

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

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Applicants: Harrison et al.

Serial No.: Not Assigned Yet Art Unit: Not Assigned Yet

Filed: Herewith Examiner: Not Assigned Yet

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

Preliminary Amendment

Dear Commissioner,

Please enter the following preliminary amendment to the application to revise/add the related applications paragraph of the specification to show Applicants' claim to domestic priority, to correct typographical errors in the specification and make certain claim amendments.

Amendments to the specification begin on page 2 of this paper.

Amendment to the claims begin on page 3 of this paper.

Remarks begin on page 5 of this paper.

Amendments to the Specification

In the Specification:

Please insert the following cross-reference paragraph after the title on page 1 of the specification:

--This application 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 20, 2017, the contents of which are hereby incorporated by reference in their entirety.- -

Amendments to the Specification

The specification has been amended because it contained embedded hyperlinks and/or other form of browser-executable code. To remove browser-executable code, throughout the specification as currently amended the embedded hyperlinks are disabled by the addition of a space after “www.”. See, e.g., page 26, paragraph [33] and page 59, paragraph [114].

The specification has been amended because it contained the use of registered trademarks that were not capitalized or accompanied by the generic terminology. In the specification as currently amended the registered trademarks are capitalized and generic terminology is included. For terms that were identified as not being registered trademarks, the ® was removed. See, e.g., pages 58-59, paragraph [114], and pages 76-77, paragraph [152].

Applicants submit herewith substituted specification as a Marked-Up Copy and a Clean Copy. No new matter is added with the amendments to the specification. Also submitted herewith is a Verified Statement Under 37 CFR §1.125(c).

Amendments to the Claims:

This listing of claims replaces all prior versions, and listings, of claims in the captioned application.

In the Claims:

1. (Currently amended) A ~~composition comprising~~ method for treating a TNF related condition, wherein the TNF related condition is active Psoriatic Arthritis, the method comprising: administering a composition comprising a safe and effective amount of at least one isolated mammalian anti-TNF antibody having a heavy chain (HC) comprising SEQ ID NO:36 and a light chain (LC) comprising SEQ ID NO:37, and at least one pharmaceutically acceptable carrier or diluent for use in the safe and effective treatment of active Psoriatic Arthritis, wherein said composition is administered via IV infusion, and wherein at week 14 of treatment patients treated with the anti-TNF antibody achieve a mean change from baseline in one or more criteria selected from the group consisting of: 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.
2. (Currently amended) The ~~composition~~ method according to claim 1, wherein said composition is administered such that said anti-TNF 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.
3. (Currently amended) The ~~composition~~ method according to any one of claims 1-2, further comprising administering said composition with or without methotrexate (MTX).
4. (Currently amended) A ~~composition comprising~~ method for treating a TNF related condition, wherein the TNF related condition is active Psoriatic Arthritis, the method comprising: administering a composition comprising a safe and effective amount of at least one isolated mammalian anti-TNF antibody having a heavy chain (HC) comprising SEQ ID NO:36 and a light chain (LC) comprising SEQ ID NO:37, and at least one pharmaceutically acceptable carrier or diluent for use in the safe and effective

~~treatment of active Psoriatic Arthritis~~, wherein said composition is administered via IV infusion, and wherein at week 24 of treatment patients treated with the anti-TNF antibody achieve a mean change from baseline in vdH-S = -0.36 ± 0.144 SE.

5. (Currently amended) The ~~composition~~method according to claim 4, wherein said composition is administered such that said anti-TNF 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.

6. (Currently amended) The ~~composition~~method according to any one of claims 4-5, further comprising administering said composition with or without methotrexate (MTX).

7. (Currently amended) A method for treating a TNF related condition, wherein the TNF related condition is active Psoriatic Arthritis, the method comprising: administering a safe and effective amount of at At least one isolated mammalian anti-TNF antibody having a heavy chain (HC) comprising SEQ ID NO:36 and a light chain (LC) comprising SEQ ID NO:37 ~~for use in the safe and effective treatment of active Psoriatic Arthritis~~, wherein said anti-TNF antibody is administered via intravenous (IV) infusion, and wherein $\geq 65\%$ of patients receiving the treatment achieve ACR20 at week 14 of treatment.

8. (Currently amended) The ~~anti-TNF antibody~~ method according to claim 7, wherein said $\geq 65\%$ of patients that achieve ACR20 at week 14 of treatment with a treatment difference (improvement compared to placebo) of $\geq 50\%$.

9. (Currently amended) The ~~anti-TNF antibody~~ method according to any one of claims 7-8, 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.

10. (Currently amended) The ~~anti-TNF antibody~~ method according to any one of claims 7-8, wherein said antibody is administered with or without methotrexate (MTX).

Remarks

In the specification, a paragraph has been added to include a cross-reference to related applications. The specification has been reviewed and amended to correct errors. Claims 1-10 have been amended. Support for the amendments to the claims can be found throughout the application as originally filed. See, for example, support for claims 1-3 can be found on pages 5-7, paragraphs [20]-[23], support for claims 4-6 can be found on pages 9-10, paragraphs [30]-[33], and support for claims 7-10 can be found on page 12, paragraphs [18]-[19]. No new matter is added with the amendments to the claims.

The specification has been amended because it contained embedded hyperlinks and/or other form of browser-executable code. To remove browser-executable code, throughout the specification as currently amended the embedded hyperlinks are disabled by the addition of a space after “www.”. See, e.g., page 26, paragraph [33] and page 59, paragraph [114].

