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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.
206389-0002-02US

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

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.

Janssen Biotech, Inc.
Exhibit 2002
Accord v. Janssen
IPR2026-00259
Ex. 2002-001

REMARKS

This application is a continuation application of US Serial No. 16/517,592, filed July 20, 2019, which is a continuation application of US Serial No. 15/818,015, filed November 20, 2017, which claims priority to US Serial No. 62/455,651, filed February 7, 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.

April 22, 2021 By: /Pallab Singh/

Pallab Singh, Ph.D., J.D.
Registration No. 70,731
Riverside Law, LLP
Glenhardie Two Corporate Center
1285 Drummers Lane, Suite 202
Wayne, PA 19087
215-268-3888 (main)
215-268-3871 (fax)
215-268-3759 (direct)
E-Mail: dockets@riversidelaw.com
Attorney for Applicants

INFORMATION DISCLOSURE STATEMENT BY APPLICANT		
	Application Number	17/237,650
	Filing Date	04/22/2021
	First Named Inventor	Diane D. Harrison
	Art Unit	OPAP
	Client Number	206389
Page 1 of 20	**Matter Number**	0002-02US

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	4757506	07/12/1988	HEICHLER JOHANNES	
	14	4766067	08/23/1988	BISWAS DEBAJIT K	
	15	4767402	08/30/1988	KOST JOSEPH	
	16	4795699	01/03/1989	TABOR STANLEY	
	17	4800159	01/24/1989	MULLIS KARY B	
	18	4816567	03/28/1989	CABILLY SHMUEL	
	19	4822776	04/18/1989	CERAMI ANTHONY	
	20	4873316	10/10/1989	MEADE HARRY	
	21	4889818	12/26/1989	GELFAND DAVID H	
	22	4921794	05/01/1990	TABOR STANLEY	
	23	4925673	05/15/1990	STEINER SOLOMON	
	24	4939666	07/03/1990	HARDMAN KARL D	
	25	4946778	08/07/1990	LADNER ROBERT C	
	26	4956288	09/11/1990	BARSOUM JAMES G	
	27	4965188	10/23/1990	MULLIS KARY B	
	28	4994370	02/19/1991	SILVER JONATHAN	
	29	5066584	11/19/1991	GYLLENSTEN ULF B	

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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	5091310	02/25/1992	INNIS MICHAEL A	
	31	5116964	05/26/1992	CAPON DANIEL J	
	32	5122464	06/16/1992	WILSON RICHARD H	
	33	5130238	07/14/1992	MALEK LAWRENCE T	
	34	5142033	08/25/1992	INNIS MICHAEL A	
	35	5149636	09/22/1992	AXEL RICHARD	
	36	5168062	12/01/1992	STINSKI MARK F	
	37	5179017	01/12/1993	AXEL RICHARD	
	38	5223409	06/29/1993	LADNER ROBERT C	
	39	5225538	07/06/1993	CAPON DANIEL J	
	40	5225539	07/06/1993	WINTER GREGORY P	
	41	5231024	07/27/1993	MOELLER ACHIM	
	42	5260203	11/09/1993	LADNER ROBERT C	
	43	5266491	11/30/1993	NAGATA SHIGEKAZU	
	44	5304489	04/19/1994	ROSEN JEFFREY M	
	45	5342613	08/30/1994	CREAVEN PATRICK J	
	46	5385839	01/31/1995	STINSKI MARK F	
	47	5403484	04/04/1995	LADNER ROBERT C	
	48	5404871	04/11/1995	GOODMAN DAVID E	
	49	5427908	06/27/1995	DOWER WILLIAM J	
	50	5447851	09/05/1995	BEUTLER BRUCE A	
	51	5455030	10/03/1995	LADNER ROBERT C	
	52	5458135	10/17/1995	PATTON JOHN S	
	53	5496549	03/05/1996	YAMAZAKI HIROH	
	54	5512544	04/30/1996	WALLACH DAVID	
	55	5514670	05/07/1996	FRIEDMAN DORON	
	56	5518889	05/21/1996	LADNER ROBERT C	
	57	5530101	06/25/1996	QUEEN CARY L	
	58	5534621	07/09/1996	LADNER ROBERT C	

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Initials	Cite No.	Document Number	Issue/Publication Date	First Named Inventor	Relevant Pages, Columns, etc.
	59	5545806	08/13/1996	LONBERG NILS	
	60	5545807	08/13/1996	SURANI AZIM M	
	61	5565362	10/15/1996	ROSEN JEFFREY M	
	62	5569825	10/29/1996	LONBERG NILS	
	63	5571698	11/05/1996	LADNER ROBERT C	
	64	5576195	11/19/1996	ROBINSON RANDY R	
	65	5580717	12/03/1996	DOWER WILLIAM J	
	66	5580734	12/03/1996	TRECO DOUGLAS A	
	67	5582996	12/10/1996	CURTIS PETER J	
	68	5585089	12/17/1996	QUEEN CARY L	
	69	5595898	01/21/1997	ROBINSON RANDY R	
	70	5601819	02/11/1997	WONG JOHNSON T	
	71	5618920	04/08/1997	ROBINSON RANDY R	
	72	5625126	04/29/1997	LONBERG NILS	
	73	5625825	04/29/1997	ROSTOKER MICHAEL D	
	74	5633425	05/27/1997	LONBERG NILS	
	75	5637052	06/10/1997	HIROTA TOSHIAKI	
	76	5641670	06/24/1997	TRECO DOUGLAS A	
	77	5643759	07/01/1997	PFREUNDSCHUH MICHAEL	
	78	5643768	07/01/1997	KAWASAKI GLENN H	
	79	5654407	08/05/1997	BOYLE PETRA	
	80	5656272	08/12/1997	LE JUNMING	
	81	5656730	08/12/1997	LEE LIHSYNG STANFORD	
	82	5658570	08/19/1997	NEWMAN ROLAND A	
	83	5658754	08/19/1997	KAWASAKI GLENN H	
	84	5661016	08/26/1997	LONBERG NILS	
	85	5693493	12/02/1997	ROBINSON RANDY R	
	86	5693762	12/02/1997	QUEEN CARY L	
	87	5698195	12/16/1997	LE JUNMING	

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Initials	Cite No.	Document Number	Issue/Publication Date	First Named Inventor	Relevant Pages, Columns, etc.
	88	5698417	12/16/1997	ROBINSON RANDY R	
	89	5698419	12/16/1997	WOLPE STEPHEN D	
	90	5698435	12/16/1997	ROBINSON RANDY R	
	91	5714352	02/03/1998	JAKOBOBITS AYA	
	92	5723323	03/03/1998	KAUFFMAN STUART ALAN	
	93	5733761	03/31/1998	TRECO DOUGLAS	
	94	5750105	05/12/1998	NEWMAN ROLAND A	
	95	5750373	05/12/1998	GARRARD LISA J	
	96	5763192	06/09/1998	KAUFFMAN STUART ALAN	
	97	5763733	06/09/1998	WHITLOW MARC	
	98	5766886	06/16/1998	STUDNICKA GARY M	
	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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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	ANAGNOSTOPULOS HIRISTO	
	126	5959083	09/28/1999	BOSSLET KLAUS	
	127	5959084	09/28/1999	RING DAVID	
	128	5962255	10/05/1999	GRIFFITHS ANDREW DAVID	
	129	5976862	11/02/1999	KAUFFMAN STUART ALAN	
	130	5989530	11/23/1999	LORENZ HERIBERT	
	131	5993833	11/30/1999	DE LACHARRIERE OLIVIER	
	132	5994616	11/30/1999	ROSEN JEFFREY M	
	133	6010902	01/04/2000	LEDBETTER JEFFREY A	
	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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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	20090214528	08/27/2009	DORAI HAIMANTI	
	150	20100251099	09/30/2010	MAKOWER DAVID	
	151	20110251099	10/13/2011	VISVANATHAN SUDHA	

FOREIGN PATENT DOCUMENTS						
Initials	Cite No.	Document Number	Publication Date	Country	Relevant Pages, Columns, etc.	T
	152	1764992A	10/21/1992	AU		X
	153	0212489B1	11/30/1994	EP		X
	154	0218868A2	04/22/1987	EP		
	155	0229046B1	05/04/1994	EP		X
	156	0229246B1	08/04/1993	EP		X
	157	0237507B1	12/27/1991	EP		
	158	0260610B1	09/01/1993	EP		X
	159	0288088B1	03/09/1994	EP		X
	160	0308378B1	11/30/1994	EP		X
	161	0350690A2	01/17/1990	EP		X
	162	0351789B1	11/25/1998	EP		X
	163	0368684B1	03/09/1994	EP		X
	164	0371998B1	03/02/1994	EP		X
	165	0380068A1	08/01/1990	EP		X
	166	0393438A2	10/24/1990	EP		X
	167	0398327B1	03/15/1995	EP		X
	168	0412486B1	11/30/1994	EP		X
	169	0433900A1	06/26/1991	EP		X

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Initials	Cite No.	Document Number	Publication Date	Country	Relevant Pages, Columns, etc.	T
	170	0438474B1	05/15/1996	EP		X
	171	0463151B1	06/12/1996	EP		X
	172	0486526B2	03/07/2001	EP		X
	173	0525570A2	02/03/1993	EP		X
	174	0526905A3	05/05/1993	EP		X
	175	0550400B1	07/10/1996	EP		X
	176	0610201B1	05/16/2001	EP		X
	177	614989A1	09/14/1994	EP		X
	178	0710719B1	03/14/2007	EP		X
	179	2870137B1	05/16/2018	EP		X
	180	2272440A	05/18/1994	GB		
	181	11127855A	05/18/1999	JP		X
	182	0212500A2	02/14/2001	WO		X
	183	0212502A2	02/14/2002	WO		X
	184	8605803A1	10/09/1986	WO		
	185	8806630A1	09/07/1988	WO		X
	186	8906283A1	07/13/1989	WO		X
	187	9000902A1	02/08/1990	WO		X
	188	9003809A1	04/19/1990	WO		X
	189	9004036A1	04/19/1990	WO		
	190	9005370A1	05/17/1990	WO		
	191	9014424A1	11/29/1990	WO		X
	192	9014430A1	11/29/1990	WO		X
	193	9014442A1	11/29/1990	WO		X
	194	9014443A1	11/29/1990	WO		X
	195	9100360A1	01/10/1991	WO		X
	196	9102078A1	02/21/1991	WO		X
	197	9109967A1	07/11/1991	WO		X
	198	9117271A1	11/14/1991	WO		

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	199	9118980A1	12/12/1991	WO		X
	200	9119818A1	12/26/1991	WO		X
	201	9200373A1	01/09/1992	WO		X
	202	9203461A1	03/05/1992	WO		
	203	9205258A1	04/02/1992	WO		X
	204	9206204A1	04/16/1992	WO		
	205	9207076A1	04/30/1992	WO		X
	206	9211272A1	07/09/1992	WO		
	207	9211383A1	07/09/1992	WO		X
	208	9213095A1	08/06/1992	WO		X
	209	9214843A1	09/03/1992	WO		X
	210	9216221A1	10/01/1992	WO		X
	211	9216553A1	10/01/1992	WO		X
	212	9218619A1	10/29/1992	WO		X
	213	9302108A1	02/04/1993	WO		X
	214	9308278A1	04/29/1993	WO		X
	215	9308829A1	05/13/1993	WO		X
	216	9311383A1	06/10/1993	WO		X
	217	9406498A1	03/31/1994	WO		X
	218	9408552A2	04/28/1994	WO		X
	219	9416970A1	08/04/1994	WO		X
	220	9418219A1	08/18/1994	WO		X
	221	9425585A1	11/10/1994	WO		X
	222	9501538A1	01/12/1995	WO		
	223	9516027A1	06/15/1995	WO		X
	224	9607754A1	03/14/1996	WO		X
	225	9619256A1	06/27/1996	WO		X
	226	9629411A1	09/26/1996	WO		
	227	9633735	10/31/1996	WO		X

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

OTHER DOCUMENTS			
Initials	Cite No.	Author, Title, Date, Pages, etc.	T
	248	(JOHNSON AND JOHNSON) SIMPONI® ARIA™ (golimumab) for infusion Receives FDA Approval for Treatment of Moderately to Severely Active Rheumatoid Arthritis 18 July, 2013 [retrieved on 18 January, 2018] pages 1-6; page 1/6, paragraph 1; page 2/6, paragraph 3; retrieved from the internet <https://www.jnj.com/media-center/press-releases/simponi-aria-golimumab-for-infusion-receives-f da-approval-for-treatment-of-moderately-to-severely-active-rheumatoid-arthritis>	
	249	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).	
	250	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. Scl., 28(2):126-130 (1992).	

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OTHER DOCUMENTS			
Initials	**Cite No.**	**Author, Title, Date, Pages, etc.**	**T**
	251	ADERKA, Dan, "Role of Tumor Necrosis Factor in the Pathogenesis of Intravascular Coagulopathy of Sepsis: Potential New Therapeutic Implications," IsrJ Med Scl, 27:52-60 (1991).	
	252	AGGARWAL, Bharat B. et al., "Human Tumor Necrosis Factor Production, Purification and Characterization," J. of Biol. Chem., 260(4):2345-2354 (1985).	
	253	AKAMA, Hideto et al., "Mononuclear Cells Enhance Prostaglandin E2 Production of Polymorphonuclear Leukocytes via Tumor Necrosis Factor a," Biochemical and Biophysical Research Comm., 168(2):857-862 (1990).	
	254	ALT, et al., "Selective Multiplication of Dihydrofolate Reductase Genes in Methotrexate-resistant Variants of Cultured Murine Cells", J. Biol. Chem. 253:1357-1370 (1978)	
	255	ANDERSON JJ, BARON G, VAN DER HEIJDE D, FELSON DT, DOUGADOS M. Ankylosing spondylitis assessment group preliminary definition of short-term improvement in ankylosing spondylitis. Arthritis Rheum. 2001 ;44(8):1876-1886.	
	256	Anonymous, "(FRMC) Simponi Aria Effective For Treating Ankylosing Spondylitis", Managed Health Care Connect, (20161115), pages 1 - 3, URL: http://www.managedhealthcareconnect.com/content/simponi-aria-effective-treating-ankylosing-spondylitis, (20180118), XP009517728	
	257	ASHKENAZI et al., "Protection against endotoxic shock by a tumor necrosis factor receptor immunoadhesin", Proc. Natl. Acad. Sci. USA 88:10535-10539 (1991);	
	258	Assessment of SpondyloArthritis. Ankylosing spondylitis disease activity score. Available at: http://www.asasgroup.org/research.php?id=01. Accessed on 17 April 2014.	
	259	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));	
	260	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)	
	261	BEBBINGTON, et al., "High-Level Expression of a Recombinant Antibody from Myeloma Cells Using a Glutamine Systhetase Gene as an Amplifiable Selectable Marker", Bio/Technology 10:169-175(1992))	
	262	BERKOW et al., Eds, The Merck Manual of Diagnosis and Therapy, Sixteenth Edition, Merck Research Laboratories, Rahway, NJ 1992 pg. 1263-1287	
	263	BEUTLER, B. et al., "Identity of tumour necrosis factor and the macrophage-secreted factor cachectin," Nature, 316:552-554 (1985).	
	264	BEUTLER, B. et al., "Passive Immunization Against Cachectin/Tumor Necrosis Factor Protects Mice from Lethal Effect of Endotoxin," Science, 229:869-871 (1985).	
	265	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).	
	266	BODMER, Mark, "Humanized Antibodies for Anti-TNF Therapy," Abstract, Endotoxemia & Sepsis Conference (1991).	
	267	BOSHART, et al., "A Very Strong Enhancer Is Located Upstream of an Immediate Early Gene of Human Cytomegalovirus", Cell 41:521-530 (1985))	
	268	BRANDT J, HAIBEL H, CORNELY D, et al. Successful treatment of active ankylosing spondylitis with the anti-tumor necrosis factor alpha monoclonal antibody infliximab. Arthritis Rheum. 2000;43(6):1346-1352	

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.

OTHER DOCUMENTS			
Initials	**Cite No.**	**Author, Title, Date, Pages, etc.**	**T**
	269	BRANDT J, KHARIOUZOV A, Listing J, et al. Six-month results of a double-blind, placebo-controlled trial of etanercept treatment in patients with active ankylosing spondylitis. Arthritis Rheum. 2003;48(6):1667-1675.	
	270	BRAUN J, BOLLOW M, NEURE L, et al. Use of immunohistologic and in situ hybridization techniques in the examination of sacroiliac joint biopsy specimens from patients with ankylosing spondylitis. Arthritis Rheum. 1995;38(4):499-505.	
	271	BRAUN J, BRANDT J, LISTING J, et al. Treatment of active ankylosing spondylitis with infliximab: a randomised controlled multicentre trial. Lancet. 2002;359(9313):1187-1193.	
	272	BREBAN M, VIGNON, E, CLAUDEPIERRE, P, et al. Efficacy of infliximab in refractory ankylosing spondylitis: results of a six-month open-label study. Rheumatology. 2002;4:1280-1285.	
	273	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).	
	274	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);	
	275	CALIN A, GARRETT S, WHITELOCK H, et al. A new approach to defining functional ability in ankylosing spondylitis: the development of the Bath Ankylosing Spondylitis Functional Index. J Rheumatol. 1994;21(12):2281-2285.	
	276	CANETE JD, LLENA J, COLLADO A, et al. Comparative cytokine gene expression in synovial tissue of early rheumatoid arthritis and seronegative spondyloarthropathies. Br J Rheumatol. 1997;36(1):38-42.	
	277	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).	
	278	CAPON et al., "Designing CD4 immunoadhesins for AIDS therapy", Nature 337:525-531 (1989),	
	279	CARTER et al., "Humanization of an anti-p185HER2 antibody for human cancer therapy", Proc. Natl. Acad. Sci. U.S.A. 89:4285 (1992)	
	280	Chothia, et al., "Canonical Structures for the Hypervariable Regions of Immunoglobulins," Journal of Molecular Biology, 196: 901-917 (1987).	
	281	CLEGG DO, REDA DJ, WEISMAN MH, et al. Comparison of sulfasalazine and placebo in the treatment of ankylosing spondylitis. A Department of Veterans Affairs Cooperative Study. Arthritis Rheum. 1996;39(12):2004-2012	
	282	COLLINS, M.S. et al., "Immunoprophylaxis of Polymicrobic Cellulitis with a Human Monoclonal Antibody Against Lipopolysaccharide Antigen of Pseudomonas aeruginosa," Abstract E-63, Abstracts of Annual Meeting 1989.	
	283	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)	
	284	Copy of Canadian Examination Report for CA application 2,994,253 dated November 26, 2018	
	285	Copy of Canadian Examination Report for CA2878319 dated 11 December 2019	
	286	CORCORAN et al., "Characterization of ligand binding by the human p55 tumour-necrosis-factor receptor", Eur. J. Biochem. 223:831-840 (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.

OTHER DOCUMENTS			
Initials	**Cite No.**	**Author, Title, Date, Pages, etc.**	**T**
	287	CRAMER et al., "Transgenic Plants for Therapeutic Proteins: Linking Upstream and Downstream Strategies", Curr. Top. Microbol. Immunol. 240:95-118 (1999)	
	288	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).	
	289	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))	
	290	CUNNINGHAM AND WELLS, "High-Resolution Epitope Mapping of hGH-Receptor Interations by Alanine-Scanning Mutagenesis", Science Ausubel, supra, Chapters 8, 15; 244:1081-1085 (1989)).	
	291	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)	
	292	DAVIS JC, VAN DER HEIJDE D, BRAUN J, et al. Recombinant human tumor necrosis factor receptor (etanercept) for treating ankylosing spondylitis. A randomized controlled trial. Arthritis Rheum. 2003;48(11):3230-3236.	
	293	DE VOS, et al., "Human Growth Hormone and Extracellular Domain of Its Receptor: Crystal Structure of the Complex", Science 255:306-312 (1992)).	
	294	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	
	295	DI GIOVINE, Francesco, S. et al., "Tumour necrosis factor in synovial exudates," Annals of the Rheumatic Diseases, 47:768-772 (1988).	
	296	DOWARD LC, SPOORENBERG A, COOK SA, et.al. Development of the ASQoL: a quality of life instrument specific to ankylosing spondylitis. Ann Rheum Dis. 2003;62(1):20-26.	
	297	Doyle et al., Rheumatology 52:1214-1219,(2013).	
	298	DUNCOMBE, Andrew S. et al., "Tumor Necrosis Factor Mediates Autocrine Growth Inhibition in a Chronic Leukemia," J Immunol, 143:3828-3834 (1989).	
	299	DUPONT et al., "Escherichia coli Diarrhea" Bacterial Infections of Humans:Epidemioloqv and Control, A.S. Evans et al., 2nd Edition, Spring Science & Business Media, New York, pqs. 239-254(1991)	
	300	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)	
	301	ECHTENACHER, Bernd et al., "Requirement of Endogenous Tumor Necrosis Factor/Cachectin for Recovery from Experimental Peritonitis," J. of Immunology, 145(11):3762-3766 (1990).	
	302	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).	
	303	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	
	304	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).	

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.

OTHER DOCUMENTS			
Initials	**Cite No.**	**Author, Title, Date, Pages, etc.**	**T**
	305	ENGELMANN, Hartmut et al., "Two Tumor Necrosis Factor-binding Proteins Purified from Human Urine," J. of Bio. Chem., 265(3):1531 -1536 (1990).	
	306	EREN et al. "Human monoclonal antibodies specific to hepatitis B virus generated in a human/mouse radiation chimera: the Trimera system", Immunol. 93: 154-161 (1998)	
	307	EUROQOL GROUP. EUROQOL - a new facility for the measurement of health-related quality of life. Health Policy. 1990;16:199-208.	
	308	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).	
	309	EXLEY, A.R. et al., "Monoclonal antibody to TNF in severe septic shock," The Lancet, 335:1275-1277(1990).	
	310	FENDLY, Brian M. et al., "Murine Monoclonal Antibodies Defining Neutralizing Epitopes on Tumor Necrosis Factor," Hybridoma, 6(4):359-370 (1987).	
	311	FISCH et al., "Site-Specific Modification of a Fragment of a Chimeric Monoclonal Antibody Using Reverse Proteolysis", Bioconjugate Chem., 3:147-153 (1992);	
	312	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),	
	313	FISHWALD et al., "High-avidity human IgGk monoclonal antibodies from a novel strain of minilocus transgenic mice", Nat Biotechnol 14(7):845-851 (1996).	
	314	FONG, Yuman and Lowry, Stephen F., "Tumor Necrosis Factor in the Pathophysiology of Infection and Sepsis," Clin Immunol Immunopathol, 55:157-170 (1990).	
	315	FONG, Yuman et al., "Antibodies to Cachectin/Tumor Necrosis Factor Reduce Interleukin 1ß and Interleukin 6 Appearance During Lethal Bacteremia," J. Exp. Med., 170:1627-1633 (1989).	
	316	FOOTE et al., "Antibody Framework Residues Affecting the Conformation of the Hypervariable Loops", Journal of Molecular Biology, 224(2), pgs. 487-499 (1992)	
	317	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).	
	318	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.	
	319	GENEBANK ACCESSION, No. M32046 (1990,June 15).	
	320	Genebank Accession, No. N90300 (Nov. 1, 1989).	
	321	GILLIES, Stephen D. et al., "High-level expression of chimeric antibodies using adapted cDNA variable region cassettes," J Immunol Methods, 125:191-202 (1989).	
	322	GORMAN JD, SACK KE, DAVIS JC JR. Treatment of ankylosing spondylitis by inhibition of tumor necrosis factor L. N Engl J Med. 2002;346(18):1349-1356.	
	323	GORMAN, S.D. and Clark, M.R., "Humanisation of monoclonal antibodies for therapy," Sem Immunol, 2:457-466 (1990).	
	324	GOSSEN, AND H. BUJARD, "Tight control of gene expression in mammalian cells by tetracycline-responsive promotoers", 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.			

OTHER DOCUMENTS			
Initials	**Cite No.**	**Author, Title, Date, Pages, etc.**	**T**
	325	GRATACOS J, COLLADO A, FILELLA X, et al. Serum cytokines (IL-6, TNF-alpha, IL-1 beta and IFN-gamma) in ankylosing spondylitis: a close correlation between serum IL-6 and disease activity and severity. Br J Rheumatol. 1994;33(10):927-931.	
	326	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);	
	327	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)	
	328	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)	
	329	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)	
	330	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)	
	331	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)	
	332	HARRIS, "Ankvlosinq Spondylitis", Chapter 6, Spondyloarthropathies, Kellev's Textbook of Rheumatology, 6th Edition, Sledqe CB, pas. 1039-1053 (2001)	
	333	HAYASHI, H. et al., "An Enzyme-linked Immunosorbent Assay for Recombinant Human Tumor Necrosis Factor Using Monoclonal Antibody," Recent Adv. Chemother, 820-821 (1985).	
	334	HAYS RD, MARTIN SA, SESTI AM, SPRITZER KL. Psychometric properties of the Medical Outcomes Study Sleep measure. Sleep Med. 2005;6(1):41-44.	
	335	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).	
	336	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).	
	337	HIRAI, Makoto et al., "Production and characterization of monoclonal antibodies to human tumor necrosis factor," J. oflmmun. Methods, 96:57-62 (1987).	
	338	HOOD et al., "Molecular Farming of Industrial Proteins from Transgenic Maize", Adv. Exp. Med. Biol. 464:127-147(1999)	
	339	INMAN RD, DAVIS JC JR, HEIJDE DV, et.al. Efficacy and safety of golimumab in patients with ankylosing spondylitis: results of a randomized, double-blind, placebo-controlled, phase III trial. Arthritis Rheum. 2008;58(11):3402.	
	340	ITOH et al., "Application of Inverse Substrates to Trypsin-Catalyzed Peptide Synthesis", Bioorg. Chem., 24(1): 59-68 (1996).	
	341	J. L. HAMLIN AND C. MA, "The mammalian dihydrofolate reductase locus", Biochem. et Biophys. Acta 1097:107-143 (1990)	
	342	Jones, et al., "Replacing the complementarity-determining regions in a human antibody with those from a mouse," Nature, 321: 522-525 (1986).	

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.

OTHER DOCUMENTS			
Initials	**Cite No.**	**Author, Title, Date, Pages, etc.**	**T**
	343	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	
	344	KAMEYAMA, Koh-zoh, et al., "Convenient plasmid vectors for construction of chimeric mouse/human antibodies," FEBS Lett, 244:301-306 (1989).	
	345	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))	
	346	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).	
	347	KENNY et al., "Production of Monoclonal Antiboodies Using a Secretion Capture Report Web", Bio/ Technol. 13:787-790 (1995).	
	348	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	
	349	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);	
	350	KOZBOR et al., "The production of monoclonal antibodies from human lymphocytes", Immunol. Today, 4:72-79(1983);	
	351	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);	
	352	LANDEWE R, BRAUN J, DEODHAR A, et.al. Efficacy of certolizumab pegol on signs and symptoms of axial spondylarthritis including ankylosing spondylitis: 24-week results of a double-blind randomised placebocontrolled Phase 3 study. Ann Rheum Dis. 2013;0:1-9.	
	353	LANGE U, TEICHMANN J, STRACKE H. Correlation between plasma TNF-alpha, IGF-1, biochemical markers of bone metabolism, markers of inflammation/disease activity, and clinical manifestations in ankylosing spondylitis. Eur J Med Res. 2000;5(12):507-511.	
	354	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	
	355	LASSALLE, Ph., et al., "Potential Implicaton of Endothelial Cells in Bronchial Asthma," Int Arch Allergy Appl Immunol, 94:233-238 (1991).	
	356	LESSLAUER et al., "Recombinant soluble tumor necrosis factor receptor proteins protect mice from lipopolysaccharide-induced lethality", Eur. J. Immunol. 21:2883-2886 (1991)	
	357	LIANG, Chi-Ming et al., "Production and Characterization of Monoclonal Antibodies Against Recombinant Human Tumor Necrosis Factor/Cachectin," Biochem. & Biophy. Res. Comm., 137(2):847-854(1986).	
	358	LOETSCHER et al., "Molecular Cloning and Expression of the Human 55 kd Tumor Necrosis Factor Receptor", Cell 61: pgs. 351-359 (1990)	
	359	LONBERG et al. "Antigen-specific human antibodies from mice comprising four distinct genetic modifications", Nature 368:856-859 (1994)	
	360	LONBERG et al., "Human Antibodies from Transgenic Mice", Int Rev Immunol 13(1):65-93 (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.

OTHER DOCUMENTS			
Initials	**Cite No.**	**Author, Title, Date, Pages, etc.**	**T**
	361	LUCAS, R. et al., "Generation and characterization of a neutralizing rat anti-rm TNF-a monoclonal antibody," Immunology, 71:218-223 (1990).	
	362	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)).	
	363	MA et al., "Immunotherapeutic potential of antibodies produced in plants", Trends Biotechnol. 13:522-7(1995)	
	364	MA et al., "Plant Antibodies for Immunotherapy", Plant Physiol. 109:341-6 (1995).	
	365	MACHADO P, LANDEWE R, LIE E, et al. Ankylosing Spondylitis Disease Activity Score (ASDAS): defining cutoff values for disease activity states and improvement scores for the Assessment of SpondyloArthritis international Society. Ann Rheum Dis. 2011;70:47-53.	
	366	MARRACK et al, "The Staphylococcal Enterotoxins and Their Relatives", Science, 248:705-711 (1990),	
	367	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).	
	368	Mendez, et al., "Functional transplant of megabase human immunoglobulin loci recapitulates human antibody response in mice," Nature Genetics, 15(2): 146-156 (1997).	
	369	MERCK SHARP & DOHME CORP., "Effect of Golimumab in Participants With Active Axial Spondylarthritis (GOAHEAD) (P07642, MK8259006)", pgs. 1-4 (2011)	
	370	Milstein, et al., "Hybrid hybridomas and their Use in Immunohistochemistry," Nature, 305: 537-540 (1983).	
	371	MOCELLIN et al., "Tumor necrosis factor, cancer and anticancer therapy", Cytokine Growth Factor Rev. 2005 Feb; 16(1) 35-53, Epub 2004 Dec 19	
	372	MOLLER, Achim et al., "Monoclonal Antibodies to Human Tumor Necrosis Factor a: In Vitro and In Vivo Application," Cytokine, 2(3):162-169 (1990).	
	373	MORRISON, Sherie L., "Transfectomas Provide Novel Chimeric Antibodies," Science, 229:1202-1207(1985).	
	374	MULLER, "Determination of Affinity and Specificity of Anti-Hapten Antibodies by Competitive Radioimmunoassay", Meth. Enzymol., 92:589-601 (1983),	
	375	MURPHY, et al., "Matrix metalloproteinase degradation of elastin, type IV collagen and proteoglycan", Biochem. J. 227:277-279 (1991)	
	376	NAGAI, M. et al., "Antibody to tumor necrosis factor (TNF) reduces endotoxin fever," Experientia, 44:606-607 (1988).	
	377	NEUBERGER, M., "Generating high-avidity human Mabs in mince", Nature Biotech. 14:826 (1996)	
	378	NGUYEN et al., "Production of Human Monoclonal Antibodies in SCID Mouse", Microbiol. Immunol. 41:901-907(1997)	
	379	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).	
	380	Notice of Allowance dated January 25, 2021 for US App. No. 16/517,592 (pages 1-8)	

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.

OTHER DOCUMENTS			
Initials	**Cite No.**	**Author, Title, Date, Pages, etc.**	**T**
	381	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).	
	382	PARRILLO, Joseph E., "Pathogenetic Mechanisms of Septic Shock," N.E. Journal of Medicine, 328(20):1471-1477 (1993).	
	383	PAULUS, H., A Preparation and Biomedical Applications of Bispecific Antibodies®, Behring Inst. Mitt, No.78:118-132 (1985).	
	384	PENNINGTON, James, "TNF: Therapeutic Target in Patients with Sepsis," ASM News, 58(9):479-482(1992).	
	385	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);	
	386	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	
	387	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).	
	388	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)	
	389	PRESTA et al., "Humanization of an Antibody Directed Against IgE", J. Immunol. 151:2623 (1993),	
	390	Reichmann, et al., "Reshaping human antibodies for therapy," Nature, 332: 323-327 (1988).	
	391	REVEILLE JD. Epidemiology of spondyloarthritis in North America. Am J Med Sci. 2011;341(4):284-286.	
	392	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).	
	393	RUDIKOFF et al., Single amino acid substitution altering antigen-binding specificity", PNAS, March 1982, Vol 79, p. 1979-83	
	394	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)	
	395	S. STEPHENS et al., "Comprehensive pharmacokinestic of a humanized antibody and analysis of residual anti-idoiotypic responses", Immunology, Vol. 85, No. 4, pgs. 668-674 XP000881488 (August 1995)	
	396	SANDHU et al., "The Use of SCID Mice in Biotechnology and as a Model for Human Disease", Crit. Rev. Biotechnol. 16:95-118 (1996)	
	397	SCALLON, et al., Functional Comparisons of Different Tumour Necrosis Factor Receptor/IgG Fusion Proteins", Cytokine 7:759-770 (1995)	
	398	SCHALL, Thomas J. et al., "Molecular Cloning and Expression of a Receptor for Human Tumor Necrosis Factor," Cell, 61:361-370 (1990).	
	399	SCOTT et al., "An Anti-Tumor Necrosis Factor-a Antibody Inhibits the Development of Experimental Skin Tumors", Mol. Can Therapy, 2003 May, 2:445-451	

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.			

OTHER DOCUMENTS			
Initials	**Cite No.**	**Author, Title, Date, Pages, etc.**	**T**
	400	SHIMAMOTO, Yoshinori et al., "Monoclonal antibodies against human recombinant tumor necrosis factor: prevention of endotoxic shock," Immunology Letters, 77:311-318 (1988).	
	401	SIEPER J, RUDWALEIT M, BARALIAKOS X, et al. The Assessment of SpondyloArthritis international Society (ASAS) handbook: a guide to assess spondyloarthritis. Ann Rheum Dis. 2009;68(2):ii1-ii44.	
	402	SILVA, Ayona T. et al., "Prophylactic and Therapeutic Effects of a Monoclonal Antibody to Tumor Necrosis Factor-a in Experimental Gram-Negative Shock," J. of Infectious Diseases, 162:421-427(1990).	
	403	SIMS et al., "A Humanized CD18 Antibody Can Block Function without Cell Destruction", J. Immunol. 151:2296(1993)	
	404	SMITH, Craig R., "Human and Chimeric Antibodies to LPS and TNF," 4Abstract, Endotoxemia & Sepsis Conference (1991).	
	405	SMITH, et al., "Human Interleukin 4: The Solution Structure of a Four-helix Bundle Protein", J. Mol. Biol. 224:899-904 (1992)	
	406	Smolen et al., "Treating spondyloarthritis, including ankylosing spondylitis and psoriatic arthritis, to target: recommendations of an international task force." Ann Rheum Dis. 2014 Jan;73(1):6-16.	
	407	SPRAGUE, et al., "Expression of a Recombinant DNA Gene Coding for the Vesiclar Stomatitis Virus Nucleocapsid Protein", J. Virol. 45:773-781 (1983)).	
	408	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).	
	409	STEADMAN' Medical Dictionary, 27th Ed. 2000 Lippincott Williams & Wilkins - "Carcinoma"	
	410	STEENBAKKERS et al., "Efficient generation of monoclonal antibodies from preselected antigen-specific B", Molec. Biol. Reports 19:125-134 (1994).	
	411	STEIN et al., "Diseases of the Hearth and Blood Vessels", Internal Medicine, 3rd 3d., pg.1-13, Little Brown and Co. Boston (1990)	
	412	STONE et al., "Solid malignancies among patients in the Wegener's Granulomatosis Etanercept Trial", Arthritis Rheum. 2006 May; 54(5) 1608-18 abstract only	
	413	STONE M, SALONEN D, LAX M, PAYNE U, LAPP V, INMAN R. Clinical and imaging correlates of response to treatment with infliximab in patients with ankylosing spondylitis. J Rheumatol. 2001;28(7):1605-1614	
	414	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).	
	415	SURESH et al., "Bispecific Monoclonal Antibodies from Hybrid Hybridomas", Methods in Enzymology 121:210 (1986)	
	416	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)	
	417	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**
	418	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).	
	419	TEMEKONIDIS TI, ALAMANOS Y, NIKAS SN, et al. Infliximab therapy in patients with ankylosing spondylitis: an open label 12 month study. Ann Rheum Dis. 2003;62(12):1218-1220.	
	420	TOUSSIROT E, LAFFORGUE P, BOUCRAUT J, et al. Serum levels of interleukin 1-beta, tumor necrosis factor-alpha, soluble interleukin 2 receptor and soluble CD8 in seronegative spondylarthropathies. Rheumatol Int. 1994;13(5):175-180.	
	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 DEN BOSCH F, KRUITHOF E, BAETEN D, et al. Effects of a loading dose regimen of three infusions of chimeric monoclonal antibody to tumour necrosis factor alpha (infliximab) in spondyloarthropathy: an open pilot study. Ann Rheum Dis. 2000;59(6):428-433.	
	425	VAN DEN BOSCH F, KRUITHOF E, BAETEN D, et al. Randomized double-blind comparison of chimeric monoclonal antibody to tumor necrosis factor LLL(infliximab) versus placebo in active spondylarthropathy. Arthritis Rheum. 2002; 46(3):755-765.	
	426	VAN DER HEIJDE D, DIJKMANS B, GEUSENS P, et al. Efficacy and safety of infliximab in patients with ankylosing spondylitis: results of a randomized, placebo-controlled trial (ASSERT). Arthritis Rheum. 2005a;52(2):582- 591.	
	427	VAN DER HEIJDE D, KIVITZ A, SCHIFF MH, et.al. Efficacy and safety of adalimumab in patients with ankylosing spondylitis: results of a multicenter, randomized, double-blind, placebo-controlled trial. Arthritis Rheum. 2006;54(7):2136-2146.	
	428	VAN DER HEIJDE D, LANDEWE R, FELDTKELLER E. Proposal of a linear definition of the Bath Ankylosing Spondylitis Metrology Index (BASMI) and comparison with the 2-step and 10-step definitions. Ann Rheum Dis. 2008;67:489-493.	
	429	VAN DER HEIJDE D, LIE E, KVIEN T K, ET AL. A highly discriminatory ASAS-endorsed disease activity score in patients with ankylosing spondylitis: For the Assessment of SpondyloArthritis international Society (ASAS). Ann Rheum Dis. 2009;68:1811-1818.	
	430	VAN DER HEIJDE D, SIEPER J, MAKSYMOWYCH WP, Assessment of SpondyloArthritis international Society, et al. 2010 Update of the international ASAS recommendations for the use of anti-TNF agents in patients with axial spondyloarthritis. Ann Rheum Dis. 2011;70(6):905-908	
	431	VAN DER HEIJDE, D. et al, "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", Journal of Rheumatology, 41, pages 1095-1103, June 2014	
	432	VAN DER LINDEN S, VAN DER HEIJDE D. Ankylosing Spondylitis. In: Ruddy S, Harris ED, Sledge CB, ed. Kelley's Textbook of Rheumatology. 6th ed, 2001 ;1039-1053.	
	433	VERHOEYEN et al., "Reshaping Human Antibodies:Grafting an Antilysozyme Activity", Science 239:1534(1988).	
	434	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).	

Examiner Signature		**Date Considered**	

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OTHER DOCUMENTS			
Initials	**Cite No.**	**Author, Title, Date, Pages, etc.**	**T**
	435	WALDMANN, Thomas A., "Monoclonal Antibodies in Diagnosis and Therapy," Science, 252:1657-1662(1991).	
	436	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.	
	437	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.	
	438	WEN et al., "Limiting diluation 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)	
	439	WERLEN et al., "Site-Specific Conjugation of an Enzyme and an Antibody Fragment", Bioconjugate Chem., 5:411-417 (1994)	
	440	Whitelam, et al., "Antibody production in transgenic plants," Biochemical Society Transactions," Transgenic Plants and Plan Biochemistry, 22: 940-944 (1994).	
	441	WHITTLE, Nigel, et al., "Construction and Expression of a CDR-Grafted Anti-TNF Antibody," J. Cell Blochem, Supl. 13A:96 (1989).	
	442	WINTER et al., "Antibody-based Therapy", Immunology Today, 14(6), pgs. 243-246 (1993)	
	443	WOOD et al, "Staphylococcal enterotoxins and the immune system", FEMS Microbiology Immunology, 76:121-134 (1991)	

Examiner Signature		**Date Considered**	
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INFORMATION DISCLOSURE STATEMENT BY APPLICANT

Application Number	17/237,650
Filing Date	04/22/2021
First Named Inventor	Diane D. Harrison
Art Unit	OPAP
Client Number	206389
Matter Number	0002-02US

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.

In accordance with 37 C.F.R. 1.97(g), the filing of this Information Disclosure Statement shall not be construed to mean that a search has been made.

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 206389-0002-02US for any such charge or credit.

ADDITIONAL COMMENTS

SIGNATURE

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

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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
17/237,650	04/22/2021	Diane D. Harrison	206389-0002-02US	8810

171672 7590 09/22/2022

Riverside Law LLP/J&J
175 Strafford Avenue
Suite 100
Wayne, PA 19087

EXAMINER	
CHANDRA, GYAN	

ART UNIT	PAPER NUMBER
1646	

NOTIFICATION DATE	DELIVERY MODE
09/22/2022	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

Office Action Summary	**Application No.** 17/237,650	**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 --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTHS FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☑ Responsive to communication(s) filed on 4/22/2021.

☐ A declaration(s)/affidavit(s) under **37 CFR 1.130(b)** was/were filed on _____.

2a)☐ This action is **FINAL.** 2b) ☑ This action is non-final.

3)☐ 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.

4)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims*

5) ☑ Claim(s) 11-20 is/are pending in the application.

5a) Of the above claim(s) _____ is/are withdrawn from consideration.

6) ☐ Claim(s) _____ is/are allowed.

7) ☑ Claim(s) 11-20 is/are rejected.

8) ☐ Claim(s) _____ is/are objected to.

9) ☐ Claim(s) _____ are subject to restriction and/or election requirement

* If any claims have been determined allowable, 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.**

Application Papers

10)☑ The specification is objected to by the Examiner.

11)☑ The drawing(s) filed on 4/22/2021 is/are: a)☑ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

Priority under 35 U.S.C. § 119

12)☐ 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)).

** See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☑ Notice of References Cited (PTO-892)

2) ☑ Information Disclosure Statement(s) (PTO/SB/08a and/or PTO/SB/08b) Paper No(s)/Mail Date 1/24/2022.

3) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date _____.

4) ☐ Other: _____.

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 has been considered.

Specification

The disclosure is objected to because it contains an embedded hyperlink and/or other form of browser-executable code (pg. 26-27, 58 and others of the specification). 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 disclosure is objected to because of the specification use a number of Trademarks (see- pg.58 [138], pg. 76 [176]). It should be **capitalized wherever it appears and be accompanied by the generic terminology**. MPEP 6.20

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.

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) 10, 13-14,16-18 and 20 are rejected under 35 U.S.C. 102(a) (1) as being anticipated by Wong et al. (US Pub. No. 2009/0123378).

The instant invention is broadly drawn to a method of treating a TNF related condition, wherein the TNF related condition is active ankylosing spondylitis, the method comprising: administering a composition comprising a safe and effective amount of at least one isolated mammalian 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, and at least one pharmaceutically acceptable carrier or diluent, wherein said composition is administered via IV infusion, and wherein a patient treated with the composition achieves an Ankylosing Spondylitis Disease Activity Score (ASDAS) inactive disease (<1.3) at 4 weeks of treatment or at 2 weeks of treatment (claims 11, 14 and 17), the method further comprising administering said composition with or without methotrexate (MTX), sulfasalazine (SSZ) or hydroxychloroquine (HCQ) (claim 13, 16, 20) and the method of claim 17, wherein said > 65% of patients that achieve ASAS20 at week 16 of treatment have a treatment difference (improvement compared to placebo) of > 45%.

Wong et al teach treating ankylosing spondylitis (AS) in a subject comprising administering an inhibitor of TNFα, wherein such inhibitor is human TNFα antibody or antigen-binding portion thereof (abstract, [0010], [0013-0016]). They teach that the antibody is Golimumab (see [0081, 0125, 0154] and claim 48). It is noted that anti-TNF antibody, golimumab, comprises amino acid sequences of 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 (as disclosed in SEQ ID NOs: 10 and 11 of US 20090214528). Wong et al teach that the treatment of AS can further comprise methotrexate, azathioprine sulphasalazine or hydroxychloroquine (see paragraph [0014, 0049, 0253, 0255] and claim 19). They teach that the response of the antibody treatment over the time is looked as Bath Ankylosing spondylitis disease activity index (BASDAI) (see[0019]). They teach that the efficacy of treatment over a period of 2, 4 weeks or more is determined BASDAI as compare to control, in particular ASAS20, ASAS50 or ASAS70 (see [0024-0033]) and they teach that the method provides at least about 2.2 in a BASDAI score [0220]. They teach that the administration of an antibody is done by infusion (see [0199, 0209]). 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 Wong et al. (US Pub. No. 2009/0123378) in view of Le et al. (US Pat. No. 5,656,272).

The instantly claimed invention is broadly drawn to a method of treating a TNF related condition, wherein the TNF related condition is active ankylosing spondylitis, the method comprising: administering a composition comprising a safe and effective amount of at least one isolated mammalian 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, wherein said composition is administered at a dose of 2 mg/kg over 30 min , at weeks 0, 4 and then every 8 weeks thereafter (claims 12, 15, 19).

The teachings of Wong et al are summarized as set forth above. Wong et al teach an anti-TNF-alpha antibody at about 5 mg/kg body weight. Wong et al teach that effective amount of treatment is refer to an effective amount at dosages and for periods of time necessary to achieve the desired therapeutic result (see [0209]). They teach that the administration of antibodies of the invention to treat AS may be for example at week 0, week 2, week 4, etc. [0211]. They teach that the antibody can be giver every other week for a period, e.g., 4, 8, 16, 32, 36, 42, 48, 52, 56, etc. [0225]. They teach that the antibody can be given to achieve a desired level of antibody in a mean serum level, e.g., 7-9 ug/mL [0228]. Wong et al. do not teach that the infusion of antibody is 2 mg/Kg and that the administration is over a period of 30 min ± 10 min.

Le et al teach use of an anti- TNFα antibody for different conditions, including Crohn's disease (abstract). They teach that the infusion of a TNFα antibodies can be 1, 5, or 10 mg/Kg body weight and for over a 60 minute period (col. 58, lines5+). A skill in the art is a physician who will decide a dose and infusion time on the basis of subject's disease severity and body weight.

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 at an effective dose of 1.0, 2.0, 5.0 or 10.0 mg per Kg body weight by infusion for a period necessary including 30, 40, 50 or 60 minutes as taught y Le et al using golimumab for treating AS as taught by Wong et al. Further, one of ordinary skill of the art would have been motivated to administer golimumab by an intravenous infusion using a dosage of 1.0 or 2.0 mg /Kg bodyweight over a period of 30 or 60 min because Le et al teach that an ant-TNF-α antibody for treating a TNF related disease. One would have a reasonable expectation

of success in administering golimumab intravenously because Le et al. teach that an anti- TNF-α antibody can be administered at a dose of 1, 2, 5, 10 mg/Kg for a period of 60 min or so and the art of administering antibody using infusion is high. A skilled physician would be able to determine the dosage, rate of administration and a period for administration depending on patient's disease severity and patient body weight. Therefore, the invention would have been obvious over the combined teachings of the prior art.

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-

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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. 17/237,650	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-20090123378-A1	05-2009	Wong; Robert L.	A61K49/0004	424/9.2
*	B	US-5656272-A	08-1997	Le; Junming	C07K14/525	424/139.1
	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	
	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.

Search Notes	Application/Control No.	Applicant(s)/Patent Under Reexamination
	17/237,650	Harrison et al.
	Examiner	Art Unit
	GYAN CHANDRA	1646

CPC - Searched*		
Symbol	**Date**	**Examiner**
c07k16/241	09/15/2022	gc
a61k39/3955	09/15/2022	gc
a61p19/02	09/15/2022	gc

CPC Combination Sets - Searched*		
Symbol	**Date**	**Examiner**

US Classification - Searched*			
Class	**Subclass**	**Date**	**Examiner**
None	None	09/15/2022	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, 2, 3, 4, 5, 6 with substitutions (see search results in SCORE)	09/13/2022	gc
claims searched in CAPLUS, Biosis, Medline (see enclosed transcript)	09/15/2022	gc
claims searched in PE2E search (see enclosed doc)	09/15/2022	gc
Inventorship search in PE2E search (see enclosed doc)	09/15/2022	gc
Inventorship search in PALM	09/15/2022	gc

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Search Notes	Application/Control No.	Applicant(s)/Patent Under Reexamination
	17/237,650	Harrison et al.
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Interference Search			
US Class/CPC Symbol	US Subclass/CPC Group	Date	Examiner

/GYAN CHANDRA/ Primary Examiner, Art Unit 1646	

INFORMATION DISCLOSURE STATEMENT BY APPLICANT		
	Application Number	17/237,650
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	First Named Inventor	Diane D. Harrison
	Art Unit	OPAP
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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	4757506	07/12/1988	HEICHLER JOHANNES	
	14	4766067	08/23/1988	BISWAS DEBAJIT K	
	15	4767402	08/30/1988	KOST JOSEPH	
	16	4795699	01/03/1989	TABOR STANLEY	
	17	4800159	01/24/1989	MULLIS KARY B	
	18	4816567	03/28/1989	CABILLY SHMUEL	
	19	4822776	04/18/1989	CERAMI ANTHONY	
	20	4873316	10/10/1989	MEADE HARRY	
	21	4889818	12/26/1989	GELFAND DAVID H	
	22	4921794	05/01/1990	TABOR STANLEY	
	23	4925673	05/15/1990	STEINER SOLOMON	
	24	4939666	07/03/1990	HARDMAN KARL D	
	25	4946778	08/07/1990	LADNER ROBERT C	
	26	4956288	09/11/1990	BARSOUM JAMES G	
	27	4965188	10/23/1990	MULLIS KARY B	
	28	4994370	02/19/1991	SILVER JONATHAN	
	29	5066584	11/19/1991	GYLLENSTEN ULF B	

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.
	30	5091310	02/25/1992	INNIS MICHAEL A	
	31	5116964	05/26/1992	CAPON DANIEL J	
	32	5122464	06/16/1992	WILSON RICHARD H	
	33	5130238	07/14/1992	MALEK LAWRENCE T	
	34	5142033	08/25/1992	INNIS MICHAEL A	
	35	5149636	09/22/1992	AXEL RICHARD	
	36	5168062	12/01/1992	STINSKI MARK F	
	37	5179017	01/12/1993	AXEL RICHARD	
	38	5223409	06/29/1993	LADNER ROBERT C	
	39	5225538	07/06/1993	CAPON DANIEL J	
	40	5225539	07/06/1993	WINTER GREGORY P	
	41	5231024	07/27/1993	MOELLER ACHIM	
	42	5260203	11/09/1993	LADNER ROBERT C	
	43	5266491	11/30/1993	NAGATA SHIGEKAZU	
	44	5304489	04/19/1994	ROSEN JEFFREY M	
	45	5342613	08/30/1994	CREAVEN PATRICK J	
	46	5385839	01/31/1995	STINSKI MARK F	
	47	5403484	04/04/1995	LADNER ROBERT C	
	48	5404871	04/11/1995	GOODMAN DAVID E	
	49	5427908	06/27/1995	DOWER WILLIAM J	
	50	5447851	09/05/1995	BEUTLER BRUCE A	
	51	5455030	10/03/1995	LADNER ROBERT C	
	52	5458135	10/17/1995	PATTON JOHN S	
	53	5496549	03/05/1996	YAMAZAKI HIROH	
	54	5512544	04/30/1996	WALLACH DAVID	
	55	5514670	05/07/1996	FRIEDMAN DORON	
	56	5518889	05/21/1996	LADNER ROBERT C	
	57	5530101	06/25/1996	QUEEN CARY L	
	58	5534621	07/09/1996	LADNER ROBERT C	

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.
	59	5545806	08/13/1996	LONBERG NILS	
	60	5545807	08/13/1996	SURANI AZIM M	
	61	5565362	10/15/1996	ROSEN JEFFREY M	
	62	5569825	10/29/1996	LONBERG NILS	
	63	5571698	11/05/1996	LADNER ROBERT C	
	64	5576195	11/19/1996	ROBINSON RANDY R	
	65	5580717	12/03/1996	DOWER WILLIAM J	
	66	5580734	12/03/1996	TRECO DOUGLAS A	
	67	5582996	12/10/1996	CURTIS PETER J	
	68	5585089	12/17/1996	QUEEN CARY L	
	69	5595898	01/21/1997	ROBINSON RANDY R	
	70	5601819	02/11/1997	WONG JOHNSON T	
	71	5618920	04/08/1997	ROBINSON RANDY R	
	72	5625126	04/29/1997	LONBERG NILS	
	73	5625825	04/29/1997	ROSTOKER MICHAEL D	
	74	5633425	05/27/1997	LONBERG NILS	
	75	5637052	06/10/1997	HIROTA TOSHIAKI	
	76	5641670	06/24/1997	TRECO DOUGLAS A	
	77	5643759	07/01/1997	PFREUNDSCHUH MICHAEL	
	78	5643768	07/01/1997	KAWASAKI GLENN H	
	79	5654407	08/05/1997	BOYLE PETRA	
	80	5656272	08/12/1997	LE JUNMING	
	81	5656730	08/12/1997	LEE LIHSYNG STANFORD	
	82	5658570	08/19/1997	NEWMAN ROLAND A	
	83	5658754	08/19/1997	KAWASAKI GLENN H	
	84	5661016	08/26/1997	LONBERG NILS	
	85	5693493	12/02/1997	ROBINSON RANDY R	
	86	5693762	12/02/1997	QUEEN CARY L	
	87	5698195	12/16/1997	LE JUNMING	

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U.S. PATENT/PUBLICATION DOCUMENTS					
Initials	Cite No.	Document Number	Issue/Publication Date	First Named Inventor	Relevant Pages, Columns, etc.
	88	5698417	12/16/1997	ROBINSON RANDY R	
	89	5698419	12/16/1997	WOLPE STEPHEN D	
	90	5698435	12/16/1997	ROBINSON RANDY R	
	91	5714352	02/03/1998	JAKOBOBITS AYA	
	92	5723323	03/03/1998	KAUFFMAN STUART ALAN	
	93	5733761	03/31/1998	TRECO DOUGLAS	
	94	5750105	05/12/1998	NEWMAN ROLAND A	
	95	5750373	05/12/1998	GARRARD LISA J	
	96	5763192	06/09/1998	KAUFFMAN STUART ALAN	
	97	5763733	06/09/1998	WHITLOW MARC	
	98	5766886	06/16/1998	STUDNICKA GARY M	
	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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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	ANAGNOSTOPULOS HIRISTO	
	126	5959083	09/28/1999	BOSSLET KLAUS	
	127	5959084	09/28/1999	RING DAVID	
	128	5962255	10/05/1999	GRIFFITHS ANDREW DAVID	
	129	5976862	11/02/1999	KAUFFMAN STUART ALAN	
	130	5989530	11/23/1999	LORENZ HERIBERT	
	131	5993833	11/30/1999	DE LACHARRIERE OLIVIER	
	132	5994616	11/30/1999	ROSEN JEFFREY M	
	133	6010902	01/04/2000	LEDBETTER JEFFREY A	
	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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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	20090214528	08/27/2009	DORAI HAIMANTI	
	150	20100251099	09/30/2010	MAKOWER DAVID	
	151	20110251099	10/13/2011	VISVANATHAN SUDHA	

FOREIGN PATENT DOCUMENTS						
Initials	Cite No.	Document Number	Publication Date	Country	Relevant Pages, Columns, etc.	T
	152	1764992A	10/21/1992	AU		X
	153	0212489B1	11/30/1994	EP		X
	154	0218868A2	04/22/1987	EP		
	155	0229046B1	05/04/1994	EP		X
	156	0229246B1	08/04/1993	EP		X
	157	0237507B1	12/27/1991	EP		
	158	0260610B1	09/01/1993	EP		X
	159	0288088B1	03/09/1994	EP		X
	160	0308378B1	11/30/1994	EP		X
	161	0350690A2	01/17/1990	EP		X
	162	0351789B1	11/25/1998	EP		X
	163	0368684B1	03/09/1994	EP		X
	164	0371998B1	03/02/1994	EP		X
	165	0380068A1	08/01/1990	EP		X
	166	0393438A2	10/24/1990	EP		X
	167	0398327B1	03/15/1995	EP		X
	168	0412486B1	11/30/1994	EP		X
	169	0433900A1	06/26/1991	EP		X

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FOREIGN PATENT DOCUMENTS						
Initials	Cite No.	Document Number	Publication Date	Country	Relevant Pages, Columns, etc.	T
	170	0438474B1	05/15/1996	EP		X
	171	0463151B1	06/12/1996	EP		X
	172	0486526B2	03/07/2001	EP		X
	173	0525570A2	02/03/1993	EP		X
	174	0526905A3	05/05/1993	EP		X
	175	0550400B1	07/10/1996	EP		X
	176	0610201B1	05/16/2001	EP		X
	177	614989A1	09/14/1994	EP		X
	178	0710719B1	03/14/2007	EP		X
	179	2870137B1	05/16/2018	EP		X
	180	2272440A	05/18/1994	GB		
	181	11127855A	05/18/1999	JP		X
	182	0212500A2	02/14/2001	WO		X
	183	0212502A2	02/14/2002	WO		X
	184	8605803A1	10/09/1986	WO		
	185	8806630A1	09/07/1988	WO		X
	186	8906283A1	07/13/1989	WO		X
	187	9000902A1	02/08/1990	WO		X
	188	9003809A1	04/19/1990	WO		X
	189	9004036A1	04/19/1990	WO		
	190	9005370A1	05/17/1990	WO		
	191	9014424A1	11/29/1990	WO		X
	192	9014430A1	11/29/1990	WO		X
	193	9014442A1	11/29/1990	WO		X
	194	9014443A1	11/29/1990	WO		X
	195	9100360A1	01/10/1991	WO		X
	196	9102078A1	02/21/1991	WO		X
	197	9109967A1	07/11/1991	WO		X
	198	9117271A1	11/14/1991	WO		

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	199	9118980A1	12/12/1991	WO		X
	200	9119818A1	12/26/1991	WO		X
	201	9200373A1	01/09/1992	WO		X
	202	9203461A1	03/05/1992	WO		
	203	9205258A1	04/02/1992	WO		X
	204	9206204A1	04/16/1992	WO		
	205	9207076A1	04/30/1992	WO		X
	206	9211272A1	07/09/1992	WO		
	207	9211383A1	07/09/1992	WO		X
	208	9213095A1	08/06/1992	WO		X
	209	9214843A1	09/03/1992	WO		X
	210	9216221A1	10/01/1992	WO		X
	211	9216553A1	10/01/1992	WO		X
	212	9218619A1	10/29/1992	WO		X
	213	9302108A1	02/04/1993	WO		X
	214	9308278A1	04/29/1993	WO		X
	215	9308829A1	05/13/1993	WO		X
	216	9311383A1	06/10/1993	WO		X
	217	9406498A1	03/31/1994	WO		X
	218	9408552A2	04/28/1994	WO		X
	219	9416970A1	08/04/1994	WO		X
	220	9418219A1	08/18/1994	WO		X
	221	9425585A1	11/10/1994	WO		X
	222	9501538A1	01/12/1995	WO		
	223	9516027A1	06/15/1995	WO		X
	224	9607754A1	03/14/1996	WO		X
	225	9619256A1	06/27/1996	WO		X
	226	9629411A1	09/26/1996	WO		
	227	9633735	10/31/1996	WO		X

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

OTHER DOCUMENTS			
Initials	Cite No.	Author, Title, Date, Pages, etc.	T
	248	(JOHNSON AND JOHNSON) SIMPONI® ARIA™ (golimumab) for infusion Receives FDA Approval for Treatment of Moderately to Severely Active Rheumatoid Arthritis 18 July, 2013 [retrieved on 18 January, 2018] pages 1-6; page 1/6, paragraph 1; page 2/6, paragraph 3; retrieved from the internet <https://www.jnj.com/media-center/press-releases/simponi-aria-golimumab-for-infusion-receives-f da-approval-for-treatment-of-moderately-to-severely-active-rheumatoid-arthritis>	
	249	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).	
	250	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. Scl., 28(2):126-130 (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 10 of 20	Matter Number	0002-02US

OTHER DOCUMENTS			
Initials	Cite No.	Author, Title, Date, Pages, etc.	T
	251	ADERKA, Dan, "Role of Tumor Necrosis Factor in the Pathogenesis of Intravascular Coagulopathy of Sepsis: Potential New Therapeutic Implications," IsrJ Med Scl, 27:52-60 (1991).	
	252	AGGARWAL, Bharat B. et al., "Human Tumor Necrosis Factor Production, Purification and Characterization," J. of Biol. Chem., 260(4):2345-2354 (1985).	
	253	AKAMA, Hideto et al., "Mononuclear Cells Enhance Prostaglandin E2 Production of Polymorphonuclear Leukocytes via Tumor Necrosis Factor a," Biochemical and Biophysical Research Comm., 168(2):857-862 (1990).	
	254	ALT, et al., "Selective Multiplication of Dihydrofolate Reductase Genes in Methotrexate-resistant Variants of Cultured Murine Cells", J. Biol. Chem. 253:1357-1370 (1978)	
	255	ANDERSON JJ, BARON G, VAN DER HEIJDE D, FELSON DT, DOUGADOS M. Ankylosing spondylitis assessment group preliminary definition of short-term improvement in ankylosing spondylitis. Arthritis Rheum. 2001 ;44(8):1876-1886.	
	256	Anonymous, "(FRMC) Simponi Aria Effective For Treating Ankylosing Spondylitis", Managed Health Care Connect, (20161115), pages 1 - 3, URL: http://www.managedhealthcareconnect.com/content/simponi-aria-effective-treating-ankylosing-spondylitis, (20180118), XP009517728	
	257	ASHKENAZI et al., "Protection against endotoxic shock by a tumor necrosis factor receptor immunoadhesin", Proc. Natl. Acad. Sci. USA 88:10535-10539 (1991);	
	258	Assessment of SpondyloArthritis. Ankylosing spondylitis disease activity score. Available at: http://www.asasgroup.org/research.php?id=01. Accessed on 17 April 2014.	
	259	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));	
	260	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)	
	261	BEBBINGTON, et al., "High-Level Expression of a Recombinant Antibody from Myeloma Cells Using a Glutamine Systhetase Gene as an Amplifiable Selectable Marker", Bio/Technology 10:169-175(1992))	
	262	BERKOW et al., Eds, The Merck Manual of Diagnosis and Therapy, Sixteenth Edition, Merck Research Laboratories, Rahway, NJ 1992 pg. 1263-1287	
	263	BEUTLER, B. et al., "Identity of tumour necrosis factor and the macrophage-secreted factor cachectin," Nature, 316:552-554 (1985).	
	264	BEUTLER, B. et al., "Passive Immunization Against Cachectin/Tumor Necrosis Factor Protects Mice from Lethal Effect of Endotoxin," Science, 229:869-871 (1985).	
	265	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).	
	266	BODMER, Mark, "Humanized Antibodies for Anti-TNF Therapy," Abstract, Endotoxemia & Sepsis Conference (1991).	
	267	BOSHART, et al., "A Very Strong Enhancer Is Located Upstream of an Immediate Early Gene of Human Cytomegalovirus", Cell 41:521-530 (1985))	
	268	BRANDT J, HAIBEL H, CORNELY D, et al. Successful treatment of active ankylosing spondylitis with the anti-tumor necrosis factor alpha monoclonal antibody infliximab. Arthritis Rheum. 2000;43(6):1346-1352	

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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ALL REFERENCES CONSIDERED EXCEPT WHERE LINED THROUGH. /G.C/

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	Client Number	206389
Page 11 of 20	Matter Number	0002-02US

OTHER DOCUMENTS			
Initials	**Cite No.**	**Author, Title, Date, Pages, etc.**	**T**
	269	BRANDT J, KHARIOUZOV A, Listing J, et al. Six-month results of a double-blind, placebo-controlled trial of etanercept treatment in patients with active ankylosing spondylitis. Arthritis Rheum. 2003;48(6):1667-1675.	
	270	BRAUN J, BOLLOW M, NEURE L, et al. Use of immunohistologic and in situ hybridization techniques in the examination of sacroiliac joint biopsy specimens from patients with ankylosing spondylitis. Arthritis Rheum. 1995;38(4):499-505.	
	271	BRAUN J, BRANDT J, LISTING J, et al. Treatment of active ankylosing spondylitis with infliximab: a randomised controlled multicentre trial. Lancet. 2002;359(9313):1187-1193.	
	272	BREBAN M, VIGNON, E, CLAUDEPIERRE, P, et al. Efficacy of infliximab in refractory ankylosing spondylitis: results of a six-month open-label study. Rheumatology. 2002;4:1280-1285.	
	273	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).	
	274	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);	
	275	CALIN A, GARRETT S, WHITELOCK H, et al. A new approach to defining functional ability in ankylosing spondylitis: the development of the Bath Ankylosing Spondylitis Functional Index. J Rheumatol. 1994;21(12):2281-2285.	
	276	CANETE JD, LLENA J, COLLADO A, et al. Comparative cytokine gene expression in synovial tissue of early rheumatoid arthritis and seronegative spondyloarthropathies. Br J Rheumatol. 1997;36(1):38-42.	
	277	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).	
	278	CAPON et al., "Designing CD4 immunoadhesins for AIDS therapy", Nature 337:525-531 (1989),	
	279	CARTER et al., "Humanization of an anti-p185HER2 antibody for human cancer therapy", Proc. Natl. Acad. Sci. U.S.A. 89:4285 (1992)	
	280	Chothia, et al., "Canonical Structures for the Hypervariable Regions of Immunoglobulins," Journal of Molecular Biology, 196: 901-917 (1987).	
	281	CLEGG DO, REDA DJ, WEISMAN MH, et al. Comparison of sulfasalazine and placebo in the treatment of ankylosing spondylitis. A Department of Veterans Affairs Cooperative Study. Arthritis Rheum. 1996;39(12):2004-2012	
	282	COLLINS, M.S. et al., "Immunoprophylaxis of Polymicrobic Cellulitis with a Human Monoclonal Antibody Against Lipopolysaccharide Antigen of Pseudomonas aeruginosa," Abstract E-63, Abstracts of Annual Meeting 1989.	
	283	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)	
	284	Copy of Canadian Examination Report for CA application 2,994,253 dated November 26, 2018	
	285	Copy of Canadian Examination Report for CA2878319 dated 11 December 2019	
	286	CORCORAN et al., "Characterization of ligand binding by the human p55 tumour-necrosis-factor receptor", Eur. J. Biochem. 223:831-840 (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 12 of 20	Matter Number	0002-02US

OTHER DOCUMENTS			
Initials	**Cite No.**	**Author, Title, Date, Pages, etc.**	**T**
	287	CRAMER et al., "Transgenic Plants for Therapeutic Proteins: Linking Upstream and Downstream Strategies", Curr. Top. Microbol. Immunol. 240:95-118 (1999)	
	288	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).	
	289	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))	
	290	CUNNINGHAM AND WELLS, "High-Resolution Epitope Mapping of hGH-Receptor Interations by Alanine-Scanning Mutagenesis", Science Ausubel, supra, Chapters 8, 15; 244:1081-1085 (1989)).	
	291	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)	
	292	DAVIS JC, VAN DER HEIJDE D, BRAUN J, et al. Recombinant human tumor necrosis factor receptor (etanercept) for treating ankylosing spondylitis. A randomized controlled trial. Arthritis Rheum. 2003;48(11):3230-3236.	
	293	DE VOS, et al., "Human Growth Hormone and Extracellular Domain of Its Receptor: Crystal Structure of the Complex", Science 255:306-312 (1992)).	
	294	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	
	295	DI GIOVINE, Francesco, S. et al., "Tumour necrosis factor in synovial exudates," Annals of the Rheumatic Diseases, 47:768-772 (1988).	
	296	DOWARD LC, SPOORENBERG A, COOK SA, et.al. Development of the ASQoL: a quality of life instrument specific to ankylosing spondylitis. Ann Rheum Dis. 2003;62(1):20-26.	
	297	Doyle et al., Rheumatology 52:1214-1219,(2013).	
	298	DUNCOMBE, Andrew S. et al., "Tumor Necrosis Factor Mediates Autocrine Growth Inhibition in a Chronic Leukemia," J Immunol, 143:3828-3834 (1989).	
	299	DUPONT et al., "Escherichia coli Diarrhea" Bacterial Infections of Humans:Epidemioloqv and Control, A.S. Evans et al., 2nd Edition, Spring Science & Business Media, New York, pqs. 239-254(1991)	
	300	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)	
	301	ECHTENACHER, Bernd et al., "Requirement of Endogenous Tumor Necrosis Factor/Cachectin for Recovery from Experimental Peritonitis," J. of Immunology, 145(11):3762-3766 (1990).	
	302	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).	
	303	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	
	304	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).	

