

REMARKS

Claims 1-33 stand rejected. Claims 1, 4-8, 10, 19, 24-31 and 33 have been amended and claim 35 has been added. The claim amendments are supported by the specification and original claims and no new matter has been added. Claims 1-33 and 35 are pending in the application.

Interview Summary

Applicant acknowledges with appreciation the courtesy shown its representative during telephone interview with Examiner Landsman on October 5 and 13, 2020. During those interviews, Examiner Landsman and Applicant's representative discussed what subject matter would likely be allowable in this application.

Objection to Claims

Claims 8 and 19 were objected to for minor informalities. In response, Applicant submits that claims 8 and 19 have been amended to more clearly define the invention and the informalities have been corrected, rendering moot the grounds for objection.

Rejection Under 35 U.S.C. § 112(b) or 35 U.S.C. § 112 (pre-AIA), Second Paragraph

Claims 4-6, 10, 19 and 24-31 stand rejected under 35 U.S.C. § 112(b) or 35 U.S.C. § 112 (pre-AIA), second paragraph, for alleged indefiniteness. In response, Applicant submits that claims 1, 4-8, 10, 19, 24-31 and 33 have been amended to more clearly define the invention. The claim amendments are supported by the specification and original claims and no new matter has been added. The claim amendments render moot the grounds for rejection and in view of the foregoing, Applicant respectfully requests withdrawal of this rejection.

Rejection Under 35 U.S.C. § 102/103

Claims 1-33 stand rejected under 35 U.S.C. § 102(a)(1) for allegedly being anticipated by or, in the alternative, under 35 U.S.C. § 103 as obvious in view of ClinicalTrials.gov entry NCT02407236 ("hereinafter referred to as "CT"). In response, Applicant submits that the claims 1-33 and 35 are not anticipated or rendered obvious by the CT reference. In particular, claim 1, as amended, recites:

A method of treating moderately to severely active ulcerative colitis (UC) in a subject in need thereof, comprising administering to the subject a pharmaceutical composition comprising a clinically proven safe and clinically proven effective amount of an anti-IL-12/IL-23p40 antibody, wherein the antibody comprises a heavy chain variable region and a light chain variable region, the heavy chain variable region comprising: a complementarity determining region heavy chain 1 (CDRH1) amino acid sequence of SEQ ID NO:1; a CDRH2 amino acid sequence of SEQ ID

NO:2; and a CDRH3 amino acid sequence of SEQ ID NO:3; and the light chain variable region comprising: a complementarity determining region light chain 1 (CDRL1) amino acid sequence of SEQ ID NO:4; a CDRL2 amino acid sequence of SEQ ID NO:5; and a CDRL3 amino acid sequence of SEQ ID NO:6, wherein after treating with the antibody, the subject is a responder to treatment by at least one measure of response to treatment selected from the group consisting of: (i) having a clinical remission based on at least one of the global definition of clinical remission with Mayo score ≤ 2 points with no individual subscore > 1 and the US definition of clinical remission with absolute stool number ≤ 3 , rectal bleeding subscore of 0 and Mayo endoscopy subscore of 0 or 1, (ii) having an endoscopic healing with a Mayo endoscopy subscore of 0 or 1, (iii) achieving a clinical response based on the Mayo endoscopy subscore, (iv) having a change from baseline in Inflammatory Bowel Disease Questionnaire (IBDQ) score, (v) having a mucosal healing, (vi) having a decrease from baseline in Mayo score, and (vii) in clinical response as determined by a decrease from baseline in the Mayo score by $\geq 30\%$ and ≥ 3 points and a decrease from baseline in the rectal bleeding subscore ≥ 1 points or a rectal bleeding subscore of 0 or 1. (emphasis added)

The initial posting of the CT reference (April 2, 2015 according to the www.clinicaltrials.gov record) is limited to certain elements describing the clinical trial to be performed; it does not disclose or suggest the subject matter of the claims, i.e., treating moderately to severely active ulcerative colitis in a subject with the recited antibody, wherein the subject is a responder to treatment based on achieving a measure of response as recited in the claims.

As of the September 24, 2018 filing date of U.S. Provisional Application No. 62/735,501 to which the present application claims priority, the CT reference did not include any clinical trial results. The CT reference indicates that the results of the clinical trial were first posted December 23, 2019, after the filing date of the present application and the priority dates to which it is entitled. Due to the uncertainty of clinical outcomes and the failure of numerous medicines to satisfy designated clinical trial endpoints, the posting of elements of a clinical trial in advance of conduct of the trial do not anticipate or render obvious the subject matter of the claims. In view of the foregoing, Applicant respectfully requests withdrawal of this rejection.

