleocapsid Protein", J. Virol. 45:773-781 (1983)).	
	410	STARNES, H. Fletcher, Jr., et al., "ANTI-IL-6 Monoclonal Antibodies Protect Against Lethal Escherichia Coll Infection and Lethal Tumor Necrosis FactorL Challenge in Mice," J Immunol, 145:4185-4191 (1990).	
	411	STEADMAN' Medical Dictionary, 27th Ed. 2000 Lippincott Williams & Wilkins - "Carcinoma"	
	412	STEENBAKKERS et al., "Efficient generation of monoclonal antibodies from preselected antigen-specific B", Molec. Biol. Reports 19:125-134 (1994).	
	413	STEIN et al., "Diseases of the Heart and Blood Vessels", Internal Medicine, 3rd 3d., pg.1-13, Little Brown and Co. Boston (1990)	
	414	STONE et al., "Solid malignancies among patients in the Wegener's Granulomatosis Etanercept Trial", Arthritis Rheum. 2006 May; 54(5) 1608-18 abstract only	
	415	SUNAHARA, N. et al., "Simple enzyme immunoassay methods for recombinant human tumor necrosis factor L and its antibodies using a bacterial cell wall carrier," J Immunol Methods, 109:203-214(1988).	
	416	SURESH et al., "Bispecific Monoclonal Antibodies from Hybrid Hybridomas", Methods in Enzymology 121:210 (1986)	
	417	TAVERNIER et al., "Analysis of the Structure-Function Relationship of Tumour Necrosis Factor. Human/Mouse Chimeric TNF Proteins: General Properties and Epitope Analysis", Journal Molecular Biology, 211, pg. 493-501 (1990)	
	418	TAYLOR et al., "A transgenic mouse that expresses a diversity of human sequence heavy and light chain immunoglobulins", Nucleic Acids Research 20(23):6287-6295 (1992),	

Examiner Signature	Date Considered
Examiner: Please initial if citation considered, whether or not citation is in conformance with MPEP Section 609. Please draw a line through the citation if it is not in conformance and it is not considered. Please include a copy of this form with the next communication to the applicant.	

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	Client Number	206389
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OTHER DOCUMENTS			
Initials	Cite No.	Author, Title, Date, Pages, etc.	T
	419	Taylor W, Gladman D, Helliwell P, Marchesoni A, Mease P, Mielants H; CASPAR Study Group. Classification criteria for psoriatic arthritis: development of new criteria from a large international study. Arthritis Rheum. 2006;54(8):2665-2673.	
	420	Taylor, et al., "Human immunoglobulin transgenes undergo rearrangement, somatic mutation and class switching in mice that lack endogenous IgM," International Immunology, 6(4): 579-591 (1994).	
	421	TRACEY, Kevin J. et al., "Anti-cachectin/TNF monoclonal antibodies prevent septic shock during lethal bacteraemia," Nature, 330:662-664 (1987).	
	422	Traunecker, et al., "Bispecific Single chain molecules (Janusins) target cytotoxic lymphocytes on HIV infected cells," EMBO Journal, 10(12): 3655-3659 (1991).	
	423	TUAILLON et al., "Human immunoglobulin heavy-chain minilocus recombination in transgenic mice: Gene-segment use in u and y transcripts", Proc Natl Acad Sci USA 90(8):3720-3724 (1993)	
	424	Van der Heijde DM, van Leeuwen MA, van Riel PL, et al. Biannual radiographic assessments of hands and feet in a three-year prospective followup of patients with early rheumatoid arthritis. Arthritis Rheum. 1992;35(1):26-34.	
	425	Van der Linden MA. Disease Activity Scores using C-reactive protein. April 5, 2004. Available at: www.umcn.nl/scientist/afdelingen/reumatologie/the_das/the_das_crp. Accessed 19 August 2005	
	426	Van Riel P, Fransen J, Scott DL. EULAR handbook of clinical assessments in rheumatoid arthritis. Third ed. Alphen Aan Den Rijn, The Netherlands: Van Zuiden Communications B.V. 2004.	
	427	Van Riel PL, van Gestel AM, Scott DL, for the EULAR Standing Committee for International Clinical Studies Including Therapeutic Trials - ESCISIT. EULAR Handbook of Clinical Assessments in Rheumatoid Arthritis. Alphen Aan Den Rijn, The Netherlands: Van Zuiden Communications B.V.; 2000:40.	
	428	Veale DJ, Markham T, Fearon U, et al. St Vincents University Hospital, Dublin, Ireland. Therapy in psoriasis and psoriatic arthritis: anti-TNF-alpha clinical and angiogenic responses. Arthritis Rheum. 2003;48(suppl):S168-S169.	
	429	VERHOEF, J. and Torensma, R., "Prospects for Monoclonal Antibodies in the Diagnosis and Treatment of Bacterial Infections," Eur. J. Clin. Microbiol. Dis., 9(4):247-250 (1990).	
	430	VERHOEYEN et al., "Reshaping Human Antibodies: Grafting an Antilysozyme Activity", Science 239:1534(1988).	
	431	VON ASMUTH, E.J.U. et al., "Tumour Necrosis Factor Alpha (TNF-a) and Interleukin 6 in a Zymosan-Induced Shock Model," Scand. J. Immunol., 32:313-319 (1990).	
	432	WALDMANN, Thomas A., "Monoclonal Antibodies in Diagnosis and Therapy," Science, 252:1657-1662(1991).	
	433	WARE JE JR, SHERBOURNE CD. The MOS 36 item short form health survey (SF 36), I. Conceptual framework and item selection. Med Care. 1992;30(6):473-483.	
	434	WARE JE, KOSINSKI M, KELLER SD. Interpretation: NormBased. In: SF-36 Physical and Mental Health Summary Scales: A User's Manual. Boston, MA: The Health Institute; 1994:8:1-8:42.	
	435	WEN et al., "Limiting dilution assay for human B cells based on their activation by mutant EL4 thymoma cells: total and antimalaria responder B cell frequencies" J. Immunol. 17:887-892 (1987)	
	436	WERLEN et al., "Site-Specific Conjugation of an Enzyme and an Antibody Fragment", Bioconjugate Chem., 5:411-417 (1994)	

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INFORMATION DISCLOSURE STATEMENT BY APPLICANT	Application Number	17320490
	Filing Date	05/14/2021
	First Named Inventor	Harrison
	Art Unit	OPAP
	Client Number	206389
Page 20 of 20	Matter Number	0003-02-US

OTHER DOCUMENTS			
Initials	Cite No.	Author, Title, Date, Pages, etc.	T
	437	Whitelam, et al., "Antibody production in transgenic plants," Biochemical Society Transactions, "Transgenic Plants and Plan Biochemistry, 22: 940-944 (1994).	
	438	WHITTLE, Nigel, et al., "Construction and Expression of a CDR-Grafted Anti-TNF Antibody," J. Cell Blochem, Supl. 13A:96 (1989).	
	439	WINTER et al., "Antibody-based Therapy", Immunology Today, 14(6), pgs. 243-246 (1993)	
	440	WOOD et al, "Staphylococcal enterotoxins and the immune system", FEMS Microbiology Immunology, 76:121-134 (1991)	
	441	Zhuang et al., 2010, Pharmacokinetics of Golimumab, an Anti-TNFalpha Human Monoclonal Antibody After Multiple Subcutaneous or Intravenous Injections in Subjects with Rheumatoid Arthritis" Clinical Pharmacology & Therapeutics, Vol. 87, Supplement 1, PI-80, p. S34-S35	
	442	Zochling J, van der Heijde D, Burgos-Vargas R, et al. ASAS/EULAR recommendations for the management of ankylosing spondylitis. Ann Rheum Dis. 2006;65(4):442-452.	

Examiner Signature	/GYAN CHANDRA/	Date Considered	04/17/2023
Examiner: Please initial if citation considered, whether or not citation is in conformance with MPEP Section 609. Please draw a line through the citation if it is not in conformance and it is not considered. Please include a copy of this form with the next communication to the applicant.			

Response to Office Action mailed April 26, 2023
U.S. Patent Application No. 17/320,490
Attorney Docket No. 206389-0003-02US

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Patent Application of:
Diane D. Harrison, et al.

Art Unit: 1646
Confirmation No.: 5386

Application No.:
17/320,490

Examiner:
Chandra, Gyan

Filing date:
May 14, 2021

Atty Docket No.:
206389-0003-02US

Title: ANTI-TNF ANTIBODIES, COMPOSITIONS, AND METHODS FOR THE
TREATMENT OF ACTIVE PSORIATIC ARTHRITIS

AMENDMENT

This Amendment is responsive to the non-final Office Action mailed on April 26, 2023 in connection with the above-referenced application. This Response is timely filed in view of the accompanying Petition for a one-month extension of time (and associated fee) which extends the deadline for a timely response to and through August 26, 2023.

This Amendment is being filed in conjunction with nineteen (19) Replacement Sheets of drawings and a Corrected Application Data Sheet.

No other fee is believed due for filing of this response. Please charge any fee that is due, and credit any overpayment, to deposit account no. 50-5366.

In the Drawings:

The attached sheets of Replacement Drawings include Figures 1-18. Figures 10 and 11A-C have been amended to darken charts and bars that were too light read or print by the office. These sheets replace originally filed Figures 1-18

REMARKS

Claims 11-20 are pending and under consideration.

Amendments to the Specification

The Specification has been amended to remove all executable code.

No new matter has been added by way of these amendments.

Amendments to the Drawings

Replacement sheets for Figures 1 through 18 are submitted herewith. Figures 10 and 11A-C have been amended to darken charts and bars to increase readability. No new matter has been added by way of the amendment to the drawings.

Amendments to the Claims

Claims 12 and 15 have been amended to remove the phrase “such that”.

No new matter has been added by way of these amendments.

Title

Applicant submits herewith a Corrected Application Data Sheet to correct the title of the present application and to match the Title present on the originally-filed Specification.

Objection to the Specification

The Examiner has objected to the Specification for inclusion of hyperlinks. The Specification has been amended to remove all browser-executable code.

Applicants respectfully request reconsideration and withdrawal of the objection.

Rejection of claims 12 and 15 under 35 U.S.C. § 112

The Examiner has rejected claims 12 and 15 under 35 U.S.C. § 112 as allegedly being indefinite due to the use of the phrase “such that”. Claims 12 and 15 have

been amended to remove the phrase “such that”. Applicants respectfully request reconsideration and withdrawal of the rejection.

Rejection of claims 11, 13, 14, 16, 17, 18 and 20 under 35 U.S.C. 102(a)(1)

The Examiner has rejected claims 11, 13, 14, 16, 17, 18 and 20 under 35 U.S.C. 102(a)(1) as allegedly being anticipated by Hoffman et al. (US Pub. No. 20080311043; hereinafter “Hoffman”). The Examiner alleges that Hoffman teaches treating psoriatic arthritis using antagonist to TNF- α intravenously biweekly, and with or without methotrexate. The Examiner also alleges that Hoffman teaches a method of determining the efficacy of TNF- α inhibitor for treating psoriatic arthritis comprising determining an ACR20 response, wherein the response is about 39%-61% or 64% or ACR50 is about 25%-46%, or by measuring a decrease in Health Assessment Questionnaire (HAQ) wherein the response is on an average a decrease of 0.3, 0.4, or 0.5.

It is well settled that “[a] claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference.” MPEP §2131 (quoting *Verdegaal Bros. v. Union Oil Co. of Calif.*, 2 USPQ2d 1051, 1053 (Fed. Cir. 1987)). “The identical invention must be shown in as complete detail as is contained in the . . . claim.” *Id.* (quoting *Richardson v. Suzuki Motor Co.*, 9 USPQ2d 1913, 1920 (Fed. Cir. 1989)). Therefore, the cited reference must describe each and every element of claims in order to anticipate these claims under § 102(a)(1).

Applicants submit that Hoffman does not anticipate any of the present claims, as Hoffman does not teach each and every element of the present claims. For example, Applicant submits that Hoffman fails to teach the specific criteria recited in the present claims. For example, with respect to claim 11, Hoffman does not teach an average decrease in HAQ score of 0.6. Rather, Hoffman describes the efficacy of a TNF- α inhibitor in treating psoriatic arthritis determined by a decrease in HAQ on an average of 0.3, 0.4, or 0.5. Further, with respect to claim 14, Hoffman does not teach an improvement in van der Heijde-Sharp score (vdH-S) of 0.36. Finally, with respect to claim 17, Hoffman does not teach $\geq 65\%$ of patients receiving the treatment achieve ACR20 at week 14 of treatment. Therefore, Applicants submit that Hoffman does not anticipate claims 11, 14, 17, and 18, or dependent

claims 13, 16 and 20, because Hoffman does not teach each and every element of the present claims.

Rejection of claims 11-20 under 35 U.S.C. 103

The Examiner has rejected claims 11-20 under 35 U.S.C. 103 as allegedly being unpatentable over Hoffman in view of Doyle et al. (2013, Rheumatology, 52: 1214-1219; hereinafter “Doyle”). The Examiner contends that Hoffman teaches treating psoriatic arthritis using an antagonist to TNF- α . The Examiner admits that Hoffman does not teach administering golimumab to a subject comprising administering 2mg/kg to a subject in need thereof. However, the Examiner alleges that Doyle teaches the administration of 2mg/kg golimumab intravenous infusion for 4 weeks and 12 weeks. The Examiner contends that it would have been obvious to administer golimumab as taught by Doyle for treating psoriatic arthritis and would have had a reasonable expectation of success in administering golimumab at 2mg/kg intravenously based on the teachings of Doyle.

According to the U.S. Supreme Court ruling in *Graham v. John Deere*, 383 U.S. 1 (1960), in making a case for obviousness, the Examiner must 1) determine the scope and content of the prior art; 2) ascertain the differences between the prior art and the claims at issue; 3) resolve the level of ordinary skill in the pertinent art; and 4) evaluate evidence of secondary considerations. These principles have been reconfirmed by the Supreme Court in *KSR International Co. v. Teleflex Inc.*, 127 S.Ct. 1727 (2007).

In *KSR Int'l Co.*, the US Supreme Court restated the requirements for a finding of obviousness. Encouraging the application of common knowledge and common sense, the Court took care to guard against hindsight bias and *ex post* reasoning and to distinguish the predictable from the unpredictable arts (“If a person of ordinary skill can implement a predictable variation, §103 likely bars its patentability.” [Emphasis added]). Based on the combination of references set forth by the Examiner, Applicants assert that the rejection of the claims under §103 could only have been made with hindsight bias and *ex post* reasoning.

When applying 35 U.S.C. § 103, the following tenets of patent law must be followed: 1) the claimed invention must be considered as a whole; 2) the references must be considered as a whole; 3) the references must be viewed without the benefit of impermissible hindsight

vision afforded by the claimed invention; and 4) reasonable expectation of success is the standard with which obviousness is determined (MPEP § 2141 II).

Cited art does not teach or suggest each and every element

Establishing a prima facie case of obviousness of a claimed invention “requires a suggestion of all limitations in a claim” in the prior art. 35 U.S.C. § 103(a); CFMT, Inc. v. Yieldup Intern. Corp., 349 F.3d 1333, 1342 (Fed. Cir. 2003) (citing In re Royka, 490 F.2d 981, 985 (CCPA 1974); see also In re Ochiai, 71 F.3d 1565, 1572 (Fed. Cir. 1995). Therefore, in order to render the instant claims obvious under 35 U.S.C. §103(a), the cited prior art must teach or suggest each and every element of the claims.

As discussed above, Applicants submit that Hoffman does not teach or suggest each and every element recited in claims 11, 14, and 17. Applicants submit that Doyle does not make up for the deficiencies of Hoffman, because Doyle does not teach or suggest the specific criteria recited in the present claims.

Further, Applicants submit that Hoffman and Doyle, alone or in combination with each other, do not teach or suggest the dosing recited in claims 12, 15 and 19. The Examiner contends that Hoffman teaches biweekly administration, preferably intravenous or infusion, of golimumab. Further, the Examiner contends that Doyle teaches administration of 2mg/kg golimumab intravenous infusion at week 0 and 12. Applicant submits that Hoffman and Doyle, alone or in combination, does not teach or suggest the IV administration of golimumab at a dose of 2 mg/kg, over 30 ± 10 minutes, at Weeks 0 and 4, and then every 8 weeks (q8w) thereafter, as recited in the present claims.

Thus, Applicants submit that Hoffman and Doyle, alone or in combination with each other, do not teach or suggest that IV infusion of the composition to a subject having active psoriatic arthritis would result in a subject with active psoriatic arthritis achieving at week 14 a mean change from baseline in one or more criteria selected from the group consisting of: HAQ-DI= -0.60 ± 0.53 SD, enthesitis = -1.87 ± 1.75 SD, dactylitis = -7.8 ± 8.57 SD, SF-36 PCS= 8.65 ± 7.60 SD, and SF-36 MCS = 5.33 ± 9.95 SD, as recited in claim 11. Similarly, Applicants submit that Hoffman and Doyle, alone or in combination with each other, do not teach or suggest that IV infusion of the composition to a subject having active psoriatic

arthritis would result in a subject with active psoriatic arthritis achieving at week 24 a mean change from baseline in vdH-S = -0.36 ± 0.144 SE, as recited in claim 14. Similarly, Applicants submit that Hoffman and Doyle, alone or in combination with each other, do not teach or suggest that IV infusion of the composition to a subject having active psoriatic arthritis would result in a ~ 65% of patients with psoriatic arthritis receiving the treatment achieving ACR20 at week 14 of treatment, as recited in claim 17. Finally, Applicants submit that Hoffman and Doyle, alone or in combination with each other, do not teach or suggest the dose and schedule recited in present claims 12, 15, and 19.

Cited art does not provide a reasonable expectation of success

Further, to establish a prima facie case of obviousness, a reference or combination of references must: (1) suggest to those of ordinary skill in the art that they should make the claimed invention, and (2) reveal to those of ordinary skill in the art that they would have a reasonable expectation of success. In re Vaeck, 20 USPQ2d 1438, 1442 (Fed. Cir. 1991). Both the suggestion and the reasonable expectation of success must be found in the prior art and not in the Applicant's disclosure. In re Dow Chemical Company, 5 USPQ2d 1529, 1531 (Fed. Cir. 1988). However, there is nothing in any of the cited references that would motivate one of ordinary skill in the art to combine the teachings of these references to produce the presently claimed invention.

"Reasonable expectation of success" is premised on predictability. In other words, to have a reasonable expectation of success, the ordinarily skilled artisan must be able to predict the likely outcome for an experiment. A direct corollary of this fact is that if one cannot predict the likely outcome for an experiment, one cannot have a reasonable expectation of success in achieving a given outcome. Indeed, the USPTO clearly recognizes the relationship between predictability and reasonable expectation of success. Specifically, MPEP 2143E articulates how to determine if a claim can be rejected on an "obvious-to-try" rationale using the following language:

Office personnel must articulate the following:

- (1) a finding that at the time of the invention, there had been a recognized problem or need in the art, which may include a design need or market pressure to solve a problem;

- (2) a finding that there had been a finite number of identified, **predictable potential solutions** to the recognized need or problem;
- (3) a finding that one of ordinary skill in the art could have pursued the known potential solutions with **a reasonable expectation of success**; and
- (4) whatever additional findings based on the Graham factual inquiries may be necessary, in view of the facts of the case under consideration, to explain a conclusion of obviousness. (emphasis added)

Thus, it is the ability to predict the outcome of a solution that underlies a reasonable expectation of success for pursuing that solution.

Applicants submit that Hoffman and Doyle do not provide a reasonable expectation of success at arriving at a method for treating psoriatic arthritis by administering to a subject having active psoriatic arthritis a composition comprising a safe and effective amount of at least one isolated mammalian anti-TNF- α antibody described in claim 11, 14 and 17. Applicants submit that Hoffman does not teach any of the recited criteria of claims 11, 14 and 17, and therefore nothing in Hoffman provides a skilled artisan with any predictability that golimumab can be delivered by IV infusion to subjects with psoriatic arthritis wherein said treatment would achieve the recited criteria of claims 11, 14 and 17. Applicants submit that Doyle does not cure any of the deficiencies of Hoffman. Doyle describes the effect of subcutaneous and intravenous golimumab on inflammatory biomarkers. However, Applicants submit that Doyle does not provide a skilled artisan with any predictability that golimumab can be delivered by IV infusion to subjects with active psoriatic arthritis to treat psoriatic arthritis, much less that subjects with active psoriatic arthritis treated with IV golimumab would achieve the recited criteria of claims 11, 14 and 17. First, Applicants submit that Doyle does not describe the effects of IV golimumab on a subject with psoriatic arthritis. Second, Doyle does not describe any clinical improvement from IV golimumab on any subject, let alone a subject with psoriatic arthritis. Third, Doyle describes a golimumab dosing schedule that is distinct from present claims 12, 15, and 19. Applicants submit that a skilled artisan reading Doyle would not have any reasonable expectation that administration of IV golimumab could be used to effectively treat psoriatic arthritis and especially achieve the recited criteria of the present claims.

Secondary Considerations

Importantly, “secondary considerations” may include evidence of commercial success, long-felt but unsolved needs, failure of others, and unexpected results. Rebuttal evidence may also include evidence that the claimed invention yields unexpectedly improved properties or properties not present in the prior art. Rebuttal evidence may also include evidence that the claimed invention yields unexpectedly improved properties or properties not present in the prior art. See MPEP § 2145.

In *Crocs, Inc. v. U.S. Int’l Trade Commission*, 598 F.3d 1294 (Fed. Cir. 2010), the Federal Circuit reaffirmed the requirements for a finding of non-obviousness in view of “unexpected results.” Rejecting the proposition that a combination of prior art elements is per se obvious, the Federal Circuit held that a claimed combination of prior art elements is non-obvious when the combination yields “more than predictable results.” In *Crocs*, testimony on record indicated that the combined elements in the shoe reduced wearer discomfort in ways that were not suggested or contemplated by the prior art. The Federal Circuit pointed out that this combination “yielded more than predictable results” and was thus patentable. *Id.* at 1310. This ruling affirmed prior holdings that inventions that have new and unexpected properties are patentable (*In re Papesch*, 315 F.2d. 381, 387 (C.C.P.A. 1963)). The determination that the result is “unexpected” depends upon what a person of ordinary skill in the art would have predicted based upon the prior art (*Procter & Gamble Co. v. Teva Pharms. USA, Inc.*, 566 F.3d 989, 997-98 (Fed. Cir. 2009); *Pfizer, Inc. v. Apotex, Inc.*, 480 F.3d 1348, 1367 (Fed. Cir. 2007)). Consistently, under MPEP § 2143 A(3), merely pointing to the presence of all claim elements in the prior art is not a complete statement of a rejection for obviousness. In accordance with MPEP § 2143 A(3), a rejection based on the rationale that the claimed invention is a combination of prior art elements is improper if it does not include a finding that results flowing from the combination would have been predictable to a person of ordinary skill in the art. MPEP § 2143 A(3). If results from the invention would not have been predictable, an obviousness rejection using the combination of prior art elements rationale is improper.

Applicants submit that the presently claimed methods of administering to a subject having active psoriatic arthritis a composition comprising a safe and effective amount of at

least one isolated mammalian anti-TNF- α antibody having the recited CDRs, wherein said composition is administered via IV infusion., produces surprising and unexpected results that could not have been predicted by the combination of Hoffman and Doyle.

For example, it is demonstrated in the present application that IV golimumab demonstrated clinically meaningful and surprisingly significant improvements of disease activity and physical function, skin psoriasis clearance, reduction in dactylitis and enthesitis, HRQoL and inhibition of structural progression. It is shown in the present application that 75.1% of subjects having active psoriatic arthritis treated with IV golimumab achieved ACR20 by 14 weeks (see Table 8 of the present application). ACR20 is a well-accepted criterion defined as a 20% improvement in a variety of measures (e.g., swollen joint count, tender joint count, patient assessment of pain, patient global assessment of disease activity, physician global assessment of disease activity, patient assessment of physical function measured by HAQ-DI, and CRP). Applicants submit that such a high proportion of patients achieving such an improvement defined by ACR20 as early as 14 weeks after initiation of treatment is unexpected and surprising. In contrast, the present application states that subcutaneous golimumab resulted in only 51% of psoriatic arthritis subjects achieving ACR20 by week 14 (see paragraph [324] of the originally filed specification). Applicants submit that the unexpected and surprising effects of the presently claimed methods could not have been expected by the teaching of Hoffman and Doyle.

For at least these reasons, Applicants submit that claims 11-20 are not rendered obvious by the combination of Hoffman and Doyle. Applicants respectfully request reconsideration and withdrawal of the rejection.

Summary

Early consideration and allowance of the claims in the present application is requested at the earliest possible time.

Respectfully submitted,

Diane D. Harrison, ET AL.

August 15, 2023

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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
17/320,490	05/14/2021	Diane D. Harrison	206389-0003-02US	5386
171672	7590	09/08/2023	EXAMINER	
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			ART UNIT	PAPER NUMBER
			1646	
			NOTIFICATION DATE	DELIVERY MODE
			09/08/2023	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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DETAILED ACTION

Notice of Pre-AIA or AIA Status

The present application, filed on or after March 16, 2013, is being examined under the first inventor to file provisions of the AIA.

Applicant's response filed on 8/15/2023 is acknowledged and fully considered.

Status of Application, Amendments, And/Or Claims

The amendments of claims 12 and 15 have been made of record.

Claims 11-20 are pending and under examination.

Response to Arguments

Claim Rejections - 35 USC § 112-withdrawn

The rejection of claims 12 and 15 under 35 U.S.C. 112(b) or 35 U.S.C. 112 (pre-AIA), second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which the inventor is withdrawn in view of Applicant's deletion of the phrase "such that" from the claims.

Claim Rejections - 35 USC § 102-maintained

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(a)(1) the claimed invention was patented, described in a printed publication, or in public use, on sale, or otherwise available to the public before the effective filing date of the claimed invention.

Claim(s) 11, 13, 14, 16, 17, 18 and 20 remain rejected under 35 U.S.C. 102(a)(1) as being anticipated by Hoffman et al (US Pub. No. 20080311043).