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 13 of 20	Matter Number	0002-02US

OTHER DOCUMENTS			
Initials	Cite No.	Author, Title, Date, Pages, etc.	T
	305	ENGELMANN, Hartmut et al., "Two Tumor Necrosis Factor-binding Proteins Purified from Human Urine," J. of Bio. Chem., 265(3):1531 -1536 (1990).	
	306	EREN et al. "Human monoclonal antibodies specific to hepatitis B virus generated in a human/mouse radiation chimera: the Trimera system", Immunol. 93: 154-161 (1998)	
	307	EUROQOL GROUP. EUROQOL - a new facility for the measurement of health-related quality of life. Health Policy. 1990;16:199-208.	
	308	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).	
	309	EXLEY, A.R. et al., "Monoclonal antibody to TNF in severe septic shock," The Lancet, 335:1275-1277(1990).	
	310	FENDLY, Brian M. et al., "Murine Monoclonal Antibodies Defining Neutralizing Epitopes on Tumor Necrosis Factor," Hybridoma, 6(4):359-370 (1987).	
	311	FISCH et al., "Site-Specific Modification of a Fragment of a Chimeric Monoclonal Antibody Using Reverse Proteolysis", Bioconjugate Chem., 3:147-153 (1992);	
	312	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),	
	313	FISHWALD et al., "High-avidity human IgGk monoclonal antibodies from a novel strain of minilocus transgenic mice", Nat Biotechnol 14(7):845-851 (1996).	
	314	FONG, Yuman and Lowry, Stephen F., "Tumor Necrosis Factor in the Pathophysiology of Infection and Sepsis," Clin Immunol Immunopathol, 55:157-170 (1990).	
	315	FONG, Yuman et al., "Antibodies to Cachectin/Tumor Necrosis Factor Reduce Interleukin 1ß and Interleukin 6 Appearance During Lethal Bacteremia," J. Exp. Med., 170:1627-1633 (1989).	
	316	FOOTE et al., "Antibody Framework Residues Affecting the Conformation of the Hypervariable Loops", Journal of Molecular Biology, 224(2), pgs. 487-499 (1992)	
	317	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).	
	318	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.	
	319	GENEBANK ACCESSION, No. M32046 (1990,June 15).	
	320	Genebank Accession, No. N90300 (Nov. 1, 1989).	
	321	GILLIES, Stephen D. et al., "High-level expression of chimeric antibodies using adapted cDNA variable region cassettes," J Immunol Methods, 125:191-202 (1989).	
	322	GORMAN JD, SACK KE, DAVIS JC JR. Treatment of ankylosing spondylitis by inhibition of tumor necrosis factor L. N Engl J Med. 2002;346(18):1349-1356.	
	323	GORMAN, S.D. and Clark, M.R., "Humanisation of monoclonal antibodies for therapy," Sem Immunol, 2:457-466 (1990).	
	324	GOSSEN, AND H. BUJARD, "Tight control of gene expression in mammalian cells by tetracycline-responsive promotoers", 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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Page 14 of 20	Matter Number	0002-02US

OTHER DOCUMENTS			
Initials	Cite No.	Author, Title, Date, Pages, etc.	T
	325	GRATACOS J, COLLADO A, FILELLA X, et al. Serum cytokines (IL-6, TNF-alpha, IL-1 beta and IFN-gamma) in ankylosing spondylitis: a close correlation between serum IL-6 and disease activity and severity. Br J Rheumatol. 1994;33(10):927-931.	
	326	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);	
	327	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)	
	328	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)	
	329	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)	
	330	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)	
	331	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)	
	332	HARRIS, "Ankvlosinq Spondylitis", Chapter 6, Spondyloarthropathies, Kellev's Textbook of Rheumatology, 6th Edition, Sledqe CB, pas. 1039-1053 (2001)	
	333	HAYASHI, H. et al., "An Enzyme-linked Immunosorbent Assay for Recombinant Human Tumor Necrosis Factor Using Monoclonal Antibody," Recent Adv. Chemother, 820-821 (1985).	
	334	HAYS RD, MARTIN SA, SESTI AM, SPRITZER KL. Psychometric properties of the Medical Outcomes Study Sleep measure. Sleep Med. 2005;6(1):41-44.	
	335	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).	
	336	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).	
	337	HIRAI, Makoto et al., "Production and characterization of monoclonal antibodies to human tumor necrosis factor," J. oflmmun. Methods, 96:57-62 (1987).	
	338	HOOD et al., "Molecular Farming of Industrial Proteins from Transgenic Maize", Adv. Exp. Med. Biol. 464:127-147(1999)	
	339	INMAN RD, DAVIS JC JR, HEIJDE DV, et.al. Efficacy and safety of golimumab in patients with ankylosing spondylitis: results of a randomized, double-blind, placebo-controlled, phase III trial. Arthritis Rheum. 2008;58(11):3402.	
	340	ITOH et al., "Application of Inverse Substrates to Trypsin-Catalyzed Peptide Synthesis", Bioorg. Chem., 24(1): 59-68 (1996).	
	341	J. L. HAMLIN AND C. MA, "The mammalian dihydrofolate reductase locus", Biochem. et Biophys. Acta 1097:107-143 (1990)	
	342	Jones, et al., "Replacing the complementarity-determining regions in a human antibody with those from a mouse," Nature, 321: 522-525 (1986).	

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.			

ALL REFERENCES CONSIDERED EXCEPT WHERE LINED THROUGH. /G.C/

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	Client Number	206389
Page 15 of 20	**Matter Number**	0002-02US

OTHER DOCUMENTS			
Initials	**Cite No.**	**Author, Title, Date, Pages, etc.**	T
	343	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	
	344	KAMEYAMA, Koh-zoh, et al., "Convenient plasmid vectors for construction of chimeric mouse/human antibodies," FEBS Lett, 244:301-306 (1989).	
	345	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))	
	346	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).	
	347	KENNY et al., "Production of Monoclonal Antiboodies Using a Secretion Capture Report Web", Bio/ Technol. 13:787-790 (1995).	
	348	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	
	349	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);	
	350	KOZBOR et al., "The production of monoclonal antibodies from human lymphocytes", Immunol. Today, 4:72-79(1983);	
	351	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);	
	352	LANDEWE R, BRAUN J, DEODHAR A, et.al. Efficacy of certolizumab pegol on signs and symptoms of axial spondylarthritis including ankylosing spondylitis: 24-week results of a double-blind randomised placebocontrolled Phase 3 study. Ann Rheum Dis. 2013;0:1-9.	
	353	LANGE U, TEICHMANN J, STRACKE H. Correlation between plasma TNF-alpha, IGF-1, biochemical markers of bone metabolism, markers of inflammation/disease activity, and clinical manifestations in ankylosing spondylitis. Eur J Med Res. 2000;5(12):507-511.	
	354	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	
	355	LASSALLE, Ph., et al., "Potential Implicaton of Endothelial Cells in Bronchial Asthma," Int Arch Allergy Appl Immunol, 94:233-238 (1991).	
	356	LESSLAUER et al., "Recombinant soluble tumor necrosis factor receptor proteins protect mice from lipopolysaccharide-induced lethality", Eur. J. Immunol. 21:2883-2886 (1991)	
	357	LIANG, Chi-Ming et al., "Production and Characterization of Monoclonal Antibodies Against Recombinant Human Tumor Necrosis Factor/Cachectin," Biochem. & Biophy. Res. Comm., 137(2):847-854(1986).	
	358	LOETSCHER et al., "Molecular Cloning and Expression of the Human 55 kd Tumor Necrosis Factor Receptor", Cell 61: pgs. 351-359 (1990)	
	359	LONBERG et al. "Antigen-specific human antibodies from mice comprising four distinct genetic modifications", Nature 368:856-859 (1994)	
	360	LONBERG et al., "Human Antibodies from Transgenic Mice", Int Rev Immunol 13(1):65-93 (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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INFORMATION DISCLOSURE STATEMENT BY APPLICANT		
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	First Named Inventor	Diane D. Harrison
	Art Unit	OPAP
	Client Number	206389
Page 16 of 20	Matter Number	0002-02US

OTHER DOCUMENTS			
Initials	Cite No.	Author, Title, Date, Pages, etc.	T
	361	LUCAS, R. et al., "Generation and characterization of a neutralizing rat anti-rm TNF-a monoclonal antibody," Immunology, 71:218-223 (1990).	
	362	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)).	
	363	MA et al., "Immunotherapeutic potential of antibodies produced in plants", Trends Biotechnol. 13:522-7(1995)	
	364	MA et al., "Plant Antibodies for Immunotherapy", Plant Physiol. 109:341-6 (1995).	
	365	MACHADO P, LANDEWE R, LIE E, et al. Ankylosing Spondylitis Disease Activity Score (ASDAS): defining cutoff values for disease activity states and improvement scores for the Assessment of SpondyloArthritis international Society. Ann Rheum Dis. 2011;70:47-53.	
	366	MARRACK et al, "The Staphylococcal Enterotoxins and Their Relatives", Science, 248:705-711 (1990),	
	367	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).	
	368	Mendez, et al., "Functional transplant of megabase human immunoglobulin loci recapitulates human antibody response in mice," Nature Genetics, 15(2): 146-156 (1997).	
	369	MERCK SHARP & DOHME CORP., "Effect of Golimumab in Participants With Active Axial Spondylarthritis (GOAHEAD) (P07642, MK8259006)", pgs. 1-4 (2011)	
	370	Milstein, et al., "Hybrid hybridomas and their Use in Immunohistochemistry," Nature, 305: 537-540 (1983).	
	371	MOCELLIN et al., "Tumor necrosis factor, cancer and anticancer therapy", Cytokine Growth Factor Rev. 2005 Feb; 16(1) 35-53, Epub 2004 Dec 19	
	372	MOLLER, Achim et al., "Monoclonal Antibodies to Human Tumor Necrosis Factor a: In Vitro and In Vivo Application," Cytokine, 2(3):162-169 (1990).	
	373	MORRISON, Sherie L., "Transfectomas Provide Novel Chimeric Antibodies," Science, 229:1202-1207(1985).	
	374	MULLER, "Determination of Affinity and Specificity of Anti-Hapten Antibodies by Competitive Radioimmunoassay", Meth. Enzymol., 92:589-601 (1983),	
	375	MURPHY, et al., "Matrix metalloproteinase degradation of elastin, type IV collagen and proteoglycan", Biochem. J. 227:277-279 (1991)	
	376	NAGAI, M. et al., "Antibody to tumor necrosis factor (TNF) reduces endotoxin fever," Experientia, 44:606-607 (1988).	
	377	NEUBERGER, M., "Generating high-avidity human Mabs in mince", Nature Biotech. 14:826 (1996)	
	378	NGUYEN et al., "Production of Human Monoclonal Antibodies in SCID Mouse", Microbiol. Immunol. 41:901-907(1997)	
	379	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).	
	380	Notice of Allowance dated January 25, 2021 for US App. No. 16/517,592 (pages 1-8)	

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 17 of 20	Matter Number	0002-02US

OTHER DOCUMENTS			
Initials	**Cite No.**	**Author, Title, Date, Pages, etc.**	**T**
	381	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).	
	382	PARRILLO, Joseph E., "Pathogenetic Mechanisms of Septic Shock," N.E. Journal of Medicine, 328(20):1471-1477 (1993).	
	383	PAULUS, H., A Preparation and Biomedical Applications of Bispecific Antibodies®, Behring Inst. Mitt, No.78:118-132 (1985).	
	384	PENNINGTON, James, "TNF: Therapeutic Target in Patients with Sepsis," ASM News, 58(9):479-482(1992).	
	385	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);	
	386	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	
	387	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).	
	388	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)	
	389	PRESTA et al., "Humanization of an Antibody Directed Against IgE", J. Immunol. 151:2623 (1993),	
	390	Reichmann, et al., "Reshaping human antibodies for therapy," Nature, 332: 323-327 (1988).	
	391	REVEILLE JD. Epidemiology of spondyloarthritis in North America. Am J Med Sci. 2011;341(4):284-286.	
	392	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).	
	393	RUDIKOFF et al., Single amino acid substitution altering antigen-binding specificity", PNAS, March 1982, Vol 79, p. 1979-83	
	394	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)	
	395	S. STEPHENS et al., "Comprehensive pharmacokinestic of a humanized antibody and analysis of residual anti-idoiotypic responses", Immunology, Vol. 85, No. 4, pgs. 668-674 XP000881488 (August 1995)	
	396	SANDHU et al., "The Use of SCID Mice in Biotechnology and as a Model for Human Disease", Crit. Rev. Biotechnol. 16:95-118 (1996)	
	397	SCALLON, et al., Functional Comparisons of Different Tumour Necrosis Factor Receptor/IgG Fusion Proteins", Cytokine 7:759-770 (1995)	
	398	SCHALL, Thomas J. et al., "Molecular Cloning and Expression of a Receptor for Human Tumor Necrosis Factor," Cell, 61:361-370 (1990).	
	399	SCOTT et al., "An Anti-Tumor Necrosis Factor-a Antibody Inhibits the Development of Experimental Skin Tumors", Mol. Can Therapy, 2003 May, 2:445-451	

Examiner Signature		**Date Considered**	
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Page 18 of 20	Matter Number	0002-02US

OTHER DOCUMENTS			
Initials	**Cite No.**	**Author, Title, Date, Pages, etc.**	**T**
	400	SHIMAMOTO, Yoshinori et al., "Monoclonal antibodies against human recombinant tumor necrosis factor: prevention of endotoxic shock," Immunology Letters, 77:311-318 (1988).	
	401	SIEPER J, RUDWALEIT M, BARALIAKOS X, et al. The Assessment of SpondyloArthritis international Society (ASAS) handbook: a guide to assess spondyloarthritis. Ann Rheum Dis. 2009;68(2):ii1-ii44.	
	402	SILVA, Ayona T. et al., "Prophylactic and Therapeutic Effects of a Monoclonal Antibody to Tumor Necrosis Factor-a in Experimental Gram-Negative Shock," J. of Infectious Diseases, 162:421-427(1990).	
	403	SIMS et al., "A Humanized CD18 Antibody Can Block Function without Cell Destruction", J. Immunol. 151:2296(1993)	
	404	SMITH, Craig R., "Human and Chimeric Antibodies to LPS and TNF," 4Abstract, Endotoxemia & Sepsis Conference (1991).	
	405	SMITH, et al., "Human Interleukin 4: The Solution Structure of a Four-helix Bundle Protein", J. Mol. Biol. 224:899-904 (1992)	
	406	Smolen et al., "Treating spondyloarthritis, including ankylosing spondylitis and psoriatic arthritis, to target: recommendations of an international task force." Ann Rheum Dis. 2014 Jan;73(1):6-16.	
	407	SPRAGUE, et al., "Expression of a Recombinant DNA Gene Coding for the Vesiclar Stomatitis Virus Nucleocapsid Protein", J. Virol. 45:773-781 (1983)).	
	408	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).	
	409	STEADMAN' Medical Dictionary, 27th Ed. 2000 Lippincott Williams & Wilkins - "Carcinoma"	
	410	STEENBAKKERS et al., "Efficient generation of monoclonal antibodies from preselected antigen-specific B", Molec. Biol. Reports 19:125-134 (1994).	
	411	STEIN et al., "Diseases of the Hearth and Blood Vessels", Internal Medicine, 3rd 3d., pg.1-13, Little Brown and Co. Boston (1990)	
	412	STONE et al., "Solid malignancies among patients in the Wegener's Granulomatosis Etanercept Trial", Arthritis Rheum. 2006 May; 54(5) 1608-18 abstract only	
	413	STONE M, SALONEN D, LAX M, PAYNE U, LAPP V, INMAN R. Clinical and imaging correlates of response to treatment with infliximab in patients with ankylosing spondylitis. J Rheumatol. 2001;28(7):1605-1614	
	414	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).	
	415	SURESH et al., "Bispecific Monoclonal Antibodies from Hybrid Hybridomas", Methods in Enzymology 121:210 (1986)	
	416	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)	
	417	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
Page 19 of 20	Matter Number	0002-02US

OTHER DOCUMENTS			
Initials	Cite No.	Author, Title, Date, Pages, etc.	T
	418	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).	
	419	TEMEKONIDIS TI, ALAMANOS Y, NIKAS SN, et al. Infliximab therapy in patients with ankylosing spondylitis: an open label 12 month study. Ann Rheum Dis. 2003;62(12):1218-1220.	
	420	TOUSSIROT E, LAFFORGUE P, BOUCRAUT J, et al. Serum levels of interleukin 1-beta, tumor necrosis factor-alpha, soluble interleukin 2 receptor and soluble CD8 in seronegative spondylarthropathies. Rheumatol Int. 1994;13(5):175-180.	
	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 DEN BOSCH F, KRUITHOF E, BAETEN D, et al. Effects of a loading dose regimen of three infusions of chimeric monoclonal antibody to tumour necrosis factor alpha (infliximab) in spondyloarthropathy: an open pilot study. Ann Rheum Dis. 2000;59(6):428-433.	
	425	VAN DEN BOSCH F, KRUITHOF E, BAETEN D, et al. Randomized double-blind comparison of chimeric monoclonal antibody to tumor necrosis factor LLL(infliximab) versus placebo in active spondylarthropathy. Arthritis Rheum. 2002; 46(3):755-765.	
	426	VAN DER HEIJDE D, DIJKMANS B, GEUSENS P, et al. Efficacy and safety of infliximab in patients with ankylosing spondylitis: results of a randomized, placebo-controlled trial (ASSERT). Arthritis Rheum. 2005a;52(2):582- 591.	
	427	VAN DER HEIJDE D, KIVITZ A, SCHIFF MH, et.al. Efficacy and safety of adalimumab in patients with ankylosing spondylitis: results of a multicenter, randomized, double-blind, placebo-controlled trial. Arthritis Rheum. 2006;54(7):2136-2146.	
	428	VAN DER HEIJDE D, LANDEWE R, FELDTKELLER E. Proposal of a linear definition of the Bath Ankylosing Spondylitis Metrology Index (BASMI) and comparison with the 2-step and 10-step definitions. Ann Rheum Dis. 2008;67:489-493.	
	429	VAN DER HEIJDE D, LIE E, KVIEN T K, ET AL. A highly discriminatory ASAS-endorsed disease activity score in patients with ankylosing spondylitis: For the Assessment of SpondyloArthritis international Society (ASAS). Ann Rheum Dis. 2009;68:1811-1818.	
	430	VAN DER HEIJDE D, SIEPER J, MAKSYMOWYCH WP, Assessment of SpondyloArthritis international Society, et al. 2010 Update of the international ASAS recommendations for the use of anti-TNF agents in patients with axial spondyloarthritis. Ann Rheum Dis. 2011;70(6):905-908	
	431	VAN DER HEIJDE, D. et al, "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", Journal of Rheumatology, 41, pages 1095-1103, June 2014	
	432	VAN DER LINDEN S, VAN DER HEIJDE D. Ankylosing Spondylitis. In: Ruddy S, Harris ED, Sledge CB, ed. Kelley's Textbook of Rheumatology. 6th ed, 2001 ;1039-1053.	
	433	VERHOEYEN et al., "Reshaping Human Antibodies:Grafting an Antilysozyme Activity", Science 239:1534(1988).	
	434	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).	

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 20 of 20	**Matter Number**	0002-02US

OTHER DOCUMENTS			
Initials	**Cite No.**	**Author, Title, Date, Pages, etc.**	**T**
	435	WALDMANN, Thomas A., "Monoclonal Antibodies in Diagnosis and Therapy," Science, 252:1657-1662(1991).	
	436	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.	
	437	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.	
	438	WEN et al., "Limiting diluation 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)	
	439	WERLEN et al., "Site-Specific Conjugation of an Enzyme and an Antibody Fragment", Bioconjugate Chem., 5:411-417 (1994)	
	440	Whitelam, et al., "Antibody production in transgenic plants," Biochemical Society Transactions," Transgenic Plants and Plan Biochemistry, 22: 940-944 (1994).	
	441	WHITTLE, Nigel, et al., "Construction and Expression of a CDR-Grafted Anti-TNF Antibody," J. Cell Biochem, Supl. 13A:96 (1989).	
	442	WINTER et al., "Antibody-based Therapy", Immunology Today, 14(6), pgs. 243-246 (1993)	
	443	WOOD et al, "Staphylococcal enterotoxins and the immune system", FEMS Microbiology Immunology, 76:121-134 (1991)	

Examiner Signature	/GYAN CHANDRA/	**Date Considered**	09/14/2022

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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=> e kim lee lian/au

E25           3     KIM LEE KYOUNG/AU
E26          64     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
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=> e lo kim hung/au

E37           1     LO KIM FLUNG/AU
E38           4     LO KIM H/AU
E39         101 --> LO KIM HUNG/AU
E40          10     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          25     LO KIN CHEUNG/AU

=> s e38-39

L4          105 ("LO KIM H"/AU OR "LO KIM HUNG"/AU)

=> s l1-4

L5          367 (L1 OR L2 OR L3 OR L4)

=> s golimumab

L6         5495 GOLIMUMAB

=> s infusion

L7       762499 INFUSION

=> s l6 (l) l7

L8          131 L6 (L) L7

=> s spondylitis

L9        56405 SPONDYLITIS

=> s l8 (l) l9

L10          22 L8 (L) L9

=> s mg/kg

'KG' IS NOT A VALID FIELD CODE
'KG' IS NOT A VALID FIELD CODE
'KG' IS NOT A VALID FIELD CODE
L11           0 MG/KG

=> s milligram (w) body (w) weight

L12           5 MILLIGRAM (W) BODY (W) WEIGHT

=> s l10 (l) l12

L13           0 L10 (L) L12

=> dup rem l10

PROCESSING COMPLETED FOR L10
L14           9 DUP REM L10 (13 DUPLICATES REMOVED)