Applicant would like to clarify that the Prior Art of Interest Not Relied Upon consisting of the Stelara – European Medicines Agency (EMA) website record does not disclose or suggest the claimed subject matter. The January 15, 2009 date listed for the EMA website record corresponds to the initial approval of Stelara in the psoriasis indication and, as of that date, did not disclose or suggest the subject matter of the claims for treatment of moderately to severely active ulcerative colitis. The EMA website Stelara record appears to have been updated to include information on the approval of Stelara (ustekinumab) in moderately to severely active ulcerative colitis in September, 2019, after the priority dates to which the present application is entitled.

Applicant respectfully submits that application is in condition for allowance and invites the Examiner to confer with Applicant's undersigned attorney for an interview on the merits prior to issuing any further rejections or objections or should any further information be required.

Respectfully submitted,

/Eric Dichter/

Eric Dichter
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Date: 16 October 2020

Listing of Claims

The following will replace any previous listing of pending claims:

1. (Currently Amended) A method of treating moderately to severely active ulcerative colitis (UC) in a subject in need thereof, comprising administering to the subject a pharmaceutical composition comprising a clinically proven safe and clinically proven effective amount of an anti-IL-12/IL-23p40 antibody, wherein the antibody comprises a heavy chain variable region and a light chain variable region, the heavy chain variable region comprising: a complementarity determining region heavy chain 1 (CDRH1) amino acid sequence of SEQ ID NO:1; a CDRH2 amino acid sequence of SEQ ID NO:2; and a CDRH3 amino acid sequence of SEQ ID NO:3; and the light chain variable region comprising: a complementarity determining region light chain 1 (CDRL1) amino acid sequence of SEQ ID NO:4; a CDRL2 amino acid sequence of SEQ ID NO:5; and a CDRL3 amino acid sequence of SEQ ID NO:6, wherein after treating with the antibody, the subject is a responder to treatment by at least one measure of response to treatment selected from the group consisting of: (i) clinical remission based on at least one of the global definition of clinical remission with Mayo score ≤ 2 points with no individual subscore > 1 and the US definition of clinical remission with absolute stool number ≤ 3 , rectal bleeding subscore of 0 and Mayo endoscopy subscore of 0 or 1, (ii) endoscopic healing with a Mayo endoscopy subscore of 0 or 1, (iii) clinical response based on the Mayo endoscopy subscore, (iv) a change from baseline in Inflammatory Bowel Disease Questionnaire (IBDQ) score, (v) mucosal healing, (vi) decrease from baseline in Mayo score, and (vii) clinical response as determined by a decrease from baseline in the Mayo score by $\geq 30\%$ and ≥ 3 points and a decrease from baseline in the rectal bleeding subscore ≥ 1 points or a rectal bleeding subscore of 0 or 1.
2. (Original) The method of claim 1, wherein the antibody comprises the heavy chain variable region of the amino acid sequence of SEQ ID NO:7 and the light chain variable region of the amino acid sequence of SEQ ID NO:8.
3. (Original) The method of claim 1, wherein the antibody comprises a heavy chain of the amino acid sequence of SEQ ID NO:10 and a light chain of the amino acid sequence of SEQ ID NO:11.
4. (Currently Amended) The method of any one of claims 1-3, wherein the antibody is in a pharmaceutical composition for intravenous administration ~~further~~ comprising a solution comprising 10 mM L-histidine, 8.5% (w/v) sucrose, 0.04% (w/v) polysorbate 80, 0.4 mg/mL L-methionine, and 20 μ g/mL EDTA disodium salt, dehydrate, at pH 6.0.
5. (Currently Amended) The method of any one of claims 1-34, wherein the antibody is in a pharmaceutical composition for subcutaneous administration ~~further~~ comprising a solution comprising 6.7 mM L-histidine, 7.6% (w/v) sucrose, 0.004% (w/v) polysorbate 80, at pH 6.0.

