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APPLICATION NO.	ISSUE DATE	PATENT NO.	ATTORNEY DOCKET NO.	CONFIRMATION NO.
16/580,509	03/30/2021	10961307	JB16010USNP1	7810

27777 7590 03/10/2021
JOSEPH F. SHIRTZ
JOHNSON & JOHNSON
ONE JOHNSON & JOHNSON PLAZA
NEW BRUNSWICK, NJ 08933-7003

ISSUE NOTIFICATION

The projected patent number and issue date are specified above.

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

The Patent Term Adjustment is 0 day(s). Any patent to issue from the above-identified application will include an indication of the adjustment on the front page.

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

Applicant will be able to obtain more detailed information by accessing the Patent Application Information Retrieval (PAIR) WEB site (<http://pair.uspto.gov>).

Any questions regarding the Patent Term Extension or Adjustment determination should be directed to the Office of Patent Legal Administration at (571)-272-7702. Questions relating to issue and publication fee payments should be directed to the Application Assistance Unit (AAU) of the Office of Data Management (ODM) at (571)-272-4200.

APPLICANT(s) (Please see PAIR WEB site <http://pair.uspto.gov> for additional applicants):

Jewel Johanss, Devon, PA;
Janssen Biotech, Inc., Horsham, PA;
Katherine Li, Wallingford, PA;
Colleen Marano, Malvern, PA;
Richard Strauss, Doylestown, PA;
Hongyan Zhang, Malvern, PA;
Christopher O'Brien, Lafayette Hill, PA;
Omoniyi Adedokun, Phoenixville, PA;
Kimberly Shields-Tuttle, West Chester, PA;

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IR 103 (Rev. 10/09)

Notice of Allowability	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--

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

1. ☒ This communication is responsive to the amendment dated 10/16/20.
☐ 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 1-33 and 35. 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>10/16/20; 11/9/20</u> . 3. ☐ Examiner's Comment Regarding Requirement for Deposit of Biological Material _____. 4. ☒ Interview Summary (PTO-413), Paper No./Mail Date. _____.	5. ☒ Examiner's Amendment/Comment 6. ☐ Examiner's Statement of Reasons for Allowance 7. ☐ Other _____.
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/ROBERT S LANDSMAN/
Primary Examiner, Art Unit 1647

EXAMINER'S AMENDMENT

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.

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 Eric Dichter on 10/28/20.

In the specification:

Amend the title to the following –

Methods of Treating Moderately to Severely Active Ulcerative Colitis by Administering An Anti-IL12/IL23 Antibody

In the claims:

In claim 1, part (iv), replace “a change” with – improvements –

In claim 14, replace “a change” with – improvements –

In claim 19, part (iv), replace “a change” with – improvements –

In claim 27, replace “a change” with – improvements --

In claim 33, part (iv), replace “a change” with – improvements –

In claim 34, part (iv), replace “a change” with – improvements –

EXAMINER'S COMMENT

Patent Application US 2020/0262908 (claims 384 and 387) teaches the use of ustekinumab for the treatment of UC. However, claim 384 appears to be focused on an ingestible device for delivery of antibodies. No data has been presented in the '908 application which would make the instant claim limitations in, e.g. claim 1, anticipated, nor obvious. Furthermore, in the absence of any dosing data or discussion in the '908 specification, the Examiner cannot make the case that the (untaught) amount of ustekinumab would have the inherent effects (i.e. meeting the "endpoint" requirements of the instant claims).

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

<i>Examiner-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: 09 November 2020

Issues Discussed:

35 U.S.C. 102

The Examiner discussed Patent Application US 2020/0262908 with Mr. Dichter. A summary of the discussion can be found in the Notice of Allowability herewith.

35 U.S.C. 103

See 35 U.S.C. 102 above

		/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: 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.