The specification has been amended because it contained the use of registered trademarks that were not capitalized or accompanied by the generic terminology. In the specification as currently amended the registered trademarks are capitalized and generic terminology is included. For terms that were identified as not being registered trademarks, the ® was removed. See, e.g., pages 58-59, paragraph [114], and pages 76-77, paragraph [152].

Applicants submit herewith substituted specification as a Marked-Up Copy and a Clean Copy. No new matter is added with the amendments to the specification. Also submitted herewith is a Verified Statement Under 37 CFR §1.125(c).

Docket No.: JBI5120USCNT1

The Examiner is invited to confer with the applicants' undersigned attorney.

No fees are believed due with this paper, but the Commissioner is hereby authorized to charge any deficiency or credit any overpayments necessitated by this Amendment to Deposit Account No. 10-0750.

Respectfully submitted,

/W SIMMONS/

William J. Simmons

Attorney for Applicants

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Dated: July 17, 2019



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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
16/517,594	07/20/2019	Diane D. Harrison	206389-0003-01US	7182
171672	7590	08/06/2020		
Riverside Law LLP/J&J Glenhardie Corporate Center, Glenhardie Two 1285 Drummers Lane, Suite 202 Wayne, PA 19087			EXAMINER CHANDRA, GYAN	
			ART UNIT	PAPER NUMBER
			1646	
			NOTIFICATION DATE	DELIVERY MODE
			08/06/2020	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 1-10 are pending and under examination.

Information Disclosure Statement

The Information Disclosure Statements (IDSs) filed on 8/13/2019 and 2/4/2020 (2) have been considered.

Specification

The disclosure is objected to because it contains an embedded hyperlink and/or other form of browser-executable code (pg. 25-27, 58 and others of the specification). Applicant is required to delete the embedded hyperlink and/or other form of browser-executable code; references to websites should be limited to the top-level domain name without any prefix such as http:// or other browser-executable code. See MPEP § 608.01.

The disclosure is objected to because of the specification use a number of Trademarks (see- pg.57 [114-75], pg. 76 [152]). It should be **capitalized wherever it appears and be accompanied by the generic terminology**. MPEP 6.20

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

Claim Objections

Claim 1 is objected to because of the following informalities:

Claim 1 is objected for the use of an abbreviated phrases (TNF) and IV, which should be described for the first time followed by an abbreviated form placed in a bracket.

The examiner suggests that syntax of claims 1-2, 4-5 and 7 can be improved by replacing the term "TNF" with the term "TNF- α " because the specification does not disclose TNF being TNF beta subtype.

Claims 1, 4 and 7 are objected for using the term "Psoriatic Arthritis" which should be replaced by the term "psoriatic arthritis" because psoriatic arthritis is a type of inflammatory arthritis.

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) 1-10 are rejected under 35 U.S.C. 102(a) (1) as being anticipated by Inman et al. (IDS, Arthritis and Rheum. 58: 3402-3412, 2008).

The instantly claimed invention is broadly drawn to a method for treating a TNF related condition, wherein the TNF related condition is active psoriatic arthritis, the method comprising: administering a composition comprising a safe and effective amount of at least one isolated mammalian anti-TNF antibody having a heavy chain (HC) comprising SEQ ID NO:36 and a light chain (LC) comprising SEQ ID NO:37, and

at least one pharmaceutically acceptable carrier or diluent, wherein said composition is administered via IV infusion, and wherein at 14 week treatment patient treated with the composition achieves a mean change from baseline in one or more criteria selected from the group consisting of: HAQ-DI = -0.60, enthesitis = -1.87, dactylitis = -7.8, SF-36 PCS = 8.65 and SF-36 MCS = 5.33 or ACR20 (claim 1, 4, 7), wherein said composition is administered such that said anti-TNF antibody is administered at a dose of 2 mg/kg, administered over 30 ± 10 minutes, at Weeks 0 and 4, and then every 8 weeks (q8w) thereafter and the method according to any one of claims 1- 2, 4-5, or 8-9, further comprising administering said composition with or without methotrexate (MTX), sulfasalazine (SSZ) or hydroxychloroquine (HCQ).

Inman et al teach a method for treating ankylosing spondylitis using golimumab antibody and a pharmaceutically acceptable carrier by a subcutaneous injection. The specification discloses that golimumab comprises a light chain comprising amino acid sequence of SEQ ID NO:37 and a heavy chain comprising amino acid sequence of SEQ ID NO: 36 (also see sequence alignment below). Regarding achieving one or more criteria selected from the group consisting of: HAQ-DI = -0.60, enthesitis = -1.87, dactylitis = -7.8, SF-36 PCS = 8.65 and SF-36 MCS = 5.33 after a treatment of 4 weeks, because the reference teaches treating 2 mg/kg or about 100 mg per subject (methods, pg. 3402), the result would be the same, unless evidence to contrary. Regarding the limitation of claim 3, 6, 10, the reference teaches that patients were allowed to continue treatment with methotrexate (MTX), sulfasalazine or hydroxychloroquine (pg. 3403, left col.). They used two dosages 50 mg or 100 mgs per subject and the determined the ankylosing spondylitis using a Bath Ankylosing spondylitis disease activity index greater

than equal or >4 and a week treat that improves in the assessment in AS (ASAS20) criteria at week 14 (Methods, pg. 3402). Inman et al do not teach administering golimumab by intravenous route. However, it is well known in the art that golimumab is being administered via intravenous or subcutaneous route for treating psoriatic arthritis Demetri et al. (US Pub. No. 2010/0266590, [0042]). Demetri et al is applied to support the state of the art and not as a prior art. Therefore, the prior art of record explicitly or implicitly anticipates the instantly claimed invention.