6. (Currently Amended) The method of claim 4, wherein the antibody is administered intravenously to the subject, ~~preferably~~ at week 0 of the treatment, at a dosage of about 6.0 mg/kg body weight of the subject or 130 mg per administration.
7. (Currently Amended) The method of claim 6, wherein the antibody is further administered subcutaneously to the subject, ~~preferably~~ at week 8 of the treatment, at a dosage of about 90 mg per administration.
8. (Currently Amended) The method of claim 7, wherein the subject had previously failed or ~~was~~ intolerant of at least one therapy selected from the group consisting of an anti-TNF, vedolizumab, corticosteroids, azathioprine (AZA), and 6 mercaptopurine (6 MP), or the subject had demonstrated corticosteroid dependence.
9. (Original) The method of claim 7, wherein the antibody is administered in a maintenance dose every 8 weeks after the treatment at week 8 or every 12 weeks after the treatment at week 8.
10. (Currently Amended) The method of claim 9, wherein the subject is identified as having a clinical remission based on at least one of the global definition and the US definition by week 16; ~~preferably by week 8, more preferably by week 2,~~ of the treatment and the clinical remission continues at least 44 weeks after week 0.
11. (Original) The method of claim 9, wherein the subject is in corticosteroid-free clinical remission at least 44 weeks after week 0.
12. (Original) The method of claim 8, wherein the subject is identified as having an endoscopic healing continuing at least 44 weeks after week 0.
13. (Original) The method of claim 9, wherein the subject is identified as achieving a clinical response based on the Mayo endoscopy subscore continuing at least 44 weeks after week 0.
14. (Original) The method of claim 9, wherein the subject is identified as having a change from baseline in Inflammatory Bowel Disease Questionnaire (IBDQ) score continuing at least 44 weeks after week 0.
15. (Original) The method of claim 9, wherein the subject is identified as having a mucosal healing continuing at least 44 weeks after week 0.
16. (Original) The method of claim 9, wherein the subject identified as having a decrease from baseline in Mayo score continuing at least 44 weeks after week 0.
17. (Original) The method of claim 9, wherein the subject is identified as having a normalization of one or more biomarkers selected from the group consisting of C-reactive protein, fecal lactoferrin and fecal calprotectin continuing at least 44 weeks after week 0.
18. (Original) The method of claim 9, wherein the subject is in clinical response as determined by a decrease from baseline in the Mayo score by $\geq 30\%$ and ≥ 3 points and a decrease from baseline in the rectal bleeding subscore ≥ 1 points or a rectal bleeding subscore of 0 or 1 continuing at least 44 weeks after week 0.

19. (Currently Amended) A method of treating moderately to severely active ulcerative colitis (UC) in a subject in need thereof, comprising:

- a. intravenously administering to the subject an anti-IL-12/IL-23p40 antibody in a first pharmaceutical composition at a dosage of about 6.0 mg/kg body weight of the subject or 130 mg per administration at week 0 of the treatment, and
- b. subcutaneously administering to the subject the anti-IL-12/IL-23p40 antibody in a second pharmaceutical composition at a dosage of 90 mg per administration, ~~preferably~~ at week 8 of the treatment,

wherein the antibody comprises a heavy chain variable region and a light chain variable region, the heavy chain variable region comprising: a complementarity determining region heavy chain 1 (CDRH1) amino acid sequence of SEQ ID NO:1; a CDRH2 amino acid sequence of SEQ ID NO:2; and a CDRH3 amino acid sequence of SEQ ID NO:3; and the light chain variable region comprising: a complementarity determining region light chain 1 (CDRL1) amino acid sequence of SEQ ID NO:4; a CDRL2 amino acid sequence of SEQ ID NO:5; and a CDRL3 amino acid sequence of SEQ ID NO:6; and

wherein the subject is a responder to treatment by at least one measure of response to treatment selected from the group consisting of: (i) having a clinical remission based on at least one of the global definition of clinical remission with Mayo score ≤ 2 points with no individual subscore > 1 and the US definition of clinical remission with absolute stool number ≤ 3 , rectal bleeding subscore of 0 and Mayo endoscopy subscore of 0 or 1, (ii) having an endoscopic healing with a Mayo endoscopy subscore of 0 or 1, (iii) achieving a clinical response based on the Mayo endoscopy subscore, (iv) having a change from baseline in Inflammatory Bowel Disease Questionnaire (IBDQ) score, (v) having a mucosal healing, (vi) having a decrease from baseline in Mayo score, and (vii) in clinical response as determined by a decrease from baseline in the Mayo score by $\geq 30\%$ and ≥ 3 points and a decrease from baseline in the rectal bleeding subscore ≥ 1 points or a rectal bleeding subscore of 0 or 1, and had previously failed or was intolerant of at least one therapy selected from the group consisting of: an anti-TNF, vedolizumab, corticosteroids, azathioprine (AZA), and 6 mercaptopurine (6 MP), or the subject had demonstrated corticosteroid dependence.

20. (Original) The method of claim 19, wherein the antibody comprises the heavy chain variable region of the amino acid sequence of SEQ ID NO:7 and the light chain variable region of the amino acid sequence of SEQ ID NO:8.
21. (Original) The method of claim 19, wherein the antibody comprises a heavy chain of the amino acid sequence of SEQ ID NO:10 and a light chain of the amino acid sequence of SEQ ID NO:11.
22. (Original) The method of any one of claims 19-21, wherein the pharmaceutical composition for intravenous administration further comprises a solution comprising 10 mM L-histidine, 8.5%