☐ 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
Reg. No. 41,708

Johnson & Johnson
One Johnson & Johnson Plaza
New Brunswick, NJ 08933-7003
(215) 628-7966

DATED: November 9, 2020

PATENT APPLICATION FEE DETERMINATION RECORD Substitute for Form PTO-875				Application or Docket Number 16/580,509		Filing Date 09/24/2019		☐ To be Mailed		
ENTITY: ☒ LARGE ☐ SMALL ☐ MICRO										
APPLICATION AS FILED - PART I										
		(Column 1)		(Column 2)						
FOR		NUMBER FILED		NUMBER EXTRA		RATE (\$)		FEE (\$)		
☐ BASIC FEE (37 CFR 1.16(a), (b), or (c))		N/A		N/A		N/A				
☐ SEARCH FEE (37 CFR 1.16(k), (l), or (m))		N/A		N/A		N/A				
☐ EXAMINATION FEE (37 CFR 1.16(o), (p), or (q))		N/A		N/A		N/A				
TOTAL CLAIMS (37 CFR 1.16(j))		minus 20 = *				x \$100 =				
INDEPENDENT CLAIMS (37 CFR 1.16(h))		minus 3 = *				x \$460 =				
☐ APPLICATION SIZE FEE (37 CFR 1.16(s))		If the specification and drawings exceed 100 sheets of paper, the application size fee due is \$310 (\$155 for small entity) for each additional 50 sheets or fraction thereof. See 35 U.S.C. 41(a)(1)(G) and 37 CFR 1.16(s).								
☐ MULTIPLE DEPENDENT CLAIM PRESENT (37 CFR 1.16(j))										
* If the difference in column 1 is less than zero, enter "0" in column 2.						TOTAL				
APPLICATION AS AMENDED - PART II										
		(Column 1)		(Column 2)		(Column 3)				
AMENDMENT	10/16/2020	CLAIMS REMAINING AFTER AMENDMENT		HIGHEST NUMBER PREVIOUSLY PAID FOR		PRESENT EXTRA		RATE (\$)		
								ADDITIONAL FEE (\$)		
	Total (37 CFR 1.16(i))	* 82	Minus	** 86	= 0	x \$100 =		0		
	Independent (37 CFR 1.16(h))	* 3	Minus	*** 3	= 0	x \$480 =		0		
	☐ Application Size Fee (37 CFR 1.16(s))									
☐ FIRST PRESENTATION OF MULTIPLE DEPENDENT CLAIM (37 CFR 1.16(j))										
								TOTAL ADD'L FEE		0
AMENDMENT		CLAIMS REMAINING AFTER AMENDMENT		HIGHEST NUMBER PREVIOUSLY PAID FOR		PRESENT EXTRA		RATE (\$)		
								ADDITIONAL FEE (\$)		
	Total (37 CFR 1.16(i))	*	Minus	**	=	x \$0 =				
	Independent (37 CFR 1.16(h))	*	Minus	***	=	x \$0 =				
	☐ Application Size Fee (37 CFR 1.16(s))									
☐ FIRST PRESENTATION OF MULTIPLE DEPENDENT CLAIM (37 CFR 1.16(j))										
								TOTAL ADD'L FEE		
* If the entry in column 1 is less than the entry in column 2, write "0" in column 3.								LIE		
** If the "Highest Number Previously Paid For" IN THIS SPACE is less than 20, enter "20".								/LINDA HUMES/		
*** If the "Highest Number Previously Paid For" IN THIS SPACE is less than 3, enter "3".										
The "Highest Number Previously Paid For" (Total or Independent) is the highest number found in the appropriate box in column 1.										

This collection of information is required by 37 CFR 1.16. 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 12 minutes to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. **SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.**

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Substitute for form 1449A/PTO INFORMATION DISCLOSURE STATEMENT BY APPLICANT (use as many sheets as necessary) Sheet 1 of 3	Application Number	16/580509
	File Date	24 September 2019
	First Named Inventor	Jewel Johannis
	Group Art Unit	1647
	Examiner Name	Robert S. Landsman
	Attorney Docket Number	JB16010USNP1

U.S. PATENT DOCUMENTS

Examiner Initials	Cite No. ¹	U.S. Patent Document		Name of Patentee or Applicant of Cited Document	Date of Publication of Cited Document mm-dd-yyyy	Pages, Columns, Lines, where relevant passages or relevant figures appear
		Number	Kind Code ² (if known)			
		US 2009/0181027	A1	Dal Monte, et al.	07/16/2009	
		US 2018/0252728	A1	Amgen, Inc.	09/06/2018	