The instant claims are broadly drawn to a method for treating a tumor necrosis factor alpha (TNF- α) related condition, wherein the TNF- α related condition is active psoriatic arthritis, the method comprising: administering to a subject having active psoriatic arthritis a composition comprising a safe and effective amount of at least one isolated mammalian anti-TNF- α antibody comprising: a. a heavy chain (HC) complementary determining region (CDR) 1 comprising an amino acid sequence of SEQ ID NO: 1; b. a HC CDR2 comprising an amino acid sequence of SEQ ID NO: 2; wherein position 1 of SEQ ID NO: 2 is phenylalanine, position 2 of SEQ ID NO: 2 is methionine, position 3 of SEQ ID NO: 2 is serine, position 4 of SEQ ID NO: 2 is tyrosine, position 10 of SEQ ID NO: 2 is lysine, position 11 of SEQ ID NO: 2 is tyrosine, and position 17 of SEQ ID NO: 2 is glycine; c. a HC CDR3 comprising an amino acid sequence of SEQ ID NO: 3; wherein position 4 of SEQ ID NO: 3 is isoleucine, position 5 of SEQ ID NO: 3 is alanine, and position 9 of SEQ ID NO: 3 is asparagine; d. a light chain (LC) CDR1 comprising an amino acid sequence of SEQ ID NO: 4; wherein position 7 of SEQ ID NO: 4 is tyrosine; e. a LC CDR2 comprising an amino acid sequence of SEQ ID NO: 5; and f. a LC CDR3 comprising an amino acid sequence of SEQ ID NO: 6, and at least one pharmaceutically acceptable carrier or diluent, wherein said composition is administered via intravenous (IV) infusion, and wherein at week 14 of treatment patients treated with the anti-TNF- α antibody achieve a mean change from baseline in one or more criteria selected from the group consisting of: Health Assessment Questionnaire Disability Index score (HAQ-DI) = -0.60 ± 0.53 SD, enthesitis = -1.87 ± 1.75 SD, dactylitis = -7.8 ± 8.57 SD, Short-Form Health Survey Physical Summary score (SF-36 PCS) = 8.65 ± 7.60 SD, and Short-Form Health Survey Mental Component Summary score (SF-36 MCS) = 5.33 ± 9.95 SD and wherein the method further comprises administering said composition with or without methotrexate (MTX).

It is noted that the search results of 4/14/2023 in PE2E show that HC CDR1-3 of SEQ ID NO: 1-3 and LC CDR1-3 of SEQ ID NO: 4-6 are six CDRs of golimumab against TNF- α . Therefore, administration of golimumab intravenously would anticipate the instantly claimed invention.

Hoffman et al teach treating psoriatic arthritis using antagonist to TNF- α [0005]. They teach a method of determining the efficacy of TNF- α inhibitor for treating psoriatic arthritis in a subject comprising determining an ACR20 response in patients who have been administered with TNF- α inhibitor, wherein response is about 39%-61% or 64% [0006-0010, 0223] or ACR50 is about 25%-46% [0011]. They teach that efficacy of TNF- α inhibitor can also be determined by measuring a decrease in Health Assessment Questionnaire (HAQ) on an average of 0.3, 0.4 or 0.5 [0024]. They teach that TNF- α inhibitor is TNF- α antibody, or antigen-binding portion thereof which is infliximab or golimumab (or CNTO 148) see paragraphs [0051 or 0079] or claim 85. They teach dosing for treating psoriatic arthritis using TNF- α inhibitor starting at 0 week and followed by bi-weekly dosing regimen [0096-0099]. They teach that the administration of TNF- α inhibitor antibody can be bi-weekly or at 4 weeks, 8 weeks, 16 weeks, 24 weeks, 26, 36, 42, 48, 52, 56 weeks etc. [0099]. They teach the administration of TNF- α antibody is preferably administered by intravenous injection or infusion [0155, 0159]. They teach stratified subject population based on methotrexate treatment [0293]. They teach the effect of TNF- α antibody effect with or without methotrexate (MTX) (see Table 33). Therefore, the instantly claimed invention is implicitly or explicitly anticipated by the prior art of record.

Applicants argue that Hoffman does not teach an average decrease of HAQ score of 0.6, rather Hoffman teaches the efficacy of a TNF- α inhibitor in treating psoriatic arthritis determined by a decrease in HAQ on an average of 0.3, 0.4 or 0.5. They argue that Hoffman does not teach an improvement in van der Heijde-Sharp score (vdH-S) of 0.36 or does not teach >65% of patient receiving the treatment achieve ACR20 at week 14 of treatment.

Applicants arguments have been fully considered but they are not persuasive because Hoffman et al teach treating psoriatic arthritis (same disease with same antibody) and therefore, the outcome would be the same, **unless the claim requires a**

specific dosage of administration. However, the claim does not require a specific dose of administration. Hoffman et al. teach a method of determining the efficacy of TNF- α inhibitor for treating psoriatic arthritis in a subject comprising determining an ACR20 response in patients who have been administered with TNF- α inhibitor, wherein response is about 39%-61% or 64% [0006-0010, 0223] or ACR50 is about 25%-46% [0011]. They teach that efficacy of TNF- α inhibitor **can also be determined by measuring a decrease in Health Assessment Questionnaire (HAQ) on an average of 0.3, 0.4 or 0.5** [0024]. Therefore, the instantly claimed invention is implicitly or explicitly anticipated by the prior art of record.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103 which forms the basis for all obviousness rejections set forth in this Office action:

A patent for a claimed invention may not be obtained, notwithstanding that the claimed invention is not identically disclosed as set forth in section 102, if the differences between the claimed invention and the prior art are such that the claimed invention as a whole would have been obvious before the effective filing date of the claimed invention to a person having ordinary skill in the art to which the claimed invention pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries for establishing a background for determining obviousness under 35 U.S.C. 103 are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating

obviousness or nonobviousness.

Claim(s) 11-20 are rejected under 35 U.S.C. 103 as being unpatentable over Hoffman et al (US Pub. No. 20080311043) in view of Doyle et al. (Rheumatology 52: 1214-1219, 2013).

The instant invention is broadly drawn to a method for treating a tumor necrosis factor alpha (TNF- α) related condition, wherein the TNF- α related condition is active psoriatic arthritis, the method comprising: administering to a subject having active psoriatic arthritis a composition comprising a safe and effective amount of at least one isolated mammalian anti-TNF- α antibody comprising: a. a heavy chain (HC) complementary determining region (CDR) 1 comprising an amino acid sequence of SEQ ID NO: 1; b. a HC CDR2 comprising an amino acid sequence of SEQ ID NO: 2; wherein position 1 of SEQ ID NO: 2 is phenylalanine, position 2 of SEQ ID NO: 2 is methionine, position 3 of SEQ ID NO: 2 is serine, position 4 of SEQ ID NO: 2 is tyrosine, position 10 of SEQ ID NO: 2 is lysine, position 11 of SEQ ID NO: 2 is tyrosine, and position 17 of SEQ ID NO: 2 is glycine; c. a HC CDR3 comprising an amino acid sequence of SEQ ID NO: 3; wherein position 4 of SEQ ID NO: 3 is isoleucine, position 5 of SEQ ID NO: 3 is alanine, and position 9 of SEQ ID NO: 3 is asparagine; d. a light chain (LC) CDR1 comprising an amino acid sequence of SEQ ID NO: 4; wherein position 7 of SEQ ID NO: 4 is tyrosine; e. a LC CDR2 comprising an amino acid sequence of SEQ ID NO: 5; and f. a LC CDR3 comprising an amino acid sequence of SEQ ID NO: 6, and at least one pharmaceutically acceptable carrier or diluent, wherein said composition is administered via intravenous (IV) infusion, and wherein at week 14 of treatment patients treated with the anti-TNF- α antibody achieve a mean change from baseline in one or more criteria selected from the group consisting of: Health Assessment Questionnaire Disability Index score (HAQ-DI) = -0.60 ± 0.53 SD, enthesitis = -1.87 ± 1.75 SD, dactylitis = -7.8 ± 8.57 SD, Short-Form Health Survey Physical Summary score (SF-36 PCS) = 8.65 ± 7.60 SD, and Short-Form Health Survey Mental Component Summary score (SF-36 MCS) = 5.33 ± 9.95 SD, wherein the composition is administered at 2 mg/kg to said subject and wherein the method further comprises administering said composition with or without methotrexate (MTX).

The teachings of Hoffman et al is set forth above. Hoffman et al do not teach administering golimumab to subject comprising 2 mg/kg to a subject in need thereof.

Doyle et al teach that the administration of golimumab by subcutaneous as well as intravenous route (see the title). They teach that administration by intravenous route is superior to subcutaneous in reducing anti-TNF α markers (see Fig. 1), pg. 1216. They teach administering 2 mg/kg golimumab iv infusion vs. subcutaneous for 4 weeks and 12 weeks (pg. 1215, Patients and Methods).

Therefore, it would have been prima facie obvious to one of ordinary skill in the art at the time of invention to administer the anti-TNF- α antibody golimumab as taught by Doyle et al for treating psoriatic arthritis as taught by Hoffman et al. Further, one of ordinary skill of the art would have been motivated to administer golimumab by an intravenous infusion because Doyle et al teach that golimumab when administered through intravenous it reduces TNF- α markers better than when administered subcutaneously. One would have a reasonable expectation of success in administering golimumab at 2 mg/kg intravenously to a subject in need thereof because Doyle et al. teach administering golimumab intravenously. Therefore, the invention is obvious over the combined teachings of the prior art.

Applicants argue that Hoffman and Doyle alone or in combination do not teach or suggest the limitation of claims 12, 14 and 17. They argue that Hoffman and Doyle alone or in combination do not teach administering golimumab a dose of 2 mg/kg over 30 minutes at weeks 0 and 4, and then every 8 weeks thereafter. They argue that the present application of golimumab by IV administration demonstrated a surprising result as compared to subcutaneous administration, wherein IV administration to psoriatic patients achieve ACR20 by 14 weeks in about 75% cases as compared to 51% in cases administered by subcutaneous route. They argue that such an outcome could not have been expected by Hoffman and Doyle.

Applicants' arguments have been fully considered but they are not persuasive because claim 11, 14 and 17 do not recite the argued limitation of "administering golimumab at a dose of 2 mg/kg over a period of 30 $\pm$ 10 minutes, at weeks 0 and 4, then every 8 weeks thereafter. Although the claims are interpreted in light of the specification, limitations

from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993). Regarding applicants' arguments that the reference Hoffman or Doyle does not teach administering golimumab at 2 mg/kg over 30 minute period, the reference Hoffman teach administering the same antibody for treating psoriatic arthritis and the reference Doyle teaches administering 2 mg/kg golimumab iv infusion vs. subcutaneous for 4 weeks and 12 weeks (pg. 1215, Patients and Methods). Regarding applicants' arguments that the instant teaching of administering golimumab in psoriatic patients results are unexpected because IV administration of golimumab in psoriatic arthritis patients result in 75% ACR vs. 51% ACR by subcutaneous, have been fully considered but the combined reference teach administering golimumab by IV and therefore, for the unexpected result the comparison should be between the IV administration of golimumab taught by Hoffman and Doyle vs. IV administration of the instant invention. As such the examiner does not find any significant difference in the instant claimed invention vs. IV infusion of golimumab taught by Hoffman in view of Doyle et al. Therefore, the rejection is maintained.

Double Patenting-maintained

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*,

686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on nonstatutory double patenting provided the reference application or patent either is shown to be commonly owned with the examined application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement. See MPEP § 717.02 for applications subject to examination under the first inventor to file provisions of the AIA as explained in MPEP § 2159. See MPEP § 2146 *et seq.* for applications not subject to examination under the first inventor to file provisions of the AIA. A terminal disclaimer must be signed in compliance with 37 CFR 1.321(b).

The USPTO Internet website contains terminal disclaimer forms which may be used. Please visit www.uspto.gov/patent/patents-forms. The filing date of the application in which the form is filed determines what form (e.g., PTO/SB/25, PTO/SB/26, PTO/AIA/25, or PTO/AIA/26) should be used. A web-based eTerminal Disclaimer may be filled out completely online using web-screens. An eTerminal Disclaimer that meets all requirements is auto-processed and approved immediately upon submission. For more information about eTerminal Disclaimers, refer to www.uspto.gov/patents/process/file/efs/guidance/eTD-info-I.jsp.

Claims 11-20 remain rejected on the ground of nonstatutory double patenting as being unpatentable over claims 1-10 of U.S. Patent No. 11,041,020. Although the claims at issue are not identical, they are not patentably distinct from each other because a method for treating a tumor necrosis factor alpha (TNF- α) related condition,

wherein the TNF- α related condition is active psoriatic arthritis, the method comprising: administering to a subject having active psoriatic arthritis a composition comprising a safe and effective amount of at least one isolated mammalian anti-TNF- α antibody comprising: a. a heavy chain (HC) complementary determining region (CDR) 1 comprising an amino acid sequence of SEQ ID NO: 1; b. a HC CDR2 comprising an amino acid sequence of SEQ ID NO: 2; wherein position 1 of SEQ ID NO: 2 is phenylalanine, position 2 of SEQ ID NO: 2 is methionine, position 3 of SEQ ID NO: 2 is serine, position 4 of SEQ ID NO: 2 is tyrosine, position 10 of SEQ ID NO: 2 is lysine, position 11 of SEQ ID NO: 2 is tyrosine, and position 17 of SEQ ID NO: 2 is glycine; c. a HC CDR3 comprising an amino acid sequence of SEQ ID NO: 3; wherein position 4 of SEQ ID NO: 3 is isoleucine, position 5 of SEQ ID NO: 3 is alanine, and position 9 of SEQ ID NO: 3 is asparagine; d. a light chain (LC) CDR1 comprising an amino acid sequence of SEQ ID NO: 4; wherein position 7 of SEQ ID NO: 4 is tyrosine; e. a LC CDR2 comprising an amino acid sequence of SEQ ID NO: 5; and f. a LC CDR3 comprising an amino acid sequence of SEQ ID NO: 6, and at least one pharmaceutically acceptable carrier or diluent, wherein said composition is administered via intravenous (IV) infusion, and wherein at week 14 of treatment patients treated with the anti-TNF- α antibody achieve a mean change from baseline in one or more criteria selected from the group consisting of: Health Assessment Questionnaire Disability Index score (HAQ-DI) = -0.60 ± 0.53 SD, enthesitis = -1.87 ± 1.75 SD, dactylitis = -7.8 ± 8.57 SD, Short-Form Health Survey Physical Summary score (SF-36 PCS) = 8.65 ± 7.60 SD, and Short-Form Health Survey Mental Component Summary score (SF-36 MCS) = 5.33 ± 9.95 SD, wherein the composition is administered at 2 mg/kg to said subject and

wherein the method further comprises administering said composition with or without methotrexate (MTX) are taught in claims 1-10 of US Pat. No.11,041,020.

It is noted that the examiner has carefully reviewed the amino acid sequences of heavy chain **(HC) SEQ ID NO: 36 which comprises HC CDR1-3 of SEQ ID NO: 1-3 and the amino acid sequence of light chain (LC) SEQ ID NO: 37 which comprises LC CDR1-3 of SEQ ID NO:4-6 as being instantly claimed.**

Applicants do not argue for the instant rejection and therefore, the rejection is maintained.

Claims 11-20 remain provisionally rejected on the ground of nonstatutory double patenting as being unpatentable over claims 8- 13 of copending Application No. 17/423,512 (reference application). Although the claims at issue are not identical, they are not patentably distinct from each other because a method for treating a tumor necrosis factor alpha (TNF-a) related condition, wherein the TNF-a related condition is active psoriatic arthritis, the method comprising: administering to a subject having active psoriatic arthritis a composition comprising a safe and effective amount of at least one isolated mammalian anti-TNF-a antibody comprising: a. a heavy chain (HC) complementary determining region (CDR) 1 comprising an amino acid sequence of SEQ ID NO: 1; b. a HC CDR2 comprising an amino acid sequence of SEQ ID NO: 2; wherein position 1 of SEQ ID NO: 2 is phenylalanine, position 2 of SEQ ID NO: 2 is methionine, position 3 of SEQ ID NO: 2 is serine, position 4 of SEQ ID NO: 2 is tyrosine, position 10 of SEQ ID NO: 2 is lysine, position 11 of SEQ ID NO: 2 is tyrosine, and position 17 of SEQ ID NO: 2 is glycine; c. a HC CDR3 comprising an amino acid sequence of SEQ ID NO: 3; wherein position 4 of SEQ ID NO: 3 is isoleucine, position 5

of SEQ ID NO: 3 is alanine, and position 9 of SEQ ID NO: 3 is asparagine; d. a light chain (LC) CDR1 comprising an amino acid sequence of SEQ ID NO: 4; wherein position 7 of SEQ ID NO: 4 is tyrosine; e. a LC CDR2 comprising an amino acid sequence of SEQ ID NO: 5; and f. a LC CDR3 comprising an amino acid sequence of SEQ ID NO: 6, and at least one pharmaceutically acceptable carrier or diluent, wherein said composition is administered via intravenous (IV) infusion, and wherein at week 14 of treatment patients treated with the anti-TNF- α antibody achieve a mean change from baseline in one or more criteria selected from the group consisting of: Health Assessment Questionnaire Disability Index score (HAQ-DI) = -0.60 ± 0.53 SD, enthesitis = -1.87 ± 1.75 SD, dactylitis = -7.8 ± 8.57 SD, Short-Form Health Survey Physical Summary score (SF-36 PCS) = 8.65 ± 7.60 SD, and Short-Form Health Survey Mental Component Summary score (SF-36 MCS) = 5.33 ± 9.95 SD, wherein the composition is administered at 2 mg/kg to said subject and wherein the method further comprises administering said composition with or without methotrexate (MTX) are taught in claims 8-13 of US Application No. 17/423,512.

This is a provisional nonstatutory double patenting rejection because the patentably indistinct claims have not in fact been patented.

Applicants do not argue for the instant rejection and therefore, the rejection is maintained.

Claims 11-20 remain provisionally rejected on the ground of nonstatutory double patenting as being unpatentable over claims 1-19 of copending Application No. 17/615,949 (reference application). Although the claims at issue are not identical, they

are not patentably distinct from each other because a method for treating a tumor necrosis factor alpha (TNF- α) related condition, wherein the TNF- α related condition is active psoriatic arthritis, the method comprising: administering to a subject having active psoriatic arthritis a composition comprising a safe and effective amount of at least one isolated mammalian anti-TNF- α antibody comprising: a. a heavy chain (HC) complementary determining region (CDR) 1 comprising an amino acid sequence of SEQ ID NO: 1; b. a HC CDR2 comprising an amino acid sequence of SEQ ID NO: 2; wherein position 1 of SEQ ID NO: 2 is phenylalanine, position 2 of SEQ ID NO: 2 is methionine, position 3 of SEQ ID NO: 2 is serine, position 4 of SEQ ID NO: 2 is tyrosine, position 10 of SEQ ID NO: 2 is lysine, position 11 of SEQ ID NO: 2 is tyrosine, and position 17 of SEQ ID NO: 2 is glycine; c. a HC CDR3 comprising an amino acid sequence of SEQ ID NO: 3; wherein position 4 of SEQ ID NO: 3 is isoleucine, position 5 of SEQ ID NO: 3 is alanine, and position 9 of SEQ ID NO: 3 is asparagine; d. a light chain (LC) CDR1 comprising an amino acid sequence of SEQ ID NO: 4; wherein position 7 of SEQ ID NO: 4 is tyrosine; e. a LC CDR2 comprising an amino acid sequence of SEQ ID NO: 5; and f. a LC CDR3 comprising an amino acid sequence of SEQ ID NO: 6, and at least one pharmaceutically acceptable carrier or diluent, wherein said composition is administered via intravenous (IV) infusion, and wherein at week 14 of treatment patients treated with the anti-TNF- α antibody achieve a mean change from baseline in one or more criteria selected from the group consisting of: Health Assessment Questionnaire Disability Index score (HAQ-DI) = -0.60 ± 0.53 SD, enthesitis = -1.87 ± 1.75 SD, dactylitis = -7.8 ± 8.57 SD, Short-Form Health Survey Physical Summary score (SF-36 PCS) = 8.65 ± 7.60 SD, and Short-Form Health Survey

Mental Component Summary score (SF-36 MCS) = 5.33 9.95 SD, wherein the composition is administered at 2 mg/kg to said subject and wherein the method further comprises administering said composition with or without methotrexate (MTX) are taught in claims 1-19 of US Application No. 17/615,949.

This is a provisional nonstatutory double patenting rejection because the patentably indistinct claims have not in fact been patented.

Applicants do not argue for the instant rejection and therefore, the rejection is maintained.

Conclusion

No claim is allowed.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to GYAN CHANDRA whose telephone number is (571)272-2922. The examiner can normally be reached Mon-Friday 8:30AM-5:00P.

Examiner interviews are available via telephone, in-person, and video conferencing using a USPTO supplied web-based collaboration tool. To schedule an interview, applicant is encouraged to use the USPTO Automated Interview Request (AIR) at <http://www.uspto.gov/interviewpractice>.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Vanessa Ford can be reached on 571-272-0857. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of published or unpublished applications may be obtained from Patent Center. Unpublished application information in Patent Center is available to registered users. To file and manage patent submissions in Patent Center, visit: <https://patentcenter.uspto.gov>. Visit <https://www.uspto.gov/patents/apply/patent-center> for more information about Patent Center and <https://www.uspto.gov/patents/docx> for information about filing in DOCX format. For additional questions, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/GYAN CHANDRA/
Primary Examiner, Art Unit 1646

Response to Office Action mailed September 09, 2023
U.S. Patent Application No. 17/320,490
Attorney Docket No. 206389-0003-02US

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Patent Application of:
Diane D. Harrison, et al.

Art Unit: 1646
Confirmation No.: 5386

Application No.:
17/320,490

Examiner:
Chandra, Gyan

Filing date:
May 14, 2021

Atty Docket No.:
206389-0003-02US

Title: ANTI-TNF ANTIBODIES, COMPOSITIONS, AND METHODS FOR THE
TREATMENT OF ACTIVE PSORIATIC ARTHRITIS

AMENDMENT

This Amendment is responsive to the Final Office Action mailed on September 08, 2023 in connection with the above-referenced application. This Amendment is timely filed in view of the deadline for a timely response to and through December 08, 2023.

This Response is accompanied by a Request for Continued Examination (and associated fee).

No other fee is believed due for filing of this response. Please charge any additional fee that is due, and credit any overpayment, to deposit account no. 50-5366.

REMARKS

Claims 11, 13, 14, 16-18, and 20 are pending and under consideration. Claims 12, 15, and 19 have been cancelled herein without prejudice or disclaimer.

Withdrawn rejections

Applicants acknowledge and thank the Examiner for the withdrawal of the rejection of claims 12 and 15 under 35 U.S.C. 112(b).

Amendments to the Claims

Claim 11 has been amended to incorporate the subject matter of claim 12.

Claim 14 has been amended to incorporate the subject matter of claim 15.

Claim 17 has been amended to incorporate the subject matter of claim 19.

Support for these amendments can be found in the Specification and at least in the original claims as filed.

No new matter has been added by way of these amendments.

Claims 12, 15, and 19 have been cancelled without disclaimer or prejudice to the inclusion of the subject matter contained therein in this or any later filed continuing application(s). No new matter has been added by way of this cancellation.

Rejection of claims 11, 13, 14, 16, 17, 18 and 20 under 35 U.S.C. 102(a)(1)

The Examiner has rejected claims 11, 13, 14, 16, 17, 18 and 20 under 35 U.S.C. 102(a)(1) as allegedly being anticipated by Hoffman et al. (US Pub. No. 20080311043; hereinafter “Hoffman”). Specifically, The Examiner alleges that Hoffman teaches treating psoriatic arthritis using antagonist to TNF- α intravenously.

It is well settled that “[a] claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference.” MPEP §2131 (quoting *Verdegaal Bros. v. Union Oil Co. of Calif.*, 2 USPQ2d 1051, 1053 (Fed. Cir. 1987)). “The identical invention must be shown in as complete detail as is contained in the . . . claim.” *Id.* (quoting *Richardson v. Suzuki Motor Co.*, 9 USPQ2d

1913, 1920 (Fed. Cir. 1989). Therefore, the cited reference must describe each and every element of claims in order to anticipate these claims under § 102(a)(1).

While not necessarily agreeing with the Examiner, but in an earnest effort to advance prosecution, Applicants have amended claim 11, upon which claim 13 depends, claim 14, upon which claim 16 depends, and claim 17, upon which claims 18 and 20 depend, to incorporate the subject matter of claims 12, 15, and 19, which were not rejected under § 102(a)(1), to recite wherein said antibody is administered at a dose of 2 mg/kg, over 30 ± 10 minutes, at Weeks 0 and 4, and then every 8 weeks (q8w) thereafter.

Applicants submit that Hoffman does not anticipate any of the present claims, as Hoffman does not teach each and every element of the present claims. For example, as noted by the Examiner, Hoffman does not teach the specific dosing regimen recited in the instant claims. Applicants further submit that Hoffman fails to teach the specific criteria recited in the present claims. For example, with respect to claim 11, Hoffman does not teach an average decrease in HAQ score of 0.6. Rather, Hoffman describes the efficacy of a TNF- α inhibitor in treating psoriatic arthritis determined by a decrease in HAQ on an average of 0.3, 0.4, or 0.5. Further, with respect to claim 14, Hoffman does not teach an improvement in van der Heijde-Sharp score (vdH-S) of 0.36. Finally, with respect to claim 17, Hoffman does not teach $\geq 65\%$ of patients receiving the treatment achieve ACR20 at week 14 of treatment.

Therefore, Applicants submit that Hoffman does not anticipate claims 11, 14, and 17, or dependent claims 13, 16, 18 and 20, because Hoffman does not teach each and every element of the present claims.

Rejection of claims 11-20 under 35 U.S.C. 103

The Examiner has rejected claims 11-20 under 35 U.S.C. 103 as allegedly being unpatentable over Hoffman in view of Doyle et al. (2013, Rheumatology, 52: 1214-1219; hereinafter “Doyle”). Specifically, the Examiner admits that Hoffman does not teach administering golimumab to a subject comprising administering 2mg/kg to a subject in need thereof but contends that Doyle teaches the administration of 2mg/kg golimumab intravenous infusion for 4 weeks and 12 weeks.

According to the U.S. Supreme Court ruling in *Graham v. John Deere*, 383 U.S. 1 (1960), in making a case for obviousness, the Examiner must 1) determine the scope and content of the prior art; 2) ascertain the differences between the prior art and the claims at issue; 3) resolve the level of ordinary skill in the pertinent art; and 4) evaluate evidence of secondary considerations. These principles have been reconfirmed by the Supreme Court in *KSR International Co. v. Teleflex Inc.*, 127 S.Ct. 1727 (2007).