- (w/v) sucrose, 0.04% (w/v) polysorbate 80, 0.4 mg/mL L-methionine, and 20 µg/mL EDTA disodium salt, dehydrate, at pH 6.0.
23. (Original) The method of claim 22, wherein the pharmaceutical composition for subcutaneous administration further comprises a solution comprising 6.7 mM L-histidine, 7.6% (w/v) sucrose, 0.004% (w/v) polysorbate 80, at pH 6.0.
24. (Currently Amended) The method of any one of claims 19-21, wherein the subject is identified as having a clinical remission based on at least one of the global definition and the US definition by week 16, ~~preferably by week 8, more preferably by week 2~~, of the treatment.
25. (Currently Amended) The method of any one of claims 19-21, wherein the subject is identified as having an endoscopic healing by week 16, ~~preferably by week 8, more preferably by week 2~~, of the treatment.
26. (Currently Amended) The method of any one of claims 19-21, wherein the subject is identified as achieving a clinical response based on the Mayo endoscopy subscore by week 16, ~~preferably by week 8, more preferably by week 2~~, of the treatment.
27. (Currently Amended) The method of any one of claims 19-21, wherein the subject is identified as having a change from baseline in Inflammatory Bowel Disease Questionnaire (IBDQ) score by week 16, ~~preferably by week 8, more preferably by week 2~~, of the treatment.
28. (Currently Amended) The method of any one of claims 19-21, wherein the subject is identified as having a mucosal healing by week 16, ~~preferably by week 8, more preferably by week 2~~, of the treatment.
29. (Currently Amended) The method of any one of claims 19-21, wherein the subject is identified as having a decrease from baseline in Mayo score by week 16, ~~preferably by week 8, more preferably by week 2~~, of the treatment.
30. (Currently Amended) The method of any one of claims 19-21, wherein the subject is identified as having a normalization of one or more biomarkers selected from the group consisting of C-reactive protein, fecal lactoferrin and fecal calprotectin by week 16, ~~preferably by week 8, more preferably by week 2~~, of the treatment.
31. (Currently Amended) The method of any one of claims 19-21, wherein the subject is in clinical response as determined by a decrease from baseline in the Mayo score by $\geq 30\%$ and ≥ 3 points and a decrease from baseline in the rectal bleeding subscore ≥ 1 points or a rectal bleeding subscore of 0 or 1 by week 16, ~~preferably by week 8, more preferably by week 2~~, of the treatment.
32. (Original) The method of any one of claims 19-21, wherein the subject is not a responder to the treatment with the antibody by week 8 and is a responder to the treatment by week 16 of the treatment.
33. (Currently Amended) A method of treating moderately to severely active ulcerative colitis (UC) in a subject in need thereof, comprising:

- a. intravenously administering to the subject an anti-IL-12/IL-23p40 antibody in a first pharmaceutical composition at a dosage of about 6.0 mg/kg body weight of the subject or 130 mg per administration at week 0 of the treatment, and
- b. subcutaneously administering to the subject the anti-IL-12/IL-23p40 antibody in a second pharmaceutical composition at a dosage of 90 mg per administration, ~~preferably~~ at week 8 of the treatment,

wherein the antibody comprises a heavy chain variable region and a light chain variable region, the heavy chain variable region comprising: a complementarity determining region heavy chain 1 (CDRH1) amino acid sequence of SEQ ID NO:1; a CDRH2 amino acid sequence of SEQ ID NO:2; and a CDRH3 amino acid sequence of SEQ ID NO:3; and the light chain variable region comprising: a complementarity determining region light chain 1 (CDRL1) amino acid sequence of SEQ ID NO:4; a CDRL2 amino acid sequence of SEQ ID NO:5; and a CDRL3 amino acid sequence of SEQ ID NO:6, followed by a maintenance therapy,

wherein the maintenance therapy comprises subcutaneously administering to the subject the anti-IL-12/IL-23p40 antibody at a dosage of 90 mg per administration, once every 8 weeks or once every 12 weeks, and wherein the maintenance therapy is provided for 44 weeks and after treating with the antibody, the subject is a responder to treatment by at least one measure of response to treatment selected from the group consisting of: (i) having a clinical remission based on at least one of the global definition of clinical remission with Mayo score ≤ 2 points with no individual subscore > 1 and the US definition of clinical remission with absolute stool number ≤ 3 , rectal bleeding subscore of 0 and Mayo endoscopy subscore of 0 or 1, (ii) having an endoscopic healing with a Mayo endoscopy subscore of 0 or 1, (iii) achieving a clinical response based on the Mayo endoscopy subscore, (iv) having a change from baseline in Inflammatory Bowel Disease Questionnaire (IBDQ) score, (v) having a mucosal healing, (vi) having a decrease from baseline in Mayo score, and (vii) in clinical response as determined by a decrease from baseline in the Mayo score by $\geq 30\%$ and ≥ 3 points and a decrease from baseline in the rectal bleeding subscore ≥ 1 points or a rectal bleeding subscore of 0 or 1.