FOREIGN PATENT DOCUMENTS

Examiner Initials	Cite No. ¹	Foreign Patent Document			Name of Patentee or Applicant of Cited Document	Date of Publication of Cited Document mm-dd-yyyy	Pages, Columns, Lines, where relevant passages or relevant figures appear	T ⁶
		Office ³	Number ⁴	Kind Code ⁵				

OTHER PRIOR ART - NON PATENT LITERATURE DOCUMENTS

Examiner's Initials*	Cite No. ¹	Include name of the author (in CAPITOL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published	T ²
		Adedokun, et al., "Ustekinumab Pharmacokinetics and Exposure Response in a Phase 3 Randomized Trial of Patients with Ulcerative Colitis," Clinical Gastroenterology and Hepatology, 18: 2244-2255 (2020).	
		Adedokun, et al., "Pharmacokinetics and Exposure Response Relationships of Ustekinumab in Patients with Crohn's Disease," Gastroenterology, 154: 1660-1671 (2018).	
		Ahern et al., "Interleukin-23 Drives Intestinal Inflammation through Direct Activity on T Cell," Immunity, 33(2):279-288 (2010)	
		Anderson et al., "Meta-analysis identifies 29 additional ulcerative colitis risk loci, increasing the number of confirmed associations to 47," Nature Genetics, 43(3):246-252 (2011)	
		Baumgart, et al., "Crohn's Disease," Lancet, 380: 1590-1605 (2012).	
		Berg et al., "Enterocolitis and Colon Cancer in Interleukin-10-deficient Mice are Associated with Aberrant Cytokine Production and CD4+ TH1-like Responses," Journal of Clinical Investigations, 98:1010-1020 (1996)	
		Steven Brant, "Promises, Delivery, and Challenges of Inflammatory Bowel Disease Risk Gene Discovery," Clinical Gastroenterology and Hepatology, 11(1):22-26 (2013)	
		Colombel et al., "Adalimumab for Maintenance of Clinical Response and Remission in Patients with Crohn's Disease: The CHARM Trial," Gastroenterology, 132:52-65 (2007)	
		Danese, et al., "Ulcerative Colitis," New England Journal of Medicine, 365:1715-1725 (2011)	

