

Attorney Docket No. 206389-0003-02US
Preliminary Amendment

Electronically Filed

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of:

Diane D. Harrison, et al.

Group Art Unit: TBD

Application No.: Not yet assigned

Examiner: TBD

Filed: Herewith

Attorney Docket No.
206389-0003-02US

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

PRELIMINARY AMENDMENT

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

In the Specification:

On page 1 of the Specification, please insert the following heading and paragraph after the title:

--CROSS REFERENCE TO RELATED APPLICATIONS

This application is a continuation application of US Serial No. 16/517,594, filed July 20, 2019, which is a continuation application of US Serial No. 15/818,063, filed November 20, 2017, which claims priority to US Serial No. 62/452,079, filed January 30, 2017, the contents of which are hereby incorporated by reference in their entirety. --

In the Claims:

This listing of claims will replace all prior versions, and listings, of claims in the application.

1 - 10. (Cancelled)

11. (New) A method for treating a tumor necrosis factor alpha (TNF- α) related condition, wherein the TNF- α related condition is active psoriatic arthritis, the method comprising: administering to a subject having active psoriatic arthritis a composition comprising a safe and effective amount of at least one isolated mammalian anti-TNF- α antibody comprising:

- a. a heavy chain (HC) complementary determining region (CDR) 1 comprising an amino acid sequence of SEQ ID NO: 1;
- b. a HC CDR2 comprising an amino acid sequence of SEQ ID NO: 2; wherein position 1 of SEQ ID NO: 2 is phenylalanine, position 2 of SEQ ID NO: 2 is methionine, position 3 of SEQ ID NO: 2 is serine, position 4 of SEQ ID NO: 2 is tyrosine, position 10 of SEQ ID NO: 2 is lysine, position 11 of SEQ ID NO: 2 is tyrosine, and position 17 of SEQ ID NO: 2 is glycine;
- c. a HC CDR3 comprising an amino acid sequence of SEQ ID NO: 3; wherein position 4 of SEQ ID NO: 3 is isoleucine, position 5 of SEQ ID NO: 3 is alanine, and position 9 of SEQ ID NO: 3 is asparagine;
- d. a light chain (LC) CDR1 comprising an amino acid sequence of SEQ ID NO: 4; wherein position 7 of SEQ ID NO: 4 is tyrosine;
- e. a LC CDR2 comprising an amino acid sequence of SEQ ID NO: 5; and
- f. a LC CDR3 comprising an amino acid sequence of SEQ ID NO: 6,

and at least one pharmaceutically acceptable carrier or diluent, wherein said composition is administered via intravenous (IV) infusion, and wherein at week 14 of treatment patients treated with the anti-TNF- α antibody achieve a mean change from baseline in one or more criteria selected from the group consisting of: Health Assessment Questionnaire Disability Index score (HAQ-DI) = -0.60 ± 0.53 SD, enthesitis = -1.87 ± 1.75 SD, dactylitis = -7.8 ± 8.57 SD, Short-Form Health Survey Physical Summary score (SF-36 PCS) = 8.65 ± 7.60 SD,

and Short-Form Health Survey Mental Component Summary score (SF-36 MCS) = 5.33 ± 9.95 SD.

12. (New) The method according to claim 11, wherein said composition is administered such that said anti-TNF- α antibody is administered at a dose of 2 mg/kg, over 30 ± 10 minutes, at Weeks 0 and 4, then every 8 weeks (q8w) thereafter.

13. (New) The method according to claim 11, further comprising administering said composition with or without methotrexate (MTX).

14. (New) A method for treating a TNF- α related condition, wherein the TNF- α related condition is active psoriatic arthritis, the method comprising: administering to a subject having active psoriatic arthritis a composition comprising a safe and effective amount of at least one isolated mammalian anti-TNF- α antibody comprising:

- a. a heavy chain (HC) complementary determining region (CDR) 1 comprising an amino acid sequence of SEQ ID NO: 1;
 - b. a HC CDR2 comprising an amino acid sequence of SEQ ID NO: 2; wherein position 1 of SEQ ID NO: 2 is phenylalanine, position 2 of SEQ ID NO: 2 is methionine, position 3 of SEQ ID NO: 2 is serine, position 4 of SEQ ID NO: 2 is tyrosine, position 10 of SEQ ID NO: 2 is lysine, position 11 of SEQ ID NO: 2 is tyrosine, and position 17 of SEQ ID NO: 2 is glycine;
 - c. a HC CDR3 comprising an amino acid sequence of SEQ ID NO: 3; wherein position 4 of SEQ ID NO: 3 is isoleucine, position 5 of SEQ ID NO: 3 is alanine, and position 9 of SEQ ID NO: 3 is asparagine;
 - d. a light chain (LC) CDR1 comprising an amino acid sequence of SEQ ID NO: 4; wherein position 7 of SEQ ID NO: 4 is tyrosine;
 - e. a LC CDR2 comprising an amino acid sequence of SEQ ID NO: 5; and
 - f. a LC CDR3 comprising an amino acid sequence of SEQ ID NO: 6,
- and at least one pharmaceutically acceptable carrier or diluent, wherein said composition is administered via IV infusion, and wherein at week 24 of treatment patients treated with the

anti-TNF- α antibody achieve a mean change from baseline in total modified van der Heijde-Sharp score (vdH-S) = -0.36 ± 0.144 SE.

15. (New) The method according to claim 14, wherein said composition is administered such that said anti-TNF- α antibody is administered at a dose of 2 mg/kg, over 30 ± 10 minutes, at Weeks 0 and 4, then every 8 weeks (q8w) thereafter.

16. (New) The method according to claim 14, further comprising administering said composition with or without methotrexate (MTX).

17. (New) A method for treating a TNF- α related condition, wherein the TNF- α related condition is active psoriatic arthritis, the method comprising: administering to a subject having active psoriatic arthritis a composition comprising a safe and effective amount of at least one isolated mammalian anti-TNF- α antibody comprising:

- a. a heavy chain (HC) complementary determining region (CDR) 1 comprising an amino acid sequence of SEQ ID NO: 1;
 - b. a HC CDR2 comprising an amino acid sequence of SEQ ID NO: 2; wherein position 1 of SEQ ID NO: 2 is phenylalanine, position 2 of SEQ ID NO: 2 is methionine, position 3 of SEQ ID NO: 2 is serine, position 4 of SEQ ID NO: 2 is tyrosine, position 10 of SEQ ID NO: 2 is lysine, position 11 of SEQ ID NO: 2 is tyrosine, and position 17 of SEQ ID NO: 2 is glycine;
 - c. a HC CDR3 comprising an amino acid sequence of SEQ ID NO: 3; wherein position 4 of SEQ ID NO: 3 is isoleucine, position 5 of SEQ ID NO: 3 is alanine, and position 9 of SEQ ID NO: 3 is asparagine;
 - d. a light chain (LC) CDR1 comprising an amino acid sequence of SEQ ID NO: 4; wherein position 7 of SEQ ID NO: 4 is tyrosine;
 - e. a LC CDR2 comprising an amino acid sequence of SEQ ID NO: 5; and
 - f. a LC CDR3 comprising an amino acid sequence of SEQ ID NO: 6,
- wherein said anti-TNF- α antibody is administered via intravenous (IV) infusion, and wherein $\geq 65\%$ of patients receiving the treatment achieve ACR20 at week 14 of treatment.

18. (New) The method according to claim 17, wherein said $\geq 65\%$ of patients that achieve ACR20 at week 14 of treatment with a treatment difference (improvement compared to placebo) of about 50%.

19. (New) The method according to claim 17, wherein said antibody is administered at a dose of 2 mg/kg, over 30 ± 10 minutes, at Weeks 0 and 4, and then every 8 weeks (q8w) thereafter.

20. (New) The method according claim 17, wherein said antibody is administered with or without methotrexate (MTX).

REMARKS

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

Amendment to the Specification

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

Amendment to the Claims

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

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

Summary

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

Favorable examination and allowance of the claims is hereby requested.

Respectfully submitted,

Diane D. Harrison, et al.

May 14, 2021

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



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.
17/320,490	05/14/2021	Diane D. Harrison	206389-0003-02US	5386
171672	7590	04/26/2023	EXAMINER	
Riverside Law LLP/J&J 175 Strafford Avenue Suite 100 Wayne, PA 19087			CHANDRA, GYAN	
			ART UNIT	PAPER NUMBER
			1646	
			NOTIFICATION DATE	DELIVERY MODE
			04/26/2023	ELECTRONIC

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

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

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

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

DETAILED ACTION

Notice of Pre-AIA or AIA Status

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

Claims 11-20 are pending and under examination.

Information Disclosure Statement

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

Specification

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

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

Drawings

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

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

Claim Rejections - 35 USC § 112

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

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

The following is a quotation of 35 U.S.C. 112 (pre-AIA), second paragraph:
The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

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

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

Claim Rejections - 35 USC § 102

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

A person shall be entitled to a patent unless –

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

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

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

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

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

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

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

Claim Rejections - 35 USC § 103

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

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

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

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

obviousness or nonobviousness.

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

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

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

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

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

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

Double Patenting

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

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

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

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

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

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

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

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

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

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

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

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

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

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

Conclusion

No claim is allowed.

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

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

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

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

Application/Control Number: 17/320,490
Art Unit: 1646

Page 15

additional questions, contact the Electronic Business Center (EBC) at 866-217-9197

(toll-free). If you would like assistance from a USPTO Customer Service

Representative, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/GYAN CHANDRA/
Primary Examiner, Art Unit 1646

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

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

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

Art Unit: 1646
Confirmation No.: 5386

Application No.:
17/320,490

Examiner:
Chandra, Gyan

Filing date:
May 14, 2021

Atty Docket No.:
206389-0003-02US

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

AMENDMENT

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

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

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

In the Specification:

Please amend the Specification as follows.

Please replace Paragraph [30], page 23, beginning with “In one approach, a hybridoma...” with the following:

-- In one approach, a hybridoma is produced by fusing a suitable immortal cell line (e.g., a myeloma cell line such as, but not limited to, Sp2/0, Sp2/0-AG14, NSO, NS1, NS2, AE-1, L.5, >243, P3X63Ag8.653, Sp2 SA3, Sp2 MAI, Sp2 SS1, Sp2 SA5, U937, MLA 144, ACT IV, MOLT4, DA-1, JURKAT, WEHI, K-562, COS, RAJI, NIH 3T3, HL-60, MLA 144, NAMAIWA, NEURO 2A, or the like, or heteromyelomas, fusion products thereof, or any cell or fusion cell derived therefrom, or any other suitable cell line as known in the art. See, e.g., [www._atcc.org](http://www.atcc.org), [www._lifetech.com](http://www.lifetech.com)., and the like, with antibody producing cells, such as, but not limited to, isolated or cloned spleen, peripheral blood, lymph, tonsil, or other immune or B cell containing cells, or any other cells expressing heavy or light chain constant or variable or framework or CDR sequences, either as endogenous or heterologous nucleic acid, as recombinant or endogenous, viral, bacterial, algal, prokaryotic, amphibian, insect, reptilian, fish, mammalian, rodent, equine, ovine, goat, sheep, primate, eukaryotic, genomic DNA, cDNA, rDNA, mitochondrial DNA or RNA, chloroplast DNA or RNA, hnRNA, mRNA, tRNA, single, double or triple stranded, hybridized, and the like or any combination thereof. See, e.g., Ausubel, supra, and Colligan, Immunology, supra, chapter 2, entirely incorporated herein by reference. --

Please replace Paragraph [33], page 25, beginning with “Methods for engineering or humanizing” with the following:

-- Methods for engineering or humanizing non-human or human antibodies can also be used and are well known in the art. Generally, a humanized or engineered antibody has one or more amino acid residues from a source which is non-human, e.g.,

but not limited to mouse, rat, rabbit, non-human primate or other mammal. These human amino acid residues are often referred to as "import" residues, which are typically taken from an "import" variable, constant or other domain of a known human sequence. Known human Ig sequences are disclosed, e.g.,

www.ncbi.nlm.nih.gov/entrez/query.fcgi; www.atcc.org/phage/hdb.html;
www.sciquest.com/; www.abcam.com/; www.antibodyresource.com/onlinecomp.html;
www.public.iastate.edu/~pedro/research_tools.html; www.mgen.uniheidelberg.de/SD/IT/IT.html; www.whfreeman.com/immunology/CH05/kuby05.htm;
www.library.thinkquest.org/12429/Immune/Antibody.html;
www.hhmi.org/grants/lectures/1996/vlab/;
www.path.cam.ac.uk/~mrc7/mikeimages.html; www.antibodyresource.com/;
mcb.harvard.edu/BioLinks/Immunology.html; www.immunologylink.com/;
pathbox.wustl.edu/~hcenter/index.html; www.biotech.ufl.edu/~hcl/;
www.pebio.com/pa/340913/340913.html; www.nal.usda.gov/awic/pubs/antibody/;
www.m.ehime-u.ac.jp/~yasuhito/Elisa.html; www.biodesign.com/table.asp;
www.icnet.uk/axp/facs/davies/links.html; www.biotech.ufl.edu/~fccl/protocol.html;
www.isac-net.org/sites_geo.html; aximt1.imt.uni-marburg.de/~rek/AEPStart.html;
baserv.uci.kun.nl/~jraats/links1.html; www.recab.uni-hd.de/immuno.bme.nwu.edu/;
www.mrc-cpe.cam.ac.uk/imt-doc/public/INTRO.html;
www.ibt.unam.mx/vir/V_mice.html; imgt.cnusc.fr:8104/;
www.biochem.ucl.ac.uk/~martin/abs/index.html; antibody.bath.ac.uk/;
abgen.cvm.tamu.edu/lab/wwwabgen.html;
www.unizh.ch/~honegger/AHOseminar/Slide01.html; www.cryst.bbk.ac.uk/~ubcg07s/;
www.nimr.mrc.ac.uk/CC/ccaewg/ccaewg.htm;
www.path.cam.ac.uk/~mrc7/humanisation/TAHHP.html;
www.ibt.unam.mx/vir/structure/stat_aim.html;
www.biosci.missouri.edu/smithgp/index.html;
www.cryst.bioc.cam.ac.uk/~fmolina/Web-pages/Pept/spottech.html;
www.jerini.de/fr_products.htm; www.patents.ibm.com/ibm.html. Kabat et al., Sequences of Proteins of Immunological Interest, U.S. Dept. Health (1983), each entirely incorporated herein by reference.

Please replace Paragraph [67], page 37, beginning with “Illustrative of cell cultures...” with the following:

--Illustrative of cell cultures useful for the production of the antibodies, specified portions or variants thereof, are mammalian cells. Mammalian cell systems often will be in the form of monolayers of cells although mammalian cell suspensions or bioreactors can also be used. A number of suitable host cell lines capable of expressing intact glycosylated proteins have been developed in the art, and include the COS-1 (e.g., ATCC CRL 1650), COS-7 (e.g., ATCC CRL-1651), HEK293, BHK21 (e.g., ATCC CRL-10), CHO (e.g., ATCC CRL 1610) and BSC-1 (e.g., ATCC CRL-26) cell lines, Cos-7 cells, CHO cells, hep G2 cells, P3X63Ag8.653, SP2/0-Ag14, 293 cells, HeLa cells and the like, which are readily available from, for example, American Type Culture Collection, Manassas, Va (www.atcc.org). Preferred host cells include cells of lymphoid origin such as myeloma and lymphoma cells. Particularly preferred host cells are P3X63Ag8.653 cells (ATCC Accession Number CRL-1580) and SP2/0-Ag14 cells (ATCC Accession Number CRL-1851). In a particularly preferred embodiment, the recombinant cell is a P3X63Ab8.653 or a SP2/0-Ag14 cell.--

Please replace Paragraph [68], page 38, beginning with “Expression vectors for these cells...” with the following:

--Expression vectors for these cells can include one or more of the following expression control sequences, such as, but not limited to an origin of replication; a promoter (e.g., late or early SV40 promoters, the CMV promoter (US Pat.Nos. 5,168,062; 5,385,839), an HSV tk promoter, a pgk (phosphoglycerate kinase) promoter, an EF-1 alpha promoter (US Pat.No. 5,266,491), at least one human immunoglobulin promoter; an enhancer, and/or processing information sites, such as ribosome binding sites, RNA splice sites, polyadenylation sites (e.g., an SV40 large T Ag poly A addition site), and transcriptional terminator sequences. See, e.g., Ausubel et al., supra; Sambrook, et al., supra. Other cells useful for production of nucleic acids or proteins of the present invention are known and/or available, for instance, from the American Type Culture Collection Catalogue of Cell Lines and Hybridomas (www.atcc.org) or other known or

commercial sources.--

Please replace Paragraph [114], page 57, beginning with “Recognized devices comprising these single vial systems” with the following:

--Recognized devices comprising these single vial systems include those pen-injector devices for delivery of a solution such as BD Pens, BD Autojector®, Humaject®, NovoPen®, B-D® Pen, AutoPen®, and OptiPen®, GenotropinPen®, Genotronorm Pen®, Humatro Pen®, Reco-Pen®, Roferon Pen®, Biojector®, iject®, J-tip Needle-Free Injector®, Intraject®, Medi-Ject®, e.g., as made or developed by Becton Dickensen (Franklin Lakes, NJ, www._bectondickenson.com), Disetronic (Burgdorf, Switzerland, www._disetronic.com); Bioject, Portland, Oregon (www._bioject.com); National Medical Products , Weston Medical (Peterborough, UK, www._westonmedical.com), Medi-Ject Corp (Minneapolis, MN, www._mediject.com). Recognized devices comprising a dual vial system include those pen-injector systems for reconstituting a lyophilized drug in a cartridge for delivery of the reconstituted solution such as the HumatroPen®. --

In the Drawings:

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

In the Claims:

This listing of claims will replace all prior versions, and listings, of claims in the application.

1 - 10. (Cancelled)

11. (Previously Presented) A method for treating a tumor necrosis factor alpha (TNF- α) related condition, wherein the TNF- α related condition is active psoriatic arthritis, the method comprising: administering to a subject having active psoriatic arthritis a composition comprising a safe and effective amount of at least one isolated mammalian anti-TNF- α antibody comprising:

- a. a heavy chain (HC) complementary determining region (CDR) 1 comprising an amino acid sequence of SEQ ID NO: 1;
 - b. a HC CDR2 comprising an amino acid sequence of SEQ ID NO: 2; wherein position 1 of SEQ ID NO: 2 is phenylalanine, position 2 of SEQ ID NO: 2 is methionine, position 3 of SEQ ID NO: 2 is serine, position 4 of SEQ ID NO: 2 is tyrosine, position 10 of SEQ ID NO: 2 is lysine, position 11 of SEQ ID NO: 2 is tyrosine, and position 17 of SEQ ID NO: 2 is glycine;
 - c. a HC CDR3 comprising an amino acid sequence of SEQ ID NO: 3; wherein position 4 of SEQ ID NO: 3 is isoleucine, position 5 of SEQ ID NO: 3 is alanine, and position 9 of SEQ ID NO: 3 is asparagine;
 - d. a light chain (LC) CDR1 comprising an amino acid sequence of SEQ ID NO: 4; wherein position 7 of SEQ ID NO: 4 is tyrosine;
 - e. a LC CDR2 comprising an amino acid sequence of SEQ ID NO: 5; and
 - f. a LC CDR3 comprising an amino acid sequence of SEQ ID NO: 6,
- and at least one pharmaceutically acceptable carrier or diluent, wherein said composition is administered via intravenous (IV) infusion, and wherein at week 14 of treatment patients treated with the anti-TNF- α antibody achieve a mean change from baseline in one or more criteria selected from the group consisting of: Health Assessment Questionnaire Disability Index score (HAQ-DI) = -0.60 ± 0.53 SD, enthesitis = -1.87 ± 1.75 SD, dactylitis = $-7.8 \pm$

8.57 SD, Short-Form Health Survey Physical Summary score (SF-36 PCS)= 8.65 ± 7.60 SD, and Short-Form Health Survey Mental Component Summary score (SF-36 MCS) = 5.33 ± 9.95 SD.

12. (Currently Amended) The method according to claim 11, wherein said ~~composition is administered such that said~~ anti-TNF- α antibody is administered at a dose of 2 mg/kg, over 30 ± 10 minutes, at Weeks 0 and 4, then every 8 weeks (q8w) thereafter.

13. (Previously Presented) The method according to claim 11, further comprising administering said composition with or without methotrexate (MTX).

14. (Previously Presented) A method for treating a TNF- α related condition, wherein the TNF- α related condition is active psoriatic arthritis, the method comprising: administering to a subject having active psoriatic arthritis a composition comprising a safe and effective amount of at least one isolated mammalian anti-TNF- α antibody comprising:

a. a heavy chain (HC) complementary determining region (CDR) 1 comprising an amino acid sequence of SEQ ID NO: 1;

b. a HC CDR2 comprising an amino acid sequence of SEQ ID NO: 2; wherein position 1 of SEQ ID NO: 2 is phenylalanine, position 2 of SEQ ID NO: 2 is methionine, position 3 of SEQ ID NO: 2 is serine, position 4 of SEQ ID NO: 2 is tyrosine, position 10 of SEQ ID NO: 2 is lysine, position 11 of SEQ ID NO: 2 is tyrosine, and position 17 of SEQ ID NO: 2 is glycine;

c. a HC CDR3 comprising an amino acid sequence of SEQ ID NO: 3; wherein position 4 of SEQ ID NO: 3 is isoleucine, position 5 of SEQ ID NO: 3 is alanine, and position 9 of SEQ ID NO: 3 is asparagine;

d. a light chain (LC) CDR1 comprising an amino acid sequence of SEQ ID NO: 4; wherein position 7 of SEQ ID NO: 4 is tyrosine;

e. a LC CDR2 comprising an amino acid sequence of SEQ ID NO: 5; and

f. a LC CDR3 comprising an amino acid sequence of SEQ ID NO: 6,

and at least one pharmaceutically acceptable carrier or diluent, wherein said composition is administered via IV infusion, and wherein at week 24 of treatment patients treated with the anti-TNF- α antibody achieve a mean change from baseline in total modified van der Heijde-Sharp score (vdH-S) = -0.36 ± 0.144 SE.

15. (Currently Amended) The method according to claim 14, wherein said ~~composition is administered such that said~~ anti-TNF- α antibody is administered at a dose of 2 mg/kg, over 30 ± 10 minutes, at Weeks 0 and 4, then every 8 weeks (q8w) thereafter.

16. (Previously Presented) The method according to claim 14, further comprising administering said composition with or without methotrexate (MTX).