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 set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied 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.

Claims 1-10 are rejected under 35 U.S.C. 103 as being unpatentable over Inman et al. (IDS, Arthritis and Rheum. 58: 3402-3412, 2008) in view of Doyle et al. (Rheumatology 52:1214-1219, 2013).

The instantly claimed invention is broadly drawn to a method for treating a TNF related condition, wherein the TNF related condition is active psoriatic arthritis, the method comprising: administering a composition comprising a safe and effective amount of at least one isolated mammalian anti-TNF antibody having a heavy chain (HC) comprising SEQ ID NO:36 and a light chain (LC) comprising SEQ ID NO:37, and at least one pharmaceutically acceptable carrier or diluent, wherein said composition is administered via IV infusion, and wherein at 14 week treatment patient treated with the composition achieves a mean change from baseline in one or more criteria selected from the group consisting of: HAQ-DI = -0.60, enthesitis = -1.87, dactylitis = -7.8, SF-36 PCS =8.65 and SF-36 MCS= 5.33 or ACR20 (claim 1, 4, 7), wherein said composition is administered such that said anti-TNF antibody is administered at a dose of 2 mg/kg, administered over 30 ± 10 minutes, at Weeks 0 and 4, and then every 8 weeks (q8w) thereafter and the method according to any one of claims 1- 2, 4-5, or 8-9, further comprising administering said composition with or without methotrexate (MTX), sulfasalazine (SSZ) or hydroxychloroquine (HCQ).

Inman et al teach a method for treating ankylosing spondylitis using golimumab antibody and a pharmaceutically acceptable carrier by a subcutaneous injection. The specification discloses that golimumab comprises a light chain comprising amino acid sequence of SEQ ID NO:37 and a heavy chain comprising amino acid sequence of SEQ ID NO: 36 (also see sequence alignment below). Regarding achieving one or more

criteria selected from the group consisting of: HAQ-DI = -0.60, enthesitis = -1.87, dactylitis = -7.8, SF-36 PCS = 8.65 and SF-36 MCS = 5.33 after a treatment of 4 weeks, because the reference teaches treating 2 mg/kg or about 100 mg per subject (methods, pg. 3402), the result would be the same, unless evidence to contrary. Regarding the limitation of claim 3, 6, 10, the reference teaches that patients were allowed to continue treatment with methotrexate (MTX), sulfasalazine or hydroxychloroquine (pg. 3403, left col.). They used two dosages 50 mg or 100 mgs per subject and the determined the ankylosing spondylitis using a Bath Ankylosing spondylitis disease activity index greater than equal or ≥ 4 and a week treat that improves in the assessment in AS (ASAS20) criteria at week 14 (Methods, pg. 3402). Inman et al do not teach administering golimumab by intravenous route.

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 ankylosing spondylitis as taught by Inman 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 intravenously because Doyle et al. teach administering golimumab intravenously. Therefore, the invention is obvious over the combined teachings of the prior art.

RESULT 1 (SEQ ID NO: 36)
AZF01829
ID AZF01829 standard; protein; 456 AA.
XX
AC AZF01829;
XX
DT 17-MAR-2011 (first entry)
XX
DE Anti-TNF alpha heavy chain region protein, SEQ ID 108.
XX
KW TNF alpha ligand; Tumor necrosis factor ligand alpha; antibody;
KW antibody production; antibody therapy; antiinflammatory; bone
resorption;
KW breast tumor; endotoxic shock; graft versus host disease;
KW growth-disorder-gen.; head and neck tumor; heavy chain;
KW hematological neoplasm; hybridoma; hypercalcemia; hyperparathyroidism;
KW immunosuppressive; inflammatory bowel disease; inflammatory disease;
KW insulin dependent diabetes; lung tumor; melanoma; menopause;
KW multiple myeloma; multiple sclerosis; neuroblastoma; oral-dental-gen.;
KW osteogenesis imperfecta; osteohalisteresis; osteomalacia; osteomyelitis;
KW osteonecrosis; osteopathic; osteopenia; osteoporosis;
KW pagets bone disease; periodontitis; prophylactic to disease;
KW prostate tumor; psoriasis; renal osteodystrophy; renal tumor;
KW rheumatoid arthritis; septic shock; squamous cell carcinoma;
therapeutic;
KW thyroid tumor.
XX
OS Unidentified.
XX
FH Key Location/Qualifiers
FT Region 31..35
FT /label= CDR1
FT Region 50..66
FT /label= CDR2
FT Region 99..115
FT /label= CDR3
XX
CC PN WO2011017294-A1.
XX
CC PD 10-FEB-2011.
XX
CC PF 03-AUG-2010; 2010WO-US044206.
XX
PR 07-AUG-2009; 2009US-0232221P.
XX
CC PA (SCHE) SCHERING CORP.
CC PA (XOMA) XOMA TECHNOLOGY LTD.

```

Query Match          100.0%;   Score 2435;   DB 18;   Length 456;
Best Local Similarity 100.0%;
Matches 456;   Conservative    0;   Mismatches    0;   Indels    0;   Gaps
0;

Qy          1  QVQLVESGGGVVQPGRSLRLSCAASGFI FSSYAMHWVRQAPGNGLEWVAFMSYDGSNKKY 60
            |||||||
Db          1  QVQLVESGGGVVQPGRSLRLSCAASGFI FSSYAMHWVRQAPGNGLEWVAFMSYDGSNKKY 60

Qy          61 ADSVKGRFTISRDN SKNTLYLQMNSLRAEDTAVYYCARDRGIAAGGNYYYYYGMDVWGQGT
120