34. (Canceled)

35. (Newly Added) A method of treating moderately to severely active ulcerative colitis (UC) in a subject in need thereof, comprising:

- a. intravenously administering to the subject an anti-IL-12/IL-23p40 antibody comprising a heavy chain variable region of the amino acid sequence of SEQ ID NO:7 and a light chain variable region of the amino acid sequence of SEQ ID NO:8, in a first pharmaceutical composition at a dosage of about 6.0 mg/kg body weight of the subject or 130 mg per administration at week 0 of the treatment, and
- b. subcutaneously administering to the subject the anti-IL-12/IL-23p40 antibody in a second pharmaceutical composition at a dosage of 90 mg per administration at week 8 of

the treatment, followed by a maintenance therapy, wherein the maintenance therapy comprises subcutaneously administering to the subject the anti-IL-12/IL-23p40 antibody at a dosage of 90 mg per administration, once every 8 weeks or once every 12 weeks, and after treating with the antibody, the subject is a responder to treatment by at least one measure of response to treatment selected from the group consisting of: (i) having a clinical remission based on at least one of the global definition of clinical remission with Mayo score ≤ 2 points with no individual subscore > 1 and the US definition of clinical remission with absolute stool number ≤ 3 , rectal bleeding subscore of 0 and Mayo endoscopy subscore of 0 or 1, (ii) having an endoscopic healing with a Mayo endoscopy subscore of 0 or 1, (iii) achieving a clinical response based on the Mayo endoscopy subscore, (iv) having a change from baseline in Inflammatory Bowel Disease Questionnaire (IBDQ) score, (v) having a mucosal healing, (vi) having a decrease from baseline in Mayo score, and (vii) in clinical response as determined by a decrease from baseline in the Mayo score by $\geq 30\%$ and ≥ 3 points and a decrease from baseline in the rectal bleeding subscore ≥ 1 points or a rectal bleeding subscore of 0 or 1.

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant:	Johanns, et al.	Confirmation Number:	7810
Serial No.:	16/580,509	Art Unit:	1647
Filed :	24 September 2019	Examiner:	Robert S. Landsman
For :	Safe and Effective Method of Treating Ulcerative Colitis with Anti-IL12/IL23 Antibody		

RESPONSE TO OFFICE ACTION

INTRODUCTORY COMMENTS

This paper is a response to the Office Communication dated 16 July 2020, setting forth a three-month shortened statutory period for reply. As this response is being filed within the requisite time period, no extensions are believed to be due.

A general authorization is hereby given to deduct any fees that may be required by this paper or any future reply to Deposit Account 10-0750/JBI6010USNP1/ED in the name of Johnson & Johnson.

Claims begin on page 2 of this paper.

Remarks begin on page 8 of this paper.

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicants:	Johanns, et al.	Confirmation Number:	7810
Serial No.:	16/580,509	Art Unit:	1647
Filed :	24 September 2019	Examiner:	Robert S. Landsman
For :	Safe and Effective Method of Treating Ulcerative Colitis with Anti-IL12/IL23 Antibody		

INFORMATION DISCLOSURE STATEMENT

Pursuant to 37 C.F.R. §1.56 and in accordance with 37 C.F.R. §§1.97-1.98, information relating to the above-identified application is hereby disclosed. Inclusion of information in this statement is not to be construed as an admission that this information is material as that term is defined in 37 C.F.R. §1.56(b).

Applicants reserve the right to establish the patentability of the claimed invention over any of the information provided herewith, and/or to prove that this information may not be prior art, and/or to prove that this information may not be enabling for the teachings purportedly offered.

This statement should not be construed as a representation that a search has been made, or that information more material to the examination of the present patent application does not exist.

☐ In accordance with §1.97(b), since this Information Disclosure Statement is being filed either within three months of the filing date of the above-identified national application (other than a continued prosecution application under §1.53(d)), within three months of the date of entry into the national stage of the above identified application as set forth in §1.491, or before the mailing date of a first Office Action on the merits of the above-identified application, or before the mailing date of a first Office Action after the filing of a request for continued examination under §1.114, no additional fee is required.

☐ In accordance with §1.129(a), this Information Disclosure Statement is being filed in connection with ☐ the first or ☐ second After Final Submission, therefore:

☐ Statement in Accordance with §1.97(e) (attached); or

☐ Please charge Deposit Account No. 10-0750/ / the fee of \$180.00 as set forth in §1.17(p).

☒ In accordance with §1.97(c), this Information Disclosure Statement is being filed after the period set forth in §1.97(b) above but before the mailing date of either a Final Action under §1.113 or a Notice of Allowance under §1.311, or an action that otherwise closes prosecution and that it is accompanied by one of:

- ☐ Statement in Accordance with §1.97(e) (attached); or
- ☒ Please charge Deposit Account No. 10-0750 the fee of \$240.00 as set forth in §1.17(p).