In *KSR Int'l Co.*, the US Supreme Court restated the requirements for a finding of obviousness. Encouraging the application of common knowledge and common sense, the Court took care to guard against hindsight bias and *ex post* reasoning and to distinguish the predictable from the unpredictable arts (“If a person of ordinary skill can implement a predictable variation, §103 likely bars its patentability.” [Emphasis added]). Based on the combination of references set forth by the Examiner, Applicants assert that the rejection of the claims under §103 could only have been made with hindsight bias and *ex post* reasoning.

When applying 35 U.S.C. § 103, the following tenets of patent law must be followed: 1) the claimed invention must be considered as a whole; 2) the references must be considered as a whole; 3) the references must be viewed without the benefit of impermissible hindsight vision afforded by the claimed invention; and 4) reasonable expectation of success is the standard with which obviousness is determined (MPEP § 2141 II).

Cited art does not teach or suggest each and every element

Establishing a prima facie case of obviousness of a claimed invention “requires a suggestion of all limitations in a claim” in the prior art. 35 U.S.C. § 103(a); *CFMT, Inc. v. Yieldup Intern. Corp.*, 349 F.3d 1333, 1342 (Fed. Cir. 2003) (citing *In re Royka*, 490 F.2d 981, 985 (CCPA 1974); see also *In re Ochiai*, 71 F.3d 1565, 1572 (Fed. Cir. 1995). Therefore, in order to render the instant claims obvious under 35 U.S.C. §103(a), the cited prior art must teach or suggest each and every element of the claims.

While not necessarily agreeing with the Examiner, but in an earnest effort to advance prosecution, as an initial matter, Applicants have cancelled claims 12, 15, and 19 thereby rendering the rejection of these claims moot, and amended claim 11, upon which claim 13 depends, claim 14, upon which claim 16 depends, and claim 17, upon which claims 18 and

20 depend, to recite wherein said antibody is administered at a dose of 2 mg/kg, over 30 ± 10 minutes, at Weeks 0 and 4, and then every 8 weeks (q8w) thereafter.

Applicants submit that Hoffman and Doyle, alone or in combination with each other, do not teach or suggest that IV infusion of the composition at the recited dosing regimen to a subject having active psoriatic arthritis would result in a subject with active psoriatic arthritis achieving at week 14 a mean change from baseline in one or more criteria selected from the group consisting of: HAQ-DI = -0.60 ± 0.53 SD, enthesitis = -1.87 ± 1.75 SD, dactylitis = -7.8 ± 8.57 SD, SF-36 PCS = 8.65 ± 7.60 SD, and SF-36 MCS = 5.33 ± 9.95 SD, as recited in claim 11. Similarly, Applicants submit that Hoffman and Doyle, alone or in combination with each other, do not teach or suggest that IV infusion of the composition at the recited dosing regimen to a subject having active psoriatic arthritis would result in a subject with active psoriatic arthritis achieving at week 24 a mean change from baseline in vdH-S = -0.36 ± 0.144 SE, as recited in claim 14. Similarly, Applicants submit that Hoffman and Doyle, alone or in combination with each other, do not teach or suggest that IV infusion of the composition at the recited dosing regimen to a subject having active psoriatic arthritis would result in a $\sim 65\%$ of patients with psoriatic arthritis receiving the treatment achieving ACR20 at week 14 of treatment, as recited in claim 17. Finally, Applicants submit that Hoffman and Doyle, alone or in combination with each other, do not teach or suggest the dose and schedule recited in instant claims.

Cited art does not provide a reasonable expectation of success

Further, to establish a prima facie case of obviousness, a reference or combination of references must: (1) suggest to those of ordinary skill in the art that they should make the claimed invention, and (2) reveal to those of ordinary skill in the art that they would have a reasonable expectation of success. In re Vaeck, 20 USPQ2d 1438, 1442 (Fed. Cir. 1991). Both the suggestion and the reasonable expectation of success must be found in the prior art and not in the Applicant's disclosure. In re Dow Chemical Company, 5 USPQ2d 1529, 1531 (Fed. Cir. 1988). However, there is nothing in any of the cited references that would motivate one of ordinary skill in the art to combine the teachings of these references to produce the presently claimed invention.

“Reasonable expectation of success” is premised on predictability. In other words, to have a reasonable expectation of success, the ordinarily skilled artisan must be able to predict the likely outcome for an experiment. A direct corollary of this fact is that if one cannot predict the likely outcome for an experiment, one cannot have a reasonable expectation of success in achieving a given outcome. Indeed, the USPTO clearly recognizes the relationship between predictability and reasonable expectation of success. Specifically, MPEP 2143E articulates how to determine if a claim can be rejected on an “obvious-to-try” rationale using the following language:

Office personnel must articulate the following:

- (1) a finding that at the time of the invention, there had been a recognized problem or need in the art, which may include a design need or market pressure to solve a problem;
- (2) a finding that there had been a finite number of identified, **predictable potential solutions** to the recognized need or problem;
- (3) a finding that one of ordinary skill in the art could have pursued the known potential solutions with **a reasonable expectation of success**; and
- (4) whatever additional findings based on the Graham factual inquiries may be necessary, in view of the facts of the case under consideration, to explain a conclusion of obviousness. (emphasis added)

Thus, it is the ability to predict the outcome of a solution that underlies a reasonable expectation of success for pursuing that solution.

Applicants submit that Hoffman and Doyle do not provide a reasonable expectation of success at arriving at a method for treating psoriatic arthritis by administering to a subject having active psoriatic arthritis at the recited dosing regimen a composition comprising a safe and effective amount of at least one isolated mammalian anti-TNF- α antibody as described in claim 11, 14 and 17. Applicants submit that Hoffman does not teach the recited dosing regimen or any of the recited criteria of claims 11, 14 and 17, and therefore nothing in Hoffman provides a skilled artisan with any predictability that golimumab can be delivered by IV infusion at the recited dosing regimen to subjects with psoriatic arthritis wherein said treatment would achieve the recited criteria of claims 11, 14 and 17. Applicants submit that Doyle does not cure any of the deficiencies of Hoffman. Applicants submit that Doyle does not provide a skilled artisan with any predictability that golimumab can be delivered by IV

infusion at the recited dosing regimen to subjects with active psoriatic arthritis to treat psoriatic arthritis, much less that subjects with active psoriatic arthritis treated with IV golimumab would achieve the recited criteria of claims 11, 14 and 17. First, Applicants submit that Doyle does not describe the effects of IV golimumab on a subject with psoriatic arthritis. Second, Doyle describes the effect of subcutaneous and intravenous golimumab in treating rheumatoid arthritis. However, psoriatic arthritis and rheumatoid arthritis are completely different diseases, therefore a skilled person would not have any reasonable expectation that administration of IV infusion of golimumab at the recited dosing regimen to a subject with psoriatic arthritis would treat active psoriatic arthritis. Further, Doyle does not describe any clinical improvement from IV golimumab on any subject, let alone a subject with psoriatic arthritis. Third, Doyle describes a golimumab dosing schedule that is distinct from instant claims 11, 14, and 17. Applicants submit that a skilled artisan reading Doyle would not have any reasonable expectation that administration of IV golimumab at the recited dosing regimen could be used to effectively treat psoriatic arthritis and especially achieve the recited criteria of the present claims.

Secondary Considerations

Importantly, “secondary considerations” may include evidence of commercial success, long-felt but unsolved needs, failure of others, and unexpected results. Rebuttal evidence may also include evidence that the claimed invention yields unexpectedly improved properties or properties not present in the prior art. Rebuttal evidence may also include evidence that the claimed invention yields unexpectedly improved properties or properties not present in the prior art. See MPEP § 2145.

In *Crocs, Inc. v. U.S. Int’l Trade Commission*, 598 F.3d 1294 (Fed. Cir. 2010), the Federal Circuit reaffirmed the requirements for a finding of non-obviousness in view of “unexpected results.” Rejecting the proposition that a combination of prior art elements is per se obvious, the Federal Circuit held that a claimed combination of prior art elements is non-obvious when the combination yields “more than predictable results.” In *Crocs*, testimony on record indicated that the combined elements in the shoe reduced wearer discomfort in ways that were not suggested or contemplated by the prior art. The Federal

Circuit pointed out that this combination “yielded more than predictable results” and was thus patentable. *Id.* at 1310. This ruling affirmed prior holdings that inventions that have new and unexpected properties are patentable (*In re Papesch*, 315 F.2d 381, 387 (C.C.P.A. 1963)). The determination that the result is “unexpected” depends upon what a person of ordinary skill in the art would have predicted based upon the prior art (*Procter & Gamble Co. v. Teva Pharms. USA, Inc.*, 566 F.3d 989, 997-98 (Fed. Cir. 2009); *Pfizer, Inc. v. Apotex, Inc.*, 480 F.3d 1348, 1367 (Fed. Cir. 2007)). Consistently, under MPEP § 2143 A(3), merely pointing to the presence of all claim elements in the prior art is not a complete statement of a rejection for obviousness. In accordance with MPEP § 2143 A(3), a rejection based on the rationale that the claimed invention is a combination of prior art elements is improper if it does not include a finding that results flowing from the combination would have been predictable to a person of ordinary skill in the art. MPEP § 2143 A(3). If results from the invention would not have been predictable, an obviousness rejection using the combination of prior art elements rationale is improper.

Applicants submit that the presently claimed methods of administering to a subject having active psoriatic arthritis a composition comprising a safe and effective amount of at least one isolated mammalian anti-TNF- α antibody having the recited CDRs, wherein said composition is administered via IV infusion at the recited dosing regimen produces surprising and unexpected results that could not have been predicted by the combination of Hoffman and Doyle.

For example, it is demonstrated in the present application that IV golimumab demonstrated clinically meaningful and surprisingly significant improvements of disease activity and physical function, skin psoriasis clearance, reduction in dactylitis and enthesitis, HRQoL and inhibition of structural progression. It is shown in the present application that 75.1% of subjects having active psoriatic arthritis treated with IV golimumab achieved ACR20 by 14 weeks (see Table 8 of the present application). ACR20 is a well-accepted criterion defined as a 20% improvement in a variety of measures (e.g., swollen joint count, tender joint count, patient assessment of pain, patient global assessment of disease activity, physician global assessment of disease activity, patient assessment of physical function measured by HAQ-DI, and CRP). Applicants submit that such a high proportion of patients

achieving such an improvement defined by ACR20 as early as 14 weeks after initiation of treatment is unexpected and surprising. In contrast, the present application states that subcutaneous golimumab resulted in only 51% of psoriatic arthritis subjects achieving ACR20 by week 14 (see paragraph [324] of the originally filed specification). Applicants submit that the unexpected and surprising effects of the presently claimed methods could not have been expected by the teaching of Hoffman and Doyle.

For at least these reasons, Applicants submit that claims 11, 13, 14, 16-18, and 20 are not rendered obvious by the combination of Hoffman and Doyle. Applicants respectfully request reconsideration and withdrawal of the rejection.

Nonstatutory Double Patenting

The Examiner has rejected claims 11-20 on the ground of non-statutory double patenting as allegedly being unpatentable over claims 1-10 of U.S. Patent No. 11,041,020. In addition, the Examiner provisionally rejected claims 11-20 on the ground of non-statutory double patenting as allegedly being unpatentable over claims 8-13 of co-pending Application No. 17/423,512. The Examiner further provisionally rejected claims 11-20 on the ground of non-statutory double patenting as allegedly being unpatentable over claims 1-19 of co-pending Application No. 17/615,949.

Applicant respectfully requests that the present double patenting rejections be held in abeyance until there is an indication of allowability outside of the double patenting rejection.

Summary

Early consideration and allowance of the claims in the present application is requested at the earliest possible time.

Respectfully submitted,

Diane D. Harrison, ET AL.

December 8, 2023

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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
17/320,490	05/14/2021	Diane D. Harrison	206389-0003-02US	5386
171672	7590	02/22/2024	EXAMINER	
Riverside Law LLP/J&J			CHANDRA, GYAN	
175 Strafford Avenue				
Suite 100				
Wayne, PA 19087				
			ART UNIT	PAPER NUMBER
			1646	
			NOTIFICATION DATE	DELIVERY MODE
			02/22/2024	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

LMorozin@ITS.JNJ.COM
dcoccia@riversidelaw.com
dockets@riversidelaw.com

DETAILED ACTION

Notice of Pre-AIA or AIA Status

The present application, filed on or after March 16, 2013, is being examined under the first inventor to file provisions of the AIA.

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 12/8/2023 has been entered.

Status of Application, Amendments, And/Or Claims

The amendments of claims 11, 14 and 17 and the cancellation of claims 12, 15 and 19 have been made of record.

Claims 11, 13-14, 16-18 and 20 are pending and under examination.

Response to Arguments

Claim Rejections - 35 USC § 102-withdrawn

The rejection of claim(s) 11, 13, 14, 16, 17, 18 and 20 remain rejected under 35 U.S.C. 102(a)(1) as being anticipated by Hoffman et al (US Pub. No. 20080311043) in view of applicant's amendments of claims 11, 14 and 17 to incorporate the limitation of claim 12 in claim 11, claim 15 in claim 14, and claim 19 in claim 17.

Claim Rejections - 35 USC § 103-withdrawn

The rejection of claim(s) 11-20 are rejected under 35 U.S.C. 103 as being unpatentable over Hoffman et al (US Pub. No. 20080311043) in view of Doyle et al.

(Rheumatology 52: 1214-1219, 2013) is withdrawn in view of applicants' arguments that the administration of golimumab clinically shows surprising results in improving disease activity and physical function, skin psoriasis clearance, reduction in dactylitis and enthesitis, HRQoL and inhibition of structural progression. Additionally, they argue that 75.1% of subjects having active psoriasis arthritis treated with IV golimumab achieved ACR 20 by 14 weeks (Table 8) and that achieving ACR20 as early as 14 weeks after initiation of treatment is unexpected and surprising which is in contrast to only 51% psoriatic arthritis subject achieved ACR20 by week 14 (paragraph [324]). Therefore, the rejection is withdrawn.

Double Patenting-maintained

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on nonstatutory double patenting provided the reference application or patent either is shown to be commonly owned with the examined application, or claims an invention made as a

result of activities undertaken within the scope of a joint research agreement. See MPEP § 717.02 for applications subject to examination under the first inventor to file provisions of the AIA as explained in MPEP § 2159. See MPEP § 2146 *et seq.* for applications not subject to examination under the first inventor to file provisions of the AIA. A terminal disclaimer must be signed in compliance with 37 CFR 1.321(b).

The USPTO Internet website contains terminal disclaimer forms which may be used. Please visit www.uspto.gov/patent/patents-forms. The filing date of the application in which the form is filed determines what form (e.g., PTO/SB/25, PTO/SB/26, PTO/AIA/25, or PTO/AIA/26) should be used. A web-based eTerminal Disclaimer may be filled out completely online using web-screens. An eTerminal Disclaimer that meets all requirements is auto-processed and approved immediately upon submission. For more information about eTerminal Disclaimers, refer to www.uspto.gov/patents/process/file/efs/guidance/eTD-info-I.jsp.

Claims 11, 13-14, 16-18 and 20 remain rejected on the ground of nonstatutory double patenting as being unpatentable over claims 1-10 of U.S. Patent No. 11,041,020. Although the claims at issue are not identical, they are not patentably distinct from each other because a method for treating a tumor necrosis factor alpha (TNF- α) related condition, wherein the TNF- α related condition is active psoriatic arthritis, the method comprising: administering to a subject having active psoriatic arthritis a composition comprising a safe and effective amount of at least one isolated mammalian anti-TNF- α antibody comprising: a. a heavy chain (HC) complementary determining region (CDR) 1 comprising an amino acid sequence of SEQ ID NO: 1; b. a HC CDR2 comprising an amino acid sequence of SEQ ID NO: 2; wherein position 1 of

SEQ ID NO: 2 is phenylalanine, position 2 of SEQ ID NO: 2 is methionine, position 3 of SEQ ID NO: 2 is serine, position 4 of SEQ ID NO: 2 is tyrosine, position 10 of SEQ ID NO: 2 is lysine, position 11 of SEQ ID NO: 2 is tyrosine, and position 17 of SEQ ID NO: 2 is glycine; c. a HC CDR3 comprising an amino acid sequence of SEQ ID NO: 3; wherein position 4 of SEQ ID NO: 3 is isoleucine, position 5 of SEQ ID NO: 3 is alanine, and position 9 of SEQ ID NO: 3 is asparagine; d. a light chain (LC) CDR1 comprising an amino acid sequence of SEQ ID NO: 4; wherein position 7 of SEQ ID NO: 4 is tyrosine; e. a LC CDR2 comprising an amino acid sequence of SEQ ID NO: 5; and f. a LC CDR3 comprising an amino acid sequence of SEQ ID NO: 6, and at least one pharmaceutically acceptable carrier or diluent, wherein said composition is administered via intravenous (IV) infusion, and wherein at week 14 of treatment patients treated with the anti-TNF- α antibody achieve a mean change from baseline in one or more criteria selected from the group consisting of: Health Assessment Questionnaire Disability Index score (HAQ-DI) = -0.60 ± 0.53 SD, enthesitis = -1.87 ± 1.75 SD, dactylitis = -7.8 ± 8.57 SD, Short-Form Health Survey Physical Summary score (SF-36 PCS) = 8.65 ± 7.60 SD, and Short-Form Health Survey Mental Component Summary score (SF-36 MCS) = 5.33 ± 9.95 SD, wherein the composition is administered at 2 mg/kg to said subject and wherein the method further comprises administering said composition with or without methotrexate (MTX) are taught in claims 1-10 of US Pat. No. 11,041,020.

It is noted that the examiner has carefully reviewed the amino acid sequences of heavy chain (HC) SEQ ID NO: 36 which comprises HC CDR1-3 of SEQ ID NO: 1-3 and the amino acid sequence of light chain (LC) SEQ ID NO: 37 which comprises LC CDR1-3 of SEQ ID NO: 4-6 as being instantly claimed.

Applicants request that the present double patenting rejection be held in abeyance until remaining other rejections are withdrawn.

Applicants arguments have been fully considered but the rejection is maintained as applicants have not filed a TD to overcome with the instant rejection.

Claims 11, 13-14, 16-18 and 20 remain provisionally rejected on the ground of nonstatutory double patenting as being unpatentable over claims 8- 13 of copending Application No. 17/423,512 (reference application). Although the claims at issue are not identical, they are not patentably distinct from each other because a method for treating a tumor necrosis factor alpha (TNF-a) related condition, wherein the TNF-a related condition is active psoriatic arthritis, the method comprising: administering to a subject having active psoriatic arthritis a composition comprising a safe and effective amount of at least one isolated mammalian anti-TNF-a antibody comprising: a. a heavy chain (HC) complementary determining region (CDR) 1 comprising an amino acid sequence of SEQ ID NO: 1; b. a HC CDR2 comprising an amino acid sequence of SEQ ID NO: 2; wherein position 1 of SEQ ID NO: 2 is phenylalanine, position 2 of SEQ ID NO: 2 is methionine, position 3 of SEQ ID NO: 2 is serine, position 4 of SEQ ID NO: 2 is tyrosine, position 10 of SEQ ID NO: 2 is lysine, position 11 of SEQ ID NO: 2 is tyrosine, and position 17 of SEQ ID NO: 2 is glycine; c. a HC CDR3 comprising an amino acid sequence of SEQ ID NO: 3; wherein position 4 of SEQ ID NO: 3 is isoleucine, position 5 of SEQ ID NO: 3 is alanine, and position 9 of SEQ ID NO: 3 is asparagine; d. a light chain (LC) CDR1 comprising an amino acid sequence of SEQ ID NO: 4; wherein position 7 of SEQ ID NO: 4 is tyrosine; e. a LC CDR2 comprising an amino acid sequence of SEQ ID NO: 5; and f. a LC CDR3 comprising an amino acid sequence of

SEQ ID NO: 6, and at least one pharmaceutically acceptable carrier or diluent, wherein said composition is administered via intravenous (IV) infusion, and wherein at week 14 of treatment patients treated with the anti-TNF- α antibody achieve a mean change from baseline in one or more criteria selected from the group consisting of: Health Assessment Questionnaire Disability Index score (HAQ-DI) = -0.60 ± 0.53 SD, enthesitis = -1.87 ± 1.75 SD, dactylitis = -7.8 ± 8.57 SD, Short-Form Health Survey Physical Summary score (SF-36 PCS) = 8.65 ± 7.60 SD, and Short-Form Health Survey Mental Component Summary score (SF-36 MCS) = 5.33 ± 9.95 SD, wherein the composition is administered at 2 mg/kg to said subject and wherein the method further comprises administering said composition with or without methotrexate (MTX) are taught in claims 8-13 of US Application No. 17/423,512.

Applicants request that the present double patenting rejection be held in abeyance until remaining other rejections are withdrawn.

Applicants arguments have been fully considered but the rejection is maintained as applicants have not filed a TD to overcome with the instant rejection.

Claims 11, 13-14, 16-18 and 20 remain provisionally rejected on the ground of nonstatutory double patenting as being unpatentable over claims 1-19 of copending Application No. 17/615,949 (reference application). Although the claims at issue are not identical, they are not patentably distinct from each other because a method for treating a tumor necrosis factor alpha (TNF- α) related condition, wherein the TNF- α related condition is active psoriatic arthritis, the method comprising: administering to a subject having active psoriatic arthritis a composition comprising a safe and effective amount of at least one isolated mammalian anti-TNF- α antibody comprising: a. a heavy chain (HC)

complementary determining region (CDR) 1 comprising an amino acid sequence of SEQ ID NO: 1; b. a HC CDR2 comprising an amino acid sequence of SEQ ID NO: 2; wherein position 1 of SEQ ID NO: 2 is phenylalanine, position 2 of SEQ ID NO: 2 is methionine, position 3 of SEQ ID NO: 2 is serine, position 4 of SEQ ID NO: 2 is tyrosine, position 10 of SEQ ID NO: 2 is lysine, position 11 of SEQ ID NO: 2 is tyrosine, and position 17 of SEQ ID NO: 2 is glycine; c. a HC CDR3 comprising an amino acid sequence of SEQ ID NO: 3; wherein position 4 of SEQ ID NO: 3 is isoleucine, position 5 of SEQ ID NO: 3 is alanine, and position 9 of SEQ ID NO: 3 is asparagine; d. a light chain (LC) CDR1 comprising an amino acid sequence of SEQ ID NO: 4; wherein position 7 of SEQ ID NO: 4 is tyrosine; e. a LC CDR2 comprising an amino acid sequence of SEQ ID NO: 5; and f. a LC CDR3 comprising an amino acid sequence of SEQ ID NO: 6, and at least one pharmaceutically acceptable carrier or diluent, wherein said composition is administered via intravenous (IV) infusion, and wherein at week 14 of treatment patients treated with the anti-TNF- α antibody achieve a mean change from baseline in one or more criteria selected from the group consisting of: Health Assessment Questionnaire Disability Index score (HAQ-DI) = -0.60 ± 0.53 SD, enthesitis = -1.87 ± 1.75 SD, dactylitis = -7.8 ± 8.57 SD, Short-Form Health Survey Physical Summary score (SF-36 PCS) = 8.65 ± 7.60 SD, and Short-Form Health Survey Mental Component Summary score (SF-36 MCS) = 5.33 ± 9.95 SD, wherein the composition is administered at 2 mg/kg to said subject and wherein the method further comprises administering said composition with or without methotrexate (MTX) are taught in claims 1-19 of US Application No. 17/615,949.

Applicants request that the present double patenting rejection be held in abeyance until remaining other rejections are withdrawn.

Applicants arguments have been fully considered but the rejection is maintained as applicants have not filed a TD to overcome with the instant rejection.

Conclusion

No claim is allowed.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to GYAN CHANDRA whose telephone number is (571)272-2922. The examiner can normally be reached Mon-Friday 8:30AM-5:00P.

Examiner interviews are available via telephone, in-person, and video conferencing using a USPTO supplied web-based collaboration tool. To schedule an interview, applicant is encouraged to use the USPTO Automated Interview Request (AIR) at <http://www.uspto.gov/interviewpractice>.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Vanessa Ford can be reached on 571-272-0857. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of published or unpublished applications may be obtained from Patent Center. Unpublished application information in Patent Center is available to registered users. To file and manage patent submissions in Patent Center, visit: <https://patentcenter.uspto.gov>. Visit <https://www.uspto.gov/patents/apply/patent-center> for more information about Patent Center and <https://www.uspto.gov/patents/docx> for information about filing in DOCX format. For additional questions, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/GYAN CHANDRA/
Primary Examiner, Art Unit 1646

<i>Search Notes</i> 	Application/Control No. 17/320,490	Applicant(s)/Patent Under Reexamination Harrison et al.
	Examiner GYAN CHANDRA	Art Unit 1646

CPC - Searched*		
Symbol	Date	Examiner
C07K16/241	02/14/2024	gc
A61K2039/505	02/14/2024	gc
a61k9/0019	02/14/2024	gc

CPC Combination Sets - Searched*		
Symbol	Date	Examiner

US Classification - Searched*			
Class	Subclass	Date	Examiner
None	None	02/14/2024	gc

* See search history printout included with this form or the SEARCH NOTES box below to determine the scope of the search.