```

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Db          |||||
120          61 ADSVKGRFTISRDN SKNTLYLQMNSLRAEDTAVYYCARDRGIAAGGNYYYYGMDVWGQGT

Qy          121 TVTVSSASTKGPSVFPLAPSSKSTSGGTAALGCLVKDYFPEPVTVSWNSGALTSGVHTF
180

Db          |||||
121          121 TVTVSSASTKGPSVFPLAPSSKSTSGGTAALGCLVKDYFPEPVTVSWNSGALTSGVHTF
180

Qy          181 AVLQSSGLYSLSSVVTVPSSSLGTQTYICNVNHKPSNTKVDKKVEPKSCDKTHTCPPCPA
240

Db          |||||
181          181 AVLQSSGLYSLSSVVTVPSSSLGTQTYICNVNHKPSNTKVDKKVEPKSCDKTHTCPPCPA
240

Qy          241 PELLGGPSVFLFPPKPKDTLMISRTPEVTCVVDVSHEDPEVKFNWYVDGVEVHNAKTKP
300

Db          |||||
241          241 PELLGGPSVFLFPPKPKDTLMISRTPEVTCVVDVSHEDPEVKFNWYVDGVEVHNAKTKP
300

Qy          301 REEQYNSTYRVVSVLTVLHQDWLNGKEYKCKVSNKALPAPIEKTISKAKGQPREPQVYTL
360

Db          |||||
301          301 REEQYNSTYRVVSVLTVLHQDWLNGKEYKCKVSNKALPAPIEKTISKAKGQPREPQVYTL
360

Qy          361 PPSRDELTKNQVSLTCLVKGFYPSDIAVEWESNGQPENNYKTTPPVLDSDGSFFLYSKLT
420

Db          |||||
361          361 PPSRDELTKNQVSLTCLVKGFYPSDIAVEWESNGQPENNYKTTPPVLDSDGSFFLYSKLT
420

Qy          421 VDKSRWQQGNVFSCSVMHEALHNHYTQKSLSLSPGK 456
Db          |||||
421          421 VDKSRWQQGNVFSCSVMHEALHNHYTQKSLSLSPGK 456

```

RESULT 1 (SEQ ID NO: 37)

AZF01828

ID AZF01828 standard; protein; 215 AA.

XX

AC AZF01828;

XX

DT 17-MAR-2011 (first entry)

XX

DE Anti-TNF alpha light chain region protein, SEQ ID 107.

XX

KW TNF alpha ligand; Tumor necrosis factor ligand alpha; antibody;

KW antibody production; antibody therapy; antiinflammatory; bone
resorption;

KW breast tumor; endotoxic shock; graft versus host disease;

KW growth-disorder-gen.; head and neck tumor; hematological neoplasm;

KW hybridoma; hypercalcemia; hyperparathyroidism; immunosuppressive;

KW inflammatory bowel disease; inflammatory disease;
KW insulin dependent diabetes; light chain; lung tumor; melanoma;
menopause;
KW multiple myeloma; multiple sclerosis; neuroblastoma; oral-dental-gen.;
KW osteogenesis imperfecta; osteohalisteresis; osteomalacia; osteomyelitis;
KW osteonecrosis; osteopathic; osteopenia; osteoporosis;
KW pagets bone disease; periodontitis; prophylactic to disease;
KW prostate tumor; psoriasis; renal osteodystrophy; renal tumor;
KW rheumatoid arthritis; septic shock; squamous cell carcinoma;
therapeutic;
KW thyroid tumor.
XX
OS Unidentified.
XX
FH Key Location/Qualifiers
FT Region 24..34
FT /label= CDR1
FT Region 50..56
FT /label= CDR2
FT Region 89..98
FT /label= CDR3
XX
CC PN WO2011017294-A1.
XX
CC PD 10-FEB-2011.
XX
CC PF 03-AUG-2010; 2010WO-US044206.
XX
PR 07-AUG-2009; 2009US-0232221P.
XX
CC PA (SCHE) SCHERING CORP.
CC PA (XOMA) XOMA TECHNOLOGY LTD.
XX
CC PI Hollenbaugh D, Levy R;
XX
DR WPI; 2011-B61300/15.
XX
CC PT New isolated antibody, specifically binds to receptor activator of
CC PT specific ligand with specific property useful for treating/preventing
CC PT medical condition, mediated by imbalance of bone formation or
resorption
CC PT e.g. osteopenic disorder.
XX
CC PS Disclosure; SEQ ID NO 107; 114pp; English.
XX
CC The present invention relates to a novel isolated antibody or its
antigen
CC -binding fragment which specifically binds to receptor activator of
CC nuclear factor-kappa (NF)-B ligand (RANKL). The present invention also
CC provides: (1) a composition comprising the antibody or its fragment in
CC association with at least one chemotherapeutic agent; (2) an isolated
CC hybridoma cell producing the antibody; (3) a method for preparing the
CC isolated antibody; (4) an isolated polypeptide; (5) an isolated
CC polynucleotide encoding the polypeptide; (6) an isolated vector
CC comprising the polynucleotide; (7) an isolated host cell comprising the
CC vector; and (8) a method for treating or preventing a medical condition

CC in a subject. The medical condition is mediated by elevated expression
or
CC activity of RANK or RANKL or by an imbalance of bone formation and bone
CC resorption. The medical condition includes inflammatory disorder,
CC psoriasis, insulin dependent diabetes, inflammatory bowel disease,
CC multiple sclerosis, toxic and septic shock, graft versus host disease,
CC osteoporosis, osteopenia, osteomyelitis, osteonecrosis, Paget's disease,
CC hypercalcemia, lytic bone metastases periodontitis, renal
osteodystrophy,
CC osteogenesis imperfecta, hyperparathyroidism, osteomalacia,
CC osteomalacia, corticosteroid treatment, childhood idiopathic bone
CC loss, age-related loss of bone mass, rheumatoid arthritis, prosthetic
CC loss of loosening, bone loss due to immobilization or menopause,
squamous
CC cell carcinoma, multiple myeloma, melanoma, neuroblastoma and cancers of
CC breast, lung, prostate, thyroid, hematologic, head and neck and renal.
CC The present sequence is a light chain region of an anti-tumor necrosis
CC factor (TNF) alpha antibody which is present in the bispecific antibody
CC used in the invention.
XX
SQ Sequence 215 AA;

Query Match 100.0%; Score 1121; DB 18; Length 215;
Best Local Similarity 100.0%;
Matches 215; Conservative 0; Mismatches 0; Indels 0; Gaps
0;

Qy 1 EIVLTQSPATLSLSPGERATLSCRASQSVSYLAWEYQQKPGQAPRLLIYDASNRATGIPA 60
|
Db 1 EIVLTQSPATLSLSPGERATLSCRASQSVSYLAWEYQQKPGQAPRLLIYDASNRATGIPA 60

Qy 61 RFSGSGSGTDFTLTISLSEPEDFAVYYCQQRSNWPPFTFGPGTKVDIKRTVAAPSVFIFP
120
|
Db 61 RFSGSGSGTDFTLTISLSEPEDFAVYYCQQRSNWPPFTFGPGTKVDIKRTVAAPSVFIFP
120

Qy 121 PSDEQLKSGTASVVCLLNNFYPREAKVQWKVDNALQSGNSQESVTEQDSKDSSTYSLSSTL
180
|
Db 121 PSDEQLKSGTASVVCLLNNFYPREAKVQWKVDNALQSGNSQESVTEQDSKDSSTYSLSSTL
180

Qy 181 TLSKADYEKHKVYACEVTHQGLSSPVTKSFNRGEC 215
|
Db 181 TLSKADYEKHKVYACEVTHQGLSSPVTKSFNRGEC 215

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 on 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 an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <https://ppair-my.uspto.gov/pair/PrivatePair>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/GYAN CHANDRA/
Primary Examiner, Art Unit 1646

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

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