☐ In accordance with §1.97(d), this Information Disclosure Statement is being filed after the mailing date of either a Final Action under §1.113 or a Notice of Allowance under §1.311 but before the payment of the Issue Fee. Applicant(s) hereby petition(s) for consideration of this Information Disclosure Statement. Included are: Statement in Accordance with §1.97(e) as set forth below and the fee of \$180.00 as set forth in §1.17(p).

☒ Copies of each of the references listed on the attached Form PTO-1449 are enclosed herewith.

☐ Copies of references listed on the attached Form PTO-1449 are enclosed herewith EXCEPT THAT:

- ☐ In view of the voluminous nature of references , and the likelihood that these references are available to the Examiner, copies are not enclosed herewith.
- ☐ If any of the foregoing publications are not available to the Examiner, Applicant will endeavor to supply copies at the Examiner's request.

☒ Copies of the U.S. patents listed on the attached Form PTO-1449 are not enclosed because this U.S. patent application was filed after June 30, 2003 or this international application has entered the national stage under 35 USC §371 after June 30, 2003 (see USPTO waiver of requirement under 37 CFR 1.98 (a)(2)(i).

☒ There are no listed references which are not in the English language.

☐ The relevance of those listed references which are not in the English language is as follows:

☐ Attached are copies of search report(s) from corresponding patent application(s), which are listed on the attached Submission Under MPEP 609 D.

☐ Attached are the following non-published pending patent applications which may be deemed relevant, which are listed on the attached Submission Under MPEP 609 D.

Please charge any deficiency or credit any overpayment to Deposit Account No. 10-0750/JB16010USNP1/ED.

Respectfully submitted,

/Eric Dichter/

Eric Dichter
Attorney for Applicants
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DATED: 16 October 2020



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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
16/580,509	09/24/2019	Jewel Johans	JB16010USNP1	7810
27777	7590	10/09/2020	EXAMINER	
JOSEPH F. SHIRTZ			LANDSMAN, ROBERT S	
JOHNSON & JOHNSON			ART UNIT	
ONE JOHNSON & JOHNSON PLAZA			PAPER NUMBER	
NEW BRUNSWICK, NJ 08933-7003			1647	
			NOTIFICATION DATE	DELIVERY MODE
			10/09/2020	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):

jnjuspatent@corus.jnj.com
lhowd@its.jnj.com
pair_jnj@firsttofile.com

<i>Applicant-Initiated Interview Summary</i>	Application No. 16/580,509	Applicant(s) Johans et al.		
	Examiner ROBERT S LANDSMAN	Art Unit 1647	AIA (First Inventor to File) Status Yes	Page 1 of 1

All Participants (applicant, applicants representative, PTO personnel)	Title	Type
ROBERT S LANDSMAN	Primary Examiner	Telephonic
Eric Dichter	Attorney of Record	

Date of Interview: 05 October 2020

Issues Discussed:

35 U.S.C. 102

Mr. Dichter discussed the "CT" reference and suggested the addition of various endpoints to, e.g., claim 1 in order to obviate the reference. It was generally argued that, while the "CT" reference may suggest various endpoints, given the nature of Phase 3 clinical trials, it would not have been obvious that the endpoints would have been met by the claimed antibody, nor would a specific patient population defined by such endpoints be anticipated.

35 U.S.C. 103

See above regarding 35 USC 102 (the cited reference was cited under 35 USC 102/103)

Proposed Amendment(s)

See above regarding 35 USC 102

		/ROBERT S LANDSMAN/ Primary Examiner, Art Unit 1647
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: The formal written reply to the last Office action must include the substance of the interview. (See MPEP section 713.04). If a reply to the last Office action has already been filed, applicant is given a non-extendable period of the longer of one month or thirty days from this interview date, or the mailing date of this interview summary form, whichever is later, to file a statement of the substance of the 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.



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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
16/580,509	09/24/2019	Jewel Johans	JB16010USNP1	7810
27777	7590	07/16/2020	EXAMINER	
JOSEPH F. SHIRTZ			LANDSMAN, ROBERT S	
JOHNSON & JOHNSON			ART UNIT	
ONE JOHNSON & JOHNSON PLAZA			PAPER NUMBER	
NEW BRUNSWICK, NJ 08933-7003			1647	
			NOTIFICATION DATE	DELIVERY MODE
			07/16/2020	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):

jnjuspatent@corus.jnj.com
lhowd@its.jnj.com
pair_jnj@firsttofile.com

Office Action Summary	Application No. 16/580,509	Applicant(s) Johans et al.	
	Examiner ROBERT S LANDSMAN	Art Unit 1647	AIA (FITF) Status Yes

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

Period for Reply

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

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

Status

- 1) ☒ Responsive to communication(s) filed on 25 June 2020.
☐ A declaration(s)/affidavit(s) under **37 CFR 1.130(b)** was/were filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ An election was made by the applicant in response to a restriction requirement set forth during the interview on ____; the restriction requirement and election have been incorporated into this action.
- 4) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims*

- 5) ☒ Claim(s) 1-33 is/are pending in the application.
5a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 6) ☐ Claim(s) ____ is/are allowed.
- 7) ☒ Claim(s) 1-33 is/are rejected.
- 8) ☐ Claim(s) ____ is/are objected to.
- 9) ☐ Claim(s) ____ are subject to restriction and/or election requirement

* If any claims have been determined allowable, you may be eligible to benefit from the **Patent Prosecution Highway** program at a participating intellectual property office for the corresponding application. For more information, please see http://www.uspto.gov/patents/init_events/pph/index.jsp or send an inquiry to PPHfeedback@uspto.gov.