Search Notes		
Search Notes	Date	Examiner
STIC search for SEQ ID NOs: 1-6 (see search results in PE2E)	04/14/2023	gc
Claims searched in PE2E (see enclosed doc)	02/14/2024	gc
claims searched in Caplus, Biosis, Medline (see enclosed transcript)	02/14/2024	gc
Inventorship search in Caplus, Biosis medline (see enclosed transcript)	02/14/2024	gc
Inventorship search in PE2E	02/14/2024	gc
Inventorship search in PALM	02/14/2024	gc

/GYAN CHANDRA/ Primary Examiner, Art Unit 1646	
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<i>Search Notes</i> 	Application/Control No. 17/320,490	Applicant(s)/Patent Under Reexamination Harrison et al.
	Examiner GYAN CHANDRA	Art Unit 1646

Interference Search			
US Class/CPC Symbol	US Subclass/CPC Group	Date	Examiner

/GYAN CHANDRA/ Primary Examiner, Art Unit 1646	
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=> e Harrison Diane D/au

E1	1	HARRISON DIANA L/AU
E2	8	HARRISON DIANE/AU
E3	66 -->	HARRISON DIANE D/AU
E4	9	HARRISON DIANE DEBORAH/AU
E5	1	HARRISON DIANE J/AU
E6	6	HARRISON DIANNE/AU
E7	2	HARRISON DIANNE F/AU
E8	5	HARRISON DIANNE M/AU
E9	1	HARRISON DICK/AU
E10	4	HARRISON DION/AU
E11	21	HARRISON DION K/AU
E12	1	HARRISON DION KEVIN/AU

=> s e3

L1 66 "HARRISON DIANE D"/AU

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E15	225 -->	HSIA ELIZABETH C/AU
E16	1	HSIA EN CHIA/AU
E17	2	HSIA F T/AU
E18	3	HSIA F Y/AU
E19	4	HSIA FAN NI/AU
E20	1	HSIA FE TSCHENG/AU
E21	1	HSIA FEN HSU/AU
E22	27	HSIA FENG CHUN/AU
E23	1	HSIA FLORENCE/AU

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E24          1      HSIA FRANCES K/AU

=> s e15

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=> e Kim Lee-Lian/au

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E26          12     KIM LEE YUL/AU
E27          0 --> KIM LEE-LIAN/AU
E28          8      KIM LEEANN/AU
E29          2      KIM LEEHWA/AU
E30          38     KIM LEEHYEON/AU
E31          8      KIM LEEHYUNG/AU
E32          5      KIM LEEJEONG/AU
E33          1      KIM LEEJIN/AU
E34          1      KIM LEEJU/AU
E35          22     KIM LEEJUN/AU
E36          1      KIM LEEK BAE/AU

=> e kim lee lian/au

E37          3      KIM LEE KYOUNG/AU
E38          71     KIM LEE KYUNG/AU
E39          18 --> KIM LEE LIAN/AU
E40          2      KIM LEE M/AU
E41          4      KIM LEE M H/AU
E42          1      KIM LEE MIN/AU
E43          1      KIM LEE MYUNG/AU
E44          5      KIM LEE MYUNG H/AU
E45          3      KIM LEE NAM/AU
E46          6      KIM LEE OH/AU
E47          6      KIM LEE RANG/AU
E48          1      KIM LEE S U/AU

=> s e39

L3           18 "KIM LEE LIAN"/AU

=> e Lo Kim Hung/au

E49          1      LO KIM FLUNG/AU
E50          4      LO KIM H/AU
E51          106 --> LO KIM HUNG/AU
E52          11     LO KIM R/AU
E53          7      LO KIM SAN/AU
E54          2      LO KIM SING/AU
E55          8      LO KIMBERLY/AU
E56          3      LO KIMBERLY L/AU
E57          3      LO KIMBERLY S L/AU
E58          4      LO KIMBY/AU
E59          2      LO KIN/AU
E60          27     LO KIN CHEUNG/AU

=> s e51

L4           106 "LO KIM HUNG"/AU

=> s l1-4

L5           316 (L1 OR L2 OR L3 OR L4)