=> s l14 and period

L15           1 L14 AND PERIOD

=> d l15 ti so py kwic


L15  ANSWER 1 OF 1  BIOSIS  COPYRIGHT (c) 2022 Clarivate Analytics  on STN
TI   Cost of Biologics per Treated Patient across Immune-mediated Inflammatory
```

Disease Indications in a Pharmacy Benefit Management Setting: A Retrospective Cohort Study.
SO Clinical Therapeutics, (AUG 2014) Vol. 36, No. 8, pp. 1231-1241. http://www.journals.elsevierhealth.com/periodicals/clithe. CODEN: CLTHDG. ISSN: 0149-2918. E-ISSN: 1879-114X.
PY 2014
AB . . . select immune-mediated inflammatory diseases: moderate to severe rheumatoid arthritis, moderate to severe plaque psoriasis, active psoriatic arthritis, and/or active ankylosing spondylitis.Methods: Using the Medco pharmacy benefits management database, data from patients aged 18 to 63 years with >= 1 claim for abatacept, adalimumab, certolizumab, etanercept, golimumab, infliximab, rituximab, or ustekinumab, dated between January 1, 2008 and August 31, 2011, were collected. Eligible patients were continuously enrolled. . . . 1 claim associated with a diagnosis of rheumatoid arthritis, moderate to severe plaque psoriasis, active psoriatic arthritis, and/or active ankylosing spondylitis in the 180 days before or 30 days after the index date. The annual total costs per treated patient were. . . . the total dose of the index biologic and all other biologics for which there was a claim in the postindex period, multiplied by the wholesale acquisition cost as of October 1, 2013, plus the costs associated with administrations (calculated as number of infusions multiplied by the 2013 Medicare Physician Fee Schedule costs).Findings: Within the study population (N = 8306; 5356 (64.5%) women, 2950. . . . indications were as follows: adalimumab, $23,427 to $26,304; infliximab, $22,824 to $28,907; and etanercept, $21,468 to $27,748, whereas abatacept, certolizumab, golimumab, rituximab, and ustekinumab were associated with a larger range: $17,017 to $41,888.Implications: The present study provides insight into the prescribing. . . .

=> d l14 1-9 ti so py kwic ibib

L14 ANSWER 1 OF 9 CAPLUS COPYRIGHT 2022 ACS on STN
TI Anti-TNF antibodies, compositions, and methods for the treatment of active ankylosing spondylitis
SO PCT Int. Appl., 229pp.
CODEN: PIXXD2
PY 2022
2022
IT Ankylosing spondylitis
Back pain
Homo sapiens
Human
Infusion drug delivery systems
Pharmaceutical dosage forms
Protein sequences
Therapy monitoring
(anti-TNF antibody golimumab for the treatment of active ankylosing spondylitis)

ACCESSION NUMBER: 2022:1572437 CAPLUS Full-text
DOCUMENT NUMBER: 179:162811
TITLE: Anti-TNF antibodies, compositions, and methods for the treatment of active ankylosing spondylitis
INVENTOR(S): Harrison, Diane D.; Hsia, Elizabeth C.; Kim, Lee-Lian; Lo, Kim Hung
PATENT ASSIGNEE(S): Janssen Biotech, Inc., USA
SOURCE: PCT Int. Appl., 229pp.
CODEN: PIXXD2
DOCUMENT TYPE: Patent
LANGUAGE: English
FAMILY ACC. NUM. COUNT: 1
PATENT INFORMATION:

PATENT NO.	KIND	DATE	APPLICATION NO.		DATE
WO 2022130281	A1	20220623	WO 2021-IB61863		20211216
US 20220195028	A1	20220623	US 2021-17552870		20211216
PRIORITY APPLN. INFO.:			US 2020-63126638	P	20201217
			US 2021-63140307	P	20210122

PATENT STATUS PATENT INFORMATION:

PATENT NO.	KIND	STATUS	STATUS DATE
WO 2022130281	A1	Alive	20220630
US 20220195028	A1	Alive	20220630

REFERENCE COUNT: 4 THERE ARE 4 CITED REFERENCES AVAILABLE FOR THIS RECORD. ALL CITATIONS AVAILABLE IN THE RE FORMAT

L14 ANSWER 2 OF 9 CAPLUS COPYRIGHT 2022 ACS on STN DUPLICATE 1
TI Safety and efficacy of intravenous golimumab in adults with ankylosing spondylitis: results through 1 year of the GO-ALIVE study
SO Journal of Rheumatology (2019), 46(10), 1277-1283
CODEN: JRHUA9; ISSN: 1499-2752
URL: http://www.jrheum.org/
PY 2019
AB Objective: Evaluate safety and efficacy of i.v. (IV) golimumab (GOL) in patients with active ankylosing spondylitis (AS) through 1 yr. Methods: A total of 208 patients were randomized to IV infusions of GOL 2 mg/kg (n = 105) at weeks 0, 4, and every 8 wk thereafter or placebo (n = 103) at weeks 0, 4, and 12, then crossover to GOL at weeks 16, 20, and every 8 wk thereafter through Week 52. Efficacy was assessed using the Assessment of Spondyloarthritis international Society (ASAS) criteria, the Ankylosing Spondylitis Disease Activity Score (ASDAS), the Bath Ankylosing Spondylitis Disease Activity Index (BASDAI), and the Bath Ankylosing Spondylitis Functional Index (BASFI). Health-related quality of life was assessed using the AS Quality of Life (ASQoL) index. Efficacy and safety were monitored through Week 52 and Week 60, resp. Results: The primary endpoint (ASAS20) and all controlled endpoints at Week 16 were achieved. At Week 52, 69.5% and 65.0% of patients in the GOL group and placebo crossover group, resp., achieved an ASAS20; 56.2% and 51.5% achieved an ASAS40; 56.2% and 55.3% achieved a BASDAI50; 24.8% and 24.3% achieved ASAS partial remission; and 25.7% and 26.2% met ASDAS inactive disease criteria (all last observation carried forward). Mean changes from baseline to Week 52 in BASFI and ASQoL scores were similar between the GOL group and the placebo crossover group (BASFI: -2.7 and -2.6; ASQoL: -5.5 and -5.4). Through Week 60, 55.4% of all GOL-treated patients had ≥ 1 adverse events (AE); 3.4% had ≥ 1 serious AE.
Conclusion: Efficacy was maintained through 1 yr with IV GOL 2 mg/kg among patients with active AS. AE were consistent with the known safety profile of GOL.

ACCESSION NUMBER:	2020:621677 CAPLUS Full-text
DOCUMENT NUMBER:	175:317623
TITLE:	Safety and efficacy of intravenous golimumab in adults with ankylosing spondylitis: results through 1 year of the GO-ALIVE study
AUTHOR(S):	Reveille, John D.; Deodhar, Atul; Caldron, Paul H.; Dudek, Anna; Harrison, Diane D.; Kim, Lilianne; Lo, Kim Hung; Leu, Jocelyn H.; Hsia, Elizabeth C.
CORPORATE SOURCE:	University of Texas McGovern Medical School, Houston, TX, USA
SOURCE:	Journal of Rheumatology (2019), 46(10), 1277-1283 CODEN: JRHUA9; ISSN: 1499-2752 URL: http://www.jrheum.org/
DIGITAL OBJECT ID:	10.3899/jrheum.180718
PUBLISHER:	Journal of Rheumatology Publishing Co. Ltd.
DOCUMENT TYPE:	Journal; (online computer file)
LANGUAGE:	English
OS.CITING REF COUNT:	2 THERE ARE 2 CAPLUS RECORDS THAT CITE THIS RECORD (2 CITINGS)
REFERENCE COUNT:	16 THERE ARE 16 CITED REFERENCES AVAILABLE FOR THIS RECORD. ALL CITATIONS AVAILABLE IN THE RE FORMAT

L14 ANSWER 3 OF 9 MEDLINE ® on STN
TI Content analysis of Twitter in relation to biological treatments for chronic inflammatory arthropathies: an exploratory study.
SO European journal of hospital pharmacy : science and practice, (2019 May) Vol. 26, No. 3, pp. 124-128. Electronic Publication Date: 24 Jan 2018
Journal code: 101578294. ISSN: 2047-9956. L-ISSN: 2047-9956.
Report No.: PMC-PMC6684072.
PY 2019

AB . . . chronic inflammatory arthropathies.

METHODS: A Twitter analysis was carried out during one month using the following keywords: 'rheumatoid arthritis', 'ankylosing spondylitis', 'psoriatic arthritis' and their biological therapies: 'abatacept', 'adalimumab', 'certolizumab', 'etanercept', 'golimumab', 'infliximab' and 'tocilizumab'. Tweets were hand-coded and filtered for content.

RESULTS: 25 441 tweets contained at least one of the. . . tweets about diseases, the term 'rheumatoid arthritis' (n= 1109) was used more frequently than 'psoriatic arthritis' (n= 233) and 'ankylosing spondylitis' (n= 155). The most commonly addressed subjects in the tweets in relation to biological therapies were related to safety/adverse events (136 of 983 (13.8%)) and to administration, particularly drug infusion (60 of 983 (6.1%)) and self-administration (57 of 983 (5.8%)). Regarding diseases, the most commonly addressed subjects were non-pharmacological recommendations. . .

ACCESSION NUMBER: 2021495265 MEDLINE Full-text
DOCUMENT NUMBER: PubMed ID: 31428318
TITLE: Content analysis of Twitter in relation to biological treatments for chronic inflammatory arthropathies: an exploratory study.
AUTHOR: Martinez-Lopez De Castro Noemi; Samartin-Ucha Marisol; Martin-Vila Alicia; Alvarez-Payero Miriam; Pineiro-Corrales Guadalupe
CORPORATE SOURCE: Department of Pharmacy, EOXI, Vigo, Spain.
AUTHOR: Martinez-Lopez De Castro Noemi; Samartin-Ucha Marisol; Alvarez-Payero Miriam; Pego-Reigosa Jose M
CORPORATE SOURCE: Group of Investigation in Rheumatology and Immune-Mediated Diseases, Instituto de Investigacion Sanitaria Galicia Sur, EOXI, Vigo, Spain.
AUTHOR: Pego-Reigosa Jose M
CORPORATE SOURCE: Rheumatology, Department of Rheumatology, EOXI, Vigo, Spain.
SOURCE: European journal of hospital pharmacy : science and practice, (2019 May) Vol. 26, No. 3, pp. 124-128. Electronic Publication Date: 24 Jan 2018 Journal code: 101578294. ISSN: 2047-9956. L-ISSN: 2047-9956. Report No.: PMC-PMC6684072.
DIGITAL OBJECT ID: http://dx.doi.org/10.1136/ejhpharm-2017-001402
PUB. COUNTRY: England: United Kingdom
DOCUMENT TYPE: Journal; Article; (JOURNAL ARTICLE)
LANGUAGE: English
FILE SEGMENT: NONMEDLINE; PUBMED-NOT-MEDLINE
FILE SEGMENT: Print; Electronic
ENTRY DATE: Entered STN: 20 Aug 2019 Last Updated on STN: 20 Aug 2019 Indexing Added: 20 Aug 2019
OS.CITING REF COUNT: 2 There are 2 MEDLINE records that cite this record
MEDLINE REFERENCE COUNT: 11 There are 11 cited references available in MEDLINE for this document.

L14 ANSWER 4 OF 9 CAPLUS COPYRIGHT 2022 ACS on STN DUPLICATE 2
TI Safety and efficacy of Golimumab administered intravenously in adults with ankylosing spondylitis: results through week 28 of the GO-ALIVE study
SO Journal of Rheumatology (2018), 45(3), 341-349 CODEN: JRHUA9; ISSN: 1499-2752
PY 2018
AB Objective.To evaluate the safety and efficacy of i.v. golimumab (GOL) in patients with active ankylosing spondylitis (AS). Methods.In a phase III, randomized, double-blind, placebo (PBO)-controlled trial, 208 patients were randomized (1:1) to i.v. (IV) infusions of GOL 2 mg/kg (n = 105) at weeks 0, 4, 12, and every 8 wk, or PBO (n =. . . of Spondyloarthritis International Society Criteria (ASAS20) at Week 16. Secondary endpoints included ASAS40, ≥ 50% improvement in the Bath Ankylosing Spondylitis Disease Activity Index (BASDAI50), and change in the Bath Ankylosing Spondylitis Functional Index (BASFI) at Week 16. Safety was monitored through Week 28. Results.Significantly greater proportions of GOL-treated patients had ASAS20. . .
IT Ankylosing spondylitis

Blood serum
Diagnosis
Homo sapiens
Human
Inflammation
Metabolic side effects of drugs
Nasopharyngitis
Pharmaceutical intravenous infusions
Pharmacokinetics
Upper respiratory infection
(safety and efficacy of golimumab administered i.v. in adults with ankylosing spondylitis)

ACCESSION NUMBER: 2019:192315 CAPLUS Full-text
DOCUMENT NUMBER: 174:574693
TITLE: Safety and efficacy of Golimumab administered intravenously in adults with ankylosing spondylitis: results through week 28 of the GO-ALIVE study
AUTHOR(S): Deodhar, Atul; Reveille, John D.; Harrison, Diane D.; Kim, Lilianne; Lo, Kim Hung; Leu, Jocelyn H.; Hsia, Elizabeth C.
CORPORATE SOURCE: Oregon Health & Science University, Portland, OR, USA
SOURCE: Journal of Rheumatology (2018), 45(3), 341-349
CODEN: JRHUA9; ISSN: 1499-2752
DIGITAL OBJECT ID: 10.3899/jrheum.170487
PUBLISHER: Journal of Rheumatology Publishing Co. Ltd.
DOCUMENT TYPE: Journal; (online computer file)
LANGUAGE: English
OS.CITING REF COUNT: 11 THERE ARE 11 CAPLUS RECORDS THAT CITE THIS RECORD (11 CITINGS)
REFERENCE COUNT: 28 THERE ARE 28 CITED REFERENCES AVAILABLE FOR THIS RECORD. ALL CITATIONS AVAILABLE IN THE RE FORMAT

L14 ANSWER 5 OF 9 CAPLUS COPYRIGHT 2022 ACS on STN DUPLICATE 3
TI Reasons for Discontinuation and Adverse Effects of TNFα Inhibitors in a Cohort of Patients With Rheumatoid Arthritis and Ankylosing Spondylitis
SO Annals of Pharmacotherapy (2017), 51(5), 388-393
CODEN: APHRER; ISSN: 1542-6270
PY 2017
AB . . . The introduction of anti-tumor necrosis factor α (anti-TNFα) drugs has improved the clin. outcomes in rheumatoid arthritis (RA) and ankylosing spondylitis (AS). However, these drugs may cause adverse effects that motivate a change in or discontinuation of the treatment. Objective: To. . . changes in the dosage regimen in a cohort of patients with RA and AS treated with infliximab, adalimumab, etanercept, and golimumab under clin. practice conditions. Methods: This was a retrospective observational study that included patients with RA or AS treated with. . . treatment. The most frequent changes were modifications in the dosing, and the most frequent adverse effects were reactions after the infusion or injection (53.8% and 66.7% in RA and AS, resp.). Drug survival of etanercept in RA (67.9%) is greater than. . .

ACCESSION NUMBER: 2018:50802 CAPLUS Full-text
DOCUMENT NUMBER: 173:125273
TITLE: Reasons for Discontinuation and Adverse Effects of TNFα Inhibitors in a Cohort of Patients With Rheumatoid Arthritis and Ankylosing Spondylitis
AUTHOR(S): Garcia-Lagunar, Maria Henar; Gutierrez-Civicos, Maria Rocio; Garcia-Simon, Maria Sergia; Conesa-Zamora, Pablo; Jimenez-Santos, Enrique; Cano-Vivar, Pedro; Garcia-Marquez, Andres; Munoz-Garcia, Iris; Viney, Alice Charlotte
CORPORATE SOURCE: Department of Hospital Pharmacy, Santa Lucia General University Hospital (HGUSL), Cartagena, Spain
SOURCE: Annals of Pharmacotherapy (2017), 51(5), 388-393
CODEN: APHRER; ISSN: 1542-6270
DIGITAL OBJECT ID: 10.1177/1060028016682330
PUBLISHER: Sage Publications
DOCUMENT TYPE: Journal; (online computer file)
LANGUAGE: English
OS.CITING REF COUNT: 5 THERE ARE 5 CAPLUS RECORDS THAT CITE THIS RECORD (5 CITINGS)

REFERENCE COUNT: 23 THERE ARE 23 CITED REFERENCES AVAILABLE FOR THIS RECORD. ALL CITATIONS AVAILABLE IN THE RE FORMAT

L14 ANSWER 6 OF 9 CAPLUS COPYRIGHT 2022 ACS on STN DUPLICATE 4
TI Immunogenicity of Biologics in Chronic Inflammatory Diseases: A Systematic Review
SO BioDrugs (2017), 31(4), 299-316
CODEN: BIDRF4; ISSN: 1173-8804
PY 2017
AB Objectives: A systematic review was conducted to explore the immunogenicity of biol. agents across inflammatory diseases and its potential impact on efficacy/safety. Methods: Literature searches were conducted through Nov. 2016 to identify controlled and observational studies of biologics/biosimilars administered for treatment of rheumatoid arthritis (RA), psoriatic arthritis (PsA), juvenile idiopathic arthritis (JIA), ankylosing spondylitis (AS), non-radiog. axial spondyloarthritis (nr-axSpA), psoriasis (Ps), Crohn's disease, and ulcerative colitis. Results: Of >21,000 screened publications, 443 were included. Anti-drug antibody (ADAb) rates varied widely among biologics across diseases (and are not directly comparable because of immunoassay heterogeneity); the highest overall rates were reported with infliximab (0-83%), adalimumab (0-54%), and infliximab biosimilar CT-P13 (21-52%), and the lowest with secukinumab (0-1%), ustekinumab (1-11%), etanercept (0-13%), and golimumab (0-19%). Most ADAbs were neutralizing, except those to abatacept and etanercept. ADAb+ vs. ADAb- patients had lower rates of clin. response to adalimumab (RA, PsA, JIA, AS, Ps), golimumab (RA), infliximab (RA, PsA, AS, Ps), rituximab (RA), ustekinumab (Ps), and CT-P13 (RA, AS). Higher rates of infusion-related reactions were reported in infliximab- and CT-P13-treated ADAb+ patients. Background immunosuppressives/anti-proliferatives reduced biol. immunogenicity across diseases. Conclusions: Based on reviewed reports, biol./biosimilar immunogenicity differs among agents, with the highest rates obsd. with infliximab and adalimumab. As ADAb formation in biol.-/biosimilar-treated patients may increase the risk of lost response, the immunogenicity of these agents is an important (albeit not the only) consideration in the treatment decision-making process.
ACCESSION NUMBER: 2017:1070060 CAPLUS Full-text
DOCUMENT NUMBER: 168:482452
TITLE: Immunogenicity of Biologics in Chronic Inflammatory Diseases: A Systematic Review
AUTHOR(S): Strand, Vibeke; Balsa, Alejandro; Al-Saleh, Jamal; Barile-Fabris, Leonor; Horiuchi, Takahiko; Takeuchi, Tsutomu; Lula, Sadiq; Hawes, Charles; Kola, Blerina; Marshall, Lisa
CORPORATE SOURCE: Division of Immunology/Rheumatology, Stanford University School of Medicine, Portola Valley, CA, 94028, USA
SOURCE: BioDrugs (2017), 31(4), 299-316
CODEN: BIDRF4; ISSN: 1173-8804
DIGITAL OBJECT ID: 10.1007/s40259-017-0231-8
PUBLISHER: Springer International Publishing AG
DOCUMENT TYPE: Journal; General Review; (online computer file)
LANGUAGE: English
OS.CITING REF COUNT: 104 THERE ARE 104 CAPLUS RECORDS THAT CITE THIS RECORD (105 CITINGS)
REFERENCE COUNT: 208 THERE ARE 208 CITED REFERENCES AVAILABLE FOR THIS RECORD. ALL CITATIONS AVAILABLE IN THE RE FORMAT

L14 ANSWER 7 OF 9 CAPLUS COPYRIGHT 2022 ACS on STN DUPLICATE 5
TI Bilateral Retrobulbar Optic Neuropathy Associated With Golimumab
SO Clinical Neuropharmacology (2017), 40(3), 149-151
CODEN: CLNEDB; ISSN: 0362-5664
PY 2017
AB We report the first documented case of retrobulbar optic neuropathy assocd. with golimumab. A 48-yr-old man was admitted with a 3-wk history of progressive visual loss of his left eye. He had received a second infusion of golimumab for ankylosing spondylitis 10 days before admission. A magnetic resonance imaging scan showed enhancement of both optic nerves and visual evoked potentials were consistent with

demyelinating bilateral optic neuropathy, although visual acuity drop in the right eye could not be detd. because of deep amblyopia. No improvement was obsd. after golimumab dechallenge or corticosteroid treatment. Demyelinating complications related to treatment with tumor necrosis factor alpha inhibitors (TNFAI) have been previously described. Golimumab, a fully human monoclonal antibody, is the most recently developed TNFAI and thus, fewer adverse effects have been reported. Further studies should be developed to elucidate if variability in golimumab's pharmacokinetics or TNF receptor binding affinity could explain different safety profiles compared with other TNFAI.

ACCESSION NUMBER: 2017:741867 CAPLUS Full-text
TITLE: Bilateral Retrobulbar Optic Neuropathy Associated With Golimumab
AUTHOR(S): de Frutos-Lezaun, Marta; Bidaguren, Aritz; de la Riva, Patricia; Meneses, Carlos F.; Olascoaga, Javier
CORPORATE SOURCE: Departments of Ophthalmology, Donostia University Hospital, Spain
SOURCE: Clinical Neuropharmacology (2017), 40(3), 149-151
CODEN: CLNEDB; ISSN: 0362-5664
DIGITAL OBJECT ID: 10.1097/WNF.0000000000000211
PUBLISHER: Lippincott Williams & Wilkins
DOCUMENT TYPE: Journal; (online computer file)
LANGUAGE: English
REFERENCE COUNT: 30 THERE ARE 30 CITED REFERENCES AVAILABLE FOR THIS RECORD. ALL CITATIONS AVAILABLE IN THE RE FORMAT

L14 ANSWER 8 OF 9 BIOSIS COPYRIGHT (c) 2022 Clarivate Analytics on STN
DUPLICATE 6
TI Cost of Biologics per Treated Patient across Immune-mediated Inflammatory Disease Indications in a Pharmacy Benefit Management Setting: A Retrospective Cohort Study.
SO Clinical Therapeutics, (AUG 2014) Vol. 36, No. 8, pp. 1231-1241.
http://www.journals.elsevierhealth.com/periodicals/clithe.
CODEN: CLTHDG. ISSN: 0149-2918. E-ISSN: 1879-114X.
PY 2014
AB. . . select immune-mediated inflammatory diseases: moderate to severe rheumatoid arthritis, moderate to severe plaque psoriasis, active psoriatic arthritis, and/or active ankylosing spondylitis.Methods: Using the Medco pharmacy benefits management database, data from patients aged 18 to 63 years with >= 1 claim for abatacept, adalimumab, certolizumab, etanercept, golimumab, infliximab, rituximab, or ustekinumab, dated between January 1, 2008 and August 31, 2011, were collected. Eligible patients were continuously enrolled. . . 1 claim associated with a diagnosis of rheumatoid arthritis, moderate to severe plaque psoriasis, active psoriatic arthritis, and/or active ankylosing spondylitis in the 180 days before or 30 days after the index date. The annual total costs per treated patient were. . . by the wholesale acquisition cost as of October 1, 2013, plus the costs associated with administrations (calculated as number of infusions multiplied by the 2013 Medicare Physician Fee Schedule costs).Findings: Within the study population (N = 8306; 5356 (64.5%) women, 2950. . . indications were as follows: adalimumab, $23,427 to $26,304; infliximab, $22,824 to $28,907; and etanercept, $21,468 to $27,748, whereas abatacept, certolizumab, golimumab, rituximab, and ustekinumab were associated with a larger range: $17,017 to $41,888.Implications: The present study provides insight into the prescribing. . .
ACCESSION NUMBER: 2014:699707 BIOSIS Full-text
DOCUMENT NUMBER: PREV201400699707
TITLE: Cost of Biologics per Treated Patient across Immune-mediated Inflammatory Disease Indications in a Pharmacy Benefit Management Setting: A Retrospective Cohort Study.
AUTHOR(S): Wu, Ning [Reprint Author]; Lee, Yuan-Chi (Daisy); Shah, Neel; Harrison, David J.
CORPORATE SOURCE: Evidera, 430 Bedford St,Suite 300, Lexington, MA 02420 USA
ning.wu@evidera.com
SOURCE: Clinical Therapeutics, (AUG 2014) Vol. 36, No. 8, pp. 1231-1241.
http://www.journals.elsevierhealth.com/periodicals/clithe.
CODEN: CLTHDG. ISSN: 0149-2918. E-ISSN: 1879-114X.
DIGITAL OBJECT ID: 10.1016/j.clinthera.2014.06.014

DOCUMENT TYPE: Article
LANGUAGE: English
ENTRY DATE: Entered STN: 8 Oct 2014
Last Updated on STN: 8 Oct 2014

L14 ANSWER 9 OF 9 CAPLUS COPYRIGHT 2022 ACS on STN DUPLICATE 7
TI Golimumab and immunogenicity? 2010 and beyond
SO Pharmazie (2011), 66(4), 233-243
CODEN: PHARAT; ISSN: 0031-7144
PY 2011
AB . . . frequent adverse event obsd. with biol. agents' therapy. Challenges of management in patients with rheumatoid arthritis, psoriatic arthritis, and ankylosing spondylitis treated with golimumab, an anti-TNF-α blocker, include limited generation of antibodies like anti-nuclear, anti-golimumab, and anti-double stranded DNA antibodies. We conducted here a meta-anal. study to evaluate and compare the newly generated antibody levels after golimumab therapy. The examn. of original clin. trials revealed that their levels were neither higher nor significant. Moreover, no evident assocns. between the induced-antibodies and lupus-like syndromes and/or infusion site reaction were reported. The reduced patients cohort and the absence of systematic newly generated antibodies follow-up might be implicated. . . predicting for their worse prognosis. Hence, further studies are required to ascertain the real impact of the induced antibodies after golimumab's therapy.
ACCESSION NUMBER: 2011:598583 CAPLUS Full-text
DOCUMENT NUMBER: 155:172145
TITLE: Golimumab and immunogenicity? 2010 and beyond
AUTHOR(S): Zidi, I.; Bouaziz, A.; Ben Amor, N.
CORPORATE SOURCE: Laboratory of Biochemistry, Research Unit 02/UR/09-01, Higher Institute of Biotechnology of Monastir, Tunisia, Tunisia
SOURCE: Pharmazie (2011), 66(4), 233-243
CODEN: PHARAT; ISSN: 0031-7144
DIGITAL OBJECT ID: 10.1691/ph.2011.0771
PUBLISHER: Govi-Verlag Pharmazeutischer Verlag GmbH
DOCUMENT TYPE: Journal; General Review
LANGUAGE: English
OS.CITING REF COUNT: 4 THERE ARE 4 CAPLUS RECORDS THAT CITE THIS RECORD (4 CITINGS)
REFERENCE COUNT: 50 THERE ARE 50 CITED REFERENCES AVAILABLE FOR THIS RECORD. ALL CITATIONS AVAILABLE IN THE RE FORMAT

=> d his

(FILE 'HOME' ENTERED AT 18:39:08 ON 15 SEP 2022)

FILE 'CAPLUS, BIOSIS, MEDLINE' ENTERED AT 18:39:33 ON 15 SEP 2022
E HARRISON DIANE D/AU
L1 74 S E3-4
E HSIA ELIZABETH C/AU
L2 274 S E14-15
E KIM LEE LIAN/AU
L3 18 S E27
E LO KIM HUNG/AU
L4 105 S E38-39
L5 367 S L1-4
L6 5495 S GOLIMUMAB
L7 762499 S INFUSION
L8 131 S L6 (L) L7
L9 56405 S SPONDYLITIS
L10 22 S L8 (L) L9
L11 0 S MG/KG
L12 5 S MILLIGRAM (W) BODY (W) WEIGHT
L13 0 S L10 (L) L12
L14 9 DUP REM L10 (13 DUPLICATES REMOVED)
L15 1 S L14 AND PERIOD

PE2E SEARCH - Search History (Prior Art)

Ref #	Hits	Search Query	DBs	Default Operator	Plurals	British Equivalents	Time Stamp
L1	151	("0000030" OR "0000059" OR "0000088" OR "0000116" OR "0000144" OR "20090214528" OR "20100251099" OR "20110251099" 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 "4757506" 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 "5116964" 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	(US-PGPUB; USPAT)	OR	ON	ON	2022/09/14 12:08 PM

		"5403484" OR "5404871" OR "5427908" OR "5447851" OR "5455030" OR "5458135" OR "5496549" OR "5512544" OR "5514670" OR "5518889" OR "5530101" OR "5534621" OR "5545807" OR "5565362" 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 "5698419" OR "5698435" OR "5714352" OR "5723323" OR "5733761" OR "5750105" OR "5750373" OR "5763192" OR "5763733" OR "5766886" OR "5770198" OR "5770222" OR "5770359" OR "5770428" OR "5789650" OR "5807706" OR "5814476" OR "5814599" OR					

		"5817483" OR "5821333" OR "5824514" OR "5827690" OR "5827739" OR "5833985" OR "5837500" OR "5839446" OR "5849695" OR "5851198" OR "5856456" OR "5871753" OR "5879681" OR "5885793" OR "5888511" OR "5919452" OR "5932448" OR "5958413" OR "5959083" OR "5959084" OR "5962255" OR "5976862" OR "5989530" OR "5993833" OR "5994616" OR "6010902" 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.					
L2	2	L1 AND golimumab	(US-PGPUB; USPAT)	OR	ON	ON	2022/09/14 05:54 PM
L3	1	L1 AND golimumab AND ankylosing	(US-PGPUB; USPAT)	OR	ON	ON	2022/09/14 06:04 PM
L4	2	L1 AND golimumab AND arthritis	(US-PGPUB; USPAT)	OR	ON	ON	2022/09/14 06:07 PM
L5	2	L1 AND golimumab AND spondylitis	(US-PGPUB; USPAT)	OR	ON	ON	2022/09/14 06:08 PM
L6	3237	golimumab AND spondylitis	(US-PGPUB; USPAT)	OR	ON	ON	2022/09/14 06:12 PM
L7	3157	golimumab AND spondylitis AND ankylosing	(US-PGPUB; USPAT)	OR	ON	ON	2022/09/14 06:13 PM
L8	120	golimumab AND spondylitis ADJ ankylosing	(US-PGPUB; USPAT)	OR	ON	ON	2022/09/14 06:13 PM

L9	67	golimumab AND spondylitis ADJ ankylosing AND @ay<"2018"	(US-PGPUB; USPAT)	OR	ON	ON	2022/09/14 06:13 PM
L10	1	golimumab SAME spondylitis ADJ ankylosing AND @ay<"2018"	(US-PGPUB; USPAT)	OR	ON	ON	2022/09/14 06:15 PM
L11	1	(golimumab OR (Cnto NEAR "148")) SAME spondylitis ADJ ankylosing AND @ay<"2018"	(US-PGPUB; USPAT)	OR	ON	ON	2022/09/14 06:17 PM
L12	6	(golimumab OR (Cnto NEAR "148")) ADJ ankylosing ADJ spondylitis	(US-PGPUB; USPAT)	OR	ON	ON	2022/09/14 06:19 PM
L13	776	(golimumab OR (Cnto NEAR "148")).clm.	(US-PGPUB; USPAT)	OR	ON	ON	2022/09/14 06:53 PM
L14	311	(golimumab OR (Cnto NEAR "148")).clm. AND spondylitis	(US-PGPUB; USPAT)	OR	ON	ON	2022/09/14 06:53 PM
L15	302	(golimumab OR (Cnto NEAR "148")).clm. AND ankylosing ADJ spondylitis	(US-PGPUB; USPAT)	OR	ON	ON	2022/09/14 06:54 PM
L16	170	(golimumab OR (Cnto NEAR "148")).clm. AND ankylosing ADJ spondylitis AND @ay<"2017"	(US-PGPUB; USPAT)	OR	ON	ON	2022/09/14 06:55 PM
L17	109	(golimumab OR (Cnto NEAR "148")).clm. AND ankylosing ADJ spondylitis AND @ay<"2017" AND methotrexate	(US-PGPUB; USPAT)	OR	ON	ON	2022/09/14 07:24 PM
L18	112	(golimumab OR (Cnto NEAR "148")).clm. AND ankylosing ADJ spondylitis AND @ay<"2017" AND (methotrexate OR sulfasalazine OR hydroxychloroquine)	(US-PGPUB; USPAT)	OR	ON	ON	2022/09/14 07:25 PM
L19	1	(golimumab OR (Cnto NEAR "148")) SAME infusion SAME (over NEAR time)	(US-PGPUB; USPAT)	OR	ON	ON	2022/09/15 01:59 PM
L20	220	(golimumab OR (Cnto NEAR "148")) SAME infusion	(US-PGPUB; USPAT)	OR	ON	ON	2022/09/15 01:59 PM
L21	12	(golimumab OR (Cnto NEAR "148")) SAME	(US-PGPUB; USPAT)	OR	ON	ON	2022/09/15 02:03 PM

		(rate NEAR infusion)					
L22	885	antibody SAME (rate NEAR infusion)	(US-PGPUB; USPAT)	OR	ON	ON	2022/09/15 02:04 PM
L23	170	antibody SAME infusion SAME rate SAME over NEAR period	(US-PGPUB; USPAT)	OR	ON	ON	2022/09/15 02:04 PM
L24	0	anti-tnf SAME antibody SAME infusion SAME rate SAME over NEAR period	(US-PGPUB; USPAT)	OR	ON	ON	2022/09/15 02:10 PM
L25	3	anti-tnf AND antibody SAME infusion SAME rate SAME over NEAR period	(US-PGPUB; USPAT)	OR	ON	ON	2022/09/15 02:10 PM
L26	4972	anti-tnf AND antibody SAME infusion	(US-PGPUB; USPAT)	OR	ON	ON	2022/09/15 02:12 PM
L27	192	anti-tnf ADJ antibody SAME infusion	(US-PGPUB; USPAT)	OR	ON	ON	2022/09/15 02:12 PM
L29	798	Janssen ADJ Biotech ADJ Inc.asn.	(US-PGPUB; USPAT)	OR	ON	ON	2022/09/15 05:40 PM
L30	18	Harrison Diane D.in.	(US-PGPUB; USPAT)	ADJ	ON	ON	2022/09/15 05:41 PM
L31	16	Hsia Elizabeth C.in.	(US-PGPUB; USPAT)	ADJ	ON	ON	2022/09/15 05:42 PM
L32	10	Kim Lee-Lian.in.	(US-PGPUB; USPAT)	ADJ	ON	ON	2022/09/15 05:49 PM
L34	11	Lo Kim Hung.in.	(US-PGPUB; USPAT)	ADJ	ON	ON	2022/09/15 05:50 PM
L35	984	L27 L29 L30 L31 L32 L34	(US-PGPUB; USPAT)	OR	ON	ON	2022/09/15 05:58 PM
L36	82	L35 AND golimumab	(US-PGPUB; USPAT)	OR	ON	ON	2022/09/15 05:59 PM
L37	7	L35 AND golimumab.clm.	(US-PGPUB; USPAT)	OR	ON	ON	2022/09/15 05:59 PM
L38	3377	c07k16/241.cpc.	(US-PGPUB; USPAT)	OR	ON	ON	2022/09/15 06:01 PM
L39	14364	a61k39/3955.cpc.	(US-PGPUB; USPAT)	OR	ON	ON	2022/09/15 06:02 PM
L40	53893	a61p19/02.cpc.	(US-PGPUB; USPAT)	OR	ON	ON	2022/09/15 06:02 PM
L41	67518	L38 OR L39 L40	(US-PGPUB; USPAT)	OR	ON	ON	2022/09/15 06:03 PM
L42	113	L41 AND golimumab AND spondilitis	(US-PGPUB; USPAT)	OR	ON	ON	2022/09/15 06:03 PM
L43	23	L41 AND golimumab AND spondilitis.clm.	(US-PGPUB; USPAT)	OR	ON	ON	2022/09/15 06:04 PM

PE2E SEARCH - Search History (Interference)

There are no Interference searches to show.

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Patent Application of: Diane D. Harrison, et al.	Art Unit: 1646 Confirmation No.: 8810
Application No.: 17/237,650	Examiner: Chandra, Gyan
Filing date: April 22, 2021	Atty Docket No.: 206389-0002-02US

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

AMENDMENT

This Amendment is responsive to the non-final Office Action mailed on September 22, 2022 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, which extends the deadline for a timely response to and through January 22, 2023.

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.

REMARKS

Claims 11-20 are pending and under consideration. Claims 1-10 have been previously cancelled.

Objection to the Specification

The Examiner has objected to the Specification for inclusion of hyperlinks and trademarks.

Applicants have amended the Specification herein to remove browser-executable code and to properly recite registered trademarks with generic terminology.

Applicants respectfully request reconsideration and withdrawal of the objection.

Rejection of claims 11, 13-14, 16-18 and 20 under 35 U.S.C. 102

The Examiner has rejected claims 11, 13-14, 16-18 and 20 under 35 U.S.C. 102 as allegedly being anticipated by Wong et al. (U.S. Patent Application Publication US2009/0123378; hereinafter "Wong"). The Examiner contends that Wong teaches treating ankylosing spondylitis in a subject comprising administering golimumab to the subject. The Examiner further contends that Wong teaches that the response of the treatment is monitored by BASDAI and that the antibody can be administered by infusion.

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 art must describe each and every element of the rejected claims in order to anticipate the claims under Section 102.

Applicants submit that Wong does not teach administering a safe and effective amount of a composition comprising the recited anti-TNF antibody, wherein said composition is administered via IV infusion such that a patient treated with the composition achieves an Ankylosing Spondylitis Disease Activity Score (ASDAS) inactive disease (<1.3)

at 4 weeks of treatment or at 2 weeks of treatment, as recited in claim 11, from which claim 13 depends.

Applicants submit that Wong does not teach administering a safe and effective amount of a composition comprising the recited anti-TNF antibody, wherein said composition is administered via IV infusion such that at week 16 of treatment patients treated with the anti-TNF antibody achieve a mean change from baseline in one or more criteria selected from the group consisting of: Bath Ankylosing Spondylitis Functional Index (BASFI) = -2.4 ± 2.1 Standard Deviation (SD), Bath Ankylosing Spondylitis Metrology Index (BASMI) = -0.4 ± 0.6 SD, 36-item Short-Form Health Survey Physical Component Summary (SF-36 PCS)= 8.5 ± 7.5 SD, 36-item Short-Form Health Survey Mental Component Summary (SF-36 MCS) = 6.5 ± 9.1 SD, and Ankylosing Spondylitis Qualify of Life questionnaire (ASQoL) = -5.4 ± 5.0 SD, as recited in claim 14, from which claim 16 depends.

Applicants submit that Wong does not teach administering a safe and effective amount of a composition comprising the recited anti-TNF antibody, wherein said composition is administered via IV infusion such that ≥ 65% of patients receiving the treatment achieve Assessment in Ankylosing Spondylitis 20 (ASAS20) at week 16 of treatment., as recited in claim 17, from which claims 18 and 20 depend.

Applicants submit that Wong, when read as a whole, does not teach a skilled artisan that the recited anti-TNF antibody (e.g., golimumab) can effectively treat a subject with ankylosing spondylitis, let alone is able to achieve the recited clinical endpoints recited in claims 11, 14 and 17. Rather, a skilled artisan, reading Wong, would recognize that Wong simply lists golimumab as an alternative anti-TNF antibody, but that Wong is singularly directed to the effects of adalimumab, a anti-TNF antibody that is distinct from the presently recited anti-TNF antibody. That is, Wong does not provide any teaching or demonstration that the recited anti-TNF antibody has any effect on subjects with ankylosing spondylitis. Therefore, Wong does not teach administering the recited anti-TNF antibody via IV infusion to a subject, wherein the subject achieves the recited clinical efficacy.

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

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 Wong in view of Le et al. (U.S. Patent No. 5,656,272; hereinafter "Le"). The Examiner admits that Wong does not teach infusion of the antibody at 2mg/kg over 30min ± 10 min, but contends that Le teaches to use of an anti-TNF antibody for other conditions where the antibody is administered at 1, 5, or 10mg/kg over 60 minutes. The Examiner contends that a skilled physician would decide dose and infusion time based on the severity of the disease and body weight, and therefore it would be obvious to administer the recited antibody at the recited dose.

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.

Applicants submit that Wong and Le, alone or in combination with each other, do not teach or suggest administering a safe and effective amount of a composition comprising the recited anti-TNF antibody, wherein said composition is administered via IV infusion such that a patient achieves the recited clinical efficacy, as recited in claims 11 (from which claims 12-13 depend), 14 (from claims 15-16 depend) and 17 (from which claims 18-20 depend).

As described above, Wong does not teach or suggest to a skilled artisan that the recited anti-TNF antibody has any effect, let alone would achieve the recited clinical efficacy. Applicants submit that Le does not make up for the deficiencies of Wong, because Le does not teach or suggest that administration of the recited anti-TNF antibody would achieve the recited clinical efficacy. Like Wong, Le does not provide any teaching or demonstration that the recited antibody (e.g., golimumab) has any effect on a subject with ankylosing spondylitis.

Further, regarding claims 12, 15 and 18, Applicants submit that Wong and Le, alone or in combination with each other, do not teach or suggest a dosing comprising golimumab being administered at a dose of 2 mg/kg, administered over 30 ± 10 minutes, at Weeks 0 and 4, and then every 8 weeks (q8w) thereafter. As admitted by the Examiner, Wong does not teach the recited dosage or infusion time. Applicants submit that Le does not make up for the deficiencies of Le, because Le does not teach or suggest administration of the specifically recited anti-TNF antibody at the specifically recited dosage and infusion time. Le is directed to a wholly different construct, and does not teach or suggest the administration of the

presently recited antibody, let alone the specifically recited dosage and infusion times to effectively treat a subject with ankylosing spondylitis to achieve the recited clinical efficacy.

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 Wong and Le do not prove a reasonable expectation of success at arriving at a method for treating ankylosing spondylitis by administering a composition comprising a safe and effective amount of the recited anti-TNF antibody, wherein said composition is administered via IV infusion.

Claim 11

The present invention is based, in part, upon the surprising discovery that IV infusion of golimumab is an effective therapy for ankylosing spondylitis, which can show efficiency as quick as 2 to 4 weeks after treatment. Applicants submit that Wong only demonstrates the efficacy of adalimumab. Nothing in Wong provides a skilled artisan with any predictability that golimumab can be delivered by IV infusion to treat ankylosing spondylitis, much less that a patient who is administered golimumab by IV infusion would achieve ASDAS inactive disease (<1.3) at 4 weeks of treatment or at 2 weeks of treatment, as recited in claim 11.

Applicants submit that Le does not cure any of the deficiencies of Wong. Applicants submit that Le does not provide a skilled artisan with any predictability that intravenous golimumab can be used to treat ankylosing spondylitis, much less that a patient who is administered intravenous golimumab would achieve ASDAS inactive disease (<1.3) at 4 weeks of treatment or 2 weeks of treatment.

First, Applicants submit that neither Wong nor Le describe the effects of IV golimumab on a subject with ankylosing spondylitis. Further, Wong and Le do not describe any clinical improvement from IV golimumab on any subject, let alone a subject with ankylosing spondylitis. Applicants submit that skilled artisan reading Wong and Le would not have any reasonable expectation that administration of IV golimumab could be used to effectively treat ankylosing spondylitis, let alone that treatment would result in clinical efficacy in 2 or 4 weeks.

Claim 14

Nothing in Wong and Le provides a skilled artisan with any predictability that golimumab can be delivered by IV infusion to treat ankylosing spondylitis, much less that at week 16 of treatment patients treated with the anti-TNF antibody achieve a mean change from baseline in one or more criteria selected from the group consisting of: Bath Ankylosing Spondylitis Functional Index (BASFI) = -2.4 ± 2.1 Standard Deviation (SD), Bath Ankylosing Spondylitis Metrology Index (BASMI) = -0.4 ± 0.6 SD, 36-item Short-Form Health Survey Physical Component Summary (SF-36 PCS)= 8.5 ± 7.5 SD, 36-item Short-Form Health Survey Mental Component Summary (SF-36 MCS) = 6.5 ± 9.1 SD, and Ankylosing Spondylitis Qualify of Life questionnaire (ASQoL) = -5.4 ± 5.0 SD, as recited in claim 14. As described above, neither Wong nor Le describe the effects of IV golimumab on a subject with ankylosing spondylitis. Further, Wong and Le do not describe any clinical improvement from IV golimumab on any subject, let alone a subject with ankylosing spondylitis. Applicants submit that a skilled artisan would not have any reasonable expectation from Wong and Le that at week 16 of treatment patients receiving IV golimumab would achieve a mean change from baseline in any of the recited criteria.

Claim 7

Nothing in Wong and Le provides a skilled artisan with any predictability that golimumab can be delivered by IV infusion to treat ankylosing spondylitis, much less that ≥ 65% of patients receiving the treatment achieve Assessment in Ankylosing Spondylitis 20 (ASAS20) at week 16 of treatment, as recited in claim 7. As described above, neither Wong nor Le describe the effects of IV golimumab on a subject with ankylosing spondylitis. Further, Wong and Le do not describe any clinical improvement from IV golimumab on any subject, let alone a subject with ankylosing spondylitis. Applicants submit that a skilled artisan would not have any reasonable expectation from Wong and Le that greater than 65% of patients receiving IV golimumab would achieve ASAS20 at week 16.

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 a composition comprising a safe and effective amount of the recited anti-TNF antibody, wherein said composition is administered via IV infusion, produces surprising and unexpected results that could not have been predicted by the combination of Wong and Le.

Smolen et al., Ann Rheum Dis 2014; 73:6–16 (hereinafter "Smolen"; and provided herein as Exhibit A), is a publication of recommendations of an international task force related to treatment targets for spondyloarthritis, including ankylosing spondylitis. See, for example, Smolen, page 9, 2nd column, 2nd to last paragraph, where it states, "Common recommendations 1. A major treatment target should be clinical remission/inactive disease…". Also, note that in the preceding paragraph, page 9, 1st column, last paragraph, the authors in Smolen indicated that the sequence of the recommendations reflects the level of importance considered by the committee for each individual bullet point. It follows, therefore, that the number 1 recommendation related to the treatment target of remission/inactive disease was considered the most important consideration of the international task force. It is demonstrated herein that IV golimumab surprisingly was able to induce inactive disease, the most important metric of ankylosing spondylitis treatment efficacy, in only 2 weeks after treatment.

As described in the present application, intravenous administration of golimumab resulted in inactive disease, as measured by ASDAS score of < 1.3, as early as 4 weeks and 2 weeks after treatment. As noted above, none of the cited references teach or suggest that an ASDAS inactive disease score could be achieved in such a short time, after only 4 weeks or 2 weeks of IV golimumab treatment. Thus, the teaching of Wong and Le, alone or in combination, could not have led a skilled artisan to expect such surprising and unpredictable results.

Achieving an ASDAS inactive disease score (i.e. <1.3) after only 2 weeks or 4 weeks of IV golimumab treatment is a very surprising and unpredictable result that would not be obvious to a person skilled in the art. For example, Van der heijde et al. J Rheumatol, 2014, 41(6): 1095-103 (hereinafter "Van der heijde"; and provided herein as Exhibit B) describes the 2-year results of a clinical trial of subcutaneous golimumab treatment and only reports proportion of patients with ADAS inactive score (<1.3) at week 14 and week 24 after subcutaneous injections of golimumab. Applicants submit that a skilled artisan, at the time of filing, could not have reasonably predicted or expected the surprising and unexpected results demonstrated herein, that patients could achieve an ASDAS inactive disease score (<1.3) in such a short time, after only 4 weeks or 2 weeks of IV golimumab treatment.

Similarly, Applicants submit that the application demonstrates that IV golimumab exhibited surprising and unexpected results in showing improved efficacy, as measured by the change from baseline in the criteria listed in claim 14 and by the proportion of subjects achieving ASAS20. Each of the clinical measures at 16 weeks post-IV golimumab was surprisingly and unexpectedly improved over the same clinical measures at 14 and 24 weeks post-subcutaneous golimumab. Applicants submit that such improved clinical efficacy of IV golimumab demonstrated by the present application would not be expected by a skilled artisan reading Wong and Le.

For at least these reasons, Applicants submit that claims 11-20 are not rendered obvious by the combination of Wong and Le. 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.

January 20, 2023 By: By: /Pallab Singh/

Pallab Singh, Ph.D., J.D.
Registration No. 70,731
Riverside Law LLP
175 Strafford Ave., Suite 100
Wayne, PA 19087
215-268-3888 (main)
215-268-3871 (fax)
215-268-3759 (direct)
E-Mail: psingh@riversidelaw.com
Attorney for Applicants

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INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(Not for submission under 37 CFR 1.99)

Application Number	17237650
Filing Date	2021-04-22
First Named Inventor	Diane D. Harrison
Art Unit	1646
Examiner Name	CHANDRA
Attorney Docket Number	206389-0002-02US

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	1	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

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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.

[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.

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	Examiner Name	CHANDRA
	Attorney Docket Number	206389-0002-02US

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)	2023-01-24
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 record s.

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.

INFORMATION DISCLOSURE STATEMENT BY APPLICANT

Application Number	17/237,650
Filing Date	04/22/2021
First Named Inventor	Diane D. Harrison
Art Unit	1646
Client Number	206389
Matter Number	0002-02US

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.

In accordance with 37 C.F.R. 1.97(g), the filing of this Information Disclosure Statement shall not be construed to mean that a search has been made.

TIMING

In accordance with 37 CFR 1.97(c), this Information Disclosure Statement is being filed after the period specified in 37 CFR 1.97(b) and before the mailing date of a Final Action under 37 CFR 1.113, a Notice of Allowance under 37 CFR 1.311, or an Action that otherwise closes prosecution in the application.

CERTIFICATION STATEMENT

No certification statement is required. This Information Disclosure Statement is being filed in accordance with 37 CFR 1.97(c) and is accompanied by the fee set forth in 37 CFR 1.17(p).

FEE

The Director is hereby authorized to charge $260 (large entity) to Deposit Account No. 50-5366. Please reference attorney docket number 206389-0002-02US for this transaction.

This Information Disclosure Statement is being filed in accordance with 37 CFR 1.97(c), and is not accompanied by one of the certification statements of 37 CFR 1.97(e). Therefore, this Information Disclosure Statement is subject to the $260 (large entity) fee set forth in 37 CFR 1.17(p).

ADDITIONAL COMMENTS

SIGNATURE

Signature	/ Pallab Singh /	**Date**	2023-01-24
Name	Pallab Singh	**Registration Number**	70731

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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
17/237,650	04/22/2021	Diane D. Harrison	206389-0002-02US	8810

171672 7590 04/04/2023

Riverside Law LLP/J&J
175 Strafford Avenue
Suite 100
Wayne, PA 19087

EXAMINER	
CHANDRA, GYAN	

ART UNIT	PAPER NUMBER
1646	

NOTIFICATION DATE	DELIVERY MODE
04/04/2023	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
dcoccia@riversidelaw.com
dockets@riversidelaw.com

Office Action Summary	**Application No.** 17/237,650	**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 --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTHS FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☑ Responsive to communication(s) filed on 1/20/2023.

☐ A declaration(s)/affidavit(s) under **37 CFR 1.130(b)** was/were filed on _____.

2a)☑ This action is **FINAL.** 2b) ☐ This action is non-final.

3)☐ 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.

4)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims*

5) ☑ Claim(s) 11-20 is/are pending in the application.

5a) Of the above claim(s) _____ is/are withdrawn from consideration.

6) ☐ Claim(s) _____ is/are allowed.

7) ☑ Claim(s) 11-20 is/are rejected.

8) ☐ Claim(s) _____ is/are objected to.

9) ☐ Claim(s) _____ are subject to restriction and/or election requirement

* If any claims have been determined allowable, 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.**

Application Papers

10)☐ The specification is objected to by the Examiner.

11)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

Priority under 35 U.S.C. § 119

12)☐ 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)).

** See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☑ Notice of References Cited (PTO-892)

2) ☑ Information Disclosure Statement(s) (PTO/SB/08a and/or PTO/SB/08b) Paper No(s)/Mail Date 1/24/2023.

3) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date _____.

4) ☐ Other: _____.

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 1/20/2023 is acknowledged and fully considered.

Status of Application, Amendments, And/Or Claims

Claims 11-20 are pending and under examination.

Information Disclosure Statement

The Information Disclosure Statement filed on 1/24/2023 has been considered.

Response to Arguments

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) 10, 13-14,16-18 and 20 remain rejected under 35 U.S.C. 102(a) (1) as being anticipated by Wong et al. (US Pub. No. 2009/0123378) for the reasons of record and as discussed below.

The instant invention is broadly drawn to a method of treating a TNF related condition, wherein the TNF related condition is active ankylosing spondylitis, the method comprising: administering a composition comprising a safe and effective amount of at least one isolated mammalian 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, and at least one pharmaceutically acceptable carrier or diluent, wherein said composition is administered via IV infusion, and wherein a patient treated with the composition achieves an Ankylosing Spondylitis Disease Activity Score (ASDAS) inactive disease (<1.3) at 4 weeks of treatment or at 2 weeks of treatment (claims 11, 14 and 17), the method further comprising administering said composition with or without methotrexate (MTX), sulfasalazine (SSZ) or hydroxychloroquine (HCQ) (claim 13, 16, 20) and the method of claim 17, wherein said > 65% of patients that achieve ASAS20 at week 16 of treatment have a treatment difference (improvement compared to placebo) of > 45%.

Wong et al teach treating ankylosing spondylitis (AS) in a subject comprising administering an inhibitor of TNFα, wherein such inhibitor is human TNFα antibody or antigen-binding portion thereof (abstract, [0010], [0013-0016]). They teach that the antibody is Golimumab (see [0081, 0125, 0154] and claim 48). It is noted that anti-TNF antibody, golimumab, comprises amino acid sequences of 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 (as disclosed in SEQ ID NOs: 10 and 11 of US 20090214528). Wong et al teach that the treatment of AS can further comprise methotrexate, azathioprine sulphasalazine or hydroxychloroquine (see paragraph [0014, 0049, 0253, 0255] and claim 19). They teach that the response of the antibody treatment over the time is looked as Bath Ankylosing spondylitis disease activity index (BASDAI) (see[0019]). They teach that the efficacy of treatment over a period of 2, 4 weeks or more is determined BASDAI as compare to control, in particular ASAS20, ASAS50 or ASAS70

(see [0024-0033]) and they teach that the method provides at least about 2.2 in a BASDAI score [0220]. They teach that the administration of an antibody is done by infusion (see [0199, 0209]). Therefore, the instantly claimed invention is implicitly or explicitly anticipated by the prior art of record.

Applicants argue (see Rem. of 1/20/2023) that Wong does not teach administering an effective amount of a composition comprising the recited anti-TNF antibody, wherein the said composition is administered via IV infusion such that a patient treated with composition achieves ASDAS in active disease (<1.3) at weeks of treatment or at 2 weeks of treatment.

Applicants' arguments have been fully considered but they are not persuasive because Wong et al teach the administration of an antibody is done by IV administration (see [0199, 0209]). They teach that the response of the antibody treatment over the time is looked as Bath Ankylosing spondylitis disease activity index (BASDAI) (see[0019]). They teach that the efficacy of treatment over a period of 2, 4 weeks or more is determined BASDAI as compare to control, in particular ASAS20, ASAS50 or ASAS70 (see [0024-0033]) and they teach that the method provides at least about 2.2 in a BASDAI score [0220]. Because Wong teaches administering a composition comprising the same antibody in an effective amount via IV route the outcome of the treatment would be the same, unless evidence to contrary. Additionally, the art of administering golimumab (the instantly claimed antibody) is well known in the art (see Bingham et al. (The effect of intravenous golimumab on health-related quality of life in Rheumatoid arthritis, J. Rheumatol. 2014, 41: 1067-1076). It is noted that Bingham et al is applied to support the state of the art and not as a prior art.

When the reference relied on expressly anticipates or makes obvious all of the elements of the claimed invention, the reference is presumed to be operable. Once such a reference is found, the burden is on applicant to rebut the presumption of operability. *In re Sasse*, 629 F.2d 675, 207 USPQ 107 (CCPA 1980). See also MPEP § 716.07. See also *In re Antor Media Corp.*, 689 F.3d 1282, 103 USPQ2d 1555 (Fed. Cir. 2012). Specifically, in *In re Antor Media Corp.*, the court stated:

"Consistent with the statutory framework and our precedent, we therefore hold that, during patent prosecution, an examiner is entitled to reject claims as anticipated by a **prior art** publication or patent without conducting an inquiry into whether or not that **prior art** reference is enabling. As long as an examiner makes a proper prima facie case of anticipation by giving adequate notice under § 132, the burden shifts to the applicant to submit rebuttal evidence of nonenablement."

Claim Rejections - 35 USC § 103-maintained

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 remain rejected under 35 U.S.C. 103 as being unpatentable over Wong et al. (US Pub. No. 2009/0123378) in view of Le et al. (US Pat. No. 5,656,272) for

the reasons of record at pg. 5-8 of the office action of 9/22/2022 and as discussed below.

Applicants argue (see Rem. of 1/20/2023) that Wong and Le alone or in combination do not teach administering an effective amount of a composition comprising the recited anti-TNF antibody, wherein the said composition is administered via IV infusion that would achieve recited clinical efficacy. They argue regarding claims 12, 15 and 18, Wong et al and Le, alone or in combination, do not teach or suggest a dosing comprising golimumab being administered at a dose of 2 mg/kg over 30 minutes, at weeks 0 and 4, and then every 8 weeks (q8w) thereafter. They argue that there is nothing in of the cited references that would motivate one of the ordinary skill in the art to combine the teachings of these references to produce the presently claimed invention. They argue that Wong et al and Le do not prove a reasonable expectation of success at arriving at a method for treating ankylosing spondylitis by administering a composition in an effective amount as being instantly claimed, wherein the administration is via IV infusion. They argue that unexpectedly improved property that golimumab shows by IV infusion is superior to subcutaneous administration is not present in the prior art (secondary consideration). They argue that Smolen et al. (Ann Rheum Dis. 2014, 73: 6-16, states that major treatment should be clinical remission/inactive disease and they argue that golimumab IV administration does achieve this goal and therefore, it is a surprising result. They argue that Van der heijde et al. (J. Rheumatol. 2014, 41: 1095-1103) describes that the 2-year results of a clinical trial of subcutaneous administration of golimumab only reports portion of patients with

ADAS inactive score (<1.3) at week 14 and 24. Therefore, they argue that one skill in the art would not have expected to have ADAS inactive score (<1.3) at 2-week time.

Applicants' arguments have been fully considered but they are not persuasive because Wong et al teach the administration of an antibody is done by IV infusion (see [0199, 0209]). Additionally, the art of administering golimumab (the instantly claimed antibody) is well known in the art (see Bingham et al. (The effect of intravenous golimumab on health-related quality of life in Rheumatoid arthritis, J. Rheumatol. 2014, 41: 1067-1076). It is noted that Bingham et al is applied to support the state of the art and not as a prior art. When the reference relied on expressly anticipates or makes obvious all of the elements of the claimed invention, the reference is presumed to be operable. Once such a reference is found, the burden is on applicant to rebut the presumption of operability. *In re Sasse,* 629 F.2d 675, 207 USPQ 107 (CCPA 1980). See also MPEP § 716.07. Regarding applicants that Van der heijde et al. teach that subcutaneous administration of golimumab results in inactive ADAS disease (<1.3) is achieved at 14 and 24 weeks, have been considered but they are not persuasive because Wong et al teach administration of golimumab via IV route (see [0199, 0209]), therefore, surprising result to compare with subcutaneous route is not a proper comparison, rather it should be compared with an example of IV administration. It is noted that a **prior art** reference provides an enabling disclosure and thus anticipates a claimed invention if the reference describes the claimed invention in sufficient detail to enable a person of ordinary skill in the art to carry out the claimed invention; "proof of efficacy is not required for a **prior art** reference to be enabling for purposes of anticipation." *Impax Labs. Inc. v. Aventis Pharm. Inc.,* 468 F.3d 1366, 1383, 81 USPQ2d

1001, 1013 (Fed. Cir. 2006). See also MPEP § 2122. Regarding applicants' arguments that Wong et al and Le do not prove a reasonable expectation of success at arriving at a method for treating ankylosing spondylitis by administering a composition in an effective amount as being instantly claimed, have been fully considered but they are not persuasive because Wong et al teach administering the same antibody as being instantly claimed via IV route in an effective amount and Le et al teach that an antibody can be administered in an amount 1, 5 or 10 mg/kg body weight for over a 60 minute period (col. 58, lines 5). Therefore, the outcome would be the same as being instantly claimed, unless evidence to contrary. Regarding applicants' arguments that Smolen et al. (Ann Rheum Dis. 2014, 73: 6-16, states that major treatment should be clinical remission/inactive disease and they argue that golimumab IV administration does achieve this goal have been persuasive but the reference Wong et al teach treating ankylosing spondylitis (AS) in a subject comprising administering an inhibitor of TNFα, wherein such inhibitor is human TNFα antibody or antigen-binding portion thereof (abstract, [0010], [0013-0016]). They teach administering golimumab antibody as being instantly claimed via IV administration. Therefore, one skill in the art would have achieve the same outcome as being instantly claimed, unless evidence to contrary. Therefore, the instantly claimed invention would have obvious over the combined teachings of the prior art.

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

Notice of References Cited	Application/Control No. 17/237,650	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					
	B					
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*		Document Number Country Code-Number-Kind Code	Date MM-YYYY	Country	Name	CPC Classification
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	P					
	Q					
	R					
	S					
	T					

NON-PATENT DOCUMENTS

*		Include as applicable: Author, Title Date, Publisher, Edition or Volume, Pertinent Pages)
	U	Bingham et al. (The effect of intravenous golimumab on health-related quality of life in Rheumatoid arthritis), J. Rheumatol. (2014), 41: 1067-1076
	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.

Search Notes	Application/Control No.	Applicant(s)/Patent Under Reexamination
	17/237,650	Harrison et al.
	Examiner	Art Unit
	GYAN CHANDRA	1646

CPC - Searched*		
Symbol	**Date**	**Examiner**
c07k16/241	03/29/2023	gc
a61k39/3955	03/29/2023	gc
a61p19/02	03/29/2023	gc

CPC Combination Sets - Searched*		
Symbol	**Date**	**Examiner**

US Classification - Searched*			
Class	**Subclass**	**Date**	**Examiner**
None	None	03/29/2023	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, 2, 3, 4, 5, 6 with substitutions (see search results in SCORE)	09/13/2022	gc
claims searched in CAPLUS, Biosis, Medline (see enclosed transcript)	03/29/2023	gc
claims searched in PE2E search (see enclosed doc)	03/29/2023	gc
Inventorship search in PE2E search (see enclosed doc)	03/29/2023	gc
Inventorship search in PALM	03/29/2023	gc

/GYAN CHANDRA/ Primary Examiner, Art Unit 1646	

Search Notes	Application/Control No.	Applicant(s)/Patent Under Reexamination
	17/237,650	Harrison et al.
	Examiner	Art Unit
	GYAN CHANDRA	1646

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

/GYAN CHANDRA/ Primary Examiner, Art Unit 1646	

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                  Makes Searching More Convenient
 NEWS 18  DEC 23  New Interactive Claim Viewer in EPFULL and PCTFULL
                  Makes Claim Analysis More Efficient
 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
 NEWS 23  MAR 10  MEDLINE(R) Reloaded and MeSH Thesaurus Updated for
                  2023 on STNext
 NEWS 24  MAR 23  Expanded Patent Authority Coverage in CA/CAplus Means
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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 e2-4

L1           83 ("HARRISON DIANE"/AU OR "HARRISON DIANE D"/AU OR "HARRISON DIANE
                DEBORAH"/AU)

=> e Hsia Elizabeth C/au

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E15         222 --> HSIA ELIZABETH C/AU
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E20           1     HSIA FE TSCHENG/AU
E21           1     HSIA FEN HSU/AU
E22          27     HSIA FENG CHUN/AU
E23           1     HSIA FLORENCE/AU
E24           1     HSIA FRANCES K/AU

=> s e14-15

L2          278 ("HSIA ELIZABETH"/AU OR "HSIA ELIZABETH C"/AU)

=> e Kim,Lee-Lian/au

E25           1     KIM ZUNG SEK/AU
E26           1     KIM ZUNG W/AU
E27           0 --> KIM,LEE-LIAN/AU
E28           1     KIM0V V L/AU
E29           1     KIM1/AU
E30           2     KIMA A/AU
E31           2     KIMA A I/AU
E32           2     KIMA AIME SEVERIN/AU
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E34           2     KIMA ALBERT S/AU
E35           1     KIMA APOS/AU
E36           3     KIMA APPOLINAIRE/AU

=> e Kim Lee Lian/au

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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
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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 e50-51

L4          109 ("LO KIM H"/AU OR "LO KIM HUNG"/AU)

=> s l1-4

L5          381 (L1 OR L2 OR L3 OR L4)

=> s golimumab

L6         5738 GOLIMUMAB

=> s l6 and spondylitis

L7         1078 L6 AND SPONDYLITIS

=> s l7 and intravenous (w) infusion

L8            5 L7 AND INTRAVENOUS (W) INFUSION

=> dup rem l8

PROCESSING COMPLETED FOR L8
L9             5 DUP REM L8 (0 DUPLICATES REMOVED)

=> s l6 and golimumab

L10        5738 L6 AND GOLIMUMAB

=> s l5 and l6

L11         185 L5 AND L6

=> s l11 and infusion and intravenous
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L12         21 L11 AND INFUSION AND INTRAVENOUS

=> dup rem l12

PROCESSING COMPLETED FOR L12
L13          11 DUP REM L12 (10 DUPLICATES REMOVED)

=> s l13 and py<2017

L14          3 L13 AND PY<2017

=> d l14 1-3 ti so py kwic ibib


L14  ANSWER 1 OF 3  CAPLUS  COPYRIGHT 2023 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
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 Sung; 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.  .  .  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
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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
AUTHOR(S): 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
CORPORATE SOURCE: Johns Hopkins University, Baltimore, MD, USA
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
OS.CITING REF COUNT: 6 THERE ARE 6 CAPLUS RECORDS THAT CITE THIS RECORD (6 CITINGS)
REFERENCE COUNT: 27 THERE ARE 27 CITED REFERENCES AVAILABLE FOR THIS RECORD. ALL CITATIONS AVAILABLE IN THE RE FORMAT

L14 ANSWER 2 OF 3 CAPLUS COPYRIGHT 2023 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
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, Lilianne; 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: 15 THERE ARE 15 CAPLUS RECORDS THAT CITE THIS RECORD (15 CITINGS)
REFERENCE COUNT: 26 THERE ARE 26 CITED REFERENCES AVAILABLE FOR THIS RECORD. ALL CITATIONS AVAILABLE IN THE RE FORMAT

L14 ANSWER 3 OF 3 CAPLUS COPYRIGHT 2023 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
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, Lilianne; 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. . . 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, Lilianne; Lo, Kim Hung; Baker, Dan; Mendelsohn, Alan; Westhovens, Rene
CORPORATE SOURCE: 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)

=> d l12 1-7 ti so py kwic ibib

L12 ANSWER 1 OF 21 CAPLUS COPYRIGHT 2023 ACS on STN
TI Safety and efficacy of intravenous golimumab in adults with ankylosing spondylitis: results through 1 year of the GO-ALIVE study
SO Journal of Rheumatology (2019), 46(10), 1277-1283
CODEN: JRHUA9; ISSN: 1499-2752
URL: http://www.jrheum.org/
PY 2019
TI Safety and efficacy of intravenous golimumab in adults with ankylosing spondylitis: results through 1 year of the GO-ALIVE study
AU Reveille, John D.; Deodhar, Atul; Caldron, Paul H.; Dudek, Anna; Harrison, Diane D.; Kim, Lilianne; Lo, Kim Hung; Leu, Jocelyn H.; Hsia, Elizabeth C.
AB Objective: Evaluate safety and efficacy of i.v. (IV) golimumab (GOL) in patients with active ankylosing spondylitis (AS) through 1 yr. Methods: A

total of 208 patients were randomized to IV infusions of GOL 2 mg/kg (n = 105) at weeks 0, 4, and every 8 wk thereafter or placebo (n =. . .

ST intravenous golimumab ankylosing spondylitis

IT Ankylosing spondylitis
Drug toxicity
Homo sapiens
Human
Pharmaceutical intravenous injections
(results of safety and efficacy of i.v. golimumab in adults with ankylosing spondylitis through 1 yr of GO-ALIVE study)

IT 476181-74-5, Golimumab
RL: ADV (Adverse effect, including toxicity); PAC (Pharmacological activity); THU (Therapeutic use); BIOL (Biological study); USES (Uses)
(results of safety and efficacy of i.v. golimumab in adults with ankylosing spondylitis through 1 yr of GO-ALIVE study)

ACCESSION NUMBER: 2020:621677 CAPLUS Full-text
DOCUMENT NUMBER: 175:317623
TITLE: Safety and efficacy of intravenous golimumab in adults with ankylosing spondylitis: results through 1 year of the GO-ALIVE study
AUTHOR(S): Reveille, John D.; Deodhar, Atul; Caldron, Paul H.; Dudek, Anna; Harrison, Diana D.; Kim, Lilianne; Lo, Kim Hung; Leu, Jocelyn H.; Hsia, Elizabeth C.
CORPORATE SOURCE: University of Texas McGovern Medical School, Houston, TX, USA
SOURCE: Journal of Rheumatology (2019), 46(10), 1277-1283
CODEN: JRHUA9; ISSN: 1499-2752
URL: http://www.jrheum.org/
DIGITAL OBJECT ID: 10.3899/jrheum.180718
PUBLISHER: Journal of Rheumatology Publishing Co. Ltd.
DOCUMENT TYPE: Journal; (online computer file)
LANGUAGE: English
OS.CITING REF COUNT: 4 THERE ARE 4 CAPLUS RECORDS THAT CITE THIS RECORD (4 CITINGS)
REFERENCE COUNT: 16 THERE ARE 16 CITED REFERENCES AVAILABLE FOR THIS RECORD. ALL CITATIONS AVAILABLE IN THE RE FORMAT

L12 ANSWER 2 OF 21 CAPLUS COPYRIGHT 2023 ACS on STN

TI Efficacy and safety of intravenous golimumab plus methotrexate in patients with rheumatoid arthritis aged < 65 years and those ≥ 65 years of age

SO Arthritis Research & Therapy (2019), 21(1), 1-9
CODEN: ARTRCV; ISSN: 1478-6362

PY 2019

TI Efficacy and safety of intravenous golimumab plus methotrexate in patients with rheumatoid arthritis aged < 65 years and those ≥ 65 years of age

AU Tesser, John; Kafka, Shelly; De Horatius, Raphael J.; Xu, Stephen; Hsia, Elizabeth C.; Turkiewicz, Anthony

AB Objective: To evaluate the safety and efficacy of i.v. golimumab + methotrexate (MTX) in patients with active rheumatoid arthritis (RA) aged < 65 years and those ≥ 65 years who. . . study. Methods: In the phase III, double-blind, randomized, placebo-controlled GO-FURTHER trial, patients with active RA were randomized to i.v. (IV) golimumab 2 mg/kg + MTX or placebo + MTX at weeks 0 and 4, then every 8 wk thereafter (with crossover to golimumab at week 16 [early escape] or week 24 [per-protocol]). The final golimumab infusion was at week 100. Assessments included American College of Rheumatol. (ACR) 20/50/70 response criteria. Efficacy and adverse events (AEs) were. . . patients < or ≥ 75 years. Results: In GO-FURTHER, 592 patients were randomized to receive placebo (n = 197) or golimumab (n = 395), 515 were aged < 65 years and 77 were ≥ 65 years. At week 24, ACR20 response rates were greater for golimumab + MTX patients compared with placebo + MTX for patients < 65 years (61.6% vs 31.3%, p < 0.001) and. . . ≥ 65 years within each treatment group. AEs in elderly patients were similar to the known safety profile of IV golimumab. Immunosenescence is known to increase the risk of infections in the elderly. Elderly patients had a numerically higher incidence of serious infections. Six malignancies occurred in golimumab-treated patients, all in patients < 65 years. Trial registration: clin. trials.gov: NCT00973479. Registered Sept. 9, 2009.