17. (Previously Presented) A method for treating a TNF- α related condition, wherein the TNF- α related condition is active psoriatic arthritis, the method comprising: administering to a subject having active psoriatic arthritis a composition comprising a safe and effective amount of at least one isolated mammalian anti-TNF- α antibody comprising:

- a. a heavy chain (HC) complementary determining region (CDR) 1 comprising an amino acid sequence of SEQ ID NO: 1;
- b. a HC CDR2 comprising an amino acid sequence of SEQ ID NO: 2; wherein position 1 of SEQ ID NO: 2 is phenylalanine, position 2 of SEQ ID NO: 2 is methionine, position 3 of SEQ ID NO: 2 is serine, position 4 of SEQ ID NO: 2 is tyrosine, position 10 of SEQ ID NO: 2 is lysine, position 11 of SEQ ID NO: 2 is tyrosine, and position 17 of SEQ ID NO: 2 is glycine;
- c. a HC CDR3 comprising an amino acid sequence of SEQ ID NO: 3; wherein position 4 of SEQ ID NO: 3 is isoleucine, position 5 of SEQ ID NO: 3 is alanine, and position 9 of SEQ ID NO: 3 is asparagine;
- d. a light chain (LC) CDR1 comprising an amino acid sequence of SEQ ID NO: 4; wherein position 7 of SEQ ID NO: 4 is tyrosine;
- e. a LC CDR2 comprising an amino acid sequence of SEQ ID NO: 5; and
- f. a LC CDR3 comprising an amino acid sequence of SEQ ID NO: 6;

wherein said anti-TNF- α antibody is administered via intravenous (IV) infusion, and wherein $\geq 65\%$ of patients receiving the treatment achieve ACR20 at week 14 of treatment.

18. (Previously Presented) The method according to claim 17, wherein said $\geq 65\%$ of patients that achieve ACR20 at week 14 of treatment with a treatment difference (improvement compared to placebo) of about 50%.

19. (Previously Presented) The method according to claim 17, wherein said antibody is administered at a dose of 2 mg/kg, over 30 ± 10 minutes, at Weeks 0 and 4, and then every 8 weeks (q8w) thereafter.

20. (Previously Presented) The method according claim 17, wherein said antibody is administered with or without methotrexate (MTX).

REMARKS

Claims 11-20 are pending and under consideration.

Amendments to the Specification

The Specification has been amended to remove all executable code.

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

Amendments to the Drawings

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

Amendments to the Claims

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

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

Title

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

Objection to the Specification

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

Applicants respectfully request reconsideration and withdrawal of the objection.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

Cited art does not teach or suggest each and every element

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

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

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

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

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

Cited art does not provide a reasonable expectation of success

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

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

Office personnel must articulate the following:

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

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

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

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

Secondary Considerations

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

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

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

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

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

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

Summary

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

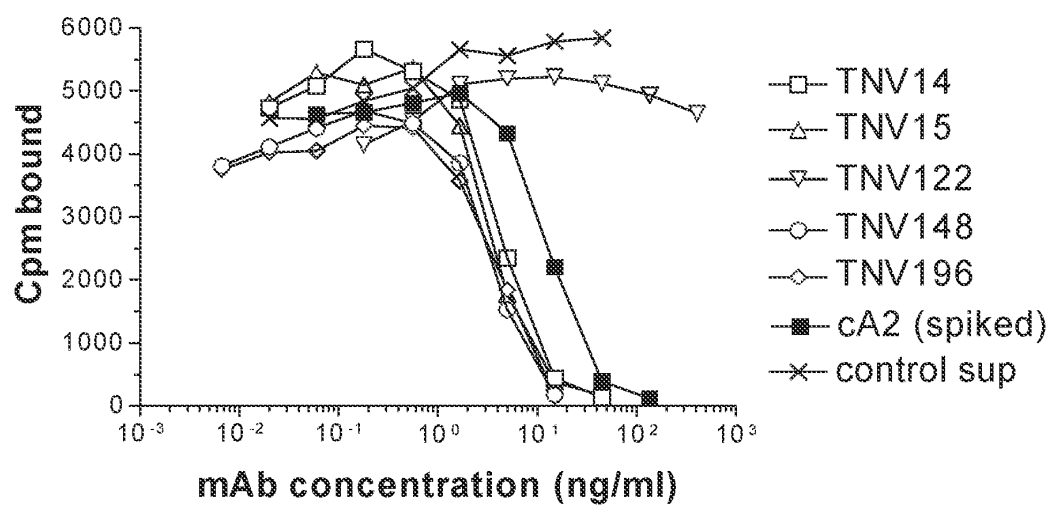
Respectfully submitted,

Diane D. Harrison, ET AL.

August 15, 2023

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)
E-Mail: dockets@riversidelaw.com
Attorney for Applicant

FIGURE 1



2/19

FIGURE 2A

TNVs ATGGGGTTTGGGCTGAGCTGGGTTTTCCTCGTTGCTCTTTTAAGA

		Q V Q L V E S G G G V
germline		CAGGTGCAGCTGGTGGAGTCTGGGGGAGGCGTG
TNVs	GGTGTCCAGTGT.....	
TNV148 (B)	GGTGTCCAGTGT.....A.....	

		V Q P G R S L R L S C A A S G
germline		GTCCAGCCTGGGAGGTCCCTGAGACTCTCCTGTGCAGCCTCTGGA
TNVs		

		F T F S <u>S Y A M H</u> W V R Q A P
germline		TTCACCTTCAGTAGCTATGCTATGCACTGGGTCCGCCAGGCTCCA
TNV14,15		
TNV148 (B)	T.....	
TNV196	C.....	

		G K G L E W V A <u>V I S Y D G S</u>
germline		GGCAAGGGGCTGGAGTGGGTGGCAGTTATATCATATGATGGAAGC
TNV14	A....C.T.....T	
TNV15	T.....T.....T	
TNV148 (B)	C.....T....G.....	
TNV196	T.....	

		<u>N K Y Y A D S V K G R F T I S</u>	SEQ ID NO:7 cont'd→
germline		AATAAATACTACGCAGACTCCGTGAAGGGCCGATTACCATCTCC	SEQ ID NO:34 cont'd→
TNV14	.GC...A.G....G.....A.....		
TNV15	..C...A.G.....C.....		
TNV148 (B)	A.G.....		
TNV196	A.G.C.....G.....		

3/19

FIGURE 2B

	R D N S K N T L Y L Q M N S L
germline	AGAGACAATTCCAAGAACACGCTGTATCTGCAAATGAACAGCCTG
TNV14	
TNV15	G.....
TNV148	C.....
TNV148B	
TNV196	T.....

	R A E D T A V Y Y C A R
germline	AGAGCTGAGGACACGGCTGTGTATTACTGTGCGAGA
TNV14,15	GATCGAGGT
TNV148 (B)	A
TNV196	T.....

	<u>Y Y Y Y Y G M D V</u> W
germline	TACTACTACTACTACGGTATGGACGTCTGG
TNV14	ATATCAGCAGGTGGAA.....
TNV15	G.C.....A.T..T.....
TNV148 (B)	...G.....A.....
TNV196	..TGG.....A.....

	G Q G T T V T V S S	SEQ ID NO:7
germline	GGGCAAGGGACCACGGTCACCGTCTCCTCAG	SEQ ID NO:34
TNV14	..C.....	
TNV15	..C.....	
TNV148 (B)	..C.....	
TNV196	..C..G.....	

4/19

FIGURE 3

TNVs	<u>ATGGAAGCCCCAGCTCAGCTTCTCTTCCTCCTGCTACTCTGGCTC</u>	
	E I V L T Q S P A T	
germline	GAAATTGTGTTGACACAGTCTCCAGCCACC	
TNVs	CCAGATACCACCGGA.....	
	L S L S P G E R A T L S C <u>R A</u>	
germline	CTGTCTTTGTCTCCAGGGGAAAGAGCCACCCTCTCCTGCAGGGCC	
TNVs		
	<u>S Q S V S S Y L A</u> W Y Q Q K P	
germline	AGTCAGAGTGTTAGCAGCTACTTAGCCTGGTACCAACAGAAACCT	
TNV14,15		
TNV148,196	TA.....	
	G Q A P R L L I Y <u>D A S N R A</u>	
germline	GGCCAGGCTCCCAGGCTCCTCATCTATGATGCATCCAACAGGGCC	
TNVs		
	<u>T</u> G I P A R F S G S G S G T D	
germline	ACTGGCATCCCAGCCAGGTTTCAGTGGCAGTGGGTCTGGGACAGAC	
TNVs		
	F T L T I S S L E P E D F A V	
germline	TTCACTCTCACCATCAGCAGCCTAGAGCCTGAAGATTTTGCAGTT	
TNVs		
	Y Y C <u>Q Q R S N W P P F T</u> F G	SEQ ID NO:8
Germline	TATTACTGTCAGCAGCGTAGCAACTGGCCTCCATTCACTTTTCGGC	SEQ ID NO:35
TNVs	A.....	
	P G T K V D I K R	
germline	CCTGGGACCAAAGTGGATATCAAACGT	
TNVs		

5/19

FIGURE 4

germline	<u>MGFGLSWVFLVALLRGVQC</u>	signal	SEQ ID NO. 32
TNVs			
germline	QVQLVESGGGVVQPGRSLRLSCAASGFTFS	FR1	SEQ ID NO. 7
TNVs			
TNV148 (B)	I..		
germline	SYAMH	CDR1	SEQ ID NO. 1
TNVs			
germline	WVRQAPGKGLEWVA	FR2	SEQ ID NO. 7
TNVs			
TNV148 (B)	N.....		
germline	VISYDGSNKYYADSVKG	CDR2	SEQ ID NO. 2
TNV14	I.L....S.K.....D		
TNV15	F.L.....K.....		
TNV148 (B)	FM.....K.....		
TNV196	F.....KS.....		
germline	RFTISRDN SKNTLYLQMN SLRAEDTAVYYCAR	FR3	SEQ ID NO. 7
TNV14			
TNV15	A.....		
TNV148	P.....		
TNV148B			
TNV196	...V.....F.....F....		
germline	-----Y Y Y Y Y G M D V	CDR3	SEQ ID NO. 3
TNV14	DRGISAGGN.....		
TNV15	...V....N.....		
TNV148 (B)	...A...N.....		
TNV196	G...N.....		
germline	WGQGT T V T V S S	J6	SEQ ID NO. 7
TNVs			

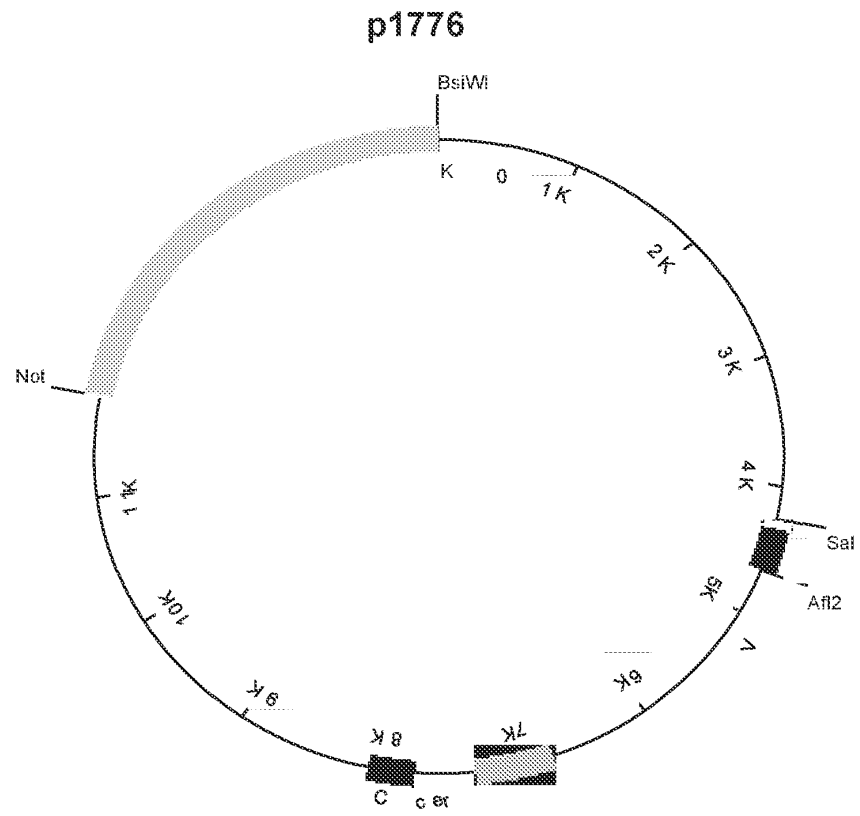
6/19

FIGURE 5

TNVs	MEAPAQLLFLLLLWLPDTTG	signal	SEQ ID NO. 33
germline	EIVLTQSPATLSLSPGERATLSC	FR1	SEQ ID NO. 8
TNVs			
germline	RASQSVSSYLA	CDR1	SEQ ID NO. 4
TNV14			
TNV15			
TNV148 (B)	Y....		
TNV196	Y....		
germline	WYQQKPGQAPRLLIY	FR2	SEQ ID NO. 8
TNVs			
germline	DASNRAT	CDR2	SEQ ID NO. 5
TNVs			
germline	GIPARFSGSGSGTDFTLTISSELPEDFAVYYC	FR3	SEQ ID NO. 8
TNVs			
germline	QQRSNWPPFT	CDR3	SEQ ID NO. 6
TNVs			
germline	FGPGTKVDIK	J3	SEQ ID NO. 8
TNVs			