=> s golimumab

L6           6005 GOLIMUMAB

=> s l5 and l6

L7           177 L5 AND L6

=> s psoriatic arthritis

```

L8 35641 PSORIATIC ARTHRITIS

=> s l7 and l8

L9 52 L7 AND L8

=> s intravenous and infusion

L10 183395 INTRAVENOUS AND INFUSION

=> s l9 (1) l10

PROXIMITY OPERATOR LEVEL NOT CONSISTENT WITH
FIELD CODE - 'AND' OPERATOR ASSUMED 'L33 (L) L37'
PROXIMITY OPERATOR LEVEL NOT CONSISTENT WITH
FIELD CODE - 'AND' OPERATOR ASSUMED 'L34 (L) L38'
PROXIMITY OPERATOR LEVEL NOT CONSISTENT WITH
FIELD CODE - 'AND' OPERATOR ASSUMED 'L35 (L) L39'
L11 3 L9 (L) L10

=> dup rem l11

PROCESSING COMPLETED FOR L11

L12 3 DUP REM L11 (0 DUPLICATES REMOVED)

=> d l12 1-3 ti so py kwic ibib

L12 ANSWER 1 OF 3 MEDLINE @ on STN

TI Effects of Intravenous Golimumab on Health-Related Quality of Life in Patients With Psoriatic Arthritis: 24-Week Results of the GO-VIBRANT Trial.

SO Value in health : the journal of the International Society for Pharmacoeconomics and Outcomes Research, (20201000) Vol. 23, No. 10, pp. 1286-1291. Electronic Publication Date: 18 Sep 2020
Journal code: 100883818. E-ISSN: 1524-4733. L-ISSN: 1098-3015.

PY 2020

TI Effects of Intravenous Golimumab on Health-Related Quality of Life in Patients With Psoriatic Arthritis: 24-Week Results of the GO-VIBRANT Trial.

AU Peterson Steven; Li Nan; Kim Lilianne; Lo Kim Hung; Harrison Diane D

CS Janssen Research & Development, LLC, Spring House, PA, USA.

AU Hsia Elizabeth C

CS Janssen Research & Development, LLC, Spring House, PA, USA, University of Pennsylvania, Philadelphia, PA, USA.

AB OBJECTIVES: Evaluate the effects of intravenous golimumab 2 mg/kg on multiple domains of health-related quality of life (HRQoL) in adult patients with active psoriatic arthritis (PsA).

METHODS: In this phase III, randomized, double-blinded, placebo-controlled study, adults with active PsA were randomized in a 1:1 ratio to receive intravenous (IV) infusions of placebo (n = 239) or golimumab 2 mg/kg (n = 241) at weeks 0, 4, 12, and 20. Physical function was assessed using the Health Assessment. . . Functional Assessment of Chronic Illness Therapy (FACIT)-Fatigue, EQ VAS, and the Dermatology Life Quality Index (DLQI).

RESULTS: Patients in the golimumab group had greater mean changes from baseline in HAQ-DI compared with placebo at weeks 8 (-0.52 vs -0.10), 14 (-0.60. . . 1.2), EQ VAS (17.2 vs 3.7), FACIT-Fatigue (7.9 vs 2.0), and DLQI (-7.2 vs -1.7) were also greater in the golimumab group versus placebo at week 8 and were maintained or increased through week 24. Greater proportions of golimumab-treated patients had improvements greater than or equal to the minimal clinically important difference (MCID) for HAQ-DI, SF-36 PCS/MCS, EQ VAS, FACIT-Fatigue, and DLQI scores at weeks 14 and 24.

CONCLUSION: Improvements in HRQoL were greater in the IV golimumab group compared with placebo and were evident at week 8 and sustained through week 24.

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ST golimumab; physical function; psoriatic arthritis; quality of life
CT . . . use
Antibodies, Monoclonal: AD, administration & dosage
*Antibodies, Monoclonal: TU, therapeutic use
*Arthritis, Psoriatic: DT, drug therapy
Double-Blind Method
Humans
Infusions, Intravenous
Quality of Life
Surveys and Questionnaires
RN 476181-74-S (golimumab)
ACCESSION NUMBER: 2023091091 MEDLINE Full-text
DOCUMENT NUMBER: PubMed ID: 33032771
TITLE: Effects of Intravenous Golimumab on Health-Related
Quality of Life in Patients With Psoriatic Arthritis:
24-Week Results of the GO-VIBRANT Trial.
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SOURCE: Value in health : the journal of the International Society
for Pharmacoeconomics and Outcomes Research, (20201000)
Vol. 23, No. 10, pp. 1286-1291. Electronic Publication
Date: 18 Sep 2020
Journal code: 100883818. E-ISSN: 1524-4733. L-ISSN:
1098-3015.
DIGITAL OBJECT ID: <http://dx.doi.org/10.1016/j.jval.2020.06.007>
PUB. COUNTRY: United States
DOCUMENT TYPE: (CLINICAL TRIAL, PHASE III)
Journal; Article; (JOURNAL ARTICLE)
(MULTICENTER STUDY)
(RANDOMIZED CONTROLLED TRIAL)
(RESEARCH SUPPORT, NON-U.S. GOV'T)
(CLINICAL TRIAL)
(CONTROLLED CLINICAL TRIAL)
LANGUAGE: English
FILE SEGMENT: MEDLINE; Priority Journals
FILE SEGMENT: Print; Electronic
ENTRY MONTH: 202102
ENTRY DATE: Entered STN: 9 Oct 2020
Last Updated on STN: 21 Feb 2021
Indexing Added: 21 Feb 2021
Entered Medline: 19 Feb 2021
OS.CITING REF COUNT: 2 There are 2 MEDLINE records that cite this record
L12 ANSWER 2 OF 3 MEDLINE @ on STN
TI Inhibition of radiographic progression across levels of composite
index-defined disease activity in patients with active psoriatic
arthritis treated with intravenous golimumab: results from a
phase-3, double-blind, placebo-controlled trial.
SO Arthritis research & therapy, (20200306) Vol. 22, No. 1, pp. 43.
Electronic Publication Date: 6 Mar 2020
Journal code: 101154438. E-ISSN: 1478-6362. L-ISSN: 1478-6354.
Report No.: PMC-PMC7059340.
PY 2020
TI Inhibition of radiographic progression across levels of composite
index-defined disease activity in patients with active psoriatic
arthritis treated with intravenous golimumab: results from a
phase-3, double-blind, placebo-controlled trial.
AU Harrison Diane D; Lo Kim Hung; Xu Stephen; Hsia Elizabeth C
CS Janssen Research & Development, LLC, Spring House, PA, USA.

AU Hsia Elizabeth C
CS University of Pennsylvania, Philadelphia, PA, USA.
AB BACKGROUND: In the GO-VIBRANT trial of intravenous golimumab in psoriatic arthritis (PsA), golimumab significantly inhibited radiographic progression. In post hoc analyses, we evaluated changes in total PsA-modified Sharp/van der Heijde scores (SHS) across. . . index-defined disease activity following treatment.

METHODS: In this phase-3, double-blind, placebo-controlled trial, 480 bio-naïve patients with active PsA randomly received intravenous golimumab 2 mg/kg (N = 241; week 0, week 4, every 8 weeks [q8w]) or placebo (N = 239; week 0, week 4, week 12, week 20) followed by golimumab (week 24, week 28, q8w) through week 52. Week 24 and week 52 SHS changes in patient subgroups, defined by levels of disease activity as assessed by several composite measures (minimal disease activity [MDA], very low disease activity [VLDA], Psoriatic Arthritis Disease Activity Score [PASDAS], Disease Activity in Psoriatic Arthritis [DAPSA], Clinical Disease Activity Index [CDAI]), were evaluated post hoc in 474 patients with evaluable radiographic data. Partially (last-observation-carried-forward methodology) and completely (nonresponder methodology) missing data were imputed.

RESULTS: Across indices, golimumab-treated patients demonstrated less radiographic progression than placebo-treated patients, regardless of disease activity state achieved via golimumab, from week 0 to 24 (e.g., mean changes in PsA-modified SHS were - 0.83 vs. 0.91, respectively, in patients achieving. . . those not achieving MDA). Treatment differences observed at week 24 persisted through week 52, despite placebo-randomized patients crossing over to golimumab at week 24 (e.g., mean changes in PsA-modified SHS from week 0 to 52 for golimumab- vs. placebo→golimumab-treated patients achieving MDA were - 1.16 vs. 1.19, respectively) and regardless of whether low disease activity was achieved (0.03 vs.. . . PASDAS, DAPSA, and CDAI composite endpoints.

CONCLUSIONS: The extent of structural damage inhibition afforded by up to 1 year of intravenous golimumab treatment paralleled levels of PsA activity, with greater progression of structural damage observed in patients with sustained higher disease activity. Among patients not achieving low levels of disease activity across several composite indices, golimumab-randomized patients appeared to exhibit far less progression of structural damage than placebo-randomized PsA patients, illustrating a potential disconnect between responses, wherein golimumab can inhibit structural damage independent of clinical effect.

TRIAL REGISTRATION: ClinicalTrials.gov. NCT02181673. Registered 04 July 2014.

ST Anti-TNF therapy; Biologic therapy; Composite indices; Intravenous golimumab; Psoriatic arthritis; Radiographic progression

CT . . .
*Arthritis, Psoriatic: DT, drug therapy
Disease Progression
Double-Blind Method
Hand Joints: DG, diagnostic imaging
*Hand Joints: DE, drug effects
Humans
Infusions, Intravenous
Middle Aged
*Radiography: MT, methods
Severity of Illness Index
Treatment Outcome

RN 476181-74-5 (golimumab)

ACCESSION NUMBER: 2022206040 MEDLINE Full-text

DOCUMENT NUMBER: PubMed ID: 32143685

TITLE: Inhibition of radiographic progression across levels of composite index-defined disease activity in patients with active psoriatic arthritis treated with intravenous golimumab: results from a phase-3, double-blind, placebo-controlled trial.

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AUTHOR: Chakravarty Soumya D
CORPORATE SOURCE: Drexel University College of Medicine, Philadelphia, PA, USA.

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CORPORATE SOURCE: University of Pennsylvania, Philadelphia, PA, USA.
AUTHOR: Kavanaugh Arthur
CORPORATE SOURCE: University of California, San Diego, San Diego, CA, USA.
SOURCE: Arthritis research & therapy, (20200306) Vol. 22, No. 1, pp. 43. Electronic Publication Date: 6 Mar 2020
Journal code: 101154438. E-ISSN: 1478-6362. L-ISSN: 1478-6354.
Report No.: PMC-PMC7059340.

DIGITAL OBJECT ID: <http://dx.doi.org/10.1186/s13075-020-2126-1>
PUB. COUNTRY: England: United Kingdom
DOCUMENT TYPE: (CLINICAL TRIAL, PHASE III)
Journal; Article; (JOURNAL ARTICLE)
(MULTICENTER STUDY)
(RANDOMIZED CONTROLLED TRIAL)
(RESEARCH SUPPORT, NON-U.S. GOV'T)
(CLINICAL TRIAL)
(CONTROLLED CLINICAL TRIAL)

LANGUAGE: English
FILE SEGMENT: MEDLINE; Priority Journals
FILE SEGMENT: Electronic
FILE SEGMENT: CLINICALTRIALS.GOV
CLINICAL TRIAL NO.: NCT02181673
ENTRY MONTH: 202101
ENTRY DATE: Entered STN: 8 Mar 2020
Last Updated on STN: 12 Jan 2021
Indexing Added: 12 Jan 2021
Entered Medline: 11 Jan 2021

GRANT FUNDING ORG.: International Janssen Research and Development
GRANT FUNDING NUM.: n/a
OS.CITING REF COUNT: 2 There are 2 MEDLINE records that cite this record
MEDLINE REFERENCE COUNT: 37 There are 37 cited references available in MEDLINE for this document.

L12 ANSWER 3 OF 3 MEDLINE @ on STN
TI Safety and Efficacy of Intravenous Goleimumab in Patients With Active Psoriatic Arthritis: Results Through Week Twenty-Four of the GO-VIBRANT Study.
SO Arthritis & rheumatology (Hoboken, N.J.), (20171100) Vol. 69, No. 11, pp. 2151-2161.
Journal code: 101623795. E-ISSN: 2326-5205. L-ISSN: 2326-5191.
Report No.: PMC-PMC5765449.
PY 2017
TI Safety and Efficacy of Intravenous Goleimumab in Patients With Active Psoriatic Arthritis: Results Through Week Twenty-Four of the GO-VIBRANT Study.
AU Harrison Diane D; Kim Lillianne; Lo Kim Hung; Leu Jocelyn H
CS Janssen Research & Development, LLC, Spring House, Pennsylvania.
AU Hsia Elizabeth C
CS Janssen Research & Development, LLC, Spring House, Pennsylvania, and University of Pennsylvania, Philadelphia.
AB OBJECTIVE: To evaluate the safety and efficacy of intravenous (IV) golimumab treatment in psoriatic arthritis (PsA).

METHODS: In this phase III, randomized, double-blind, placebo-controlled trial, patients were randomly assigned to receive IV placebo (n = 239) or golimumab at 2 mg/kg (n = 241) at weeks 0, 4, 12, and 20. The primary end point was the proportion. . . modifications for patients with PsA.

RESULTS: At week 14, an ACR20 response was achieved by 75.1% of patients in the golimumab group compared with 21.8% of patients in the placebo

group (P < 0.001). Greater proportions of golimumab-treated patients had an ACR50 response (43.6% versus 6.3%), an ACR70 response (24.5% versus 2.1%), and a PASI75 response (59.2% versus 13.6%) at week 14 (P < 0.001 for all). Patients in the golimumab group had greater mean changes at week 14 in HAQ DI score (-0.60 versus -0.12; P < 0.001). At week 24, the mean change in total PSA-modified SHS was -0.4 in the golimumab group and 2.0 in the placebo group (P < 0.001). Through week 24, 40.6% of patients in the placebo group and 46.3% of patients in the golimumab group had ≥ 1 adverse event (AE); infections were the most common type.

CONCLUSION: Patients receiving IV golimumab at 2 mg/kg had significantly greater improvements in the signs and symptoms of PSA and less radiographic progression through week. . .

CT . . .
*Arthritis, Psoriatic: DT, drug therapy
Demyelinating Diseases: CI, chemically induced
Double-Blind Method
Drug Therapy, Combination
Glucocorticoids: TU, therapeutic use
Humans
Infusions, Intravenous
Methotrexate: TU, therapeutic use
Middle Aged
Neoplasms: CI, chemically induced
Opportunistic Infections: CI, chemically induced
Patient Reported Outcome. . .
RN 476181-74-5 (golimumab); 59-05-2 (Methotrexate)
ACCESSION NUMBER: 2018872692 MEDLINE Full-text
DOCUMENT NUMBER: PubMed ID: 28805045
TITLE: Safety and Efficacy of Intravenous Golimumab in Patients With Active Psoriatic Arthritis: Results Through Week Twenty-Four of the GO-VIBRANT Study.
AUTHOR: Kavanaugh Arthur
CORPORATE SOURCE: University of California at San Diego, La Jolla.
AUTHOR: Husni M Elaine
CORPORATE SOURCE: Cleveland Clinic, Cleveland, Ohio.
AUTHOR: Harrison Diane D; Kim Lillianne; Lo Kim Hung; Leu Jocelyn H
CORPORATE SOURCE: Janssen Research & Development, LLC, Spring House, Pennsylvania.
AUTHOR: Hsia Elizabeth C
CORPORATE SOURCE: Janssen Research & Development, LLC, Spring House, Pennsylvania, and University of Pennsylvania, Philadelphia.
SOURCE: Arthritis & rheumatology (Hoboken, N.J.), (20171100) Vol. 69, No. 11, pp. 2151-2161.
Journal code: 101623795. E-ISSN: 2326-5205. L-ISSN: 2326-5191.
Report No.: PMC-PMC5765449.
DIGITAL OBJECT ID: <http://dx.doi.org/10.1002/art.40226>
PUB. COUNTRY: United States
DOCUMENT TYPE: (CLINICAL TRIAL, PHASE III)
Journal; Article; (JOURNAL ARTICLE)
(MULTICENTER STUDY)
(RANDOMIZED CONTROLLED TRIAL)
(RESEARCH SUPPORT, NON-U.S. GOV'T)
(CLINICAL TRIAL)
(CONTROLLED CLINICAL TRIAL)
LANGUAGE: English
FILE SEGMENT: MEDLINE; Priority Journals
FILE SEGMENT: Print
FILE SEGMENT: CLINICALTRIALS.GOV
CLINICAL TRIAL NO.: NCT02181673
ENTRY MONTH: 201711
ENTRY DATE: Entered STN: 14 Aug 2017
Last Updated on STN: 7 Nov 2017
Indexing Added: 7 Nov 2017
Entered Medline: 6 Nov 2017
OS.CITING REF COUNT: 45 There are 45 MEDLINE records that cite this record
MEDLINE REFERENCE COUNT: 24 There are 24 cited references available in MEDLINE for this document.

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(FILE 'HOME' ENTERED AT 10:10:43 ON 14 FEB 2024)

FILE 'CAPLUS, BIOSIS, MEDLINE' ENTERED AT 10:11:00 ON 14 FEB 2024

		E HARRISON DIANE D/AU
L1	66	S E3
		E HSIA ELIZABETH C/AU
L2	225	S E15
		E KIM LEE-LIAN/AU
		E KIM LEE LIAN/AU
L3	18	S E39
		E LO KIM HUNG/AU
L4	106	S E51
L5	316	S L1-4
L6	6005	S GOLIMUMAB
L7	177	S L5 AND L6
L8	35641	S PSORIATIC ARTHRITIS
L9	52	S L7 AND L8
L10	183395	S INTRAVENOUS AND INFUSION
L11	3	S L9 (L) L10
L12	3	DUP REM L11 (0 DUPLICATES REMOVED)

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PE2E SEARCH - Search History (Prior Art)

Ref #	Hits	Search Query	DBs	Default Operator	Plurals	British Equivalents	Time Stamp
L67	1	17/320490	(US-PGPUB; USPAT; USOCR; FIT (AP, AT, AU, BE, BG, BR, BY, CA, CH, CN, CS, CU, CZ, DD, DE, DK, EA, EE, EP, ES, FI, FR, GB, HR, HU, ID, IE, IL, IS, IT, JP, KR, LT, LU, LV, MA, MC, MD, MY, NL, NO, NZ, OA, PH, PL, PT, RO, RS, RU, SE, SG, SI, SK, SU, TH, TN, TR, TW, UA, VN, WO); FPRS; EPO; JPO; DERWENT)	OR	ON	ON	2024/02/14 09:46 AM
L68	138	Harrison Diane D.in.	(US-PGPUB; USPAT; USOCR; FIT (AP, AT, AU, BE, BG, BR, BY, CA, CH, CN, CS, CU, CZ, DD, DE, DK, EA, EE, EP, ES, FI, FR, GB, HR, HU, ID, IE, IL, IS, IT, JP, KR, LT, LU, LV, MA, MC, MD, MY, NL, NO, NZ, OA, PH, PL, PT, RO, RS, RU, SE, SG, SI, SK, SU, TH, TN, TR, TW, UA, VN, WO); FPRS; EPO; JPO; DERWENT)	ADJ	ON	ON	2024/02/14 09:46 AM
L69	138	Harrison Diane D.inv.	(US-PGPUB; USPAT; USOCR; FIT (AP, AT, AU, BE, BG, BR, BY, CA, CH, CN, CS, CU, CZ, DD, DE, DK, EA, EE, EP, ES, FI, FR, GB, HR, HU, ID, IE, IL, IS, IT, JP, KR, LT, LU, LV, MA, MC, MD, MY, NL, NO, NZ, OA, PH, PL, PT, RO, RS, RU, SE, SG, SI, SK, SU, TH, TN, TR, TW, UA, VN, WO); FPRS; EPO; JPO; DERWENT)	ADJ	ON	ON	2024/02/14 09:46 AM
L70	76	Hsia Elizabeth C.in.	(US-PGPUB; USPAT; USOCR; FIT (AP, AT, AU, BE, BG, BR, BY, CA, CH, CN, CS, CU, CZ, DD, DE, DK, EA, EE, EP, ES, FI, FR, GB,	ADJ	ON	ON	2024/02/14 09:46 AM

L71	72	Kim Lee Lian.in.	HR, HU, ID, IE, IL, IS, IT, JP, KR, LT, LU, LV, MA, MC, MD, MY, NL, NO, NZ, OA, PH, PL, PT, RO, RS, RU, SE, SG, SI, SK, SU, TH, TN, TR, TW, UA, VN, WO); FPRS; EPO; JPO; DERWENT) (US-PGPUB; USPAT; USOCR; FIT (AP, AT, AU, BE, BG, BR, BY, CA, CH, CN, CS, CU, CZ, DD, DE, DK, EA, EE, EP, ES, FI, FR, GB, HR, HU, ID, IE, IL, IS, IT, JP, KR, LT, LU, LV, MA, MC, MD, MY, NL, NO, NZ, OA, PH, PL, PT, RO, RS, RU, SE, SG, SI, SK, SU, TH, TN, TR, TW, UA, VN, WO); FPRS; EPO; JPO; DERWENT)	ADJ	ON	ON	2024/02/14 09:46 AM
L72	70	Lo kim hung.in.	(US-PGPUB; USPAT; USOCR; FIT (AP, AT, AU, BE, BG, BR, BY, CA, CH, CN, CS, CU, CZ, DD, DE, DK, EA, EE, EP, ES, FI, FR, GB, HR, HU, ID, IE, IL, IS, IT, JP, KR, LT, LU, LV, MA, MC, MD, MY, NL, NO, NZ, OA, PH, PL, PT, RO, RS, RU, SE, SG, SI, SK, SU, TH, TN, TR, TW, UA, VN, WO); FPRS; EPO; JPO; DERWENT)	ADJ	ON	ON	2024/02/14 09:46 AM
L73	175	L2 OR L3 OR L4 OR L5 OR L6	(US-PGPUB; USPAT; USOCR; FIT (AP, AT, AU, BE, BG, BR, BY, CA, CH, CN, CS, CU, CZ, DD, DE, DK, EA, EE, EP, ES, FI, FR, GB, HR, HU, ID, IE, IL, IS, IT, JP, KR, LT, LU, LV, MA, MC, MD, MY, NL, NO, NZ, OA, PH, PL, PT, RO, RS, RU, SE, SG, SI, SK, SU, TH, TN, TR, TW, UA, VN, WO); FPRS; EPO; JPO; DERWENT)	ADJ	ON	ON	2024/02/14 09:46 AM
L74	57	L7 AND golimumab AND psoriat\$2 AND	(US-PGPUB; USPAT; USOCR; FIT (AP, AT,	ADJ	ON	ON	2024/02/14 09:46 AM

		arthritis	AU, BE, BG, BR, BY, CA, CH, CN, CS, CU, CZ, DD, DE, DK, EA, EE, EP, ES, FI, FR, GB, HR, HU, ID, IE, IL, IS, IT, JP, KR, LT, LU, LV, MA, MC, MD, MY, NL, NO, NZ, OA, PH, PL, PT, RO, RS, RU, SE, SG, SI, SK, SU, TH, TN, TR, TW, UA, VN, WO); FPRS; EPO; JPO; DERWENT)				
L75	56	L7 AND golimumab AND psoriatis AND arthritis AND intravenous	(US-PGPUB; USPAT; USOCR; FIT (AP, AT, AU, BE, BG, BR, BY, CA, CH, CN, CS, CU, CZ, DD, DE, DK, EA, EE, EP, ES, FI, FR, GB, HR, HU, ID, IE, IL, IS, IT, JP, KR, LT, LU, LV, MA, MC, MD, MY, NL, NO, NZ, OA, PH, PL, PT, RO, RS, RU, SE, SG, SI, SK, SU, TH, TN, TR, TW, UA, VN, WO); FPRS; EPO; JPO; DERWENT)	ADJ	ON	ON	2024/02/14 09:46 AM
L76	11033	golimumab AND psoriatis AND arthritis AND intravenous	(US-PGPUB; USPAT; USOCR; FIT (AP, AT, AU, BE, BG, BR, BY, CA, CH, CN, CS, CU, CZ, DD, DE, DK, EA, EE, EP, ES, FI, FR, GB, HR, HU, ID, IE, IL, IS, IT, JP, KR, LT, LU, LV, MA, MC, MD, MY, NL, NO, NZ, OA, PH, PL, PT, RO, RS, RU, SE, SG, SI, SK, SU, TH, TN, TR, TW, UA, VN, WO); FPRS; EPO; JPO; DERWENT)	ADJ	ON	ON	2024/02/14 09:46 AM
L77	1145	golimumab AND psoriatis AND arthritis AND intravenous.clm.	(US-PGPUB; USPAT; USOCR; FIT (AP, AT, AU, BE, BG, BR, BY, CA, CH, CN, CS, CU, CZ, DD, DE, DK, EA, EE, EP, ES, FI, FR, GB, HR, HU, ID, IE, IL, IS, IT, JP, KR, LT, LU, LV, MA, MC, MD, MY, NL, NO, NZ, OA, PH, PL, PT, RO, RS, RU, SE, SG, SI, SK, SU, TH, TN, TR, TW, UA, VN, WO); FPRS; EPO; JPO; DERWENT)	ADJ	ON	ON	2024/02/14 09:46 AM

L78	293	golimumab.clm. AND psoriatis AND arthritis AND intravenous.clm.	JPO; DERWENT) (US-PGPUB; USPAT; USOCR; FIT (AP, AT, AU, BE, BG, BR, BY, CA, CH, CN, CS, CU, CZ, DD, DE, DK, EA, EE, EP, ES, FI, FR, GB, HR, HU, ID, IE, IL, IS, IT, JP, KR, LT, LU, LV, MA, MC, MD, MY, NL, NO, NZ, OA, PH, PL, PT, RO, RS, RU, SE, SG, SI, SK, SU, TH, TN, TR, TW, UA, VN, WO); FPRS; EPO; JPO; DERWENT)	ADJ	ON	ON	2024/02/14 09:46 AM
L79	194	golimumab.clm. AND psoriatis AND arthritis.clm. AND intravenous.clm.	(US-PGPUB; USPAT; USOCR; FIT (AP, AT, AU, BE, BG, BR, BY, CA, CH, CN, CS, CU, CZ, DD, DE, DK, EA, EE, EP, ES, FI, FR, GB, HR, HU, ID, IE, IL, IS, IT, JP, KR, LT, LU, LV, MA, MC, MD, MY, NL, NO, NZ, OA, PH, PL, PT, RO, RS, RU, SE, SG, SI, SK, SU, TH, TN, TR, TW, UA, VN, WO); FPRS; EPO; JPO; DERWENT)	ADJ	ON	ON	2024/02/14 09:46 AM
L80	4	L13 AND SEQ ADJ ID ADJ No ADJ "37"	(US-PGPUB; USPAT; USOCR; FIT (AP, AT, AU, BE, BG, BR, BY, CA, CH, CN, CS, CU, CZ, DD, DE, DK, EA, EE, EP, ES, FI, FR, GB, HR, HU, ID, IE, IL, IS, IT, JP, KR, LT, LU, LV, MA, MC, MD, MY, NL, NO, NZ, OA, PH, PL, PT, RO, RS, RU, SE, SG, SI, SK, SU, TH, TN, TR, TW, UA, VN, WO); FPRS; EPO; JPO; DERWENT)	ADJ	ON	ON	2024/02/14 09:46 AM
L81	23812	C07K16/241.cpc.	(US-PGPUB; USPAT; USOCR; FIT (AP, AT, AU, BE, BG, BR, BY, CA, CH, CN, CS, CU, CZ, DD, DE, DK, EA, EE, EP, ES, FI, FR, GB, HR, HU, ID, IE, IL, IS, IT, JP, KR, LT, LU, LV, MA, MC, MD, MY, NL, NO, NZ, OA, PH, PL,	ADJ	ON	ON	2024/02/14 09:46 AM

L82	355030	A61K2039/505.cpc.	PT, RO, RS, RU, SE, SG, SI, SK, SU, TH, TN, TR, TW, UA, VN, WO); FPRS; EPO; JPO; DERWENT) (US-PGPUB; USPAT; USOCR; FIT (AP, AT, AU, BE, BG, BR, BY, CA, CH, CN, CS, CU, CZ, DD, DE, DK, EA, EE, EP, ES, FI, FR, GB, HR, HU, ID, IE, IL, IS, IT, JP, KR, LT, LU, LV, MA, MC, MD, MY, NL, NO, NZ, OA, PH, PL, PT, RO, RS, RU, SE, SG, SI, SK, SU, TH, TN, TR, TW, UA, VN, WO); FPRS; EPO; JPO; DERWENT)	ADJ	ON	ON	2024/02/14 09:46 AM
L83	280893	a61k9/0019.cpc.	(US-PGPUB; USPAT; USOCR; FIT (AP, AT, AU, BE, BG, BR, BY, CA, CH, CN, CS, CU, CZ, DD, DE, DK, EA, EE, EP, ES, FI, FR, GB, HR, HU, ID, IE, IL, IS, IT, JP, KR, LT, LU, LV, MA, MC, MD, MY, NL, NO, NZ, OA, PH, PL, PT, RO, RS, RU, SE, SG, SI, SK, SU, TH, TN, TR, TW, UA, VN, WO); FPRS; EPO; JPO; DERWENT)	ADJ	ON	ON	2024/02/14 09:46 AM
L84	11016	L15 AND L16	(US-PGPUB; USPAT; USOCR; FIT (AP, AT, AU, BE, BG, BR, BY, CA, CH, CN, CS, CU, CZ, DD, DE, DK, EA, EE, EP, ES, FI, FR, GB, HR, HU, ID, IE, IL, IS, IT, JP, KR, LT, LU, LV, MA, MC, MD, MY, NL, NO, NZ, OA, PH, PL, PT, RO, RS, RU, SE, SG, SI, SK, SU, TH, TN, TR, TW, UA, VN, WO); FPRS; EPO; JPO; DERWENT)	ADJ	ON	ON	2024/02/14 09:46 AM
L85	2961	L18 AND psoriatis\$2 AND arthritis	(US-PGPUB; USPAT; USOCR; FIT (AP, AT, AU, BE, BG, BR, BY, CA, CH, CN, CS, CU, CZ, DD, DE, DK, EA, EE, EP, ES, FI, FR, GB,	ADJ	ON	ON	2024/02/14 09:46 AM

L86	2842	L18 AND psoriatis\$2 ADJ arthritis	HR, HU, ID, IE, IL, IS, IT, JP, KR, LT, LU, LV, MA, MC, MD, MY, NL, NO, NZ, OA, PH, PL, PT, RO, RS, RU, SE, SG, SI, SK, SU, TH, TN, TR, TW, UA, VN, WO); FPRS; EPO; JPO; DERWENT) (US-PGPUB; USPAT; USOCR; FIT (AP, AT, AU, BE, BG, BR, BY, CA, CH, CN, CS, CU, CZ, DD, DE, DK, EA, EE, EP, ES, FI, FR, GB, HR, HU, ID, IE, IL, IS, IT, JP, KR, LT, LU, LV, MA, MC, MD, MY, NL, NO, NZ, OA, PH, PL, PT, RO, RS, RU, SE, SG, SI, SK, SU, TH, TN, TR, TW, UA, VN, WO); FPRS; EPO; JPO; DERWENT)	ADJ	ON	ON	2024/02/14 09:46 AM
L87	203	L18 AND psoriatis\$2 ADJ arthritis SAME intravenous AND antibod\$3	(US-PGPUB; USPAT; USOCR; FIT (AP, AT, AU, BE, BG, BR, BY, CA, CH, CN, CS, CU, CZ, DD, DE, DK, EA, EE, EP, ES, FI, FR, GB, HR, HU, ID, IE, IL, IS, IT, JP, KR, LT, LU, LV, MA, MC, MD, MY, NL, NO, NZ, OA, PH, PL, PT, RO, RS, RU, SE, SG, SI, SK, SU, TH, TN, TR, TW, UA, VN, WO); FPRS; EPO; JPO; DERWENT)	ADJ	ON	ON	2024/02/14 09:46 AM
L88	197	L21 AND TNF	(US-PGPUB; USPAT; USOCR; FIT (AP, AT, AU, BE, BG, BR, BY, CA, CH, CN, CS, CU, CZ, DD, DE, DK, EA, EE, EP, ES, FI, FR, GB, HR, HU, ID, IE, IL, IS, IT, JP, KR, LT, LU, LV, MA, MC, MD, MY, NL, NO, NZ, OA, PH, PL, PT, RO, RS, RU, SE, SG, SI, SK, SU, TH, TN, TR, TW, UA, VN, WO); FPRS; EPO; JPO; DERWENT)	ADJ	ON	ON	2024/02/14 09:46 AM
L89	0	L21 AND TNF AND SEQ ADJ ID ADJ No	(US-PGPUB; USPAT; USOCR; FIT (AP, AT,	ADJ	ON	ON	2024/02/14 09:46 AM

		ADJ "37"	AU, BE, BG, BR, BY, CA, CH, CN, CS, CU, CZ, DD, DE, DK, EA, EE, EP, ES, FI, FR, GB, HR, HU, ID, IE, IL, IS, IT, JP, KR, LT, LU, LV, MA, MC, MD, MY, NL, NO, NZ, OA, PH, PL, PT, RO, RS, RU, SE, SG, SI, SK, SU, TH, TN, TR, TW, UA, VN, WO); FPRS; EPO; JPO; DERWENT)				
L90	57	L21 AND TNF AND SEQ ADJ ID NEAR "37"	(US-PGPUB; USPAT; USOCR; FIT (AP, AT, AU, BE, BG, BR, BY, CA, CH, CN, CS, CU, CZ, DD, DE, DK, EA, EE, EP, ES, FI, FR, GB, HR, HU, ID, IE, IL, IS, IT, JP, KR, LT, LU, LV, MA, MC, MD, MY, NL, NO, NZ, OA, PH, PL, PT, RO, RS, RU, SE, SG, SI, SK, SU, TH, TN, TR, TW, UA, VN, WO); FPRS; EPO; JPO; DERWENT)	ADJ	ON	ON	2024/02/14 09:46 AM
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		"6017732" OR					
		"6037453" OR					
		"6060285" OR					
		"6106833" OR					
		"6132992" OR					
		"6180370" OR					
		"6190691" OR					

L92	4	"6193967" OR "6204023" OR "6210668" OR "6277969" OR "7521206" OR "7691378" OR "8241899" OR "9512065").pn. ("0000030" OR "0000059" OR "0000088" OR "0000116" OR "0000144" OR "20020168360" OR "20080311043" OR "20090028794" OR "20090214528" OR "20100266590" OR "3773919" OR "4239754" OR "4309989" OR "4399216" OR "4603106" OR "4634665" OR "4656134" OR "4668218" OR "4676980" OR "4683195" OR "4683202" OR "4704692" OR "4766067" OR "4767402" OR "4795699" OR "4800159" OR "4816567" OR "4822776" OR "4873316" OR "4889818" OR "4921794" OR "4925673" OR "4939666" OR "4946778" OR "4956288" OR "4965188" OR "4994370" OR "5066584" OR "5091310" OR "5122464" OR "5130238" OR "5142033" OR "5149636" OR "5168062" OR "5179017" OR "5223409" OR "5225538" OR "5225539" OR "5231024" OR	(US-PGPUB; USPAT)	ADJ	ON	ON	2024/02/14 09:46 AM
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		"5260203" OR "5266491" OR "5304489" OR "5342613" OR "5385839" OR "5403484" OR "5404871" OR "5427908" OR "5447851" OR "5455030" OR "5458135" OR "5496549" OR "5514670" OR "5518889" OR "5530101" OR "5534621" OR "5545806" OR "5545807" OR "5569825" OR "5571698" OR "5576195" OR "5580717" OR "5580734" OR "5582996" OR "5585089" OR "5595898" OR "5601819" OR "5618920" OR "5625126" OR "5625825" OR "5633425" OR "5637052" OR "5641670" OR "5643759" OR "5643768" OR "5654407" OR "5656272" OR "5656730" OR "5658570" OR "5658754" OR "5661016" OR "5693493" OR "5693762" OR "5698195" OR "5698417" OR "5698419" OR "5714352" OR "5723323" OR "5733746" OR "5733761" OR "5750105" OR "5750373" OR "5763192" OR "5763733" OR "5766886" OR "5767260" OR "5770198" OR "5770222" OR					
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L99	1	"9512065").pn. AND golimumab AND psoriatic ADJ arthritis AND intravenous AND methotrexate AND week\$1 AND acr20 ("0000030" OR "0000059" OR "0000088" OR "0000116" OR "0000144" OR "20020168360" OR "20080311043" OR "20090028794" OR "20090214528" OR "20100266590" OR "3773919" OR "4239754" OR "4309989" OR "4399216" OR "4603106" OR "4634665" OR "4656134" OR "4668218" OR "4676980" OR "4683195" OR "4683202" OR "4704692" OR "4766067" OR "4767402" OR "4795699" OR "4800159" OR "4816567" OR "4822776" OR "4873316" OR "4889818" OR "4921794" OR "4925673" OR "4939666" OR "4946778" OR "4956288" OR "4965188" OR "4994370" OR "5066584" OR "5091310" OR "5122464" OR "5130238" OR "5142033" OR "5149636" OR "5168062" OR "5179017" OR "5223409" OR "5225538" OR "5225539" OR "5231024" OR "5260203" OR "5266491" OR	(US-PGPUB; USPAT)	ADJ	ON	ON	2024/02/14 09:46 AM
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L101	138	Harrison Diane D.in.	IT, JP, KR, LT, LU, LV, MA, MC, MD, MY, NL, NO, NZ, OA, PH, PL, PT, RO, RS, RU, SE, SG, SI, SK, SU, TH, TN, TR, TW, UA, VN, WO); FPRS; EPO; JPO; DERWENT) (US-PGPUB; USPAT; USOCR; FIT (AP, AT, AU, BE, BG, BR, BY, CA, CH, CN, CS, CU, CZ, DD, DE, DK, EA, EE, EP, ES, FI, FR, GB, HR, HU, ID, IE, IL, IS, IT, JP, KR, LT, LU, LV, MA, MC, MD, MY, NL, NO, NZ, OA, PH, PL, PT, RO, RS, RU, SE, SG, SI, SK, SU, TH, TN, TR, TW, UA, VN, WO); FPRS; EPO; JPO; DERWENT)	ADJ	ON	ON	2024/02/14 09:46 AM
L102	138	Harrison Diane D.inv.	(US-PGPUB; USPAT; USOCR; FIT (AP, AT, AU, BE, BG, BR, BY, CA, CH, CN, CS, CU, CZ, DD, DE, DK, EA, EE, EP, ES, FI, FR, GB, HR, HU, ID, IE, IL, IS, IT, JP, KR, LT, LU, LV, MA, MC, MD, MY, NL, NO, NZ, OA, PH, PL, PT, RO, RS, RU, SE, SG, SI, SK, SU, TH, TN, TR, TW, UA, VN, WO); FPRS; EPO; JPO; DERWENT)	ADJ	ON	ON	2024/02/14 09:46 AM
L103	76	Hsia Elizabeth C.in.	(US-PGPUB; USPAT; USOCR; FIT (AP, AT, AU, BE, BG, BR, BY, CA, CH, CN, CS, CU, CZ, DD, DE, DK, EA, EE, EP, ES, FI, FR, GB, HR, HU, ID, IE, IL, IS, IT, JP, KR, LT, LU, LV, MA, MC, MD, MY, NL, NO, NZ, OA, PH, PL, PT, RO, RS, RU, SE, SG, SI, SK, SU, TH, TN, TR, TW, UA, VN, WO); FPRS; EPO; JPO; DERWENT)	ADJ	ON	ON	2024/02/14 09:46 AM
L104	72	Kim Lee Lian.in.	(US-PGPUB; USPAT; USOCR; FIT (AP, AT, AU, BE, BG, BR, BY,	ADJ	ON	ON	2024/02/14 09:46 AM

L105	70	Lo kim hung.in.	CA, CH, CN, CS, CU, CZ, DD, DE, DK, EA, EE, EP, ES, FI, FR, GB, HR, HU, ID, IE, IL, IS, IT, JP, KR, LT, LU, LV, MA, MC, MD, MY, NL, NO, NZ, OA, PH, PL, PT, RO, RS, RU, SE, SG, SI, SK, SU, TH, TN, TR, TW, UA, VN, WO); FPRS; EPO; JPO; DERWENT) (US-PGPUB; USPAT; USOCR; FIT (AP, AT, AU, BE, BG, BR, BY, CA, CH, CN, CS, CU, CZ, DD, DE, DK, EA, EE, EP, ES, FI, FR, GB, HR, HU, ID, IE, IL, IS, IT, JP, KR, LT, LU, LV, MA, MC, MD, MY, NL, NO, NZ, OA, PH, PL, PT, RO, RS, RU, SE, SG, SI, SK, SU, TH, TN, TR, TW, UA, VN, WO); FPRS; EPO; JPO; DERWENT)	ADJ	ON	ON	2024/02/14 09:46 AM
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PE2E SEARCH - Search History (Interference)