ST golimumab methotrexate antiarthritic agent rheumatoid arthritis age

IT Acute pancreatitis
Aging, animal
Antiarthritics
Basal cell carcinoma
Bone fracture
Bowen disease
Brain infarction
Candida albicans
Cellulitis
Cholecystitis
Chronic lymphocytic leukemia
Clostridium difficile
Combination chemotherapy
Diverticulitis
Flushing
Hemorrhoid
Homo sapiens
Human
Hypertension
Interstitial lung disease
Mammary gland neoplasm
Mycosis
Myocardial infarction
Neoplasm
Pancreatitis
Pharmaceutical intravenous infusions
Pneumonia
Rheumatoid arthritis
Sepsis
Septic arthritis
Septic shock
Tuberculosis
Urinary system infection
Uterine cervical carcinoma
(efficacy and safety of i.v. golimumab plus methotrexate in patients with rheumatoid arthritis aged < 65 years and those greater than or equal to 65 years of age)

IT Corticosteroids
RL: BSU (Biological study, unclassified); BIOL (Biological study)
(efficacy and safety of i.v. golimumab plus methotrexate in patients with rheumatoid arthritis aged < 65 years and those greater than or equal to 65 years of age)

IT Abscess
(rectal; efficacy and safety of i.v. golimumab plus methotrexate in patients with rheumatoid arthritis aged < 65 years and those greater than or equal to 65 years of age)

IT 59-05-2, Methotrexate 476181-74-5, Golimumab
RL: PAC (Pharmacological activity); THU (Therapeutic use); BIOL (Biological study); USES (Uses)
(efficacy and safety of i.v. golimumab plus methotrexate in patients with rheumatoid arthritis aged < 65 years and those greater than or equal to 65 years of age)

ACCESSION NUMBER: 2019:1636875 CAPLUS Full-text
DOCUMENT NUMBER: 174:901313
TITLE: Efficacy and safety of intravenous golimumab plus methotrexate in patients with rheumatoid arthritis aged < 65 years and those ≥ 65 years of age
AUTHOR(S): Tesser, John; Kafka, Shelly; De Horatius, Raphael J.; Xu, Stephen; Ssia, Elizabeth C.; Turkiewicz, Anthony
CORPORATE SOURCE: Arizona Arthritis and Rheumatology Associates, Phoenix, AZ, USA
SOURCE: Arthritis Research & Therapy (2019), 21(1), 1-9
CODEN: ARTRCV; ISSN: 1478-6362
DIGITAL OBJECT ID: 10.1186/s13075-019-1968-x
PUBLISHER: BioMed Central Ltd.
DOCUMENT TYPE: Journal; (online computer file)
LANGUAGE: English
REFERENCE COUNT: 29 THERE ARE 29 CITED REFERENCES AVAILABLE FOR THIS RECORD. ALL CITATIONS AVAILABLE IN THE RE FORMAT

L12 ANSWER 3 OF 21 CAPLUS COPYRIGHT 2023 ACS on STN
TI Safety and efficacy of Golimumab administered intravenously in adults with ankylosing spondylitis: results through week 28 of the GO-ALIVE study
SO Journal of Rheumatology (2018), 45(3), 341-349
CODEN: JRHUA9; ISSN: 1499-2752
PY 2018
TI Safety and efficacy of Golimumab administered intravenously in adults with ankylosing spondylitis: results through week 28 of the GO-ALIVE study
AU Deodhar, Atul; Reveille, John D.; Harrison, Diane D.; Kim, Lilianne; Lo, Kim Hung; Leu, Jocelyn H.; Hsia, Elizabeth C.
AB Objective.To evaluate the safety and efficacy of i.v. golimumab (GOL) in patients with active ankylosing spondylitis (AS). Methods.In a phase III, randomized, double-blind, placebo (PBO)-controlled trial, 208 patients were randomized (1:1) to i.v. (IV) infusions of GOL 2 mg/kg (n = 105) at weeks 0, 4, 12, and every 8 wk, or PBO (n =. . .
ST ankylosing spondylitis nasopharyngitis golimumab adalimumab certolizumab etanercept CRP pharmacokinetics
IT Ankylosing spondylitis
Blood serum
Diagnosis
Homo sapiens
Human
Inflammation
Metabolic side effects of drugs
Nasopharyngitis
Pharmaceutical intravenous infusions
Pharmacokinetics
Upper respiratory infection
(safety and efficacy of golimumab administered i.v. in adults with ankylosing spondylitis)
IT C-reactive protein
Tumor necrosis factors
RL: BSU (Biological study, unclassified); BIOL (Biological study)
(safety and efficacy of golimumab administered i.v. in adults with ankylosing spondylitis)
IT 9000-86-6, Alanine aminotransferase 9000-97-9, Aspartate aminotransferase
RL: BSU (Biological study, unclassified); BIOL (Biological study)
(safety and efficacy of golimumab administered i.v. in adults with ankylosing spondylitis)
IT 59-05-2 170277-31-3 185243-69-0 331731-18-1 428863-50-7 476181-74-5
RL: THU (Therapeutic use); BIOL (Biological study); USES (Uses)
(safety and efficacy of golimumab administered i.v. in adults with ankylosing spondylitis)
ACCESSION NUMBER: 2019:192315 CAPLUS Full-text
DOCUMENT NUMBER: 174:574693
TITLE: Safety and efficacy of Golimumab administered intravenously in adults with ankylosing spondylitis: results through week 28 of the GO-ALIVE study
AUTHOR(S): Deodhar, Atul; Reveille, John D.; Harrison, Diane D.; Kim, Lilianne; Lo, Kim Hung; Leu, Jocelyn H.; Hsia, Elizabeth C.
CORPORATE SOURCE: Oregon Health & Science University, Portland, OR, USA
SOURCE: Journal of Rheumatology (2018), 45(3), 341-349
CODEN: JRHUA9; ISSN: 1499-2752
DIGITAL OBJECT ID: 10.3899/jrheum.170487
PUBLISHER: Journal of Rheumatology Publishing Co. Ltd.
DOCUMENT TYPE: Journal; (online computer file)
LANGUAGE: English
OS.CITING REF COUNT: 12 THERE ARE 12 CAPLUS RECORDS THAT CITE THIS RECORD (12 CITINGS)
REFERENCE COUNT: 28 THERE ARE 28 CITED REFERENCES AVAILABLE FOR THIS RECORD. ALL CITATIONS AVAILABLE IN THE RE FORMAT

L12 ANSWER 4 OF 21 CAPLUS COPYRIGHT 2023 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
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
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. . . 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
AUTHOR(S):	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
CORPORATE SOURCE:	Johns Hopkins University, Baltimore, MD, USA
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
OS.CITING REF COUNT:	6 THERE ARE 6 CAPLUS RECORDS THAT CITE THIS RECORD

(6 CITINGS)
REFERENCE COUNT: 27 THERE ARE 27 CITED REFERENCES AVAILABLE FOR THIS RECORD. ALL CITATIONS AVAILABLE IN THE RE FORMAT

L12 ANSWER 5 OF 21 CAPLUS COPYRIGHT 2023 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
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, Lilianne; Lo, Kim Kung; Sheng, Shihong; Noonan, Lenore; Lu, Jiandong; Xu, Zhenhua; Leu, Jocelyn; Baker, Daniel; Bingham, Clifton O.
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: 15 THERE ARE 15 CAPLUS RECORDS THAT CITE THIS RECORD (15 CITINGS)
REFERENCE COUNT: 26 THERE ARE 26 CITED REFERENCES AVAILABLE FOR THIS RECORD. ALL CITATIONS AVAILABLE IN THE RE FORMAT

L12 ANSWER 6 OF 21 CAPLUS COPYRIGHT 2023 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
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, Lilianne; Lo, Kim Hung; Baker, Dan; Mendelsohn, Alan; Westhovens, Rene
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. . . 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, Lilianne; Lo, Kim Hung; Baker, Dan; Mendelsohn, Alan; Westhovens, Rene
CORPORATE SOURCE: 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)

L12 ANSWER 7 OF 21 BIOSIS COPYRIGHT (c) 2023 Clarivate Analytics on STN
TI Safety and Efficacy of Intravenous Golimumab in Adults with Ankylosing Spondylitis: Results through 1 Year of the GO-ALIVE Study.
SO Journal of Rheumatology, (OCT 1 2019) Vol. 46, No. 10, pp. 1277-1283. http://www.jrheum.org.
CODEN: JRHUA9. ISSN: 0315-162X. E-ISSN: 1499-2752.
PY 2019
TI Safety and Efficacy of Intravenous Golimumab in Adults with Ankylosing Spondylitis: Results through 1 Year of the GO-ALIVE Study.
AU Reveille, John D.; Deodhar, Atul; Caldron, Paul H.; Dudek, Anna; Harrison, Diane D.; Kim, Lilianne; Lo, Kim Hung; Leu, Jocelyn H.; Hsia, Elizabeth C. [Reprint Author]
AB Objective. Evaluate safety and efficacy of intravenous (IV) golimumab (GOL) in patients with active ankylosing spondylitis (AS) through 1 year.Methods. A total of 208 patients were randomized to IV infusions of GOL 2 mg/kg (n = 105) at weeks 0, 4, and every 8 weeks thereafter or placebo (n =. . .
IT . . .
disease, joint disease, connective tissue disease, immune system disease, drug therapy, diagnosis
Spondylitis, Ankylosing (MeSH)
IT Chemicals & Biochemicals
placebo: metabolic-drug; golimumab: antiarthritic-drug, intravenous administration, safety, efficacy, dosage, pharmacodynamics

ACCESSION NUMBER: 2020:284383 BIOSIS Full-text
DOCUMENT NUMBER: PREV202000284383
TITLE: Safety and Efficacy of Intravenous Golimumab in Adults with Ankylosing Spondylitis: Results through 1 Year of the GO-ALIVE Study.
AUTHOR(S): Reveille, John D.; Deodhar, Atul; Caldron, Paul H.; Dudek, Anna; Harrison, Diane D.; Kim, Lilianne; Lo, Kim Hung; Leu, Jocelyn H.; Hsia, Elizabeth C. [Reprint Author]
CORPORATE SOURCE: Janssen Res and Dev LLC, 1400 McKean Rd,POB 776, Spring House, PA 19477 USA
ehsia@its.jnj.com
SOURCE: Journal of Rheumatology, (OCT 1 2019) Vol. 46, No. 10, pp. 1277-1283. http://www.jrheum.org.
CODEN: JRHUA9. ISSN: 0315-162X. E-ISSN: 1499-2752.
DIGITAL OBJECT ID: 10.3899/jrheum.180718
DOCUMENT TYPE: Article
LANGUAGE: English
ENTRY DATE: Entered STN: 18 Mar 2020
Last Updated on STN: 18 Mar 2020

=> s l12 and py<2017

L15 9 L12 AND PY<2017

=> d l15 1-9 ti so py kwic ibib

L15 ANSWER 1 OF 9 CAPLUS COPYRIGHT 2023 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
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 Sung; 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. . . 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
AUTHOR(S):	Bingham, Clifton O., III; Mendelsohn, Alan M.; Kim, Lilianne; Xu, Zhenhua; Leu, Jocelyn; Han, Chenglong; Lo, Kim Kung; Westhovens, Rene; Weinblatt, Michael E.; on behalf of the GO-FURTHER Investigators
CORPORATE SOURCE:	Johns Hopkins University, Baltimore, MD, USA
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
OS.CITING REF COUNT:	6 THERE ARE 6 CAPLUS RECORDS THAT CITE THIS RECORD (6 CITINGS)
REFERENCE COUNT:	27 THERE ARE 27 CITED REFERENCES AVAILABLE FOR THIS RECORD. ALL CITATIONS AVAILABLE IN THE RE FORMAT

L15 ANSWER 2 OF 9 CAPLUS COPYRIGHT 2023 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

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, Lilianne; Lo, Kim Kung; 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: 15 THERE ARE 15 CAPLUS RECORDS THAT CITE THIS RECORD (15 CITINGS)
REFERENCE COUNT: 26 THERE ARE 26 CITED REFERENCES AVAILABLE FOR THIS RECORD. ALL CITATIONS AVAILABLE IN THE RE FORMAT

L15 ANSWER 3 OF 9 CAPLUS COPYRIGHT 2023 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
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, Lilianne; 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. . . 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, Lilianne; Lo, Kim Hung; Baker, Dan; Mendelsohn, Alan; Westhovens, Rene
CORPORATE SOURCE: 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)

L15 ANSWER 4 OF 9 BIOSIS COPYRIGHT (c) 2023 Clarivate Analytics 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, (DEC 2015) Vol. 67, No. 12, pp. 1627-1636. http://onlinelibrary.wiley.com/journal/10.1002/(ISSN)2151-4658. ISSN: 2151-464X. E-ISSN: 2151-4658.

PY 2015

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 [Reprint Author]; Mendelsohn, Alan M.; Kim, Lilianne; Xu, Zhenhua; Leu, Jocelyn; Han, Chenglong; Lo, Kim Hung; Westhovens, Rene; Weinblatt, Michael E.; GO-FURTHER INVESTIGATORS

SO Arthritis Care & Research, (DEC 2015) Vol. 67, No. 12, pp. 1627-1636. http://onlinelibrary.wiley.com/journal/10.1002/(ISSN)2151-4658. ISSN: 2151-464X. E-ISSN: 2151-4658.

AB Objective. To evaluate the safety, efficacy, pharmacokinetics, immunogenicity, and radiographic progression through 2 years of treatment with intravenous (IV) golimumab plus methotrexate (MTX) in an open-label extension of a phase III trial of patients with active rheumatoid arthritis (RA) despite. . . therapy.Methods. In the phase III, double-blind, randomized, placebo-controlled GO-FURTHER trial, 592

patients with active RA were randomized (2: 1) to intravenous golimumab 2 mg/kg plus MTX (Group 1) or placebo plus MTX (Group 2) at weeks 0 and 4, then every 8 weeks 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 Rheumatology 20%, 50%, 70% (ACR20, ACR50, ACR70) response criteria, 28-joint count. . . followup through week 112; 79.1% had an adverse event, and 18.2% had a serious adverse event.Conclusion. Clinical response to IV golimumab plus MTX was maintained through week 100. Radiographic progression following golimumab treatment was clinically insignificant between week 52 and week 100. No unexpected adverse events occurred through week 112, and the. . .

ACCESSION NUMBER: 2016:160095 BIOSIS Full-text
DOCUMENT NUMBER: PREV201600160095
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.
AUTHOR(S): Bingham, Clifton O. III [Reprint Author]; Mendelsohn, Alan M.; Kim, Lilianne; Xu, Zhenhua; Leu, Jocelyn; Han, Chenglong; Lo, Kim Hung; Westhovens, Rene; Weinblatt, Michael E.; GO-FURTHER INVESTIGATORS
CORPORATE SOURCE: Mason Lord Ctr Tower,Room 404,5200 Eastern Ave, Baltimore, MD 21224 USA
cbingha2@jhmi.edu
SOURCE: Arthritis Care & Research, (DEC 2015) Vol. 67, No. 12, pp. 1627-1636.
http://onlinelibrary.wiley.com/journal/10.1002/(ISSN)2151-4658.
ISSN: 2151-464X. E-ISSN: 2151-4658.
DIGITAL OBJECT ID: 10.1002/acr.22556
DOCUMENT TYPE: Article
LANGUAGE: English
ENTRY DATE: Entered STN: 27 Jan 2016
Last Updated on STN: 15 Jan 2020

L15 ANSWER 5 OF 9 BIOSIS COPYRIGHT (c) 2023 Clarivate Analytics 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, (DEC 2014) Vol. 73, No. 12, pp. 2152-2159. http://ard.bmj.com/.
CODEN: ARDIAO. ISSN: 0003-4967. E-ISSN: 1468-2060.
PY 2014
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,. . .
AU Weinblatt, Michael E. [Reprint Author]; 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.; GO-FURTHER Investigators
SO Annals of the Rheumatic Diseases, (DEC 2014) Vol. 73, No. 12, pp. 2152-2159. http://ard.bmj.com/.
CODEN: ARDIAO. ISSN: 0003-4967. E-ISSN: 1468-2060.
AB Objective Report on radiographic effects and maintenance of clinical benefit with intravenous 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 intravenous golimumab 2 mg/kg or placebo infusions at weeks 0 and 4 and then every 8 weeks; 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. . . safety data up to 1 year are reported here.Results Significant and rapid clinical improvement was observed up to wk24 of intravenous golimumab

therapy. Golimumab+MTX treated patients demonstrated less radiographic progression than placebo treated patients at wk24 (vdH-S score mean change 0.03 vs 1.09; p<0.001). . . approximately 80% maintained this response up until wk52. Through an average of 43.5 weeks 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, intravenous golimumab+MTX yielded significant inhibition of structural damage at wk24 and wk52, and sustained clinical improvement in signs and symptoms with no. . .

IT . . .
disease, drug therapy, symptom, active RA

IT Chemicals & Biochemicals
C reactive protein [CRP]; rheumatoid factor; anticyclic citrullinated protein antibody; golimumab: immunologic-drug, antiarthritic-drug, intravenous administration, safety, efficacy, adverse effects, dosage, pharmacodynamics, phase III clinical trial; methotrexate [MTX]: enzyme inhibitor-drug, antiarthritic-drug, immunologic-drug, pharmacodynamics, efficacy, adverse. . .

ACCESSION NUMBER: 2015:30816 BIOSIS Full-text
DOCUMENT NUMBER: PREV201500030816
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. [Reprint Author]; 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.; GO-FURTHER Investigators
CORPORATE SOURCE: Harvard Univ, Brigham and Womens Hosp, Div Rheumatol Immunol and Allergy, Sch Med, 75 Francis St, Boston, MA 02115 USA
mweinblatt@partners.org
SOURCE: Annals of the Rheumatic Diseases, (DEC 2014) Vol. 73, No. 12, pp. 2152-2159. http://ard.bmj.com/.
CODEN: ARDIAO. ISSN: 0003-4967. E-ISSN: 1468-2060.
DIGITAL OBJECT ID: 10.1136/annrheumdis-2013-203742
DOCUMENT TYPE: Article
LANGUAGE: English
ENTRY DATE: Entered STN: 17 Dec 2014
Last Updated on STN: 25 Sep 2019

L15 ANSWER 6 OF 9 BIOSIS COPYRIGHT (c) 2023 Clarivate Analytics 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, (JUN 2014) Vol. 41, No. 6, pp. 1067-1076. http://www.jrheum.org.
CODEN: JRHUA9. ISSN: 0315-162X. E-ISSN: 1499-2752.
PY 2014
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 [Reprint Author]; Weinblatt, Michael; Han, Chenglong; Gathany, Timothy A.; Kim, Lilianne; Lo, Kim Hung; Baker, Dan; Mendelsohn, Alan; Westhovens, Rene
SO Journal of Rheumatology, (JUN 2014) Vol. 41, No. 6, pp. 1067-1076. http://www.jrheum.org.
CODEN: JRHUA9. ISSN: 0315-162X. E-ISSN: 1499-2752.
AB Objective. To evaluate the effects of intravenous (IV) golimumab 2 mg/kg + methotrexate (MTX) on patient-reported measures of health-related quality of life (HRQOL) in patients with active rheumatoid arthritis. . . 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 weeks thereafter. All patients continued stable oral MTX (15-25 mg/wk). HRQOL assessments. . . questionnaire, 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 observed for golimumab + MTX-treated patients at Week 12, Week 16, and Week 24, and greater proportions of golimumab + MTX-treated patients had clinically meaningful improvements in these measures. Greater reductions in disease effect on productivity were observed with golimumab + MTX versus placebo + MTX at Week 24 ($p < 0.001$). Improvements in physical function, HRQOL, fatigue, and productivity significantly correlated with disease activity improvement.Conclusion. In active RA, IV golimumab + MTX significantly improved physical function, HRQOL, fatigue, and productivity using multiple measurement tools; all correlated with improvements in disease.
. .
IT . . .
connective tissue disease, drug therapy, diagnosis
Arthritis, Rheumatoid (MeSH)
IT Chemicals & Biochemicals
methotrexate: enzyme inhibitor-drug, antiarthritic-drug, immunologic-drug, dosage, oral administration; golimumab: immunologic-drug, antiarthritic-drug, intravenous administration, efficacy, dosage, pharmacodynamics, phase III clinical trial
ACCESSION NUMBER: 2014:510667 BIOSIS Full-text
DOCUMENT NUMBER: PREV201400510667
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 [Reprint Author]; Weinblatt, Michael; Han, Chenglong; Gathany, Timothy A.; Kim, Lilianne; Lo, Kim Hung; Baker, Dan; Mendelsohn, Alan; Westhovens, Rene
CORPORATE SOURCE: Johns Hopkins Univ, Div Rheumatol, 5200 Eastern Ave,Mason F Lord Bldg,Ctr Tower,Room, Baltimore, MD 21224 USA
cbingha2@jhmi.edu
SOURCE: Journal of Rheumatology, (JUN 2014) Vol. 41, No. 6, pp. 1067-1076. http://www.jrheum.org.
CODEN: JRHUA9. ISSN: 0315-162X. E-ISSN: 1499-2752.
DIGITAL OBJECT ID: 10.3899/jrheum.130864
DOCUMENT TYPE: Article
LANGUAGE: English
ENTRY DATE: Entered STN: 9 Jul 2014
Last Updated on STN: 20 May 2015

L15 ANSWER 7 OF 9 MEDLINE ® 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 Dec) Vol. 67, No. 12, pp. 1627-36.
Journal code: 101518086. E-ISSN: 2151-4658. L-ISSN: 2151-464X.
Report No.: PMC-PMC5063174.
PY 2015
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 Mendelsohn Alan M; Kim Lilianne; Xu Zhenhua; Leu Jocelyn; Lo Kim Hung
CS Janssen Research and Development, Spring House, Pennsylvania.
SO Arthritis care & research, (2015 Dec) Vol. 67, No. 12, pp. 1627-36.
Journal code: 101518086. E-ISSN: 2151-4658. L-ISSN: 2151-464X.
Report No.: PMC-PMC5063174.
AB OBJECTIVE: To evaluate the safety, efficacy, pharmacokinetics, immunogenicity, and radiographic progression through 2 years of treatment with intravenous (IV) golimumab plus methotrexate (MTX) in an open-label extension of a phase III trial of patients with active rheumatoid arthritis (RA) despite. . . therapy.

METHODS: In the phase III, double-blind, randomized, placebo-controlled GO-FURTHER trial, 592 patients with active RA were randomized (2:1) to

intravenous golimumab 2 mg/kg plus MTX (Group 1) or placebo plus MTX (Group 2) at weeks 0 and 4, then every 8 weeks 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 Rheumatology 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: Clinical response to IV golimumab plus MTX was maintained through week 100. Radiographic progression following golimumab treatment was clinically insignificant between week 52 and week 100. No unexpected adverse events occurred through week 112, and the. . .

CT Administration, Intravenous
*Antibodies, Monoclonal: AD, administration & dosage
Antibodies, Monoclonal: AE, adverse effects
Antibodies, Monoclonal: PK, pharmacokinetics
*Antirheumatic Agents: AD,. . .

RN 9007-41-4 (C-Reactive Protein); 476181-74-5 (golimumab); 59-05-2 (Methotrexate)

ACCESSION NUMBER: 2015497806 MEDLINE Full-text
DOCUMENT NUMBER: PubMed ID: 25623393
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.
AUTHOR: Bingham Clifton O 3rd
CORPORATE SOURCE: Johns Hopkins University, Baltimore, Maryland.
AUTHOR: Mendelsohn Alan M; Kim Lilianne; Xu Zhenhua; Leu Jocelyn; Lo Kim Kung
CORPORATE SOURCE: Janssen Research and Development, Spring House, Pennsylvania.
AUTHOR: Han Chenglong
CORPORATE SOURCE: Janssen Global Service, Malvern, Pennsylvania.
AUTHOR: Westhovens Rene
CORPORATE SOURCE: UZ KU, Leuven, Belgium.
AUTHOR: Weinblatt Michael E
CORPORATE SOURCE: Brigham and Women's Hospital, Boston, Massachusetts.
GROUP AUTHORS: Group Authors: GO-FURTHER Investigators
SOURCE: Arthritis care & research, (2015 Dec) Vol. 67, No. 12, pp. 1627-36.
Journal code: 101518086. E-ISSN: 2151-4658. L-ISSN: 2151-464X.
Report No.: PMC-PMC5063174.
DIGITAL OBJECT ID: http://dx.doi.org/10.1002/acr.22556
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.: NCT00973479
ENTRY MONTH: 201605
ENTRY DATE: Entered STN: 28 Jan 2015
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Indexing Added: 19 May 2016
Entered Medline: 18 May 2016
OS.CITING REF COUNT: 6 There are 6 MEDLINE records that cite this record
MEDLINE REFERENCE COUNT: 25 There are 25 cited references available in MEDLINE for this document.

L15 ANSWER 8 OF 9 MEDLINE ® 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 The Journal of rheumatology, (2014 Jun) Vol. 41, No. 6, pp. 1067-76. Electronic Publication Date: 1 May 2014 Journal code: 7501984. ISSN: 0315-162X. L-ISSN: 0315-162X.
PY 2014
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 3rd; Weinblatt Michael; Han Chenglong; Gathany Timothy A; Kim Lilianne; Lo Kim Hung; Baker Dan; Mendelsohn Alan; Westhovens Rene
CS From the Division of Rheumatology and Allergy and Clinical Immunology, Johns. . .
SO The Journal of rheumatology, (2014 Jun) Vol. 41, No. 6, pp. 1067-76. Electronic Publication Date: 1 May 2014 Journal code: 7501984. ISSN: 0315-162X. L-ISSN: 0315-162X.
AB OBJECTIVE: To evaluate the effects of intravenous (IV) golimumab 2 mg/kg + methotrexate (MTX) on patient-reported measures of health-related quality of life (HRQOL) in patients with active rheumatoid arthritis. . . 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 weeks 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 observed for golimumab + MTX-treated patients at Week 12, Week 16, and Week 24, and greater proportions of golimumab + MTX-treated patients had clinically meaningful improvements in these measures. Greater reductions in disease effect on productivity were observed with golimumab + MTX versus placebo + MTX at Week 24 ($p < 0.001$). Improvements in physical function, HRQOL, fatigue, and productivity significantly correlated with disease activity improvement.

CONCLUSION: In active RA, IV golimumab + MTX significantly improved physical function, HRQOL, fatigue, and productivity using multiple measurement tools; all correlated with improvements in disease. . .
RN 476181-74-5 (golimumab)
ACCESSION NUMBER: 2014686491 MEDLINE Full-text
DOCUMENT NUMBER: PubMed ID: 24786931
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: Bingham Clifton O 3rd; Weinblatt Michael; Han Chenglong; Gathany Timothy A; Kim Lilianne; Lo Kim Hung; Baker Dan; Mendelsohn Alan; Westhovens Rene
CORPORATE SOURCE: From the Division of Rheumatology and Allergy and Clinical Immunology, Johns Hopkins University, Baltimore, Maryland, Department of Clinical Rheumatology, Brigham and Women's Hospital, Boston, Massachusetts, Patient Reported Outcomes, Janssen Global Services LLC, Malvern, Pennsylvania, Biostatistics and Immunology, Janssen Research & Development LLC, Spring House, Pennsylvania, USA, Department of Rheumatology, UZ Gasthuisberg, KU Leuven, Belgium.C.O. Bingham III, MD, Division of Rheumatology and Allergy and Clinical Immunology, Johns Hopkins University, M. Weinblatt, MD, Department of Clinical Rheumatology, Brigham and Women's Hospital, C. Han, PhD, T.A. Gathany, PhD, Patient Reported Outcomes, Janssen Global Services, L. Kim, PhD, K.H. Lo, PhD, Biostatistics, Janssen Research & Development LLC, D. Baker, MD, A. Mendelsohn, MD, Immunology, Janssen Research & Development LLC, R. Westhovens, MD, Department of Rheumatology, University Hospitals Leuven, Department of Development and Regeneration, KU Leuven. cbingha3@jhmi.edu
SOURCE: The Journal of rheumatology, (2014 Jun) Vol. 41, No. 6,

pp. 1067-76. Electronic Publication Date: 1 May 2014
Journal code: 7501984. ISSN: 0315-162X. L-ISSN: 0315-162X.
DIGITAL OBJECT ID: http://dx.doi.org/10.3899/jrheum.130864
PUB. COUNTRY: Canada
DOCUMENT TYPE: (CLINICAL TRIAL, PHASE III)
Journal; Article; (JOURNAL ARTICLE)
(MULTICENTER STUDY)
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(RESEARCH SUPPORT, NON-U.S. GOV'T)
(CLINICAL TRIAL)
(CONTROLLED CLINICAL TRIAL)
LANGUAGE: English
FILE SEGMENT: MEDLINE; Priority Journals
FILE SEGMENT: Print; Electronic
FILE SEGMENT: CLINICALTRIALS.GOV
CLINICAL TRIAL NO.: NCT00973479
ENTRY MONTH: 201502
ENTRY DATE: Entered STN: 3 May 2014
Last Updated on STN: 20 Feb 2015
Indexing Added: 20 Feb 2015
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OS.CITING REF COUNT: 7 There are 7 MEDLINE records that cite this record

L15 ANSWER 9 OF 9 MEDLINE ® 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 Dec) Vol. 73, No. 12, pp. 2152-9. Electronic Publication Date: 3 Sep 2013
Journal code: 0372355. E-ISSN: 1468-2060. L-ISSN: 0003-4967.
Report No.: PMC-PMC4251163.
PY 2014
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,. . .
AU Mendelsohn Alan M; Kim Lilianne; Lo Kim Hung; Sheng Shihong; Noonan Lenore; Lu Jiandong; Xu Zhenhua; Leu Jocelyn; Baker Daniel
CS Janssen Research & Development, LLC,. . .
SO Annals of the rheumatic diseases, (2014 Dec) Vol. 73, No. 12, pp. 2152-9. Electronic Publication Date: 3 Sep 2013
Journal code: 0372355. E-ISSN: 1468-2060. L-ISSN: 0003-4967.
Report. . .
AB OBJECTIVE: Report on radiographic effects and maintenance of clinical benefit with intravenous golimumab 2 mg/kg+methotrexate (MTX) for up to week (wk) 52 in active rheumatoid arthritis (RA).

METHODS: Patients (n=592) with active RA. . . weeks) participated in this multicentre, international, randomised, double blind, placebo controlled, phase 3 study. Patients were randomised (2:1) to receive intravenous golimumab 2 mg/kg or placebo infusions at weeks 0 and 4 and then every 8 weeks; 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. . . data up to 1 year are reported here.

RESULTS: Significant and rapid clinical improvement was observed up to wk24 of intravenous golimumab therapy. Golimumab+MTX treated patients demonstrated less radiographic progression than placebo treated patients at wk24 (vdH-S score mean change 0.03 vs 1.09; p<0.001). . . approximately 80% maintained this response up until wk52. Through an average of 43.5 weeks 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, intravenous golimumab+MTX yielded significant inhibition of structural damage at wk24 and wk52, and sustained clinical improvement in signs and symptoms with no. . .

RN 476181-74-8 (golimumab); 59-05-2 (Methotrexate)
ACCESSION NUMBER: 2013950073 MEDLINE Full-text
DOCUMENT NUMBER: PubMed ID: 24001888
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: Weinblatt Michael E
CORPORATE SOURCE: Division of Rheumatology, Immunology and Allergy, Brigham and Women's Hospital, Boston, Massachusetts, USA.
AUTHOR: Westhovens Rene
CORPORATE SOURCE: Department of Development and Regeneration KU Leuven, Skeletal Biology and Engineering Research Centre, Leuven, Belgium Department of Rheumatology, University Hospitals Leuven, Leuven, Belgium.
AUTHOR: Mendelsohn Alan M; Kim Lilianne; Lo Kim Hung; Sheng Shihong; Noonan Lenore; Lu Jiandong; Xu Zhenhua; Leu Jocelyn; Baker Daniel
CORPORATE SOURCE: Janssen Research & Development, LLC, Spring House, Pennsylvania, USA.
AUTHOR: Bingham Clifton O
CORPORATE SOURCE: Johns Hopkins University Baltimore, Baltimore, Maryland, USA.
GROUP AUTHORS: Group Authors: GO-FURTHER investigators
SOURCE: Annals of the rheumatic diseases, (2014 Dec) Vol. 73, No. 12, pp. 2152-9. Electronic Publication Date: 3 Sep 2013
Journal code: 0372355. E-ISSN: 1468-2060. L-ISSN: 0003-4967.
Report No.: PMC-PMC4251163.
DIGITAL OBJECT ID: http://dx.doi.org/10.1136/annrheumdis-2013-203742
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: Print; Electronic
FILE SEGMENT: EUDRACT
FILE SEGMENT: CLINICALTRIALS.GOV
CLINICAL TRIAL NO.: 2008-006064-11; NCT00973479
ENTRY MONTH: 201412
ENTRY DATE: Entered STN: 5 Sep 2013
Last Updated on STN: 31 Dec 2014
Indexing Added: 31 Dec 2014
Entered Medline: 30 Dec 2014
OS.CITING REF COUNT: 15 There are 15 MEDLINE records that cite this record
MEDLINE REFERENCE COUNT: 23 There are 23 cited references available in MEDLINE for this document.

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L4          109 S E50-51
L5          381 S L1-4
L6         5738 S GOLIMUMAB
L7         1078 S L6 AND SPONDYLITIS
L8            5 S L7 AND INTRAVENOUS (W) INFUSION
L9            5 DUP REM L8 (0 DUPLICATES REMOVED)
L10        5738 S L6 AND GOLIMUMAB
L11         185 S L5 AND L6
L12          21 S L11 AND INFUSION AND INTRAVENOUS
L13          11 DUP REM L12 (10 DUPLICATES REMOVED)
L14           3 S L13 AND PY<2017
L15           9 S L12 AND PY<2017

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Receipt date: 01/24/2023

Doc code: IDS
Doc description: Information Disclosure Statement (IDS) Filed

PTO/SB/08a (02-18)
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INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(Not for submission under 37 CFR 1.99)

Application Number	17237650
Filing Date	2021-04-22
First Named Inventor	Diane D. Harrison
Art Unit	1646
Examiner Name	CHANDRA
Attorney Docket Number	206389-0002-02US

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INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Not for submission under 37 CFR 1.99)		
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	Filing Date	2021-04-22
	First Named Inventor	Diane D. Harrison
	Art Unit	1646
	Examiner Name	CHANDRA
	Attorney Docket Number	206389-0002-02US

/G.C/	1	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

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EXAMINER SIGNATURE

Examiner Signature	/GYAN CHANDRA/	Date Considered	03/29/2023

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INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(Not for submission under 37 CFR 1.99)

Application Number	17237650
Filing Date	2021-04-22
First Named Inventor	Diane D. Harrison
Art Unit	1646
Examiner Name	CHANDRA
Attorney Docket Number	206389-0002-02US

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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☐ 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).

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☒ 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)	2023-01-24
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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L45	117	2009/0123378 AND administration AND iv	(US-PGPUB; USPAT)	OR	ON	ON	2023/03/29 02:42 PM
L46	1	"20090123378".pn. AND administration AND iv	(US-PGPUB; USPAT)	OR	ON	ON	2023/03/29 02:42 PM
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		"5851198" OR "5856456" OR "5871753" OR "5879681" OR "5885793" OR "5888511" OR "5919452" OR "5932448" OR "5958413" OR "5959083" OR "5959084" OR "5962255" OR "5976862" OR "5989530" OR "5993833" OR "5994616" OR "6010902" 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 golimumab					
L50	151	("0000030" OR "0000059" OR "0000088" OR "0000116" OR "0000144" OR "20090214528" OR "20100251099" OR "20110251099" 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 "4757506" OR "4766067" OR "4767402" OR "4795699" OR "4800159" OR "4816567" OR	(US-PGPUB; USPAT)	OR	ON	ON	2023/03/29 03:07 PM

		"4822776" OR "4873316" OR "4889818" OR "4921794" OR "4925673" OR "4939666" OR "4946778" OR "4956288" OR "4965188" OR "4994370" OR "5066584" OR "5116964" 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 "5404871" OR "5427908" OR "5447851" OR "5455030" OR "5458135" OR "5496549" OR "5512544" OR "5514670" OR "5518889" OR "5530101" OR "5534621" OR "5545807" OR "5565362" 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 "5698419" OR "5698435" OR "5714352" OR "5723323" OR "5733761" OR "5750105" OR "5750373" OR "5763192" OR "5763733" OR "5766886" OR "5770198" OR "5770222" OR "5770359" OR "5770428" OR "5789650" OR "5807706" OR "5814476" OR "5814599" OR "5817483" OR "5821333" OR "5824514" OR "5827690" OR "5827739" OR "5833985" OR "5837500" OR "5839446" OR "5849695" OR "5851198" OR "5856456" OR "5871753" OR "5879681" OR "5885793" OR "5888511" OR "5919452" OR "5932448" OR "5958413" OR "5959083" OR "5959084" OR "5962255" OR "5976862" OR "5989530" OR "5993833" OR "5994616" OR "6010902" 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.					
L51	2	L1 AND golimumab	(US-PGPUB; USPAT)	OR	ON	ON	2023/03/29 03:07 PM
L52	1	L1 AND golimumab AND ankylosing	(US-PGPUB; USPAT)	OR	ON	ON	2023/03/29 03:07 PM
L53	2	L1 AND golimumab AND arthritis	(US-PGPUB; USPAT)	OR	ON	ON	2023/03/29 03:07 PM
L54	2	L1 AND golimumab AND spondylitis	(US-PGPUB; USPAT)	OR	ON	ON	2023/03/29 03:07 PM
L55	3510	golimumab AND spondylitis	(US-PGPUB; USPAT)	OR	ON	ON	2023/03/29 03:07 PM
L56	3428	golimumab AND spondylitis AND ankylosing	(US-PGPUB; USPAT)	OR	ON	ON	2023/03/29 03:07 PM
L57	136	golimumab AND spondylitis ADJ ankylosing	(US-PGPUB; USPAT)	OR	ON	ON	2023/03/29 03:07 PM
L58	68	golimumab AND spondylitis ADJ ankylosing AND @ay<"2018"	(US-PGPUB; USPAT)	OR	ON	ON	2023/03/29 03:07 PM
L59	1	golimumab SAME spondylitis ADJ ankylosing AND @ay<"2018"	(US-PGPUB; USPAT)	OR	ON	ON	2023/03/29 03:07 PM
L60	1	(golimumab OR (Cnto NEAR "148")) SAME spondylitis ADJ ankylosing AND @ay<"2018"	(US-PGPUB; USPAT)	OR	ON	ON	2023/03/29 03:07 PM
L61	7	(golimumab OR (Cnto NEAR "148")) ADJ ankylosing ADJ spondylitis	(US-PGPUB; USPAT)	OR	ON	ON	2023/03/29 03:07 PM
L62	847	(golimumab OR (Cnto NEAR "148")).clm.	(US-PGPUB; USPAT)	OR	ON	ON	2023/03/29 03:07 PM
L63	340	(golimumab OR (Cnto NEAR "148")).clm. AND spondylitis	(US-PGPUB; USPAT)	OR	ON	ON	2023/03/29 03:07 PM
L64	331	(golimumab OR (Cnto NEAR "148")).clm. AND ankylosing ADJ spondylitis	(US-PGPUB; USPAT)	OR	ON	ON	2023/03/29 03:07 PM
L65	172	(golimumab OR (Cnto NEAR "148")).clm. AND	(US-PGPUB; USPAT)	OR	ON	ON	2023/03/29 03:07 PM

		ankylosing ADJ spondylitis AND @ay<"2017"					
L66	110	(golimumab OR (Cnto NEAR "148")).clm. AND ankylosing ADJ spondylitis AND @ay<"2017" AND methotrexate	(US-PGPUB; USPAT)	OR	ON	ON	2023/03/29 03:07 PM
L67	113	(golimumab OR (Cnto NEAR "148")).clm. AND ankylosing ADJ spondylitis AND @ay<"2017" AND (methotrexate OR sulfasalazine OR hydroxychloroquine)	(US-PGPUB; USPAT)	OR	ON	ON	2023/03/29 03:07 PM
L68	1	(golimumab OR (Cnto NEAR "148")) SAME infusion SAME (over NEAR time)	(US-PGPUB; USPAT)	OR	ON	ON	2023/03/29 03:07 PM
L69	247	(golimumab OR (Cnto NEAR "148")) SAME infusion	(US-PGPUB; USPAT)	OR	ON	ON	2023/03/29 03:07 PM
L70	14	(golimumab OR (Cnto NEAR "148")) SAME (rate NEAR infusion)	(US-PGPUB; USPAT)	OR	ON	ON	2023/03/29 03:07 PM
L71	933	antibody SAME (rate NEAR infusion)	(US-PGPUB; USPAT)	OR	ON	ON	2023/03/29 03:07 PM
L72	181	antibody SAME infusion SAME rate SAME over NEAR period	(US-PGPUB; USPAT)	OR	ON	ON	2023/03/29 03:07 PM
L73	0	anti-tnf SAME antibody SAME infusion SAME rate SAME over NEAR period	(US-PGPUB; USPAT)	OR	ON	ON	2023/03/29 03:07 PM
L74	3	anti-tnf AND antibody SAME infusion SAME rate SAME over NEAR period	(US-PGPUB; USPAT)	OR	ON	ON	2023/03/29 03:07 PM
L75	5145	anti-tnf AND antibody SAME infusion	(US-PGPUB; USPAT)	OR	ON	ON	2023/03/29 03:07 PM
L76	198	anti-tnf ADJ antibody SAME infusion	(US-PGPUB; USPAT)	OR	ON	ON	2023/03/29 03:07 PM
L77	871	Janssen ADJ Biotech ADJ Inc.asn.	(US-PGPUB; USPAT)	OR	ON	ON	2023/03/29 03:07 PM
L78	20	Harrison Diane D.in.	(US-PGPUB; USPAT)	ADJ	ON	ON	2023/03/29 03:07 PM
L79	18	Hsia Elizabeth C.in.	(US-PGPUB; USPAT)	ADJ	ON	ON	2023/03/29 03:07 PM
L80	12	Kim Lee-Lian.in.	(US-PGPUB; USPAT)	ADJ	ON	ON	2023/03/29 03:07 PM
L81	13	Lo Kim Hung.in.	(US-PGPUB; USPAT)	ADJ	ON	ON	2023/03/29

							03:07 PM
L82	1061	L27 L29 L30 L31 L32 L34	(US-PGPUB; USPAT)	OR	ON	ON	2023/03/29 03:07 PM
L83	98	L35 AND golimumab	(US-PGPUB; USPAT)	OR	ON	ON	2023/03/29 03:07 PM
L84	10	L35 AND golimumab.clm.	(US-PGPUB; USPAT)	OR	ON	ON	2023/03/29 03:07 PM
L85	3481	c07k16/241.cpc.	(US-PGPUB; USPAT)	OR	ON	ON	2023/03/29 03:07 PM
L86	15121	a61k39/3955.cpc.	(US-PGPUB; USPAT)	OR	ON	ON	2023/03/29 03:07 PM
L87	54512	a61p19/02.cpc.	(US-PGPUB; USPAT)	OR	ON	ON	2023/03/29 03:07 PM
L88	68922	L38 OR L39 L40	(US-PGPUB; USPAT)	OR	ON	ON	2023/03/29 03:07 PM
L89	117	L41 AND golimumab AND spondilitis	(US-PGPUB; USPAT)	OR	ON	ON	2023/03/29 03:07 PM
L90	23	L41 AND golimumab AND spondilitis.clm.	(US-PGPUB; USPAT)	OR	ON	ON	2023/03/29 03:07 PM
L91	60	golimumab AND spondylitis ADJ ankylosing AND @ay<"2018" AND infusion	(US-PGPUB; USPAT)	OR	ON	ON	2023/03/29 03:07 PM
L92	117	2009/0123378 AND administration AND iv	(US-PGPUB; USPAT)	OR	ON	ON	2023/03/29 03:07 PM
L93	1	"20090123378".pn. AND administration AND iv	(US-PGPUB; USPAT)	OR	ON	ON	2023/03/29 03:07 PM
L94	1	"20090123378".pn. AND administration AND intraven$5	(US-PGPUB; USPAT)	OR	ON	ON	2023/03/29 03:07 PM
L95	151	("0000030" OR "0000059" OR "0000088" OR "0000116" OR "0000144" OR "20090214528" OR "20100251099" OR "20110251099" 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 "4757506" OR	(US-PGPUB; USPAT)	OR	ON	ON	2023/03/29 03:07 PM

		"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 "5116964" 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 "5404871" OR "5427908" OR "5447851" OR "5455030" OR "5458135" OR "5496549" OR "5512544" OR "5514670" OR "5518889" OR "5530101" OR "5534621" OR "5545807" OR "5565362" 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					

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L96	2	("0000030" OR "0000059" OR "0000088" OR "0000116" OR "0000144" OR "20090214528" OR "20100251099" OR "20110251099" 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 "4757506" 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 "5116964" OR "5122464" OR "5130238" OR "5142033" OR "5149636" OR "5168062" OR	(US-PGPUB; USPAT)	OR	ON	ON	2023/03/29 03:07 PM

		"5179017" OR "5223409" OR "5225538" OR "5225539" OR "5231024" OR "5260203" OR "5266491" OR "5304489" OR "5342613" OR "5385839" OR "5403484" OR "5404871" OR "5427908" OR "5447851" OR "5455030" OR "5458135" OR "5496549" OR "5512544" OR "5514670" OR "5518889" OR "5530101" OR "5534621" OR "5545807" OR "5565362" 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 "5698419" OR "5698435" OR "5714352" OR "5723323" OR "5733761" OR "5750105" OR "5750373" OR "5763192" OR					

		"5763733" OR "5766886" OR "5770198" OR "5770222" OR "5770359" OR "5770428" OR "5789650" OR "5807706" OR "5814476" OR "5814599" OR "5817483" OR "5821333" OR "5824514" OR "5827690" OR "5827739" OR "5833985" OR "5837500" OR "5839446" OR "5849695" OR "5851198" OR "5856456" OR "5871753" OR "5879681" OR "5885793" OR "5888511" OR "5919452" OR "5932448" OR "5958413" OR "5959083" OR "5959084" OR "5962255" OR "5976862" OR "5989530" OR "5993833" OR "5994616" OR "6010902" 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 golimumab					

PE2E SEARCH - Search History (Interference)

There are no Interference searches to show.

PTO/SB/30EFS (02-18)
Approved for use through 11/30/2020. OMB 0651-0031
U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number.

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

Application Number	17/237,650	Filing Date	2021-04-22	Docket Number (if applicable)	206389-0002-02US	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

PTO/SB/30EFS (02-18)
Approved for use through 11/30/2020. OMB 0651-0031
U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE

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Signature of Registered U.S. Patent Practitioner			
Signature	/Pallab Singh/	Date (YYYY-MM-DD)	2023-07-05
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.

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Patent Application of: Diane D. Harrison, et al.	Art Unit: 1646 Confirmation No.: 8810
Application No.: 17/237,650	Examiner: Chandra, Gyan
Filing date: April 22, 2021	Atty Docket No.: 206389-0002-02US

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

AMENDMENT

This Amendment is responsive to the final Office Action mailed on April 4, 2023 in connection with the above-referenced application. This Response is timely filed in view of the deadline for a timely response being to and through July 5, 2023 (July 4, 2023 being a federal holiday.

This Amendment is being filed in conjunction with a Request for Continued Examination (and associated fee).

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.

REMARKS

Claims 11, 13, 14, 16-18 and 20 are pending and under consideration. Claims 1-10 have been previously cancelled. Claims 12, 15 and 19 have been cancelled herein.

Claim Amendments

Claims 11, 14 and 17 have been amended to recite that the antibody is administered via IV infusion at a dose of 2 mg/kg, administered over 30 ± 10 minutes, at Weeks 0 and 4, and then every 8 weeks (q8w) thereafter. Support for these amendments can be found at least in previous claims 12, 15 and 19. No new matter has been added by way of these amendments.

Claims 12, 15 and 19 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).

Rejection of claims 11, 13-14, 16-18 and 20 under 35 U.S.C. 102

The Examiner has rejected claims 11, 13-14, 16-18 and 20 under 35 U.S.C. 102 as allegedly being anticipated by Wong et al. (U.S. Patent Application Publication US2009/0123378; hereinafter "Wong"). The Examiner contends that Wong teaches treating ankylosing spondylitis in a subject comprising administering golimumab to the subject. The Examiner further contends that Wong teaches that the response of the treatment is monitored by BASDAI and that the antibody can be administered by infusion.

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 art must describe each and every element of the rejected claims in order to anticipate the claims under Section 102.

While not necessarily agreeing with the Examiner, but rather in a good faith effort to advance prosecution, Applicant has amended claim 11 (upon which claim 13 depends), claim

14 (upon which claim 16 depends), and clam 17 (upon which claims 18 and 20 depend), to recite that the antibody is administered via IV infusion at a dose of 2 mg/kg, administered over 30 ± 10 minutes, at Weeks 0 and 4, and then every 8 weeks (q8w) thereafter. Applicants submit that Wong does not teach each and every element of claim 11, 14 and 17 because Wong does not teach the antibody is administered via IV infusion at a dose of 2 mg/kg, administered over 30 ± 10 minutes, at Weeks 0 and 4, and then every 8 weeks (q8w) thereafter.

Further, Applicant reiterates that Wong does not teach a method wherein the patient achieves any of the recited clinical criteria recited in claims 11, 14 and 17.

Applicants submit that Wong, when read as a whole, does not teach a skilled artisan that the recited anti-TNF antibody (e.g., golimumab) can effectively treat a subject with ankylosing spondylitis, let alone is able to achieve the recited clinical endpoints recited in claims 11, 14 and 17. Rather, a skilled artisan, reading Wong, would recognize that Wong simply lists golimumab as an alternative anti-TNF antibody, but that Wong is singularly directed to the effects of adalimumab, a anti-TNF antibody that is distinct from the presently recited anti-TNF antibody. That is, Wong does not provide any teaching or demonstration that the recited anti-TNF antibody has any effect on subjects with ankylosing spondylitis. Therefore, Wong does not teach administering the recited anti-TNF antibody via IV infusion to a subject, wherein the subject achieves the recited clinical efficacy.

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

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 Wong in view of Le et al. (U.S. Patent No. 5,656,272; hereinafter "Le"). The Examiner admits that Wong does not teach infusion of the antibody at 2mg/kg over 30min ± 10 min, but contends that Le teaches to use of an anti-TNF antibody for other conditions where the antibody is administered at 1, 5, or 10mg/kg over 60 minutes. The Examiner contends that a skilled physician would decide dose and infusion time based on the

severity of the disease and body weight, and therefore it would be obvious to administer the recited antibody at the recited dose.

As an initial matter, Applicant has cancelled claims 12, 15 and 19, thereby rendering the rejection of these claims moot.

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 described above, Applicant has amended claim 11, 14 and 17 to recite to recite that the antibody is administered via IV infusion at a dose of 2 mg/kg, administered over 30 ± 10 minutes, at Weeks 0 and 4, and then every 8 weeks (q8w) thereafter. Applicants submit that Wong and Le, alone or in combination with each other, do not teach or suggest a dosing comprising golimumab being administered at a dose of 2 mg/kg, administered over 30 ± 10 minutes, at Weeks 0 and 4, and then every 8 weeks (q8w) thereafter. As admitted by the Examiner, Wong does not teach the recited dosage or infusion time. Applicants submit that Le does not make up for the deficiencies of Le, because Le does not teach or suggest administration of the specifically recited anti-TNF antibody at the specifically recited dosage and infusion time. Le is directed to a wholly different construct, and does not teach or suggest the administration of the presently recited antibody, let alone the specifically recited dosage and infusion times to effectively treat a subject with ankylosing spondylitis to achieve the recited clinical efficacy.

Applicants submit that Wong and Le, alone or in combination with each other, do not teach or suggest administering a safe and effective amount of a composition comprising the recited anti-TNF antibody, wherein said composition is administered via IV infusion such that a patient achieves the recited clinical efficacy, as recited in claims 11, 14 and 17. As described above, Wong does not teach or suggest to a skilled artisan that the recited anti-TNF antibody has any effect, let alone would achieve the recited clinical efficacy. Applicants submit that Le does not make up for the deficiencies of Wong, because Le does not teach or suggest that administration of the recited anti-TNF antibody would achieve the recited clinical efficacy. Like Wong, Le does not provide any teaching or demonstration that the recited antibody (e.g., golimumab) has any effect on a subject with ankylosing spondylitis.

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 Wong and Le do not prove a reasonable expectation of success at arriving at a method for treating ankylosing spondylitis by administering a composition comprising a safe and effective amount of the recited anti-TNF antibody via IV infusion at a dose of 2 mg/kg, administered over 30 ± 10 minutes, at Weeks 0 and 4, and then every 8 weeks (q8w) thereafter.

Claim 11

The present invention is based, in part, upon the surprising discovery that IV infusion of golimumab is an effective therapy for ankylosing spondylitis, which can show efficiency as quick as 2 to 4 weeks after treatment. Applicants submit that Wong only demonstrates the efficacy of adalimumab. Nothing in Wong provides a skilled artisan with any predictability that golimumab can be delivered by IV infusion to treat ankylosing spondylitis, much less that a patient who is administered golimumab by IV infusion at a dose of 2 mg/kg, administered over 30 ± 10 minutes, at Weeks 0 and 4, and then every 8 weeks (q8w) thereafter would achieve ASDAS inactive disease (<1.3) at 4 weeks of treatment or at 2 weeks of treatment, as recited in claim 11.

Applicants submit that Le does not cure any of the deficiencies of Wong. Applicants submit that Le does not provide a skilled artisan with any predictability that intravenous golimumab can be used to treat ankylosing spondylitis, much less that a patient who is administered intravenous golimumab would achieve ASDAS inactive disease (<1.3) at 4 weeks of treatment or 2 weeks of treatment.

First, Applicants submit that neither Wong nor Le describe the effects of IV golimumab on a subject with ankylosing spondylitis. In fact, Wong and Le do not teach the effects of golimumab at all. Rather, Wong and Le describe the effects of a wholly different anti-TNF antibodies. A skilled artisan would recognize that the effects of different antibodies to the same target are unpredictable (see for example, Mpofu et al., 2005, Rheumatology, 44:271-273, provided herein as "Exhibit C"). Exhibit C describes that TNF inhibitors are not the same, but rather have different mechanisms, efficacy, and side effects. A skilled artisan would therefore recognize that one cannot simply assume that a given inhibitor (e.g. golimumab) can be used in a way that may be described for a different TNF inhibitor. Therefore, a skilled artisan would have no reasonable expectation of success in specifically choosing golimumab from the laundry list of alternative TNF-inhibitors of Wong and specifically administering golimumab by IV infusion at a dose of 2 mg/kg, administered over 30 ± 10 minutes, at Weeks 0 and 4, and then every 8 weeks (q8w) thereafter, which is a dosing regimen not even contemplated by Le.

Further, Wong and Le do not describe any clinical improvement from IV golimumab on any subject, let alone a subject with ankylosing spondylitis. Applicants submit that skilled artisan reading Wong and Le would not have any reasonable expectation that administration of IV golimumab could be used to effectively treat ankylosing spondylitis, let alone that treatment would result in clinical efficacy in 2 or 4 weeks.

Claim 14

Nothing in Wong and Le provides a skilled artisan with any predictability that golimumab can be delivered by IV infusion to treat ankylosing spondylitis, much less that a patient who is administered golimumab by IV infusion at a dose of 2 mg/kg, administered over 30 ± 10 minutes, at Weeks 0 and 4, and then every 8 weeks (q8w) thereafter would achieve at week 16 a mean change from baseline in one or more criteria selected from the group consisting of: Bath Ankylosing Spondylitis Functional Index (BASFI) = -2.4 ± 2.1 Standard Deviation (SD), Bath Ankylosing Spondylitis Metrology Index (BASMI) = -0.4 ± 0.6 SD, 36-item Short-Form Health Survey Physical Component Summary (SF-36 PCS)= 8.5 ± 7.5 SD, 36-item Short-Form Health Survey Mental Component Summary (SF-36 MCS) = 6.5 ± 9.1 SD, and Ankylosing Spondylitis Qualify of Life questionnaire (ASQoL) = -5.4 ± 5.0 SD, as recited in claim 14.

As described above, neither Wong nor Le describe the effects of IV golimumab on a subject with ankylosing spondylitis. In fact, Wong and Le do not teach the effects of golimumab at all. Rather, Wong and Le describe the effects of a wholly different anti-TNF antibodies. A skilled artisan would recognize that the effects of different antibodies to the same target are unpredictable (see for example, Mpofu et al., 2005, Rheumatology, 44:271-273, provided herein as "Exhibit C"). Exhibit C describes that TNF inhibitors are not the same, but rather have different mechanisms, efficacy, and side effects. A skilled artisan would therefore recognize that one cannot simply assume that a given inhibitor (e.g. golimumab) can be used in a way that may be described for a different TNF inhibitor. Therefore, a skilled artisan would have no reasonable expectation of success in specifically choosing golimumab from the laundry list of alternative TNF-inhibitors of Wong and specifically administering golimumab by IV infusion at a dose of 2 mg/kg, administered over

30 ± 10 minutes, at Weeks 0 and 4, and then every 8 weeks (q8w) thereafter, which is a dosing regimen not even contemplated by Le.

Further, Wong and Le do not describe any clinical improvement from IV golimumab on any subject, let alone a subject with ankylosing spondylitis. Applicants submit that a skilled artisan would not have any reasonable expectation from Wong and Le that at week 16 of treatment patients receiving IV golimumab would achieve a mean change from baseline in any of the recited criteria.

Claim 17

Nothing in Wong and Le provides a skilled artisan with any predictability that golimumab can be delivered by IV infusion to treat ankylosing spondylitis, much less that IV infusion at a dose of 2 mg/kg, administered over 30 ± 10 minutes, at Weeks 0 and 4, and then every 8 weeks (q8w) thereafter would result in ≥ 65% of patients receiving the treatment achieve Assessment in Ankylosing Spondylitis 20 (ASAS20) at week 16 of treatment, as recited in claim 17.

As described above, neither Wong nor Le describe the effects of IV golimumab on a subject with ankylosing spondylitis. In fact, Wong and Le do not teach the effects of golimumab at all. Rather, Wong and Le describe the effects of a wholly different anti-TNF antibodies. A skilled artisan would recognize that the effects of different antibodies to the same target are unpredictable (see for example, Mpofu et al., 2005, Rheumatology, 44:271-273, provided herein as "Exhibit C"). Exhibit C describes that TNF inhibitors are not the same, but rather have different mechanisms, efficacy, and side effects. A skilled artisan would therefore recognize that one cannot simply assume that a given inhibitor (e.g. golimumab) can be used in a way that may be described for a different TNF inhibitor. Therefore, a skilled artisan would have no reasonable expectation of success in specifically choosing golimumab from the laundry list of alternative TNF-inhibitors of Wong and specifically administering golimumab by IV infusion at a dose of 2 mg/kg, administered over 30 ± 10 minutes, at Weeks 0 and 4, and then every 8 weeks (q8w) thereafter, which is a dosing regimen not even contemplated by Le.

Further, Wong and Le do not describe any clinical improvement from IV golimumab on any subject, let alone a subject with ankylosing spondylitis. Applicants submit that a skilled artisan would not have any reasonable expectation from Wong and Le that greater than 65% of patients receiving IV golimumab would achieve ASAS20 at week 16.

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 a composition comprising a safe and effective amount of the recited anti-TNF antibody, wherein said composition is administered via IV infusion at a dose of 2 mg/kg, administered over 30 ± 10 minutes, at Weeks 0 and 4, and then every 8 weeks (q8w) thereafter, produces surprising and unexpected results that could not have been predicted by the combination of Wong and Le.

Smolen et al., Ann Rheum Dis 2014; 73:6–16 (hereinafter "Smolen"; and provided previously Exhibit A), is a publication of recommendations of an international task force related to treatment targets for spondyloarthritis, including ankylosing spondylitis. See, for example, Smolen, page 9, 2nd column, 2nd to last paragraph, where it states, "Common recommendations 1. A major treatment target should be clinical remission/inactive disease…". Also, note that in the preceding paragraph, page 9, 1st column, last paragraph, the authors in Smolen indicated that the sequence of the recommendations reflects the level of importance considered by the committee for each individual bullet point. It follows, therefore, that the number 1 recommendation related to the treatment target of remission/inactive disease was considered the most important consideration of the international task force. It is demonstrated herein that IV golimumab administered at a dose of 2 mg/kg, administered over 30 ± 10 minutes, at Weeks 0 and 4, and then every 8 weeks (q8w) thereafter surprisingly was able to induce inactive disease, the most important metric of ankylosing spondylitis treatment efficacy, in only 2 weeks after treatment.

As described in the present application, intravenous administration of golimumab resulted in inactive disease, as measured by ASDAS score of < 1.3, as early as 4 weeks and 2 weeks after treatment. As noted above, none of the cited references teach or suggest that an ASDAS inactive disease score could be achieved in such a short time, after only 4 weeks or 2 weeks of IV golimumab treatment. Thus, the teaching of Wong and Le, alone or in combination, could not have led a skilled artisan to expect such surprising and unpredictable results.

Achieving an ASDAS inactive disease score (i.e. <1.3) after only 2 weeks or 4 weeks of IV golimumab treatment is a very surprising and unpredictable result that would not be obvious to a person skilled in the art. For example, Van der heijde et al. J Rheumatol, 2014, 41(6): 1095-103 (hereinafter "Van der heijde"; and provided previously as Exhibit B) describes the 2-year results of a clinical trial of subcutaneous golimumab treatment and only reports proportion of patients with ADAS inactive score (<1.3) at week 14 and week 24 after subcutaneous injections of golimumab. Applicants submit that a skilled artisan, at the time of filing, could not have reasonably predicted or expected the surprising and unexpected results demonstrated herein, that patients could achieve an ASDAS inactive disease score (<1.3) in such a short time, after only 4 weeks or 2 weeks of IV golimumab treatment.

Similarly, Applicants submit that the application demonstrates that IV golimumab administered at a dose of 2 mg/kg, administered over 30 ± 10 minutes, at Weeks 0 and 4, and then every 8 weeks (q8w) thereafter exhibited surprising and unexpected results in showing improved efficacy, as measured by the change from baseline in the criteria listed in claim 14 and by the proportion of subjects achieving ASAS20. Each of the clinical measures at 16 weeks post-IV golimumab was surprisingly and unexpectedly improved over the same clinical measures at 14 and 24 weeks post-subcutaneous golimumab. Applicants submit that such improved clinical efficacy of IV golimumab demonstrated by the present application would not be expected by a skilled artisan reading Wong and Le.

For at least these reasons, Applicants submit that the pending claims are not rendered obvious by the combination of Wong and Le. 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.

July 5, 2023 By: By: /Pallab Singh/

Pallab Singh, Ph.D., J.D.
Registration No. 70,731
Riverside Law LLP
175 Strafford Ave., Suite 100
Wayne, PA 19087
215-268-3888 (main)
215-268-3871 (fax)
215-268-3759 (direct)
E-Mail: psingh@riversidelaw.com
Attorney for Applicants

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Patent Application of: Diane D. Harrison, et al.	Art Unit: 1646 Confirmation No.: 8810
Application No.: 17/237,650	Examiner: Chandra, Gyan
Filing date: April 22, 2021	Atty Docket No.: 206389-0002-02US

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

AMENDMENT

This Amendment is responsive to the final Office Action mailed on April 4, 2023 in connection with the above-referenced application. This Response is timely filed in view of the deadline for a timely response being to and through July 5, 2023 (July 4, 2023 being a federal holiday.

This Amendment is being filed in conjunction with a Request for Continued Examination (and associated fee).

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 UNITED STATES PATENT AND TRADEMARK OFFICE

Patent Application of: Diane D. Harrison, et al.	Art Unit: 1646 Confirmation No.: 8810
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NOTICE OF ALLOWANCE AND FEE(S) DUE

171672 7590 08/04/2023

Riverside Law LLP/J&J
175 Strafford Avenue
Suite 100
Wayne, PA 19087

EXAMINER
CHANDRA, GYAN

ART UNIT	PAPER NUMBER
1646	

DATE MAILED: 08/04/2023

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
17/237,650	04/22/2021	Diane D. Harrison	206389-0002-02US	8810

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	11/06/2023

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 EFS-Web.

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

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

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

171672 7590 08/04/2023

Riverside Law LLP/J&J
175 Strafford Avenue
Suite 100
Wayne, PA 19087

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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 EFS-Web 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.
17/237,650	04/22/2021	Diane D. Harrison	206389-0002-02US	8810

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	11/06/2023

EXAMINER	ART UNIT	CLASS-SUBCLASS
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 Patent Center or EFS-Web ❑ 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

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.

❑ Applicant asserting small entity status. See 37 CFR 1.27

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.

❑ Applicant changing to regular undiscounted fee 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.
17/237,650	04/22/2021	Diane D. Harrison	206389-0002-02US	8810

171672 7590 08/04/2023

Riverside Law LLP/J&J
175 Strafford Avenue
Suite 100
Wayne, PA 19087

EXAMINER	
CHANDRA, GYAN	
ART UNIT	PAPER NUMBER
1646	

DATE MAILED: 08/04/2023

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. 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 disclosure of these records is required by the Freedom of Information Act.
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 inspection 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.

Notice of Allowability	Application No. 17/237,650	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 on 7/5/2023.
   ☐ 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 _____.
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 _____.

/GYAN CHANDRA/
Primary Examiner, Art Unit 1646

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 7/5/2023 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.

EXAMINER'S COMMENT

Claim Rejections - 35 USC § 102-withdrawn

The rejection of claim(s) 11, 13-14,16-18 and 20 under 35 U.S.C. 102(a) (1) as being anticipated by Wong et al. (US Pub. No. 2009/0123378) is withdrawn in view of applicant's amendments to incorporate the limitation of non-rejected claims 12, 15 and 19 under 35 USC 102.

Claim Rejections - 35 USC § 103-withdrawn

The rejection of claim(s) 11, 13-14, 16-18 and 20 under 35 U.S.C. 103 as being unpatentable over Wong et al. (US Pub. No. 2009/0123378) in view of Le et al. (US Pat. No. 5,656,272) is withdrawn in view of applicant's arguments that the specifically recited antibody at specifically recited dosage and infusion time would not be obvious to one skill in the art (page 9 of Rem.). Additionally, applicants argue that Wong does not teach or suggest to treat ankylosing spondylitis using golimumab by IV infusion at dose 2 mg/kg administered over 30 ±10 minutes, at Weeks 0 and 4, and every 8 weeks (q8w). Applicants cite reference Mpofu et al (as exhibit C, but the examiner did not find the reference) to support that monoclonal antibody against TNF-α work differently and specific dosage, route and the duration of administration may not always be translated with another antibody or anti-TNF-α, and the end result achieved is important in therapy. The reference Mpofu et al is cited on pto-892. In totality, applicants' arguments are persuasive, therefore the rejection is withdrawn.

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

Notice of References Cited	Application/Control No. 17/237,650	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					
	B					
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	D					
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	N					
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	Q					
	R					
	S					
	T					

NON-PATENT DOCUMENTS

*		Include as applicable: Author, Title Date, Publisher, Edition or Volume, Pertinent Pages)
	U	Mpofu et al., Rheumatology, 44: 271-273, 2005
	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.

Search Notes	Application/Control No.	Applicant(s)/Patent Under Reexamination
	17/237,650	Harrison et al.
	Examiner	Art Unit
	GYAN CHANDRA	1646

CPC - Searched*		
Symbol	**Date**	**Examiner**
c07k16/241	07/27/2023	gc
a61k39/3955	07/27/2023	gc
a61p19/02	07/27/2023	gc

CPC Combination Sets - Searched*		
Symbol	**Date**	**Examiner**

US Classification - Searched*			
Class	**Subclass**	**Date**	**Examiner**
None	None	07/27/2023	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, 2, 3, 4, 5, 6 with substitutions (see search results in SCORE)	09/13/2022	gc
claims searched in CAPLUS, Biosis, Medline (see enclosed transcript)	07/27/2023	gc
claims searched in PE2E search (see enclosed doc)	07/27/2023	gc
Inventorship search in PE2E search (see enclosed doc)	07/27/2023	gc
Inventorship search in PALM	07/27/2023	gc

/GYAN CHANDRA/ Primary Examiner, Art Unit 1646	

Search Notes	Application/Control No.	Applicant(s)/Patent Under Reexamination
	17/237,650	Harrison et al.
	Examiner	Art Unit
	GYAN CHANDRA	1646

Interference Search			
US Class/CPC Symbol	US Subclass/CPC Group	Date	Examiner
C07K	16/241	07/27/2023	gc

/GYAN CHANDRA/ Primary Examiner, Art Unit 1646	

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                  a standalone database on STNext
 NEWS  6  JUN 22  Claims for Four Additional Patent Authorities Added to
                  CA/CAplus
 NEWS  7  JUN 24  SMARTracker SDI Option Now Supported in Derwent Files
 NEWS  8  JUN 24  Expanded Claims Coverage and Enhanced HIT Displays of
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                  Georgia Increases Comprehensiveness of INPADOC
 NEWS 10  SEP 14  New Preference Setting for Transcript Options Helps
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 NEWS 11  SEP 22  CAS STNext Structure Editor Update Preserves Functionality,
                  Increases Flexibility
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                  Databases on CAS STNext
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 NEWS 14  NOV  7  EPFULL Reload on STNext Features New Independent Claims
                  Searching Capabilities
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 NEWS 16  DEC 05  Expanded access to Taiwanese patent information provided
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                  in CAplus(SM)
 NEWS 17  DEC 05  New Implementation of Derwent Drug File (DRUGU/DDFU)
                  Makes Searching More Convenient
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                  Makes Claim Analysis More Efficient
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 NEWS 20  FEB 23  Derwent World Patents Index - Manual Code revision 2023
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 NEWS 22  MAR 23  Expanded Patent Authority Coverage in CA/CAplus Means
                  Access to More Inventions, More Complete Patent
                  Families
 NEWS 23  MAY 12  Claim Tags Enhancement Extended to Include WO Patents
 NEWS 24  MAY 15  May 2023 Update to Emtree(R) Now Available in Embase(R)
 NEWS 25  JUL 05  Reloaded Japanese Patent Full-Text Database JPFULL Provides
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 NEWS 26  JUL 06  Interactive Claims Viewer Enhancements: JPFULL Now Supported,
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                                                     ENTRY         SESSION
FULL ESTIMATED COST                                   0.28            0.28

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FILE 'MEDLINE' ENTERED AT 10:58:04 ON 27 JUL 2023

=> 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         223 --> 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
E24           1     HSIA FRANCES K/AU

=> s e15

L2          223 "HSIA ELIZABETH C"/AU

=> e Kim Lee Lian/au

E25           3     KIM LEE KYOUNG/AU
E26          69     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
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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         106 --> LO KIM HUNG/AU
E40          10     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          27     LO KIN CHEUNG/AU

=> s 39

L4     1594193 39

=> s e39

L5          106 "LO KIM HUNG"/AU

=> s l1-3 or l5

L6          314 (L1 OR L2 OR L3) OR L5

=> s golimumab

L7         5841 GOLIMUMAB

=> s intravenous (w) infusion

L8        60379 INTRAVENOUS (W) INFUSION

=> s l7 (l) l8

L9           10 L7 (L) L8

=> dup rem l10

L10 IS NOT VALID HERE
The L-number entered has not been defined in this session, or it
has been deleted.  To see the L-numbers currently defined in this
session, enter DISPLAY HISTORY at an arrow prompt (=>).

=> dup rem l9

PROCESSING COMPLETED FOR L9
L10            9 DUP REM L9 (1 DUPLICATE REMOVED)

=> s 2 mg/kg

'KG' IS NOT A VALID FIELD CODE
'KG' IS NOT A VALID FIELD CODE
'KG' IS NOT A VALID FIELD CODE
L11            0 2 MG/KG

=> s mg per kilogram

L12        1350 MG PER KILOGRAM

=> s l10 (l) l12
```