Art Unit: 1646
Confirmation No.: 7182

Application No.:
16/517,594

Examiner:
Chandra, Gyan

Filing date:
July 20, 2019

Atty Docket No.:
206389-0003-01US

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 August 6, 2020 in connection with the above-referenced application. This Response is timely filed in view of the deadline for a timely response being to and through November 6, 2020.

No 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 Claims:

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

1. (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~~ 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 having a heavy chain (HC) comprising SEQ ID NO:36 and a light chain (LC) comprising SEQ ID NO:37, 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: 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.
2. (Currently amended) The method according to claim 1, 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.
3. (Previously presented) The method according to any one of claims 1-2, further comprising administering said composition with or without methotrexate (MTX).
4. (Currently amended) A method for treating a TNF- α related condition, wherein the TNF- α related condition is active ~~Psoriatic Arthritis~~ 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 having a heavy chain (HC) comprising SEQ ID NO:36 and a light chain (LC) comprising SEQ ID NO:37, 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 vdH-S = -0.36 ± 0.144 SE.

5. (Currently amended) The method according to claim 4, 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.

6. (Previously presented) The method according to any one of claims 4-5, further comprising administering said composition with or without methotrexate (MTX).

7. (Currently amended) A method for treating a TNF- α related condition, wherein the TNF- α related condition is active ~~Psoriatic Arthritis~~ 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 having a heavy chain (HC) comprising SEQ ID NO:36 and a light chain (LC) comprising SEQ ID NO:37, 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.

8. (Previously presented) The method according to claim 7, wherein said $\sim 65\%$ of patients that achieve ACR20 at week 14 of treatment with a treatment difference (improvement compared to placebo) of $\sim 50\%$.

9. (Previously presented) The method according to any one of claims 7-8, 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.

10. (Previously presented) The method according to any one of claims 7-8, wherein said antibody is administered with or without methotrexate (MTX).

REMARKS

Claims 1-10 are pending and under consideration.

Claim Amendments

Claims 1, 4 and 7 have been amended to recite “psoriatic arthritis” and that the method comprises administering the composition to a subject having active psoriatic arthritis.

Claims 1, 2, 4, 5 and 7 have been amended to recite TNF- α .

Support for these amendments can be found throughout the originally filed Specification. No new matter has been added by way of these amendments.

Objection to the Specification

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

Applicants submit that the Specification was amended to remove browser-executable code and to properly recite registered trademarks with generic terminology in the Preliminary Amendment and Substitute Specification filed on July 20, 2019.

Applicants respectfully request reconsideration and withdrawal of the objection.

Claim Objections

The Examiner has objected to claims 1, 4 and 7 for various informalities,

The Examiner contends that TNF and IV should be described in a non-abbreviated form in claim 1. Applicants have amended claim 1 to include the non-abbreviated form of these terms.

The Examiner contends that the term “Psoriatic Arthritis” should be replaced with “psoriatic arthritis.” While not necessarily agreeing with the Examiner, claims 1, 4 and 7 have been amended to recite “psoriatic arthritis.”

The Examiner has suggested that the claims be amended to recite “TNF- α ” instead of “TNF.” While not necessarily agreeing with the Examiner, Applicants have amended the claims throughout to recite “TNF- α .”

Applicants respectfully request reconsideration and withdrawal of the objection.

Rejection of claims 1-10 under 35 U.S.C. 102(a)(1)

The Examiner has rejected claims 1-10 under 35 U.S.C. 102(a)(1) as allegedly being anticipated by Inman et al. (2008, Arthritis and Rheum, 58: 3402-3412; hereinafter “Inman”). The Examiner contends that Inman teaches treating ankylosing spondylitis using golimumab by subcutaneous injection, and that is well-known that golimumab is being administered via intravenous or subcutaneous route for treating psoriatic arthritis. The Examiner contends that Inman explicitly or implicitly anticipates the pending claims.

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 necessary agreeing with the Examiner, but rather in a good-faith effort to advance prosecution, Applicants have amended claim 1 (from which claims 2 and 3 depend), claim 4 (from which claims 5 and 6 depend) and claim 7 (from which claims 8-10 depend) to recite 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 a heavy chain (HC) comprising SEQ ID NO:36 and a light chain (LC) comprising SEQ ID NO:37, wherein said composition is administered via IV infusion.

Applicants submit that Inman does not teach each and every element of the pending claims, because Inman does not teach administering the composition to a subject with active psoriatic arthritis via IV infusion. Rather, as stated by the Examiner, Inman discusses treating ankylosing spondylitis by subcutaneous injection of golimumab.

The Examiner indicates that because Inman teaches administering 2mg/kg or about 100mg per subject, the result would be the same. Applicants submit that the alleged teaching of Inman with respect to subcutaneous injection of golimumab to subjects with ankylosing spondylitis cannot explicitly or implicitly teach any of the recited criteria in subjects with