There are no Interference searches to show.

INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Not for submission under 37 CFR 1.99)	Application Number		17320490	
	Filing Date		2021-05-14	
	First Named Inventor	Elizabeth C. Hsia		
	Art Unit	1646		
	Examiner Name	CHANDRA, GYAN		
	Attorney Docket Number	206389-0003-02-US		

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Examiner Initial*	Cite No	Publication Number	Kind Code ¹	Publication Date	Name of Patentee or Applicant of cited Document	Pages, Columns, Lines where Relevant Passages or Relevant Figures Appear
	1	20030049725		2003-03-13	HEAVNER GEORGE	
	2	20070071747		2007-03-29	HOFFMAN REBECCA S	
	3	20110251099		2011-10-13	VISVANATHAN SUDHA	
	4	20160130340		2016-05-12	SMITH JEFFREY T L	

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**INFORMATION DISCLOSURE
STATEMENT BY APPLICANT**
(Not for submission under 37 CFR 1.99)

Application Number		17320490
Filing Date		2021-05-14
First Named Inventor	Elizabeth C. Hsia	
Art Unit	1646	
Examiner Name	CHANDRA, GYAN	
Attorney Docket Number	206389-0003-02-US	

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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, pages(s), volume-issue number(s), publisher, city and/or country where published.	T ⁵
	1	Kavanaugh A, McInnes I, Mease P, Krueger GG, Gladman D, Gomez-Reino J, Papp K, Zrubek J, Mudivarthi S, Mack M, Visvanathan S, Beutler A. Golimumab, a new human tumor necrosis factor alpha antibody, administered every four weeks as a subcutaneous injection in psoriatic arthritis: Twenty-four-week efficacy and safety results of a randomized, placebo-controlled study. Arthritis Rheum. 2009 Apr;60(4):976-86.	☐
	2	Marichal-Gallardo PA, Alvarez MM. State-of-the-art in downstream processing of monoclonal antibodies: process trends in design and validation. Biotechnol Prog. 2012 Jul;28(4):899-916.	☐
	3	Shu Rong et al., Golimumab: A New Drug Against Rheumatoid ArthritisChinese Journal of Pharmacoepidemiology, Volume 20, No. 01 (an English translation of the abstrast is appended) 2011	☐
	4	van der Heijde D, Deodhar A, Braun J, Mack M, Hsu B, Gathany TA, Inman RD, Han C; GO-RAISE investigators. The effect of golimumab therapy on disease activity and health-related quality of life in patients with ankylosing spondylitis: 2-year results of the GO-RAISE trial. J Rheumatol. 2014 Jun;41(6):1095-103.	☐
	5	Zhuang Y, Xu Z, Frederick B, de Vries DE, Ford JA, Keen M, Doyle MK, Petty KJ, Davis HM, Zhou H. Golimumab pharmacokinetics after repeated subcutaneous and intravenous administrations in patients with rheumatoid arthritis and the effect of concomitant methotrexate: an open-label, randomized study. Clin Ther. 2012 Jan;34(1):77-90.	☐
	6	Zidi I, Bouaziz A, Mnif W, Bartegi A, Al-Hizab FA, Amor NB. Golimumab therapy of rheumatoid arthritis: an overview. Scand J Immunol. 2010 Aug;72(2):75-85.	☐

If you wish to add additional non-patent literature document citation information please click the Add button

EXAMINER SIGNATURE

Examiner Signature		Date Considered	
--------------------	--	-----------------	--

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through a citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

**INFORMATION DISCLOSURE
STATEMENT BY APPLICANT**
(Not for submission under 37 CFR 1.99)

Application Number	17320490
Filing Date	2021-05-14
First Named Inventor	Elizabeth C. Hsia
Art Unit	1646
Examiner Name	CHANDRA, GYAN
Attorney Docket Number	206389-0003-02-US

¹ See Kind Codes of USPTO Patent Documents at www.USPTO.GOV or MPEP 901.04. ² Enter office that issued the document, by the two-letter code (WIPO Standard ST.3). ³ For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. ⁴ Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST.16 if possible. ⁵ Applicant is to place a check mark here if English language translation is attached.

**INFORMATION DISCLOSURE
STATEMENT BY APPLICANT**
(Not for submission under 37 CFR 1.99)

Application Number	17320490
Filing Date	2021-05-14
First Named Inventor	Elizabeth C. Hsia
Art Unit	1646
Examiner Name	CHANDRA, GYAN
Attorney Docket Number	206389-0003-02-US

CERTIFICATION STATEMENT

Please see 37 CFR 1.97 and 1.98 to make the appropriate selection(s):

- ☐ That each item of information contained in the information disclosure statement was first cited in any communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing of the information disclosure statement. See 37 CFR 1.97(e)(1).

OR

- ☐ That no item of information contained in the information disclosure statement was cited in a communication from a foreign patent office in a counterpart foreign application, and, to the knowledge of the person signing the certification after making reasonable inquiry, no item of information contained in the information disclosure statement was known to any individual designated in 37 CFR 1.56(c) more than three months prior to the filing of the information disclosure statement. See 37 CFR 1.97(e)(2).

- ☐ See attached certification statement.
- ☐ The fee set forth in 37 CFR 1.17 (p) has been submitted herewith.
- ☒ A certification statement is not submitted herewith.

SIGNATURE

A signature of the applicant or representative is required in accordance with CFR 1.33, 10.18. Please see CFR 1.4(d) for the form of the signature.

Signature	/Pallab Singh/	Date (YYYY-MM-DD)	2024-05-22
Name/Print	Pallab Singh	Registration Number	70731

This collection of information is required by 37 CFR 1.97 and 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 1 hour to complete, including gathering, preparing and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. **SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.**

Privacy Act Statement

The Privacy Act of 1974 (P.L. 93-579) requires that you be given certain information in connection with your submission of the attached form related to a patent application or patent. Accordingly, pursuant to the requirements of the Act, please be advised that: (1) the general authority for the collection of this information is 35 U.S.C. 2(b)(2); (2) furnishing of the information solicited is voluntary; and (3) the principal purpose for which the information is used by the U.S. Patent and Trademark Office is to process and/or examine your submission related to a patent application or patent. If you do not furnish the requested information, the U.S. Patent and Trademark Office may not be able to process and/or examine your submission, which may result in termination of proceedings or abandonment of the application or expiration of the patent.

The information provided by you in this form will be subject to the following routine uses:

1. The information on this form will be treated confidentially to the extent allowed under the Freedom of Information Act (5 U.S.C. 552) and the Privacy Act (5 U.S.C. 552a). Records from this system of records may be disclosed to the Department of Justice to determine whether the Freedom of Information Act requires disclosure of these records.
2. A record from this system of records may be disclosed, as a routine use, in the course of presenting evidence to a court, magistrate, or administrative tribunal, including disclosures to opposing counsel in the course of settlement negotiations.
3. A record in this system of records may be disclosed, as a routine use, to a Member of Congress submitting a request involving an individual, to whom the record pertains, when the individual has requested assistance from the Member with respect to the subject matter of the record.
4. A record in this system of records may be disclosed, as a routine use, to a contractor of the Agency having need for the information in order to perform a contract. Recipients of information shall be required to comply with the requirements of the Privacy Act of 1974, as amended, pursuant to 5 U.S.C. 552a(m).
5. A record related to an International Application filed under the Patent Cooperation Treaty in this system of records may be disclosed, as a routine use, to the International Bureau of the World Intellectual Property Organization, pursuant to the Patent Cooperation Treaty.
6. A record in this system of records may be disclosed, as a routine use, to another federal agency for purposes of National Security review (35 U.S.C. 181) and for review pursuant to the Atomic Energy Act (42 U.S.C. 218(c)).
7. A record from this system of records may be disclosed, as a routine use, to the Administrator, General Services, or his/her designee, during an inspection of records conducted by GSA as part of that agency's responsibility to recommend improvements in records management practices and programs, under authority of 44 U.S.C. 2904 and 2906. Such disclosure shall be made in accordance with the GSA regulations governing inspection of records for this purpose, and any other relevant (i.e., GSA or Commerce) directive. Such disclosure shall not be used to make determinations about individuals.
8. A record from this system of records may be disclosed, as a routine use, to the public after either publication of the application pursuant to 35 U.S.C. 122(b) or issuance of a patent pursuant to 35 U.S.C. 151. Further, a record may be disclosed, subject to the limitations of 37 CFR 1.14, as a routine use, to the public if the record was filed in an application which became abandoned or in which the proceedings were terminated and which application is referenced by either a published application, an application open to public inspections or an issued patent.
9. A record from this system of records may be disclosed, as a routine use, to a Federal, State, or local law enforcement agency, if the USPTO becomes aware of a violation or potential violation of law or regulation.

REQUEST FOR CONTINUED EXAMINATION(RCE)TRANSMITTAL (Submitted Only via EFS-Web)

Application Number	17/320,490	Filing Date	2021-05-14	Docket Number (if applicable)	206389-0003-02US	Art Unit	1646
First Named Inventor	Diane D. Harrison			Examiner Name	Chandra, Gyan		

This is a Request for Continued Examination (RCE) under 37 CFR 1.114 of the above-identified application.

Request for Continued Examination (RCE) practice under 37 CFR 1.114 does not apply to any utility or plant application filed prior to June 8, 1995, or to any design application. The Instruction Sheet for this form is located at WWW.USPTO.GOV

SUBMISSION REQUIRED UNDER 37 CFR 1.114

Note: If the RCE is proper, any previously filed unentered amendments and amendments enclosed with the RCE will be entered in the order in which they were filed unless applicant instructs otherwise. If applicant does not wish to have any previously filed unentered amendment(s) entered, applicant must request non-entry of such amendment(s).

☐ Previously submitted. If a final Office action is outstanding, any amendments filed after the final Office action may be considered as a submission even if this box is not checked.

☐ Consider the arguments in the Appeal Brief or Reply Brief previously filed on _____

☐ Other _____

☒ Enclosed

☒ Amendment/Reply

☐ Information Disclosure Statement (IDS)

☐ Affidavit(s)/ Declaration(s)

☐ Other _____

MISCELLANEOUS

☐ Suspension of action on the above-identified application is requested under 37 CFR 1.103(c) for a period of months _____
(Period of suspension shall not exceed 3 months; Fee under 37 CFR 1.17(i) required)

☐ Other _____

FEES

The RCE fee under 37 CFR 1.17(e) is required by 37 CFR 1.114 when the RCE is filed.

☒ The Director is hereby authorized to charge any underpayment of fees, or credit any overpayments, to
Deposit Account No 505366

SIGNATURE OF APPLICANT, ATTORNEY, OR AGENT REQUIRED

☒ Patent Practitioner Signature

☐ Applicant Signature

Signature of Registered U.S. Patent Practitioner			
Signature	/Pallab Singh/	Date (YYYY-MM-DD)	2024-05-22
Name	Pallab Singh	Registration Number	70731

This collection of information is required by 37 CFR 1.114. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.11 and 1.14. This collection is estimated to take 12 minutes to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450.

If you need assistance in completing the form, call 1-800-PTO-9199 and select option 2.

Privacy Act Statement

The Privacy Act of 1974 (P.L. 93-579) requires that you be given certain information in connection with your submission of the attached form related to a patent application or patent. Accordingly, pursuant to the requirements of the Act, please be advised that: (1) the general authority for the collection of this information is 35 U.S.C. 2(b)(2); (2) furnishing of the information solicited is voluntary; and (3) the principal purpose for which the information is used by the U.S. Patent and Trademark Office is to process and/or examine your submission related to a patent application or patent. If you do not furnish the requested information, the U.S. Patent and Trademark Office may not be able to process and/or examine your submission, which may result in termination of proceedings or abandonment of the application or expiration of the patent.

The information provided by you in this form will be subject to the following routine uses:

1. The information on this form will be treated confidentially to the extent allowed under the Freedom of Information Act (5 U.S.C. 552) and the Privacy Act (5 U.S.C. 552a). Records from this system of records may be disclosed to the Department of Justice to determine whether the Freedom of Information Act requires disclosure of these records.
2. A record from this system of records may be disclosed, as a routine use, in the course of presenting evidence to a court, magistrate, or administrative tribunal, including disclosures to opposing counsel in the course of settlement negotiations.
3. A record in this system of records may be disclosed, as a routine use, to a Member of Congress submitting a request involving an individual, to whom the record pertains, when the individual has requested assistance from the Member with respect to the subject matter of the record.
4. A record in this system of records may be disclosed, as a routine use, to a contractor of the Agency having need for the information in order to perform a contract. Recipients of information shall be required to comply with the requirements of the Privacy Act of 1974, as amended, pursuant to 5 U.S.C. 552a(m).
5. A record related to an International Application filed under the Patent Cooperation Treaty in this system of records may be disclosed, as a routine use, to the International Bureau of the World Intellectual Property Organization, pursuant to the Patent Cooperation Treaty.
6. A record in this system of records may be disclosed, as a routine use, to another federal agency for purposes of National Security review (35 U.S.C. 181) and for review pursuant to the Atomic Energy Act (42 U.S.C. 218(c)).
7. A record from this system of records may be disclosed, as a routine use, to the Administrator, General Services, or his/her designee, during an inspection of records conducted by GSA as part of that agency's responsibility to recommend improvements in records management practices and programs, under authority of 44 U.S.C. 2904 and 2906. Such disclosure shall be made in accordance with the GSA regulations governing inspection of records for this purpose, and any other relevant (i.e., GSA or Commerce) directive. Such disclosure shall not be used to make determinations about individuals.
8. A record from this system of records may be disclosed, as a routine use, to the public after either publication of the application pursuant to 35 U.S.C. 122(b) or issuance of a patent pursuant to 35 U.S.C. 151. Further, a record may be disclosed, subject to the limitations of 37 CFR 1.14, as a routine use, to the public if the record was filed in an application which became abandoned or in which the proceedings were terminated and which application is referenced by either a published application, an application open to public inspections or an issued patent.
9. A record from this system of records may be disclosed, as a routine use, to a Federal, State, or local law enforcement agency, if the USPTO becomes aware of a violation or potential violation of law or regulation.

Response to Final Office Action mailed February 22, 2024
U.S. Patent Application No. 17/320,490
Attorney Docket No. 206389-0003-02US

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Patent Application of:
Diane D. Harrison, et al.

Art Unit: 1646
Confirmation No.: 5386

Application No.:
17/320,490

Examiner:
Chandra, Gyan

Filing date:
May 14, 2021

Atty Docket No.:
206389-0003-02US

Title: ANTI-TNF ANTIBODIES, COMPOSITIONS, AND METHODS FOR THE
TREATMENT OF ACTIVE PSORIATIC ARTHRITIS

AMENDMENT

This Amendment is responsive to the Final Office Action mailed on February 22, 2024 in connection with the above-referenced application. This Amendment is timely filed in view of the deadline for a timely response to and through May 22, 2024.

This Response is accompanied by a Request for Continued Examination (and associated fee).

This Amendment is accompanied by a Terminal Disclaimer, and the associated fee.

No other fee is believed due for filing of this response. Please charge any additional fee that is due, and credit any overpayment, to deposit account no. 50-5366.

REMARKS

Claims 11, 13, 14, 16-18, and 20 are pending and under consideration.

Withdrawn rejections

Applicant acknowledges and thanks the Examiner for the withdrawal of the rejection of claims 11, 13, 14, 16, 17, 18, and 20 under 35 U.S.C. 102(a)(1) and claims 11-20 under 35 U.S.C. 103.

Claim amendments

Claim 20 has been amended to correct a typographical error.

No new matter has been added by way of this amendment.

Nonstatutory Double Patenting

The Examiner has rejected claims 11, 13, 14, 16-18, and 20 on the ground of nonstatutory double patenting as allegedly being unpatentable over claims 1-10 of U.S. Patent No. 11,041,020. Specifically, the Examiner alleges that the amino acid sequences of heavy chain (HC) SEQ ID NO: 36 which comprises HC CDR1-3 of SEQ ID NO: 1-3 and the amino acid sequence of light chain (LC) SEQ ID NO: 37 which comprises LC CDR1-3 of SEQ ID NO: 4-6 are instantly claimed.

While not necessarily agreeing with the Examiner, but rather in an earnest effort to advance prosecution, Applicant understands that a timely filed Terminal Disclaimer in compliance with 37 C.F.R. § 1.321(c) may be used to overcome such a nonstatutory double patenting rejection. Accordingly, Applicant is filing the appropriate Terminal Disclaimer herewith.

In addition, the Examiner provisionally rejected claims 11, 13, 14, 16-18, and 20 on the ground of nonstatutory double patenting as allegedly being unpatentable over claims 8-13 of co-pending Application No. 17/423,512. Lastly, the Examiner provisionally rejected claims 11, 13, 14, 16-18, and 20 on the ground of nonstatutory double patenting as allegedly being unpatentable over claims 1-19 of co-pending Application No. 17/615,949.

MPEP § 804(I)(B)(1)(b) provides that, in cases where the provisional nonstatutory double patenting rejection is the only rejection remaining in an application and the application under examination has the earliest effective U.S. filing date, then the examiner should withdraw the rejection in the application having the earliest effective U.S. filing date and permit that application to issue as a patent.

Applicant respectfully submits that that the present application has an effective filing date of November 20, 2017, which pre-dates the effective filing date of Application No. 17/423,512 and Application No. 17/615,949, and thus respectfully requests that this rejection on the ground of nonstatutory provisional double patenting be withdrawn.

Therefore, Applicant submits that the double patenting rejections have been overcome.

Summary

Early consideration and allowance of the claims in the present application is requested at the earliest possible time.

Respectfully submitted,

Diane D. Harrison, ET AL.

May 22, 2024

By: /Pallab Singh/
Pallab Singh, Ph.D., J.D.
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**UNITED STATES
PATENT AND TRADEMARK OFFICE**

Commissioner for Patents
United States Patent and Trademark Office
P.O. Box 1450
Alexandria, VA 22313 - 1450
www.uspto.gov

APPROVAL LETTER

APPLICATION #
17/320,490

FILING DATE
05/14/2021

APPLICANT/PATENT UNDER REEXAMINATION
Diane Harrison

Title of Invention

ANTI-TNF ANTIBODIES, COMPOSITIONS, AND METHODS FOR THE TREATMENT OF ACTIVE
ANKYLOSING SPONDYLITIS

Electronic terminal disclaimer filed on 05/22/2024



Approved

This patent is subject to a Terminal Disclaimer

Approved / Disapproved by: Electronic Terminal Disclaimer automatically approved



UNITED STATES
PATENT AND TRADEMARK OFFICE

P.O. Box 1450
Alexandria, VA 22313 - 1450
www.uspto.gov

TERMINAL DISCLAIMER TO OBVIATE A DOUBLE PATENTING REJECTION OVER A PRIOR PATENT

APPLICATION #
17320490

FILING DATE
05/14/2021

FIRST NAMED INVENTOR
Diane Harrison

ATTORNEY DOCKET #
206389-0003-02US

Title of Invention

ANTI-TNF ANTIBODIES, COMPOSITIONS, AND METHODS FOR THE TREATMENT OF ACTIVE
ANKYLOSING SPONDYLITIS



Filing of terminal disclaimer does not obviate requirement for response under 37 CFR 1.111 to outstanding
Office Action



This electronic Terminal Disclaimer is not being used for a Joint Research Agreement.

Owner	Percent Interest
Janssen Biotech, Inc.	100%
Total	100%

The owner(s) of percent interest listed above in the instant application hereby disclaims, except as provided below, the terminal part of the statutory term of any patent granted on the instant application which would extend beyond the expiration date of the full statutory term of any patent granted on pending reference Application Number(s)

Application #	Filing Date
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as the term of any patent granted on said reference application may be shortened by any terminal disclaimer filed prior to the grant of any patent on the pending reference application. The owner hereby agrees that any patent so granted on the instant application shall be enforceable only for and during such period that it and any patent

granted on the reference application are commonly owned. This agreement runs with any patent granted on the instant application and is binding upon the grantee, its successors or assigns.

In making the above disclaimer, the owner does not disclaim the terminal part of any patent granted on the instant application that would extend to the expiration date of the full statutory term of any patent granted on said reference application, "as the term of any patent granted on said reference application may be shortened by any terminal disclaimer filed prior to the grant of any patent on the pending reference application," in the event that any such patent granted on the pending reference application: expires for failure to pay a maintenance fee, is held unenforceable, is found invalid by a court of competent jurisdiction, is statutorily disclaimed in whole or terminally disclaimed under 37 CFR 1.321, has all claims canceled by a reexamination certificate, is reissued, or is in any manner terminated prior to the expiration of its full statutory term as shortened by any terminal disclaimer filed prior to its grant.

The owner(s) of percent interest listed above in the instant application hereby disclaims, except as provided below, the terminal part of the statutory term of any patent granted on the instant application which would extend beyond the expiration date of the full statutory term of prior patent number(s)

Patent #

11041020

as the term of said prior patent is presently shortened by any terminal disclaimer. The owner hereby agrees that any patent so granted on the instant application shall be enforceable only for and during such period that it and the prior patent are commonly owned. This agreement runs with any patent granted on the instant application and is binding upon the grantee, its successors or assigns.

In making the above disclaimer, the owner does not disclaim the terminal part of the term of any patent granted on the instant application that would extend to the expiration date of the full statutory term of the prior patent, "as the term of said prior patent is presently shortened by any terminal disclaimer," in the event that said prior patent later:

- expires for failure to pay a maintenance fee;
- is held unenforceable;
- is found invalid by a court of competent jurisdiction;
- is statutorily disclaimed in whole or terminally disclaimed under 37 CFR 1.321;
- has all claims canceled by a reexamination certificate;
- is reissued; or
- is in any manner terminated prior to the expiration of its full statutory term as presently shortened by any terminal disclaimer.



Terminal disclaimer fee under 37 CFR 1.20(d) included with Electronic Terminal Disclaimer request.

Applicant claims the following entity status:

Regular Undiscounted

I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of the application or any patent issued thereon.

I certify, in accordance with 37 CFR 1.4(d)(4) that I am: An attorney or agent registered to practice before the Patent and Trademark Office who is of record in this application

Signature	Name	Registration #
/Pallab Singh/	Pallab Singh	70731

* Statement under 37 CFR 3.73(b) is required if terminal disclaimer is signed by the assignee (owner). Form PTO/SB/96 may be used for making this certification. See MPEP 324.



NOTICE OF ALLOWANCE AND FEE(S) DUE

171672 7590 06/20/2024
Riverside Law LLP/J&J
175 Strafford Avenue
Suite 100
Wayne, PA 19087

EXAMINER

CHANDRA, GYAN

ART UNIT

PAPER NUMBER

1646

DATE MAILED: 06/20/2024

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
17/320,490	05/14/2021	Diane D. Harrison	206389-0003-02US	5386

TITLE OF INVENTION: ANTI-TNF ANTIBODIES, COMPOSITIONS, AND METHODS FOR THE TREATMENT OF ACTIVE ANKYLOSING SPONDYLITIS

APPLN. TYPE	ENTITY STATUS	ISSUE FEE DUE	PUBLICATION FEE DUE	PREV. PAID ISSUE FEE	TOTAL FEE(S) DUE	DATE DUE
nonprovisional	UNDISCOUNTED	\$1200	\$0.00	\$0.00	\$1200	09/20/2024

THE APPLICATION IDENTIFIED ABOVE HAS BEEN EXAMINED AND IS ALLOWED FOR ISSUANCE AS A PATENT. PROSECUTION ON THE MERITS IS CLOSED. THIS NOTICE OF ALLOWANCE IS NOT A GRANT OF PATENT RIGHTS. THIS APPLICATION IS SUBJECT TO WITHDRAWAL FROM ISSUE AT THE INITIATIVE OF THE OFFICE OR UPON PETITION BY THE APPLICANT. SEE 37 CFR 1.313 AND MPEP 1308.

THE ISSUE FEE AND PUBLICATION FEE (IF REQUIRED) MUST BE PAID WITHIN THREE MONTHS FROM THE MAILING DATE OF THIS NOTICE OR THIS APPLICATION SHALL BE REGARDED AS ABANDONED. THIS STATUTORY PERIOD CANNOT BE EXTENDED. SEE 35 U.S.C. 151. THE ISSUE FEE DUE INDICATED ABOVE DOES NOT REFLECT A CREDIT FOR ANY PREVIOUSLY PAID ISSUE FEE IN THIS APPLICATION. IF AN ISSUE FEE HAS PREVIOUSLY BEEN PAID IN THIS APPLICATION (AS SHOWN ABOVE), THE RETURN OF PART B OF THIS FORM WILL BE CONSIDERED A REQUEST TO REAPPLY THE PREVIOUSLY PAID ISSUE FEE TOWARD THE ISSUE FEE NOW DUE.

HOW TO REPLY TO THIS NOTICE:

I. Review the ENTITY STATUS shown above. If the ENTITY STATUS is shown as SMALL or MICRO, verify whether entitlement to that entity status still applies.

If the ENTITY STATUS is the same as shown above, pay the TOTAL FEE(S) DUE shown above.

If the ENTITY STATUS is changed from that shown above, on PART B - FEE(S) TRANSMITTAL, complete section number 5 titled "Change in Entity Status (from status indicated above)".

For purposes of this notice, small entity fees are 40% the amount of undiscounted fees, and micro entity fees are 20% the amount of undiscounted fees.

II. PART B - FEE(S) TRANSMITTAL, or its equivalent, must be completed and returned to the United States Patent and Trademark Office (USPTO) with your ISSUE FEE and PUBLICATION FEE (if required). If you are charging the fee(s) to your deposit account, section "4b" of Part B - Fee(s) Transmittal should be completed. If an equivalent of Part B is filed, a request to reapply a previously paid issue fee must be clearly made, and delays in processing may occur due to the difficulty in recognizing the paper as an equivalent of Part B.

III. All communications regarding this application must give the application number. Please direct all communications prior to issuance to Mail Stop ISSUE FEE unless advised to the contrary.

IMPORTANT REMINDER: Maintenance fees are due in utility patents issuing on applications filed on or after Dec. 12, 1980. It is patentee's responsibility to ensure timely payment of maintenance fees when due. More information is available at www.uspto.gov/PatentMaintenanceFees.

PART B - FEE(S) TRANSMITTAL

Complete and send this form, together with applicable fee(s), by mail or fax, or via the USPTO patent electronic filing system.

By mail, send to: Mail Stop ISSUE FEE
Commissioner for Patents
P.O. Box 1450
Alexandria, Virginia 22313-1450

By fax, send to: (571)-273-2885