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L13          0 L10 (L) L12

=> s l6 and l10

L14          2 L6 AND L10

=> d l14


L14  ANSWER 1 OF 2  CAPLUS  COPYRIGHT 2023 ACS on STN
AN   2019:1636875  CAPLUS Full-text
DN   174:901313
TI   Efficacy and safety of intravenous golimumab plus methotrexate in patients
     with rheumatoid arthritis aged < 65 years and those ≥ 65 years of
     age
AU   Tesser, John; Kafka, Shelly; De Horatius, Raphael J.; Xu, Stephen; Ssia,
     Elizabeth C.; Turkiewicz, Anthony
CS   Arizona Arthritis and Rheumatology Associates, Phoenix, AZ, USA
SO   Arthritis Research & Therapy (2019), 21(1), 1-9
     CODEN: ARTRCV; ISSN: 1478-6362
DOI  10.1186/s13075-019-1968-x
PB   BioMed Central Ltd.
DT   Journal; (online computer file)
LA   English
RE.CNT  29    THERE ARE 29 CITED REFERENCES AVAILABLE FOR THIS RECORD
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=> d l14 1-2 ti so py kwic ibib


L14  ANSWER 1 OF 2  CAPLUS  COPYRIGHT 2023 ACS on STN
TI   Efficacy and safety of intravenous golimumab plus methotrexate in patients
     with rheumatoid arthritis aged < 65 years and those ≥ 65 years of
     age
SO   Arthritis Research & Therapy (2019), 21(1), 1-9
     CODEN: ARTRCV; ISSN: 1478-6362
PY   2019
AU   Tesser, John; Kafka, Shelly; De Horatius, Raphael J.; Xu, Stephen; Ssia,
     Elizabeth C.; Turkiewicz, Anthony
IT   Acute pancreatitis
     Aging, animal
     Antiarthritics
     Basal cell carcinoma
     Bone fracture
     Bowen disease
     Brain infarction
     Candida albicans
     Cellulitis
     Cholecystitis
     Chronic lymphocytic leukemia
     Clostridium difficile
     Combination chemotherapy
     Diverticulitis
     Flushing
     Hemorrhoid
     Homo sapiens
     Human
     Hypertension
     Interstitial lung disease
     Mammary gland neoplasm
     Mycosis
     Myocardial infarction
     Neoplasm
     Pancreatitis
     Pharmaceutical intravenous infusions
     Pneumonia
     Rheumatoid arthritis
     Sepsis
     Septic arthritis
```

Septic shock
Tuberculosis
Urinary system infection
Uterine cervical carcinoma
(efficacy and safety of i.v. golimumab plus methotrexate in patients with rheumatoid arthritis aged < 65 years and those greater than or equal to 65 years of age)

ACCESSION NUMBER: 2019:1636875 CAPLUS Full-text
DOCUMENT NUMBER: 174:901313
TITLE: Efficacy and safety of intravenous golimumab plus methotrexate in patients with rheumatoid arthritis aged < 65 years and those ≥ 65 years of age
AUTHOR(S): Tesser, John; Kafka, Shelly; De Horatius, Raphael J.; Xu, Stephen; Hsia, Elizabeth C.; Turkiewicz, Anthony
CORPORATE SOURCE: Arizona Arthritis and Rheumatology Associates, Phoenix, AZ, USA
SOURCE: Arthritis Research & Therapy (2019), 21(1), 1-9
CODEN: ARTRCV; ISSN: 1478-6362
DIGITAL OBJECT ID: 10.1186/s13075-019-1968-x
PUBLISHER: BioMed Central Ltd.
DOCUMENT TYPE: Journal; (online computer file)
LANGUAGE: English
REFERENCE COUNT: 29 THERE ARE 29 CITED REFERENCES AVAILABLE FOR THIS RECORD. ALL CITATIONS AVAILABLE IN THE RE FORMAT

L14 ANSWER 2 OF 2 CAPLUS COPYRIGHT 2023 ACS on STN
TI Safety and efficacy of Golimumab administered intravenously in adults with ankylosing spondylitis: results through week 28 of the GO-ALIVE study
SO Journal of Rheumatology (2018), 45(3), 341-349
CODEN: JRHUA9; ISSN: 1499-2752
PY 2018
AU Deodhar, Atul; Reveille, John D.; Harrison, Diane D.; Kim, Lilianne; Lo, Kim Hung; Leu, Jocelyn H.; Hsia, Elizabeth C.
IT Ankylosing spondylitis
Blood serum
Diagnosis
Homo sapiens
Human
Inflammation
Metabolic side effects of drugs
Nasopharyngitis
Pharmaceutical intravenous infusions
Pharmacokinetics
Upper respiratory infection
(safety and efficacy of golimumab administered i.v. in adults with ankylosing spondylitis)

ACCESSION NUMBER: 2019:192315 CAPLUS Full-text
DOCUMENT NUMBER: 174:574693
TITLE: Safety and efficacy of Golimumab administered intravenously in adults with ankylosing spondylitis: results through week 28 of the GO-ALIVE study
AUTHOR(S): Deodhar, Atul; Reveille, John D.; Harrison, Diane D.; Kim, Lilianne; Lo, Kim Hung; Leu, Jocelyn H.; Hsia, Elizabeth C.
CORPORATE SOURCE: Oregon Health & Science University, Portland, OR, USA
SOURCE: Journal of Rheumatology (2018), 45(3), 341-349
CODEN: JRHUA9; ISSN: 1499-2752
DIGITAL OBJECT ID: 10.3899/jrheum.170487
PUBLISHER: Journal of Rheumatology Publishing Co. Ltd.
DOCUMENT TYPE: Journal; (online computer file)
LANGUAGE: English
OS.CITING REF COUNT: 14 THERE ARE 14 CAPLUS RECORDS THAT CITE THIS RECORD (14 CITINGS)
REFERENCE COUNT: 28 THERE ARE 28 CITED REFERENCES AVAILABLE FOR THIS RECORD. ALL CITATIONS AVAILABLE IN THE RE FORMAT

=> d l10 1-9 ti so py kwic ibib

L10 ANSWER 1 OF 9 CAPLUS COPYRIGHT 2023 ACS on STN

TI Materials and methods utilizing anti-tumor necrosis factor (TNF) antibodies, such as golimumab, for treating juvenile idiopathic arthritis
SO PCT Int. Appl., 239pp.
CODEN: PIXXD2
PY 2021
2021
2021
2022
2022
2023
2023
2023
2023
IT Antirheumatic agents
Child
Clinical trials, phase III
Combination chemotherapy
Homo sapiens
Human
Juvenile rheumatoid arthritis
Pharmaceutical intravenous infusions
Pharmaceutical intravenous injections
(materials and methods utilizing anti-tumor necrosis factor (TNF) antibodies, such as golimumab, for treating juvenile idiopathic arthritis)

ACCESSION NUMBER: 2021:2388140 CAPLUS Full-text
DOCUMENT NUMBER: 176:497569
TITLE: Materials and methods utilizing anti-tumor necrosis factor (TNF) antibodies, such as golimumab, for treating juvenile idiopathic arthritis
INVENTOR(S): Bensley, Karen; Clark, Michael; Leu, Jocelyn; Xu, Zhenhua
PATENT ASSIGNEE(S): Janssen Biotech, Inc., USA
SOURCE: PCT Int. Appl., 239pp.
CODEN: PIXXD2
DOCUMENT TYPE: Patent
LANGUAGE: English
FAMILY ACC. NUM. COUNT: 1
PATENT INFORMATION:

PATENT NO.	KIND	DATE	APPLICATION NO.	DATE
WO 2021220140	A1	20211104	WO 2021-IB53429	20210426
CA 3127807	A1	20211027	CA 2021-3127807	20210426
US 20210340245	A1	20211104	US 2021-17240609	20210426
CN 115461365	A	20221209	CN 2021-80031397	20210426
BR 112022021766	A2	20221213	BR 2022-112022021766	20210426
AU 2021263136	A1	20230105	AU 2021-263136	20210426
KR 2023005284	A	20230109	KR 2022-7041143	20210426
EP 4143226	A1	20230308	EP 2021-797784	20210426
JP 2023524668	T	20230613	JP 2022-565551	20210426

PRIORITY APPLN. INFO.:
US 2020-63015889 P 20200427
US 2020-63015894 P 20200427
US 2020-63015902 P 20200427
WO 2021-IB53429 W 20210426

PATENT STATUS PATENT INFORMATION:

PATENT NO.	KIND	STATUS	STATUS DATE
WO 2021220140	A1	Alive	20211125
CA 3127807	A1	Alive	20211125
US 20210340245	A1	Transitional	20230713
CN 115461365	A	Alive	20221215
BR 112022021766	A2	Alive	20221222
AU 2021263136	A1	Alive	20230112
KR 2023005284	A	Alive	20230126
EP 4143226	A1	Alive	20230309

REFERENCE COUNT: 4 THERE ARE 4 CITED REFERENCES AVAILABLE FOR THIS RECORD. ALL CITATIONS AVAILABLE IN THE RE FORMAT

LINK INFORMATION

PUBLICATIONS	APPLICATIONS	REGISTER
AU 2021263136 A1	AU 2021-263136	Register

BR 112022021766 A2	BR 2022-112022021766	Register
CA 3127807 A1	CA 2021-3127807	Register
CN 115461365 A	CN 2021-80031397	Register|Global Dossier
EP 4143226 A1	EP 2021-797784	Register|Federated Reg.
JP 2023524668 T	JP 2022-565551	Register|Global Dossier
KR 2023005284 A	KR 2022-7041143	Register|Global Dossier
US 20210340245 A1	US 2021-17240609	Register|Global Dossier
WO 2021220140 A1	WO 2021-IB53429	Register|Global Dossier

L10 ANSWER 2 OF 9 MEDLINE ® on STN

TI Subcutaneous golimumab induced and maintained clinical response in a child with a biological-experienced steroid-refractory flare of ulcerative colitis: A case report.

SO Medicine, (2021 Sep 24) Vol. 100, No. 38, pp. e27283.
Journal code: 2985248R. E-ISSN: 1536-5964. L-ISSN: 0025-7974.
Report No.: PMC-PMC8462589.

PY 2021

AB INTRODUCTION: Golimumab is a fully human antitumor necrosis monoclonal antibody that can be administered by either subcutaneous injection or intravenous infusion. Golimumab is approved for the treatment of the adults with rheumatic diseases, and ulcerative colitis, Whereas in children, golimumab is indicated only for the treatment of active polyarticular juvenile idiopathic arthritis. We have written on the off-label use of subcutaneous golimumab, which helped to induce and maintain remission on a low-weight biologically experienced child with steroid-refractory ulcerative colitis flare.

PATIENT CONCERNS:. . . adalimumab were unavailable in Syria. Child's parents opposed colectomy as a treatment option.

DIAGNOSIS: Ulcerative colitis flare.

INTERVENTIONS: A subcutaneous golimumab with a loading dose of 200 mg at week 0, followed by 100 mg at week 2, then 50 mg. . . Pediatric Ulcerative Colitis Activity Index and Mayo scores were 5 and 2 points, respectively. No adverse events were documented.

CONCLUSION: Golimumab has shown potential efficacy and safety in the treatment of ulcerative colitis in children which may indicate a significant future role for subcutaneous golimumab in pediatrics ulcerative colitis.

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ACCESSION NUMBER: 2024612351 MEDLINE Full-text
DOCUMENT NUMBER: PubMed ID: 34559136
TITLE: Subcutaneous golimumab induced and maintained clinical response in a child with a biological-experienced steroid-refractory flare of ulcerative colitis: A case report.
AUTHOR: Alhalabi Marouf
AUTHOR IDENTIFIERS: ORCID: https://orcid.org/0000-0001-5027-2096
CORPORATE SOURCE: Gastroenterology Department, Damascus Hospital, Damascus, Syria.
AUTHOR: Eddin Kamal Alaa; Cheha Khaled; Abbas Ahmad
SOURCE: Medicine, (2021 Sep 24) Vol. 100, No. 38, pp. e27283.
Journal code: 2985248R. E-ISSN: 1536-5964. L-ISSN: 0025-7974.
Report No.: PMC-PMC8462589.
DIGITAL OBJECT ID: http://dx.doi.org/10.1097/MD.0000000000027283
PUB. COUNTRY: United States
DOCUMENT TYPE: (CASE REPORTS)
Journal; Article; (JOURNAL ARTICLE)
LANGUAGE: English
FILE SEGMENT: MEDLINE; Priority Journals
FILE SEGMENT: Print
ENTRY MONTH: 202110
ENTRY DATE: Entered STN: 24 Sep 2021
Last Updated on STN: 3 Oct 2021
Indexing Added: 3 Oct 2021
Entered Medline: 1 Oct 2021
OS.CITING REF COUNT: 2 There are 2 MEDLINE records that cite this record
MEDLINE REFERENCE COUNT: 50 There are 50 cited references available in

MEDLINE for this document.

L10 ANSWER 3 OF 9 BIOSIS COPYRIGHT (c) 2023 Clarivate Analytics on STN
TI Subcutaneous golimumab induced and maintained clinical response in a child with a biological-experienced steroid-refractory flare of ulcerative colitis A case report.
SO Medicine (Hagerstown), (SEP 24 2021) Vol. 100, No. 38, pp. Article No.: e27283. http://journals.lww.com/md-journal/pages/default.aspx.
CODEN: MEDIAV. ISSN: 0025-7974. E-ISSN: 1536-5964.
PY 2021
AB Introduction: Golimumab is a fully human antitumor necrosis monoclonal antibody that can be administered by either subcutaneous injection or intravenous infusion. Golimumab is approved for the treatment of the adults with rheumatic diseases, and ulcerative colitis, Whereas in children, golimumab is indicated only for the treatment of active polyarticular juvenile idiopathic arthritis. We have written on the off-label use of subcutaneous golimumab, which helped to induce and maintain remission on a low-weight biologically experienced child with steroid-refractory ulcerative colitis flare.Patient concerns: A. . . tacrolimus, and adalimumab were unavailable in Syria. Child's parents opposed colectomy as a treatment option.Diagnosis: Ulcerative colitis flare.Interventions: A subcutaneous golimumab with a loading dose of 200 mg at week 0, followed by 100 mg at week 2, then 50 mg. . . The Pediatric Ulcerative Colitis Activity Index and Mayo scores were 5 and 2 points, respectively. No adverse events were documented.Conclusion: Golimumab has shown potential efficacy and safety in the treatment of ulcerative colitis in children which may indicate a significant future role for subcutaneous golimumab in pediatrics ulcerative colitis.
ACCESSION NUMBER: 2021:891956 BIOSIS Full-text
DOCUMENT NUMBER: PREV202100891956
TITLE: Subcutaneous golimumab induced and maintained clinical response in a child with a biological-experienced steroid-refractory flare of ulcerative colitis A case report.
AUTHOR(S): Alhalabi, Marouf [Reprint Author]; Eddin, Kemal Alaa; Cheha, Khaled; Abbas, Ahmad
CORPORATE SOURCE: Damascus Hosp, Almujtahed St, Damascus, Syria
e.marouf@hotmail.com
SOURCE: Medicine (Hagerstown), (SEP 24 2021) Vol. 100, No. 38, pp. Article No.: e27283.
http://journals.lww.com/md-journal/pages/default.aspx.
CODEN: MEDIAV. ISSN: 0025-7974. E-ISSN: 1536-5964.
DIGITAL OBJECT ID: 10.1097/MD.0000000000027283
DOCUMENT TYPE: Article
LANGUAGE: English
ENTRY DATE: Entered STN: 6 Oct 2021
Last Updated on STN: 6 Oct 2021

L10 ANSWER 4 OF 9 CAPLUS COPYRIGHT 2023 ACS on STN
TI Use of anti-TNF antibody, golimumab, in compositions and methods for treatment of polyarticular juvenile idiopathic arthritis
SO PCT Int. Appl., 238pp.
CODEN: PIXXD2
PY 2020
2020
2021
2021
2021
2021
2022
2022
IT Antiarthritics
Child
Combination chemotherapy
Homo sapiens
Human
Juvenile rheumatoid arthritis
Passive immunotherapy
Pharmaceutical intravenous infusions
Protein sequences
Unit dose drug delivery systems
(use of anti-TNF antibody, golimumab, in compns. and methods

for treatment of polyarticular juvenile idiopathic arthritis)
ACCESSION NUMBER: 2020:1420974 CAPLUS Full-text
DOCUMENT NUMBER: 173:275081
TITLE: Use of anti-TNF antibody, golimumab, in compositions and methods for treatment of polyarticular juvenile idiopathic arthritis
INVENTOR(S): Bensley, Karen; Clark, Michael; Leu, Jocelyn; Xu, Zhenhua
PATENT ASSIGNEE(S): Janssen Biotech, Inc., USA
SOURCE: PCT Int. Appl., 238pp.
CODEN: PIXXD2
DOCUMENT TYPE: Patent
LANGUAGE: English
FAMILY ACC. NUM. COUNT: 1
PATENT INFORMATION:

PATENT NO.	KIND	DATE	APPLICATION NO.		DATE
WO 2020148651	A1	20200723	WO 2020-IB50266		20200114
CA 3126654	A1	20200723	CA 2020-3126654		20200114
AU 2020208828	A1	20210805	AU 2020-208828		20200114
KR 2021116540	A	20210927	KR 2021-7025727		20200114
CN 113574066	A	20211029	CN 2020-80021619		20200114
EP 3911676	A1	20211124	EP 2020-701516		20200114
JP 2022518208	T	20220314	JP 2021-540796		20200114
US 20220153827	A1	20220519	US 2021-17423177		20210715
PRIORITY APPLN. INFO.:			US 2019-62792568	P	20190115
			US 2019-62820593	P	20190319
			US 2019-62899171	P	20190912
			WO 2020-IB50266	W	20200114

PATENT STATUS PATENT INFORMATION:

PATENT NO.	KIND	STATUS	STATUS DATE
WO 2020148651	A1	Alive	20201203
CA 3126654	A1	Alive	20210826
AU 2020208828	A1	Alive	20210812
KR 2021116540	A	Alive	20211118
CN 113574066	A	Alive	20211123
EP 3911676	A1	Alive	20211126
US 20220153827	A1	Alive	20220527

ASSIGNMENT HISTORY FOR US PATENT AVAILABLE IN LSUS DISPLAY FORMAT
REFERENCE COUNT: 6 THERE ARE 6 CITED REFERENCES AVAILABLE FOR THIS RECORD. ALL CITATIONS AVAILABLE IN THE RE FORMAT

LINK INFORMATION

PUBLICATIONS	APPLICATIONS	REGISTER
AU 2020208828 A1	AU 2020-208828	Register
CA 3126654 A1	CA 2020-3126654	Register
CN 113574066 A	CN 2020-80021619	Register|Global Dossier
EP 3911676 A1	EP 2020-701516	Register|Federated Reg.
JP 2022518208 T	JP 2021-540796	Register|Global Dossier
KR 2021116540 A	KR 2021-7025727	Register|Global Dossier
US 20220153827 A1	US 2021-17423177	Register|Global Dossier
WO 2020148651 A1	WO 2020-IB50266	Register|Global Dossier

L10 ANSWER 5 OF 9 CAPLUS COPYRIGHT 2023 ACS on STN
TI Efficacy and safety of intravenous golimumab plus methotrexate in patients with rheumatoid arthritis aged < 65 years and those ≥ 65 years of age
SO Arthritis Research & Therapy (2019), 21(1), 1-9
CODEN: ARTRCV; ISSN: 1478-6362
PY 2019
IT Acute pancreatitis
Aging, animal
Antiarthritics
Basal cell carcinoma
Bone fracture
Bowen disease
Brain infarction
Candida albicans
Cellulitis
Cholecystitis

Chronic lymphocytic leukemia
Clostridium difficile
Combination chemotherapy
Diverticulitis
Flushing
Hemorrhoid
Homo sapiens
Human
Hypertension
Interstitial lung disease
Mammary gland neoplasm
Mycosis
Myocardial infarction
Neoplasm
Pancreatitis
Pharmaceutical intravenous infusions
Pneumonia
Rheumatoid arthritis
Sepsis
Septic arthritis
Septic shock
Tuberculosis
Urinary system infection
Uterine cervical carcinoma
(efficacy and safety of i.v. golimumab plus methotrexate in patients with rheumatoid arthritis aged < 65 years and those greater than or equal to 65 years of age)

ACCESSION NUMBER: 2019:1636875 CAPLUS Full-text
DOCUMENT NUMBER: 174:901313
TITLE: Efficacy and safety of intravenous golimumab plus methotrexate in patients with rheumatoid arthritis aged < 65 years and those ≥ 65 years of age
AUTHOR(S): Tesser, John; Kafka, Shelly; De Horatius, Raphael J.; Xu, Stephen; Hsia, Elizabeth C.; Turkiewicz, Anthony
CORPORATE SOURCE: Arizona Arthritis and Rheumatology Associates, Phoenix, AZ, USA
SOURCE: Arthritis Research & Therapy (2019), 21(1), 1-9
CODEN: ARTRCV; ISSN: 1478-6362
DIGITAL OBJECT ID: 10.1186/s13075-019-1968-x
PUBLISHER: BioMed Central Ltd.
DOCUMENT TYPE: Journal; (online computer file)
LANGUAGE: English
REFERENCE COUNT: 29 THERE ARE 29 CITED REFERENCES AVAILABLE FOR THIS RECORD. ALL CITATIONS AVAILABLE IN THE RE FORMAT

L10 ANSWER 6 OF 9 CAPLUS COPYRIGHT 2023 ACS on STN
TI Safety and efficacy of Golimumab administered intravenously in adults with ankylosing spondylitis: results through week 28 of the GO-ALIVE study
SO Journal of Rheumatology (2018), 45(3), 341-349
CODEN: JRHUA9; ISSN: 1499-2752
PY 2018
IT Ankylosing spondylitis
Blood serum
Diagnosis
Homo sapiens
Human
Inflammation
Metabolic side effects of drugs
Nasopharyngitis
Pharmaceutical intravenous infusions
Pharmacokinetics
Upper respiratory infection
(safety and efficacy of golimumab administered i.v. in adults with ankylosing spondylitis)

ACCESSION NUMBER: 2019:192315 CAPLUS Full-text
DOCUMENT NUMBER: 174:574693
TITLE: Safety and efficacy of Golimumab administered intravenously in adults with ankylosing spondylitis: results through week 28 of the GO-ALIVE study
AUTHOR(S): Deodhar, Atul; Reveille, John D.; Harrison, Diane D.; Kim, Lilianne; Lo, Kim Hung; Leu, Jocelyn H.; Hsia, Elizabeth C.

CORPORATE SOURCE: Oregon Health & Science University, Portland, OR, USA
SOURCE: Journal of Rheumatology (2018), 45(3), 341-349
CODEN: JRHUA9; ISSN: 1499-2752
DIGITAL OBJECT ID: 10.3899/jrheum.170487
PUBLISHER: Journal of Rheumatology Publishing Co. Ltd.
DOCUMENT TYPE: Journal; (online computer file)
LANGUAGE: English
OS.CITING REF COUNT: 14 THERE ARE 14 CAPLUS RECORDS THAT CITE THIS RECORD (14 CITINGS)
REFERENCE COUNT: 28 THERE ARE 28 CITED REFERENCES AVAILABLE FOR THIS RECORD. ALL CITATIONS AVAILABLE IN THE RE FORMAT

L10 ANSWER 7 OF 9 CAPLUS COPYRIGHT 2023 ACS on STN
TI Randomised clinical trial: a placebo-controlled study of intravenous golimumab induction therapy for ulcerative colitis
SO Alimentary Pharmacology and Therapeutics (2015), 42(5), 504-514
CODEN: APTHEN; ISSN: 0269-2813
PY 2015
IT Blood serum
Clinical trials
Cough
Headache
Homo sapiens
Human
Inflammatory bowel disease
Pharmaceutical intravenous infusions
Pharmacodynamics
Pharyngitis
Ulcerative colitis
(placebo-controlled randomized clin. trial of i.v. golimumab induction therapy for ulcerative colitis)
ACCESSION NUMBER: 2015:1289183 CAPLUS Full-text
DOCUMENT NUMBER: 164:525260
TITLE: Randomised clinical trial: a placebo-controlled study of intravenous golimumab induction therapy for ulcerative colitis
AUTHOR(S): Rutgeerts, P.; Feagan, B. G.; Marano, C. W.; Padgett, L.; Strauss, R.; Johanns, J.; Adedokun, O. J.; Guzzo, C.; Zhang, H.; Colombel, J.-F.; Reinisch, W.; Gibson, P. R.; Sandborn, W. J.
CORPORATE SOURCE: PURSUIT-IV Study Group, University Hospital, Louvain, Belg.
SOURCE: Alimentary Pharmacology and Therapeutics (2015), 42(5), 504-514
CODEN: APTHEN; ISSN: 0269-2813
DIGITAL OBJECT ID: 10.1111/apt.13291
PUBLISHER: Wiley-Blackwell
DOCUMENT TYPE: Journal; (online computer file)
LANGUAGE: English
OS.CITING REF COUNT: 22 THERE ARE 22 CAPLUS RECORDS THAT CITE THIS RECORD (22 CITINGS)
REFERENCE COUNT: 20 THERE ARE 20 CITED REFERENCES AVAILABLE FOR THIS RECORD. ALL CITATIONS AVAILABLE IN THE RE FORMAT

L10 ANSWER 8 OF 9 MEDLINE ® on STN
TI Golimumab intravenous infusion for the treatment of rheumatoid arthritis.
SO The Nurse practitioner, (2015 Mar 12) Vol. 40, No. 3, pp. 15-8.
Journal code: 7603663. E-ISSN: 1538-8662. L-ISSN: 0361-1817.
PY 2015
TI Golimumab intravenous infusion for the treatment of rheumatoid arthritis.
ACCESSION NUMBER: 2015555760 MEDLINE Full-text
DOCUMENT NUMBER: PubMed ID: 25679139
TITLE: Golimumab intravenous infusion for the treatment of rheumatoid arthritis.
AUTHOR: McCarty Delilah J
CORPORATE SOURCE: Delilah J. McCarty is an assistant professor of pharmacy practice at Wingate University School of Pharmacy, Wingate, N.C.
SOURCE: The Nurse practitioner, (2015 Mar 12) Vol. 40, No. 3, pp. 15-8.
Journal code: 7603663. E-ISSN: 1538-8662. L-ISSN: 0361-1817.

DIGITAL OBJECT ID: http://dx.doi.org/10.1097/01.NPR.0000460861.12501.92
PUB. COUNTRY: United States
DOCUMENT TYPE: News Announcement
LANGUAGE: English
FILE SEGMENT: MEDLINE; Priority Journals
FILE SEGMENT: Print
ENTRY MONTH: 201504
ENTRY DATE: Entered STN: 16 Feb 2015
Last Updated on STN: 15 Apr 2015
Indexing Added: 15 Apr 2015
Entered Medline: 14 Apr 2015

L10 ANSWER 9 OF 9 BIOSIS COPYRIGHT (c) 2023 Clarivate Analytics on STN
DUPLICATE 1
TI Golimumab, a New Human Anti-Tumor Necrosis Factor alpha Antibody, Administered Intravenously in Patients With Active Rheumatoid Arthritis Forty-Eight-Week Efficacy and Safety Results of a Phase III Randomized, Double-Blind, Placebo-Controlled Study.
SO Arthritis & Rheumatism, (APR 2010) Vol. 62, No. 4, pp. 917-928. http://onlinelibrary.wiley.com/journal/10.1002/(ISSN)1529-0131. CODEN: ARHEAW. ISSN: 0004-3591. E-ISSN: 1529-0131.
PY 2010
AB Objective. To assess the efficacy and safety of intravenous administration of golimumab in patients with rheumatoid arthritis (RA).Methods. Adult patients with RA in whom disease activity was persistent despite treatment with methotrexate (MTX) at a dosage of 15-25 mg/week for >= 4 weeks were randomized to receive intravenous infusions of placebo plus MTX or intravenous infusions of golimumab at a dose of 2 mg/kg or 4 mg/kg, with or without MTX, every 12 weeks through week 48. Patients. . . end point was not met (at week 14, an ACR50 response was observed in 21% of the patients treated with golimumab plus MTX compared with 13% of the patients treated with placebo plus MTX [P = 0.051]). By week 24, significantly more patients treated with golimumab plus MTX had achieved an ACR50 response. Differences in the proportion of patients achieving an ACR50 response between the group receiving golimumab monotherapy and the group receiving placebo plus MTX were not significant at either week 14 (16% versus 13%) or week. . . 9%). At week 48, the proportions of patients achieving ACR20 and ACR50 responses were highest among those who had received golimumab 4 mg/kg plus MTX (70% and 48%, respectively). Concomitant treatment with MTX was associated with a lower incidence of antibodies to golimumab. The most commonly reported adverse events through week 48 were infections (48% of patients treated with golimumab with or without MTX and 41% of patients receiving placebo plus MTX).Conclusion. The primary end point was not met. However, intravenously administered golimumab plus MTX appears to have benefit in the longer-term reduction of RA signs/symptoms in MTX-resistant patients, with no unexpected safety. . .
ACCESSION NUMBER: 2010:425724 BIOSIS Full-text
DOCUMENT NUMBER: PREV201000425724
TITLE: Golimumab, a New Human Anti-Tumor Necrosis Factor alpha Antibody, Administered Intravenously in Patients With Active Rheumatoid Arthritis Forty-Eight-Week Efficacy and Safety Results of a Phase III Randomized, Double-Blind, Placebo-Controlled Study.
AUTHOR(S): Kremer, Joel [Reprint Author]; Ritchlin, Christopher; Mendelsohn, Alan; Baker, Daniel; Kim, Lilianne; Xu, Zhenhua; Han, John; Taylor, Peter
CORPORATE SOURCE: Ctr Rheumatol, 1367 Washington Ave, Albany, NY 12206 USA jkremer@joint-docs.com
SOURCE: Arthritis & Rheumatism, (APR 2010) Vol. 62, No. 4, pp. 917-928. http://onlinelibrary.wiley.com/journal/10.1002/(ISSN)1529-0131.
CODEN: ARHEAW. ISSN: 0004-3591. E-ISSN: 1529-0131.
DIGITAL OBJECT ID: 10.1002/art.27348
DOCUMENT TYPE: Article
LANGUAGE: English
ENTRY DATE: Entered STN: 28 Jul 2010
Last Updated on STN: 9 Sep 2020

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=> s l10 and ankylosisng

L15          0 L10 AND ANKYLOSISNG

=> s l10 and ankylosing

L16          1 L10 AND ANKYLOSING

=> d l16 ti so py kwic ibib


L16  ANSWER 1 OF 1  CAPLUS  COPYRIGHT 2023 ACS on STN
TI   Safety and efficacy of Golimumab administered intravenously in adults with
     ankylosing spondylitis: results through week 28 of the GO-ALIVE study
SO   Journal of Rheumatology (2018), 45(3), 341-349
     CODEN: JRHUA9; ISSN: 1499-2752
PY   2018
TI   Safety and efficacy of Golimumab administered intravenously in adults with
     ankylosing spondylitis: results through week 28 of the GO-ALIVE study
AB   Objective.To evaluate the safety and efficacy of i.v. golimumab (GOL) in
     patients with active ankylosing spondylitis (AS).  Methods.In a phase
     III, randomized, double-blind, placebo (PBO)-controlled trial, 208
     patients were randomized (1:1) to i.v. (IV) infusions.  .  .  Assessment
     of Spondyloarthritis International Society Criteria (ASAS20) at Week 16.
     Secondary endpoints included ASAS40, ≥ 50% improvement in the Bath
     Ankylosing Spondylitis Disease Activity Index (BASDAI50), and change in
     the Bath Ankylosing Spondylitis Functional Index (BASFI) at Week 16.
     Safety was monitored through Week 28.  Results.Significantly greater
     proportions of GOL-treated patients had.  .  .
ST   ankylosing spondylitis nasopharyngitis golimumab adalimumab certolizumab
     etanercept CRP pharmacokinetics
IT   Ankylosing spondylitis
     Blood serum
     Diagnosis
     Homo sapiens
     Human
     Inflammation
     Metabolic side effects of drugs
     Nasopharyngitis
     Pharmaceutical intravenous infusions
     Pharmacokinetics
     Upper respiratory infection
        (safety and efficacy of golimumab administered i.v. in adults
        with ankylosing spondylitis)
IT   C-reactive protein
     Tumor necrosis factors
     RL: BSU (Biological study, unclassified); BIOL (Biological study)
        (safety and efficacy of golimumab administered i.v. in adults with
        ankylosing spondylitis)
IT   9000-86-6, Alanine aminotransferase   9000-97-9, Aspartate
     aminotransferase
     RL: BSU (Biological study, unclassified); BIOL (Biological study)
        (safety and efficacy of golimumab administered i.v. in adults with
        ankylosing spondylitis)
IT   59-05-2   170277-31-3   185243-69-0   331731-18-1   428863-50-7
     476181-74-5
     RL: THU (Therapeutic use); BIOL (Biological study); USES (Uses)
        (safety and efficacy of golimumab administered i.v. in adults with
        ankylosing spondylitis)
ACCESSION NUMBER:         2019:192315  CAPLUS Full-text
DOCUMENT NUMBER:          174:574693
TITLE:                    Safety and efficacy of Golimumab administered
                          intravenously in adults with ankylosing spondylitis:
                          results through week 28 of the GO-ALIVE study
AUTHOR(S):                Deodhar, Atul; Reveille, John D.; Harrison, Diane D.;
                          Kim, Lilianne; Lo, Kim Hung; Leu, Jocelyn H.; Hsia,
                          Elizabeth C.
CORPORATE SOURCE:         Oregon Health & Science University, Portland, OR, USA
SOURCE:                   Journal of Rheumatology (2018), 45(3), 341-349
                          CODEN: JRHUA9; ISSN: 1499-2752
DIGITAL OBJECT ID:        10.3899/jrheum.170487
PUBLISHER:                Journal of Rheumatology Publishing Co. Ltd.
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LANGUAGE:                English
OS.CITING REF COUNT:     14    THERE ARE 14 CAPLUS RECORDS THAT CITE THIS
                               RECORD (14 CITINGS)
REFERENCE COUNT:         28    THERE ARE 28 CITED REFERENCES AVAILABLE FOR THIS
                               RECORD. ALL CITATIONS AVAILABLE IN THE RE FORMAT


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     (FILE 'HOME' ENTERED AT 10:57:49 ON 27 JUL 2023)

     FILE 'CAPLUS, BIOSIS, MEDLINE' ENTERED AT 10:58:04 ON 27 JUL 2023
                  E HARRISON DIANE D/AU
L1             66 S E3
                  E HSIA ELIZABETH C/AU
L2            223 S E15
                  E KIM LEE LIAN/AU
L3             18 S E27
                  E LO KIM HUNG/AU
L4        1594193 S 39
L5            106 S E39
L6            314 S L1-3 OR L5
L7           5841 S GOLIMUMAB
L8          60379 S INTRAVENOUS (W) INFUSION
L9             10 S L7 (L) L8
L10             9 DUP REM L9 (1 DUPLICATE REMOVED)
L11             0 S 2 MG/KG
L12          1350 S MG PER KILOGRAM
L13             0 S L10 (L) L12
L14             2 S L6 AND L10
L15             0 S L10 AND ANKYLOSISNG
L16             1 S L10 AND ANKYLOSING

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PE2E SEARCH - Search History (Prior Art)

Ref #	Hits	Search Query	DBs	Default Operator	Plurals	British Equivalents	Time Stamp
L97	151	("0000030" OR "0000059" OR "0000088" OR "0000116" OR "0000144" OR "20090214528" OR "20100251099" OR "20110251099" 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 "4757506" 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 "5116964" 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	(US-PGPUB; USPAT)	OR	ON	ON	2023/07/27 10:40 AM

		"5403484" OR "5404871" OR "5427908" OR "5447851" OR "5455030" OR "5458135" OR "5496549" OR "5512544" OR "5514670" OR "5518889" OR "5530101" OR "5534621" OR "5545807" OR "5565362" 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 "5698419" OR "5698435" OR "5714352" OR "5723323" OR "5733761" OR "5750105" OR "5750373" OR "5763192" OR "5763733" OR "5766886" OR "5770198" OR "5770222" OR "5770359" OR "5770428" OR "5789650" OR "5807706" OR "5814476" OR "5814599" OR					

		"5817483" OR "5821333" OR "5824514" OR "5827690" OR "5827739" OR "5833985" OR "5837500" OR "5839446" OR "5849695" OR "5851198" OR "5856456" OR "5871753" OR "5879681" OR "5885793" OR "5888511" OR "5919452" OR "5932448" OR "5958413" OR "5959083" OR "5959084" OR "5962255" OR "5976862" OR "5989530" OR "5993833" OR "5994616" OR "6010902" 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.					
L98	2	L1 AND golimumab	(US-PGPUB; USPAT)	OR	ON	ON	2023/07/27 10:40 AM
L99	1	L1 AND golimumab AND ankylosing	(US-PGPUB; USPAT)	OR	ON	ON	2023/07/27 10:40 AM
L100	2	L1 AND golimumab AND arthritis	(US-PGPUB; USPAT)	OR	ON	ON	2023/07/27 10:40 AM
L101	2	L1 AND golimumab AND spondylitis	(US-PGPUB; USPAT)	OR	ON	ON	2023/07/27 10:40 AM
L102	3695	golimumab AND spondylitis	(US-PGPUB; USPAT)	OR	ON	ON	2023/07/27 10:40 AM
L103	3610	golimumab AND spondylitis AND ankylosing	(US-PGPUB; USPAT)	OR	ON	ON	2023/07/27 10:40 AM
L104	144	golimumab AND spondylitis ADJ ankylosing	(US-PGPUB; USPAT)	OR	ON	ON	2023/07/27 10:40 AM

L105	68	golimumab AND spondylitis ADJ ankylosing AND @ay<"2018"	(US-PGPUB; USPAT)	OR	ON	ON	2023/07/27 10:40 AM
L106	1	golimumab SAME spondylitis ADJ ankylosing AND @ay<"2018"	(US-PGPUB; USPAT)	OR	ON	ON	2023/07/27 10:40 AM
L107	1	(golimumab OR (Cnto NEAR "148")) SAME spondylitis ADJ ankylosing AND @ay<"2018"	(US-PGPUB; USPAT)	OR	ON	ON	2023/07/27 10:40 AM
L108	9	(golimumab OR (Cnto NEAR "148")) ADJ ankylosing ADJ spondylitis	(US-PGPUB; USPAT)	OR	ON	ON	2023/07/27 10:40 AM
L109	892	(golimumab OR (Cnto NEAR "148")).clm.	(US-PGPUB; USPAT)	OR	ON	ON	2023/07/27 10:40 AM
L110	351	(golimumab OR (Cnto NEAR "148")).clm. AND spondylitis	(US-PGPUB; USPAT)	OR	ON	ON	2023/07/27 10:40 AM
L111	342	(golimumab OR (Cnto NEAR "148")).clm. AND ankylosing ADJ spondylitis	(US-PGPUB; USPAT)	OR	ON	ON	2023/07/27 10:40 AM
L112	173	(golimumab OR (Cnto NEAR "148")).clm. AND ankylosing ADJ spondylitis AND @ay<"2017"	(US-PGPUB; USPAT)	OR	ON	ON	2023/07/27 10:40 AM
L113	110	(golimumab OR (Cnto NEAR "148")).clm. AND ankylosing ADJ spondylitis AND @ay<"2017" AND methotrexate	(US-PGPUB; USPAT)	OR	ON	ON	2023/07/27 10:40 AM
L114	113	(golimumab OR (Cnto NEAR "148")).clm. AND ankylosing ADJ spondylitis AND @ay<"2017" AND (methotrexate OR sulfasalazine OR hydroxychloroquine)	(US-PGPUB; USPAT)	OR	ON	ON	2023/07/27 10:40 AM
L115	1	(golimumab OR (Cnto NEAR "148")) SAME infusion SAME (over NEAR time)	(US-PGPUB; USPAT)	OR	ON	ON	2023/07/27 10:40 AM
L116	268	(golimumab OR (Cnto NEAR "148")) SAME infusion	(US-PGPUB; USPAT)	OR	ON	ON	2023/07/27 10:40 AM
L117	14	(golimumab OR (Cnto NEAR "148")) SAME	(US-PGPUB; USPAT)	OR	ON	ON	2023/07/27 10:40 AM

		(rate NEAR infusion)					
L118	955	antibody SAME (rate NEAR infusion)	(US-PGPUB; USPAT)	OR	ON	ON	2023/07/27 10:40 AM
L119	186	antibody SAME infusion SAME rate SAME over NEAR period	(US-PGPUB; USPAT)	OR	ON	ON	2023/07/27 10:40 AM
L120	1	anti-tnf SAME antibody SAME infusion SAME rate SAME over NEAR period	(US-PGPUB; USPAT)	OR	ON	ON	2023/07/27 10:40 AM
L121	4	anti-tnf AND antibody SAME infusion SAME rate SAME over NEAR period	(US-PGPUB; USPAT)	OR	ON	ON	2023/07/27 10:40 AM
L122	5260	anti-tnf AND antibody SAME infusion	(US-PGPUB; USPAT)	OR	ON	ON	2023/07/27 10:40 AM
L123	201	anti-tnf ADJ antibody SAME infusion	(US-PGPUB; USPAT)	OR	ON	ON	2023/07/27 10:40 AM
L124	909	Janssen ADJ Biotech ADJ Inc.asn.	(US-PGPUB; USPAT)	OR	ON	ON	2023/07/27 10:40 AM
L125	21	Harrison Diane D.in.	(US-PGPUB; USPAT)	ADJ	ON	ON	2023/07/27 10:40 AM
L126	18	Hsia Elizabeth C.in.	(US-PGPUB; USPAT)	ADJ	ON	ON	2023/07/27 10:40 AM
L127	12	Kim Lee-Lian.in.	(US-PGPUB; USPAT)	ADJ	ON	ON	2023/07/27 10:40 AM
L128	13	Lo Kim Hung.in.	(US-PGPUB; USPAT)	ADJ	ON	ON	2023/07/27 10:40 AM
L129	1103	L27 L29 L30 L31 L32 L34	(US-PGPUB; USPAT)	OR	ON	ON	2023/07/27 10:40 AM
L130	104	L35 AND golimumab	(US-PGPUB; USPAT)	OR	ON	ON	2023/07/27 10:40 AM
L131	10	L35 AND golimumab.clm.	(US-PGPUB; USPAT)	OR	ON	ON	2023/07/27 10:40 AM
L132	3544	c07k16/241.cpc.	(US-PGPUB; USPAT)	OR	ON	ON	2023/07/27 10:40 AM
L133	15566	a61k39/3955.cpc.	(US-PGPUB; USPAT)	OR	ON	ON	2023/07/27 10:40 AM
L134	54874	a61p19/02.cpc.	(US-PGPUB; USPAT)	OR	ON	ON	2023/07/27 10:40 AM
L135	69746	L38 OR L39 L40	(US-PGPUB; USPAT)	OR	ON	ON	2023/07/27 10:40 AM
L136	117	L41 AND golimumab AND spondilitis	(US-PGPUB; USPAT)	OR	ON	ON	2023/07/27 10:40 AM
L137	23	L41 AND golimumab AND spondilitis.clm.	(US-PGPUB; USPAT)	OR	ON	ON	2023/07/27 10:40 AM
L138	60	golimumab AND spondylitis ADJ ankylosing AND @ay<"2018" AND infusion	(US-PGPUB; USPAT)	OR	ON	ON	2023/07/27 10:40 AM

L139	117	2009/0123378 AND administration AND iv	(US-PGPUB; USPAT)	OR	ON	ON	2023/07/27 10:40 AM
L140	1	"20090123378".pn. AND administration AND iv	(US-PGPUB; USPAT)	OR	ON	ON	2023/07/27 10:40 AM
L141	1	"20090123378".pn. AND administration AND intraven$5	(US-PGPUB; USPAT)	OR	ON	ON	2023/07/27 10:40 AM
L142	151	("0000030" OR "0000059" OR "0000088" OR "0000116" OR "0000144" OR "20090214528" OR "20100251099" OR "20110251099" 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 "4757506" 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 "5116964" OR "5122464" OR "5130238" OR "5142033" OR "5149636" OR "5168062" OR "5179017" OR "5223409" OR "5225538" OR "5225539" OR "5231024" OR "5260203" OR	(US-PGPUB; USPAT)	OR	ON	ON	2023/07/27 10:40 AM

		"5266491" OR "5304489" OR "5342613" OR "5385839" OR "5403484" OR "5404871" OR "5427908" OR "5447851" OR "5455030" OR "5458135" OR "5496549" OR "5512544" OR "5514670" OR "5518889" OR "5530101" OR "5534621" OR "5545807" OR "5565362" 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 "5698419" OR "5698435" OR "5714352" OR "5723323" OR "5733761" OR "5750105" OR "5750373" OR "5763192" OR "5763733" OR "5766886" OR "5770198" OR "5770222" OR "5770359" OR "5770428" OR					

		"5789650" OR "5807706" OR "5814476" OR "5814599" OR "5817483" OR "5821333" OR "5824514" OR "5827690" OR "5827739" OR "5833985" OR "5837500" OR "5839446" OR "5849695" OR "5851198" OR "5856456" OR "5871753" OR "5879681" OR "5885793" OR "5888511" OR "5919452" OR "5932448" OR "5958413" OR "5959083" OR "5959084" OR "5962255" OR "5976862" OR "5989530" OR "5993833" OR "5994616" OR "6010902" 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.					
L143	2	("0000030" OR "0000059" OR "0000088" OR "0000116" OR "0000144" OR "20090214528" OR "20100251099" OR "20110251099" OR "3773919" OR "4239754" OR "4309989" OR "4399216" OR "4603106" OR "4634665" OR	(US-PGPUB; USPAT)	OR	ON	ON	2023/07/27 10:40 AM

		"4656134" OR "4668218" OR "4676980" OR "4683195" OR "4683202" OR "4704692" OR "4757506" 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 "5116964" 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 "5404871" OR "5427908" OR "5447851" OR "5455030" OR "5458135" OR "5496549" OR "5512544" OR "5514670" OR "5518889" OR "5530101" OR "5534621" OR "5545807" OR "5565362" 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 "5698419" OR "5698435" OR "5714352" OR "5723323" OR "5733761" OR "5750105" OR "5750373" OR "5763192" OR "5763733" OR "5766886" OR "5770198" OR "5770222" OR "5770359" OR "5770428" OR "5789650" OR "5807706" OR "5814476" OR "5814599" OR "5817483" OR "5821333" OR "5824514" OR "5827690" OR "5827739" OR "5833985" OR "5837500" OR "5839446" OR "5849695" OR "5851198" OR "5856456" OR "5871753" OR "5879681" OR "5885793" OR "5888511" OR "5919452" OR "5932448" OR "5958413" OR "5959083" OR					

		"5959084" OR "5962255" OR "5976862" OR "5989530" OR "5993833" OR "5994616" OR "6010902" 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 golimumab					
L144	151	("0000030" OR "0000059" OR "0000088" OR "0000116" OR "0000144" OR "20090214528" OR "20100251099" OR "20110251099" 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 "4757506" 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	(US-PGPUB; USPAT)	OR	ON	ON	2023/07/27 10:40 AM

		"5066584" OR "5116964" 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 "5404871" OR "5427908" OR "5447851" OR "5455030" OR "5458135" OR "5496549" OR "5512544" OR "5514670" OR "5518889" OR "5530101" OR "5534621" OR "5545807" OR "5565362" 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 "5698419" OR					

		"5698435" OR "5714352" OR "5723323" OR "5733761" OR "5750105" OR "5750373" OR "5763192" OR "5763733" OR "5766886" OR "5770198" OR "5770222" OR "5770359" OR "5770428" OR "5789650" OR "5807706" OR "5814476" OR "5814599" OR "5817483" OR "5821333" OR "5824514" OR "5827690" OR "5827739" OR "5833985" OR "5837500" OR "5839446" OR "5849695" OR "5851198" OR "5856456" OR "5871753" OR "5879681" OR "5885793" OR "5888511" OR "5919452" OR "5932448" OR "5958413" OR "5959083" OR "5959084" OR "5962255" OR "5976862" OR "5989530" OR "5993833" OR "5994616" OR "6010902" 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.					
L145	2	L1 AND golimumab	(US-PGPUB; USPAT)	OR	ON	ON	2023/07/27

							10:40 AM
L146	1	L1 AND golimumab AND ankylosing	(US-PGPUB; USPAT)	OR	ON	ON	2023/07/27 10:40 AM
L147	2	L1 AND golimumab AND arthritis	(US-PGPUB; USPAT)	OR	ON	ON	2023/07/27 10:40 AM
L148	2	L1 AND golimumab AND spondylitis	(US-PGPUB; USPAT)	OR	ON	ON	2023/07/27 10:40 AM
L149	3695	golimumab AND spondylitis	(US-PGPUB; USPAT)	OR	ON	ON	2023/07/27 10:40 AM
L150	3610	golimumab AND spondylitis AND ankylosing	(US-PGPUB; USPAT)	OR	ON	ON	2023/07/27 10:40 AM
L151	144	golimumab AND spondylitis ADJ ankylosing	(US-PGPUB; USPAT)	OR	ON	ON	2023/07/27 10:40 AM
L152	68	golimumab AND spondylitis ADJ ankylosing AND @ay<"2018"	(US-PGPUB; USPAT)	OR	ON	ON	2023/07/27 10:40 AM
L153	1	golimumab SAME spondylitis ADJ ankylosing AND @ay<"2018"	(US-PGPUB; USPAT)	OR	ON	ON	2023/07/27 10:40 AM
L154	1	(golimumab OR (Cnto NEAR "148")) SAME spondylitis ADJ ankylosing AND @ay<"2018"	(US-PGPUB; USPAT)	OR	ON	ON	2023/07/27 10:40 AM
L155	9	(golimumab OR (Cnto NEAR "148")) ADJ ankylosing ADJ spondylitis	(US-PGPUB; USPAT)	OR	ON	ON	2023/07/27 10:40 AM
L156	892	(golimumab OR (Cnto NEAR "148")).clm.	(US-PGPUB; USPAT)	OR	ON	ON	2023/07/27 10:40 AM
L157	351	(golimumab OR (Cnto NEAR "148")).clm. AND spondylitis	(US-PGPUB; USPAT)	OR	ON	ON	2023/07/27 10:40 AM
L158	342	(golimumab OR (Cnto NEAR "148")).clm. AND ankylosing ADJ spondylitis	(US-PGPUB; USPAT)	OR	ON	ON	2023/07/27 10:40 AM
L159	173	(golimumab OR (Cnto NEAR "148")).clm. AND ankylosing ADJ spondylitis AND @ay<"2017"	(US-PGPUB; USPAT)	OR	ON	ON	2023/07/27 10:40 AM
L160	110	(golimumab OR (Cnto NEAR "148")).clm. AND ankylosing ADJ spondylitis AND @ay<"2017" AND methotrexate	(US-PGPUB; USPAT)	OR	ON	ON	2023/07/27 10:40 AM
L161	113	(golimumab OR (Cnto	(US-PGPUB; USPAT)	OR	ON	ON	2023/07/27

		NEAR "148")).clm. AND ankylosing ADJ spondylitis AND @ay<"2017" AND (methotrexate OR sulfasalazine OR hydroxychloroquine)					10:40 AM
L162	1	(golimumab OR (Cnto NEAR "148")) SAME infusion SAME (over NEAR time)	(US-PGPUB; USPAT)	OR	ON	ON	2023/07/27 10:40 AM
L163	268	(golimumab OR (Cnto NEAR "148")) SAME infusion	(US-PGPUB; USPAT)	OR	ON	ON	2023/07/27 10:40 AM
L164	14	(golimumab OR (Cnto NEAR "148")) SAME (rate NEAR infusion)	(US-PGPUB; USPAT)	OR	ON	ON	2023/07/27 10:40 AM
L165	955	antibody SAME (rate NEAR infusion)	(US-PGPUB; USPAT)	OR	ON	ON	2023/07/27 10:40 AM
L166	186	antibody SAME infusion SAME rate SAME over NEAR period	(US-PGPUB; USPAT)	OR	ON	ON	2023/07/27 10:40 AM
L167	1	anti-tnf SAME antibody SAME infusion SAME rate SAME over NEAR period	(US-PGPUB; USPAT)	OR	ON	ON	2023/07/27 10:40 AM
L168	4	anti-tnf AND antibody SAME infusion SAME rate SAME over NEAR period	(US-PGPUB; USPAT)	OR	ON	ON	2023/07/27 10:40 AM
L169	5260	anti-tnf AND antibody SAME infusion	(US-PGPUB; USPAT)	OR	ON	ON	2023/07/27 10:40 AM
L170	201	anti-tnf ADJ antibody SAME infusion	(US-PGPUB; USPAT)	OR	ON	ON	2023/07/27 10:40 AM
L171	909	Janssen ADJ Biotech ADJ Inc.asn.	(US-PGPUB; USPAT)	OR	ON	ON	2023/07/27 10:40 AM
L172	21	Harrison Diane D.in.	(US-PGPUB; USPAT)	ADJ	ON	ON	2023/07/27 10:40 AM
L173	18	Hsia Elizabeth C.in.	(US-PGPUB; USPAT)	ADJ	ON	ON	2023/07/27 10:40 AM
L174	12	Kim Lee-Lian.in.	(US-PGPUB; USPAT)	ADJ	ON	ON	2023/07/27 10:40 AM
L175	13	Lo Kim Hung.in.	(US-PGPUB; USPAT)	ADJ	ON	ON	2023/07/27 10:40 AM
L176	1103	L27 L29 L30 L31 L32 L34	(US-PGPUB; USPAT)	OR	ON	ON	2023/07/27 10:40 AM
L177	104	L35 AND golimumab	(US-PGPUB; USPAT)	OR	ON	ON	2023/07/27 10:40 AM
L178	10	L35 AND golimumab.clm.	(US-PGPUB; USPAT)	OR	ON	ON	2023/07/27 10:40 AM
L179	3544	c07k16/241.cpc.	(US-PGPUB; USPAT)	OR	ON	ON	2023/07/27 10:40 AM

L180	15566	a61k39/3955.cpc.	(US-PGPUB; USPAT)	OR	ON	ON	2023/07/27 10:40 AM
L181	54874	a61p19/02.cpc.	(US-PGPUB; USPAT)	OR	ON	ON	2023/07/27 10:40 AM
L182	69746	L38 OR L39 L40	(US-PGPUB; USPAT)	OR	ON	ON	2023/07/27 10:40 AM
L183	117	L41 AND golimumab AND spondilitis	(US-PGPUB; USPAT)	OR	ON	ON	2023/07/27 10:40 AM
L184	23	L41 AND golimumab AND spondilitis.clm.	(US-PGPUB; USPAT)	OR	ON	ON	2023/07/27 10:40 AM
L185	60	golimumab AND spondylitis ADJ ankylosing AND @ay<"2018" AND infusion	(US-PGPUB; USPAT)	OR	ON	ON	2023/07/27 10:40 AM
L186	117	2009/0123378 AND administration AND iv	(US-PGPUB; USPAT)	OR	ON	ON	2023/07/27 10:40 AM
L187	1	"20090123378".pn. AND administration AND iv	(US-PGPUB; USPAT)	OR	ON	ON	2023/07/27 10:40 AM
L188	1	"20090123378".pn. AND administration AND intraven$5	(US-PGPUB; USPAT)	OR	ON	ON	2023/07/27 10:40 AM
L189	151	("0000030" OR "0000059" OR "0000088" OR "0000116" OR "0000144" OR "20090214528" OR "20100251099" OR "20110251099" 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 "4757506" OR "4766067" OR "4767402" OR "4795699" OR "4800159" OR "4816567" OR "4822776" OR "4873316" OR "4889818" OR "4921794" OR "4925673" OR "4939666" OR	(US-PGPUB; USPAT)	OR	ON	ON	2023/07/27 10:40 AM

		"4946778" OR "4956288" OR "4965188" OR "4994370" OR "5066584" OR "5116964" 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 "5404871" OR "5427908" OR "5447851" OR "5455030" OR "5458135" OR "5496549" OR "5512544" OR "5514670" OR "5518889" OR "5530101" OR "5534621" OR "5545807" OR "5565362" 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 "5698419" OR "5698435" OR "5714352" OR "5723323" OR "5733761" OR "5750105" OR "5750373" OR "5763192" OR "5763733" OR "5766886" OR "5770198" OR "5770222" OR "5770359" OR "5770428" OR "5789650" OR "5807706" OR "5814476" OR "5814599" OR "5817483" OR "5821333" OR "5824514" OR "5827690" OR "5827739" OR "5833985" OR "5837500" OR "5839446" OR "5849695" OR "5851198" OR "5856456" OR "5871753" OR "5879681" OR "5885793" OR "5888511" OR "5919452" OR "5932448" OR "5958413" OR "5959083" OR "5959084" OR "5962255" OR "5976862" OR "5989530" OR "5993833" OR "5994616" OR "6010902" 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.					
L190	2	("0000030" OR "0000059" OR "0000088" OR "0000116" OR "0000144" OR "20090214528" OR "20100251099" OR "20110251099" 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 "4757506" 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 "5116964" 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)	OR	ON	ON	2023/07/27 10:40 AM

		"5404871" OR "5427908" OR "5447851" OR "5455030" OR "5458135" OR "5496549" OR "5512544" OR "5514670" OR "5518889" OR "5530101" OR "5534621" OR "5545807" OR "5565362" 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 "5698419" OR "5698435" OR "5714352" OR "5723323" OR "5733761" OR "5750105" OR "5750373" OR "5763192" OR "5763733" OR "5766886" OR "5770198" OR "5770222" OR "5770359" OR "5770428" OR "5789650" OR "5807706" OR "5814476" OR "5814599" OR "5817483" OR					

		"5821333" OR "5824514" OR "5827690" OR "5827739" OR "5833985" OR "5837500" OR "5839446" OR "5849695" OR "5851198" OR "5856456" OR "5871753" OR "5879681" OR "5885793" OR "5888511" OR "5919452" OR "5932448" OR "5958413" OR "5959083" OR "5959084" OR "5962255" OR "5976862" OR "5989530" OR "5993833" OR "5994616" OR "6010902" 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 golimumab					

PE2E SEARCH - Search History (Interference)

There are no Interference searches to show.

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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
17/237,650	04/22 2021	Diane D. Harrison	206389-0002-02US	8810

171672 7590 09/13/2023

Riverside Law LLP/J&J
175 Strafford Avenue
Suite 100
Wayne, PA 19087

EXAMINER
CHANDRA, GYAN

ART UNIT	PAPER NUMBER
1646	

NOTIFICATION DATE	DELIVERY MODE
09/13/2023	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):

I.Morozin@ITS.JNJ.COM
dcoccia@riversidelaw.com
dockets@riversidelaw.com

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

Application No. : 17237650
Applicant : Harrison
Filing Date : 04/22/2021
Date Mailed : 09/13/2023

NOTICE TO FILE CORRECTED APPLICATION PAPERS

Notice of Allowance Mailed

This application has been accorded an Allowance Date and is being prepared for issuance. The application, however, is incomplete for the reasons below.

Applicant is given two (2) months from the mail date of this Notice within which to respond. This time period for reply is extendable under 37 CFR 1.136(a) for only TWO additional MONTHS.

The informalities requiring correction are indicated in the attachment(s). If the informality pertains to the abstract, specification (including claims) or drawings, the informality must be corrected with an amendment in compliance with 37 CFR 1.121 (or, if the application is a reissue application, 37 CFR 1.173). Such an amendment may be filed after payment of the issue fee if limited to correction of informalities noted herein. See Waiver of 37 CFR 1.312 for Documents Required by the Office of Patent Publication, 1280 Off. Gaz. Patent Office 918 (March 23, 2004). In addition, if the informality is not corrected until after payment of the issue fee, for purposes of 35 U.S.C. 154(b)(1)(iv), "all outstanding requirements" will be considered to have been satisfied when the informality has been corrected. A failure to respond within the above-identified time period will result in the application being ABANDONED.

See attachment(s).

A copy of this notice MUST be returned with the reply. Please address response to "Mail Stop Issue Fee, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450".

/Kam Sin/
Publication Branch
Office of Data Management
(571) 272-4200

Application No. 17237650 **Drawings filed: 04/22/2021**

IDENTIFICATION OF DRAWING DEFICIENCIES

- [ ] There is a hole or the image thereof within the illustration. FIG(s)
- [ ] The illustration is penetrated or traversed by a solid or broken line that is not intended to be part of the drawing, such as a dark line caused by a flaw in the copying process. FIG(s)
- [ ] An ink stamp or the image thereof obscures part of the illustration. FIG(s)
- [ ] The drawing is marred by black smudges, obliterations, or fax/copier marks (for example, speckles or dots in a substantial portion of the drawing). FIG(s)
- [ ] Figure numbers are duplicated or missing. FIG(s)
- [ ] Drawing sheet or figure is missing. FIG(s)
- [ ] Numbers, letters, or reference characters in the drawing have been crossed out or are illegibly handwritten. FIG(s)
- [ ] The character of the lines, numbers, and letters is poor. FIG(s)
- [ ] The drawing's background shows that the original drawing was made on graph paper or other paper with a pattern or decoration. FIG(s)
- [ ] The FIG. number label is placed in a location that causes the drawing to be read upside down. FIG(s)
- [X] Data, a reference number, or part of the drawing is truncated or missing, or a lead line has no reference number. FIG(s) 6
- [ ] The drawing and/or the FIG. label contain(s) foreign language. FIG(s)
- [ ] This utility application contains a photograph of a view that is capable of being illustrated as a line drawing. FIG(s)
- [ ] A petition under 37 CFR 1.84(a)(2) to accept color drawings has been granted, but the brief description of the drawings in the specification does not contain (or has not been amended to contain) the paragraph required by 37 CFR 1.84(a)(2)(iii).
- [ ] This reissue application contains added and/or amended drawings that are not labeled as "New" or "Amended" or "Canceled" as required by 37 CFR 1.173(b)(3). FIG(s)
- [ ] This Design reissue application contains a drawing that is labeled as "Canceled" but is not surrounded by brackets, or a drawing that is surrounded by brackets but is not labeled as "Canceled." See 37 CFR 1.173(b)(3). FIG(s)
- [ ] OTHER:
- [ ] COMMENTS:

ELECTRONICALLY FILED

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Patent application of:
Diane D. Harrison, et al.

Group Art Unit: 1646
Confirmation No.: 8810

Application No.: 17/237,650

Examiner: Chandra, Gyan

Filed: April 22, 2021

Attorney Docket No.:
206389-0002-02US

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

AMENDMENT AND RESPONSE TO NOTICE TO FILE CORRECTED APPLICATION PAPERS

This Response serves to address the Notice to File Corrected Application Papers issued September 13, 2023, in connection with the above-referenced application. This Response is timely filed in view of the deadline for a timely response being to and through November 13, 2023.

This Response is accompanied by nineteen (19) Replacement Sheets of Drawings.

No fees are believed due in connection with this response. Please charge any fee that is due, or credit any overpayment, to Deposit Account No. 50-5366.

In the Drawings

Please replace the drawings on file with the accompanying nineteen (19) Replacement Sheets of Drawings.

REMARKS

In the Drawings

Accompanying this response are nineteen (19) Replacement Sheets of drawings, intended to replace the originally filed drawings on file in the application. Figure 6 has been amended to incorporate any truncated or missing parts.

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

Response to Notice

The Notice indicates that data, reference number, or part of the drawing is truncated or missing in Figure 6. Figure 6 has been amended to incorporate any truncated or missing parts. In response to the present Notice, Applicant submits that the presently filed amendments fully address the issues cited in the notice.

Summary

Applicant respectfully submits that the present amendments correct all deficiencies indicated in the Notice and have introduced no new matter.

Respectfully submitted,

Diane D. Harrison, et al.

October 18, 2023

By: /Pallab Singh/

Pallab Singh, Ph.D.
Registration No. 70,731
Riverside Law LLP
175 Strafford Ave, Suite 100
Wayne, PA 19087
(215) 268-3888 (main)
(215) 268-3871 (fax)
E-Mail: dockets@riversidelaw.com
Attorney for Applicants

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APPLICATION NO.	ISSUE DATE	PATENT NO.	ATTORNEY DOCKET NO.	CONFIRMATION NO.
17/237,650	01/02/2024	11858985	206389-0002-02US	8810

171672 7590 12/13/2023

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.

The USPTO is implementing electronic patent issuance with a transition period, during which period the USPTO will mail a ceremonial paper copy of the electronic patent grant to the correspondence address of record. Additional copies of the patent (i.e., certified and presentation copies) may be ordered for a fee from the USPTO's Certified Copy Center at https://certifiedcopycenter.uspto.gov/index.html. The Certified Copy Center may be reached at (800)972-6382.

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 59 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.

INVENTOR(s) (Please see PATENT CENTER site https://patentcenter.uspto.gov for additional inventors):

Diane D. Harrison, Philadelphia, PA;
Elizabeth C. Hsia, Kenneth Square, PA;
Lee-Lian Kim, North Wales, PA;
Kim Hung Lo, Exton, PA;

APPLICANT(s) (Please see PATENT CENTER site https://patentcenter.uspto.gov for additional applicants):

Janssen Biotech, Inc., Horsham, PA;

The United States represents the largest, most dynamic marketplace in the world and is an unparalleled location for business investment, innovation, and commercialization of new technologies. The USA offers tremendous resources and advantages for those who invest and manufacture goods here. Through SelectUSA, our nation works to encourage and facilitate business investment. To learn more about why the USA is the best country in the world to develop technology, manufacture products, and grow your business, visit SelectUSA.gov.

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PETITION TO WITHDRAW AN APPLICATION FROM ISSUE AFTER PAYMENT OF THE ISSUE FEE UNDER 37 CFR 1.313(c)(2) with Assigned Patent Number)

APPLICATION #	ATTORNEY DOCKET #	FILING DATE
17237650	206389-0002-02US	04/22/2021

Title of Invention

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

Application Information

CONFIRMATION #	8810	FILING DATE	04/22/2021
ART UNIT	1646	FIRST NAMED INVENTOR	Diane Harrison
EXAMINER	GYAN CHANDRA		

An application may be withdrawn from issue for further action upon petition by the applicant. To request that the Office withdraw an application from issue, applicant must file a petition under this section including the fee set forth in § 1.17(h) and a showing of good and sufficient reasons why withdrawal of the application from issue is necessary.

APPLICANT HEREBY PETITIONS TO WITHDRAW THIS APPLICATION FROM ISSUE UNDER 37 CFR 1.313(c).

A grantable petition requires the following items:

(1) Petition fee; and
(2) One of the following reasons: A grantable petition requires the following items: (a) Unpatentability of one or more claims, which must be accompanied by an unequivocal statement that one or more claims are unpatentable, an amendment to such claim or claims, and an explanation as to how the amendment causes such claim or claims to be patentable;
(b) Consideration of a request for continued examination in compliance with § 1.114 (for a utility or plant application only); or
(c) Express abandonment of the application. Such express abandonment may be in favor of a continuing application, but not a CPA under 37 CFR 1.53(d).

Reason for withdrawal

Consideration of a request for continued examination - RCE request, submission, and fee are attached

Applicant claims the following entity status

Regular Undiscounted

Signature

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 has been given power of attorney in this application

Signature	Name	Registration #
/Pallab Singh/	Pallab Singh	70731

UNITED STATES
PATENT AND TRADEMARK OFFICE

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

GRANT LETTER

APPLICATION #	DECISION DATE	DECISION ON PETITION #	ATTORNEY DOCKET NUMBER
17/237,650	12/21/2023	37 CFR 1.313(c)(2)	206389-0002-02US

Title of Invention

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

In re Application of Diane Harrison

This is an electronic decision on the petition under 37 CFR 1.313(c)(2), filed December 21, 2023 to withdraw the above-identified application from issue after payment of the issue fee.

The request is **GRANTED.**

The above-identified application is withdrawn from issue for consideration of a submission under 37 CFR 1.114 (request for continued examination). See 37 CFR 1.313(c)(2).

Petitioner is advised that the issue fee paid in this application cannot be refunded. If, however, this application is again allowed, petitioner may request that it be applied towards the issue fee required by the new Notice of Allowance.

The application is being referred to Technology Center AU for processing of the request for continuing examination under 37 CFR 1.114 .

Telephone inquired concerning this decision should be directed to the Patent Electronic Business Center (EBC) at 866-217-9197.

Office of Petitions

PTO/SB/08a (01-22)
Approved for use through 05/31/2024. OMB 0651-0031
U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number.

INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(Not for submission under 37 CFR 1.99)

Application Number	17237650
Filing Date	2021-04-22
First Named Inventor	Diane D. Harrison
Art Unit	1646
Examiner Name	Chandra, Gyan
Attorney Docket Number	206389-0002-02US

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Examiner Initial*	Cite No	Patent Number	Kind Code[1]	Issue Date	Name of Patentee or Applicant of cited Document	Pages,Columns,Lines where Relevant Passages or Relevant Figures Appear
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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]

INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Not for submission under 37 CFR 1.99)		
	Application Number	17237650
	Filing Date	2021-04-22
	First Named Inventor	Diane D. Harrison
	Art Unit	1646
	Examiner Name	Chandra, Gyan
	Attorney Docket Number	206389-0002-02US

	1	Zidi et al., 2010, "Golimumab Therapy of Rheumatoid Arthritis: An Overview." Scandinavian Journal of Immunology. 72, 75-85	☐
	2	Marichal-Gallardo et al., 2012, "State-of-the-art in downstream processing of monoclonal antibodies: process trends in design and validation." Biotechnol Prog. 28(4), 899-916	☐
	3	Chen et al., 2004 "Methotrexate for ankylosing spondylitis" Cochrane Database of Systematic Reviews, Issue 3. Art. No.: CD004524.	☐

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

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.

[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	17237650
	Filing Date	2021-04-22
	First Named Inventor	Diane D. Harrison
	Art Unit	1646
	Examiner Name	Chandra, Gyan
	Attorney Docket Number	206389-0002-02US

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)	2023-12-21
Name/Print	Pallab Singh	Registration Number	70,731

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 record s.

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.

PTO/SB/30EFS (01-22)
Approved for use through 05/31/2024. OMB 0651-0031
U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE
Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number.

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

Application Number	17/237,650	Filing Date	2021-04-22	Docket Number (if applicable)	206389-0002-02US	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

PTO/SB/30EFS (01-22)
Approved for use through 05/31/2024. OMB 0651-0031
U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE
Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number.

Signature of Registered U.S. Patent Practitioner			
Signature	/Pallab Singh/	Date (YYYY-MM-DD)	2023-12-21
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.

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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)).

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PTO/SB/08a (01-22)
Approved for use through 05/31/2024. OMB 0651-0031
U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number.

INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(Not for submission under 37 CFR 1.99)

Application Number	17237650
Filing Date	2021-04-22
First Named Inventor	Diane D. Harrison
Art Unit	1646
Examiner Name	CHANDRA, GYAN
Attorney Docket Number	206389-0002-02US

U.S.PATENTS Remove

Examiner Initial*	Cite No	Patent Number	Kind Code[1]	Issue Date	Name of Patentee or Applicant of cited Document	Pages,Columns,Lines where Relevant Passages or Relevant Figures Appear
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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]

INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Not for submission under 37 CFR 1.99)		
	Application Number	17237650
	Filing Date	2021-04-22
	First Named Inventor	Diane D. Harrison
	Art Unit	1646
	Examiner Name	CHANDRA, GYAN
	Attorney Docket Number	206389-0002-02US

	1	Johnson & Johnson, "New Phase 3 Data Show Simponi Aria® (Golimumab) Significantly Improved Signs And Symptoms In Patients With Active Ankylosing Spondylitis" 14 November 2016 (14-11-2016)	☐
	2	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.	☐

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

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.

[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	17237650
	Filing Date	2021-04-22
	First Named Inventor	Diane D. Harrison
	Art Unit	1646
	Examiner Name	CHANDRA, GYAN
	Attorney Docket Number	206389-0002-02US

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)	2024-03-06
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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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.

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INFORMATION DISCLOSURE STATEMENT BY APPLICANT

Application Number	17/237,650
Filing Date	04/22/2021
First Named Inventor	Diane D. Harrison
Art Unit	1646
Client Number	206389
Matter Number	0002-02US

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, nor is it intended to constitute an admission that such information is "analogous prior art".

In accordance with 37 C.F.R. 1.97(g), the filing of this Information Disclosure Statement shall not be construed to mean that a search has been made.

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 206389-0002-02US for any such charge or credit.

ADDITIONAL COMMENTS

SIGNATURE

Signature	/Pallab Singh/	**Date**	2024-03-06
Name	Pallab Singh	**Registration Number**	70731

UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

NOTICE OF ALLOWANCE AND FEE(S) DUE

171672 7590 03/13/2024

Riverside Law LLP/J&J
175 Strafford Avenue
Suite 100
Wayne, PA 19087

EXAMINER
CHANDRA, GYAN

ART UNIT	PAPER NUMBER
1646	

DATE MAILED: 03/13/2024

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
17/237,650	04/22/2021	Diane D. Harrison	206389-0002-02US	8810

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	$1200.00	$0	06/13/2024

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 03/13/2024
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.
17/237,650	04/22/2021	Diane D. Harrison	206389-0002-02US	8810

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	$1200.00	$0	06/13/2024

EXAMINER	ART UNIT	CLASS-SUBCLASS
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

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.

❑ Applicant asserting small entity status. See 37 CFR 1.27

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.

❑ Applicant changing to regular undiscounted fee 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.
17/237,650	04/22/2021	Diane D. Harrison	206389-0002-02US	8810

171672 7590 03/13/2024

Riverside Law LLP/J&J
175 Strafford Avenue
Suite 100
Wayne, PA 19087

EXAMINER	
CHANDRA, GYAN	
ART UNIT	PAPER NUMBER
1646	

DATE MAILED: 03/13/2024

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;
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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. 17/237,650	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 on 12/21/2023.
   ☐ 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 12/21/2023.
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 _____.

/GYAN CHANDRA/
Primary Examiner, Art Unit 1646

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 allowance. 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, prosecution in this application has been reopened pursuant to 37 CFR 1.114. Applicant's submission filed on 12/21/2023 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.

Information Disclosure Statement

The Information Disclosure Statement filed on 12/21/2023 has been considered.

EXAMINER'S COMMENT

Claims 11, 13-14, 16-18 and 20 were allowed (see NOA of 8/4/2023).

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

Search Notes	Application/Control No.	Applicant(s)/Patent Under Reexamination
	17/237,650	Harrison et al.
	Examiner	Art Unit
	GYAN CHANDRA	1646

CPC - Searched*		
Symbol	**Date**	**Examiner**
c07k16/241	02/29/2024	gc
a61k39/3955	02/29/2024	gc
a61p19/02	02/29/2024	gc

CPC Combination Sets - Searched*		
Symbol	**Date**	**Examiner**

US Classification - Searched*			
Class	**Subclass**	**Date**	**Examiner**
None	None	02/29/2024	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, 2, 3, 4, 5, 6 with substitutions (see search results in SCORE)	09/13/2022	gc
claims searched in CAPLUS, Biosis, Medline (see enclosed transcript)	02/29/2024	gc
claims searched in PE2E search (see enclosed doc)	02/29/2024	gc
Inventorship search in PE2E search (see enclosed doc)	02/29/2024	gc
Inventorship search in PALM	02/29/2024	gc

/GYAN CHANDRA/ Primary Examiner, Art Unit 1646	

Search Notes	Application/Control No.	Applicant(s)/Patent Under Reexamination
	17/237,650	Harrison et al.
	Examiner	Art Unit
	GYAN CHANDRA	1646

Interference Search			
US Class/CPC Symbol	US Subclass/CPC Group	Date	Examiner
C07K	16/241	02/29/2024	gc

/GYAN CHANDRA/ Primary Examiner, Art Unit 1646	

Issue Classification	Application/Control No.	Applicant(s)/Patent Under Reexamination
	17/237,650	Harrison et al.
	Examiner	**Art Unit**
	GYAN CHANDRA	1646

CPC						
Symbol					**Type**	**Version**
C07K	/	16	/	241	F	2013-01-01
A61K	/	9	/	0019	I	2013-01-01
A61K	/	39	/	3955	I	2013-01-01
A61K	/	31	/	519	I	2013-01-01
A61K	/	31	/	4402	I	2013-01-01
A61P	/	19	/	02	I	2018-01-01
A61K	/	31	/	4706	I	2013-01-01
A61K	/	2039	/	505	A	2013-01-01
C07K	/	2317	/	21	A	2013-01-01
C07K	/	2317	/	92	A	2013-01-01
C07K	/	2317	/	76	A	2013-01-01
A61K	/	2039	/	545	A	2013-01-01

CPC Combination Sets								
Symbol					**Type**	**Set**	**Ranking**	**Version**
	/		/					

NONE		**Total Claims Allowed:**	
(Assistant Examiner)	(Date)	7	
/GYAN CHANDRA/ Primary Examiner, Art Unit 1646	29 February 2024	O.G. Print Claim(s)	O.G. Print Figure
(Primary Examiner)	(Date)	1	None

U.S. Patent and Trademark Office — Part of Paper No.: 20240229

Issue Classification	Application/Control No.	Applicant(s)/Patent Under Reexamination
	17/237,650	Harrison et al.
	Examiner	**Art Unit**
	GYAN CHANDRA	1646

INTERNATIONAL CLASSIFICATION					
CLAIMED					
C07K	/	16	/	24	

NON-CLAIMED					
	/		/		

US ORIGINAL CLASSIFICATION	
CLASS	**SUBCLASS**
424	142.1

CROSS REFERENCES(S)						
CLASS	**SUBCLASS (ONE SUBCLASS PER BLOCK)**					

NONE (Assistant Examiner)	(Date)	**Total Claims Allowed:** 7	
/GYAN CHANDRA/ Primary Examiner, Art Unit 1646 (Primary Examiner)	29 February 2024 (Date)	O.G. Print Claim(s) 1	O.G. Print Figure None

U.S. Patent and Trademark Office — Part of Paper No.: 20240229

Issue Classification	Application/Control No.	Applicant(s)/Patent Under Reexamination
	17/237,650	Harrison et al.
	Examiner	**Art Unit**
	GYAN CHANDRA	1646

☑ Claims renumbered in the same order as presented by applicant ☐ CPA ☐ T.D. ☐ R.1.47

CLAIMS

Final	Original	Final	Original	Final	Original	Final	Original	Final	Original	Final	Original	Final	Original	Final	Original
	11														
	13														
	14														
	16														
	17														
	18														
	20														

NONE		**Total Claims Allowed:**	
(Assistant Examiner)	(Date)	7	
/GYAN CHANDRA/ Primary Examiner, Art Unit 1646	29 February 2024	O.G. Print Claim(s)	O.G. Print Figure
(Primary Examiner)	(Date)	1	None

```
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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 e3-4

L1           75 ("HARRISON DIANE D"/AU OR "HARRISON DIANE DEBORAH"/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 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
E24           1     HSIA FRANCES K/AU

=> s e14-15

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

```
=> 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         107 --> 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          28     LO KIN CHEUNG/AU

=> s e38-39

L4          111 ("LO KIM H"/AU OR "LO KIM HUNG"/AU)

=> s l1-4

L5          380 (L1 OR L2 OR L3 OR L4)

=> s golimumab

L6         6022 GOLIMUMAB

=> s l5 and l6

L7          186 L5 AND L6

=> s l7 and intravenous infusion

L8            2 L7 AND INTRAVENOUS INFUSION

=> d l8 1-2 ti so py kwic ibib


L8   ANSWER 1 OF 2  CAPLUS  COPYRIGHT 2024 ACS on STN
TI   Efficacy and safety of intravenous golimumab plus methotrexate in
     patients with rheumatoid arthritis aged < 65 years and those ≥ 65
     years of age
SO   Arthritis Research & Therapy (2019), 21(1), 1-9
     CODEN: ARTRCV; ISSN: 1478-6362
PY   2019
TI   Efficacy and safety of intravenous golimumab plus methotrexate in
     patients with rheumatoid arthritis aged < 65 years and those ≥ 65
     years of age
AU   Tesser, John; Kafka, Shelly; De Horatius, Raphael J.; Xu, Stephen; Hsia,
     Elisabeth C.; Turkiewicz, Anthony
AB   Objective: To evaluate the safety and efficacy of i.v. golimumab +
     methotrexate (MTX) in patients with active rheumatoid arthritis (RA) aged
     < 65 years and those ≥ 65 years who.  .  .  study.  Methods: In the
```

phase III, double-blind, randomized, placebo-controlled GO-FURTHER trial, patients with active RA were randomized to i.v. (IV) golimumab 2 mg/kg + MTX or placebo + MTX at weeks 0 and 4, then every 8 wk thereafter (with crossover to golimumab at week 16 [early escape] or week 24 [per-protocol]). The final golimumab infusion was at week 100. Assessments included American College of Rheumatol. (ACR) 20/50/70 response criteria. Efficacy and adverse events (AEs). . . patients < or ≥ 75 years. Results: In GO-FURTHER, 592 patients were randomized to receive placebo (n = 197) or golimumab (n = 395), 515 were aged < 65 years and 77 were ≥ 65 years. At week 24, ACR20 response rates were greater for golimumab + MTX patients compared with placebo + MTX for patients < 65 years (61.6% vs 31.3%, p < 0.001) and. . . ≥ 65 years within each treatment group. AEs in elderly patients were similar to the known safety profile of IV golimumab. Immunosenescence is known to increase the risk of infections in the elderly. Elderly patients had a numerically higher incidence of serious infections. Six malignancies occurred in golimumab-treated patients, all in patients < 65 years. Trial registration: clin. trials.gov: NCT00973479. Registered Sept. 9, 2009.