Application Papers

- 10) ☐ The specification is objected to by the Examiner.
- 11) ☒ The drawing(s) filed on 24 September 2019 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

Priority under 35 U.S.C. § 119

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

Certified copies:

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

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

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Information Disclosure Statement(s) (PTO/SB/08a and/or PTO/SB/08b)
Paper No(s)/Mail Date ____.
- 3) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date ____.
- 4) ☐ Other: ____.

DETAILED ACTION

Notice of Pre-AIA or AIA Status

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

1. Formal Matters

- A. In the response dated 6/25/20, Applicants elected Group I without traverse. Therefore, this restriction is deemed proper and is made FINAL.
- B. Claims 1-33 are pending and are the subject of this Office Action.

2. Specification

- A. If applicable, the first line of the specification should be updated to reflect the status (e.g. "now U.S. Patent No.", or "now abandoned") of any parent applications. Similarly, though none could be found, any U.S. or Foreign Applications cited in the specification which have since issued should be updated with the corresponding Patent No.
- B. Though none could be found, any listing of references in the specification is not a proper information disclosure statement. 37 CFR 1.98(b) requires a list of all patents, publications, or other information submitted for consideration by the Office, and MPEP § 609.04(a) states, "the list may not be incorporated into the specification but must be submitted in a separate paper." Therefore, unless the references have been cited by the examiner on form PTO-892, they have not been considered.
- C. Though no issues could be found, Applicant is advised that embedded hyperlinks and/or other forms of browser-executable code are impermissible and require deletion. The attempt to incorporate subject matter into the patent application by reference to a hyperlink and/or other forms of browser-executable code is considered to be an improper incorporation by reference. See MPEP 608.01(p), paragraph I regarding incorporation by reference. It is noted that the recitation of "www." alone, as opposed to "<http://www>.", is also active and should not be used.

D. Though no issues could be found, trademarks should be capitalized wherever they appear and be accompanied by the generic terminology. Although the use of trademarks is permissible in patent applications, the proprietary nature of the marks should be respected and every effort made to prevent their use in any manner which might adversely affect their validity as trademarks.

E. Though no issues could be found, according to 37 CFR 1.821(d) (MPEP § 2422), where the description or claims of a patent application discuss a sequence listing that is set forth in the "Sequence Listing" in accordance with paragraph (c) of this section, reference must be made to the sequence by use of the assigned identifier, in the text of the description or claims, even if the sequence is also embedded in the text of the description or claims of the patent application.

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

3. Claim Objections

- A. Claim 8 is objected to since it should recite "was" instead of "were".
- B. Claim 19 is objected to since the "a" before "responded" in the "wherein" clause should be deleted.

4. Claim Rejections - 35 USC § 112(b)

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.

- A. A broad range or limitation together with a narrow range or limitation that falls within the broad range or limitation (in the same claim) is considered indefinite, since the resulting claim does not clearly

set forth the metes and bounds of the patent protection desired. See MPEP § 2173.05(c). Note the explanation given by the Board of Patent Appeals and Interferences in *Ex parte Wu*, 10 USPQ2d 2031, 2033 (Bd. Pat. App. & Inter. 1989), as to where broad language is followed by "such as" and then narrow language. The Board stated that this can render a claim indefinite by raising a question or doubt as to whether the feature introduced by such language is (a) merely exemplary of the remainder of the claim, and therefore not required, or (b) a required feature of the claims. Note also, for example, the decisions of *Ex parte Steigewald*, 131 USPQ 74 (Bd. App. 1961); *Ex parte Hall*, 83 USPQ 38 (Bd. App. 1948); and *Ex parte Hasche*, 86 USPQ 481 (Bd. App. 1949). In the present instance, claim 10 recites the broad limitation "week 2", and the claim also recites "week 8" and "week 16" which is the narrower statement of the range/limitation. Claims 24-31 have similar issues.

B. Regarding claims 6, 10, 19 and 24-31, the phrase "preferably" 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). While there are some differences as compared to "such as" or "for example", it is still unclear as to whether the limitations are required, or simply preferred.

C. Claims 4 and 5 recite the limitation "the pharmaceutical composition for intravenous" and "...subcutaneous", respectively. There is insufficient antecedent basis for this limitation in the claim.