INSTRUCTIONS: This form should be used for transmitting the ISSUE FEE and PUBLICATION FEE (if required). Blocks 1 through 5 should be completed where appropriate. All further correspondence will be mailed to the current correspondence address as indicated unless corrected below or directed otherwise in Block 1, by (a) specifying a new correspondence address; and/or (b) indicating a separate "FEE ADDRESS" for maintenance fee notifications. **Because electronic patent issuance may occur shortly after issue fee payment, any desired continuing application should preferably be filed prior to payment of this issue fee in order not to jeopardize copendency.**

CURRENT CORRESPONDENCE ADDRESS (Note: Use Block 1 for any change of address)

171672 7590 06/20/2024
Riverside Law LLP/J&J
175 Strafford Avenue
Suite 100
Wayne, PA 19087

Note: A certificate of mailing can only be used for domestic mailings of the Fee(s) Transmittal. This certificate cannot be used for any other accompanying papers. Each additional paper, such as an assignment or formal drawing, must have its own certificate of mailing or transmission.

Certificate of Mailing or Transmission

I hereby certify that this Fee(s) Transmittal is being deposited with the United States Postal Service with sufficient postage for first class mail in an envelope addressed to the Mail Stop ISSUE FEE address above, or being transmitted to the USPTO via the USPTO patent electronic filing system or by facsimile to (571) 273-2885, on the date below.

_____ (Typed or printed name)
_____ (Signature)
_____ (Date)

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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17/320,490 05/14/2021 Diane D. Harrison 206389-0003-02US 5386

TITLE OF INVENTION: ANTI-TNF ANTIBODIES, COMPOSITIONS, AND METHODS FOR THE TREATMENT OF ACTIVE ANKYLOSING SPONDYLITIS

APPLN. TYPE	ENTITY STATUS	ISSUE FEE DUE	PUBLICATION FEE DUE	PREV. PAID ISSUE FEE	TOTAL FEE(S) DUE	DATE DUE
nonprovisional	UNDISCOUNTED	\$1200	\$0.00	\$0.00	\$1200	09/20/2024

EXAMINER	ART UNIT	CLASS-SUBCLASS
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CHANDRA, GYAN 1646 424-142100

1. Change of correspondence address or indication of "Fee Address" (37 CFR 1.363).

☐ Change of correspondence address (or Change of Correspondence Address form PTO/AIA/122 or PTO/SB/122) attached.

☐ "Fee Address" indication (or "Fee Address" Indication form PTO/AIA/47 or PTO/SB/47; Rev 03-02 or more recent) attached. **Use of a Customer Number is required.**

2. For printing on the patent front page, list

- (1) The names of up to 3 registered patent attorneys or agents OR, alternatively,
(2) The name of a single firm (having as a member a registered attorney or agent) and the names of up to 2 registered patent attorneys or agents. If no name is listed, no name will be printed.

1 _____
2 _____
3 _____

3. ASSIGNEE NAME AND RESIDENCE DATA TO BE PRINTED ON THE PATENT (print or type)

PLEASE NOTE: Unless an assignee is identified below, no assignee data will appear on the patent. If an assignee is identified below, the document must have been previously recorded, or filed for recordation, as set forth in 37 CFR 3.11 and 37 CFR 3.81(a). Completion of this form is NOT a substitute for filing an assignment.

(A) NAME OF ASSIGNEE

(B) RESIDENCE: (CITY and STATE OR COUNTRY)

Please check the appropriate assignee category or categories (will not be printed on the patent) : ☐ Individual ☐ Corporation or other private group entity ☐ Government

4a. Fees submitted: ☐ Issue Fee ☐ Publication Fee (if required)

4b. Method of Payment: (Please first reapply any previously paid fee shown above)

☐ Electronic Payment via the USPTO patent electronic filing system ☐ Enclosed check ☐ Non-electronic payment by credit card (Attach form PTO-2038)

☐ The Director is hereby authorized to charge the required fee(s), any deficiency, or credit any overpayment to Deposit Account No. _____

5. Change in Entity Status (from status indicated above)

☐ Applicant certifying micro entity status. See 37 CFR 1.29

☐ Applicant asserting small entity status. See 37 CFR 1.27

☐ Applicant changing to regular undiscounted fee status.

NOTE: Absent a valid certification of Micro Entity Status (see forms PTO/SB/15A and 15B), issue fee payment in the micro entity amount will not be accepted at the risk of application abandonment.

NOTE: If the application was previously under micro entity status, checking this box will be taken to be a notification of loss of entitlement to micro entity status.

NOTE: Checking this box will be taken to be a notification of loss of entitlement to small or micro entity status, as applicable.

NOTE: This form must be signed in accordance with 37 CFR 1.31 and 1.33. See 37 CFR 1.4 for signature requirements and certifications.

Authorized Signature _____

Date _____

Typed or printed name _____

Registration No. _____



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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
17/320,490	05/14/2021	Diane D. Harrison	206389-0003-02US	5386
171672	7590	06/20/2024	EXAMINER	
Riverside Law LLP/J&J			CHANDRA, GYAN	
175 Strafford Avenue			ART UNIT	
Suite 100			PAPER NUMBER	
Wayne, PA 19087			1646	

DATE MAILED: 06/20/2024

Determination of Patent Term Adjustment under 35 U.S.C. 154 (b) (Applications filed on or after May 29, 2000)

The Office has discontinued providing a Patent Term Adjustment (PTA) calculation with the Notice of Allowance.

Section 1(h)(2) of the AIA Technical Corrections Act amended 35 U.S.C. 154(b)(3)(B)(i) to eliminate the requirement that the Office provide a patent term adjustment determination with the notice of allowance. See Revisions to Patent Term Adjustment, 78 Fed. Reg. 19416, 19417 (Apr. 1, 2013). Therefore, the Office is no longer providing an initial patent term adjustment determination with the notice of allowance. The Office will continue to provide a patent term adjustment determination with the Issue Notification Letter that is mailed to applicant approximately three weeks prior to the issue date of the patent, and will include the patent term adjustment on the patent. Any request for reconsideration of the patent term adjustment determination (or reinstatement of patent term adjustment) should follow the process outlined in 37 CFR 1.705.

Any questions regarding the Patent Term Extension or Adjustment determination should be directed to the Office of Patent Legal Administration at (571)-272-7702. Questions relating to issue and publication fee payments should be directed to the Customer Service Center of the Office of Patent Publication at 1-(888)-786-0101 or (571)-272-4200.

OMB Clearance and PRA Burden Statement for PTOL-85 Part B

The Paperwork Reduction Act (PRA) of 1995 requires Federal agencies to obtain Office of Management and Budget approval before requesting most types of information from the public. When OMB approves an agency request to collect information from the public, OMB (i) provides a valid OMB Control Number and expiration date for the agency to display on the instrument that will be used to collect the information and (ii) requires the agency to inform the public about the OMB Control Number's legal significance in accordance with 5 CFR 1320.5(b).

The information collected by PTOL-85 Part B is required by 37 CFR 1.311. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 30 minutes to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, Virginia 22313-1450. **DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, Virginia 22313-1450.** Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it displays a valid OMB control number.

Privacy Act Statement

The Privacy Act of 1974 (P.L. 93-579) requires that you be given certain information in connection with your submission of the attached form related to a patent application or patent. The United States Patent and Trademark Office (USPTO) collects the information in this record under authority of 35 U.S.C. 2. The USPTO's system of records is used to manage all applicant and owner information including name, citizenship, residence, post office address, and other information with respect to inventors and their legal representatives pertaining to the applicant's/owner's activities in connection with the invention for which a patent is sought or has been granted. The applicable Privacy Act System of Records Notice for the information collected in this form is COMMERCE/PAT-TM-7 Patent Application Files, available in the Federal Register at 78 FR 19243 (March 29, 2013).

<https://www.govinfo.gov/content/pkg/FR-2013-03-29/pdf/2013-07341.pdf>

Routine uses of the information in this record may include disclosure to:

- 1) law enforcement, in the event that the system of records indicates a violation or potential violation of law;
- 2) a federal, state, local, or international agency, in response to its request;
- 3) a contractor of the USPTO having need for the information in order to perform a contract;
- 4) the Department of Justice for determination of whether the Freedom of Information Act (FOIA) requires disclosure of the record;
- 5) a Member of Congress submitting a request involving an individual to whom the record pertains, when the individual has requested the Member's assistance with respect to the subject matter of the record;
- 6) a court, magistrate, or administrative tribunal, in the course of presenting evidence, including disclosures to opposing counsel in the course of settlement negotiations;
- 7) the Administrator, General Services Administration (GSA), or their designee, during an inspection of records conducted by GSA under authority of 44 U.S.C. 2904 and 2906, in accordance with the GSA regulations and any other relevant (i.e., GSA or Commerce) directive, where such disclosure shall not be used to make determinations about individuals;
- 8) another federal agency for purposes of National Security review (35 U.S.C. 181) and for review pursuant to the Atomic Energy Act (42 U.S.C. 218(c));
- 9) the Office of Personnel Management (OPM) for personnel research purposes; and
- 10) the Office of Management and Budget (OMB) for legislative coordination and clearance.

If you do not furnish the information requested on this form, the USPTO may not be able to process and/or examine your submission, which may result in termination of proceedings, abandonment of the application, and/or expiration of the patent.

Notice of Allowability	Application No. 17/320,490	Applicant(s) Harrison et al.	
	Examiner GYAN CHANDRA	Art Unit 1646	AIA (FITF) Status Yes

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--

All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. **THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS.** This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

1. ☒ This communication is responsive to the RCE filed in 5/22/2024.
☐ A declaration(s)/affidavit(s) under **37 CFR 1.130(b)** was/were filed on _____.

2. ☐ An election was made by the applicant in response to a restriction requirement set forth during the interview on _____; the restriction requirement and election have been incorporated into this action.

3. ☒ The allowed claim(s) is/are See Continuation Sheet. As a result of the allowed claim(s), you may be eligible to benefit from the **Patent Prosecution Highway** program at a participating intellectual property office for the corresponding application. For more information, please see http://www.uspto.gov/patents/init_events/pph/index.jsp or send an inquiry to **PPHfeedback@uspto.gov**.

4. ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
Certified copies:
a) ☐ All b) ☐ Some* c) ☐ None of the:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).
* Certified copies not received: _____.

Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application.
THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.

5. ☐ CORRECTED DRAWINGS (as "replacement sheets") must be submitted.
☐ including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No./Mail Date _____.

Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet. Replacement sheet(s) should be labeled as such in the header according to 37 CFR 1.121(d).

6. ☐ DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

Attachment(s)

1. ☐ Notice of References Cited (PTO-892) 2. ☒ Information Disclosure Statements (PTO/SB/08), Paper No./Mail Date <u>5/22/2024</u> . 3. ☐ Examiner's Comment Regarding Requirement for Deposit of Biological Material _____. 4. ☐ Interview Summary (PTO-413), Paper No./Mail Date. _____.	5. ☒ Examiner's Amendment/Comment 6. ☐ Examiner's Statement of Reasons for Allowance 7. ☐ Other _____.
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/GYAN CHANDRA/ Primary Examiner, Art Unit 1646	
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Continuation of 3. The allowed claim(s) is/are: 11,13-14,16-18 and 20

DETAILED ACTION

Notice of Pre-AIA or AIA Status

The present application, filed on or after March 16, 2013, is being examined under the first inventor to file provisions of the AIA.

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 5/22/2024 has been entered.

Status of Application, Amendments, And/Or Claims

The amendment of claim 20 has been made of record.

Claims 11, 13-14, 16-18 and 20 are pending and under examination.

Information Disclosure Statement

The Information Disclosure Statement filed on 5/22/2024 has been considered.

EXAMINER'S COMMENT

Double Patenting-withdrawn

The rejection of claims 11, 13-14, 16-18 and 20 remain rejected on the ground of nonstatutory double patenting as being unpatentable over claims 1-10 of U.S. Patent No. 11,041,020 is withdrawn in view of applicant's filing of an electronic Terminal Disclaimer on 5/22/2024.

Conclusion

Claims 11, 13-14, 16-18 and 20 are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to GYAN CHANDRA whose telephone number is (571)272-2922. The examiner can normally be reached Mon-Friday 8:30AM-5:00P.

Examiner interviews are available via telephone, in-person, and video conferencing using a USPTO supplied web-based collaboration tool. To schedule an interview, applicant is encouraged to use the USPTO Automated Interview Request (AIR) at <http://www.uspto.gov/interviewpractice>.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Vanessa Ford can be reached on 571-272-0857. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of published or unpublished applications may be obtained from Patent Center. Unpublished application information in Patent Center is available to registered users. To file and manage patent submissions in Patent Center, visit: <https://patentcenter.uspto.gov>. Visit <https://www.uspto.gov/patents/apply/patent-center> for more information about Patent Center and <https://www.uspto.gov/patents/docx> for information about filing in DOCX format. For additional questions, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/GYAN CHANDRA/
Primary Examiner, Art Unit 1646

<i>Search Notes</i> 	Application/Control No. 17/320,490	Applicant(s)/Patent Under Reexamination Harrison et al.
	Examiner GYAN CHANDRA	Art Unit 1646

CPC - Searched*		
Symbol	Date	Examiner
C07K16/241	06/04/2024	gc
A61K2039/505	06/04/2024	gc
a61k9/0019	06/04/2024	gc

CPC Combination Sets - Searched*		
Symbol	Date	Examiner

US Classification - Searched*			
Class	Subclass	Date	Examiner
None	None	06/04/2024	gc

* See search history printout included with this form or the SEARCH NOTES box below to determine the scope of the search.

Search Notes		
Search Notes	Date	Examiner
STIC search for SEQ ID NOs: 1-6 (see search results in PE2E)	04/14/2023	gc
Claims searched in PE2E (see enclosed doc)	06/04/2024	gc
claims searched in Caplus, Biosis, Medline (see enclosed transcript)	06/04/2024	gc
Inventorship search in Caplus, Biosis medline (see enclosed transcript)	06/04/2024	gc
Inventorship search in PE2E	06/04/2024	gc
Inventorship search in PALM	06/04/2024	gc

/GYAN CHANDRA/ Primary Examiner, Art Unit 1646	
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<i>Search Notes</i> 	Application/Control No. 17/320,490	Applicant(s)/Patent Under Reexamination Harrison et al.
	Examiner GYAN CHANDRA	Art Unit 1646

Interference Search			
US Class/CPC Symbol	US Subclass/CPC Group	Date	Examiner
A61K	2039	505	gc

/GYAN CHANDRA/ Primary Examiner, Art Unit 1646	
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PE2E SEARCH - Search History (Prior Art)

Ref #	Hits	Search Query	DBs	Default Operator	Plurals	British Equivalents	Time Stamp
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		"5658754" OR					
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		"5750373" OR					
		"5763192" OR					
		"5763733" OR					
		"5766886" OR					
		"5767260" OR					
		"5770198" OR					
		"5770222" OR					
		"5770359" OR					
		"5770428" OR					
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		"5849695" OR					
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		"5976862" OR					
		"5989530" OR					
		"5993833" OR					

L136	1	"5994616" OR "6010902" OR "6017732" OR "6037453" OR "6060285" OR "6106833" OR "6132992" OR "6180370" OR "6190691" OR "6193967" OR "6204023" OR "6210668" OR "6277969" OR "7521206" OR "7691378" OR "8241899" OR "9512065").pn. AND antibod\$3 AND anti- Tnf.clm. AND intravenous ADJ infusion 17/320490	(US-PGPUB; USPAT; USOCR; FIT (AP, AT, AU, BE, BG, BR, BY, CA, CH, CN, CS, CU, CZ, DD, DE, DK, EA, EE, EP, ES, FI, FR, GB, HR, HU, ID, IE, IL, IS, IT, JP, KR, LT, LU, LV, MA, MC, MD, MY, NL, NO, NZ, OA, PH, PL, PT, RO, RS, RU, SE, SG, SI, SK, SU, TH, TN, TR, TW, UA, VN, WO); FPRS; EPO; JPO; DERWENT)	OR	ON	ON	2024/06/04 02:31 PM
L137	141	Harrison Diane D.in.	(US-PGPUB; USPAT; USOCR; FIT (AP, AT, AU, BE, BG, BR, BY, CA, CH, CN, CS, CU, CZ, DD, DE, DK, EA, EE, EP, ES, FI, FR, GB, HR, HU, ID, IE, IL, IS, IT, JP, KR, LT, LU, LV, MA, MC, MD, MY, NL, NO, NZ, OA, PH, PL, PT, RO, RS, RU, SE, SG, SI, SK, SU, TH, TN, TR, TW, UA, VN, WO); FPRS; EPO; JPO; DERWENT)	ADJ	ON	ON	2024/06/04 02:31 PM
L138	141	Harrison Diane D.inv.	(US-PGPUB; USPAT; USOCR; FIT (AP, AT, AU, BE, BG, BR, BY, CA, CH, CN, CS, CU, CZ, DD, DE, DK, EA, EE, EP, ES, FI, FR, GB,	ADJ	ON	ON	2024/06/04 02:31 PM

L139	79	Hsia Elizabeth C.in.	HR, HU, ID, IE, IL, IS, IT, JP, KR, LT, LU, LV, MA, MC, MD, MY, NL, NO, NZ, OA, PH, PL, PT, RO, RS, RU, SE, SG, SI, SK, SU, TH, TN, TR, TW, UA, VN, WO); FPRS; EPO; JPO; DERWENT)	ADJ	ON	ON	2024/06/04 02:31 PM
L140	75	Kim Lee Lian.in.	(US-PGPUB; USPAT; USOCR; FIT (AP, AT, AU, BE, BG, BR, BY, CA, CH, CN, CS, CU, CZ, DD, DE, DK, EA, EE, EP, ES, FI, FR, GB, HR, HU, ID, IE, IL, IS, IT, JP, KR, LT, LU, LV, MA, MC, MD, MY, NL, NO, NZ, OA, PH, PL, PT, RO, RS, RU, SE, SG, SI, SK, SU, TH, TN, TR, TW, UA, VN, WO); FPRS; EPO; JPO; DERWENT)	ADJ	ON	ON	2024/06/04 02:31 PM
L141	73	Lo kim hung.in.	(US-PGPUB; USPAT; USOCR; FIT (AP, AT, AU, BE, BG, BR, BY, CA, CH, CN, CS, CU, CZ, DD, DE, DK, EA, EE, EP, ES, FI, FR, GB, HR, HU, ID, IE, IL, IS, IT, JP, KR, LT, LU, LV, MA, MC, MD, MY, NL, NO, NZ, OA, PH, PL, PT, RO, RS, RU, SE, SG, SI, SK, SU, TH, TN, TR, TW, UA, VN, WO); FPRS; EPO; JPO; DERWENT)	ADJ	ON	ON	2024/06/04 02:31 PM
L142	178	L2 OR L3 OR L4 OR L5 OR L6	(US-PGPUB; USPAT; USOCR; FIT (AP, AT,	ADJ	ON	ON	2024/06/04 02:31 PM

			AU, BE, BG, BR, BY, CA, CH, CN, CS, CU, CZ, DD, DE, DK, EA, EE, EP, ES, FI, FR, GB, HR, HU, ID, IE, IL, IS, IT, JP, KR, LT, LU, LV, MA, MC, MD, MY, NL, NO, NZ, OA, PH, PL, PT, RO, RS, RU, SE, SG, SI, SK, SU, TH, TN, TR, TW, UA, VN, WO); FPRS; EPO; JPO; DERWENT)				
L143	60	L7 AND golimumab AND psoriat\$2 AND arthritis	(US-PGPUB; USPAT; USOCR; FIT (AP, AT, AU, BE, BG, BR, BY, CA, CH, CN, CS, CU, CZ, DD, DE, DK, EA, EE, EP, ES, FI, FR, GB, HR, HU, ID, IE, IL, IS, IT, JP, KR, LT, LU, LV, MA, MC, MD, MY, NL, NO, NZ, OA, PH, PL, PT, RO, RS, RU, SE, SG, SI, SK, SU, TH, TN, TR, TW, UA, VN, WO); FPRS; EPO; JPO; DERWENT)	ADJ	ON	ON	2024/06/04 02:31 PM
L144	59	L7 AND golimumab AND psoriat\$2 AND arthritis AND intravenous	(US-PGPUB; USPAT; USOCR; FIT (AP, AT, AU, BE, BG, BR, BY, CA, CH, CN, CS, CU, CZ, DD, DE, DK, EA, EE, EP, ES, FI, FR, GB, HR, HU, ID, IE, IL, IS, IT, JP, KR, LT, LU, LV, MA, MC, MD, MY, NL, NO, NZ, OA, PH, PL, PT, RO, RS, RU, SE, SG, SI, SK, SU, TH, TN, TR, TW, UA, VN, WO); FPRS; EPO; JPO; DERWENT)	ADJ	ON	ON	2024/06/04 02:31 PM
L145	11597	golimumab AND psoriat\$2 AND arthritis AND intravenous	(US-PGPUB; USPAT; USOCR; FIT (AP, AT, AU, BE, BG, BR, BY, CA, CH, CN, CS, CU, CZ, DD, DE, DK, EA, EE, EP, ES, FI, FR, GB, HR, HU, ID, IE, IL, IS, IT, JP, KR, LT, LU, LV, MA, MC, MD, MY, NL, NO, NZ, OA, PH, PL, PT, RO, RS, RU, SE, SG, SI, SK, SU, TH, TN, TR, TW, UA, VN, WO); FPRS; EPO; JPO; DERWENT)	ADJ	ON	ON	2024/06/04 02:31 PM

L146	1209	golimumab AND psoriatis AND arthritis AND intravenous.clm.	JPO; DERWENT) (US-PGPUB; USPAT; USOCR; FIT (AP, AT, AU, BE, BG, BR, BY, CA, CH, CN, CS, CU, CZ, DD, DE, DK, EA, EE, EP, ES, FI, FR, GB, HR, HU, ID, IE, IL, IS, IT, JP, KR, LT, LU, LV, MA, MC, MD, MY, NL, NO, NZ, OA, PH, PL, PT, RO, RS, RU, SE, SG, SI, SK, SU, TH, TN, TR, TW, UA, VN, WO); FPRS; EPO; JPO; DERWENT)	ADJ	ON	ON	2024/06/04 02:31 PM
L147	310	golimumab.clm. AND psoriatis AND arthritis AND intravenous.clm.	(US-PGPUB; USPAT; USOCR; FIT (AP, AT, AU, BE, BG, BR, BY, CA, CH, CN, CS, CU, CZ, DD, DE, DK, EA, EE, EP, ES, FI, FR, GB, HR, HU, ID, IE, IL, IS, IT, JP, KR, LT, LU, LV, MA, MC, MD, MY, NL, NO, NZ, OA, PH, PL, PT, RO, RS, RU, SE, SG, SI, SK, SU, TH, TN, TR, TW, UA, VN, WO); FPRS; EPO; JPO; DERWENT)	ADJ	ON	ON	2024/06/04 02:31 PM
L148	210	golimumab.clm. AND psoriatis AND arthritis.clm. AND intravenous.clm.	(US-PGPUB; USPAT; USOCR; FIT (AP, AT, AU, BE, BG, BR, BY, CA, CH, CN, CS, CU, CZ, DD, DE, DK, EA, EE, EP, ES, FI, FR, GB, HR, HU, ID, IE, IL, IS, IT, JP, KR, LT, LU, LV, MA, MC, MD, MY, NL, NO, NZ, OA, PH, PL, PT, RO, RS, RU, SE, SG, SI, SK, SU, TH, TN, TR, TW, UA, VN, WO); FPRS; EPO; JPO; DERWENT)	ADJ	ON	ON	2024/06/04 02:31 PM
L149	4	L13 AND SEQ ADJ ID ADJ No ADJ "37"	(US-PGPUB; USPAT; USOCR; FIT (AP, AT, AU, BE, BG, BR, BY, CA, CH, CN, CS, CU, CZ, DD, DE, DK, EA, EE, EP, ES, FI, FR, GB, HR, HU, ID, IE, IL, IS, IT, JP, KR, LT, LU, LV, MA, MC, MD, MY, NL, NO, NZ, OA, PH, PL,	ADJ	ON	ON	2024/06/04 02:31 PM

L150	24164	C07K16/241.cpc.	PT, RO, RS, RU, SE, SG, SI, SK, SU, TH, TN, TR, TW, UA, VN, WO); FPRS; EPO; JPO; DERWENT) (US-PGPUB; USPAT; USOCR; FIT (AP, AT, AU, BE, BG, BR, BY, CA, CH, CN, CS, CU, CZ, DD, DE, DK, EA, EE, EP, ES, FI, FR, GB, HR, HU, ID, IE, IL, IS, IT, JP, KR, LT, LU, LV, MA, MC, MD, MY, NL, NO, NZ, OA, PH, PL, PT, RO, RS, RU, SE, SG, SI, SK, SU, TH, TN, TR, TW, UA, VN, WO); FPRS; EPO; JPO; DERWENT)	ADJ	ON	ON	2024/06/04 02:31 PM
L151	364554	A61K2039/505.cpc.	(US-PGPUB; USPAT; USOCR; FIT (AP, AT, AU, BE, BG, BR, BY, CA, CH, CN, CS, CU, CZ, DD, DE, DK, EA, EE, EP, ES, FI, FR, GB, HR, HU, ID, IE, IL, IS, IT, JP, KR, LT, LU, LV, MA, MC, MD, MY, NL, NO, NZ, OA, PH, PL, PT, RO, RS, RU, SE, SG, SI, SK, SU, TH, TN, TR, TW, UA, VN, WO); FPRS; EPO; JPO; DERWENT)	ADJ	ON	ON	2024/06/04 02:31 PM
L152	286101	a61k9/0019.cpc.	(US-PGPUB; USPAT; USOCR; FIT (AP, AT, AU, BE, BG, BR, BY, CA, CH, CN, CS, CU, CZ, DD, DE, DK, EA, EE, EP, ES, FI, FR, GB, HR, HU, ID, IE, IL, IS, IT, JP, KR, LT, LU, LV, MA, MC, MD, MY, NL, NO, NZ, OA, PH, PL, PT, RO, RS, RU, SE, SG, SI, SK, SU, TH, TN, TR, TW, UA, VN, WO); FPRS; EPO; JPO; DERWENT)	ADJ	ON	ON	2024/06/04 02:31 PM
L153	11158	L15 AND L16	(US-PGPUB; USPAT; USOCR; FIT (AP, AT, AU, BE, BG, BR, BY, CA, CH, CN, CS, CU, CZ, DD, DE, DK, EA, EE, EP, ES, FI, FR, GB,	ADJ	ON	ON	2024/06/04 02:31 PM

L154	3046	L18 AND psoriatis\$2 AND arthritis	HR, HU, ID, IE, IL, IS, IT, JP, KR, LT, LU, LV, MA, MC, MD, MY, NL, NO, NZ, OA, PH, PL, PT, RO, RS, RU, SE, SG, SI, SK, SU, TH, TN, TR, TW, UA, VN, WO); FPRS; EPO; JPO; DERWENT) (US-PGPUB; USPAT; USOCR; FIT (AP, AT, AU, BE, BG, BR, BY, CA, CH, CN, CS, CU, CZ, DD, DE, DK, EA, EE, EP, ES, FI, FR, GB, HR, HU, ID, IE, IL, IS, IT, JP, KR, LT, LU, LV, MA, MC, MD, MY, NL, NO, NZ, OA, PH, PL, PT, RO, RS, RU, SE, SG, SI, SK, SU, TH, TN, TR, TW, UA, VN, WO); FPRS; EPO; JPO; DERWENT)	ADJ	ON	ON	2024/06/04 02:31 PM
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FILE 'MEDLINE' ENTERED AT 14:43:21 ON 04 JUN 2024

=> e Harrison Diane D/au

E1	1	HARRISON DIANA L/AU
E2	8	HARRISON DIANE/AU
E3	66 -->	HARRISON DIANE D/AU
E4	9	HARRISON DIANE DEBORAH/AU
E5	1	HARRISON DIANE J/AU
E6	6	HARRISON DIANNE/AU
E7	2	HARRISON DIANNE F/AU
E8	5	HARRISON DIANNE M/AU
E9	1	HARRISON DICK/AU
E10	4	HARRISON DION/AU
E11	21	HARRISON DION K/AU
E12	1	HARRISON DION KEVIN/AU

=> s e3

L1 66 "HARRISON DIANE D"/AU

=> e Hsia Elizabeth C/au

E13	7	HSIA ELISA/AU
E14	56	HSIA ELIZABETH/AU
E15	225 -->	HSIA ELIZABETH C/AU
E16	1	HSIA ELLEN BRITO/AU
E17	1	HSIA EN CHIA/AU
E18	2	HSIA F T/AU
E19	3	HSIA F Y/AU
E20	4	HSIA FAN NI/AU
E21	1	HSIA FE TSCHENG/AU
E22	1	HSIA FEN HSU/AU
E23	27	HSIA FENG CHUN/AU
E24	1	HSIA FLORENCE/AU

=> s e14-15

L2 281 ("HSIA ELIZABETH"/AU OR "HSIA ELIZABETH C"/AU)

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=> e kim lee lian/au

E25      3      KIM LEE KYOUNG/AU
E26     71      KIM LEE KYUNG/AU
E27     18 --> KIM LEE LIAN/AU
E28      2      KIM LEE M/AU
E29      4      KIM LEE M H/AU
E30      1      KIM LEE MIN/AU
E31      1      KIM LEE MYUNG/AU
E32      5      KIM LEE MYUNG H/AU
E33      3      KIM LEE NAM/AU
E34      6      KIM LEE OH/AU
E35      6      KIM LEE RANG/AU
E36      1      KIM LEE S U/AU

=> s e27

L3      18 "KIM LEE LIAN"/AU

=> e lo kim hung/au

E37      1      LO KIM FLUNG/AU
E38      4      LO KIM H/AU
E39     108 --> LO KIM HUNG/AU
E40     11      LO KIM R/AU
E41      7      LO KIM SAN/AU
E42      2      LO KIM SING/AU
E43      8      LO KIMBERLY/AU
E44      3      LO KIMBERLY L/AU
E45      3      LO KIMBERLY S L/AU
E46      4      LO KIMBY/AU
E47      2      LO KIN/AU
E48     29      LO KIN CHEUNG/AU

=> s e38-39

L4      112 ("LO KIM H"/AU OR "LO KIM HUNG"/AU)

=> s l1-4

L5      372 (L1 OR L2 OR L3 OR L4)

=> s golimumab

L6      6122 GOLIMUMAB

=> s psoriatic arthritis

L7      36688 PSORIATIC ARTHRITIS

=> s l6 (1) l7

L8      675 L6 (L) L7

=> s l8 and intravenous (w) infusion

L9      0 L8 AND INTRAVENOUS (W) INFUSION

=> s l8 and intravenous infusion

L10     0 L8 AND INTRAVENOUS INFUSION

=> s l8 and infusion

L11     18 L8 AND INFUSION

=> s l11 and (intravenous or iv)

L12     3 L11 AND (INTRAVENOUS OR IV)

=> s l5 and golimumab

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L13      186 L5 AND GOLIMUMAB
=> s l13 and infusion

L14      22 L13 AND INFUSION
=> s l14 and (iv or intravenous)

L15      21 L14 AND (IV OR INTRAVENOUS)
=> dup rem l15

PROCESSING COMPLETED FOR L15
L16      11 DUP REM L15 (10 DUPLICATES REMOVED)
=> dup rem l12

PROCESSING COMPLETED FOR L12
L17      3 DUP REM L12 (0 DUPLICATES REMOVED)
=> s l16-17

L18      11 (L16 OR L17)
=> s l18 and variant

L19      0 L18 AND VARIANT
=> s l18 and py<2017

L20      3 L18 AND PY<2017
=> s l18 and py<2018

L21      4 L18 AND PY<2018
=> d l21 1-4 ti so py au kwic ibib

L21 ANSWER 1 OF 4 CAPLUS COPYRIGHT 2024 ACS on STN
TI Maintenance of Clinical and Radiographic Benefit With Intravenous
Golimumab Therapy in Patients With Active Rheumatoid Arthritis Despite
Methotrexate Therapy: Week-112 Efficacy and Safety Results of the
Open-Label Long-Term Extension of a Phase III, Double-Blind, Randomized,
Placebo-Controlled Trial
SO Arthritis Care & Research (2015), 67(12), 1627-1636
CODEN: ARCREG; ISSN: 2151-464X
PY 2015
AU Bingham, Clifton O., III; Mendelsohn, Alan M.; Kim, Lilianne; Xu, Zhenhua;
Leu, Jocelyn; Han, Chenglong; Lo, Kim Hung; Westhovens, Rene; Weinblatt,
Michael E.; on behalf of the GO-FURTHER Investigators
TI Maintenance of Clinical and Radiographic Benefit With Intravenous
Golimumab Therapy in Patients With Active Rheumatoid Arthritis Despite
Methotrexate Therapy: Week-112 Efficacy and Safety Results of the
Open-Label Long-Term Extension. . .
AU Bingham, Clifton O., III; Mendelsohn, Alan M.; Kim, Lilianne; Xu, Zhenhua;
Leu, Jocelyn; Han, Chenglong; Lo, Kim Hung; Westhovens, Rene; Weinblatt,
Michael E.; on behalf of the GO-FURTHER Investigators
SO Arthritis Care & Research (2015), 67(12), 1627-1636
CODEN: ARCREG; ISSN: 2151-464X
AB Objective : To evaluate the safety, efficacy, pharmacokinetics,
immunogenicity, and radiog. progression through 2 years of treatment with
i.v. (IV) golimumab plus methotrexate (MTX) in an open-label extension
of a phase III trial of patients with active rheumatoid arthritis (RA)
despite. . . : In the phase III, double-blind, randomized,
placebo-controlled GO-FURTHER trial, 592 patients with active RA were
randomized (2:1) to i.v. golimumab 2 mg/kg plus MTX (Group 1) or placebo
plus MTX (Group 2) at weeks 0 and 4, then every 8 wk thereafter; placebo
patients crossed over to golimumab at week 16 (early escape) or week 24
(crossover). The final golimumab infusion was at week 100.
Assessments included American College of Rheumatol. 20%, 50%, 70% (ACR20,
ACR50, ACR70) response criteria, 28-joint count. . . through week 112;