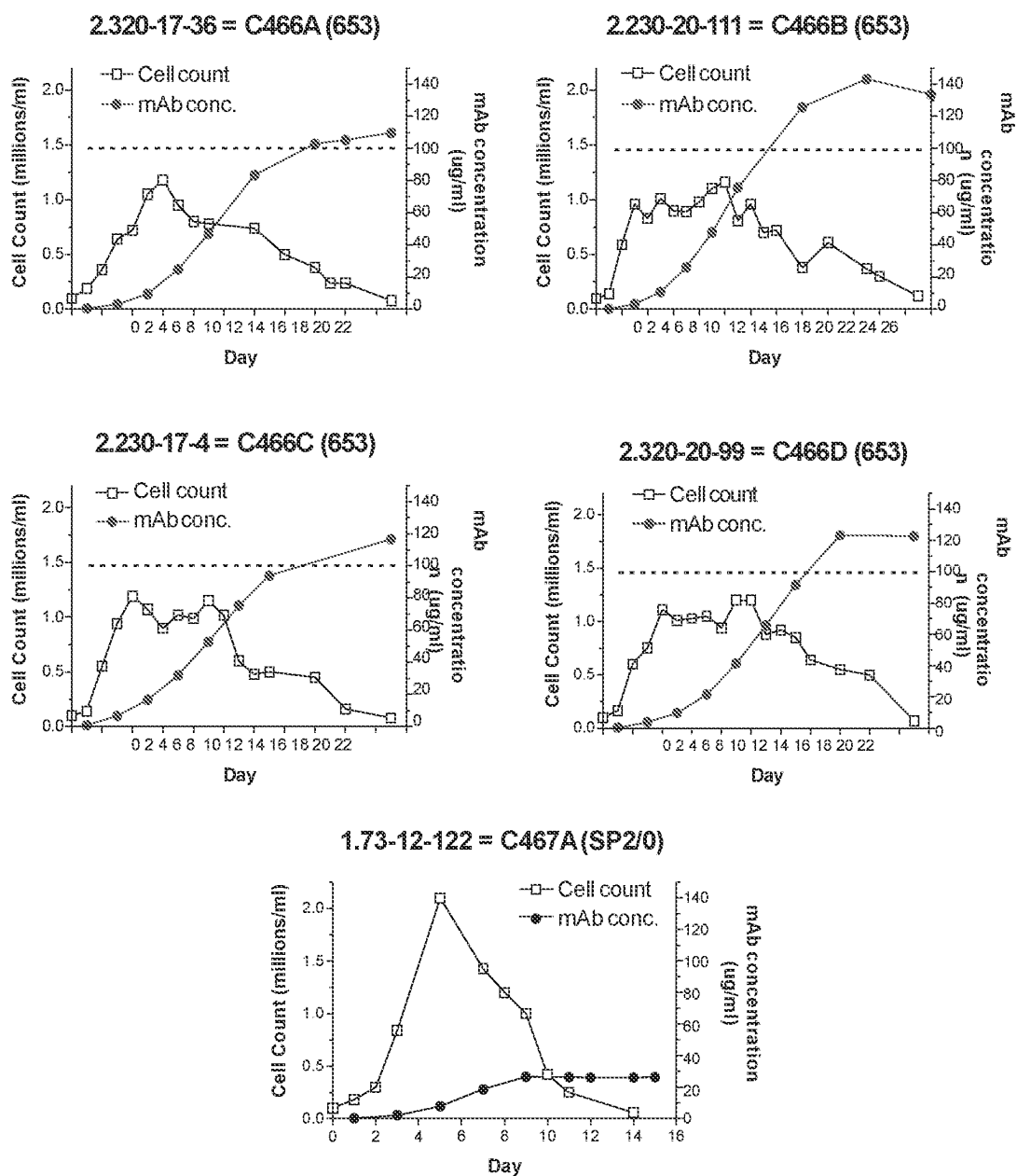
7/19

FIGURE 6



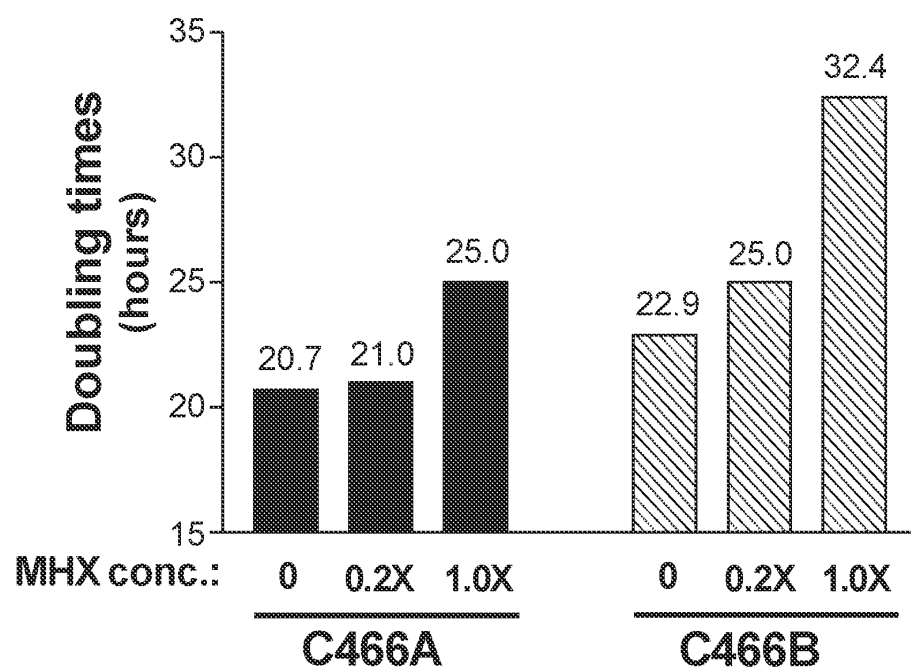
8/19

FIGURE 7



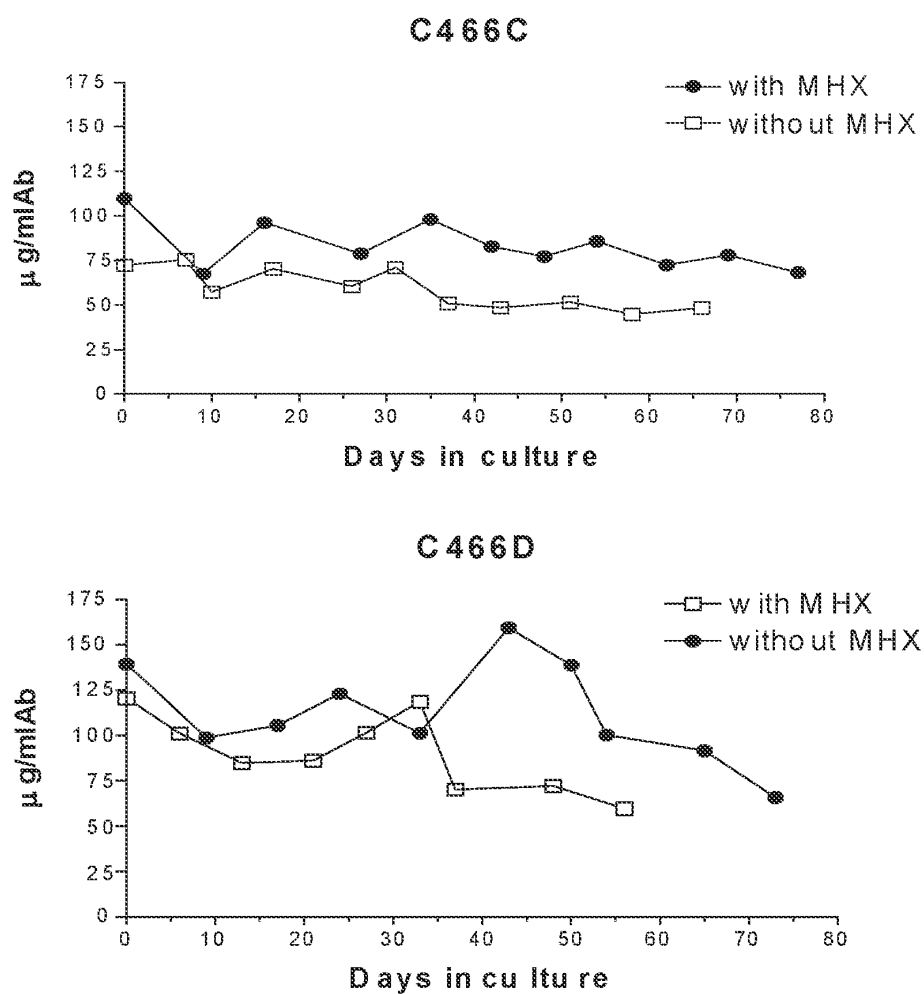
9/19

FIGURE 8



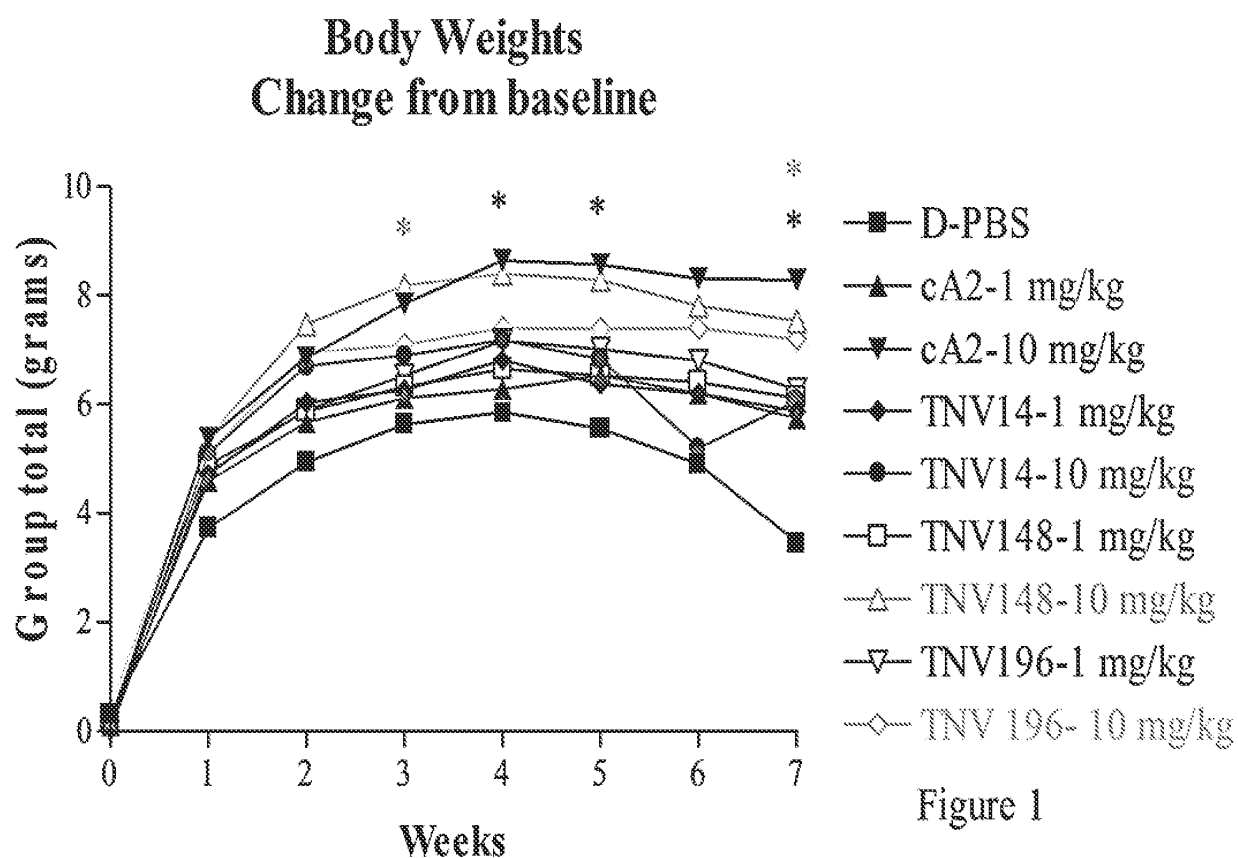
10/19

FIGURE 9



11/19

FIGURE 10



12/19

FIGURE 11A

Arthritic Index

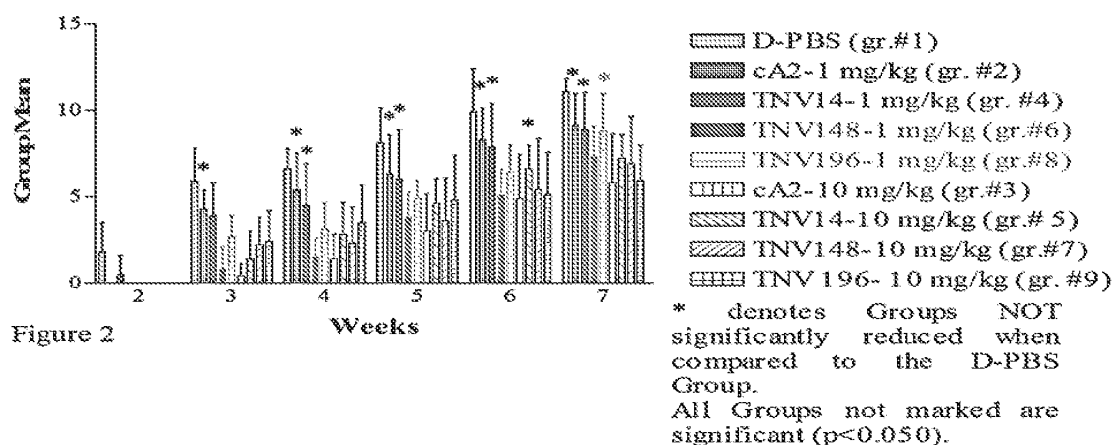


FIGURE 11B

Arthritic Index

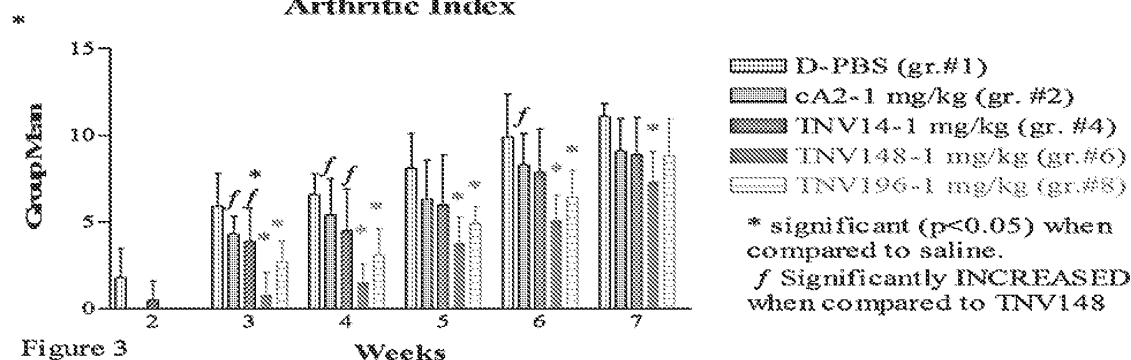
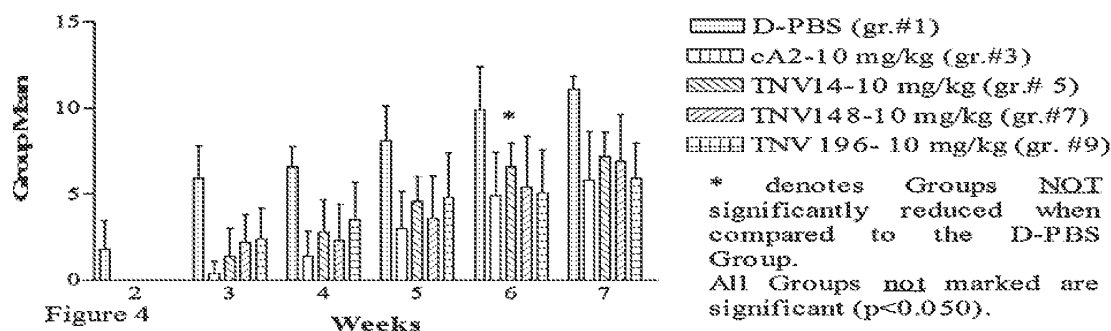