active psoriatic arthritis treated with the recited composition. That is, a different route of administration given to subjects with a different disease, as taught by Inman does not necessarily result in the recited criteria in subjects with active psoriatic arthritis treated with the recited composition.

Applicants submit that subcutaneous administration of 100mg golimumab per subject with ankylosing spondylitis would not necessarily 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 1. Similarly, Applicants submit that subcutaneous administration of 100mg golimumab per subject with ankylosing spondylitis would not necessarily 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 4. Similarly, Applicants submit that subcutaneous administration of 100mg golimumab per subject with ankylosing spondylitis would not necessarily result in a ~ 65% of patients with psoriatic arthritis receiving the treatment achieving ACR20 at week 14 of treatment, as recited in claim 7.

Claims 2, 5 and 8

Regarding claims 2, 5 and 8, Applicants submit that Inman does not teach a dosing comprising golimumab being administered at a dose of 2 mg/kg, administered over 30 ± 10 minutes, at Weeks 0 and 4, and then every 8 weeks (q8w) thereafter.

Rejection of claims 1-10 under 35 U.S.C. 103

The Examiner has rejected claims 1-10 under 35 U.S.C. 103 as allegedly being unpatentable over Inman in view of Doyle et al. (2013, Rheumatology, 52: 1214-1219; hereinafter “Doyle”). The Examiner contends that Inman teaches a method for treating ankylosing spondylitis using golimumab by subcutaneous injection. The Examiner admits that Inman does not teach administering golimumab by intravenous route. However, the Examiner contends that Doyle teaches administration of golimumab by subcutaneous and intravenous routes. The Examiner contends that it would have been obvious for a skilled

artisan to administer golimumab as taught by Doyle for treating ankylosing spondylitis as taught by Inman.

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

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

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

Cited art does not teach or suggest each and every element

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

As described above, have amended claim 1 (from which claims 2 and 3 depend), claim 4 (from which claims 5 and 6 depend) and claim 7 (from which claims 8-10 depend) to

recite 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 a heavy chain (HC) comprising SEQ ID NO:36 and a light chain (LC) comprising SEQ ID NO:37, wherein said composition is administered via IV infusion.

Applicants submit that Inman and Doyle, alone or in combination with each other, do not teach or suggest each and every element of the amended claims. As discussed above, Applicants submit that Inman does not teach each and every element of the pending claims, because Inman does not teach administering the composition to a subject with active psoriatic arthritis via IV infusion. Rather, as stated by the Examiner, Inman discusses treating ankylosing spondylitis by subcutaneous injection of golimumab. Applicants submit that Doyle does not make up for the deficiencies of Inman, because Doyle does not teach or suggest administering the composition to a subject with active psoriatic arthritis via IV infusion.

Further, Applicants submit that Inman and Doyle, alone or in combination with each other, do not teach or suggest each any of the recited criteria in subjects with active psoriatic arthritis treated with the recited composition. The Examiner indicates that because Inman teaches administering 2mg/kg or about 100mg per subject, the result would be the same. As discussed above, Applicants submit that the alleged teaching of Inman with respect to subcutaneous injection of golimumab to subjects with ankylosing spondylitis cannot explicitly or implicitly teach any of the recited criteria in subjects with active psoriatic arthritis treated with the recited composition. Applicants submit that Doyle does not make up for the deficiency of Inman, because Doyle does not teach IV administration of the recited composition to subjects with active psoriatic arthritis and thus cannot explicitly or implicitly teach any of the recited criteria in subjects with active psoriatic arthritis treated with the recited composition.

Thus, Applicants submit that Inman 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 1. Similarly, Applicants submit that Inman 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 4. Similarly, Applicants submit that Inman 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 7.

Claims 2, 5 and 8

Regarding claims 2, 5 and 8, Applicants submit that Inman and Doyle, alone or in combination with each other, do not teach or suggest a dosing comprising golimumab being administered at a dose of 2 mg/kg, administered over 30 ± 10 minutes, at Weeks 0 and 4, and then every 8 weeks (q8w) thereafter.

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 Inman and Doyle do not prove 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 having a heavy chain (HC) comprising SEQ ID NO:36 and a light chain (LC) comprising SEQ ID NO:37, and at least one pharmaceutically acceptable carrier or diluent, wherein said composition is administered via intravenous (IV) infusion.

As described above, Inman describes subcutaneous administration of golimumab to subjects with ankylosing spondylitis. Nothing in Inman provides 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 1, 4 and 7. Applicants submit that Doyle does not cure any of the deficiencies of Inman. 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 1, 4 and 7. 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 that inflammatory biomarkers began to increase in subjects where golimumab was administered intravenously. Finally, Doyle describes the limitations of its study – small sample size that is not optimal for assessing pharmacodynamic effects (see Doyle, page 1217; paragraph spanning the 1st and 2nd columns). Applicants submit that skilled artisan reading Doyle would not have any reasonable expectation that administration of IV golimumab could be used to effectively treat psoriatic arthritis.