ST golimumab methotrexate antiarthritic agent rheumatoid arthritis age

IT Acute pancreatitis
Aging, animal
Antiarthritics
Basal cell carcinoma
Bone fracture
Bowen disease
Brain infarction
Cancer
Candida albicans
Cellulitis
Cholecystitis
Chronic lymphocytic leukemia
Clostridium difficile
Combination chemotherapy
Diverticulitis
Flushing
Hemorrhoid
Homo sapiens
Human
Hypertension
Interstitial lung disease
Mammary gland neoplasm
Mycosis
Myocardial infarction
Neoplasm
Pancreatitis
Pharmaceutical intravenous infusions
Pneumonia
Rheumatoid arthritis
Sepsis
Septic arthritis
Septic shock
Tuberculosis
Urinary system infection
Uterine cervical carcinoma
(efficacy and safety of i.v. golimumab plus methotrexate in patients with rheumatoid arthritis aged < 65 years and those greater than or equal to 65 years of age)

IT Corticosteroids
RL: BSU (Biological study, unclassified); BIOL (Biological study)
(efficacy and safety of i.v. golimumab plus methotrexate in patients with rheumatoid arthritis aged < 65 years and those greater than or equal to 65 years of age)

IT Abscess
(rectal; efficacy and safety of i.v. golimumab plus methotrexate in patients with rheumatoid arthritis aged < 65 years and those greater than or equal to 65 years of age)

IT 59-05-2, Methotrexate 476181-74-5, Golimumab
RL: PAC (Pharmacological activity); THU (Therapeutic use); BIOL (Biological study); USES (Uses)
(efficacy and safety of i.v. golimumab plus methotrexate in patients with rheumatoid arthritis aged < 65 years and those greater

than or equal to 65 years of age)
ACCESSION NUMBER: 2019:1636875 CAPLUS Full-text
DOCUMENT NUMBER: 174:901313
TITLE: Efficacy and safety of intravenous golimumab plus methotrexate in patients with rheumatoid arthritis aged < 65 years and those ≥ 65 years of age
AUTHOR(S): Tesser, John; Kafka, Shelly; De Horatius, Raphael J.; Xu, Stephen; Hsia, Elizabeth C.; Turkiewicz, Anthony
CORPORATE SOURCE: Arizona Arthritis and Rheumatology Associates, Phoenix, AZ, USA
SOURCE: Arthritis Research & Therapy (2019), 21(1), 1-9
CODEN: ARTRCV; ISSN: 1478-6362
DIGITAL OBJECT ID: 10.1186/s13075-019-1968-x
PUBLISHER: BioMed Central Ltd.
DOCUMENT TYPE: Journal; (online computer file)
LANGUAGE: English
REFERENCE COUNT: 29 THERE ARE 29 CITED REFERENCES AVAILABLE FOR THIS RECORD. ALL CITATIONS AVAILABLE IN THE RE FORMAT

L8 ANSWER 2 OF 2 CAPLUS COPYRIGHT 2024 ACS on STN
TI Safety and efficacy of Golimumab administered intravenously in adults with ankylosing spondylitis: results through week 28 of the GO-ALIVE study
SO Journal of Rheumatology (2018), 45(3), 341-349
CODEN: JRHUA9; ISSN: 1499-2752
PY 2018
TI Safety and efficacy of Golimumab administered intravenously in adults with ankylosing spondylitis: results through week 28 of the GO-ALIVE study
AU Deodhar, Atul; Reveille, John D.; Harrison, Diane D.; Kim, Lilianne; Lo, Kim Hung; Leu, Jocelyn H.; Hsia, Elizabeth C.
AB Objective.To evaluate the safety and efficacy of i.v. golimumab (GOL) in patients with active ankylosing spondylitis (AS). Methods.In a phase III, randomized, double-blind, placebo (PBO)-controlled trial, 208 patients were. . .
ST ankylosing spondylitis nasopharyngitis golimumab adalimumab certolizumab etanercept CRP pharmacokinetics
IT Ankylosing spondylitis
Blood serum
Diagnosis
Homo sapiens
Human
Inflammation
Metabolic side effects of drugs
Nasopharyngitis
Pharmaceutical intravenous infusions
Pharmacokinetics
Upper respiratory infection
(safety and efficacy of golimumab administered i.v. in adults with ankylosing spondylitis)
IT C-reactive protein
Tumor necrosis factors
RL: BSU (Biological study, unclassified); BIOL (Biological study)
(safety and efficacy of golimumab administered i.v. in adults with ankylosing spondylitis)
IT 9000-86-6, Alanine aminotransferase 9000-97-9, Aspartate aminotransferase
RL: BSU (Biological study, unclassified); BIOL (Biological study)
(safety and efficacy of golimumab administered i.v. in adults with ankylosing spondylitis)
IT 59-05-2 170277-31-3 185243-69-0 331731-18-1 428863-50-7 476181-74-5
RL: THU (Therapeutic use); BIOL (Biological study); USES (Uses)
(safety and efficacy of golimumab administered i.v. in adults with ankylosing spondylitis)
ACCESSION NUMBER: 2019:192315 CAPLUS Full-text
DOCUMENT NUMBER: 174:574693
TITLE: Safety and efficacy of Golimumab administered intravenously in adults with ankylosing spondylitis: results through week 28 of the GO-ALIVE study
AUTHOR(S): Deodhar, Atul; Reveille, John D.; Harrison, Diane D.; Kim, Lilianne; Lo, Kim Hung; Leu, Jocelyn H.; Hsia, Elizabeth C.
CORPORATE SOURCE: Oregon Health & Science University, Portland, OR, USA

SOURCE: Journal of Rheumatology (2018), 45(3), 341-349
CODEN: JRHUA9; ISSN: 1499-2752
DIGITAL OBJECT ID: 10.3899/jrheum.170487
PUBLISHER: Journal of Rheumatology Publishing Co. Ltd.
DOCUMENT TYPE: Journal; (online computer file)
LANGUAGE: English
OS.CITING REF COUNT: 17 THERE ARE 17 CAPLUS RECORDS THAT CITE THIS RECORD (17 CITINGS)
REFERENCE COUNT: 28 THERE ARE 28 CITED REFERENCES AVAILABLE FOR THIS RECORD. ALL CITATIONS AVAILABLE IN THE RE FORMAT

=> s l6 and intravenous infusion

L9 37 L6 AND INTRAVENOUS INFUSION

=> dup rem l9

PROCESSING COMPLETED FOR L9
L10 36 DUP REM L9 (1 DUPLICATE REMOVED)

=> s l6 (l) intravenous infusion

L11 10 L6 (L) INTRAVENOUS INFUSION

=> dup rem

ENTER L# LIST OR (END):l11

PROCESSING COMPLETED FOR L11
L12 9 DUP REM L11 (1 DUPLICATE REMOVED)

=> s l12 and 2 mg/kg

'KG' IS NOT A VALID FIELD CODE
'KG' IS NOT A VALID FIELD CODE
'KG' IS NOT A VALID FIELD CODE
L13 0 L12 AND 2 MG/KG

=> s l12 and mg/kg

'KG' IS NOT A VALID FIELD CODE
'KG' IS NOT A VALID FIELD CODE
'KG' IS NOT A VALID FIELD CODE
L14 0 L12 AND MG/KG

=> d l12 1-9 ti so py kwic ibib

L12 ANSWER 1 OF 9 CAPLUS COPYRIGHT 2024 ACS on STN
TI Materials and methods utilizing anti-tumor necrosis factor (TNF) antibodies, such as golimumab, for treating juvenile idiopathic arthritis
SO PCT Int. Appl., 239pp.
CODEN: PIXXD2
PY 2021
2021
2021
2022
2022
2023
2023
2023
2023
IT Antirheumatic agents
Child
Clinical trials, phase III
Combination chemotherapy
Homo sapiens
Human
Juvenile rheumatoid arthritis
Pharmaceutical intravenous infusions

Pharmaceutical intravenous injections
(materials and methods utilizing anti-tumor necrosis factor (TNF) antibodies, such as golimumab, for treating juvenile idiopathic arthritis)

ACCESSION NUMBER: 2021:2388140 CAPLUS Full-text
DOCUMENT NUMBER: 176:497569
TITLE: Materials and methods utilizing anti-tumor necrosis factor (TNF) antibodies, such as golimumab, for treating juvenile idiopathic arthritis
INVENTOR(S): Bensley, Karen; Clark, Michael; Leu, Jocelyn; Xu, Zhenhua
PATENT ASSIGNEE(S): Janssen Biotech, Inc., USA
ULTIMATE OWNER: JOHNSON & JOHNSON INC
ULTIMATE OWNER STANDARD: Johnson & Johnson
SOURCE: PCT Int. Appl., 239pp.
CODEN: PIXXD2
DOCUMENT TYPE: Patent
LANGUAGE: English
FAMILY ACC. NUM. COUNT: 1
PATENT INFORMATION:

PATENT NO.	KIND	DATE	APPLICATION NO.	DATE
WO 2021220140	A1	20211104	WO 2021-IB53429	20210426
CA 3127807	A1	20211027	CA 2021-3127807	20210426
US 20210340245	A1	20211104	US 2021-17240609	20210426
CN 115461365	A	20221209	CN 2021-80031397	20210426
BR 112022021766	A2	20221213	BR 2022-112022021766	20210426
AU 2021263136	A1	20230105	AU 2021-263136	20210426
KR 2023005284	A	20230109	KR 2022-7041143	20210426
EP 4143226	A1	20230308	EP 2021-797784	20210426
JP 2023524668	T	20230613	JP 2022-565551	20210426

PRIORITY APPLN. INFO.:

US 2020-63015889	P	20200427
US 2020-63015894	P	20200427
US 2020-63015902	P	20200427
WO 2021-IB53429	W	20210426

PATENT STATUS PATENT INFORMATION:

PATENT NO.	KIND	STATUS	STATUS DATE
WO 2021220140	A1	Alive	20211125
CA 3127807	A1	Alive	20211125
US 20210340245	A1	Alive	20231012
CN 115461365	A	Alive	20221215
BR 112022021766	A2	Alive	20221222
AU 2021263136	A1	Alive	20230112
KR 2023005284	A	Alive	20230126
EP 4143226	A1	Alive	20230309
JP 2023524668	T	Alive	20230629

ASSIGNMENT HISTORY FOR US PATENT AVAILABLE IN LSUS DISPLAY FORMAT
REFERENCE COUNT: 4 THERE ARE 4 CITED REFERENCES AVAILABLE FOR THIS RECORD. ALL CITATIONS AVAILABLE IN THE RE FORMAT

LINK INFORMATION

PUBLICATIONS	APPLICATIONS	REGISTER
AU 2021263136 A1	AU 2021-263136	Register
BR 112022021766 A2	BR 2022-112022021766	Register
CA 3127807 A1	CA 2021-3127807	Register
CN 115461365 A	CN 2021-80031397	Register|Global Dossier
EP 4143226 A1	EP 2021-797784	Register|Federated Reg.
JP 2023524668 T	JP 2022-565551	Register|Global Dossier
KR 2023005284 A	KR 2022-7041143	Register|Global Dossier
US 20210340245 A1	US 2021-17240609	Register|Global Dossier
WO 2021220140 A1	WO 2021-IB53429	Register|Global Dossier

L12 ANSWER 2 OF 9 MEDLINE ® on STN
TI Subcutaneous golimumab induced and maintained clinical response in a child with a biological-experienced steroid-refractory flare of ulcerative colitis: A case report.
SO Medicine, (2021 Sep 24) Vol. 100, No. 38, pp. e27283.
Journal code: 2985248R. E-ISSN: 1536-5964. L-ISSN: 0025-7974.
Report No.: PMC-PMC8462589.
PY 2021

AB INTRODUCTION: Golimumab is a fully human antitumor necrosis monoclonal antibody that can be administered by either subcutaneous injection or intravenous infusion. Golimumab is approved for the treatment of the adults with rheumatic diseases, and ulcerative colitis, Whereas in children, golimumab is indicated only for the treatment of active polyarticular juvenile idiopathic arthritis. We have written on the off-label use of subcutaneous golimumab, which helped to induce and maintain remission on a low-weight biologically experienced child with steroid-refractory ulcerative colitis flare.

PATIENT CONCERNS:. . . adalimumab were unavailable in Syria. Child's parents opposed colectomy as a treatment option.

DIAGNOSIS: Ulcerative colitis flare.

INTERVENTIONS: A subcutaneous golimumab with a loading dose of 200 mg at week 0, followed by 100 mg at week 2, then 50 mg. . . Pediatric Ulcerative Colitis Activity Index and Mayo scores were 5 and 2 points, respectively. No adverse events were documented.

CONCLUSION: Golimumab has shown potential efficacy and safety in the treatment of ulcerative colitis in children which may indicate a significant future role for subcutaneous golimumab in pediatrics ulcerative colitis.

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ACCESSION NUMBER: 2024612351 MEDLINE Full-text
DOCUMENT NUMBER: PubMed ID: 34559136
TITLE: Subcutaneous golimumab induced and maintained clinical response in a child with a biological-experienced steroid-refractory flare of ulcerative colitis: A case report.
AUTHOR: Alhalabi Marouf
AUTHOR IDENTIFIERS: ORCID: https://orcid.org/0000-0001-5027-2096
CORPORATE SOURCE: Gastroenterology Department, Damascus Hospital, Damascus, Syria.
AUTHOR: Eddin Kamal Alaa; Cheha Khaled; Abbas Ahmad
SOURCE: Medicine, (2021 Sep 24) Vol. 100, No. 38, pp. e27283. Journal code: 2985248R. E-ISSN: 1536-5964. L-ISSN: 0025-7974.
Report No.: PMC-PMC8462589.
DIGITAL OBJECT ID: http://dx.doi.org/10.1097/MD.0000000000027283
PUB. COUNTRY: United States
DOCUMENT TYPE: (CASE REPORTS)
Journal; Article; (JOURNAL ARTICLE)
LANGUAGE: English
FILE SEGMENT: MEDLINE; Priority Journals
FILE SEGMENT: Print
ENTRY MONTH: 202110
ENTRY DATE: Entered STN: 24 Sep 2021
Last Updated on STN: 3 Oct 2021
Indexing Added: 3 Oct 2021
Entered Medline: 1 Oct 2021
OS.CITING REF COUNT: 2 There are 2 MEDLINE records that cite this record
MEDLINE REFERENCE COUNT: 48 There are 48 cited references available in MEDLINE for this document.

L12 ANSWER 3 OF 9 BIOSIS COPYRIGHT (c) 2024 Clarivate Analytics on STN
TI Subcutaneous golimumab induced and maintained clinical response in a child with a biological-experienced steroid-refractory flare of ulcerative colitis A case report.
SO Medicine (Hagerstown), (SEP 24 2021) Vol. 100, No. 38, pp. Article No.: e27283. http://journals.lww.com/md-journal/pages/default.aspx.
CODEN: MEDIAV. ISSN: 0025-7974. E-ISSN: 1536-5964.
PY 2021
AB Introduction: Golimumab is a fully human antitumor necrosis monoclonal antibody that can be administered by either subcutaneous injection or intravenous infusion. Golimumab is approved for the treatment of the adults with rheumatic diseases, and ulcerative colitis, Whereas in children, golimumab is indicated only for the treatment of active polyarticular juvenile idiopathic arthritis. We have written on the off-label use of subcutaneous golimumab, which helped to induce and

maintain remission on a low-weight biologically experienced child with steroid-refractory ulcerative colitis flare.Patient concerns: A. . . tacrolimus, and adalimumab were unavailable in Syria. Child's parents opposed colectomy as a treatment option.Diagnosis: Ulcerative colitis flare.Interventions: A subcutaneous golimumab with a loading dose of 200 mg at week 0, followed by 100 mg at week 2, then 50 mg. . . The Pediatric Ulcerative Colitis Activity Index and Mayo scores were 5 and 2 points, respectively. No adverse events were documented.Conclusion: Golimumab has shown potential efficacy and safety in the treatment of ulcerative colitis in children which may indicate a significant future role for subcutaneous golimumab in pediatrics ulcerative colitis.

ACCESSION NUMBER: 2021:891956 BIOSIS Full-text
DOCUMENT NUMBER: PREV202100891956
TITLE: Subcutaneous golimumab induced and maintained clinical response in a child with a biological-experienced steroid-refractory flare of ulcerative colitis A case report.
AUTHOR(S): Alhalabi, Marouf [Reprint Author]; Eddin, Kemal Alaa; Cheha, Khaled; Abbas, Ahmad
CORPORATE SOURCE: Damascus Hosp, Almujtahed St, Damascus, Syria
e.marouf@hotmail.com
SOURCE: Medicine (Hagerstown), (SEP 24 2021) Vol. 100, No. 38, pp. Article No.: e27283.
http://journals.lww.com/md-journal/pages/default.aspx.
CODEN: MEDIAV. ISSN: 0025-7974. E-ISSN: 1536-5964.
DIGITAL OBJECT ID: 10.1097/MD.0000000000027283
DOCUMENT TYPE: Article
LANGUAGE: English
ENTRY DATE: Entered STN: 6 Oct 2021
Last Updated on STN: 6 Oct 2021

L12 ANSWER 4 OF 9 CAPLUS COPYRIGHT 2024 ACS on STN
TI Use of anti-TNF antibody, golimumab, in compositions and methods for treatment of polyarticular juvenile idiopathic arthritis
SO PCT Int. Appl., 238pp.
CODEN: PIXXD2
PY 2020
2020
2021
2021
2021
2021
2021
2022
2022
IT Antiarthritics
Child
Combination chemotherapy
Homo sapiens
Human
Juvenile rheumatoid arthritis
Passive immunotherapy
Pharmaceutical intravenous infusions
Protein sequences
Unit dose drug delivery systems
(use of anti-TNF antibody, golimumab, in compns. and methods for treatment of polyarticular juvenile idiopathic arthritis)
ACCESSION NUMBER: 2020:1420974 CAPLUS Full-text
DOCUMENT NUMBER: 173:275081
TITLE: Use of anti-TNF antibody, golimumab, in compositions and methods for treatment of polyarticular juvenile idiopathic arthritis
INVENTOR(S): Bensley, Karen; Clark, Michael; Leu, Jocelyn; Xu, Zhenhua
PATENT ASSIGNEE(S): Janssen Biotech, Inc., USA
ULTIMATE OWNER: JOHNSON & JOHNSON INC
ULTIMATE OWNER STANDARD: Johnson & Johnson
SOURCE: PCT Int. Appl., 238pp.
CODEN: PIXXD2
DOCUMENT TYPE: Patent
LANGUAGE: English
FAMILY ACC. NUM. COUNT: 1

PATENT INFORMATION:

PATENT NO.	KIND	DATE	APPLICATION NO.		DATE
WO 2020148651	A1	20200723	WO 2020-IB50266		20200114
CA 3126654	A1	20200723	CA 2020-3126654		20200114
AU 2020208828	A1	20210805	AU 2020-208828		20200114
KR 2021116540	A	20210927	KR 2021-7025727		20200114
CN 113574066	A	20211029	CN 2020-80021619		20200114
MX 2021008537	A	20211112	MX 2021-8537		20200114
EP 3911676	A1	20211124	EP 2020-701516		20200114
JP 2022518208	T	20220314	JP 2021-540796		20200114
US 20220153827	A1	20220519	US 2021-17423177		20210715
PRIORITY APPLN. INFO.:			US 2019-62792568	P	20190115
			US 2019-62820593	P	20190319
			US 2019-62899171	P	20190912
			WO 2020-IB50266	W	20200114

PATENT STATUS PATENT INFORMATION:

PATENT NO.	KIND	STATUS	STATUS DATE
WO 2020148651	A1	Dead	20230914
CA 3126654	A1	Alive	20210826
AU 2020208828	A1	Alive	20210812
KR 2021116540	A	Alive	20211118
CN 113574066	A	Alive	20211123
MX 2021008537	A	Alive	20230608
EP 3911676	A1	Alive	20211126
JP 2022518208	T	Alive	20220324
US 20220153827	A1	Alive	20220527

ASSIGNMENT HISTORY FOR US PATENT AVAILABLE IN LSUS DISPLAY FORMAT
REFERENCE COUNT: 6 THERE ARE 6 CITED REFERENCES AVAILABLE FOR THIS RECORD. ALL CITATIONS AVAILABLE IN THE RE FORMAT

LINK INFORMATION

PUBLICATIONS	APPLICATIONS	REGISTER
AU 2020208828 A1	AU 2020-208828	Register
CA 3126654 A1	CA 2020-3126654	Register
CN 113574066 A	CN 2020-80021619	Register|Global Dossier
EP 3911676 A1	EP 2020-701516	Register|Federated Reg.
JP 2022518208 T	JP 2021-540796	Register|Global Dossier
KR 2021116540 A	KR 2021-7025727	Register|Global Dossier
MX 2021008537 A	MX 2021-8537	Register
US 20220153827 A1	US 2021-17423177	Register|Global Dossier
WO 2020148651 A1	WO 2020-IB50266	Register|Global Dossier

L12 ANSWER 5 OF 9 CAPLUS COPYRIGHT 2024 ACS on STN
TI Efficacy and safety of intravenous golimumab plus methotrexate in patients with rheumatoid arthritis aged < 65 years and those ≥ 65 years of age
SO Arthritis Research & Therapy (2019), 21(1), 1-9
CODEN: ARTRCV; ISSN: 1478-6362
PY 2019
IT Acute pancreatitis
Aging, animal
Antiarthritics
Basal cell carcinoma
Bone fracture
Bowen disease
Brain infarction
Cancer
Candida albicans
Cellulitis
Cholecystitis
Chronic lymphocytic leukemia
Clostridium difficile
Combination chemotherapy
Diverticulitis
Flushing
Hemorrhoid
Homo sapiens
Human
Hypertension

Interstitial lung disease
Mammary gland neoplasm
Mycosis
Myocardial infarction
Neoplasm
Pancreatitis
Pharmaceutical intravenous infusions
Pneumonia
Rheumatoid arthritis
Sepsis
Septic arthritis
Septic shock
Tuberculosis
Urinary system infection
Uterine cervical carcinoma
(efficacy and safety of i.v. golimumab plus methotrexate in patients with rheumatoid arthritis aged < 65 years and those greater than or equal to 65 years of age)

ACCESSION NUMBER: 2019:1636875 CAPLUS Full-text
DOCUMENT NUMBER: 174:901313
TITLE: Efficacy and safety of intravenous golimumab plus methotrexate in patients with rheumatoid arthritis aged < 65 years and those ≥ 65 years of age
AUTHOR(S): Tesser, John; Kafka, Shelly; De Horatius, Raphael J.; Xu, Stephen; Hsia, Elizabeth C.; Turkiewicz, Anthony
CORPORATE SOURCE: Arizona Arthritis and Rheumatology Associates, Phoenix, AZ, USA
SOURCE: Arthritis Research & Therapy (2019), 21(1), 1-9
CODEN: ARTRCV; ISSN: 1478-6362
DIGITAL OBJECT ID: 10.1186/s13075-019-1968-x
PUBLISHER: BioMed Central Ltd.
DOCUMENT TYPE: Journal; (online computer file)
LANGUAGE: English
REFERENCE COUNT: 29 THERE ARE 29 CITED REFERENCES AVAILABLE FOR THIS RECORD. ALL CITATIONS AVAILABLE IN THE RE FORMAT

L12 ANSWER 6 OF 9 CAPLUS COPYRIGHT 2024 ACS on STN
TI Safety and efficacy of Golimumab administered intravenously in adults with ankylosing spondylitis: results through week 28 of the GO-ALIVE study
SO Journal of Rheumatology (2018), 45(3), 341-349
CODEN: JRHUA9; ISSN: 1499-2752
PY 2018
IT Ankylosing spondylitis
Blood serum
Diagnosis
Homo sapiens
Human
Inflammation
Metabolic side effects of drugs
Nasopharyngitis
Pharmaceutical intravenous infusions
Pharmacokinetics
Upper respiratory infection
(safety and efficacy of golimumab administered i.v. in adults with ankylosing spondylitis)

ACCESSION NUMBER: 2019:192315 CAPLUS Full-text
DOCUMENT NUMBER: 174:574693
TITLE: Safety and efficacy of Golimumab administered intravenously in adults with ankylosing spondylitis: results through week 28 of the GO-ALIVE study
AUTHOR(S): Deodhar, Atul; Reveille, John D.; Harrison, Diane D.; Kim, Lilianne; Lo, Kim Hung; Leu, Jocelyn H.; Hsia, Elizabeth C.
CORPORATE SOURCE: Oregon Health & Science University, Portland, OR, USA
SOURCE: Journal of Rheumatology (2018), 45(3), 341-349
CODEN: JRHUA9; ISSN: 1499-2752
DIGITAL OBJECT ID: 10.3899/jrheum.170487
PUBLISHER: Journal of Rheumatology Publishing Co. Ltd.
DOCUMENT TYPE: Journal; (online computer file)
LANGUAGE: English
OS.CITING REF COUNT: 17 THERE ARE 17 CAPLUS RECORDS THAT CITE THIS RECORD (17 CITINGS)

REFERENCE COUNT: 28 THERE ARE 28 CITED REFERENCES AVAILABLE FOR THIS RECORD. ALL CITATIONS AVAILABLE IN THE RE FORMAT

L12 ANSWER 7 OF 9 CAPLUS COPYRIGHT 2024 ACS on STN
TI Randomised clinical trial: a placebo-controlled study of intravenous golimumab induction therapy for ulcerative colitis
SO Alimentary Pharmacology and Therapeutics (2015), 42(5), 504-514
CODEN: APTHEN; ISSN: 0269-2813
PY 2015
IT Blood serum
Clinical trials
Cough
Headache
Homo sapiens
Human
Inflammatory bowel disease
Pharmaceutical intravenous infusions
Pharmacodynamics
Pharyngitis
Ulcerative colitis
(placebo-controlled randomized clin. trial of i.v. golimumab induction therapy for ulcerative colitis)
ACCESSION NUMBER: 2015:1289183 CAPLUS Full-text
DOCUMENT NUMBER: 164:525260
TITLE: Randomised clinical trial: a placebo-controlled study of intravenous golimumab induction therapy for ulcerative colitis
AUTHOR(S): Rutgeerts, P.; Feagan, B. G.; Marano, C. W.; Padgett, L.; Strauss, R.; Johanns, J.; Adedokun, O. J.; Guzzo, C.; Zhang, H.; Colombel, J.-F.; Reinisch, W.; Gibson, P. R.; Sandborn, W. J.
CORPORATE SOURCE: PURSUIT-IV Study Group, University Hospital, Louvain, Belg.
SOURCE: Alimentary Pharmacology and Therapeutics (2015), 42(5), 504-514
CODEN: APTHEN; ISSN: 0269-2813
DIGITAL OBJECT ID: 10.1111/apt.13291
PUBLISHER: Wiley-Blackwell
DOCUMENT TYPE: Journal; (online computer file)
LANGUAGE: English
OS.CITING REF COUNT: 26 THERE ARE 26 CAPLUS RECORDS THAT CITE THIS RECORD (26 CITINGS)
REFERENCE COUNT: 20 THERE ARE 20 CITED REFERENCES AVAILABLE FOR THIS RECORD. ALL CITATIONS AVAILABLE IN THE RE FORMAT

L12 ANSWER 8 OF 9 MEDLINE ® on STN
TI Golimumab intravenous infusion for the treatment of rheumatoid arthritis.
SO The Nurse practitioner, (2015 Mar 12) Vol. 40, No. 3, pp. 15-8.
Journal code: 7603663. E-ISSN: 1538-8662. L-ISSN: 0361-1817.
PY 2015
TI Golimumab intravenous infusion for the treatment of rheumatoid arthritis.
ACCESSION NUMBER: 2015555760 MEDLINE Full-text
DOCUMENT NUMBER: PubMed ID: 25679139
TITLE: Golimumab intravenous infusion for the treatment of rheumatoid arthritis.
AUTHOR: McCarty Delilah J
CORPORATE SOURCE: Delilah J. McCarty is an assistant professor of pharmacy practice at Wingate University School of Pharmacy, Wingate, N.C.
SOURCE: The Nurse practitioner, (2015 Mar 12) Vol. 40, No. 3, pp. 15-8.
Journal code: 7603663. E-ISSN: 1538-8662. L-ISSN: 0361-1817.
DIGITAL OBJECT ID: http://dx.doi.org/10.1097/01.NPR.0000460861.12501.92
PUB. COUNTRY: United States
DOCUMENT TYPE: News Announcement
LANGUAGE: English
FILE SEGMENT: MEDLINE; Priority Journals
FILE SEGMENT: Print
ENTRY MONTH: 201504
ENTRY DATE: Entered STN: 16 Feb 2015
Last Updated on STN: 15 Apr 2015

Indexing Added: 15 Apr 2015
Entered Medline: 14 Apr 2015

L12 ANSWER 9 OF 9 BIOSIS COPYRIGHT (c) 2024 Clarivate Analytics on STN
DUPLICATE 1
TI Golimumab, a New Human Anti-Tumor Necrosis Factor alpha Antibody, Administered Intravenously in Patients With Active Rheumatoid Arthritis Forty-Eight-Week Efficacy and Safety Results of a Phase III Randomized, Double-Blind, Placebo-Controlled Study.
SO Arthritis & Rheumatism, (APR 2010) Vol. 62, No. 4, pp. 917-928. http://onlinelibrary.wiley.com/journal/10.1002/(ISSN)1529-0131. CODEN: ARHEAW. ISSN: 0004-3591. E-ISSN: 1529-0131.
PY 2010
AB Objective. To assess the efficacy and safety of intravenous administration of golimumab in patients with rheumatoid arthritis (RA).Methods. Adult patients with RA in whom disease activity was persistent despite treatment with methotrexate (MTX) at a dosage of 15-25 mg/week for >= 4 weeks were randomized to receive intravenous infusions of placebo plus MTX or intravenous infusions of golimumab at a dose of 2 mg/kg or 4 mg/kg, with or without MTX, every 12 weeks through week 48. Patients. . . end point was not met (at week 14, an ACR50 response was observed in 21% of the patients treated with golimumab plus MTX compared with 13% of the patients treated with placebo plus MTX [P = 0.051]). By week 24, significantly more patients treated with golimumab plus MTX had achieved an ACR50 response. Differences in the proportion of patients achieving an ACR50 response between the group receiving golimumab monotherapy and the group receiving placebo plus MTX were not significant at either week 14 (16% versus 13%) or week. . . 9%). At week 48, the proportions of patients achieving ACR20 and ACR50 responses were highest among those who had received golimumab 4 mg/kg plus MTX (70% and 48%, respectively). Concomitant treatment with MTX was associated with a lower incidence of antibodies to golimumab. The most commonly reported adverse events through week 48 were infections (48% of patients treated with golimumab with or without MTX and 41% of patients receiving placebo plus MTX).Conclusion. The primary end point was not met. However, intravenously administered golimumab plus MTX appears to have benefit in the longer-term reduction of RA signs/symptoms in MTX-resistant patients, with no unexpected safety. . .
ACCESSION NUMBER: 2010:425724 BIOSIS Full-text
DOCUMENT NUMBER: PREV201000425724
TITLE: Golimumab, a New Human Anti-Tumor Necrosis Factor alpha Antibody, Administered Intravenously in Patients With Active Rheumatoid Arthritis Forty-Eight-Week Efficacy and Safety Results of a Phase III Randomized, Double-Blind, Placebo-Controlled Study.
AUTHOR(S): Kremer, Joel [Reprint Author]; Ritchlin, Christopher; Mendelsohn, Alan; Baker, Daniel; Kim, Lilianne; Xu, Zhenhua; Han, John; Taylor, Peter
CORPORATE SOURCE: Ctr Rheumatol, 1367 Washington Ave, Albany, NY 12206 USA jkremer@joint-docs.com
SOURCE: Arthritis & Rheumatism, (APR 2010) Vol. 62, No. 4, pp. 917-928. http://onlinelibrary.wiley.com/journal/10.1002/(ISSN)1529-0131.
CODEN: ARHEAW. ISSN: 0004-3591. E-ISSN: 1529-0131.
DIGITAL OBJECT ID: 10.1002/art.27348
DOCUMENT TYPE: Article
LANGUAGE: English
ENTRY DATE: Entered STN: 28 Jul 2010
Last Updated on STN: 9 Sep 2020

=> d his

(FILE 'HOME' ENTERED AT 19:05:39 ON 29 FEB 2024)

FILE 'CAPLUS, BIOSIS, MEDLINE' ENTERED AT 19:06:52 ON 29 FEB 2024
E HARRISON DIANE D/AU
L1 75 S E3-4
E HSIA ELIZABETH C/AU

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L2          281 S E14-15
                E KIM LEE LIAN/AU
L3           18 S E27
                E LO KIM HUNG/AU
L4          111 S E38-39
L5          380 S L1-4
L6         6022 S GOLIMUMAB
L7          186 S L5 AND L6
L8            2 S L7 AND INTRAVENOUS INFUSION
L9           37 S L6 AND INTRAVENOUS INFUSION
L10          36 DUP REM L9 (1 DUPLICATE REMOVED)
L11          10 S  L6 (L) INTRAVENOUS INFUSION
L12           9 DUP REM L11 (1 DUPLICATE REMOVED)
L13           0 S L12 AND 2 MG/KG
L14           0 S L12 AND MG/KG

=>
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PE2E SEARCH - Search History (Prior Art)

Ref #	Hits	Search Query	DBs	Default Operator	Plurals	British Equivalents	Time Stamp
L199	151	("0000030" OR "0000059" OR "0000088" OR "0000116" OR "0000144" OR "20090214528" OR "20100251099" OR "20110251099" 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 "4757506" 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 "5116964" 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	(US-PGPUB; USPAT)	OR	ON	ON	2024/02/29 06:53 PM

		"5385839" OR "5403484" OR "5404871" OR "5427908" OR "5447851" OR "5455030" OR "5458135" OR "5496549" OR "5512544" OR "5514670" OR "5518889" OR "5530101" OR "5534621" OR "5545807" OR "5565362" 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 "5698419" OR "5698435" OR "5714352" OR "5723323" OR "5733761" OR "5750105" OR "5750373" OR "5763192" OR "5763733" OR "5766886" OR "5770198" OR "5770222" OR "5770359" OR "5770428" OR "5789650" OR "5807706" OR "5814476" OR					

		"5814599" OR "5817483" OR "5821333" OR "5824514" OR "5827690" OR "5827739" OR "5833985" OR "5837500" OR "5839446" OR "5849695" OR "5851198" OR "5856456" OR "5871753" OR "5879681" OR "5885793" OR "5888511" OR "5919452" OR "5932448" OR "5958413" OR "5959083" OR "5959084" OR "5962255" OR "5976862" OR "5989530" OR "5993833" OR "5994616" OR "6010902" 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.						
L200	2	L1 AND golimumab	(US-PGPUB; USPAT)	OR	ON	ON	2024/02/29 06:53 PM
L201	1	L1 AND golimumab AND ankylosing	(US-PGPUB; USPAT)	OR	ON	ON	2024/02/29 06:53 PM
L202	2	L1 AND golimumab AND arthritis	(US-PGPUB; USPAT)	OR	ON	ON	2024/02/29 06:53 PM
L203	2	L1 AND golimumab AND spondylitis	(US-PGPUB; USPAT)	OR	ON	ON	2024/02/29 06:53 PM
L204	4014	golimumab AND spondylitis	(US-PGPUB; USPAT)	OR	ON	ON	2024/02/29 06:53 PM
L205	3925	golimumab AND spondylitis AND ankylosing	(US-PGPUB; USPAT)	OR	ON	ON	2024/02/29 06:53 PM
L206	165	golimumab AND	(US-PGPUB; USPAT)	OR	ON	ON	2024/02/29

		spondylitis ADJ ankylosing					06:53 PM
L207	68	golimumab AND spondylitis ADJ ankylosing AND @ay<"2018"	(US-PGPUB; USPAT)	OR	ON	ON	2024/02/29 06:53 PM
L208	1	golimumab SAME spondylitis ADJ ankylosing AND @ay<"2018"	(US-PGPUB; USPAT)	OR	ON	ON	2024/02/29 06:53 PM
L209	1	(golimumab OR (Cnto NEAR "148")) SAME spondylitis ADJ ankylosing AND @ay<"2018"	(US-PGPUB; USPAT)	OR	ON	ON	2024/02/29 06:53 PM
L210	9	(golimumab OR (Cnto NEAR "148")) ADJ ankylosing ADJ spondylitis	(US-PGPUB; USPAT)	OR	ON	ON	2024/02/29 06:53 PM
L211	954	(golimumab OR (Cnto NEAR "148")).clm.	(US-PGPUB; USPAT)	OR	ON	ON	2024/02/29 06:53 PM
L212	375	(golimumab OR (Cnto NEAR "148")).clm. AND spondylitis	(US-PGPUB; USPAT)	OR	ON	ON	2024/02/29 06:53 PM
L213	366	(golimumab OR (Cnto NEAR "148")).clm. AND ankylosing ADJ spondylitis	(US-PGPUB; USPAT)	OR	ON	ON	2024/02/29 06:53 PM
L214	174	(golimumab OR (Cnto NEAR "148")).clm. AND ankylosing ADJ spondylitis AND @ay<"2017"	(US-PGPUB; USPAT)	OR	ON	ON	2024/02/29 06:53 PM
L215	111	(golimumab OR (Cnto NEAR "148")).clm. AND ankylosing ADJ spondylitis AND @ay<"2017" AND methotrexate	(US-PGPUB; USPAT)	OR	ON	ON	2024/02/29 06:53 PM
L216	114	(golimumab OR (Cnto NEAR "148")).clm. AND ankylosing ADJ spondylitis AND @ay<"2017" AND (methotrexate OR sulfasalazine OR hydroxychloroquine)	(US-PGPUB; USPAT)	OR	ON	ON	2024/02/29 06:53 PM
L217	2	(golimumab OR (Cnto NEAR "148")) SAME infusion SAME (over NEAR time)	(US-PGPUB; USPAT)	OR	ON	ON	2024/02/29 06:53 PM
L218	296	(golimumab OR (Cnto NEAR "148")) SAME infusion	(US-PGPUB; USPAT)	OR	ON	ON	2024/02/29 06:53 PM

L219	14	(golimumab OR (Cnto NEAR "148")) SAME (rate NEAR infusion)	(US-PGPUB; USPAT)	OR	ON	ON	2024/02/29 06:53 PM
L220	1011	antibody SAME (rate NEAR infusion)	(US-PGPUB; USPAT)	OR	ON	ON	2024/02/29 06:53 PM
L221	188	antibody SAME infusion SAME rate SAME over NEAR period	(US-PGPUB; USPAT)	OR	ON	ON	2024/02/29 06:53 PM
L222	1	anti-tnf SAME antibody SAME infusion SAME rate SAME over NEAR period	(US-PGPUB; USPAT)	OR	ON	ON	2024/02/29 06:53 PM
L223	4	anti-tnf AND antibody SAME infusion SAME rate SAME over NEAR period	(US-PGPUB; USPAT)	OR	ON	ON	2024/02/29 06:53 PM
L224	5464	anti-tnf AND antibody SAME infusion	(US-PGPUB; USPAT)	OR	ON	ON	2024/02/29 06:53 PM
L225	202	anti-tnf ADJ antibody SAME infusion	(US-PGPUB; USPAT)	OR	ON	ON	2024/02/29 06:53 PM
L226	976	Janssen ADJ Biotech ADJ Inc.asn.	(US-PGPUB; USPAT)	OR	ON	ON	2024/02/29 06:53 PM
L227	21	Harrison Diane D.in.	(US-PGPUB; USPAT)	ADJ	ON	ON	2024/02/29 06:53 PM
L228	18	Hsia Elizabeth C.in.	(US-PGPUB; USPAT)	ADJ	ON	ON	2024/02/29 06:53 PM
L229	12	Kim Lee-Lian.in.	(US-PGPUB; USPAT)	ADJ	ON	ON	2024/02/29 06:53 PM
L230	13	Lo Kim Hung.in.	(US-PGPUB; USPAT)	ADJ	ON	ON	2024/02/29 06:53 PM
L231	1171	L27 L29 L30 L31 L32 L34	(US-PGPUB; USPAT)	OR	ON	ON	2024/02/29 06:53 PM
L232	114	L35 AND golimumab	(US-PGPUB; USPAT)	OR	ON	ON	2024/02/29 06:53 PM
L233	10	L35 AND golimumab.clm.	(US-PGPUB; USPAT)	OR	ON	ON	2024/02/29 06:53 PM
L234	3651	c07k16/241.cpc.	(US-PGPUB; USPAT)	OR	ON	ON	2024/02/29 06:53 PM
L235	16310	a61k39/3955.cpc.	(US-PGPUB; USPAT)	OR	ON	ON	2024/02/29 06:53 PM
L236	55467	a61p19/02.cpc.	(US-PGPUB; USPAT)	OR	ON	ON	2024/02/29 06:53 PM
L237	71130	L38 OR L39 L40	(US-PGPUB; USPAT)	OR	ON	ON	2024/02/29 06:53 PM
L238	117	L41 AND golimumab AND spondilitis	(US-PGPUB; USPAT)	OR	ON	ON	2024/02/29 06:53 PM
L239	23	L41 AND golimumab AND spondilitis.clm.	(US-PGPUB; USPAT)	OR	ON	ON	2024/02/29 06:53 PM
L240	60	golimumab AND spondylitis ADJ ankylosing AND	(US-PGPUB; USPAT)	OR	ON	ON	2024/02/29 06:53 PM

		@ay<"2018" AND infusion					
L241	117	2009/0123378 AND administration AND iv	(US-PGPUB; USPAT)	OR	ON	ON	2024/02/29 06:53 PM
L242	1	"20090123378".pn. AND administration AND iv	(US-PGPUB; USPAT)	OR	ON	ON	2024/02/29 06:53 PM
L243	1	"20090123378".pn. AND administration AND intraven$5	(US-PGPUB; USPAT)	OR	ON	ON	2024/02/29 06:53 PM
L244	151	("0000030" OR "0000059" OR "0000088" OR "0000116" OR "0000144" OR "20090214528" OR "20100251099" OR "20110251099" 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 "4757506" 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 "5116964" OR "5122464" OR "5130238" OR "5142033" OR "5149636" OR "5168062" OR "5179017" OR "5223409" OR "5225538" OR	(US-PGPUB; USPAT)	OR	ON	ON	2024/02/29 06:53 PM

		"5225539" OR "5231024" OR "5260203" OR "5266491" OR "5304489" OR "5342613" OR "5385839" OR "5403484" OR "5404871" OR "5427908" OR "5447851" OR "5455030" OR "5458135" OR "5496549" OR "5512544" OR "5514670" OR "5518889" OR "5530101" OR "5534621" OR "5545807" OR "5565362" 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 "5698419" OR "5698435" OR "5714352" OR "5723323" OR "5733761" OR "5750105" OR "5750373" OR "5763192" OR "5763733" OR "5766886" OR "5770198" OR					

		"5770222" OR "5770359" OR "5770428" OR "5789650" OR "5807706" OR "5814476" OR "5814599" OR "5817483" OR "5821333" OR "5824514" OR "5827690" OR "5827739" OR "5833985" OR "5837500" OR "5839446" OR "5849695" OR "5851198" OR "5856456" OR "5871753" OR "5879681" OR "5885793" OR "5888511" OR "5919452" OR "5932448" OR "5958413" OR "5959083" OR "5959084" OR "5962255" OR "5976862" OR "5989530" OR "5993833" OR "5994616" OR "6010902" 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.					
L245	2	("0000030" OR "0000059" OR "0000088" OR "0000116" OR "0000144" OR "20090214528" OR "20100251099" OR "20110251099" OR "3773919" OR "4239754" OR	(US-PGPUB; USPAT)	OR	ON	ON	2024/02/29 06:53 PM

		"4309989" OR "4399216" OR "4603106" OR "4634665" OR "4656134" OR "4668218" OR "4676980" OR "4683195" OR "4683202" OR "4704692" OR "4757506" 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 "5116964" 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 "5404871" OR "5427908" OR "5447851" OR "5455030" OR "5458135" OR "5496549" OR "5512544" OR "5514670" OR "5518889" OR "5530101" OR "5534621" OR "5545807" OR "5565362" OR "5569825" OR					

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L246	151	("0000030" OR "0000059" OR "0000088" OR "0000116" OR "0000144" OR "20090214528" OR "20100251099" OR "20110251099" 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 "4757506" OR "4766067" OR "4767402" OR "4795699" OR "4800159" OR "4816567" OR "4822776" OR "4873316" OR "4889818" OR "4921794" OR "4925673" OR	(US-PGPUB; USPAT)	OR	ON	ON	2024/02/29 06:53 PM

		"4939666" OR "4946778" OR "4956288" OR "4965188" OR "4994370" OR "5066584" OR "5116964" 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 "5404871" OR "5427908" OR "5447851" OR "5455030" OR "5458135" OR "5496549" OR "5512544" OR "5514670" OR "5518889" OR "5530101" OR "5534621" OR "5545807" OR "5565362" 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					

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		"7521206" OR "7691378" OR "8241899" OR "9512065").pn.					
L247	2	L1 AND golimumab	(US-PGPUB; USPAT)	OR	ON	ON	2024/02/29 06:53 PM
L248	1	L1 AND golimumab AND ankylosing	(US-PGPUB; USPAT)	OR	ON	ON	2024/02/29 06:53 PM
L249	2	L1 AND golimumab AND arthritis	(US-PGPUB; USPAT)	OR	ON	ON	2024/02/29 06:53 PM
L250	2	L1 AND golimumab AND spondylitis	(US-PGPUB; USPAT)	OR	ON	ON	2024/02/29 06:53 PM
L251	4014	golimumab AND spondylitis	(US-PGPUB; USPAT)	OR	ON	ON	2024/02/29 06:53 PM
L252	3925	golimumab AND spondylitis AND ankylosing	(US-PGPUB; USPAT)	OR	ON	ON	2024/02/29 06:53 PM
L253	165	golimumab AND spondylitis ADJ ankylosing	(US-PGPUB; USPAT)	OR	ON	ON	2024/02/29 06:53 PM
L254	68	golimumab AND spondylitis ADJ ankylosing AND @ay<"2018"	(US-PGPUB; USPAT)	OR	ON	ON	2024/02/29 06:53 PM
L255	1	golimumab SAME spondylitis ADJ ankylosing AND @ay<"2018"	(US-PGPUB; USPAT)	OR	ON	ON	2024/02/29 06:53 PM
L256	1	(golimumab OR (Cnto NEAR "148")) SAME spondylitis ADJ ankylosing AND @ay<"2018"	(US-PGPUB; USPAT)	OR	ON	ON	2024/02/29 06:53 PM
L257	9	(golimumab OR (Cnto NEAR "148")) ADJ ankylosing ADJ spondylitis	(US-PGPUB; USPAT)	OR	ON	ON	2024/02/29 06:53 PM
L258	954	(golimumab OR (Cnto NEAR "148")).clm.	(US-PGPUB; USPAT)	OR	ON	ON	2024/02/29 06:53 PM
L259	375	(golimumab OR (Cnto NEAR "148")).clm. AND spondylitis	(US-PGPUB; USPAT)	OR	ON	ON	2024/02/29 06:53 PM
L260	366	(golimumab OR (Cnto NEAR "148")).clm. AND ankylosing ADJ spondylitis	(US-PGPUB; USPAT)	OR	ON	ON	2024/02/29 06:53 PM
L261	174	(golimumab OR (Cnto NEAR "148")).clm. AND ankylosing ADJ spondylitis AND @ay<"2017"	(US-PGPUB; USPAT)	OR	ON	ON	2024/02/29 06:53 PM
L262	111	(golimumab OR (Cnto	(US-PGPUB; USPAT)	OR	ON	ON	2024/02/29

		NEAR "148")).clm. AND ankylosing ADJ spondylitis AND @ay<"2017" AND methotrexate					06:53 PM
L263	114	(golimumab OR (Cnto NEAR "148")).clm. AND ankylosing ADJ spondylitis AND @ay<"2017" AND (methotrexate OR sulfasalazine OR hydroxychloroquine)	(US-PGPUB; USPAT)	OR	ON	ON	2024/02/29 06:53 PM
L264	2	(golimumab OR (Cnto NEAR "148")) SAME infusion SAME (over NEAR time)	(US-PGPUB; USPAT)	OR	ON	ON	2024/02/29 06:53 PM
L265	296	(golimumab OR (Cnto NEAR "148")) SAME infusion	(US-PGPUB; USPAT)	OR	ON	ON	2024/02/29 06:53 PM
L266	14	(golimumab OR (Cnto NEAR "148")) SAME (rate NEAR infusion)	(US-PGPUB; USPAT)	OR	ON	ON	2024/02/29 06:53 PM
L267	1011	antibody SAME (rate NEAR infusion)	(US-PGPUB; USPAT)	OR	ON	ON	2024/02/29 06:53 PM
L268	188	antibody SAME infusion SAME rate SAME over NEAR period	(US-PGPUB; USPAT)	OR	ON	ON	2024/02/29 06:53 PM
L269	1	anti-tnf SAME antibody SAME infusion SAME rate SAME over NEAR period	(US-PGPUB; USPAT)	OR	ON	ON	2024/02/29 06:53 PM
L270	4	anti-tnf AND antibody SAME infusion SAME rate SAME over NEAR period	(US-PGPUB; USPAT)	OR	ON	ON	2024/02/29 06:53 PM
L271	5464	anti-tnf AND antibody SAME infusion	(US-PGPUB; USPAT)	OR	ON	ON	2024/02/29 06:53 PM
L272	202	anti-tnf ADJ antibody SAME infusion	(US-PGPUB; USPAT)	OR	ON	ON	2024/02/29 06:53 PM
L273	976	Janssen ADJ Biotech ADJ Inc.asn.	(US-PGPUB; USPAT)	OR	ON	ON	2024/02/29 06:53 PM
L274	21	Harrison Diane D.in.	(US-PGPUB; USPAT)	ADJ	ON	ON	2024/02/29 06:53 PM
L275	18	Hsia Elizabeth C.in.	(US-PGPUB; USPAT)	ADJ	ON	ON	2024/02/29 06:53 PM
L276	12	Kim Lee-Lian.in.	(US-PGPUB; USPAT)	ADJ	ON	ON	2024/02/29 06:53 PM
L277	13	Lo Kim Hung.in.	(US-PGPUB; USPAT)	ADJ	ON	ON	2024/02/29 06:53 PM
L278	1171	L27 L29 L30 L31 L32 L34	(US-PGPUB; USPAT)	OR	ON	ON	2024/02/29 06:53 PM

L279	114	L35 AND golimumab	(US-PGPUB; USPAT)	OR	ON	ON	2024/02/29 06:53 PM
L280	10	L35 AND golimumab.clm.	(US-PGPUB; USPAT)	OR	ON	ON	2024/02/29 06:53 PM
L281	3651	c07k16/241.cpc.	(US-PGPUB; USPAT)	OR	ON	ON	2024/02/29 06:53 PM
L282	16310	a61k39/3955.cpc.	(US-PGPUB; USPAT)	OR	ON	ON	2024/02/29 06:53 PM
L283	55467	a61p19/02.cpc.	(US-PGPUB; USPAT)	OR	ON	ON	2024/02/29 06:53 PM
L284	71130	L38 OR L39 L40	(US-PGPUB; USPAT)	OR	ON	ON	2024/02/29 06:53 PM
L285	117	L41 AND golimumab AND spondilitis	(US-PGPUB; USPAT)	OR	ON	ON	2024/02/29 06:53 PM
L286	23	L41 AND golimumab AND spondilitis.clm.	(US-PGPUB; USPAT)	OR	ON	ON	2024/02/29 06:53 PM
L287	60	golimumab AND spondylitis ADJ ankylosing AND @ay<"2018" AND infusion	(US-PGPUB; USPAT)	OR	ON	ON	2024/02/29 06:53 PM
L288	117	2009/0123378 AND administration AND iv	(US-PGPUB; USPAT)	OR	ON	ON	2024/02/29 06:53 PM
L289	1	"20090123378".pn. AND administration AND iv	(US-PGPUB; USPAT)	OR	ON	ON	2024/02/29 06:53 PM
L290	1	"20090123378".pn. AND administration AND intraven$5	(US-PGPUB; USPAT)	OR	ON	ON	2024/02/29 06:53 PM
L291	151	("0000030" OR "0000059" OR "0000088" OR "0000116" OR "0000144" OR "20090214528" OR "20100251099" OR "20110251099" 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 "4757506" OR "4766067" OR "4767402" OR "4795699" OR "4800159" OR	(US-PGPUB; USPAT)	OR	ON	ON	2024/02/29 06:53 PM

		"4816567" OR "4822776" OR "4873316" OR "4889818" OR "4921794" OR "4925673" OR "4939666" OR "4946778" OR "4956288" OR "4965188" OR "4994370" OR "5066584" OR "5116964" 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 "5404871" OR "5427908" OR "5447851" OR "5455030" OR "5458135" OR "5496549" OR "5512544" OR "5514670" OR "5518889" OR "5530101" OR "5534621" OR "5545807" OR "5565362" 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 "5698419" OR "5698435" OR "5714352" OR "5723323" OR "5733761" OR "5750105" OR "5750373" OR "5763192" OR "5763733" OR "5766886" OR "5770198" OR "5770222" OR "5770359" OR "5770428" OR "5789650" OR "5807706" OR "5814476" OR "5814599" OR "5817483" OR "5821333" OR "5824514" OR "5827690" OR "5827739" OR "5833985" OR "5837500" OR "5839446" OR "5849695" OR "5851198" OR "5856456" OR "5871753" OR "5879681" OR "5885793" OR "5888511" OR "5919452" OR "5932448" OR "5958413" OR "5959083" OR "5959084" OR "5962255" OR "5976862" OR "5989530" OR "5993833" OR "5994616" OR "6010902" 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.					
L292	2	("0000030" OR "0000059" OR "0000088" OR "0000116" OR "0000144" OR "20090214528" OR "20100251099" OR "20110251099" 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 "4757506" 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 "5116964" OR "5122464" OR "5130238" OR "5142033" OR "5149636" OR "5168062" OR "5179017" OR "5223409" OR "5225538" OR "5225539" OR	(US-PGPUB; USPAT)	OR	ON	ON	2024/02/29 06:53 PM

		"5231024" OR "5260203" OR "5266491" OR "5304489" OR "5342613" OR "5385839" OR "5403484" OR "5404871" OR "5427908" OR "5447851" OR "5455030" OR "5458135" OR "5496549" OR "5512544" OR "5514670" OR "5518889" OR "5530101" OR "5534621" OR "5545807" OR "5565362" 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 "5698419" OR "5698435" OR "5714352" OR "5723323" OR "5733761" OR "5750105" OR "5750373" OR "5763192" OR "5763733" OR "5766886" OR "5770198" OR "5770222" OR					

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L293	151	("0000030" OR "0000059" OR "0000088" OR "0000116" OR "0000144" OR "20090214528" OR "20100251099" OR "20110251099" OR "3773919" OR "4239754" OR	(US-PGPUB; USPAT)	OR	ON	ON	2024/02/29 06:53 PM

		"4309989" OR "4399216" OR "4603106" OR "4634665" OR "4656134" OR "4668218" OR "4676980" OR "4683195" OR "4683202" OR "4704692" OR "4757506" 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 "5116964" 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 "5404871" OR "5427908" OR "5447851" OR "5455030" OR "5458135" OR "5496549" OR "5512544" OR "5514670" OR "5518889" OR "5530101" OR "5534621" OR "5545807" OR "5565362" OR "5569825" OR					

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		"5919452" OR "5932448" OR "5958413" OR "5959083" OR "5959084" OR "5962255" OR "5976862" OR "5989530" OR "5993833" OR "5994616" OR "6010902" 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.					
L294	2	L1 AND golimumab	(US-PGPUB; USPAT)	OR	ON	ON	2024/02/29 06:53 PM
L295	1	L1 AND golimumab AND ankylosing	(US-PGPUB; USPAT)	OR	ON	ON	2024/02/29 06:53 PM
L296	2	L1 AND golimumab AND arthritis	(US-PGPUB; USPAT)	OR	ON	ON	2024/02/29 06:53 PM
L297	2	L1 AND golimumab AND spondylitis	(US-PGPUB; USPAT)	OR	ON	ON	2024/02/29 06:53 PM
L298	4014	golimumab AND spondylitis	(US-PGPUB; USPAT)	OR	ON	ON	2024/02/29 06:53 PM
L299	3925	golimumab AND spondylitis AND ankylosing	(US-PGPUB; USPAT)	OR	ON	ON	2024/02/29 06:53 PM
L300	165	golimumab AND spondylitis ADJ ankylosing	(US-PGPUB; USPAT)	OR	ON	ON	2024/02/29 06:53 PM
L301	68	golimumab AND spondylitis ADJ ankylosing AND @ay<"2018"	(US-PGPUB; USPAT)	OR	ON	ON	2024/02/29 06:53 PM
L302	1	golimumab SAME spondylitis ADJ ankylosing AND @ay<"2018"	(US-PGPUB; USPAT)	OR	ON	ON	2024/02/29 06:53 PM
L303	1	(golimumab OR (Cnto NEAR "148")) SAME spondylitis ADJ ankylosing AND @ay<"2018"	(US-PGPUB; USPAT)	OR	ON	ON	2024/02/29 06:53 PM

L304	9	(golimumab OR (Cnto NEAR "148")) ADJ ankylosing ADJ spondylitis	(US-PGPUB; USPAT)	OR	ON	ON	2024/02/29 06:53 PM
L305	954	(golimumab OR (Cnto NEAR "148")).clm.	(US-PGPUB; USPAT)	OR	ON	ON	2024/02/29 06:53 PM
L306	375	(golimumab OR (Cnto NEAR "148")).clm. AND spondylitis	(US-PGPUB; USPAT)	OR	ON	ON	2024/02/29 06:53 PM
L307	366	(golimumab OR (Cnto NEAR "148")).clm. AND ankylosing ADJ spondylitis	(US-PGPUB; USPAT)	OR	ON	ON	2024/02/29 06:53 PM
L308	174	(golimumab OR (Cnto NEAR "148")).clm. AND ankylosing ADJ spondylitis AND @ay<"2017"	(US-PGPUB; USPAT)	OR	ON	ON	2024/02/29 06:53 PM
L309	111	(golimumab OR (Cnto NEAR "148")).clm. AND ankylosing ADJ spondylitis AND @ay<"2017" AND methotrexate	(US-PGPUB; USPAT)	OR	ON	ON	2024/02/29 06:53 PM
L310	114	(golimumab OR (Cnto NEAR "148")).clm. AND ankylosing ADJ spondylitis AND @ay<"2017" AND (methotrexate OR sulfasalazine OR hydroxychloroquine)	(US-PGPUB; USPAT)	OR	ON	ON	2024/02/29 06:53 PM
L311	2	(golimumab OR (Cnto NEAR "148")) SAME infusion SAME (over NEAR time)	(US-PGPUB; USPAT)	OR	ON	ON	2024/02/29 06:53 PM
L312	296	(golimumab OR (Cnto NEAR "148")) SAME infusion	(US-PGPUB; USPAT)	OR	ON	ON	2024/02/29 06:53 PM
L313	14	(golimumab OR (Cnto NEAR "148")) SAME (rate NEAR infusion)	(US-PGPUB; USPAT)	OR	ON	ON	2024/02/29 06:53 PM
L314	1011	antibody SAME (rate NEAR infusion)	(US-PGPUB; USPAT)	OR	ON	ON	2024/02/29 06:53 PM
L315	188	antibody SAME infusion SAME rate SAME over NEAR period	(US-PGPUB; USPAT)	OR	ON	ON	2024/02/29 06:53 PM
L316	1	anti-tnf SAME antibody SAME infusion SAME rate SAME over NEAR period	(US-PGPUB; USPAT)	OR	ON	ON	2024/02/29 06:53 PM
L317	4	anti-tnf AND antibody SAME infusion SAME	(US-PGPUB; USPAT)	OR	ON	ON	2024/02/29 06:53 PM

		rate SAME over NEAR period					
L318	5464	anti-tnf AND antibody SAME infusion	(US-PGPUB; USPAT)	OR	ON	ON	2024/02/29 06:53 PM
L319	202	anti-tnf ADJ antibody SAME infusion	(US-PGPUB; USPAT)	OR	ON	ON	2024/02/29 06:53 PM
L320	976	Janssen ADJ Biotech ADJ Inc.asn.	(US-PGPUB; USPAT)	OR	ON	ON	2024/02/29 06:53 PM
L321	21	Harrison Diane D.in.	(US-PGPUB; USPAT)	ADJ	ON	ON	2024/02/29 06:53 PM
L322	18	Hsia Elizabeth C.in.	(US-PGPUB; USPAT)	ADJ	ON	ON	2024/02/29 06:53 PM
L323	12	Kim Lee-Lian.in.	(US-PGPUB; USPAT)	ADJ	ON	ON	2024/02/29 06:53 PM
L324	13	Lo Kim Hung.in.	(US-PGPUB; USPAT)	ADJ	ON	ON	2024/02/29 06:53 PM
L325	1171	L27 L29 L30 L31 L32 L34	(US-PGPUB; USPAT)	OR	ON	ON	2024/02/29 06:53 PM

PE2E SEARCH - Search History (Interference)

There are no Interference searches to show.

Doc code: IDS
Doc description: Information Disclosure Statement (IDS) Filed

PTO/SB/08a (01-22)
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	17237650
Filing Date	2021-04-22
First Named Inventor	Diane D. Harrison
Art Unit	1646
Examiner Name	Chandra, Gyan
Attorney Docket Number	206389-0002-02US

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Examiner Initial*	Cite No	Patent Number	Kind Code[1]	Issue Date	Name of Patentee or Applicant of cited Document	Pages,Columns,Lines where Relevant Passages or Relevant Figures Appear
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	Attorney Docket Number	206389-0002-02US

	1	Zidi et al., 2010, "Golimumab Therapy of Rheumatoid Arthritis: An Overview." Scandinavian Journal of Immunology. 72, 75-85	☐
	2	Marichal-Gallardo et al., 2012, "State-of-the-art in downstream processing of monoclonal antibodies: process trends in design and validation." Biotechnol Prog. 28(4), 899-916	☐
	3	Chen et al., 2004 "Methotrexate for ankylosing spondylitis" Cochrane Database of Systematic Reviews, Issue 3. Art. No.: CD004524.	☐

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EXAMINER SIGNATURE

Examiner Signature	/GYAN CHANDRA/	Date Considered	02/29/2024

*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.

[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.

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Art Unit	1646
Examiner Name	Chandra, Gyan
Attorney Docket Number	206389-0002-02US

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)	2023-12-21
Name/Print	Pallab Singh	Registration Number	70,731

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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.

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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.

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Art Unit	1646
Examiner Name	CHANDRA, GYAN
Attorney Docket Number	206389-0002-02US

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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]

INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Not for submission under 37 CFR 1.99)		
	Application Number	17237650
	Filing Date	2021-04-22
	First Named Inventor	Diane D. Harrison
	Art Unit	1646
	Examiner Name	CHANDRA, GYAN
	Attorney Docket Number	206389-0002-02US

	1	Anonymous, "SIMPONI ARIA(TM) (golimumab) for infusion Receives FDA Approval for TREATMENT OF MODERATELY TO SEVERELY ACTIVE Rheumatoid arthritis", JOHNSON AND JOHNSON, (20130718), 6 pages, URL: https://www.jnj.com/media-center/press-releases/simponi-aria-golimumab-for-infusion-receives-fda-approval-for-treatment-of-moderately-to-severely-active-rheumatoid-arthritis, (20181214), XP055534592	☐
	2	Barbara Gandek ET AL, "Psychometric evaluation of the SF-36 health survey in Medicare managed care", Health care financing review, United States, (20040101), page 5, URL: http://www.ncbi.nlm.nih.gov/pubmed/15493441, XP055155378	☐
	3	Deodhar et al. "Safety and Efficacy of Golimumab Administered Intravenously in Adults with Ankylosing Spondylitis: Results through Week 28 of the GO-ALIVE Study" J Rheum. March 2018;45:341, 9 pages.	☐
	4	Haywood KL, Garratt AM, Dziedzic K, Dawes PT. Generic measures of health-related quality of life in ankylosing spondylitis: reliability, validity and responsiveness. Rheumatology (Oxford). 2002 Dec;41(12):1380-7.	☐
	5	Johnson & Johnson, “New Phase 3 Data Show Simponi Aria® (Golimumab) Significantly Improved Signs And Symptoms In Patients With Active Ankylosing Spondylitis” 14 November 2016 (14-11-2016) 12 pages.	☐
	6	Reveille et al. "Safety and Efficacy of Intravenous Golimumab in Adults with Ankylosing Spondylitis: Results through 1 Year of the GO-ALIVE Study." J Rheum. October 2019, 7 pages. DOI: 10.3899/jrheum.180718	☐
	7	Rudwaleit M, Gooch K, Michel B, Herold M, Thörner A, Wong R, Kron M, Chen N, Kupper H. Adalimumab improves sleep and sleep quality in patients with active ankylosing spondylitis. J Rheumatol. 2011 Jan;38(1):79-86.	☐
	8	SALAFFI FAUSTO ET AL, "The health-related quality of life in rheumatoid arthritis, ankylosing spondylitis, and psoriatic arthritis: a comparison with a selected sample of healthy people", HEALTH AND QUALITY OF LIFE OUTCOMES, BIOMED CENTRAL, LONDON, GB, (20090318), vol. 7, no. 1, doi:10.1186/1477-7525-7-25, ISSN 1477-7525, page 25, XP021050341	☐
	9	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.	☐

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

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	17237650
Filing Date	2021-04-22
First Named Inventor	Diane D. Harrison
Art Unit	1646
Examiner Name	CHANDRA, GYAN
Attorney Docket Number	206389-0002-02US

[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	17237650
	Filing Date	2021-04-22
	First Named Inventor	Diane D. Harrison
	Art Unit	1646
	Examiner Name	CHANDRA, GYAN
	Attorney Docket Number	206389-0002-02US

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)	2024-06-13
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 record s.