FIGURE 11C

Arthritic Index



13/19

FIGURE 12

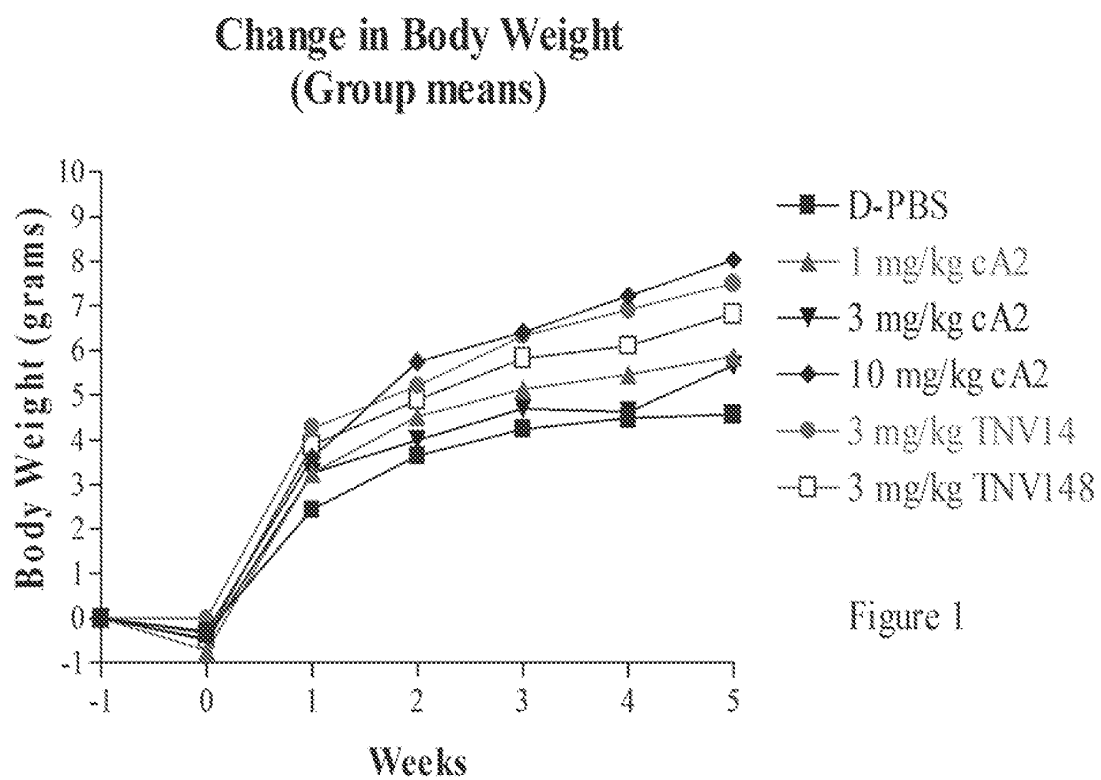


Figure 1

14/19

FIGURE 13A

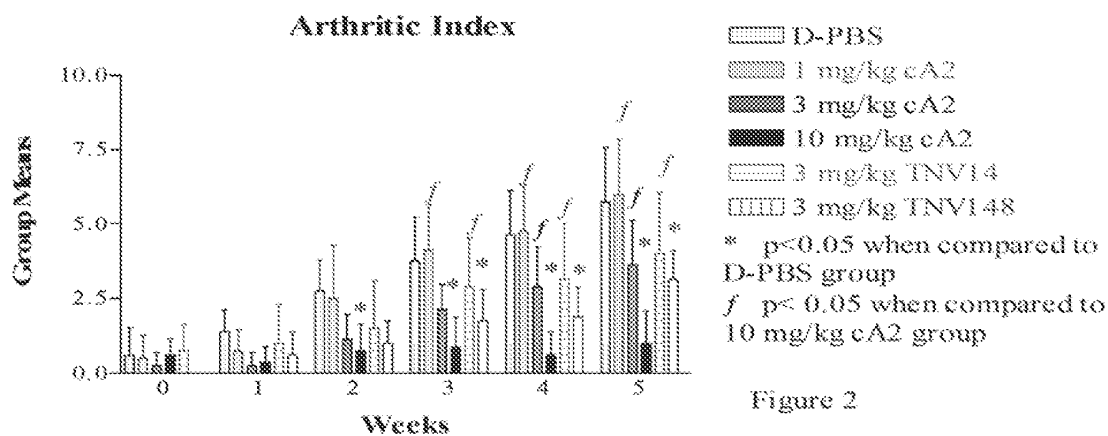


FIGURE 13B

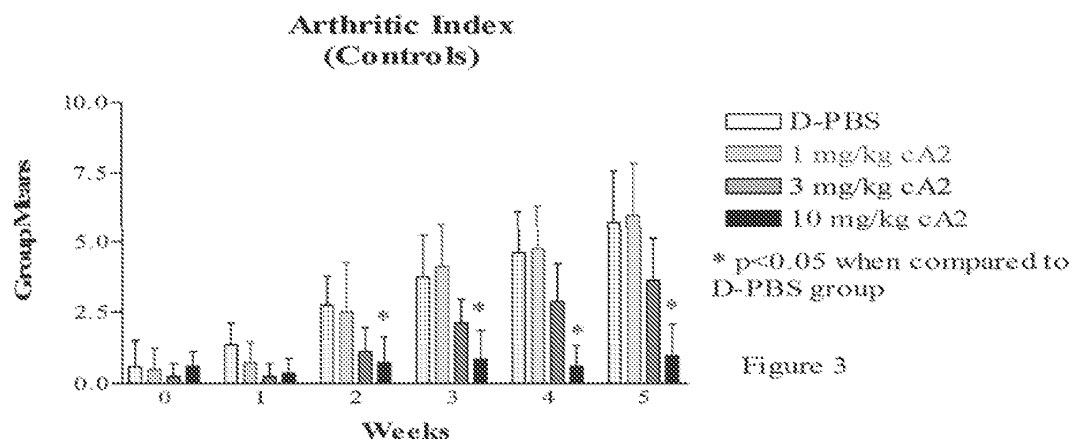


FIGURE 13C

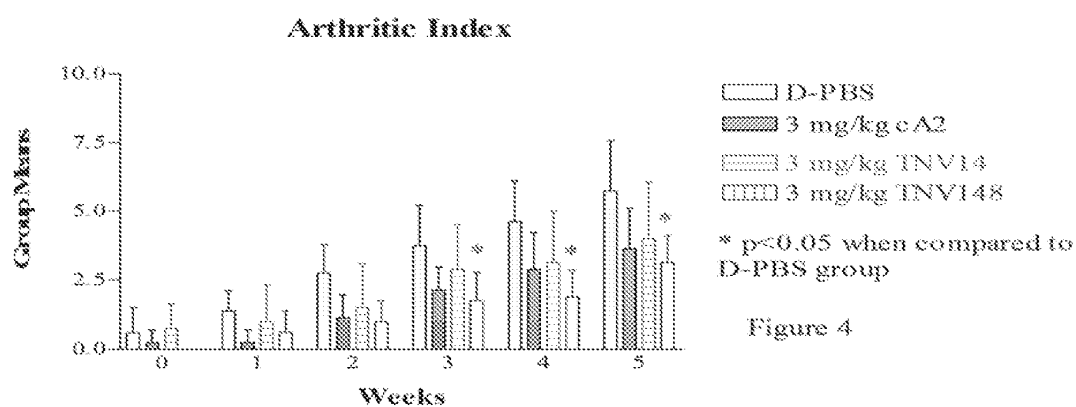
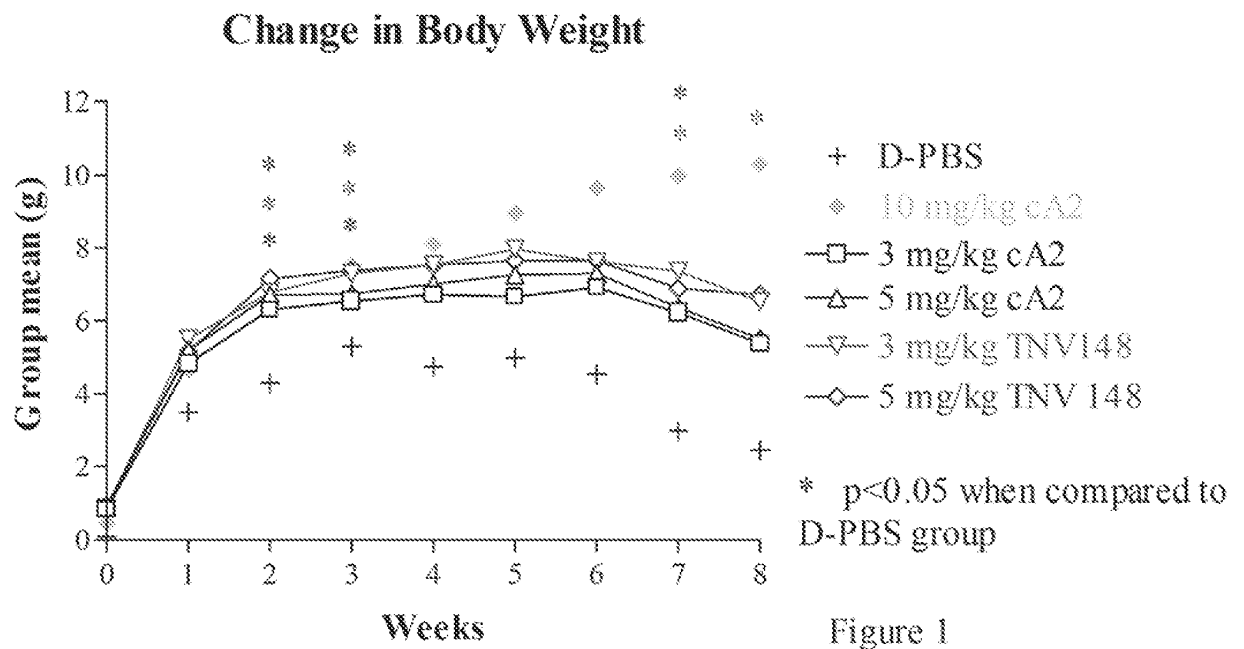