	Davidson et al., "IL-12, But Not IFN- γ Plays a Major Role in Sustaining the Chronic Phase of Colitis in IL-10-Deficient Mice," <i>Journal of Immunology</i> , 161:3143–3149 (1998)	
	Feagan et al., "Vedolizumab as Induction and Maintenance Therapy for Ulcerative Colitis," <i>New England Journal of Medicine</i> , 369:699–710 (2013)	
	Feagan, et al., "Ustekinumab as Induction and Maintenance Therapy for Crohn's Disease," <i>New England Journal of Medicine</i> , 375 (20): 1946-1960 (2016).	
	Geremia et al., "Innate and adaptive immunity in inflammatory bowel disease," <i>Autoimmunity Reviews</i> , 13:3-10 (2014).	
	Hanauer et al., "Maintenance infliximab for Crohn's Disease: the ACCENT I randomized trial," <i>Lancet</i> . 359:1541-1549 (2002)	
	Hanauer, et al., "IM-UNITI: Three-year Efficacy, Safety, and Immunogenicity of Ustekinumab Treatment of Crohn's Disease," <i>Journal of Crohn's and Colitis</i> : 23-32 (2020).	
	Janssen Research & Development, LLC, "A Study to Evaluate the Safety and Efficacy of Ustekinumab Induction and Maintenance Therapy in participants with Moderately to Severely Active Ulcerative Colitis (UNIFI)," (12/19/2019).	
	Janssen Research & Development, LLC, "A Multicenter, Randomized, Double-blind, Placebo-controlled, Proof-of-Concept Study of Ustekinumab in Subjects with Active Systemic Lupus Erythematosus," Clinical Trial Number NCT0239061, Approved 01/18/2017.	
	Li, et al., "Relationship Between Combined Histologic and Endoscopic Endpoints and Efficacy of Ustekinumab Treatment in Patients with Ulcerative Colitis," <i>Gastroenterology</i> , S0016-5085 (20): 35107-6 (Journal Pre-proof August 2020).	
	Loftus, et al., "Epidemiology of inflammatory bowel disease," <i>Gastroenterology Clinics of North America</i> , 31:1-20 (2002)	
	Edward V. Loftus, Jr., "Clinical Epidemiology of Inflammatory Bowel Disease: Incidence, Prevalence, and Environmental Influences," <i>Gastroenterology</i> , 126(6):1504-1517 (2004).	
	Neurath et al., "Antibodies to Interleukin 12 Abrogate Established Experimental Colitis in Mice," <i>Journal of Experimental Medicine</i> , 182(5):1281-1290 (1995)	
	Neurath, "Cytokines in inflammatory bowel disease," <i>Nature Revs Immunology</i> , 14(5):329-42 (2014)	
	Papp, et al., "Efficacy and Safety of Ustekinumab, A Human Interleukin-12/23 Monoclonal Antibody, in Patients with Psoriasis: 52 Week Results from a Randomised, Double-Blind, Placebo-Controlled Trial (PHOENIX 2), <i>The Lancet</i> , 371: 1675-1684 (2008).	
	Sandborn et al., "Adalimumab Induces and Maintains Clinical Remission in Patients With Moderate-to-Severe Ulcerative Colitis," <i>Gastroenterology</i> . 142:257–265 (2012)	
	Sandborn et al., "A Randomized Trial of Ustekinumab, a Human Interleukin-12/23 Monoclonal Antibody, in Patients with Moderate-to-Severe Crohn's Disease," <i>Gastroenterology</i> . 135(4):1130-1141 (2008)	
	Sandborn et al., "Vedolizumab as Induction and Maintenance Therapy for Crohn's Disease," <i>New England Journal of Medicine</i> , 369:711-721 (2013)	
	Sandborn, et al., "Long-Term Efficacy and Safety of Ustekinumab for Crohn's disease through the second year of therapy," <i>Alimentary Pharmacology & Therapeutics</i> , 48: 65-77 (2018).	

		Sandborn, et al., "Ustekinumab Induction and Maintenance Therapy in Refractory Crohn's Disease," The New England Journal of Medicine, 367: 1519-1528 (2012).	
		Sands, et al., "Safety and Efficacy of Ustekinumab Induction Therapy in Patients with Moderate to Severe Ulcerative Colitis: Results from the Phase 3 UNIFI Study," American College of Gastroenterology Conference, Philadelphia, Pennsylvania (October 2018). (Poster Presentation).	
		Sands, et al., "Ustekinumab as Induction and Maintenance Therapy for Ulcerative Colitis," The New England Journal of Medicine, 381(13): 1201-1214 (2019).	
		Simon, et al., "Ustekinumab for the treatment of Crohn's disease: can it find its niche?" Therapeutic Advances in Gastroenterology, 9 (1): 26-36 (2016).	
		Tally et al., "An Evidence-Based Systematic Review of Medical Therapies for Inflammatory Bowel Disease," American Journal of Gastroenterology, 106 Suppl 1:S2-S25 (2011)	
		Uhlir et al., "Differential Activity of IL-12 and IL-23 in Mucosal and Systemic Innate Immune Pathology," Immunity. 25:309 318 (2006)	
		Yen et al., "IL-23 is essential for T cell-mediated colitis and promoted inflammation via IL-17 and IL-6," The Journal of Clinical Investigation, 116(5):1310-1316 (2006)	
		Yu et al., "Expression of Interleukin-22/STAT3 signaling pathway in ulcerative colitis and related carcinogenesis," World Journal of Gastroenterology, 19(17):2638-2649 (2013)	
		PCT Search Report dated 01/13/2020.	

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

1 Unique citation designation number. 2 Applicant is to place a check mark here if English language Translation is attached.

Burden Hour Statement: This form is estimated to take 2.0 hours to complete. Time will vary depending upon the needs of the individual case. Any comments on the amount of time you are required to complete this form should be sent to the Chief Information Officer, U. S. Patent and Trademark Office, Washington, DC 20231.

DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Assistant Commissioner for Patents, Washington, DC 20231.