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.

INFORMATION DISCLOSURE STATEMENT BY APPLICANT

Application Number	17/237,650
Filing Date	04/22/2021
First Named Inventor	Diane D. Harrison
Art Unit	1646
Client Number	206389
Page 1 of 1	**Matter Number**	0002-02US

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, nor is it intended to constitute an admission that such information is "analogous prior art".

In accordance with 37 C.F.R. 1.97(g), the filing of this Information Disclosure Statement shall not be construed to mean that a search has been made.

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 206389-0002-02US for any such charge or credit.

ADDITIONAL COMMENTS

SIGNATURE

Signature	/Pallab Singh/	**Date**	2024-06-13
Name	Pallab Singh	**Registration Number**	70731

SyncIDS.com

PTO/SB/30EFS (01-22)
Approved for use through 05/31/2024. OMB 0651-0031
U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE
Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number.

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

Application Number	17/237,650	Filing Date	2021-04-22	Docket Number (if applicable)	206389-0002-02US	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

PTO/SB/30EFS (01-22)
Approved for use through 05/31/2024. OMB 0651-0031
U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE
Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number.

Signature of Registered U.S. Patent Practitioner			
Signature	/Pallab Singh/	Date (YYYY-MM-DD)	2024-06-13
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

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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.

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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.

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UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
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www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
17/237,650	04/22/2021	Diane D. Harrison	206389-0002-02US	8810

171672 7590 07/02/2024

Riverside Law LLP/J&J
175 Strafford Avenue
Suite 100
Wayne, PA 19087

EXAMINER	
CHANDRA, GYAN	

ART UNIT	PAPER NUMBER
1646	

NOTIFICATION DATE	DELIVERY MODE
07/02/2024	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

Office Action Summary	**Application No.** 17/237,650	**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 --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTHS FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☑ Responsive to communication(s) filed on the RCE filed on 6/13/2024.

☐ A declaration(s)/affidavit(s) under **37 CFR 1.130(b)** was/were filed on _____.

2a)☐ This action is **FINAL.** 2b) ☑ This action is non-final.

3)☐ 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.

4)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims*

5) ☑ Claim(s) 11,13-14,16-18 and 20 is/are pending in the application.

5a) Of the above claim(s) _____ is/are withdrawn from consideration.

6) ☐ Claim(s) _____ is/are allowed.

7) ☑ Claim(s) 11,13-14,16-18 and 20 is/are rejected.

8) ☐ Claim(s) _____ is/are objected to.

9) ☐ Claim(s) _____ are subject to restriction and/or election requirement

* If any claims have been determined allowable, 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.**

Application Papers

10)☐ The specification is objected to by the Examiner.

11)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

Priority under 35 U.S.C. § 119

12)☐ 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)).

** See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)

2) ☑ Information Disclosure Statement(s) (PTO/SB/08a and/or PTO/SB/08b) Paper No(s)/Mail Date 3/6/2024 and 6/13/2024.

3) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date _____.

4) ☐ Other: _____.

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 allowance. 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, prosecution in this application has been reopened pursuant to 37 CFR 1.114. Applicant's submission filed on 6/13/2024 has been entered.

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

Information Disclosure Statement

The Information Disclosure Statements (IDSs) filed on 3/6/2024 and 6/13/2024 have been considered. The crossed-out references of 6/13/2024 have already been considered in the IDS of 3//6/2024.

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, 16-18 and 20 are rejected under 35 U.S.C. 102(a)(1) as being anticipated by Johnson & Johnson, Pharmaceuticals, Nov. 14, 2016) or Janssen Immunology (PRNewswire,News provides by Janssen Research and Development, Nov. 14, 2016).

The instant invention is broadly drawn to a method of treating a TNF related condition, wherein the TNF related condition is active ankylosing spondylitis, the method comprising: administering a composition comprising a safe and effective amount of at least one isolated mammalian 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, and at least one pharmaceutically acceptable carrier or diluent, wherein said composition is administered via IV infusion at a dose of 2 mg/kg, administered over 30 ± 10 minutes, at weeks 0 and 4, and then every 8 weeks (q8w) thereafter, and wherein a patient treated with the composition achieves an Ankylosing Spondylitis

Disease Activity Score (ASDAS) inactive disease (<1.3) at 4 weeks of treatment or at 2 weeks of treatment (claims 11, 14 and 17), the method further comprising administering said composition with or without methotrexate (MTX), sulfasalazine (SSZ) or hydroxychloroquine (HCQ) (claim 13, 16, 20) and the method of claim 17, wherein said > 65% of patients that achieve ASAS20 at week 16 of treatment have a treatment difference (improvement compared to placebo) of > 45%.

It is noted that the instantly claimed invention comprise an anti-TNF-alpha antibody golimumab which is the same as evidenced by Wong et al. (see below).

Johnson & Johnson teaches data form GO-ALIVE study using golimumab 2 mg/kg, 30 min infusion for Ankylosing Spondylitis. They teach that 2 mg/kg infusion dose has been approved by FDA. Johnson & Johnson teaches that 47.6% of patients receiving golimumab (SIMPOI ARIA) achieved an ASAS40 response compared with 8.7% of patients receiving placebo (pg. 2).

Janssen R&D teaches that findings from a pivotal phase 3 study shows efficacy of IV administered golimumab in the treatment of ankylosing spondylitis. Janssen R&D teaches that the administration of golimumab 2 mg/kg showed that 73.3% of patients with ankylosing spondylitis achieved 20% improvement as compared to 26.2% of patient receiving placebo. Janssen R&D teaches that Bath ankylosing spondylitis functional index (BASMI) = -2.4 for golimumab as compared to -0.5 for placebo group. Therefore, the instantly claimed invention is anticipated by the prior art of record, unless evidence to contrary.

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, 13-14, 16-18 and 20 are rejected under 35 U.S.C. 103 as being unpatentable over Wong et al (IDS, US Pub. No. 2009/0123378) in view of Johnson & Johnson, (IDS, Press release, July. 18, 2013) or Zhuang et al. (IDS, Clin. Therapeutics, 34, Number 1, 77-90, 2012).

The instant invention is broadly drawn to a method of treating a TNF related condition, wherein the TNF related condition is active ankylosing spondylitis, the method comprising: administering a composition comprising a safe and effective amount of at least one isolated mammalian 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, and at least one pharmaceutically acceptable carrier or diluent, wherein said composition is administered via IV infusion at a dose of 2 mg/kg, administered over 30 ± 10 minutes, at weeks 0 and 4, and then every 8 weeks (q8w) thereafter, and wherein a patient treated with the composition achieves an Ankylosing Spondylitis Disease Activity Score (ASDAS) inactive disease (<1.3) at 4 weeks of treatment or at 2 weeks of treatment (claims 11, 14 and 17), the method further comprising administering said composition with or without methotrexate (MTX), sulfasalazine (SSZ) or hydroxychloroquine (HCQ) (claim 13, 16, 20) and the method of claim 17, wherein said > 65% of patients that achieve ASAS20 at week 16 of treatment have a treatment difference (improvement compared to placebo) of > 45%.

Wong et al teach treating ankylosing spondylitis (AS) in a subject comprising administering an inhibitor of TNFα, wherein such inhibitor is human TNFα antibody or antigen-binding portion thereof (abstract, [0010], [0013-0016]). They teach that the

antibody is Golimumab (see [0081, 0125, 0154] and claim 48). It is noted that anti-TNF antibody, golimumab, comprises amino acid sequences of 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 (as disclosed in SEQ ID NOs: 10 and 11 of US 20090214528). Wong et al teach that the treatment of AS can further comprise methotrexate, azathioprine sulphasalazine or hydroxychloroquine (see paragraph [0014, 0049, 0253, 0255] and claim 19). They teach that the response of the antibody treatment over the time is looked as Bath Ankylosing spondylitis disease activity index (BASDAI) (see[0019]). They teach that the efficacy of treatment over a period of 2, 4 weeks or more is determined BASDAI as compare to control, in particular ASAS20, ASAS50 or ASAS70 (see [0024-0033]) and they teach that the method provides at least about 2.2 in a BASDAI score [0220]. **They teach that the administration of an antibody is done by**

infusion (see [0199, 0209]). They do not teach administering Golimumab antibody by IV infusion at a dose of 2 mg/kg over a period of 30 ± 10 min.

Johnson & Johnson teaches the US Food and Drug Administration (FDA) authorized golimumab for infusion for treatment of adults with moderately or severely active rheumatoid arthritis in combination with methotrexate, wherein the golimumab is administered at 2 mg/kg given as intravenous infusion over a time period of 30 minutes at weeks 0 and 4, and then every 8 weeks thereafter (page 1). Ankylosing spondylitis is a severe rheumatoid arthritis of spinal joints. Therefore, one skill in the art would provide the same dosage as approved by FDA (see above).

Zhuang et al. teach treating patients with RA by administering golimumab at 2 mg/kg at 0 and every12 weeks (see Methods). They teach golimumab administration can be with or without methotrexate (see pg. 77). They teach administering golimumab for a period of 30 minute (see pg. 81, right col.).

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 at an effective dose of 2 mg/kg infusion for a period necessary including 30 minutes as taught by Johnson and Johnson or Zhuang et al. using golimumab for treating Ankylosing spondylitis as taught by Wong et al. Further, one of ordinary skill of the art would have been motivated to administer golimumab by an intravenous infusion using a dosage of 2 mg/kg over a period of 30 min because Zhuang et al and Johnson and Johnson both teach treating severe rheumatoid arthritis by administering golimumab at 2 mg/kg for a period of 30 min by IV infusion. One would have a reasonable expectation of success in administering golimumab intravenously because Johnson and Johnson teach that the

US FDA has approved treating severe rheumatoid arthritis using 2 mg/kg golimumab administration by intravenous infusion over a period of 30 min and Zhuang et al also teach administering 2 mg/kg golimumab IV infusion for a period of 30 min. Therefore, it would have been obvious to one ordinary skill in the art (e.g., a physician) to treat ankylosing spondylitis using 2 mg/kg golimumab by intravenous administration for a period of 30 min.

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 filing of a terminal disclaimer by itself is not a complete reply to a nonstatutory double patenting (NSDP) rejection. A complete reply requires that the terminal disclaimer be accompanied by a reply requesting reconsideration of the prior Office action. Even where the NSDP rejection is provisional the reply must be complete. See MPEP § 804, subsection I.B.1. For a reply to a non-final Office action, see 37 CFR 1.111(a). For a reply to final Office action, see 37 CFR 1.113(c). A request for reconsideration while not provided for in 37 CFR 1.113(c) may be filed after final for consideration. See MPEP §§ 706.07(e) and 714.13.

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Claims 11, 13-14, 16-18 and 20 are rejected on the ground of nonstatutory double patenting as being unpatentable over claims 1-10 of U.S. Patent No. 11,014982.

Although the claims at issue are not identical, they are not patentably distinct from each other because a method of treating a TNF related condition, wherein the TNF related condition is active ankylosing spondylitis, the method comprising: administering a composition comprising a safe and effective amount of at least one isolated mammalian 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, and at least one pharmaceutically acceptable carrier or diluent, wherein said composition is administered via IV infusion at a dose of 2 mg/kg, administered over 30 ± 10 minutes, at weeks 0 and 4, and then every 8 weeks (q8w) thereafter, and wherein a patient treated with the composition achieves an Ankylosing Spondylitis Disease Activity Score (ASDAS) inactive disease (<1.3) at 4 weeks of treatment or at 2 weeks of treatment (claims 11, 14 and 17), the method further comprising administering said composition with or without methotrexate (MTX), sulfasalazine (SSZ) or hydroxychloroquine (HCQ) (claim

13, 16, 20) and the method of claim 17, wherein said > 65% of patients that achieve ASAS20 at week 16 of treatment have a treatment difference (improvement compared to placebo) of > 45% are taught in claims 1-10 of US Pat. No. 11,014,982. Additionally, claims 1, 4 and 7 of US Pat. No. 11,014,982 teaches treating ankylosing spondylitis using an antibody having a heavy chain of SEQ ID NO: 36 and a light chain having the amino acid sequence of SEQ ID NO: 37 (which is present in golimumab) by infusion. claim 2 of US Pat. No. 11,014,982 teaches a dose of 2mg/kg of said antibody to be administered over a period of 30±10 min. Claim 3 of US Pat. No. 11,014,982 teaches administering said antibody with or without methotrexate.

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.

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/GYAN CHANDRA/
Primary Examiner, Art Unit 1646

Search Notes	Application/Control No.	Applicant(s)/Patent Under Reexamination
	17/237,650	Harrison et al.
	Examiner	Art Unit
	GYAN CHANDRA	1646

CPC - Searched*		
Symbol	**Date**	**Examiner**
c07k16/241	06/21/2024	gc
a61k39/3955	06/21/2024	gc
a61p19/02	06/21/2024	gc

CPC Combination Sets - Searched*		
Symbol	**Date**	**Examiner**

US Classification - Searched*			
Class	**Subclass**	**Date**	**Examiner**
None	None	06/21/2024	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, 2, 3, 4, 5, 6 with substitutions (see search results in SCORE)	09/13/2022	gc
claims searched in CAPLUS, Biosis, Medline (see enclosed transcript)	06/21/2024	gc
claims searched in PE2E search (see enclosed doc)	06/21/2024	gc
Inventorship search in PE2E search (see enclosed doc)	06/21/2024	gc
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	Examiner	Art Unit
	GYAN CHANDRA	1646

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

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Doc code: IDS
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INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(Not for submission under 37 CFR 1.99)

Application Number	17237650
Filing Date	2021-04-22
First Named Inventor	Diane D. Harrison
Art Unit	1646
Examiner Name	CHANDRA, GYAN
Attorney Docket Number	206389-0002-02US

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	Examiner Name	CHANDRA, GYAN
	Attorney Docket Number	206389-0002-02US

	1	Anonymous, "SIMPONI ARIA(TM) (golimumab) for infusion Receives FDA Approval for TREATMENT OF MODERATELY TO SEVERELY ACTIVE Rheumatoid arthritis", JOHNSON AND JOHNSON, (20130718), 6 pages, URL: https://www.jnj.com/media-center/press-releases/simponi-aria-golimumab-for-infusion-receives-fda-approval-for-treatment-of-moderately-to-severely-active-rheumatoid-arthritis, (20181214), XP055534592	☐
	2	Barbara Gandek ET AL, "Psychometric evaluation of the SF-36 health survey in Medicare managed care", Health care financing review, United States, (20040101), page 5, URL: http://www.ncbi.nlm.nih.gov/pubmed/15493441, XP055155378	☐
	3	Deodhar et al. "Safety and Efficacy of Golimumab Administered Intravenously in Adults with Ankylosing Spondylitis: Results through Week 28 of the GO-ALIVE Study" J Rheum. March 2018;45:341, 9 pages.	☐
	4	Haywood KL, Garratt AM, Dziedzic K, Dawes PT. Generic measures of health-related quality of life in ankylosing spondylitis: reliability, validity and responsiveness. Rheumatology (Oxford). 2002 Dec;41(12):1380-7.	☐
/G.C/	5	Johnson & Johnson, "New Phase 3 Data Show Simponi Aria® (Golimumab) Significantly Improved Signs And Symptoms In Patients With Active Ankylosing Spondylitis" 14 November 2016 (14-11-2016) 12 pages.	☐
	6	Reveille et al. "Safety and Efficacy of Intravenous Golimumab in Adults with Ankylosing Spondylitis: Results through 1 Year of the GO-ALIVE Study." J Rheum. October 2019, 7 pages. DOI: 10.3899/jrheum.180718	☐
	7	Rudwaleit M, Gooch K, Michel B, Herold M, Thörner A, Wong R, Kron M, Chen N, Kupper H. Adalimumab improves sleep and sleep quality in patients with active ankylosing spondylitis. J Rheumatol. 2011 Jan;38(1):79-86.	☐
	8	SALAFFI FAUSTO ET AL, "The health-related quality of life in rheumatoid arthritis, ankylosing spondylitis, and psoriatic arthritis: a comparison with a selected sample of healthy people", HEALTH AND QUALITY OF LIFE OUTCOMES, BIOMED CENTRAL, LONDON, GB, (20090318), vol. 7, no. 1, doi:10.1186/1477-7525-7-25, ISSN 1477-7525, page 25, XP021050341	☐
/G.C/	9	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.	☐

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Examiner Signature	/GYAN CHANDRA/	Date Considered	06/21/2024

*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.

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First Named Inventor	Diane D. Harrison
Art Unit	1646
Examiner Name	CHANDRA, GYAN
Attorney Docket Number	206389-0002-02US

[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.

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First Named Inventor	Diane D. Harrison
Art Unit	1646
Examiner Name	CHANDRA, GYAN
Attorney Docket Number	206389-0002-02US

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)	2024-06-13
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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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 e3-4

L1           75 ("HARRISON DIANE D"/AU OR "HARRISON DIANE DEBORAH"/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 e15

L2          225 "HSIA ELIZABETH C"/AU
```

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=> e Kim Lee Lian/au

E25           3     KIM LEE KYOUNG/AU
E26          72     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          329 (L1 OR L2 OR L3 OR L4)

=> s golimumab

L6         6135 GOLIMUMAB

=> s simponi

L7          174 SIMPONI

=> s l6 or l7

L8         6200 L6 OR L7

=> s intravenous (w) infusion

L9        61767 INTRAVENOUS (W) INFUSION

=> s (intravenous or iv) near infusion

MISSING OPERATOR IV) NEAR
The search profile that was entered contains terms or
nested terms that are not separated by a logical operator.

=> s (intravenous or iv) (l) infusion

L10      183728 (INTRAVENOUS OR IV) (L) INFUSION

=> s l8 (l) l10

L11          60 L8 (L) L10
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=> s l11 and py<2017

L12         30 L11 AND PY<2017

=> s 2 mg and mg/kg

'KG' IS NOT A VALID FIELD CODE
'KG' IS NOT A VALID FIELD CODE
'KG' IS NOT A VALID FIELD CODE
L13          0 2 MG AND MG/KG

=> s 2mg/kg

'KG' IS NOT A VALID FIELD CODE
'KG' IS NOT A VALID FIELD CODE
'KG' IS NOT A VALID FIELD CODE
L14          0 2MG/KG

=> s l12 and (milligram or mg) (w) (kilogram or kg)

L15         23 L12 AND (MILLIGRAM OR MG) (W) (KILOGRAM OR KG)

=> dup rem l15

PROCESSING COMPLETED FOR L15
L16          10 DUP REM L15 (13 DUPLICATES REMOVED)

=> d l16 1-10 ti so py kwic au ibib


L16  ANSWER 1 OF 10  BIOSIS  COPYRIGHT (c) 2024 Clarivate Analytics  on STN
     DUPLICATE 1
TI   Prescribing Patterns of Intravenous Golimumab for Rheumatoid Arthritis.
SO   Clinical Therapeutics, (SEP 2015) Vol. 37, No. 9, pp. 2028-2036.
     http://www.journals.elsevierhealth.com/periodicals/clithe.
     CODEN: CLTHDG. ISSN: 0149-2918. E-ISSN: 1879-114X.
PY   2015
SO   Clinical Therapeutics, (SEP 2015) Vol. 37, No. 9, pp. 2028-2036.
     http://www.journals.elsevierhealth.com/periodicals/clithe.
     CODEN: CLTHDG. ISSN: 0149-2918. E-ISSN: 1879-114X.
AB   Purpose: The use of intravenous golimumab (GLM-IV), in combination
     with methotrexate, was approved by the US Food and Drug Administration in
     July 2013 for the treatment of moderate to severe, active rheumatoid
     arthritis (RA).  GLM-IV is available in 50-mg vials, and the prescribing
     information specifies a dosing regimen of 2 mg/kg at 0 and 4 weeks and
     then every 8 weeks thereafter.  The purpose of this study was to examine
     the patterns of prescribing and administration of GLM-IV, including the
     demographic, clinical, and utilization characteristics of patients with RA
     newly treated with GLM-IV.Methods: Rheumatology practices across the
     continental United States were solicited for a chart-review study.
     Inclusion criteria were: (1) diagnosis of RA; (2) current treatment with
     GLM-IV; (3) age 18 years; and (4) lack of pregnancy (in female
     patients).  Physicians were offered a monetary incentive for each.  .  .
     chart data extraction and included fields for demographic characteristics,
     available comorbid diagnoses, prior RA treatments, and doses and dates of
     GLM-IV administration.Findings: A total of 117 eligible patient charts
     from 15 rheumatologist practices were reviewed.  The patient sample was
     predominantly female.  .  .  mean (SD) age of 55.4 (14.5) years.  A total
     of 55.6% of patients had evidence of biologic treatment before receiving
     GLM-IV, and 53% had at least 1 comorbid condition.  In total, 300
     individual GLM-IV infusions from this sample were reviewed.  Due to
     the relatively recent approval of GLM-IV use by the US Food and Drug
     Administration, the majority of patients in this sample (69.2%) had
     received only between 2 and 4 infusions at the time of the review.  For
     infusion records with valid dose data, the mean number of administered
     vials was 3.6 (0.8) (total dose, 180 mg); the majority of patients
     received a dose consistent with the prescribed dose of 2 mg/kg.
     Combination therapy with methotrexate was observed in the charts of a
     minority of patients (27.4%).  The mean interval between induction and the
     first follow-up infusion was 32.9 (11.4) days, with a mean maintenance
     interval of 56.5 (13.3) days. (C) 2015 The Authors.  Published by
     Elsevier.  .  .
```

AU Brady, Brenna L. [Reprint Author]; Tkacz, Joseph P.; Lofland, Jennifer; Meyer, Roxanne; Bolge, Susan C.
ACCESSION NUMBER: 2015:746290 BIOSIS Full-text
DOCUMENT NUMBER: PREV201500746290
TITLE: Prescribing Patterns of Intravenous Golimumab for Rheumatoid Arthritis.
AUTHOR(S): Brady, Brenna L. [Reprint Author]; Tkacz, Joseph P.; Lofland, Jennifer; Meyer, Roxanne; Bolge, Susan C.
CORPORATE SOURCE: Hlth Analyt LLC, 9200 Rumsey Rd,Suite 215, Columbia, MD 21045 USA
bbrady@healthanalytic.com
SOURCE: Clinical Therapeutics, (SEP 2015) Vol. 37, No. 9, pp. 2028-2036.
http://www.journals.elsevierhealth.com/periodicals/clithe.
CODEN: CLTHDG. ISSN: 0149-2918. E-ISSN: 1879-114X.
DIGITAL OBJECT ID: 10.1016/j.clinthera.2015.06.017
DOCUMENT TYPE: Article
LANGUAGE: English
ENTRY DATE: Entered STN: 21 Oct 2015
Last Updated on STN: 12 Jun 2019

L16 ANSWER 2 OF 10 CAPLUS COPYRIGHT 2024 ACS on STN DUPLICATE 2
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
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. . .
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
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
AUTHOR(S): 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
CORPORATE SOURCE: Johns Hopkins University, Baltimore, MD, USA
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
OS.CITING REF COUNT: 6 THERE ARE 6 CAPLUS RECORDS THAT CITE THIS RECORD

(6 CITINGS)
REFERENCE COUNT: 27 THERE ARE 27 CITED REFERENCES AVAILABLE FOR THIS RECORD. ALL CITATIONS AVAILABLE IN THE RE FORMAT

L16 ANSWER 3 OF 10 CAPLUS COPYRIGHT 2024 ACS on STN DUPLICATE 3
TI Randomised clinical trial: a placebo-controlled study of intravenous golimumab induction therapy for ulcerative colitis
SO Alimentary Pharmacology and Therapeutics (2015), 42(5), 504-514
CODEN: APTHEN; ISSN: 0269-2813
PY 2015
SO Alimentary Pharmacology and Therapeutics (2015), 42(5), 504-514
CODEN: APTHEN; ISSN: 0269-2813
AB Summary : Background : Tumor necrosis factor alpha (TNFα)-antagonism effectively treats ulcerative colitis (UC). The golimumab clin. program evaluated s.c. (SC) and i.v. (IV) induction, and SC maintenance regimens, in TNFα-antagonist-naive patients with moderate-to-severe active UC despite conventional treatment. Aim : To evaluate dose-response relationship, select IV golimumab induction doses for continued development, and evaluate the safety and efficacy of selected doses. Methods : Adults with Mayo scores. . . multicenter, randomised, double-blind, placebo-controlled, integrated Phase 2/3 dose-finding/dose-confirming study. In Phase 2, 176 patients were randomised (1:1:1:1) to a single IV infusion of placebo, 1-, 2- or 4-mg/kg golimumab. While Phase 2 data were analyzed to select doses for continued development, 71 addnl. patients were randomised. Phase 3 enrollment stopped after 44 addnl. patients were randomised (1:1:1) to placebo, 2- or 4-mg/kg golimumab. Due to insufficient power for the Phase 3 primary endpoint anal. (clin. response at week 6), efficacy analyses are considered exploratory and include all randomised patients. Results : No dose-response was obsd. in Phase 2; however, higher serum golimumab exposure was assocd. with greater proportions of patients achieving more favorable clin. outcomes, clin. response and greater improvement in Mayo. . . serum concns. Among all randomised patients, numerically greater proportions were in clin. response at week 6 in the 2- and 4-mg/kg golimumab groups compared with placebo [44.0% (33/75) and 41.6% (32/77) vs. 30.1% (22/73)]. Conclusions : Efficacy with single-dose golimumab IV induction was lower than expected and less than obsd. in the SC induction study. No new safety findings were obsd.. . .
IT Blood serum
Clinical trials
Cough
Headache
Homo sapiens
Human
Inflammatory bowel disease
Pharmaceutical intravenous infusions
Pharmacodynamics
Pharyngitis
Ulcerative colitis
(placebo-controlled randomized clin. trial of i.v. golimumab induction therapy for ulcerative colitis)
AU Rutgeerts, P.; Feagan, B. G.; Marano, C. W.; Padgett, L.; Strauss, R.; Johanns, J.; Adedokun, O. J.; Guzzo, C.; Zhang, H.; Colombel, J.-F.; Reinisch, W.; Gibson, P. R.; Sandborn, W. J.
ACCESSION NUMBER: 2015:1289183 CAPLUS Full-text
DOCUMENT NUMBER: 164:525260
TITLE: Randomised clinical trial: a placebo-controlled study of intravenous golimumab induction therapy for ulcerative colitis
AUTHOR(S): Rutgeerts, P.; Feagan, B. G.; Marano, C. W.; Padgett, L.; Strauss, R.; Johanns, J.; Adedokun, O. J.; Guzzo, C.; Zhang, H.; Colombel, J.-F.; Reinisch, W.; Gibson, P. R.; Sandborn, W. J.
CORPORATE SOURCE: PURSUIT-IV Study Group, University Hospital, Louvain, Belg.
SOURCE: Alimentary Pharmacology and Therapeutics (2015), 42(5), 504-514
CODEN: APTHEN; ISSN: 0269-2813
DIGITAL OBJECT ID: 10.1111/apt.13291
PUBLISHER: Wiley-Blackwell
DOCUMENT TYPE: Journal; (online computer file)

LANGUAGE: English
OS.CITING REF COUNT: 26 THERE ARE 26 CAPLUS RECORDS THAT CITE THIS RECORD (26 CITINGS)
REFERENCE COUNT: 20 THERE ARE 20 CITED REFERENCES AVAILABLE FOR THIS RECORD. ALL CITATIONS AVAILABLE IN THE RE FORMAT

L16 ANSWER 4 OF 10 BIOSIS COPYRIGHT (c) 2024 Clarivate Analytics on STN
DUPLICATE 4
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, (DEC 2014) Vol. 73, No. 12, pp. 2152-2159. http://ard.bmj.com/.
CODEN: ARDIAO. ISSN: 0003-4967. E-ISSN: 1468-2060.
PY 2014
SO Annals of the Rheumatic Diseases, (DEC 2014) Vol. 73, No. 12, pp. 2152-2159. http://ard.bmj.com/.
CODEN: ARDIAO. ISSN: 0003-4967. E-ISSN: 1468-2060.
AB Objective Report on radiographic effects and maintenance of clinical benefit with intravenous golimumab 2 mg/kg+methotrexate (MTX) for up to week (wk) 52 in active rheumatoid arthritis (RA).Methods Patients (n=592) with active RA (>= 6/66 swollen,. . . participated in this multicentre, international, randomised, double blind, placebo controlled, phase 3 study. Patients were randomised (2: 1) to receive intravenous golimumab 2 mg/kg or placebo infusions at weeks 0 and 4 and then every 8 weeks; 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 and wk52. . . safety data up to 1 year are reported here.Results Significant and rapid clinical improvement was observed up to wk24 of intravenous golimumab therapy. Golimumab+MTX treated patients demonstrated less radiographic progression than placebo treated patients at wk24 (vdH-S score mean change 0.03 vs 1.09; p<0.001). . . approximately 80% maintained this response up until wk52. Through an average of 43.5 weeks 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, intravenous golimumab+MTX yielded significant inhibition of structural damage at wk24 and wk52, and sustained clinical improvement in signs and symptoms with no. . .
AU Weinblatt, Michael E. [Reprint Author]; 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.; GO-FURTHER Investigators
ACCESSION NUMBER: 2015:30816 BIOSIS Full-text
DOCUMENT NUMBER: PREV201500030816
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. [Reprint Author]; 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.; GO-FURTHER Investigators
CORPORATE SOURCE: Harvard Univ, Brigham and Womens Hosp, Div Rheumatol Immunol and Allergy, Sch Med, 75 Francis St, Boston, MA 02115 USA
mweinblatt@partners.org
SOURCE: Annals of the Rheumatic Diseases, (DEC 2014) Vol. 73, No. 12, pp. 2152-2159. http://ard.bmj.com/.
CODEN: ARDIAO. ISSN: 0003-4967. E-ISSN: 1468-2060.
DIGITAL OBJECT ID: 10.1136/annrheumdis-2013-203742
DOCUMENT TYPE: Article
LANGUAGE: English
ENTRY DATE: Entered STN: 17 Dec 2014
Last Updated on STN: 25 Sep 2019

L16 ANSWER 5 OF 10 CAPLUS COPYRIGHT 2024 ACS on STN DUPLICATE 5
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
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 (RA) despite. . . 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. . .
AU Bingham, Clifton O., III; Weinblatt, Michael; Han, Chenglong; Gathany, Timothy A.; Kim, Lilianne; Lo, Kim Hung; Baker, Dan; Mendelsohn, Alan; Westhovens, Rene
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, Lilianne; Lo, Kim Hung; Baker, Dan; Mendelsohn, Alan; Westhovens, Rene
CORPORATE SOURCE: 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)

L16 ANSWER 6 OF 10 MEDLINE ® on STN
TI Intravenous golimumab in rheumatoid arthritis.
SO Expert review of clinical immunology, (2014 Jul) Vol. 10, No. 7, pp. 823-30. Electronic Publication Date: 15 May 2014
Journal code: 101271248. E-ISSN: 1744-8409. L-ISSN: 1744-666X.
PY 2014
SO Expert review of clinical immunology, (2014 Jul) Vol. 10, No. 7, pp. 823-30. Electronic Publication Date: 15 May 2014
Journal code: 101271248. E-ISSN: 1744-8409. L-ISSN: 1744-666X.
AB Intravenous golimumab in a dosage of 2 mg/kg, initially given every 4 weeks but then every 8 weeks, in addition to methotrexate, is effective in the treatment of patients with rheumatoid arthritis. This weight-based infusion is administered over thirty minutes with an acceptable safety profile. Since it is a relatively new formulation, more time will. . .
AU Cohen Marc D; Keystone Edward C
ACCESSION NUMBER: 2014731206 MEDLINE Full-text
DOCUMENT NUMBER: PubMed ID: 24831189

TITLE: Intravenous golimumab in rheumatoid arthritis.
AUTHOR: Cohen Marc D
CORPORATE SOURCE: Mayo Clinic, 668 Humboldt St, Denver, CO 80218, USA.
AUTHOR: Keystone Edward C
SOURCE: Expert review of clinical immunology, (2014 Jul) Vol. 10, No. 7, pp. 823-30. Electronic Publication Date: 15 May 2014
Journal code: 101271248. E-ISSN: 1744-8409. L-ISSN: 1744-666X.
DIGITAL OBJECT ID: http://dx.doi.org/10.1586/1744666X.2014.918847
PUB. COUNTRY: England: United Kingdom
DOCUMENT TYPE: Journal; Article; (JOURNAL ARTICLE)
General Review; (REVIEW)
LANGUAGE: English
FILE SEGMENT: MEDLINE; Priority Journals
FILE SEGMENT: Print; Electronic
ENTRY MONTH: 201502
ENTRY DATE: Entered STN: 17 May 2014
Last Updated on STN: 14 Feb 2015
Indexing Added: 14 Feb 2015
Entered Medline: 13 Feb 2015
OS.CITING REF COUNT: 5 There are 5 MEDLINE records that cite this record

L16 ANSWER 7 OF 10 BIOSIS COPYRIGHT (c) 2024 Clarivate Analytics on STN
DUPLICATE 6
TI Intravenous golimumab is effective in patients with active rheumatoid arthritis despite methotrexate therapy with responses as early as week 2: results of the phase 3, randomised, multicentre, double-blind, placebo-controlled GO-FURTHER trial.
SO Annals of the Rheumatic Diseases, (MAR 2013) Vol. 72, No. 3, pp. 381-389. http://ard.bmj.com/.
CODEN: ARDIAO. ISSN: 0003-4967. E-ISSN: 1468-2060.
PY 2013
SO Annals of the Rheumatic Diseases, (MAR 2013) Vol. 72, No. 3, pp. 381-389. http://ard.bmj.com/.
CODEN: ARDIAO. ISSN: 0003-4967. E-ISSN: 1468-2060.
AB Objectives Evaluate the efficacy of intravenous golimumab 2 mg/kg + methotrexate (MTX) in patients with active rheumatoid arthritis (RA) receiving MTX.Methods Patients (n = 592) with active disease (>=. . . at screening) despite MTX (15-25 mg/week) participated in this double-blind, placebo-controlled, phase 3 study. Patients were randomised (2:1) to receive intravenous golimumab 2 mg/kg, or placebo infusions at weeks 0 and 4 and every (q) 8 weeks; patients continued MTX. Placebo patients with < 10% improvement in combined swollen/tender joint counts at week 16 could early escape to intravenous golimumab 2 mg/kg. The primary endpoint was week 14 American College of Rheumatology 20% (ACR20) response. Analyses employed non-responder imputation and last-observation-carried-forward.Results At week 14, significantly (p < 0.001) larger proportions of golimumab + MTX than placebo + MTX patients achieved ACR20 response (59% vs 25%, respectively), a disease activity score of good/moderate. . . questionnaire scores (0.500 vs 0.125). Improvements versus placebo + MTX were observed by week 2. Similar proportions of patients receiving golimumab + MTX and placebo + MTX, respectively, reported adverse events through week 16 (47% and 44%) and week 24 (53% and 49%). Serious adverse events were reported by more golimumab + MTX (4.1%) than placebo + MTX (2%) patients at week 24.Conclusion The addition of intravenous golimumab rapidly and significantly improved signs and symptoms in patients with active RA despite ongoing MTX, in some patients by week. . .
AU Weinblatt, Michael E. [Reprint Author]; Bingham, Clifton O. III; Mendelsohn, Alan M.; Kim, Lilianne; Mack, Michael; Lu, Jiandong; Baker, Daniel; Westhovens, Rene
ACCESSION NUMBER: 2013:227925 BIOSIS Full-text
DOCUMENT NUMBER: PREV201300227925
TITLE: Intravenous golimumab is effective in patients with active rheumatoid arthritis despite methotrexate therapy with responses as early as week 2: results of the phase 3, randomised, multicentre, double-blind, placebo-controlled GO-FURTHER trial.
AUTHOR(S): Weinblatt, Michael E. [Reprint Author]; Bingham, Clifton O. III; Mendelsohn, Alan M.; Kim, Lilianne; Mack, Michael; Lu, Jiandong; Baker, Daniel; Westhovens, Rene

CORPORATE SOURCE: Brigham and Womens Hosp, Dept Rheumatol, 75 Francis St, Boston, MA 02115 USA
mweinblatt@partners.org
SOURCE: Annals of the Rheumatic Diseases, (MAR 2013) Vol. 72, No. 3, pp. 381-389. http://ard.bmj.com/.
CODEN: ARDIAO. ISSN: 0003-4967. E-ISSN: 1468-2060.
DIGITAL OBJECT ID: 10.1136/annrheumdis-2012-201411
DOCUMENT TYPE: Article
LANGUAGE: English
ENTRY DATE: Entered STN: 13 Mar 2013
Last Updated on STN: 25 Sep 2019

L16 ANSWER 8 OF 10 CAPLUS COPYRIGHT 2024 ACS on STN DUPLICATE 7
TI Golimumab Pharmacokinetics After Repeated Subcutaneous and Intravenous Administrations in Patients with Rheumatoid Arthritis and the Effect of Concomitant Methotrexate: An Open-Label, Randomized Study
SO Clinical Therapeutics (2012), 34(1), 77-90
CODEN: CLTHDG; ISSN: 0149-2918
PY 2012
SO Clinical Therapeutics (2012), 34(1), 77-90
CODEN: CLTHDG; ISSN: 0149-2918
AB Background: The pharmacokinetics of golimumab, a human monoclonal antibody that inhibits the activity of tumor necrosis factor α, after a single s.c. (SC) or i.v. (IV) administration have been previously studied. Objectives: The purpose of this study was to assess the pharmacokinetics of golimumab after multiple SC or IV administrations in patients with active rheumatoid arthritis (RA). The effect of concomitant methotrexate (MTX) use on golimumab pharmacokinetics was evaluated. Methods: In this open-label, randomized, Phase I study, 49 adult patients with RA received SC golimumab 100 mg (n = 33) every 4 wk through week 20 or IV golimumab 2 mg/kg (n = 16) at weeks 0 and 12. Serial blood samples were collected, and serum golimumab concn. was measured with an electrochemiluminescent immunoassay. Golimumab pharmacokinetic parameters were derived with the use of a noncompartmental anal. Adverse events were monitored at every visit. Results: The population was predominantly Caucasian (84%) and female (76%), and the median age was 57 years. After SC golimumab administration, the serum golimumab concn. achieved steady state by ~12 wk with mean trough serum concns. ranging from 1.15 to 1.24 μg/mL. After the final 30-min IV infusion of golimumab 2 mg/kg, the mean (SD) clearance (CL) was 7.5 (2.6) mL/d/kg. The mean terminal half-life after SC and IV administrations was ~13 days. The mean abs. bioavailability for SC golimumab was estd. to be 53%. The geometric mean of golimumab CL/F in patients with and without concomitant MTX use was 13.9 and 21.2 mL/d/kg, resp., and the geometric mean ratio of CL/F was 65.5% (90% CI: 45.2%-94.9%, P = 0.06). Golimumab was generally well tolerated. No malignancies or deaths occurred during the study. Conclusions: Pharmacokinetics of golimumab were consistent after SC or IV administration in this population of patients with RA. Golimumab was well tolerated and no unexpected adverse events were obsd. in this trial. ClinialTrials.gov identifier: NCT01362153.
AU Zhuang, Yanli; Xu, Zhenhua; Frederick, Bart; de Vries, Dick E.; Ford, Joyce A.; Keen, Monica; Doyle, Mittie K.; Petty, Kevin J.; Davis, Hugh M.; Zhou, Honghui
ACCESSION NUMBER: 2012:143775 CAPLUS Full-text
DOCUMENT NUMBER: 157:217097
TITLE: Golimumab Pharmacokinetics After Repeated Subcutaneous and Intravenous Administrations in Patients with Rheumatoid Arthritis and the Effect of Concomitant Methotrexate: An Open-Label, Randomized Study
AUTHOR(S): Zhuang, Yanli; Xu, Zhenhua; Frederick, Bart; de Vries, Dick E.; Ford, Joyce A.; Keen, Monica; Doyle, Mittie K.; Petty, Kevin J.; Davis, Hugh M.; Zhou, Honghui
CORPORATE SOURCE: Janssen Research & Development, LLC, Malvern, PA, USA
SOURCE: Clinical Therapeutics (2012), 34(1), 77-90
CODEN: CLTHDG; ISSN: 0149-2918
DIGITAL OBJECT ID: 10.1016/j.clinthera.2011.11.015
PUBLISHER: Elsevier
DOCUMENT TYPE: Journal; (online computer file)
LANGUAGE: English
OS.CITING REF COUNT: 54 THERE ARE 54 CAPLUS RECORDS THAT CITE THIS RECORD (54 CITINGS)

REFERENCE COUNT: 36 THERE ARE 36 CITED REFERENCES AVAILABLE FOR THIS RECORD. ALL CITATIONS AVAILABLE IN THE RE FORMAT

L16 ANSWER 9 OF 10 BIOSIS COPYRIGHT (c) 2024 Clarivate Analytics on STN
DUPLICATE 8
TI Golimumab, a New Human Anti-Tumor Necrosis Factor alpha Antibody, Administered Intravenously in Patients With Active Rheumatoid Arthritis Forty-Eight-Week Efficacy and Safety Results of a Phase III Randomized, Double-Blind, Placebo-Controlled Study.
SO Arthritis & Rheumatism, (APR 2010) Vol. 62, No. 4, pp. 917-928. http://onlinelibrary.wiley.com/journal/10.1002/(ISSN)1529-0131. CODEN: ARHEAW. ISSN: 0004-3591. E-ISSN: 1529-0131.
PY 2010
SO Arthritis & Rheumatism, (APR 2010) Vol. 62, No. 4, pp. 917-928. http://onlinelibrary.wiley.com/journal/10.1002/(ISSN)1529-0131. CODEN: ARHEAW. ISSN: 0004-3591. E-ISSN: 1529-0131.
AB Objective. To assess the efficacy and safety of intravenous administration of golimumab in patients with rheumatoid arthritis (RA).Methods. Adult patients with RA in whom disease activity was persistent despite treatment with methotrexate (MTX) at a dosage of 15-25 mg/week for >= 4 weeks were randomized to receive intravenous infusions of placebo plus MTX or intravenous infusions of golimumab at a dose of 2 mg/kg or 4 mg/kg, with or without MTX, every 12 weeks through week 48. Patients with <20% improvement in the swollen and tender joint. . . end point was not met (at week 14, an ACR50 response was observed in 21% of the patients treated with golimumab plus MTX compared with 13% of the patients treated with placebo plus MTX [P = 0.051]). By week 24, significantly more patients treated with golimumab plus MTX had achieved an ACR50 response. Differences in the proportion of patients achieving an ACR50 response between the group receiving golimumab monotherapy and the group receiving placebo plus MTX were not significant at either week 14 (16% versus 13%) or week. . . 9%). At week 48, the proportions of patients achieving ACR20 and ACR50 responses were highest among those who had received golimumab 4 mg/kg plus MTX (70% and 48%, respectively). Concomitant treatment with MTX was associated with a lower incidence of antibodies to golimumab. The most commonly reported adverse events through week 48 were infections (48% of patients treated with golimumab with or without MTX and 41% of patients receiving placebo plus MTX).Conclusion. The primary end point was not met. However, intravenously administered golimumab plus MTX appears to have benefit in the longer-term reduction of RA signs/symptoms in MTX-resistant patients, with no unexpected safety. . .
AU Kremer, Joel [Reprint Author]; Ritchlin, Christopher; Mendelsohn, Alan; Baker, Daniel; Kim, Lilianne; Xu, Zhenhua; Han, John; Taylor, Peter
ACCESSION NUMBER: 2010:425724 BIOSIS Full-text
DOCUMENT NUMBER: PREV201000425724
TITLE: Golimumab, a New Human Anti-Tumor Necrosis Factor alpha Antibody, Administered Intravenously in Patients With Active Rheumatoid Arthritis Forty-Eight-Week Efficacy and Safety Results of a Phase III Randomized, Double-Blind, Placebo-Controlled Study.
AUTHOR(S): Kremer, Joel [Reprint Author]; Ritchlin, Christopher; Mendelsohn, Alan; Baker, Daniel; Kim, Lilianne; Xu, Zhenhua; Han, John; Taylor, Peter
CORPORATE SOURCE: Ctr Rheumatol, 1367 Washington Ave, Albany, NY 12206 USA jkremer@joint-docs.com
SOURCE: Arthritis & Rheumatism, (APR 2010) Vol. 62, No. 4, pp. 917-928. http://onlinelibrary.wiley.com/journal/10.1002/(ISSN)1529-0131.
CODEN: ARHEAW. ISSN: 0004-3591. E-ISSN: 1529-0131.
DIGITAL OBJECT ID: 10.1002/art.27348
DOCUMENT TYPE: Article
LANGUAGE: English
ENTRY DATE: Entered STN: 28 Jul 2010
Last Updated on STN: 9 Sep 2020

L16 ANSWER 10 OF 10 BIOSIS COPYRIGHT (c) 2024 Clarivate Analytics on STN
DUPLICATE 9
TI Pharmacokinetics and safety of golimumab, a fully human anti-TNF-alpha monoclonal antibody, in subjects with rheumatoid arthritis.
SO Journal of Clinical Pharmacology, (MAR 2007) Vol. 47, No. 3, pp. 383-396.

CODEN: JCPCBR. ISSN: 0091-2700.
PY 2007
SO Journal of Clinical Pharmacology, (MAR 2007) Vol. 47, No. 3, pp. 383-396.
CODEN: JCPCBR. ISSN: 0091-2700.
AB Golimumab is a fully human antitumor necrosis factor alpha (TNF-alpha) monoclonal antibody that is being developed for intravenous and subcutaneous administration. To assess the pharmacokinetics and safety of the intravenous formulation of golimumab, 36 adult subjects with rheumatoid arthritis were randomly assigned to receive a single infusion of placebo or golimumab (0.1, 0.3, 1, 3, 6, or 10 mg/kg). Serum concentrations of golimumab were determined using a validated enzyme-linked immunosorbent assay method. In addition to the noncompartmental analysis and compartmental modeling, a population. . . manner. The median half-life ranged from 7 to 20 days. A 2-compartment population pharmacokinetic model adequately described the pharmacokinetics of golimumab. The following pharmacokinetic parameters (typical value [% coefficient of variation]) were estimated from the population pharmacokinetic model: clearance (CL 0.40. . . 15.0%. Body weight was found to be an important covariate on V-c. Golimumub was generally well tolerated. The pharmacokinetics of golimumab appeared to be linear over the dose range evaluated in this study.
AU Zhou, Honghui [Reprint Author]; Jang, Haishan; Fleischmann, Roy M.; Bouman-Thio, Esther; Xu, Zhenhua; Marini, Joseph C.; Pendley, Charles; Jiao, Qun; Shankar, Gopi; Marciniak, Stanley J.; Cohen, Stanley B.; Rahman, Mahboob U.; Baker, Daniel; Mascelli, Mary Ann; Davis, Hugh M.; Everitt, Daniel E.
ACCESSION NUMBER: 2007:236518 BIOSIS Full-text
DOCUMENT NUMBER: PREV200700237961
TITLE: Pharmacokinetics and safety of golimumab, a fully human anti-TNF-alpha monoclonal antibody, in subjects with rheumatoid arthritis.
AUTHOR(S): Zhou, Honghui [Reprint Author]; Jang, Haishan; Fleischmann, Roy M.; Bouman-Thio, Esther; Xu, Zhenhua; Marini, Joseph C.; Pendley, Charles; Jiao, Qun; Shankar, Gopi; Marciniak, Stanley J.; Cohen, Stanley B.; Rahman, Mahboob U.; Baker, Daniel; Mascelli, Mary Ann; Davis, Hugh M.; Everitt, Daniel E.
CORPORATE SOURCE: Centocor Res and Dev Inc, Clin Pharmacol and Expt Med, 200 Great Valley Pkwy, Malvern, PA 19355 USA
SOURCE: Journal of Clinical Pharmacology, (MAR 2007) Vol. 47, No. 3, pp. 383-396.
CODEN: JCPCBR. ISSN: 0091-2700.
DOCUMENT TYPE: Article
LANGUAGE: English
ENTRY DATE: Entered STN: 11 Apr 2007
Last Updated on STN: 11 Apr 2007

=> s l16 and ankylosing (w) spondylitis

L17 0 L16 AND ANKYLOSING (W) SPONDYLITIS

=> s l8 and ankylosing (w) spondylitis

L18 1114 L8 AND ANKYLOSING (W) SPONDYLITIS

=> s l18 and (intravenous or iv) (w) infusion

L19 13 L18 AND (INTRAVENOUS OR IV) (W) INFUSION

=> s l19 and (milligram or mg) (w) (kg or killogram)

L20 6 L19 AND (MILLIGRAM OR MG) (W) (KG OR KILLOGRAM)

=> dup rem l20

PROCESSING COMPLETED FOR L20
L21 2 DUP REM L20 (4 DUPLICATES REMOVED)

=> s l21 and py<2017

L22 0 L21 AND PY<2017

=> s l21 and py<2018

L23 0 L21 AND PY<2018

=> d l21 1-2 ti so py kwic au ibib

L21 ANSWER 1 OF 2 CAPLUS COPYRIGHT 2024 ACS on STN DUPLICATE 1
TI Safety and efficacy of intravenous golimumab in adults with ankylosing spondylitis: results through 1 year of the GO-ALIVE study
SO Journal of Rheumatology (2019), 46(10), 1277-1283
CODEN: JRHUA9; ISSN: 1499-2752
URL: http://www.jrheum.org/
PY 2019
TI Safety and efficacy of intravenous golimumab in adults with ankylosing spondylitis: results through 1 year of the GO-ALIVE study
AB Objective: Evaluate safety and efficacy of i.v. (IV) golimumab (GOL) in patients with active ankylosing spondylitis (AS) through 1 yr. Methods: A total of 208 patients were randomized to IV infusions of GOL 2 mg/kg (n = 105) at weeks 0, 4, and every 8 wk thereafter or placebo (n = 103) at weeks 0,. . . every 8 wk thereafter through Week 52. Efficacy was assessed using the Assessment of Spondyloarthritis international Society (ASAS) criteria, the Ankylosing Spondylitis Disease Activity Score (ASDAS), the Bath Ankylosing Spondylitis Disease Activity Index (BASDAI), and the Bath Ankylosing Spondylitis Functional Index (BASFI). Health-related quality of life was assessed using the AS Quality of Life (ASQoL) index. Efficacy and safety. . . adverse events (AE); 3.4% had ≥ 1 serious AE. Conclusion: Efficacy was maintained through 1 yr with IV GOL 2 mg/kg among patients with active AS. AE were consistent with the known safety profile of GOL.
ST intravenous golimumab ankylosing spondylitis
IT Ankylosing spondylitis
Drug toxicity
Homo sapiens
Human
Pharmaceutical intravenous injections
(results of safety and efficacy of i.v. golimumab in adults with ankylosing spondylitis through 1 yr of GO-ALIVE study)
IT 476181-74-5, Golimumab
RL: ADV (Adverse effect, including toxicity); PAC (Pharmacological activity); THU (Therapeutic use); BIOL (Biological study); USES (Uses)
(results of safety and efficacy of i.v. golimumab in adults with ankylosing spondylitis through 1 yr of GO-ALIVE study)
AU Reveille, John D.; Deodhar, Atul; Caldron, Paul H.; Dudek, Anna; Harrison, Diane D.; Kim, Lilianne; Lo, Kim Hung; Leu, Jocelyn H.; Hsia, Elizabeth C.
ACCESSION NUMBER: 2020:621677 CAPLUS Full-text
DOCUMENT NUMBER: 175:317623
TITLE: Safety and efficacy of intravenous golimumab in adults with ankylosing spondylitis: results through 1 year of the GO-ALIVE study
AUTHOR(S): Reveille, John D.; Deodhar, Atul; Caldron, Paul H.; Dudek, Anna; Harrison, Diane D.; Kim, Lilianne; Lo, Kim Hung; Leu, Jocelyn H.; Hsia, Elizabeth C.
CORPORATE SOURCE: University of Texas McGovern Medical School, Houston, TX, USA
SOURCE: Journal of Rheumatology (2019), 46(10), 1277-1283
CODEN: JRHUA9; ISSN: 1499-2752
URL: http://www.jrheum.org/
DIGITAL OBJECT ID: 10.3899/jrheum.180718
PUBLISHER: Journal of Rheumatology Publishing Co. Ltd.
DOCUMENT TYPE: Journal; (online computer file)
LANGUAGE: English
OS.CITING REF COUNT: 5 THERE ARE 5 CAPLUS RECORDS THAT CITE THIS RECORD (5 CITINGS)
REFERENCE COUNT: 16 THERE ARE 16 CITED REFERENCES AVAILABLE FOR THIS RECORD. ALL CITATIONS AVAILABLE IN THE RE FORMAT

L21 ANSWER 2 OF 2 CAPLUS COPYRIGHT 2024 ACS on STN DUPLICATE 2

TI Safety and efficacy of Golimumab administered intravenously in adults with ankylosing spondylitis: results through week 28 of the GO-ALIVE study
SO Journal of Rheumatology (2018), 45(3), 341-349
CODEN: JRHUA9; ISSN: 1499-2752
PY 2018
TI Safety and efficacy of Golimumab administered intravenously in adults with ankylosing spondylitis: results through week 28 of the GO-ALIVE study
AB Objective.To evaluate the safety and efficacy of i.v. golimumab (GOL) in patients with active ankylosing spondylitis (AS). Methods.In a phase III, randomized, double-blind, placebo (PBO)-controlled trial, 208 patients were randomized (1:1) to i.v. (IV) infusions of GOL 2 mg/kg (n = 105) at weeks 0, 4, 12, and every 8 wk, or PBO (n = 103) at weeks 0,. . . Assessment of Spondyloarthritis International Society Criteria (ASAS20) at Week 16. Secondary endpoints included ASAS40, ≥ 50% improvement in the Bath Ankylosing Spondylitis Disease Activity Index (BASDAI50), and change in the Bath Ankylosing Spondylitis Functional Index (BASFI) at Week 16. Safety was monitored through Week 28. Results.Significantly greater proportions of GOL-treated patients had ASAS20. . .
ST ankylosing spondylitis nasopharyngitis golimumab adalimumab certolizumab etanercept CRP pharmacokinetics
IT Ankylosing spondylitis
Blood serum
Diagnosis
Homo sapiens
Human
Inflammation
Metabolic side effects of drugs
Nasopharyngitis
Pharmaceutical intravenous infusions
Pharmacokinetics
Upper respiratory infection
(safety and efficacy of golimumab administered i.v. in adults with ankylosing spondylitis)
IT C-reactive protein
Tumor necrosis factors
RL: BSU (Biological study, unclassified); BIOL (Biological study)
(safety and efficacy of golimumab administered i.v. in adults with ankylosing spondylitis)
IT 9000-86-6, Alanine aminotransferase 9000-97-9, Aspartate aminotransferase
RL: BSU (Biological study, unclassified); BIOL (Biological study)
(safety and efficacy of golimumab administered i.v. in adults with ankylosing spondylitis)
IT 59-05-2 170277-31-3 185243-69-0 331731-18-1 428863-50-7 476181-74-5
RL: THU (Therapeutic use); BIOL (Biological study); USES (Uses)
(safety and efficacy of golimumab administered i.v. in adults with ankylosing spondylitis)
AU Deodhar, Atul; Reveille, John D.; Harrison, Diane D.; Kim, Lilianne; Lo, Kim Hung; Leu, Jocelyn H.; Hsia, Elizabeth C.
ACCESSION NUMBER: 2019:192315 CAPLUS Full-text
DOCUMENT NUMBER: 174:574693
TITLE: Safety and efficacy of Golimumab administered intravenously in adults with ankylosing spondylitis: results through week 28 of the GO-ALIVE study
AUTHOR(S): Deodhar, Atul; Reveille, John D.; Harrison, Diane D.; Kim, Lilianne; Lo, Kim Hung; Leu, Jocelyn H.; Hsia, Elizabeth C.
CORPORATE SOURCE: Oregon Health & Science University, Portland, OR, USA
SOURCE: Journal of Rheumatology (2018), 45(3), 341-349
CODEN: JRHUA9; ISSN: 1499-2752
DIGITAL OBJECT ID: 10.3899/jrheum.170487
PUBLISHER: Journal of Rheumatology Publishing Co. Ltd.
DOCUMENT TYPE: Journal; (online computer file)
LANGUAGE: English
OS.CITING REF COUNT: 19 THERE ARE 19 CAPLUS RECORDS THAT CITE THIS RECORD (19 CITINGS)
REFERENCE COUNT: 28 THERE ARE 28 CITED REFERENCES AVAILABLE FOR THIS RECORD. ALL CITATIONS AVAILABLE IN THE RE FORMAT

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     (FILE 'HOME' ENTERED AT 18:36:07 ON 21 JUN 2024)

     FILE 'CAPLUS, BIOSIS, MEDLINE' ENTERED AT 18:36:33 ON 21 JUN 2024
                 E HARRISON DIANE D/AU
L1            75 S E3-4
                 E HSIA ELIZABETH C/AU
L2           225 S E15
                 E KIM LEE LIAN/AU
L3            18 S E27
                 E LO KIM HUNG/AU
L4           112 S E38-39
L5           329 S L1-4
L6          6135 S GOLIMUMAB
L7           174 S SIMPONI
L8          6200 S L6 OR L7
L9         61767 S INTRAVENOUS (W) INFUSION
L10       183728 S (INTRAVENOUS OR IV) (L) INFUSION
L11           60 S L8 (L) L10
L12           30 S L11 AND PY<2017
L13            0 S 2 MG AND MG/KG
L14            0 S 2MG/KG
L15           23 S L12 AND (MILLIGRAM OR MG) (W) (KILOGRAM OR KG)
L16           10 DUP REM L15 (13 DUPLICATES REMOVED)
L17            0 S L16 AND ANKYLOSING (W) SPONDYLITIS
L18         1114 S L8 AND ANKYLOSING (W) SPONDYLITIS
L19           13 S L18 AND (INTRAVENOUS OR IV) (W) INFUSION
L20            6 S L19 AND (MILLIGRAM OR MG) (W) (KG OR KILLOGRAM)
L21            2 DUP REM L20 (4 DUPLICATES REMOVED)
L22            0 S L21 AND PY<2017
L23            0 S L21 AND PY<2018

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PE2E SEARCH - Search History (Prior Art)

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Ex. 2002-339

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L403	2	L1 AND golimumab	(US-PGPUB; USPAT)	OR	ON	ON	2024/06/21 03:07 PM
L404	1	L1 AND golimumab AND ankylosing	(US-PGPUB; USPAT)	OR	ON	ON	2024/06/21 03:07 PM
L405	2	L1 AND golimumab AND arthritis	(US-PGPUB; USPAT)	OR	ON	ON	2024/06/21 03:07 PM
L406	2	L1 AND golimumab AND spondylitis	(US-PGPUB; USPAT)	OR	ON	ON	2024/06/21 03:07 PM
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L409	172	golimumab AND	(US-PGPUB; USPAT)	OR	ON	ON	2024/06/21

		spondylitis ADJ ankylosing					03:07 PM
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L412	1	(golimumab OR (Cnto NEAR "148")) SAME spondylitis ADJ ankylosing AND @ay<"2018"	(US-PGPUB; USPAT)	OR	ON	ON	2024/06/21 03:07 PM
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L418	111	(golimumab OR (Cnto NEAR "148")).clm. AND ankylosing ADJ spondylitis AND @ay<"2017" AND methotrexate	(US-PGPUB; USPAT)	OR	ON	ON	2024/06/21 03:07 PM
L419	114	(golimumab OR (Cnto NEAR "148")).clm. AND ankylosing ADJ spondylitis AND @ay<"2017" AND (methotrexate OR sulfasalazine OR hydroxychloroquine)	(US-PGPUB; USPAT)	OR	ON	ON	2024/06/21 03:07 PM
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L422	15	(golimumab OR (Cnto NEAR "148")) SAME (rate NEAR infusion)	(US-PGPUB; USPAT)	OR	ON	ON	2024/06/21 03:07 PM
L423	1042	antibody SAME (rate NEAR infusion)	(US-PGPUB; USPAT)	OR	ON	ON	2024/06/21 03:07 PM
L424	190	antibody SAME infusion SAME rate SAME over NEAR period	(US-PGPUB; USPAT)	OR	ON	ON	2024/06/21 03:07 PM
L425	1	anti-tnf SAME antibody SAME infusion SAME rate SAME over NEAR period	(US-PGPUB; USPAT)	OR	ON	ON	2024/06/21 03:07 PM
L426	5	anti-tnf AND antibody SAME infusion SAME rate SAME over NEAR period	(US-PGPUB; USPAT)	OR	ON	ON	2024/06/21 03:07 PM
L427	5931	anti-tnf AND antibody SAME infusion	(US-PGPUB; USPAT)	OR	ON	ON	2024/06/21 03:07 PM
L428	214	anti-tnf ADJ antibody SAME infusion	(US-PGPUB; USPAT)	OR	ON	ON	2024/06/21 03:07 PM
L429	1027	Janssen ADJ Biotech ADJ Inc.asn.	(US-PGPUB; USPAT)	OR	ON	ON	2024/06/21 03:07 PM
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L431	19	Hsia Elizabeth C.in.	(US-PGPUB; USPAT)	ADJ	ON	ON	2024/06/21 03:07 PM
L432	13	Kim Lee-Lian.in.	(US-PGPUB; USPAT)	ADJ	ON	ON	2024/06/21 03:07 PM
L433	14	Lo Kim Hung.in.	(US-PGPUB; USPAT)	ADJ	ON	ON	2024/06/21 03:07 PM
L434	1233	L27 L29 L30 L31 L32 L34	(US-PGPUB; USPAT)	OR	ON	ON	2024/06/21 03:07 PM
L435	128	L35 AND golimumab	(US-PGPUB; USPAT)	OR	ON	ON	2024/06/21 03:07 PM
L436	11	L35 AND golimumab.clm.	(US-PGPUB; USPAT)	OR	ON	ON	2024/06/21 03:07 PM
L437	3699	c07k16/241.cpc.	(US-PGPUB; USPAT)	OR	ON	ON	2024/06/21 03:07 PM
L438	16663	a61k39/3955.cpc.	(US-PGPUB; USPAT)	OR	ON	ON	2024/06/21 03:07 PM
L439	55742	a61p19/02.cpc.	(US-PGPUB; USPAT)	OR	ON	ON	2024/06/21 03:07 PM
L440	71767	L38 OR L39 L40	(US-PGPUB; USPAT)	OR	ON	ON	2024/06/21 03:07 PM
L441	119	L41 AND golimumab AND spondilitis	(US-PGPUB; USPAT)	OR	ON	ON	2024/06/21 03:07 PM
L442	23	L41 AND golimumab AND spondilitis.clm.	(US-PGPUB; USPAT)	OR	ON	ON	2024/06/21 03:07 PM
L443	60	golimumab AND spondylitis ADJ ankylosing AND	(US-PGPUB; USPAT)	OR	ON	ON	2024/06/21 03:07 PM

		@ay<"2018" AND infusion					
L444	117	2009/0123378 AND administration AND iv	(US-PGPUB; USPAT)	OR	ON	ON	2024/06/21 03:07 PM
L445	1	"20090123378".pn. AND administration AND iv	(US-PGPUB; USPAT)	OR	ON	ON	2024/06/21 03:07 PM
L446	1	"20090123378".pn. AND administration AND intraven$5	(US-PGPUB; USPAT)	OR	ON	ON	2024/06/21 03:07 PM
L447	151	("0000030" OR "0000059" OR "0000088" OR "0000116" OR "0000144" OR "20090214528" OR "20100251099" OR "20110251099" 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 "4757506" 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 "5116964" OR "5122464" OR "5130238" OR "5142033" OR "5149636" OR "5168062" OR "5179017" OR "5223409" OR "5225538" OR	(US-PGPUB; USPAT)	OR	ON	ON	2024/06/21 03:07 PM