FIGURE 14



16/19

FIGURE 15

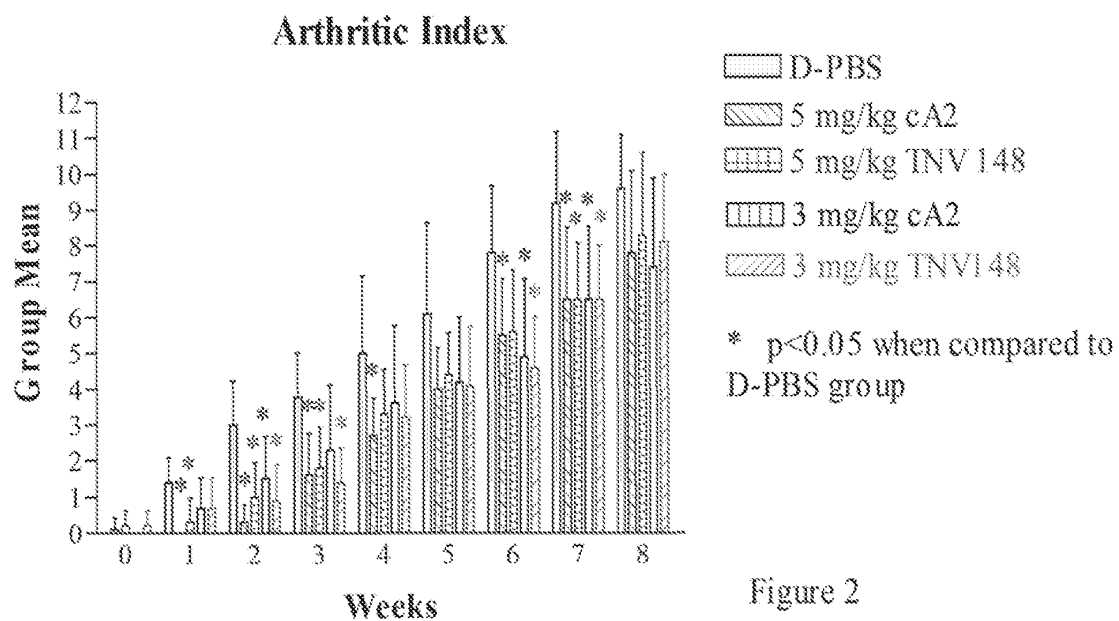


Figure 2

17/19

FIGURE 16

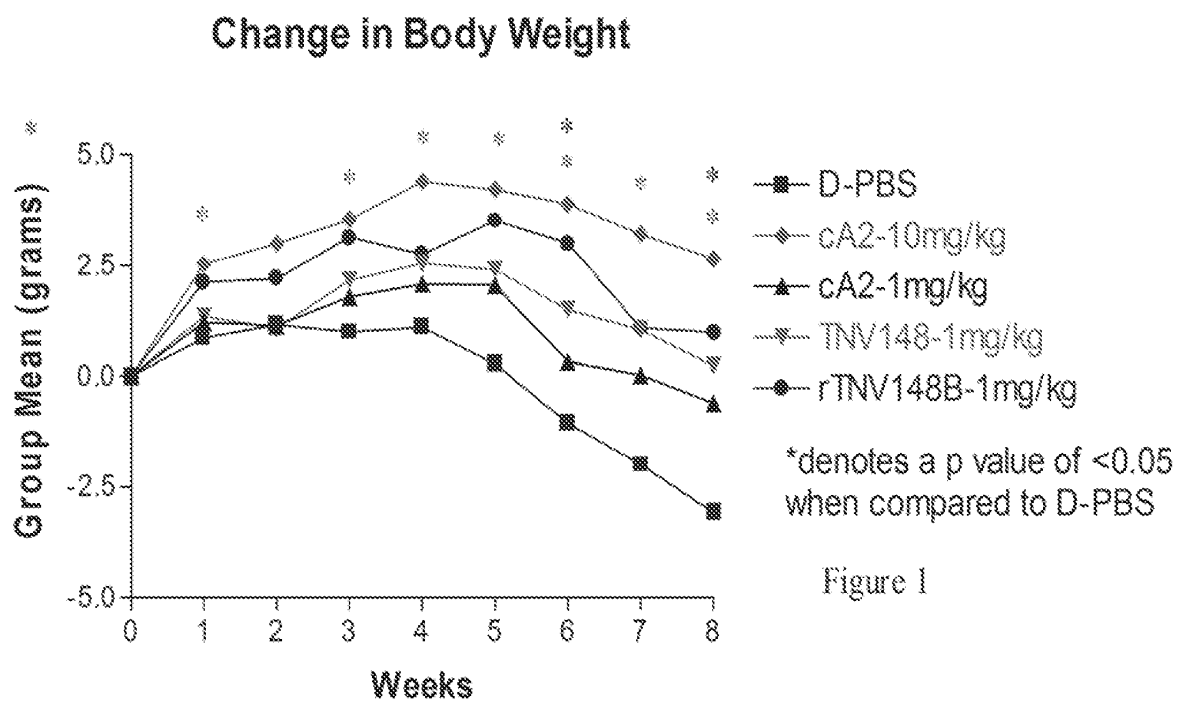


FIGURE 17

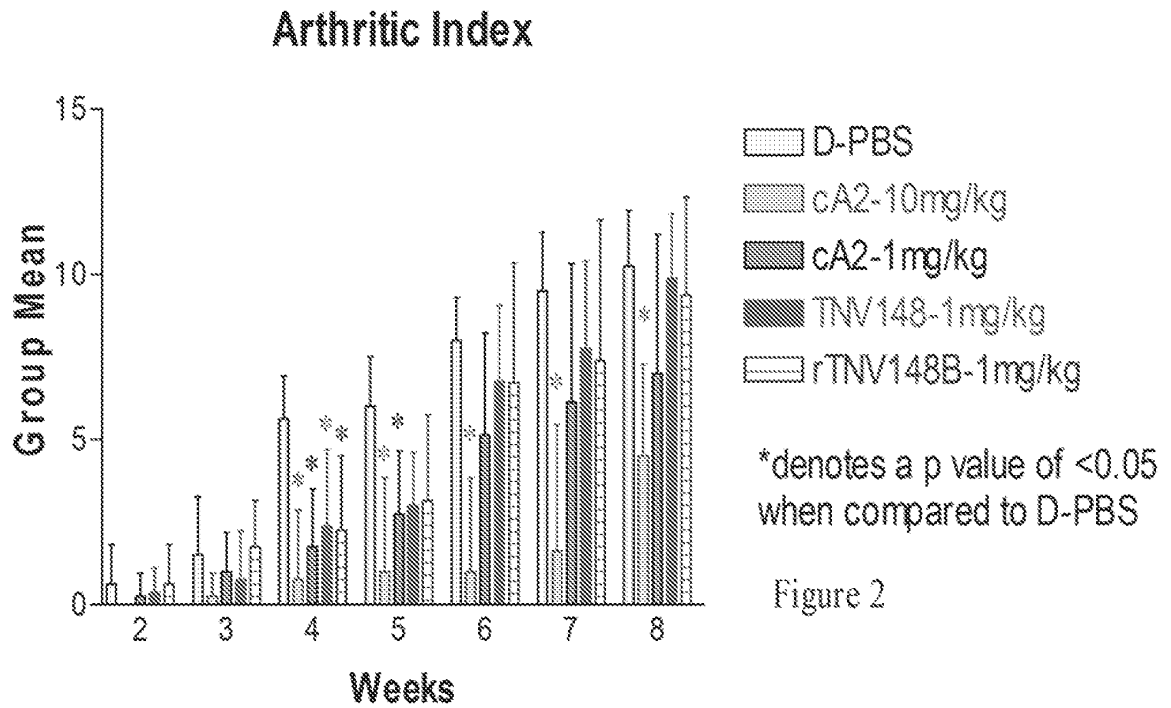
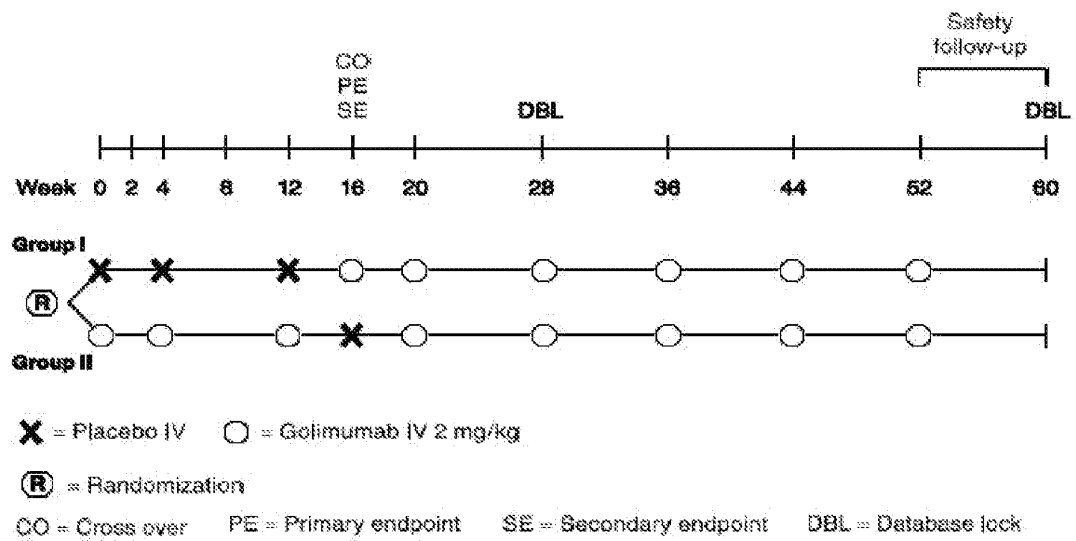


FIGURE 18

Schematic Overview of the Study





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.
17/320,490	05/14/2021	Diane D. Harrison	206389-0003-02US	5386
171672	7590	09/08/2023		
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
			09/08/2023	ELECTRONIC

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

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

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

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

DETAILED ACTION

Notice of Pre-AIA or AIA Status

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

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

Status of Application, Amendments, And/Or Claims

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

Claims 11-20 are pending and under examination.

Response to Arguments

Claim Rejections - 35 USC § 112-withdrawn

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

Claim Rejections - 35 USC § 102-maintained

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

A person shall be entitled to a patent unless –

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

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

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

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

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

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

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

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

Claim Rejections - 35 USC § 103

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

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

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

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

obviousness or nonobviousness.

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

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

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

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

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

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

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

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

Double Patenting-maintained

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

Conclusion

No claim is allowed.

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

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

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

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

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

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

/GYAN CHANDRA/
Primary Examiner, Art Unit 1646

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

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

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

Art Unit: 1646
Confirmation No.: 5386

Application No.:
17/320,490

Examiner:
Chandra, Gyan

Filing date:
May 14, 2021

Atty Docket No.:
206389-0003-02US

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

AMENDMENT

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

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

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

In the Claims:

This listing of claims will replace all prior versions, and listings, of claims in the application.

1 - 10. (Cancelled)

11. (Currently Amended) A method for treating a tumor necrosis factor alpha (TNF- α) related condition, wherein the TNF- α related condition is active psoriatic arthritis, the method comprising: administering to a subject having active psoriatic arthritis a composition comprising a safe and effective amount of at least one isolated mammalian anti-TNF- α antibody comprising:

- a. a heavy chain (HC) complementary determining region (CDR) 1 comprising an amino acid sequence of SEQ ID NO: 1;
 - b. a HC CDR2 comprising an amino acid sequence of SEQ ID NO: 2; wherein position 1 of SEQ ID NO: 2 is phenylalanine, position 2 of SEQ ID NO: 2 is methionine, position 3 of SEQ ID NO: 2 is serine, position 4 of SEQ ID NO: 2 is tyrosine, position 10 of SEQ ID NO: 2 is lysine, position 11 of SEQ ID NO: 2 is tyrosine, and position 17 of SEQ ID NO: 2 is glycine;
 - c. a HC CDR3 comprising an amino acid sequence of SEQ ID NO: 3; wherein position 4 of SEQ ID NO: 3 is isoleucine, position 5 of SEQ ID NO: 3 is alanine, and position 9 of SEQ ID NO: 3 is asparagine;
 - d. a light chain (LC) CDR1 comprising an amino acid sequence of SEQ ID NO: 4; wherein position 7 of SEQ ID NO: 4 is tyrosine;
 - e. a LC CDR2 comprising an amino acid sequence of SEQ ID NO: 5; and
 - f. a LC CDR3 comprising an amino acid sequence of SEQ ID NO: 6,
- and at least one pharmaceutically acceptable carrier or diluent, wherein said composition is administered via intravenous (IV) infusion, wherein said anti-TNF- α antibody is administered at a dose of 2 mg/kg, over 30 ± 10 minutes, at Weeks 0 and 4, then every 8 weeks (q8w) thereafter, and wherein at week 14 of treatment patients treated with the anti-

TNF- α antibody achieve a mean change from baseline in one or more criteria selected from the group consisting of: Health Assessment Questionnaire Disability Index score (HAQ-DI) = -0.60 ± 0.53 SD, enthesitis = -1.87 ± 1.75 SD, dactylitis = -7.8 ± 8.57 SD, Short-Form Health Survey Physical Summary score (SF-36 PCS) = 8.65 ± 7.60 SD, and Short-Form Health Survey Mental Component Summary score (SF-36 MCS) = 5.33 ± 9.95 SD.