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 a heavy chain (HC) comprising SEQ ID NO:36 and a light chain (LC) comprising SEQ ID NO:37, wherein said composition is administered via IV infusion., produces surprising and unexpected results that could not have been predicted by the combination of Inman 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 Inman and Doyle.

For at least these reasons, Applicants submit that claims 1-10 are not rendered obvious by the combination of Inman and Doyle. Applicants respectfully request reconsideration and withdrawal of the rejection.

Response to Office Action dated August 6, 2020
U.S. Patent Application No.: 16/517,594

Summary

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

Respectfully submitted,

Diane D. Harrison, ET AL.

November 5, 2020

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171672 7590 02/18/2021
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EXAMINER

CHANDRA, GYAN

ART UNIT

PAPER NUMBER

1646

DATE MAILED: 02/18/2021

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
16/517,594	07/20/2019	Diane D. Harrison	206389-0003-01US	7182

TITLE OF INVENTION: METHODS FOR THE TREATMENT OF ACTIVE PSORIATIC ARTHRITIS

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	05/18/2021

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 1/2 the amount of undiscounted fees, and micro entity fees are 1/2 the amount of small entity fees.

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

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

PART B - FEE(S) TRANSMITTAL

Complete and send this form, together with applicable fee(s), by mail or fax, or via EFS-Web.

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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 including the Patent, advance orders and notification of maintenance fees 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.

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

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
16/517,594	07/20/2019	Diane D. Harrison	206389-0003-01US	7182

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nonprovisional	UNDISCOUNTED	\$1200	\$0.00	\$0.00	\$1200	05/18/2021

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/SB/122) attached.

☐ "Fee Address" indication (or "Fee Address" Indication form PTO/SB/47; Rev 03-09 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.

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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) ☐ Advance Order - # of Copies _____

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

☐ Electronic Payment via EFS-Web ☐ Enclosed check ☐ Non-electronic payment by credit card (Attach form PTO-2038)

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

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

☐ Applicant certifying micro entity status. See 37 CFR 1.29

☐ Applicant asserting small entity status. See 37 CFR 1.27

☐ Applicant changing to regular undiscounted fee status.

NOTE: Absent a valid certification of Micro Entity Status (see forms PTO/SB/15A and 15B), issue fee payment in the micro entity amount will not be accepted at the risk of application abandonment. **NOTE:** If the application was previously under micro entity status, checking this box will be taken to be a notification of loss of entitlement to micro entity status.

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

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

Authorized Signature _____

Date _____

Typed or printed name _____

Registration No. _____



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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
16/517,594	07/20/2019	Diane D. Harrison	206389-0003-01US	7182
171672	7590	02/18/2021	EXAMINER	
Riverside Law LLP/J&J Glenhardie Corporate Center, Glenhardie Two 1285 Drummers Lane, Suite 202 Wayne, PA 19087			CHANDRA, GYAN	
			ART UNIT	PAPER NUMBER
			1646	

DATE MAILED: 02/18/2021

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

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

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

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

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

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

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

Privacy Act Statement

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

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

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

Notice of Allowability	Application No. 16/517,594	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 11/5/2020.
☐ 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 1-10. As a result of the allowed claim(s), you may be eligible to benefit from the **Patent Prosecution Highway** program at a participating intellectual property office for the corresponding application. For more information, please see http://www.uspto.gov/patents/init_events/pph/index.jsp or send an inquiry to PPHfeedback@uspto.gov.

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

Certified copies:
a) ☐ All b) ☐ Some *c) ☐ None of the:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

* Certified copies not received: _____.

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

5. ☐ CORRECTED DRAWINGS (as "replacement sheets") must be submitted.
☐ including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No./Mail Date _____.
Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet. Replacement sheet(s) should be labeled as such in the header according to 37 CFR 1.121(d).