		"5225539" OR "5231024" OR "5260203" OR "5266491" OR "5304489" OR "5342613" OR "5385839" OR "5403484" OR "5404871" OR "5427908" OR "5447851" OR "5455030" OR "5458135" OR "5496549" OR "5512544" OR "5514670" OR "5518889" OR "5530101" OR "5534621" OR "5545807" OR "5565362" 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 "5698419" OR "5698435" OR "5714352" OR "5723323" OR "5733761" OR "5750105" OR "5750373" OR "5763192" OR "5763733" OR "5766886" OR "5770198" OR					

		"5770222" OR "5770359" OR "5770428" OR "5789650" OR "5807706" OR "5814476" OR "5814599" OR "5817483" OR "5821333" OR "5824514" OR "5827690" OR "5827739" OR "5833985" OR "5837500" OR "5839446" OR "5849695" OR "5851198" OR "5856456" OR "5871753" OR "5879681" OR "5885793" OR "5888511" OR "5919452" OR "5932448" OR "5958413" OR "5959083" OR "5959084" OR "5962255" OR "5976862" OR "5989530" OR "5993833" OR "5994616" OR "6010902" 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.					
L448	2	("0000030" OR "0000059" OR "0000088" OR "0000116" OR "0000144" OR "20090214528" OR "20100251099" OR "20110251099" OR "3773919" OR "4239754" OR	(US-PGPUB; USPAT)	OR	ON	ON	2024/06/21 03:07 PM

		"4309989" OR "4399216" OR "4603106" OR "4634665" OR "4656134" OR "4668218" OR "4676980" OR "4683195" OR "4683202" OR "4704692" OR "4757506" 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 "5116964" 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 "5404871" OR "5427908" OR "5447851" OR "5455030" OR "5458135" OR "5496549" OR "5512544" OR "5514670" OR "5518889" OR "5530101" OR "5534621" OR "5545807" OR "5565362" 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 "5698419" OR "5698435" OR "5714352" OR "5723323" OR "5733761" OR "5750105" OR "5750373" OR "5763192" OR "5763733" OR "5766886" OR "5770198" OR "5770222" OR "5770359" OR "5770428" OR "5789650" OR "5807706" OR "5814476" OR "5814599" OR "5817483" OR "5821333" OR "5824514" OR "5827690" OR "5827739" OR "5833985" OR "5837500" OR "5839446" OR "5849695" OR "5851198" OR "5856456" OR "5871753" OR "5879681" OR "5885793" OR "5888511" OR					

		"5919452" OR "5932448" OR "5958413" OR "5959083" OR "5959084" OR "5962255" OR "5976862" OR "5989530" OR "5993833" OR "5994616" OR "6010902" 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 golimumab					
L449	151	("0000030" OR "0000059" OR "0000088" OR "0000116" OR "0000144" OR "20090214528" OR "20100251099" OR "20110251099" 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 "4757506" OR "4766067" OR "4767402" OR "4795699" OR "4800159" OR "4816567" OR "4822776" OR "4873316" OR "4889818" OR "4921794" OR "4925673" OR	(US-PGPUB; USPAT)	OR	ON	ON	2024/06/21 03:07 PM

		"4939666" OR "4946778" OR "4956288" OR "4965188" OR "4994370" OR "5066584" OR "5116964" 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 "5404871" OR "5427908" OR "5447851" OR "5455030" OR "5458135" OR "5496549" OR "5512544" OR "5514670" OR "5518889" OR "5530101" OR "5534621" OR "5545807" OR "5565362" 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					

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		"7521206" OR "7691378" OR "8241899" OR "9512065").pn.					
L450	2	L1 AND golimumab	(US-PGPUB; USPAT)	OR	ON	ON	2024/06/21 03:07 PM
L451	1	L1 AND golimumab AND ankylosing	(US-PGPUB; USPAT)	OR	ON	ON	2024/06/21 03:07 PM
L452	2	L1 AND golimumab AND arthritis	(US-PGPUB; USPAT)	OR	ON	ON	2024/06/21 03:07 PM
L453	2	L1 AND golimumab AND spondylitis	(US-PGPUB; USPAT)	OR	ON	ON	2024/06/21 03:07 PM
L454	4172	golimumab AND spondylitis	(US-PGPUB; USPAT)	OR	ON	ON	2024/06/21 03:07 PM
L455	4082	golimumab AND spondylitis AND ankylosing	(US-PGPUB; USPAT)	OR	ON	ON	2024/06/21 03:07 PM
L456	172	golimumab AND spondylitis ADJ ankylosing	(US-PGPUB; USPAT)	OR	ON	ON	2024/06/21 03:07 PM
L457	68	golimumab AND spondylitis ADJ ankylosing AND @ay<"2018"	(US-PGPUB; USPAT)	OR	ON	ON	2024/06/21 03:07 PM
L458	1	golimumab SAME spondylitis ADJ ankylosing AND @ay<"2018"	(US-PGPUB; USPAT)	OR	ON	ON	2024/06/21 03:07 PM
L459	1	(golimumab OR (Cnto NEAR "148")) SAME spondylitis ADJ ankylosing AND @ay<"2018"	(US-PGPUB; USPAT)	OR	ON	ON	2024/06/21 03:07 PM
L460	9	(golimumab OR (Cnto NEAR "148")) ADJ ankylosing ADJ spondylitis	(US-PGPUB; USPAT)	OR	ON	ON	2024/06/21 03:07 PM
L461	977	(golimumab OR (Cnto NEAR "148")).clm.	(US-PGPUB; USPAT)	OR	ON	ON	2024/06/21 03:07 PM
L462	390	(golimumab OR (Cnto NEAR "148")).clm. AND spondylitis	(US-PGPUB; USPAT)	OR	ON	ON	2024/06/21 03:07 PM
L463	381	(golimumab OR (Cnto NEAR "148")).clm. AND ankylosing ADJ spondylitis	(US-PGPUB; USPAT)	OR	ON	ON	2024/06/21 03:07 PM
L464	174	(golimumab OR (Cnto NEAR "148")).clm. AND ankylosing ADJ spondylitis AND @ay<"2017"	(US-PGPUB; USPAT)	OR	ON	ON	2024/06/21 03:07 PM
L465	111	(golimumab OR (Cnto	(US-PGPUB; USPAT)	OR	ON	ON	2024/06/21

		NEAR "148")).clm. AND ankylosing ADJ spondylitis AND @ay<"2017" AND methotrexate					03:07 PM
L466	114	(golimumab OR (Cnto NEAR "148")).clm. AND ankylosing ADJ spondylitis AND @ay<"2017" AND (methotrexate OR sulfasalazine OR hydroxychloroquine)	(US-PGPUB; USPAT)	OR	ON	ON	2024/06/21 03:07 PM
L467	2	(golimumab OR (Cnto NEAR "148")) SAME infusion SAME (over NEAR time)	(US-PGPUB; USPAT)	OR	ON	ON	2024/06/21 03:07 PM
L468	307	(golimumab OR (Cnto NEAR "148")) SAME infusion	(US-PGPUB; USPAT)	OR	ON	ON	2024/06/21 03:07 PM
L469	15	(golimumab OR (Cnto NEAR "148")) SAME (rate NEAR infusion)	(US-PGPUB; USPAT)	OR	ON	ON	2024/06/21 03:07 PM
L470	1042	antibody SAME (rate NEAR infusion)	(US-PGPUB; USPAT)	OR	ON	ON	2024/06/21 03:07 PM
L471	190	antibody SAME infusion SAME rate SAME over NEAR period	(US-PGPUB; USPAT)	OR	ON	ON	2024/06/21 03:07 PM
L472	1	anti-tnf SAME antibody SAME infusion SAME rate SAME over NEAR period	(US-PGPUB; USPAT)	OR	ON	ON	2024/06/21 03:07 PM
L473	5	anti-tnf AND antibody SAME infusion SAME rate SAME over NEAR period	(US-PGPUB; USPAT)	OR	ON	ON	2024/06/21 03:07 PM
L474	5931	anti-tnf AND antibody SAME infusion	(US-PGPUB; USPAT)	OR	ON	ON	2024/06/21 03:07 PM
L475	214	anti-tnf ADJ antibody SAME infusion	(US-PGPUB; USPAT)	OR	ON	ON	2024/06/21 03:07 PM
L476	1027	Janssen ADJ Biotech ADJ Inc.asn.	(US-PGPUB; USPAT)	OR	ON	ON	2024/06/21 03:07 PM
L477	22	Harrison Diane D.in.	(US-PGPUB; USPAT)	ADJ	ON	ON	2024/06/21 03:07 PM
L478	19	Hsia Elizabeth C.in.	(US-PGPUB; USPAT)	ADJ	ON	ON	2024/06/21 03:07 PM
L479	13	Kim Lee-Lian.in.	(US-PGPUB; USPAT)	ADJ	ON	ON	2024/06/21 03:07 PM
L480	14	Lo Kim Hung.in.	(US-PGPUB; USPAT)	ADJ	ON	ON	2024/06/21 03:07 PM
L481	1233	L27 L29 L30 L31 L32 L34	(US-PGPUB; USPAT)	OR	ON	ON	2024/06/21 03:07 PM

L482	128	L35 AND golimumab	(US-PGPUB; USPAT)	OR	ON	ON	2024/06/21 03:07 PM
L483	11	L35 AND golimumab.clm.	(US-PGPUB; USPAT)	OR	ON	ON	2024/06/21 03:07 PM
L484	3699	c07k16/241.cpc.	(US-PGPUB; USPAT)	OR	ON	ON	2024/06/21 03:07 PM
L485	16663	a61k39/3955.cpc.	(US-PGPUB; USPAT)	OR	ON	ON	2024/06/21 03:07 PM
L486	55742	a61p19/02.cpc.	(US-PGPUB; USPAT)	OR	ON	ON	2024/06/21 03:07 PM
L487	71767	L38 OR L39 L40	(US-PGPUB; USPAT)	OR	ON	ON	2024/06/21 03:07 PM
L488	119	L41 AND golimumab AND spondilitis	(US-PGPUB; USPAT)	OR	ON	ON	2024/06/21 03:07 PM
L489	23	L41 AND golimumab AND spondilitis.clm.	(US-PGPUB; USPAT)	OR	ON	ON	2024/06/21 03:07 PM
L490	60	golimumab AND spondylitis ADJ ankylosing AND @ay<"2018" AND infusion	(US-PGPUB; USPAT)	OR	ON	ON	2024/06/21 03:07 PM
L491	117	2009/0123378 AND administration AND iv	(US-PGPUB; USPAT)	OR	ON	ON	2024/06/21 03:07 PM
L492	1	"20090123378".pn. AND administration AND iv	(US-PGPUB; USPAT)	OR	ON	ON	2024/06/21 03:07 PM
L493	1	"20090123378".pn. AND administration AND intraven$5	(US-PGPUB; USPAT)	OR	ON	ON	2024/06/21 03:07 PM

PE2E SEARCH - Search History (Interference)

There are no Interference searches to show.

Doc code: IDS
Doc description: Information Disclosure Statement (IDS) Filed

PTO/SB/08a (01-22)
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	17237650
Filing Date	2021-04-22
First Named Inventor	Diane D. Harrison
Art Unit	1646
Examiner Name	CHANDRA, GYAN
Attorney Docket Number	206389-0002-02US

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ALL REFERENCES CONSIDERED EXCEPT WHERE LINED THROUGH. /G.C/

INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Not for submission under 37 CFR 1.99)		
	Application Number	17237650
	Filing Date	2021-04-22
	First Named Inventor	Diane D. Harrison
	Art Unit	1646
	Examiner Name	CHANDRA, GYAN
	Attorney Docket Number	206389-0002-02US

	1	Johnson & Johnson, "New Phase 3 Data Show Simponi Aria® (Golimumab) Significantly Improved Signs And Symptoms In Patients With Active Ankylosing Spondylitis" 14 November 2016 (14-11-2016)	☐
	2	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.	☐

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

EXAMINER SIGNATURE

Examiner Signature	/GYAN CHANDRA/	Date Considered	06/21/2024

*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.

[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.

ALL REFERENCES CONSIDERED EXCEPT WHERE LINED THROUGH. /G.C/

INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(Not for submission under 37 CFR 1.99)

Application Number	17237650
Filing Date	2021-04-22
First Named Inventor	Diane D. Harrison
Art Unit	1646
Examiner Name	CHANDRA, GYAN
Attorney Docket Number	206389-0002-02US

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)	2024-03-06
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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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.

ALL REFERENCES CONSIDERED EXCEPT WHERE LINED THROUGH. /G.C/

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Patent Application of: Diane D. Harrison, et al.	Art Unit: 1646 Confirmation No.: 8810
Application No.: 17/237,650	Examiner: Chandra, Gyan
Filing date: April 22, 2021	Atty Docket No.: 206389-0002-02US

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

RESPONSE

This Response is responsive to the Non-Final Office Action mailed on July 02, 2024 in connection with the above-referenced application. This Amendment is being timely filed, with a one (1) month extension of time (EOT), and associated fee, extending the deadline for a timely response to and through November 04, 2024 (November 02, 2024 being a Saturday and November 03, 2024 being a Sunday).

This Response is accompanied by a Declaration by Diane Harrison.

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 1-10, 12, 15, and 19 have been previously cancelled.

Rejection of claims 11, 13, 14, 16-18 and 20 under 35 U.S.C. 102

The Examiner has rejected claims 11, 13, 14, 16-18 and 20 under 35 U.S.C. 102 as allegedly being anticipated by Johnson & Johnson (Pharmaceuticals, Nov. 14, 2016) or Janssen Immunology (PRNewswire, News provided by Janssen Research and Development, Nov. 14, 2016). The Examiner contends that Johnson & Johnson teaches using golimumab 2 mg/kg, 30 min infusion for Ankylosing Spondylitis and that 47.6% of patients receiving golimumab achieved an ASAS40 response compared with the 8.7% of patients receiving placebo. The Examiner further contends that Janssen Immunology teaches the administration of golimumab 2 mg/kg showed 73.3% of patient with ankylosing spondylitis achieved 20% improvement as compared to 26.2% of patients receiving placebo and that Bath ankylosing spondylitis functional index (BASMI) = -2.4 for golimumab as compared to -0.5 for placebo group.

Applicant respectfully submits that 35 U.S.C. § 102(b)(1)(A) states,

> A disclosure **made 1 year or less** before the effective filing date of a claimed invention shall not be prior art to the claimed invention under subsection (a)(1) if…the disclosure was made by the inventor or joint inventor or by another who obtained the subject matter disclosed directly or indirectly from the inventor or a joint inventor.

Applicant respectfully submits that, the present claims are fully supported by the as-filed Specification and by the corresponding priority application, U.S. Provisional Application No. 62/455,651, filed February 07, 2017. Applicant submits that the publication date of Johnson & Johnson is November 14, 2016, which is less than 1 year prior to the February 07, 2017 filing date of the priority application. Applicant further submits that Johnson & Johnson is a disclosure made by the inventor or joint inventor or by another who obtained the subject matter disclosed directly or indirectly from the inventor or a joint inventor i.e., Diane D. Harrison, Elizabeth C. Hsia, Lee-Lian Kim, and Kim Hung Lo. Applicant submits that the Janssen Immunology (PRNewswire, News provided by Janssen

Research and Development, Nov. 14, 2016) reference is identical to the Johnson & Johnson disclosure published November 14, 2016, and thus was also made by the inventor or joint inventor or by another who obtained the subject matter disclosed directly or indirectly from the inventor or a joint inventor i.e., Diane D. Harrison, Elizabeth C. Hsia, Lee-Lian Kim, and Kim Hung Lo.

Applicant submits that the Declaration of inventor Diane Harrison, filed herewith, pursuant to 37 C.F.R. § 1.130(a), establishes that the disclosure of Johnson & Johnson was made by another who obtained the subject matter disclosed directly or indirectly from the inventor or joint inventor of the present application, i.e., Diane D. Harrison, Elizabeth C. Hsia, Lee-Lian Kim, and Kim Hung Lo.

Applicant further submits that the Declaration of inventor Diane Harrison, filed herewith, pursuant to 37 C.F.R. § 1.130(a), establishes that the disclosure of Janssen Immunology was made by another who obtained the subject matter disclosed directly or indirectly from the inventor or joint inventor of the present application, i.e., Diane D. Harrison, Elizabeth C. Hsia, Lee-Lian Kim, and Kim Hung Lo.

For these reasons, Applicant respectfully requests reconsideration and withdrawal of the rejection.

Rejection of claims 11, 13, 14, 16-18 and 20 under 35 U.S.C. 103

The Examiner has rejected claims 11, 13, 14, 16-18 and 20 under 35 U.S.C. 103 as allegedly being unpatentable over Wong et al (U.S. Patent Application Publication US2009/0123378; hereinafter "Wong") in view of Johnson & Johnson (Johnson and Johnson, 2013, Press release) or Zhuang et al (Zhuang et al., 2012, Clin Ther., 34(1):77-90). Specifically, the Examiner acknowledges that Wong does not teach administering golimumab antibody by IV infusion at a dose of 2 mg/kg over a period of 30 ± 10 mins, but alleges Johnson & Johnson and Zhuang teach administering golimumab at 2 mg/kg for the treatment of rheumatoid arthritis.

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, Applicant asserts 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 reference must teach or suggest each and every element of the claims.

Applicant submits that claims 11, 14 and 17 recite a method for treating active ankylosing spondylitis, the method comprising administering via IV infusion at a dose of 2 mg/kg, administered over 30 ± 10 minutes, at Weeks 0 and 4, and then every 8 weeks (q8w) thereafter. Applicant submits that Wong, Johnson & Johnson, and Zhuang, alone or in combination with each other, do not teach or suggest a method for treating active ankylosing spondylitis, the method comprising administering via IV infusion at a dose of 2 mg/kg, administered over 30 ± 10 minutes, at Weeks 0 and 4, and then every 8 weeks (q8w)

thereafter. As admitted by the Examiner, Wong does not teach the recited dosage or infusion time. Applicant submits that neither Johnson & Johnson or Zhuang make up for the deficiencies of Wong, because Johnson & Johnson or Zhuang do not teach or suggest administration of the specifically recited anti-TNF antibody at the specifically recited dosage and infusion time for the treatment of ankylosing spondylitis. Johnson & Johnson and Zhuang are directed to a different disease (i.e. rheumatoid arthritis), and do not teach or suggest the specifically recited dosage and infusion times to effectively treat a subject with ankylosing spondylitis to achieve the recited clinical efficacy. Applicant submits that ankylosing spondylitis and rheumatoid arthritis have different symptomatology and etiology and are recognized as separate and distinct clinical entities. Thus, a skilled person cannot predict from the cited references what efficacy would be achieved by IV infusion of golimumab for treating active ankylosing spondylitis.

Applicant submits that Wong, Johnson & Johnson, and Zhuang, alone or in combination with each other, do not teach or suggest administering a safe and effective amount of a composition comprising the recited anti-TNF antibody for the treatment of ankylosing spondylitis, let alone that the said composition is administered via IV infusion such that a patient achieves the recited clinical efficacy, as recited in claims 11, 14 and 17. As described above, Wong does not teach or suggest to a skilled artisan that the recited anti-TNF antibody has any effect, let alone would achieve the recited clinical efficacy. Applicant submits that Johnson & Johnson and Zhuang do not make up for the deficiencies of Wong, because Johnson & Johnson and Zhuang do not teach or suggest administration of the recited anti-TNF antibody at the recited dosing regimen for the treatment of ankylosing spondylitis or that the specific recited dosing regimen would achieve the recited clinical efficacy. Like Wong, Johnson & Johnson and Zhuang do not provide any teaching or demonstration that the recited antibody has any effect on a subject with ankylosing spondylitis.

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.

Applicant submits that Wong, Johnson & Johnson, and Zhuang do not prove a reasonable expectation of success at arriving at a method for treating ankylosing spondylitis by administering a composition comprising a safe and effective amount of the recited anti-

TNF antibody via IV infusion at a dose of 2 mg/kg, administered over 30 ± 10 minutes, at Weeks 0 and 4, and then every 8 weeks (q8w) thereafter.

Claim 11

The present invention is based, in part, upon the surprising discovery that IV infusion of golimumab is an effective therapy for ankylosing spondylitis, which can show efficiency as quick as 2 to 4 weeks after treatment. Applicant submits that Wong only demonstrates the efficacy of adalimumab. Nothing in Wong provides a skilled artisan with any predictability that golimumab can be delivered by IV infusion to treat ankylosing spondylitis, much less that a patient who is administered golimumab by IV infusion at a dose of 2 mg/kg, administered over 30 ± 10 minutes, at Weeks 0 and 4, and then every 8 weeks (q8w) thereafter would achieve ASDAS inactive disease (<1.3) at 4 weeks of treatment or at 2 weeks of treatment, as recited in claim 11.

Applicant submits that Johnson & Johnson and Zhuang do not cure any of the deficiencies of Wong. Applicant submits that Johnson & Johnson and Zhuang do not provide a skilled artisan with any predictability that intravenous golimumab can be used to treat ankylosing spondylitis, much less that a patient who is administered intravenous golimumab would achieve ASDAS inactive disease (<1.3) at 4 weeks of treatment or 2 weeks of treatment.

First, Applicant submits that neither Wong nor Johnson & Johnson and Zhuang describe the effects of IV golimumab on a subject with ankylosing spondylitis. In fact, Wong does not teach the effects of golimumab at all. Rather, Wong describes the effects of a wholly different anti-TNF antibodies. Further Johnson & Johnson and Zhuang do not teach the effects of golimumab in treating ankylosing spondylitis, let alone the improvements in the recited clinical metrics. A skilled artisan would recognize that the effects of different antibodies to the same target are highly unpredictable. Furthermore, a skilled artisan would recognize that the effects of the same antibody for the treatment of different diseases are highly unpredictable. Thus, a skilled artisan would have no reasonable expectation of success in specifically choosing golimumab from the laundry list of alternative TNF-inhibitors of Wong and specifically administering golimumab by IV infusion at a dose of 2 mg/kg,

administered over 30 ± 10 minutes, at Weeks 0 and 4, and then every 8 weeks (q8w) thereafter to treat ankylosing spondylitis, which is a disease not even contemplated by Johnson & Johnson and Zhuang.

Further, Wong, Johnson & Johnson, and Zhuang do not describe any clinical improvement from IV golimumab on any subject with ankylosing spondylitis. Applicant submits that skilled artisan reading Wong, Johnson & Johnson, or Zhuang would not have any reasonable expectation that administration of IV golimumab could be used to effectively treat ankylosing spondylitis, let alone that treatment would result in clinical efficacy in 2 or 4 weeks.

Claim 14

Nothing in Wong, Johnson & Johnson, and Zhuang provides a skilled artisan with any predictability that golimumab can be delivered by IV infusion to treat ankylosing spondylitis, much less that a patient who is administered golimumab by IV infusion at a dose of 2 mg/kg, administered over 30 ± 10 minutes, at Weeks 0 and 4, and then every 8 weeks (q8w) thereafter would achieve at week 16 a mean change from baseline in one or more criteria selected from the group consisting of: Bath Ankylosing Spondylitis Functional Index (BASFI) = -2.4 ± 2.1 Standard Deviation (SD), Bath Ankylosing Spondylitis Metrology Index (BASMI) = -0.4 ± 0.6 SD, 36-item Short-Form Health Survey Physical Component Summary (SF-36 PCS)= 8.5 ± 7.5 SD, 36-item Short-Form Health Survey Mental Component Summary (SF-36 MCS) = 6.5 ± 9.1 SD, and Ankylosing Spondylitis Qualify of Life questionnaire (ASQoL) = -5.4 ± 5.0 SD, as recited in claim 14.

As described above, neither Wong nor Johnson & Johnson and Zhuang describe the effects of IV golimumab on a subject with ankylosing spondylitis. In fact, Wong does not teach the effects of golimumab at all. Rather, Wong describes the effects of a wholly different anti-TNF antibodies. Further Johnson & Johnson and Zhuang do not teach the effects of golimumab in treating ankylosing spondylitis, let alone the improvements in the recited clinical metrics. A skilled artisan would recognize that the effects of different antibodies to the same target are highly unpredictable. Furthermore, a skilled artisan would recognize that the effects of the same antibody for the treatment of different diseases are

highly unpredictable. Thus, a skilled artisan would have no reasonable expectation of success in specifically choosing golimumab from the laundry list of alternative TNF-inhibitors of Wong and specifically administering golimumab by IV infusion at a dose of 2 mg/kg, administered over 30 ± 10 minutes, at Weeks 0 and 4, and then every 8 weeks (q8w) thereafter to treat ankylosing spondylitis, which is a disease not even contemplated by Johnson & Johnson and Zhuang.

Further, Wong, Johnson & Johnson, and Zhuang do not describe any clinical improvement from IV golimumab on any subject with ankylosing spondylitis. Applicant submits that a skilled artisan would not have any reasonable expectation from Wong, Johnson & Johnson, and Zhuang that at week 16 of treatment patients receiving IV golimumab would achieve a mean change from baseline in any of the recited criteria.

Claim 17

Nothing in Wong, Johnson & Johnson, and Zhuang provide a skilled artisan with any predictability that golimumab can be delivered by IV infusion to treat ankylosing spondylitis, much less that IV infusion at a dose of 2 mg/kg, administered over 30 ± 10 minutes, at Weeks 0 and 4, and then every 8 weeks (q8w) thereafter would result in ≥ 65% of patients receiving the treatment achieve Assessment in Ankylosing Spondylitis 20 (ASAS20) at week 16 of treatment, as recited in claim 17.

As described above, neither Wong nor Johnson & Johnson and Zhuang describe the effects of IV golimumab on a subject with ankylosing spondylitis. In fact, Wong does not teach the effects of golimumab at all. Rather, Wong describes the effects of a wholly different anti-TNF antibodies. Further Johnson & Johnson and Zhuang do not teach the effects of golimumab in treating ankylosing spondylitis, let alone the improvements in the recited clinical metrics. A skilled artisan would recognize that the effects of different antibodies to the same target are highly unpredictable. Furthermore, a skilled artisan would recognize that the effects of the same antibody for the treatment of different diseases are highly unpredictable. Thus, a skilled artisan would have no reasonable expectation of success in specifically choosing golimumab from the laundry list of alternative TNF-inhibitors of Wong and specifically administering golimumab by IV infusion at a dose of 2 mg/kg,

administered over 30 ± 10 minutes, at Weeks 0 and 4, and then every 8 weeks (q8w) thereafter to treat ankylosing spondylitis, which is a disease not even contemplated by Johnson & Johnson and Zhuang.

Further, Wong, Johnson & Johnson, and Zhuang do not describe any clinical improvement from IV golimumab on any subject with ankylosing spondylitis. Applicant submits that a skilled artisan would not have any reasonable expectation from Wong, Johnson & Johnson, and Zhuang that greater than 65% of patients receiving IV golimumab would achieve ASAS20 at week 16.

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.

Applicant submits that the presently claimed methods of administering a composition comprising a safe and effective amount of the recited anti-TNF antibody for the treatment of active ankylosing spondylitis, wherein said composition is administered via IV infusion at a dose of 2 mg/kg, administered over 30 ± 10 minutes, at Weeks 0 and 4, and then every 8 weeks (q8w) thereafter, produces surprising and unexpected results that could not have been predicted by the combination of Wong, Johnson & Johnson, and Zhuang.

Smolen et al., Ann Rheum Dis 2014; 73:6–16 (hereinafter "Smolen"; and provided previously Exhibit A), is a publication of recommendations of an international task force related to treatment targets for spondyloarthritis, including ankylosing spondylitis. See, for example, Smolen, page 9, 2nd column, 2nd to last paragraph, where it states, "Common recommendations 1. A major treatment target should be clinical remission/inactive disease…". Also, note that in the preceding paragraph, page 9, 1st column, last paragraph, the authors in Smolen indicated that the sequence of the recommendations reflects the level of importance considered by the committee for each individual bullet point. It follows, therefore, that the number 1 recommendation related to the treatment target of remission/inactive disease was considered the most important consideration of the international task force. It is demonstrated herein that IV golimumab administered at a dose of 2 mg/kg, administered over 30 ± 10 minutes, at Weeks 0 and 4, and then every 8 weeks (q8w) thereafter surprisingly was able to induce inactive disease, the most important metric of ankylosing spondylitis treatment efficacy, in only 2 weeks after treatment.

As described in the present application, intravenous administration of golimumab resulted in inactive disease, as measured by ASDAS score of < 1.3, as early as 4 weeks and 2 weeks after treatment. As noted above, none of the cited references teach or suggest that an

ASDAS inactive disease score could be achieved in such a short time, after only 4 weeks or 2 weeks of IV golimumab treatment. Thus, the teaching of Wong, Johnson & Johnson, and Zhuang, alone or in combination, could not have led a skilled artisan to expect such surprising and unpredictable results.

Achieving an ASDAS inactive disease score (i.e. <1.3) after only 2 weeks or 4 weeks of IV golimumab treatment is a very surprising and unpredictable result that would not be obvious to a person skilled in the art. For example, Van der heijde et al. J Rheumatol, 2014, 41(6): 1095-103 (hereinafter "Van der heijde"; and provided previously as Exhibit B) describes the 2-year results of a clinical trial of subcutaneous golimumab treatment and only reports proportion of patients with ADAS inactive score (<1.3) at week 14 and week 24 after subcutaneous injections of golimumab. Applicant submits that a skilled artisan, at the time of filing, could not have reasonably predicted or expected the surprising and unexpected results demonstrated herein, that patients could achieve an ASDAS inactive disease score (<1.3) in such a short time, after only 4 weeks or 2 weeks of IV golimumab treatment.

Similarly, Applicant submits that the application demonstrates that IV golimumab administered at a dose of 2 mg/kg, administered over 30 ± 10 minutes, at Weeks 0 and 4, and then every 8 weeks (q8w) thereafter exhibited surprising and unexpected results in showing improved efficacy, as measured by the change from baseline in the criteria listed in claim 14 and by the proportion of subjects achieving ASAS20. Each of the clinical measures at 16 weeks post-IV golimumab was surprisingly and unexpectedly improved over the same clinical measures at 14 and 24 weeks post-subcutaneous golimumab. Applicant submits that such improved clinical efficacy of IV golimumab demonstrated by the present application would not be expected by a skilled artisan reading Wong, Johnson & Johnson, and Zhuang.

For at least these reasons, Applicant submits that the pending claims are not rendered obvious by the combination of Wong, Johnson & Johnson, and Zhuang. Applicant respectfully requests reconsideration and withdrawal of the rejection.

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. 11,014,982 (U.S. Application Number 16/517,592). Specifically, the Examiner alleges although the claims at issue are not identical, they are not patentably distinct from each other because a method of treating ankylosing spondylitis, the method comprising: administering the recited antibodies, and wherein a patient treated with the composition achieves an ankylosing spondylitis disease activity score (ASDAS) inactive disease (<1.3) at 4 weeks of treatment or at 2 weeks of treatment is allegedly taught in clams 1-10 of U.S. Patent No. 11,014,982.

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 provisional rejection. Accordingly, Applicant is filing the appropriate Terminal Disclaimer herewith. Therefore, Applicant submits that the double patenting rejection has 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.

November 04, 2024 By: By: /Pallab Singh/

Pallab Singh, Ph.D., J.D.
Registration No. 70,731
Riverside Law LLP
175 Strafford Ave., Suite 100
Wayne, PA 19087
215-268-3888 (main)
215-268-3871 (fax)
215-268-3759 (direct)
E-Mail: psingh@riversidelaw.com
Attorney for Applicants

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 #	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET #
17237650	04/22/2021	Diane Harrison	206389-0002-02US

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

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 #
11014982

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 statemnts 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

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* 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.

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 #	FILING DATE	APPLICANT/PATENT UNDER REEXAMINATION
17/237,650	04/22/2021	Diane Harrison

Title of Invention

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

Electronic terminal disclaimer filed on 11/04/2024

Approved

This patent is subject to a Terminal Disclaimer

Approved / Disapproved by: Electronic Terminal Disclaimer automatically approved

UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

NOTICE OF ALLOWANCE AND FEE(S) DUE

171672 7590 01/13/2025

Riverside Law LLP/J&J
175 Strafford Avenue
Suite 100
Wayne, PA 19087

EXAMINER
CHANDRA, GYAN

ART UNIT	PAPER NUMBER
1674	

DATE MAILED: 01/13/2025

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
17/237,650	04/22/2021	Diane D. Harrison	206389-0002-02US	8810

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	$1200.00	$0	04/14/2025

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 01/13/2025
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.
17/237,650	04/22/2021	Diane D. Harrison	206389-0002-02US	8810

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	$1200.00	$0	04/14/2025

EXAMINER	ART UNIT	CLASS-SUBCLASS
CHANDRA, GYAN	1674	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

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.

❑ Applicant asserting small entity status. See 37 CFR 1.27

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.

❑ Applicant changing to regular undiscounted fee 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. _____

UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
17/237,650	04/22/2021	Diane D. Harrison	206389-0002-02US	8810

171672 7590 01/13/2025

Riverside Law LLP/J&J
175 Strafford Avenue
Suite 100
Wayne, PA 19087

EXAMINER	
CHANDRA, GYAN	
ART UNIT	PAPER NUMBER
1674	

DATE MAILED: 01/13/2025

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. 17/237,650	Applicant(s) Harrison et al.	
	Examiner GYAN CHANDRA	Art Unit 1674	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 11/4/2024.
   ☐ 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 _____.
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 _____.

/GYAN CHANDRA/
Primary Examiner, Art Unit 1674

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.

Applicant's response and a Declaration of Diane Harrison under 37 CFR 1.130 filed on 11/4/2024 are acknowledged and fully considered.

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

EXAMINER'S COMMENT

Claim Rejections - 35 USC § 102-*withdrawn*

The rejection of claim(s) 11, 13-14, 16-18 and 20 under 35 U.S.C. 102(a)(1) as being anticipated by Johnson & Johnson, Pharmaceuticals, Nov. 14, 2016) or Janssen Immunology (PRNewswire,News provides by Janssen Research and Development, Nov. 14, 2016) is withdrawn in view of applicant's filing of the Declaration under 37 CFR 1.130 by Diane Harrison that the subject matter is disclosed directly or indirectly from the inventor or a joint inventor.

Claim Rejections - 35 USC § 103-*withdrawn*

Claim(s) 11, 13-14, 16-18 and 20 are rejected under 35 U.S.C. 103 as being unpatentable over Wong et al (IDS, US Pub. No. 2009/0123378) in view of Johnson & Johnson, (IDS, Press release, July. 18, 2013) or Zhuang et al. (IDS, Clin. Therapeutics, 34, Number 1, 77-90, 2012) is withdrawn in view of applicant's declaration by Diane Harrison that makes Johnson & Johnson reference unavailable and in view of their arguments that ankylosing spondylitis is different from rheumatoid arthritis. They argue that Zhuang et al do not teach or suggest administering the instantly recited anti-TNF

antibody dosage and infusion time for the treatment of ankylosing spondylitis. Applicant's arguments have been found persuasive and therefore, the rejection is withdrawn.

Double Patenting

The rejection of claims 11, 13-14, 16-18 and 20 on the ground of nonstatutory double patenting as being unpatentable over claims 1-10 of U.S. Patent No. 11,014982 is withdrawn in view of applicant's filing of an electronic Terminal Disclaimer on 11/4/2024.

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 1674

Issue Classification	Application/Control No.	Applicant(s)/Patent Under Reexamination
	17/237,650	Harrison et al.
	Examiner	**Art Unit**
	GYAN CHANDRA	1674

CPC						
Symbol					**Type**	**Version**
C07K	/	16	/	241	F	2013-01-01
A61K	/	9	/	0019	I	2013-01-01
A61K	/	39	/	3955	I	2013-01-01
A61K	/	31	/	519	I	2013-01-01
A61K	/	31	/	4402	I	2013-01-01
A61P	/	19	/	02	I	2018-01-01
A61K	/	31	/	4706	I	2013-01-01
A61K	/	2039	/	505	A	2013-01-01
C07K	/	2317	/	21	A	2013-01-01
C07K	/	2317	/	92	A	2013-01-01
C07K	/	2317	/	76	A	2013-01-01
A61K	/	2039	/	545	A	2013-01-01

CPC Combination Sets								
Symbol					**Type**	**Set**	**Ranking**	**Version**
	/		/					

NONE		**Total Claims Allowed:**	
(Assistant Examiner)	(Date)	7	
/GYAN CHANDRA/ Primary Examiner, Art Unit 1674	05 December 2024	O.G. Print Claim(s)	O.G. Print Figure
(Primary Examiner)	(Date)	1	None

U.S. Patent and Trademark Office — Part of Paper No.: 20241205

Issue Classification	Application/Control No.	Applicant(s)/Patent Under Reexamination
	17/237,650	Harrison et al.
	Examiner	**Art Unit**
	GYAN CHANDRA	1674

INTERNATIONAL CLASSIFICATION					
CLAIMED					
C07K	/	16	/	24	
NON-CLAIMED					
	/		/		

US ORIGINAL CLASSIFICATION	
CLASS	**SUBCLASS**
424	142.1

CROSS REFERENCES(S)						
CLASS	**SUBCLASS (ONE SUBCLASS PER BLOCK)**					

NONE		**Total Claims Allowed:**	
(Assistant Examiner)	(Date)	7	
/GYAN CHANDRA/ Primary Examiner, Art Unit 1674	05 December 2024	O.G. Print Claim(s)	O.G. Print Figure
(Primary Examiner)	(Date)	1	None

U.S. Patent and Trademark Office — Part of Paper No.: 20241205

Issue Classification	Application/Control No.	Applicant(s)/Patent Under Reexamination
	17/237,650	Harrison et al.
	Examiner	**Art Unit**
	GYAN CHANDRA	1674

☑ Claims renumbered in the same order as presented by applicant ☐ CPA ☑ T.D. ☐ R.1.47

CLAIMS

Final	Original	Final	Original	Final	Original	Final	Original	Final	Original	Final	Original	Final	Original	Final	Original
	11														
	13														
	14														
	16														
	17														
	18														
	20														

NONE		**Total Claims Allowed:**	
(Assistant Examiner)	(Date)	7	
/GYAN CHANDRA/ Primary Examiner, Art Unit 1674	05 December 2024	O.G. Print Claim(s)	O.G. Print Figure
(Primary Examiner)	(Date)	1	None

U.S. Patent and Trademark Office — Part of Paper No.: 20241205

Search Notes	Application/Control No.	Applicant(s)/Patent Under Reexamination
	17/237,650	Harrison et al.
	Examiner	Art Unit
	GYAN CHANDRA	1674

CPC - Searched*		
Symbol	**Date**	**Examiner**
c07k16/241	12/05/2024	gc
a61k39/3955	12/05/2024	gc
a61p19/02	12/05/2024	gc

CPC Combination Sets - Searched*		
Symbol	**Date**	**Examiner**

US Classification - Searched*			
Class	**Subclass**	**Date**	**Examiner**
None	None	12/05/2024	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, 2, 3, 4, 5, 6 with substitutions (see search results in SCORE)	09/13/2022	gc
claims searched in CAPLUS, Biosis, Medline (see enclosed transcript)	06/21/2024	gc
claims searched in PE2E search (see enclosed doc)	12/05/2024	gc
Inventorship search in PE2E search (see enclosed doc)	12/05/2024	gc
Inventorship search in PALM	12/05/2024	gc

/GYAN CHANDRA/ Primary Examiner, Art Unit 1674	

Search Notes	Application/Control No.	Applicant(s)/Patent Under Reexamination
	17/237,650	Harrison et al.
	Examiner	Art Unit
	GYAN CHANDRA	1674

Interference Search			
US Class/CPC Symbol	US Subclass/CPC Group	Date	Examiner
C07K	16/241	12/05/2024	gc

/GYAN CHANDRA/ Primary Examiner, Art Unit 1674	

PE2E SEARCH - Search History (Prior Art)

Ref #	Hits	Search Query	DBs	Default Operator	Plurals	British Equivalents	Time Stamp
L802	151	("0000030" OR "0000059" OR "0000088" OR "0000116" OR "0000144" OR "20090214528" OR "20100251099" OR "20110251099" 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 "4757506" 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 "5116964" 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	(US-PGPUB; USPAT)	OR	ON	ON	2024/12/05 02:14 PM

		"5385839" OR "5403484" OR "5404871" OR "5427908" OR "5447851" OR "5455030" OR "5458135" OR "5496549" OR "5512544" OR "5514670" OR "5518889" OR "5530101" OR "5534621" OR "5545807" OR "5565362" 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 "5698419" OR "5698435" OR "5714352" OR "5723323" OR "5733761" OR "5750105" OR "5750373" OR "5763192" OR "5763733" OR "5766886" OR "5770198" OR "5770222" OR "5770359" OR "5770428" OR "5789650" OR "5807706" OR "5814476" OR					

		"5814599" OR "5817483" OR "5821333" OR "5824514" OR "5827690" OR "5827739" OR "5833985" OR "5837500" OR "5839446" OR "5849695" OR "5851198" OR "5856456" OR "5871753" OR "5879681" OR "5885793" OR "5888511" OR "5919452" OR "5932448" OR "5958413" OR "5959083" OR "5959084" OR "5962255" OR "5976862" OR "5989530" OR "5993833" OR "5994616" OR "6010902" 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.						
L803	2	L1 AND golimumab	(US-PGPUB; USPAT)	OR	ON	ON	2024/12/05 02:14 PM
L804	1	L1 AND golimumab AND ankylosing	(US-PGPUB; USPAT)	OR	ON	ON	2024/12/05 02:14 PM
L805	2	L1 AND golimumab AND arthritis	(US-PGPUB; USPAT)	OR	ON	ON	2024/12/05 02:14 PM
L806	2	L1 AND golimumab AND spondylitis	(US-PGPUB; USPAT)	OR	ON	ON	2024/12/05 02:14 PM
L807	4391	golimumab AND spondylitis	(US-PGPUB; USPAT)	OR	ON	ON	2024/12/05 02:14 PM
L808	4299	golimumab AND spondylitis AND ankylosing	(US-PGPUB; USPAT)	OR	ON	ON	2024/12/05 02:14 PM
L809	186	golimumab AND	(US-PGPUB; USPAT)	OR	ON	ON	2024/12/05

		spondylitis ADJ ankylosing					02:14 PM
L810	68	golimumab AND spondylitis ADJ ankylosing AND @ay<"2018"	(US-PGPUB; USPAT)	OR	ON	ON	2024/12/05 02:14 PM
L811	1	golimumab SAME spondylitis ADJ ankylosing AND @ay<"2018"	(US-PGPUB; USPAT)	OR	ON	ON	2024/12/05 02:14 PM
L812	1	(golimumab OR (Cnto NEAR "148")) SAME spondylitis ADJ ankylosing AND @ay<"2018"	(US-PGPUB; USPAT)	OR	ON	ON	2024/12/05 02:14 PM
L813	9	(golimumab OR (Cnto NEAR "148")) ADJ ankylosing ADJ spondylitis	(US-PGPUB; USPAT)	OR	ON	ON	2024/12/05 02:14 PM
L814	1018	(golimumab OR (Cnto NEAR "148")).clm.	(US-PGPUB; USPAT)	OR	ON	ON	2024/12/05 02:14 PM
L815	407	(golimumab OR (Cnto NEAR "148")).clm. AND spondylitis	(US-PGPUB; USPAT)	OR	ON	ON	2024/12/05 02:14 PM
L816	397	(golimumab OR (Cnto NEAR "148")).clm. AND ankylosing ADJ spondylitis	(US-PGPUB; USPAT)	OR	ON	ON	2024/12/05 02:14 PM
L817	174	(golimumab OR (Cnto NEAR "148")).clm. AND ankylosing ADJ spondylitis AND @ay<"2017"	(US-PGPUB; USPAT)	OR	ON	ON	2024/12/05 02:14 PM
L818	111	(golimumab OR (Cnto NEAR "148")).clm. AND ankylosing ADJ spondylitis AND @ay<"2017" AND methotrexate	(US-PGPUB; USPAT)	OR	ON	ON	2024/12/05 02:14 PM
L819	114	(golimumab OR (Cnto NEAR "148")).clm. AND ankylosing ADJ spondylitis AND @ay<"2017" AND (methotrexate OR sulfasalazine OR hydroxychloroquine)	(US-PGPUB; USPAT)	OR	ON	ON	2024/12/05 02:14 PM
L820	2	(golimumab OR (Cnto NEAR "148")) SAME infusion SAME (over NEAR time)	(US-PGPUB; USPAT)	OR	ON	ON	2024/12/05 02:14 PM
L821	341	(golimumab OR (Cnto NEAR "148")) SAME infusion	(US-PGPUB; USPAT)	OR	ON	ON	2024/12/05 02:14 PM

L822	16	(golimumab OR (Cnto NEAR "148")) SAME (rate NEAR infusion)	(US-PGPUB; USPAT)	OR	ON	ON	2024/12/05 02:14 PM
L823	1084	antibody SAME (rate NEAR infusion)	(US-PGPUB; USPAT)	OR	ON	ON	2024/12/05 02:14 PM
L824	194	antibody SAME infusion SAME rate SAME over NEAR period	(US-PGPUB; USPAT)	OR	ON	ON	2024/12/05 02:14 PM
L825	1	anti-tnf SAME antibody SAME infusion SAME rate SAME over NEAR period	(US-PGPUB; USPAT)	OR	ON	ON	2024/12/05 02:14 PM
L826	5	anti-tnf AND antibody SAME infusion SAME rate SAME over NEAR period	(US-PGPUB; USPAT)	OR	ON	ON	2024/12/05 02:14 PM
L827	5904	anti-tnf AND antibody SAME infusion	(US-PGPUB; USPAT)	OR	ON	ON	2024/12/05 02:14 PM
L828	221	anti-tnf ADJ antibody SAME infusion	(US-PGPUB; USPAT)	OR	ON	ON	2024/12/05 02:14 PM
L829	1095	Janssen ADJ Biotech ADJ Inc.asn.	(US-PGPUB; USPAT)	OR	ON	ON	2024/12/05 02:14 PM
L830	23	Harrison Diane D.in.	(US-PGPUB; USPAT)	ADJ	ON	ON	2024/12/05 02:14 PM
L831	20	Hsia Elizabeth C.in.	(US-PGPUB; USPAT)	ADJ	ON	ON	2024/12/05 02:14 PM
L832	14	Kim Lee-Lian.in.	(US-PGPUB; USPAT)	ADJ	ON	ON	2024/12/05 02:14 PM
L833	15	Lo Kim Hung.in.	(US-PGPUB; USPAT)	ADJ	ON	ON	2024/12/05 02:14 PM
L834	1307	L27 L29 L30 L31 L32 L34	(US-PGPUB; USPAT)	OR	ON	ON	2024/12/05 02:14 PM
L835	141	L35 AND golimumab	(US-PGPUB; USPAT)	OR	ON	ON	2024/12/05 02:14 PM
L836	10	L35 AND golimumab.clm.	(US-PGPUB; USPAT)	OR	ON	ON	2024/12/05 02:14 PM
L837	3782	c07k16/241.cpc.	(US-PGPUB; USPAT)	OR	ON	ON	2024/12/05 02:14 PM
L838	17231	a61k39/3955.cpc.	(US-PGPUB; USPAT)	OR	ON	ON	2024/12/05 02:14 PM
L839	56208	a61p19/02.cpc.	(US-PGPUB; USPAT)	OR	ON	ON	2024/12/05 02:14 PM
L840	72826	L38 OR L39 L40	(US-PGPUB; USPAT)	OR	ON	ON	2024/12/05 02:14 PM
L841	122	L41 AND golimumab AND spondilitis	(US-PGPUB; USPAT)	OR	ON	ON	2024/12/05 02:14 PM
L842	23	L41 AND golimumab AND spondilitis.clm.	(US-PGPUB; USPAT)	OR	ON	ON	2024/12/05 02:14 PM
L843	60	golimumab AND spondylitis ADJ ankylosing AND	(US-PGPUB; USPAT)	OR	ON	ON	2024/12/05 02:14 PM

		@ay<"2018" AND infusion					
L844	118	2009/0123378 AND administration AND iv	(US-PGPUB; USPAT)	OR	ON	ON	2024/12/05 02:14 PM
L845	1	"20090123378".pn. AND administration AND iv	(US-PGPUB; USPAT)	OR	ON	ON	2024/12/05 02:14 PM
L846	1	"20090123378".pn. AND administration AND intraven$5	(US-PGPUB; USPAT)	OR	ON	ON	2024/12/05 02:14 PM
L847	151	("0000030" OR "0000059" OR "0000088" OR "0000116" OR "0000144" OR "20090214528" OR "20100251099" OR "20110251099" 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 "4757506" 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 "5116964" OR "5122464" OR "5130238" OR "5142033" OR "5149636" OR "5168062" OR "5179017" OR "5223409" OR "5225538" OR	(US-PGPUB; USPAT)	OR	ON	ON	2024/12/05 02:14 PM

		"5225539" OR "5231024" OR "5260203" OR "5266491" OR "5304489" OR "5342613" OR "5385839" OR "5403484" OR "5404871" OR "5427908" OR "5447851" OR "5455030" OR "5458135" OR "5496549" OR "5512544" OR "5514670" OR "5518889" OR "5530101" OR "5534621" OR "5545807" OR "5565362" 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 "5698419" OR "5698435" OR "5714352" OR "5723323" OR "5733761" OR "5750105" OR "5750373" OR "5763192" OR "5763733" OR "5766886" OR "5770198" OR					

		"5770222" OR "5770359" OR "5770428" OR "5789650" OR "5807706" OR "5814476" OR "5814599" OR "5817483" OR "5821333" OR "5824514" OR "5827690" OR "5827739" OR "5833985" OR "5837500" OR "5839446" OR "5849695" OR "5851198" OR "5856456" OR "5871753" OR "5879681" OR "5885793" OR "5888511" OR "5919452" OR "5932448" OR "5958413" OR "5959083" OR "5959084" OR "5962255" OR "5976862" OR "5989530" OR "5993833" OR "5994616" OR "6010902" 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.					
L848	2	("0000030" OR "0000059" OR "0000088" OR "0000116" OR "0000144" OR "20090214528" OR "20100251099" OR "20110251099" OR "3773919" OR "4239754" OR	(US-PGPUB; USPAT)	OR	ON	ON	2024/12/05 02:14 PM

		"4309989" OR "4399216" OR "4603106" OR "4634665" OR "4656134" OR "4668218" OR "4676980" OR "4683195" OR "4683202" OR "4704692" OR "4757506" 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 "5116964" 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 "5404871" OR "5427908" OR "5447851" OR "5455030" OR "5458135" OR "5496549" OR "5512544" OR "5514670" OR "5518889" OR "5530101" OR "5534621" OR "5545807" OR "5565362" OR "5569825" OR					

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L849	151	("0000030" OR "0000059" OR "0000088" OR "0000116" OR "0000144" OR "20090214528" OR "20100251099" OR "20110251099" 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 "4757506" OR "4766067" OR "4767402" OR "4795699" OR "4800159" OR "4816567" OR "4822776" OR "4873316" OR "4889818" OR "4921794" OR "4925673" OR	(US-PGPUB; USPAT)	OR	ON	ON	2024/12/05 02:14 PM

		"4939666" OR "4946778" OR "4956288" OR "4965188" OR "4994370" OR "5066584" OR "5116964" 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 "5404871" OR "5427908" OR "5447851" OR "5455030" OR "5458135" OR "5496549" OR "5512544" OR "5514670" OR "5518889" OR "5530101" OR "5534621" OR "5545807" OR "5565362" 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					

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		"7521206" OR "7691378" OR "8241899" OR "9512065").pn.					
L850	2	L1 AND golimumab	(US-PGPUB; USPAT)	OR	ON	ON	2024/12/05 02:14 PM
L851	1	L1 AND golimumab AND ankylosing	(US-PGPUB; USPAT)	OR	ON	ON	2024/12/05 02:14 PM
L852	2	L1 AND golimumab AND arthritis	(US-PGPUB; USPAT)	OR	ON	ON	2024/12/05 02:14 PM
L853	2	L1 AND golimumab AND spondylitis	(US-PGPUB; USPAT)	OR	ON	ON	2024/12/05 02:14 PM
L854	4391	golimumab AND spondylitis	(US-PGPUB; USPAT)	OR	ON	ON	2024/12/05 02:14 PM
L855	4299	golimumab AND spondylitis AND ankylosing	(US-PGPUB; USPAT)	OR	ON	ON	2024/12/05 02:14 PM
L856	186	golimumab AND spondylitis ADJ ankylosing	(US-PGPUB; USPAT)	OR	ON	ON	2024/12/05 02:14 PM
L857	68	golimumab AND spondylitis ADJ ankylosing AND @ay<"2018"	(US-PGPUB; USPAT)	OR	ON	ON	2024/12/05 02:14 PM
L858	1	golimumab SAME spondylitis ADJ ankylosing AND @ay<"2018"	(US-PGPUB; USPAT)	OR	ON	ON	2024/12/05 02:14 PM
L859	1	(golimumab OR (Cnto NEAR "148")) SAME spondylitis ADJ ankylosing AND @ay<"2018"	(US-PGPUB; USPAT)	OR	ON	ON	2024/12/05 02:14 PM
L860	9	(golimumab OR (Cnto NEAR "148")) ADJ ankylosing ADJ spondylitis	(US-PGPUB; USPAT)	OR	ON	ON	2024/12/05 02:14 PM
L861	1018	(golimumab OR (Cnto NEAR "148")).clm.	(US-PGPUB; USPAT)	OR	ON	ON	2024/12/05 02:14 PM
L862	407	(golimumab OR (Cnto NEAR "148")).clm. AND spondylitis	(US-PGPUB; USPAT)	OR	ON	ON	2024/12/05 02:14 PM
L863	397	(golimumab OR (Cnto NEAR "148")).clm. AND ankylosing ADJ spondylitis	(US-PGPUB; USPAT)	OR	ON	ON	2024/12/05 02:14 PM
L864	174	(golimumab OR (Cnto NEAR "148")).clm. AND ankylosing ADJ spondylitis AND @ay<"2017"	(US-PGPUB; USPAT)	OR	ON	ON	2024/12/05 02:14 PM
L865	111	(golimumab OR (Cnto	(US-PGPUB; USPAT)	OR	ON	ON	2024/12/05

		NEAR "148")).clm. AND ankylosing ADJ spondylitis AND @ay<"2017" AND methotrexate					02:14 PM
L866	114	(golimumab OR (Cnto NEAR "148")).clm. AND ankylosing ADJ spondylitis AND @ay<"2017" AND (methotrexate OR sulfasalazine OR hydroxychloroquine)	(US-PGPUB; USPAT)	OR	ON	ON	2024/12/05 02:14 PM
L867	2	(golimumab OR (Cnto NEAR "148")) SAME infusion SAME (over NEAR time)	(US-PGPUB; USPAT)	OR	ON	ON	2024/12/05 02:14 PM
L868	341	(golimumab OR (Cnto NEAR "148")) SAME infusion	(US-PGPUB; USPAT)	OR	ON	ON	2024/12/05 02:14 PM
L869	16	(golimumab OR (Cnto NEAR "148")) SAME (rate NEAR infusion)	(US-PGPUB; USPAT)	OR	ON	ON	2024/12/05 02:14 PM
L870	1084	antibody SAME (rate NEAR infusion)	(US-PGPUB; USPAT)	OR	ON	ON	2024/12/05 02:14 PM
L871	194	antibody SAME infusion SAME rate SAME over NEAR period	(US-PGPUB; USPAT)	OR	ON	ON	2024/12/05 02:14 PM
L872	1	anti-tnf SAME antibody SAME infusion SAME rate SAME over NEAR period	(US-PGPUB; USPAT)	OR	ON	ON	2024/12/05 02:14 PM
L873	5	anti-tnf AND antibody SAME infusion SAME rate SAME over NEAR period	(US-PGPUB; USPAT)	OR	ON	ON	2024/12/05 02:14 PM
L874	5904	anti-tnf AND antibody SAME infusion	(US-PGPUB; USPAT)	OR	ON	ON	2024/12/05 02:14 PM
L875	221	anti-tnf ADJ antibody SAME infusion	(US-PGPUB; USPAT)	OR	ON	ON	2024/12/05 02:14 PM
L876	1095	Janssen ADJ Biotech ADJ Inc.asn.	(US-PGPUB; USPAT)	OR	ON	ON	2024/12/05 02:14 PM
L877	23	Harrison Diane D.in.	(US-PGPUB; USPAT)	ADJ	ON	ON	2024/12/05 02:14 PM
L878	20	Hsia Elizabeth C.in.	(US-PGPUB; USPAT)	ADJ	ON	ON	2024/12/05 02:14 PM
L879	14	Kim Lee-Lian.in.	(US-PGPUB; USPAT)	ADJ	ON	ON	2024/12/05 02:14 PM
L880	15	Lo Kim Hung.in.	(US-PGPUB; USPAT)	ADJ	ON	ON	2024/12/05 02:14 PM
L881	1307	L27 L29 L30 L31 L32 L34	(US-PGPUB; USPAT)	OR	ON	ON	2024/12/05 02:14 PM

L882	141	L35 AND golimumab	(US-PGPUB; USPAT)	OR	ON	ON	2024/12/05 02:14 PM
L883	10	L35 AND golimumab.clm.	(US-PGPUB; USPAT)	OR	ON	ON	2024/12/05 02:14 PM
L884	3782	c07k16/241.cpc.	(US-PGPUB; USPAT)	OR	ON	ON	2024/12/05 02:14 PM
L885	17231	a61k39/3955.cpc.	(US-PGPUB; USPAT)	OR	ON	ON	2024/12/05 02:14 PM
L886	56208	a61p19/02.cpc.	(US-PGPUB; USPAT)	OR	ON	ON	2024/12/05 02:14 PM
L887	72826	L38 OR L39 L40	(US-PGPUB; USPAT)	OR	ON	ON	2024/12/05 02:14 PM
L888	122	L41 AND golimumab AND spondilitis	(US-PGPUB; USPAT)	OR	ON	ON	2024/12/05 02:14 PM
L889	23	L41 AND golimumab AND spondilitis.clm.	(US-PGPUB; USPAT)	OR	ON	ON	2024/12/05 02:14 PM
L890	60	golimumab AND spondylitis ADJ ankylosing AND @ay<"2018" AND infusion	(US-PGPUB; USPAT)	OR	ON	ON	2024/12/05 02:14 PM
L891	118	2009/0123378 AND administration AND iv	(US-PGPUB; USPAT)	OR	ON	ON	2024/12/05 02:14 PM
L892	1	"20090123378".pn. AND administration AND iv	(US-PGPUB; USPAT)	OR	ON	ON	2024/12/05 02:14 PM
L893	1	"20090123378".pn. AND administration AND intraven$5	(US-PGPUB; USPAT)	OR	ON	ON	2024/12/05 02:14 PM
L894	151	("0000030" OR "0000059" OR "0000088" OR "0000116" OR "0000144" OR "20090214528" OR "20100251099" OR "20110251099" 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 "4757506" OR "4766067" OR "4767402" OR "4795699" OR "4800159" OR	(US-PGPUB; USPAT)	OR	ON	ON	2024/12/05 02:14 PM

		"4816567" OR "4822776" OR "4873316" OR "4889818" OR "4921794" OR "4925673" OR "4939666" OR "4946778" OR "4956288" OR "4965188" OR "4994370" OR "5066584" OR "5116964" 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 "5404871" OR "5427908" OR "5447851" OR "5455030" OR "5458135" OR "5496549" OR "5512544" OR "5514670" OR "5518889" OR "5530101" OR "5534621" OR "5545807" OR "5565362" 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 "5698419" OR "5698435" OR "5714352" OR "5723323" OR "5733761" OR "5750105" OR "5750373" OR "5763192" OR "5763733" OR "5766886" OR "5770198" OR "5770222" OR "5770359" OR "5770428" OR "5789650" OR "5807706" OR "5814476" OR "5814599" OR "5817483" OR "5821333" OR "5824514" OR "5827690" OR "5827739" OR "5833985" OR "5837500" OR "5839446" OR "5849695" OR "5851198" OR "5856456" OR "5871753" OR "5879681" OR "5885793" OR "5888511" OR "5919452" OR "5932448" OR "5958413" OR "5959083" OR "5959084" OR "5962255" OR "5976862" OR "5989530" OR "5993833" OR "5994616" OR "6010902" 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.					
L895	2	("0000030" OR "0000059" OR "0000088" OR "0000116" OR "0000144" OR "20090214528" OR "20100251099" OR "20110251099" 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 "4757506" 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 "5116964" OR "5122464" OR "5130238" OR "5142033" OR "5149636" OR "5168062" OR "5179017" OR "5223409" OR "5225538" OR "5225539" OR	(US-PGPUB; USPAT)	OR	ON	ON	2024/12/05 02:14 PM

		"5231024" OR "5260203" OR "5266491" OR "5304489" OR "5342613" OR "5385839" OR "5403484" OR "5404871" OR "5427908" OR "5447851" OR "5455030" OR "5458135" OR "5496549" OR "5512544" OR "5514670" OR "5518889" OR "5530101" OR "5534621" OR "5545807" OR "5565362" 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 "5698419" OR "5698435" OR "5714352" OR "5723323" OR "5733761" OR "5750105" OR "5750373" OR "5763192" OR "5763733" OR "5766886" OR "5770198" OR "5770222" OR					

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L896	151	("0000030" OR "0000059" OR "0000088" OR "0000116" OR "0000144" OR "20090214528" OR "20100251099" OR "20110251099" OR "3773919" OR "4239754" OR	(US-PGPUB; USPAT)	OR	ON	ON	2024/12/05 02:14 PM

		"4309989" OR "4399216" OR "4603106" OR "4634665" OR "4656134" OR "4668218" OR "4676980" OR "4683195" OR "4683202" OR "4704692" OR "4757506" 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 "5116964" 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 "5404871" OR "5427908" OR "5447851" OR "5455030" OR "5458135" OR "5496549" OR "5512544" OR "5514670" OR "5518889" OR "5530101" OR "5534621" OR "5545807" OR "5565362" OR "5569825" OR					

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L897	2	L1 AND golimumab	(US-PGPUB; USPAT)	OR	ON	ON	2024/12/05 02:14 PM

PE2E SEARCH - Search History (Interference)

There are no Interference searches to show.

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APPLICATION NO.	ISSUE DATE	PATENT NO.	ATTORNEY DOCKET NO.	CONFIRMATION NO.
17/237,650	05/06/2025	12291566	206389-0002-02US	8810

171672 7590 04/16/2025

Riverside Law LLP/J&J
175 Strafford Avenue
Suite 100
Wayne, PA 19087

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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 0 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.

INVENTOR(s) (Please see PATENT CENTER site https://patentcenter.uspto.gov for additional inventors):

Diane D. Harrison, Philadelphia, PA;
Elizabeth C. Hsia, Kenneth Square, PA;
Lee-Lian Kim, North Wales, PA;
Kim Hung Lo, Exton, PA;

APPLICANT(s) (Please see PATENT CENTER site https://patentcenter.uspto.gov for additional applicants):

Janssen Biotech, Inc., Horsham, PA;

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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
17/237,650	04/22/2021	Diane D. Harrison	206389-0002-02US	8810

171672 7590 05/06/2025

Riverside Law LLP/J&J
175 Strafford Avenue
Suite 100
Wayne, PA 19087

EXAMINER	
CHANDRA, GYAN	

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NOTIFICATION DATE	DELIVERY MODE
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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):

JNJUSPATENT@ITS.JNJ.COM
dcoccia@riversidelaw.com
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APPLICATION NO.	ISSUE DATE	PATENT NO.
17/237,650	06-May-2025	12291566

Riverside Law LLP/J&J
175 Strafford Avenue
Wayne, PA 19087

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