12. (Cancelled)

13. (Previously Presented) The method according to claim 11, further comprising administering said composition with or without methotrexate (MTX).

14. (Currently Amended) A method for treating a TNF- α related condition, wherein the TNF- α related condition is active psoriatic arthritis, the method comprising: administering to a subject having active psoriatic arthritis a composition comprising a safe and effective amount of at least one isolated mammalian anti-TNF- α antibody comprising:

- a. a heavy chain (HC) complementary determining region (CDR) 1 comprising an amino acid sequence of SEQ ID NO: 1;
- b. a HC CDR2 comprising an amino acid sequence of SEQ ID NO: 2; wherein position 1 of SEQ ID NO: 2 is phenylalanine, position 2 of SEQ ID NO: 2 is methionine, position 3 of SEQ ID NO: 2 is serine, position 4 of SEQ ID NO: 2 is tyrosine, position 10 of SEQ ID NO: 2 is lysine, position 11 of SEQ ID NO: 2 is tyrosine, and position 17 of SEQ ID NO: 2 is glycine;
- c. a HC CDR3 comprising an amino acid sequence of SEQ ID NO: 3; wherein position 4 of SEQ ID NO: 3 is isoleucine, position 5 of SEQ ID NO: 3 is alanine, and position 9 of SEQ ID NO: 3 is asparagine;
- d. a light chain (LC) CDR1 comprising an amino acid sequence of SEQ ID NO: 4; wherein position 7 of SEQ ID NO: 4 is tyrosine;
- e. a LC CDR2 comprising an amino acid sequence of SEQ ID NO: 5; and
- f. a LC CDR3 comprising an amino acid sequence of SEQ ID NO: 6,

and at least one pharmaceutically acceptable carrier or diluent, wherein said composition is administered via IV infusion, wherein said anti-TNF- α antibody is administered at a dose of 2 mg/kg, over 30 ± 10 minutes, at Weeks 0 and 4, then every 8 weeks (q8w) thereafter, and wherein at week 24 of treatment patients treated with the anti-TNF- α antibody achieve a mean change from baseline in total modified van der Heijde-Sharp score (vdH-S) = -0.36 ± 0.144 SE.

15. (Cancelled)

16. (Previously Presented) The method according to claim 14, further comprising administering said composition with or without methotrexate (MTX).

17. (Currently Amended) A method for treating a TNF- α related condition, wherein the TNF- α related condition is active psoriatic arthritis, the method comprising: administering to a subject having active psoriatic arthritis a composition comprising a safe and effective amount of at least one isolated mammalian anti-TNF- α antibody comprising:

- a. a heavy chain (HC) complementary determining region (CDR) 1 comprising an amino acid sequence of SEQ ID NO: 1;
- b. a HC CDR2 comprising an amino acid sequence of SEQ ID NO: 2; wherein position 1 of SEQ ID NO: 2 is phenylalanine, position 2 of SEQ ID NO: 2 is methionine, position 3 of SEQ ID NO: 2 is serine, position 4 of SEQ ID NO: 2 is tyrosine, position 10 of SEQ ID NO: 2 is lysine, position 11 of SEQ ID NO: 2 is tyrosine, and position 17 of SEQ ID NO: 2 is glycine;
- c. a HC CDR3 comprising an amino acid sequence of SEQ ID NO: 3; wherein position 4 of SEQ ID NO: 3 is isoleucine, position 5 of SEQ ID NO: 3 is alanine, and position 9 of SEQ ID NO: 3 is asparagine;
- d. a light chain (LC) CDR1 comprising an amino acid sequence of SEQ ID NO: 4; wherein position 7 of SEQ ID NO: 4 is tyrosine;
- e. a LC CDR2 comprising an amino acid sequence of SEQ ID NO: 5; and
- f. a LC CDR3 comprising an amino acid sequence of SEQ ID NO: 6;

wherein said anti-TNF- α antibody is administered via intravenous (IV) infusion, wherein said antibody is administered at a dose of 2 mg/kg, over 30 ± 10 minutes, at Weeks 0 and 4, and then every 8 weeks (q8w) thereafter, and wherein $\geq 65\%$ of patients receiving the treatment achieve ACR20 at week 14 of treatment.

18. (Previously Presented) The method according to claim 17, wherein said $\geq 65\%$ of patients that achieve ACR20 at week 14 of treatment with a treatment difference (improvement compared to placebo) of about 50%.

19. (Cancelled)

20. (Previously Presented) The method according claim 17, wherein said antibody is administered with or without methotrexate (MTX).

REMARKS

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

Withdrawn rejections

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

Amendments to the Claims

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

Cited art does not teach or suggest each and every element

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

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

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

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

Cited art does not provide a reasonable expectation of success

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

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

Office personnel must articulate the following:

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

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

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

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

Secondary Considerations

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

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

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

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

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

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

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

Nonstatutory Double Patenting

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

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

Response to Office Action dated September 08, 2023
U.S. Patent Application No.: 17/320,490

Summary

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

Respectfully submitted,

Diane D. Harrison, ET AL.