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

Attachment(s)

1. ☐ Notice of References Cited (PTO-892) 2. ☒ Information Disclosure Statements (PTO/SB/08), Paper No./Mail Date <u>11/9/2020</u> . 3. ☐ Examiner's Comment Regarding Requirement for Deposit of Biological Material _____. 4. ☒ Interview Summary (PTO-413), Paper No./Mail Date. <u>2/5/2021</u> .	5. ☒ Examiner's Amendment/Comment 6. ☐ Examiner's Statement of Reasons for Allowance 7. ☐ Other _____.
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/GYAN CHANDRA/ Primary Examiner, Art Unit 1646	
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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 11/5/2020 is acknowledged and fully considered.

Status of Application, Amendments, And/Or Claims

The amendments of claims 1-2, 4-5 and 7 have been made of record.

Claims 1-10 are pending and under examination.

Information Disclosure Statement

The Information Disclosure Statement filed on 11/9/2020 has been considered.

EXAMINER'S COMMENT

Claim Rejections - 35 USC § 102-withdrawn

The rejection of claim(s) 1-10 under 35 U.S.C. 102(a) (1) as being anticipated by Inman et al. (IDS, Arthritis and Rheum. 58: 3402-3412, 2008) is withdrawn in view of applicant's amendments to the claims and for the reason that the prior art does not teach the limitation "administration via intravenous".

Claim Rejections - 35 USC § 103-withdrawn

The rejection of claims 1-10 under 35 U.S.C. 103 as being unpatentable over Inman et al. (IDS, Arthritis and Rheum. 58: 3402-3412, 2008) in view of Doyle et al. (Rheumatology 52:1214-1219, 2013) is withdrawn in view of applicant's amendments to the claim and in view of applicants' arguments that the instant specification discloses a surprising results of achieving 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. They argue that the composition comprising a safe and effective amount of at least one isolated mammalian anti-TNF- α antibody having a heavy chain (HC) comprising SEQ ID NO:36 and a light chain (LC) comprising SEQ ID NO:37 and that the administration of said anti-TNF- α antibody is administered via intravenous (IV) infusion achieves > 65% ACR20 at week 14 of treatment in the subjects having active psoriatic arthritis. This have been found persuasive and therefore, the rejection is withdrawn.

EXAMINER'S AMENDMENT

An examiner's amendment to the record appears below. Should the changes and/or additions be unacceptable to applicant, an amendment may be filed as provided by 37 CFR 1.312. To ensure consideration of such an amendment, it MUST be submitted no later than the payment of the issue fee.

Authorization for this examiner's amendment was given in an interview with attorney Pallab Singh on 2/5/2021.

The application has been amended as follows:

In claim 1, line 9

Replace the term "HAQ-DI" with the term "Health Assessment Questionnaire Disability Index score (HAQ-DI)"

In claim 1, line 10

Replace the term "SF-36 PCS" with the term "36-item Short-Form Health Survey Physical Component Summary score (SF-36 MCS)"

In claim 1, line 11

Replace the term "SF-36 MCS" with the term "36-item Short-Form Health Survey Mental Component Summary score (SF-36 MCS)"

In claim 4, last line

Replace the term "vdH-S" with the term "van der Heijde-Sharp score (vdH-S)"

In claim 8, line 1

Replace the term "~65%" with the term "≥ 65%"

In claim 8, last line

Replace the term "~ 50%" with the term "about 50%"

Title

The title of the invention is not descriptive. The title has been replaced with "METHODS FOR THE TREATMENT OF ACTIVE PSORIATIC ARTHRITIS" to better present the allowed subject matter.

Conclusion

Claims 1-10 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 on 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 an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <https://ppair-my.uspto.gov/pair/PrivatePair>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/GYAN CHANDRA/
Primary Examiner, Art Unit 1646

<i>Examiner-Initiated Interview Summary</i>	Application No. 16/517,594	Applicant(s) Harrison et al.		
	Examiner GYAN CHANDRA	Art Unit 1646	AIA (First Inventor to File) Status Yes	Page 1 of 1

All Participants (applicant, applicants representative, PTO personnel)	Title	Type
GYAN CHANDRA	Primary Examiner	Telephonic
PALLAB SINGH	Attorney	

Date of Interview: 05 February 2021

Issues Discussed:

35 U.S.C. 112

The examiner discussed claim 8 with applicant's attorney Pallab Singh regarding using use of the term "said ~65%" where as claim 7 used the term => 65%. Additionally, the examiner discussed use of abbreviated terms in claim 1 and 4. Applicant's attorney has authorized the examiner to amend the claims to describe the abbreviated terms.

/GYAN CHANDRA/ Primary Examiner, Art Unit 1646	
Applicant is reminded that a complete written statement as to the substance of the interview must be made of record in the application file. It is the applicants responsibility to provide the written statement, unless the interview was initiated by the Examiner and the Examiner has indicated that a written summary will be provided. See MPEP 713.04 Please further see: MPEP 713.04 Title 37 Code of Federal Regulations (CFR) § 1.133 Interviews, paragraph (b) 37 CFR § 1.2 Business to be transacted in writing	

Applicant recordation instructions: It is not necessary for applicant to provide a separate record of the substance of interview.

Examiner recordation instructions: Examiners must summarize the substance of any interview of record. A complete and proper recordation of the substance of an interview should include the items listed in MPEP 713.04 for complete and proper recordation including the identification of the general thrust of each argument or issue discussed, a general indication of any other pertinent matters discussed regarding patentability and the general results or outcome of the interview, to include an indication as to whether or not agreement was reached on the issues raised.