D. Claim 6 is rejected under 35 U.S.C. 112(b) or 35 U.S.C. 112 (pre-AIA), second paragraph, as failing to set forth the subject matter which the inventor or a joint inventor, or for pre-AIA the applicant(s) regard as their invention. The claim recites "preferably at week 0". However, this is confusing since the claim depends from claim 1, which is a method of treating. It is unclear how a subject can be treated when no antibody has yet been administered. In other words, it would seem logical to administer the antibody at week 0, which would indicate the start of treatment. If the antibody were administered after week 0, then treatment would not have yet begun (i.e. until the antibody was administered).

5. Claim Rejections - 35 USC § 102/103

In the event the determination of the status of the application as subject to AIA 35 U.S.C. 102 and 103 (or as subject to pre-AIA 35 U.S.C. 102 and 103) is incorrect, any correction of the statutory basis for the rejection will not be considered a new ground of rejection if the prior art relied upon, and the rationale supporting the rejection, would be the same under either status.

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.

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.

This application currently names joint inventors. In considering patentability of the claims the examiner presumes that the subject matter of the various claims was commonly owned as of the effective filing date of the claimed invention(s) absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and effective filing dates of each claim that was not commonly owned as of the effective filing date of the later invention in order for the examiner to consider

the applicability of 35 U.S.C. 102(b)(2)(C) for any potential 35 U.S.C. 102(a)(2) prior art against the later invention.

Claims 1-33 are rejected under 35 U.S.C. 102(a)(1) as anticipated by or, in the alternative, under 35 U.S.C. 103 as obvious over as being unpatentable over ClinicalTrials.gov ("CT"). The claims are drawn to the use of ustekinumab (STELARA®) for the treatment of UC.

CT teaches the use of this drug for the instantly claimed purpose. The claims also recite IV and SC administration, as well as various parameters/endpoints. These routes of administration and endpoints are taught by CT (see "Arms and Interventions" and "Outcome Measures"). Formulations such as those recited in claims 4 and 5 do not appear to be taught by CT. However, it would be expected that the CT formulation, which was being used in Phase 3 human trials, would be identical to that claimed. Regardless, where the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation." *In re Aller*, 220 F.2d 454, 454, 105 USPQ 223,235, (CCPA 1955). Regarding claims such as 8, CT is silent regarding the use of the antibody in patients not responsive to other treatments. However, it would have been expected, or it would have been obvious to have used such a novel treatment in those not responding to current (at the time) treatments.

6. Prior Art of Interest Not Relied Upon

The following website teaches that STELARA® was approved for human treatment in 2009. However, it does not teach more than the CT reference cited above under 35 USC 102/103 -

www.ema.europa.eu > medicines > human > EPAR > SL... ▼

Stelara | European Medicines Agency

Jan 15, 2009 - ... moderately to severely active ulcerative colitis (inflammation of the large intestine causing ulceration ... Stelara contains the active substance ustekinumab.

- moderately to severely active ulcerative colitis (inflammation of the large intestine causing ulceration and bleeding) in adults whose condition has not improved enough with other treatments for ulcerative colitis or who cannot receive such treatments.

Publication details

Marketing-authorisation holder	Janssen-Cilag International NV
Revision	32
Date of issue of marketing authorisation valid throughout the European Union	15/01/2009

7. Conclusion

No claim is allowable.

Advisory information

Any inquiry concerning this communication or earlier communications from the examiner should be directed to ROBERT S LANDSMAN whose telephone number is (571)272-0888. The examiner can normally be reached M-F 8 AM – 6 PM (eastern).

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, Joanne Hama, can be reached at (571)272-2911. 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 <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/ROBERT S LANDSMAN/
Primary Examiner, Art Unit 1647

Notice of References Cited	Application/Control No. 16/580,509		Applicant(s)/Patent Under Reexamination Johans et al.	
	Examiner ROBERT S LANDSMAN		Art Unit 1647	Page 1 of 1

U.S. PATENT DOCUMENTS

*		Document Number Country Code-Number-Kind Code	Date MM-YYYY	Name	CPC Classification	US Classification
	A					
	B					
	C					
	D					
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	J					
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FOREIGN PATENT DOCUMENTS

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

NON-PATENT DOCUMENTS

*		Include as applicable: Author, Title Date, Publisher, Edition or Volume, Pertinent Pages)
*	U	https://www.ema.europa.eu/en/medicines/human/EPAR/stelara . Accessed from the internet 7/13/20. Date provided by GOOGLE search - Jan 15. 2009
*	V	https://clinicaltrials.gov/ct2/show/NCT02407236 . Accessed from the internet 7/13/20
	W	
	X	

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

U.S. Patent and Trademark Office
PTO-892 (Rev. 01-2001)

Notice of References Cited

Part of Paper No. 20200710