December 8, 2023

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)
E-Mail: dockets@riversidelaw.com
Attorney for Applicant



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.
17/320,490	05/14/2021	Diane D. Harrison	206389-0003-02US	5386
171672	7590	02/22/2024		
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
			02/22/2024	ELECTRONIC

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

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

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

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

DETAILED ACTION

Notice of Pre-AIA or AIA Status

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

Continued Examination Under 37 CFR 1.114

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

Status of Application, Amendments, And/Or Claims

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

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

Response to Arguments

Claim Rejections - 35 USC § 102-withdrawn

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

Claim Rejections - 35 USC § 103-withdrawn

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

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

Double Patenting-maintained

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

Conclusion

No claim is allowed.

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

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

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

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

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

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

/GYAN CHANDRA/
Primary Examiner, Art Unit 1646

Doc code: RCEX

Doc description: Request for Continued Examination (RCE)

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

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

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

SUBMISSION REQUIRED UNDER 37 CFR 1.114

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

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

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

☐ Other _____

☒ Enclosed

☒ Amendment/Reply

☐ Information Disclosure Statement (IDS)

☐ Affidavit(s)/ Declaration(s)

☐ Other _____

MISCELLANEOUS

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

☐ Other _____

FEES

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

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

SIGNATURE OF APPLICANT, ATTORNEY, OR AGENT REQUIRED

☒ Patent Practitioner Signature

☐ Applicant Signature

Doc code: RCEX

Doc description: Request for Continued Examination (RCE)

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)	2024-05-22
Name	Pallab Singh	Registration Number	70731

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

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

Privacy Act Statement

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

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

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

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

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

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

Art Unit: 1646
Confirmation No.: 5386

Application No.:
17/320,490

Examiner:
Chandra, Gyan

Filing date:
May 14, 2021

Atty Docket No.:
206389-0003-02US

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

AMENDMENT

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

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

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

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

In the Claims:

This listing of claims will replace all prior versions, and listings, of claims in the application.

1 - 10. (Cancelled)

11. (Previously Presented) A method for treating a tumor necrosis factor alpha (TNF- α) related condition, wherein the TNF- α related condition is active psoriatic arthritis, the method comprising: administering to a subject having active psoriatic arthritis a composition comprising a safe and effective amount of at least one isolated mammalian anti-TNF- α antibody comprising:

- a. a heavy chain (HC) complementary determining region (CDR) 1 comprising an amino acid sequence of SEQ ID NO: 1;
 - b. a HC CDR2 comprising an amino acid sequence of SEQ ID NO: 2; wherein position 1 of SEQ ID NO: 2 is phenylalanine, position 2 of SEQ ID NO: 2 is methionine, position 3 of SEQ ID NO: 2 is serine, position 4 of SEQ ID NO: 2 is tyrosine, position 10 of SEQ ID NO: 2 is lysine, position 11 of SEQ ID NO: 2 is tyrosine, and position 17 of SEQ ID NO: 2 is glycine;
 - c. a HC CDR3 comprising an amino acid sequence of SEQ ID NO: 3; wherein position 4 of SEQ ID NO: 3 is isoleucine, position 5 of SEQ ID NO: 3 is alanine, and position 9 of SEQ ID NO: 3 is asparagine;
 - d. a light chain (LC) CDR1 comprising an amino acid sequence of SEQ ID NO: 4; wherein position 7 of SEQ ID NO: 4 is tyrosine;
 - e. a LC CDR2 comprising an amino acid sequence of SEQ ID NO: 5; and
 - f. a LC CDR3 comprising an amino acid sequence of SEQ ID NO: 6,
- and at least one pharmaceutically acceptable carrier or diluent, wherein said composition is administered via intravenous (IV) infusion, wherein said anti-TNF- α antibody is administered at a dose of 2 mg/kg, over 30 ± 10 minutes, at Weeks 0 and 4, then every 8 weeks (q8w) thereafter, and wherein at week 14 of treatment patients treated with the anti-

TNF- α antibody achieve a mean change from baseline in one or more criteria selected from the group consisting of: Health Assessment Questionnaire Disability Index score (HAQ-DI) = -0.60 ± 0.53 SD, enthesitis = -1.87 ± 1.75 SD, dactylitis = -7.8 ± 8.57 SD, Short-Form Health Survey Physical Summary score (SF-36 PCS) = 8.65 ± 7.60 SD, and Short-Form Health Survey Mental Component Summary score (SF-36 MCS) = 5.33 ± 9.95 SD.

12. (Cancelled)

13. (Previously Presented) The method according to claim 11, further comprising administering said composition with or without methotrexate (MTX).

14. (Previously Presented) A method for treating a TNF- α related condition, wherein the TNF- α related condition is active psoriatic arthritis, the method comprising: administering to a subject having active psoriatic arthritis a composition comprising a safe and effective amount of at least one isolated mammalian anti-TNF- α antibody comprising:

- a. a heavy chain (HC) complementary determining region (CDR) 1 comprising an amino acid sequence of SEQ ID NO: 1;
- b. a HC CDR2 comprising an amino acid sequence of SEQ ID NO: 2; wherein position 1 of SEQ ID NO: 2 is phenylalanine, position 2 of SEQ ID NO: 2 is methionine, position 3 of SEQ ID NO: 2 is serine, position 4 of SEQ ID NO: 2 is tyrosine, position 10 of SEQ ID NO: 2 is lysine, position 11 of SEQ ID NO: 2 is tyrosine, and position 17 of SEQ ID NO: 2 is glycine;
- c. a HC CDR3 comprising an amino acid sequence of SEQ ID NO: 3; wherein position 4 of SEQ ID NO: 3 is isoleucine, position 5 of SEQ ID NO: 3 is alanine, and position 9 of SEQ ID NO: 3 is asparagine;
- d. a light chain (LC) CDR1 comprising an amino acid sequence of SEQ ID NO: 4; wherein position 7 of SEQ ID NO: 4 is tyrosine;
- e. a LC CDR2 comprising an amino acid sequence of SEQ ID NO: 5; and
- f. a LC CDR3 comprising an amino acid sequence of SEQ ID NO: 6,

and at least one pharmaceutically acceptable carrier or diluent, wherein said composition is administered via IV infusion, wherein said anti-TNF- α antibody is administered at a dose of 2 mg/kg, over 30 ± 10 minutes, at Weeks 0 and 4, then every 8 weeks (q8w) thereafter, and wherein at week 24 of treatment patients treated with the anti-TNF- α antibody achieve a mean change from baseline in total modified van der Heijde-Sharp score (vdH-S) = -0.36 ± 0.144 SE.

15. (Cancelled)

16. (Previously Presented) The method according to claim 14, further comprising administering said composition with or without methotrexate (MTX).

17. (Previously Presented) A method for treating a TNF- α related condition, wherein the TNF- α related condition is active psoriatic arthritis, the method comprising: administering to a subject having active psoriatic arthritis a composition comprising a safe and effective amount of at least one isolated mammalian anti-TNF- α antibody comprising:

- a. a heavy chain (HC) complementary determining region (CDR) 1 comprising an amino acid sequence of SEQ ID NO: 1;
- b. a HC CDR2 comprising an amino acid sequence of SEQ ID NO: 2; wherein position 1 of SEQ ID NO: 2 is phenylalanine, position 2 of SEQ ID NO: 2 is methionine, position 3 of SEQ ID NO: 2 is serine, position 4 of SEQ ID NO: 2 is tyrosine, position 10 of SEQ ID NO: 2 is lysine, position 11 of SEQ ID NO: 2 is tyrosine, and position 17 of SEQ ID NO: 2 is glycine;
- c. a HC CDR3 comprising an amino acid sequence of SEQ ID NO: 3; wherein position 4 of SEQ ID NO: 3 is isoleucine, position 5 of SEQ ID NO: 3 is alanine, and position 9 of SEQ ID NO: 3 is asparagine;
- d. a light chain (LC) CDR1 comprising an amino acid sequence of SEQ ID NO: 4; wherein position 7 of SEQ ID NO: 4 is tyrosine;
- e. a LC CDR2 comprising an amino acid sequence of SEQ ID NO: 5; and
- f. a LC CDR3 comprising an amino acid sequence of SEQ ID NO: 6;

wherein said anti-TNF- α antibody is administered via intravenous (IV) infusion, wherein said antibody is administered at a dose of 2 mg/kg, over 30 ± 10 minutes, at Weeks 0 and 4, and then every 8 weeks (q8w) thereafter, and wherein $\geq 65\%$ of patients receiving the treatment achieve ACR20 at week 14 of treatment.

18. (Previously Presented) The method according to claim 17, wherein said $\geq 65\%$ of patients that achieve ACR20 at week 14 of treatment with a treatment difference (improvement compared to placebo) of about 50%.

19. (Cancelled)

20. (Currently Amended) The method according to claim 17, wherein said antibody is administered with or without methotrexate (MTX).

REMARKS

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

Withdrawn rejections

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

Claim amendments

Claim 20 has been amended to correct a typographical error.

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

Nonstatutory Double Patenting

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

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

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

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

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

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

Summary

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

Respectfully submitted,

Diane D. Harrison, ET AL.

May 22, 2024

By: /Pallab Singh/
Pallab Singh, Ph.D., J.D.
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 Applicant



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

EXAMINER

CHANDRA, GYAN

ART UNIT

PAPER NUMBER

1646

DATE MAILED: 06/20/2024

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

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

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

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

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

HOW TO REPLY TO THIS NOTICE:

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

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

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

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

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

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

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

PART B - FEE(S) TRANSMITTAL

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

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

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

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

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

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

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

Certificate of Mailing or Transmission

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

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

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

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

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

EXAMINER	ART UNIT	CLASS-SUBCLASS
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,

1 _____

(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.

2 _____

3 _____

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

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

(A) NAME OF ASSIGNEE

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

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

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

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

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

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

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

☐ Applicant certifying micro entity status. See 37 CFR 1.29

☐ Applicant asserting small entity status. See 37 CFR 1.27

☐ Applicant changing to regular undiscounted fee status.

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

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

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

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

Authorized Signature _____

Date _____

Typed or printed name _____

Registration No. _____



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.
17/320,490	05/14/2021	Diane D. Harrison	206389-0003-02US	5386
171672	7590	06/20/2024	EXAMINER	
Riverside Law LLP/J&J 175 Strafford Avenue Suite 100 Wayne, PA 19087			CHANDRA, GYAN	
			ART UNIT	PAPER NUMBER
			1646	

DATE MAILED: 06/20/2024

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

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

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

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

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

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

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

Privacy Act Statement

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

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

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

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

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

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

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

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

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

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

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

4. ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

Certified copies:

a) ☐ All b) ☐ Some* c) ☐ None of the:

1. ☐ Certified copies of the priority documents have been received.

2. ☐ Certified copies of the priority documents have been received in Application No. ____.

3. ☐ Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

* Certified copies not received: ____.

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

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

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

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

Attachment(s)

1. ☐ Notice of References Cited (PTO-892)	5. ☒ Examiner's Amendment/Comment
2. ☒ Information Disclosure Statements (PTO/SB/08), Paper No./Mail Date <u>5/22/2024</u> .	6. ☐ Examiner's Statement of Reasons for Allowance
3. ☐ Examiner's Comment Regarding Requirement for Deposit of Biological Material ____.	7. ☐ Other ____.
4. ☐ Interview Summary (PTO-413), Paper No./Mail Date. ____.	

/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 5/22/2024 has been entered.

Status of Application, Amendments, And/Or Claims

The amendment of claim 20 has been made of record.

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

Information Disclosure Statement

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

EXAMINER'S COMMENT

Double Patenting-withdrawn

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

Conclusion

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

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

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

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

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

/GYAN CHANDRA/
Primary Examiner, Art Unit 1646