```

79.1% had an adverse event, and 18.2% had a serious adverse event.
 Conclusion : Clin. response to IV golimumab plus MTX was maintained
 through week 100. Radiog. progression following golimumab treatment was
 clin. insignificant between week 52 and week 100. No unexpected adverse
 events occurred through week 112, and the. . .

ST rheumatoid arthritis Methotrexate Golimumab

IT Drug toxicity

Homo sapiens

Human

Infusion drug delivery systems

Necrosis

Pharmacokinetics

Rheumatoid arthritis

(maintenance of Clin. and Radiog. Benefit With I.v. Golimumab

Therapy in Patients With Active Rheumatoid Arthritis Despite

Methotrexate Therapy: Week-112 Efficacy and Safety Results of the

Open-Label Long-Term Extension of a P)

IT C-reactive protein

RL: BSU (Biological study, unclassified); BIOL (Biological study)

(maintenance of Clin. and Radiog. Benefit With I.v. Golimumab

Therapy in Patients With Active Rheumatoid Arthritis Despite

Methotrexate Therapy: Week-112 Efficacy and Safety Results of the

Open-Label Long-Term Extension of a P)

IT 59-05-2, Methotrexate 476181-74-5, Golimumab

RL: ADV (Adverse effect, including toxicity); PAC (Pharmacological

activity); THU (Therapeutic use); BIOL (Biological study); USES (Uses)

(maintenance of Clin. and Radiog. Benefit With I.v. Golimumab

Therapy in Patients With Active Rheumatoid Arthritis Despite

Methotrexate Therapy: Week-112 Efficacy and Safety Results of the

Open-Label Long-Term Extension of a P)

ACCESSION NUMBER: 2015:1938584 CAPLUS Full-text

DOCUMENT NUMBER: 163:714334

TITLE: Maintenance of Clinical and Radiographic Benefit With

Intravenous Golimumab Therapy in Patients With

Active Rheumatoid Arthritis Despite Methotrexate

Therapy: Week-112 Efficacy and Safety Results of the

Open-Label Long-Term Extension of a Phase III,

Double-Blind, Randomized, Placebo-Controlled Trial

Bingham, Clifton O., III; Mendelsohn, Alan M.; Kim,

Lillianne; Xu, Zhenhua; Leu, Jocelyn; Han, Chenglong;

Lo, Kim Hung; Westhovens, Rene; Weinblatt, Michael

E.; on behalf of the GO-FURTHER Investigators

Johns Hopkins University, Baltimore, MD, USA

CORPORATE SOURCE:

SOURCE: Arthritis Care & Research (2015), 67(12), 1627-1636

CODEN: ARCREG; ISSN: 2151-464X

DIGITAL OBJECT ID: 10.1002/acr.22556

PUBLISHER: John Wiley & Sons, Inc.

DOCUMENT TYPE: Journal; (online computer file)

LANGUAGE: English

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L21 ANSWER 2 OF 4 CAPLUS COPYRIGHT 2024 ACS on STN

TI Radiographic benefit and maintenance of clinical benefit with
 intravenous golimumab therapy in patients with active rheumatoid
 arthritis despite methotrexate therapy: results up to.1 year of the phase
 3, randomised, multicentre, double blind, placebo controlled GO-FURTHER
 trial

SO Annals of the Rheumatic Diseases (2014), 73(12), 2152-2159

CODEN: ARDIAO; ISSN: 0003-4967

PY 2014

AU Weinblatt, Michael E.; Westhovens, Rene; Mendelsohn, Alan M.; Kim,

Lillianne; Lo, Kim Hung; Sheng, Shihong; Noonan, Lenore; Lu, Jiandong;

Xu, Zhenhua; Leu, Jocelyn; Baker, Daniel; Bingham, Clifton O.

TI Radiographic benefit and maintenance of clinical benefit with
 intravenous golimumab therapy in patients with active rheumatoid
 arthritis despite methotrexate therapy: results up to.1 year of the phase
 3, randomised, multicentre,. . .

AU Weinblatt, Michael E.; Westhovens, Rene; Mendelsohn, Alan M.; Kim,

Lillianne; Lo, Kim Hung; Sheng, Shihong; Noonan, Lenore; Lu, Jiandong;

Xu, Zhenhua; Leu, Jocelyn; Baker, Daniel; Bingham, Clifton O.
 SO Annals of the Rheumatic Diseases (2014), 73(12), 2152-2159
 CODEN: ARDIAO; ISSN: 0003-4967
 AB Objective: Report on radiog. effects and maintenance of clin. benefit with
 i.v. golimumab 2 mg/kg+methotrexate (MTX) for up to week (wk) 52 in
 active rheumatoid arthritis (RA). Methods: Patients (n=592) with active
 RA. . . participated in this multicentre, international, randomised,
 double blind, placebo controlled, phase 3 study. Patients were randomised
 (2:1) to receive i.v. golimumab 2 mg/kg or placebo infusions at weeks
 0 and 4 and then every 8 wk; patients continued their stable MTX regimen.
 Placebo patients started golimumab 2 mg/kg at wk16 (early escape; <10%
 improvement in tender and swollen joints) or wk24 (crossover by design).
 Week 24. . . up to 1 yr are reported here. Results: Significant and
 rapid clin. improvement was obsd. up to wk24 of i.v. golimumab therapy.
 Golimumab+MTX treated patients demonstrated less radiog. progression
 than placebo treated patients at wk24 (vdH-S score mean change 0.03 vs
 1.09; p<0.001). . . approx. 80% maintained this response up until wk52.
 Through an av. of 43.5 wk of follow-up, 64.6% of patients receiving
 golimumab+MTX reported adverse events, most commonly non-serious
 infections. Conclusions: In patients with active RA despite MTX, i.v.
 golimumab+MTX yielded significant inhibition of structural damage at
 wk24 and wk52, and sustained clin. improvement in signs and symptoms with
 no. . .
 ST rheumatoid arthritis golimumab methotrexate intravenous antirheumatic
 toxicity
 IT Antirheumatic agents
 Drug toxicity
 Homo sapiens
 Human
 Immunity
 Pharmaceutical intravenous injections
 Pharmacokinetics
 Rheumatoid arthritis
 (phase 3 randomized double blind placebo controlled GO-FURTHER trial
 for anal. of radiog. effect and clin. benefit with i.v.
 golimumab therapy in patients with active rheumatoid arthritis
 despite methotrexate therapy)
 IT 476181-74-5, Golimumab
 RL: ADV (Adverse effect, including toxicity); PAC (Pharmacological
 activity); PKT (Pharmacokinetics); THU (Therapeutic use); BIOL (Biological
 study); USES (Uses)
 (phase 3 randomized double blind placebo controlled GO-FURTHER trial
 for anal. of radiog. effect and clin. benefit with i.v.
 golimumab therapy in patients with active rheumatoid arthritis
 despite methotrexate therapy)
 IT 59-05-2, Methotrexate
 RL: ADV (Adverse effect, including toxicity); PAC (Pharmacological
 activity); THU (Therapeutic use); BIOL (Biological study); USES (Uses)
 (phase 3 randomized double blind placebo controlled GO-FURTHER trial
 for anal. of radiog. effect and clin. benefit with i.v.
 golimumab therapy in patients with active rheumatoid arthritis
 despite methotrexate therapy)
 ACCESSION NUMBER: 2015:27135 CAPLUS Full-text
 DOCUMENT NUMBER: 163:198547
 TITLE: Radiographic benefit and maintenance of clinical
 benefit with intravenous golimumab therapy in
 patients with active rheumatoid arthritis despite
 methotrexate therapy: results up to 1 year of the
 phase 3, randomised, multicentre, double blind,
 placebo controlled GO-FURTHER trial
 AUTHOR(S): Weinblatt, Michael E.; Westhovens, Rene; Mendelsohn,
 Alan M.; Kim, Lilianne; Lo, Kim Hung; Sheng,
 Shihong; Noonan, Lenore; Lu, Jiandong; Xu, Zhenhua;
 Leu, Jocelyn; Baker, Daniel; Bingham, Clifton O.
 CORPORATE SOURCE: GO-FURTHER Investigators, Division of Rheumatology,
 Immunology and Allergy, Brigham and Women's Hospital,
 Boston, MA, USA
 SOURCE: Annals of the Rheumatic Diseases (2014), 73(12),
 2152-2159
 CODEN: ARDIAO; ISSN: 0003-4967
 DIGITAL OBJECT ID: 10.1136/annrheumdis-2013-203742
 PUBLISHER: BMJ Publishing Group

DOCUMENT TYPE: Journal
 LANGUAGE: English
 OS.CITING REF COUNT: 16 THERE ARE 16 CAPLUS RECORDS THAT CITE THIS
 RECORD (16 CITINGS)
 REFERENCE COUNT: 26 THERE ARE 26 CITED REFERENCES AVAILABLE FOR THIS
 RECORD. ALL CITATIONS AVAILABLE IN THE RE FORMAT

L21 ANSWER 3 OF 4 CAPLUS COPYRIGHT 2024 ACS on STN
 TI The effect of intravenous golimumab on health-related quality of life
 in rheumatoid arthritis: 24-week results of the phase III GO-FURTHER Trial
 SO Journal of Rheumatology (2014), 41(6), 1067-1076
 CODEN: JRHUA9; ISSN: 0315-162X
 PY 2014
 AU Bingham, Clifton O., III; Weinblatt, Michael; Han, Chenglong; Gathany,
 Timothy A.; Kim, Lillianne; Lo, Kim Hung; Baker, Dan; Mendelsohn, Alan;
 Westhovens, Rene
 TI The effect of intravenous golimumab on health-related quality of life
 in rheumatoid arthritis: 24-week results of the phase III GO-FURTHER Trial
 AU Bingham, Clifton O., III; Weinblatt, Michael; Han, Chenglong; Gathany,
 Timothy A.; Kim, Lillianne; Lo, Kim Hung; Baker, Dan; Mendelsohn, Alan;
 Westhovens, Rene
 SO Journal of Rheumatology (2014), 41(6), 1067-1076
 CODEN: JRHUA9; ISSN: 0315-162X
 AB Objective. To evaluate the effects of i.v. (IV) golimumab 2 mg/kg +
 methotrexate (MTX) on patient-reported measures of health-related quality
 of life (HRQOL) in patients with active rheumatoid arthritis. . . MTX
 therapy. Methods. In this randomized, multicenter, double-blind,
 placebo-controlled, phase III trial, adults with RA were randomly assigned
 to receive IV placebo (n = 197) or golimumab 2 mg/kg (n = 395)
 infusions at Week 0, Week 4, and every 8 wk thereafter. All patients
 continued stable oral MTX (15-25 mg/wk). HRQOL assessments. . . and
 disease effect on productivity [10-cm visual analog scale (VAS)].
 Results. Mean HAQ-DI improvements from baseline were significantly greater
 with golimumab + MTX than placebo + MTX at Week 14 and Week 24 (p <
 0.001). Significantly greater improvements in all 8 individual SF-36
 subscores and both the SF-36 PCS and MCS scores (p < 0.001) also
 accompanied golimumab + MTX therapy. Improved EQ-5D and EQ-5D VAS (p <
 0.001) and FACIT-Fatigue (p < 0.001) scores were also obsd. for
 golimumab + MTX-treated patients at Week 12, Week 16, and Week 24, and
 greater proportions of golimumab + MTX-treated patients had clin.
 meaningful improvements in these measures. Greater redns. in disease
 effect on productivity were obsd. with golimumab + MTX vs. placebo + MTX
 at Week 24 (p < 0.001). Improvements in phys. function, HRQOL, fatigue,
 and productivity significantly correlated with disease activity
 improvement. Conclusion. In active RA, IV golimumab + MTX
 significantly improved phys. function, HRQOL, fatigue, and productivity
 using multiple measurement tools; all correlated with improvements in
 disease. . .
 ST rheumatoid arthritis life intravenous golimumab human health quality
 IT Diffusion
 Emotion
 Fatigue, biological
 Human
 Immunotherapy
 Pharmaceutical intravenous injections
 Rheumatoid arthritis
 (results on effect of i.v. golimumab on health-related
 quality of life in rheumatoid arthritis in 24 wk phase III)
 IT 59-05-2, Methotrexate 476181-74-5, Golimumab
 RL: PAC (Pharmacological activity); THU (Therapeutic use); BIOL
 (Biological study); USES (Uses)
 (results on effect of i.v. golimumab on health-related
 quality of life in rheumatoid arthritis in 24 wk phase III)
 ACCESSION NUMBER: 2014:1197008 CAPLUS Full-text
 DOCUMENT NUMBER: 161:577527
 TITLE: The effect of intravenous golimumab on
 health-related quality of life in rheumatoid
 arthritis: 24-week results of the phase III GO-FURTHER
 Trial
 AUTHOR(S): Bingham, Clifton O., III; Weinblatt, Michael; Han,
 Chenglong; Gathany, Timothy A.; Kim, Lillianne; Lo,
 Kim Hung; Baker, Dan; Mendelsohn, Alan; Westhovens,

CORPORATE SOURCE: Rene
 Division of Rheumatology and Allergy and Clinical
 Immunology, Johns Hopkins University, Baltimore, MD,
 USA
 SOURCE: Journal of Rheumatology (2014), 41(6), 1067-1076
 CODEN: JRHUA9; ISSN: 0315-162X
 DIGITAL OBJECT ID: 10.3899/jrheum.130864
 PUBLISHER: Journal of Rheumatology Publishing Co. Ltd.
 DOCUMENT TYPE: Journal
 LANGUAGE: English
 OS.CITING REF COUNT: 4 THERE ARE 4 CAPLUS RECORDS THAT CITE THIS RECORD
 (4 CITINGS)

L21 ANSWER 4 OF 4 MEDLINE @ on STN
 TI Safety and Efficacy of Intravenous Golimumab in Patients With Active
 Psoriatic Arthritis: Results Through Week Twenty-Four of the
 GO-VIBRANT Study.
 SO Arthritis & rheumatology (Hoboken, N.J.), (20171100) Vol. 69, No. 11,
 pp. 2151-2161.
 Journal code: 101623795. E-ISSN: 2326-5205. L-ISSN: 2326-5191.
 Report No.: PMC-PMC5765449.
 PY 2017
 AU Kavanaugh Arthur; Husni M Elaine; Harrison Diane D; Kim Lillianne; Lo
 Kim Hung; Leu Jocelyn H; Hsia Elizabeth C
 TI Safety and Efficacy of Intravenous Golimumab in Patients With Active
 Psoriatic Arthritis: Results Through Week Twenty-Four of the
 GO-VIBRANT Study.
 AU Harrison Diane D; Kim Lillianne; Lo Kim Hung; Leu Jocelyn H
 CS Janssen Research & Development, LLC, Spring House, Pennsylvania.
 AU Hsia Elizabeth C
 CS Janssen Research & Development, LLC, Spring House, Pennsylvania, and
 University of Pennsylvania, Philadelphia.
 SO Arthritis & rheumatology (Hoboken, N.J.), (20171100) Vol. 69, No. 11,
 pp. 2151-2161.
 Journal code: 101623795. E-ISSN: 2326-5205. L-ISSN: 2326-5191.
 Report No.: PMC-PMC5765449.
 AB OBJECTIVE: To evaluate the safety and efficacy of intravenous (IV)
 golimumab treatment in psoriatic arthritis (PsA).

METHODS: In this phase III, randomized, double-blind, placebo-controlled
 trial, patients were randomly assigned to receive IV placebo (n = 239)
 or golimumab at 2 mg/kg (n = 241) at weeks 0, 4, 12, and 20. The
 primary end point was the proportion. . . modifications for patients
 with PsA.

RESULTS: At week 14, an ACR20 response was achieved by 75.1% of patients
 in the golimumab group compared with 21.8% of patients in the placebo
 group (P < 0.001). Greater proportions of golimumab-treated patients
 had an ACR50 response (43.6% versus 6.3%), an ACR70 response (24.5% versus
 2.1%), and a PASI75 response (59.2% versus 13.6%) at week 14 (P < 0.001
 for all). Patients in the golimumab group had greater mean changes at
 week 14 in HAQ DI score (-0.60 versus -0.12; P < 0.001). At week 24, the
 mean change in total PsA-modified SHS was -0.4 in the golimumab group
 and 2.0 in the placebo group (P < 0.001). Through week 24, 40.6% of
 patients in the placebo group and 46.3% of patients in the golimumab
 group had ≥1 adverse event (AE); infections were the most common
 type.

CONCLUSION: Patients receiving IV golimumab at 2 mg/kg had
 significantly greater improvements in the signs and symptoms of PsA and
 less radiographic progression through week. . .

CT . . .
 *Arthritis, Psoriatic: DT, drug therapy
 Demyelinating Diseases: CI, chemically induced
 Double-Blind Method
 Drug Therapy, Combination
 Glucocorticoids: TU, therapeutic use
 Humans
 Infusions, Intravenous
 Methotrexate: TU, therapeutic use
 Middle Aged
 Neoplasms: CI, chemically induced

Opportunistic Infections: CI, chemically induced
Patient Reported Outcome. . .
RN 476181-74-5 (golimumab); 59-05-2 (Methotrexate)
ACCESSION NUMBER: 2018872692 MEDLINE Full-text
DOCUMENT NUMBER: PubMed ID: 28805045
TITLE: Safety and Efficacy of Intravenous Golimumab in
Patients With Active Psoriatic Arthritis: Results
Through Week Twenty-Four of the GO-VIBRANT Study.
AUTHOR: Kavanaugh Arthur
CORPORATE SOURCE: University of California at San Diego, La Jolla.
AUTHOR: Husni M Elaine
CORPORATE SOURCE: Cleveland Clinic, Cleveland, Ohio.
AUTHOR: Harrison Diane D; Kim Lillianne; Lo Kim Hung; Leu Jocelyn H
CORPORATE SOURCE: Janssen Research & Development, LLC, Spring House,
Pennsylvania.
AUTHOR: Hsia Elizabeth C
CORPORATE SOURCE: Janssen Research & Development, LLC, Spring House,
Pennsylvania, and University of Pennsylvania, Philadelphia.
SOURCE: Arthritis & rheumatology (Hoboken, N.J.), (20171100) Vol.
69, No. 11, pp. 2151-2161.
Journal code: 101623795. E-ISSN: 2326-5205. L-ISSN:
2326-5191.
Report No.: PMC-PMC5765449.
DIGITAL OBJECT ID: http://dx.doi.org/10.1002/art.40226
PUB. COUNTRY: United States
DOCUMENT TYPE: (CLINICAL TRIAL, PHASE III)
Journal; Article; (JOURNAL ARTICLE)
(MULTICENTER STUDY)
(RANDOMIZED CONTROLLED TRIAL)
(RESEARCH SUPPORT, NON-U.S. GOV'T)
(CLINICAL TRIAL)
(CONTROLLED CLINICAL TRIAL)
LANGUAGE: English
FILE SEGMENT: MEDLINE; Priority Journals
FILE SEGMENT: Print
FILE SEGMENT: CLINICALTRIALS.GOV
CLINICAL TRIAL NO.: NCT02181673
ENTRY MONTH: 201711
ENTRY DATE: Entered STN: 14 Aug 2017
Last Updated on STN: 7 Nov 2017
Indexing Added: 7 Nov 2017
Entered Medline: 6 Nov 2017
OS.CITING REF COUNT: 45 There are 45 MEDLINE records that cite this record
MEDLINE REFERENCE COUNT: 24 There are 24 cited references available in
MEDLINE for this document.

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L4 112 S E38-39
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L6 6122 S GOLIMUMAB
L7 36688 S PSORIATIC ARTHRITIS
L8 675 S L6 (L) L7
L9 0 S L8 AND INTRAVENOUS (W) INFUSION
L10 0 S L8 AND INTRAVENOUS INFUSION
L11 18 S L8 AND INFUSION
L12 3 S L11 AND (INTRAVENOUS OR IV)
L13 186 S L5 AND GOLIMUMAB
L14 22 S L13 AND INFUSION

L15	21 S L14 AND (IV OR INTRAVENOUS)
L16	11 DUP REM L15 (10 DUPLICATES REMOVED)
L17	3 DUP REM L12 (0 DUPLICATES REMOVED)
L18	11 S L16-17
L19	0 S L18 AND VARIANT
L20	3 S L18 AND PY<2017
L21	4 S L18 AND PY<2018

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Doc code: IDS

PTO/SB/08a (01-22)

Doc description: Information Disclosure Statement (IDS) Filed

Approved for use through 05/31/2024. OMB 0651-0031

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INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Not for submission under 37 CFR 1.99)	Application Number		17320490	
	Filing Date		2021-05-14	
	First Named Inventor	Elizabeth C. Hsia		
	Art Unit	1646		
	Examiner Name	CHANDRA, GYAN		
	Attorney Docket Number	206389-0003-02-US		

U.S.PATENTS

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	1	20030049725		2003-03-13	HEAVNER GEORGE	
	2	20070071747		2007-03-29	HOFFMAN REBECCA S	
	3	20110251099		2011-10-13	VISVANATHAN SUDHA	
	4	20160130340		2016-05-12	SMITH JEFFREY T L	

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INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(Not for submission under 37 CFR 1.99)

Application Number	17320490
Filing Date	2021-05-14
First Named Inventor	Elizabeth C. Hsia
Art Unit	1646
Examiner Name	CHANDRA, GYAN
Attorney Docket Number	206389-0003-02-US

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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, pages(s), volume-issue number(s), publisher, city and/or country where published.	T ⁵
	1	Kavanaugh A, McInnes I, Mease P, Krueger GG, Gladman D, Gomez-Reino J, Papp K, Zrubek J, Mudivarthi S, Mack M, Visvanathan S, Beutler A. Golimumab, a new human tumor necrosis factor alpha antibody, administered every four weeks as a subcutaneous injection in psoriatic arthritis: Twenty-four-week efficacy and safety results of a randomized, placebo-controlled study. Arthritis Rheum. 2009 Apr;60(4):976-86.	☐
	2	Marichal-Gallardo PA, Alvarez MM. State-of-the-art in downstream processing of monoclonal antibodies: process trends in design and validation. Biotechnol Prog. 2012 Jul;28(4):899-916.	☐
	3	Shu Rong et al., Golimumab: A New Drug Against Rheumatoid Arthritis Chinese Journal of Pharmacoepidemiology, Volume 20, No. 01 (an English translation of the abstract is appended) 2011	☐
	4	van der Heijde D, Deodhar A, Braun J, Mack M, Hsu B, Gathany TA, Inman RD, Han C; GO-RAISE investigators. The effect of golimumab therapy on disease activity and health-related quality of life in patients with ankylosing spondylitis: 2-year results of the GO-RAISE trial. J Rheumatol. 2014 Jun;41(6):1095-103.	☐
	5	Zhuang Y, Xu Z, Frederick B, de Vries DE, Ford JA, Keen M, Doyle MK, Petty KJ, Davis HM, Zhou H. Golimumab pharmacokinetics after repeated subcutaneous and intravenous administrations in patients with rheumatoid arthritis and the effect of concomitant methotrexate: an open-label, randomized study. Clin Ther. 2012 Jan;34(1):77-90.	☐
	6	Zidi I, Bouaziz A, Mnif W, Bartegi A, Al-Hizab FA, Amor NB. Golimumab therapy of rheumatoid arthritis: an overview. Scand J Immunol. 2010 Aug;72(2):75-85.	☐

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EXAMINER SIGNATURE

Examiner Signature	/GYAN CHANDRA/	Date Considered	06/04/2024
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**INFORMATION DISCLOSURE
STATEMENT BY APPLICANT**
(Not for submission under 37 CFR 1.99)

Application Number	17320490
Filing Date	2021-05-14
First Named Inventor	Elizabeth C. Hsia
Art Unit	1646
Examiner Name	CHANDRA, GYAN
Attorney Docket Number	206389-0003-02-US

¹ See Kind Codes of USPTO Patent Documents at www.USPTO.GOV or MPEP 901.04. ² Enter office that issued the document, by the two-letter code (WIPO Standard ST.3). ³ For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. ⁴ Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST.16 if possible. ⁵ Applicant is to place a check mark here if English language translation is attached.

**INFORMATION DISCLOSURE
STATEMENT BY APPLICANT**
(Not for submission under 37 CFR 1.99)

Application Number	17320490
Filing Date	2021-05-14
First Named Inventor	Elizabeth C. Hsia
Art Unit	1646
Examiner Name	CHANDRA, GYAN
Attorney Docket Number	206389-0003-02-US

CERTIFICATION STATEMENT

Please see 37 CFR 1.97 and 1.98 to make the appropriate selection(s):

- ☐ That each item of information contained in the information disclosure statement was first cited in any communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing of the information disclosure statement. See 37 CFR 1.97(e)(1).

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- ☐ See attached certification statement.
- ☐ The fee set forth in 37 CFR 1.17 (p) has been submitted herewith.
- ☒ A certification statement is not submitted herewith.

SIGNATURE

A signature of the applicant or representative is required in accordance with CFR 1.33, 10.18. Please see CFR 1.4(d) for the form of the signature.

Signature	/Pallab Singh/	Date (YYYY-MM-DD)	2024-05-22
Name/Print	Pallab Singh	Registration Number	70731

This collection of information is required by 37 CFR 1.97 and 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 1 hour to complete, including gathering, preparing and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. **SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.**

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APPLICATION NO.	ISSUE DATE	PATENT NO.	ATTORNEY DOCKET NO.	CONFIRMATION NO.
17/320,490	10/22/2024	12122824	206389-0003-02US	5386

171672 7590 10/02/2024
Riverside Law LLP/J&J
175 Strafford Avenue
Suite 100
Wayne, PA 19087

ISSUE NOTIFICATION

The projected patent number and issue date are specified above. The patent will issue electronically. The electronically issued patent is the official patent grant pursuant to 35 U.S.C. § 153. The patent may be accessed on or after the issue date through Patent Center at <https://patentcenter.uspto.gov/>. The patent will be available in both the public and the private sides of Patent Center. Further assistance in electronically accessing the patent, or about Patent Center, is available by calling the Patent Electronic Business Center at 1-888-217-9197.

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Determination of Patent Term Adjustment under 35 U.S.C. 154 (b) (application filed on or after May 29, 2000)

The Patent Term Adjustment is 266 day(s). Any patent to issue from the above-identified application will include an indication of the adjustment on the front page.

If a Continued Prosecution Application (CPA) was filed in the above-identified application, the filing date that determines Patent Term Adjustment is the filing date of the most recent CPA.

Applicant will be able to obtain more detailed information by accessing the Patent Center (<https://patentcenter.uspto.gov>).

Any questions regarding the Patent Term Extension or Adjustment determination should be directed to the Office of Patent Legal Administration at (571)-272-7702. Questions relating to issue and publication fee payments should be directed to the Application Assistance Unit (AAU) of the Office of Patents Stakeholder Experience (OPSE), Stakeholder Support Division (SSD) at (571)-272-4200.

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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
17/320,490	05/14/2021	Diane D. Harrison	206389-0003-02US	5386
171672	7590	10/22/2024	EXAMINER	
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			ART UNIT	PAPER NUMBER
			1646	
			NOTIFICATION DATE	DELIVERY MODE
			10/22/2024	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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APPLICATION NO.	ISSUE DATE	PATENT NO.
17/320,490	22-Oct-2024	12122824

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