① of 3

PATENT COOPERATION TREATY

From the INTERNATIONAL SEARCHING AUTHORITY

PCT

To: Joseph F. Shirtz
Johnson & Johnson
One Johnson & Johnson Plaza
New Brunswick, New Jersey 08933
United States of America

RECEIVED
JAN 16 2020
PCT PATENT DEPT.

NOTIFICATION OF TRANSMITTAL OF
THE INTERNATIONAL SEARCH REPORT AND
THE WRITTEN OPINION OF THE INTERNATIONAL
SEARCHING AUTHORITY, OR THE DECLARATION

(PCT Rule 44.1)

Date of mailing
(day/month/year)

13 JAN 2020

Applicant's or agent's file reference JBI6010WOPCT1	FOR FURTHER ACTION See paragraphs 1 and 4 below
International application No. PCT/IB19/58098	International filing date (day/month/year) 24 September 2019 (24.09.2019)
Applicant JANSSEN BIOTECH, INC.	

1. ☒ The applicant is hereby notified that the international search report and the written opinion of the International Searching Authority have been established and are transmitted herewith.

Filing of amendments and statement under Article 19:

The applicant is entitled, if he so wishes, to amend the claims of the international application (see Rule 46):

When? The time limit for filing such amendments is normally two months from the date of transmittal of the international search report.

How? Directly to the International Bureau preferably through ePCT, or on paper to:
The International Bureau of WIPO, 34, chemin des Colombettes, 1211 Geneva 20, Switzerland
(Facsimile No.: +41 22 338 82 70)

For more detailed instructions, see the *PCT Applicant's Guide*, International Phase, paragraphs 9.004—9.011.

2. ☐ The applicant is hereby notified that no international search report will be established and that the declaration under Article 17(2)(a) to that effect and the written opinion of the International Searching Authority are transmitted herewith.

3. ☐ With regard to any protest against payment of (an) additional fee(s) under Rule 40.2, the applicant is notified that:
- ☐ the protest together with the decision thereon has been transmitted to the International Bureau together with any request to forward the texts of both the protest and the decision thereon to the designated Offices.
 - ☐ no decision has been made yet on the protest; the applicant will be notified as soon as a decision is made.

4. Reminders

The applicant may submit comments on an informal basis on the written opinion of the International Searching Authority to the International Bureau. These comments will be made available to the public after international publication. The International Bureau will send a copy of such comments to all designated Offices unless an international preliminary examination report has been or is to be established.

Shortly after the expiration of 18 months from the priority date, the international application will be published by the International Bureau. If the applicant wishes to avoid or postpone publication, a notice of withdrawal of the international application, or of the priority claim, must reach the International Bureau before the completion of the technical preparations for international publication (Rules 90bis.1 and 90bis.3).

Within 19 months from the priority date, but only in respect of some designated Offices, a demand for international preliminary examination must be filed if the applicant wishes to postpone the entry into the national phase until 30 months from the priority date (in some Offices even later); otherwise, the applicant must, within 20 months from the priority date, perform the prescribed acts for entry into the national phase before those designated Offices. In respect of other designated Offices, the time limit of 30 months (or later) will apply even if no demand is filed within 19 months. For details about the applicable time limits, Office by Office, see www.wipo.int/pct/en/texts/time_limits.html and the *PCT Applicant's Guide*, National Chapters.

Within 22 months from the priority date, the applicant may request that a supplementary international search be carried out by a different International Searching Authority that offers this service (Rule 45bis.1). The procedure for requesting supplementary international search is described in the *PCT Applicant's Guide*, International Phase, paragraphs 8.006-8.032.

Name and mailing address of the ISA/US Mail Stop PCT, Attn: ISA/US Commissioner for Patents P.O. Box 1450, Alexandria, Virginia 22313-1450 Facsimile No. 571-273-8300	Authorized officer Shane Thomas Telephone No. PCT Helpdesk: 571-272-4300
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Form PCT/ISA/220 (revised January 2019)

PATENT COOPERATION TREATY

2023

From the INTERNATIONAL SEARCHING AUTHORITY

PCT

To: Joseph F. Shirtz
Johnson & Johnson
One Johnson & Johnson Plaza
New Brunswick, New Jersey 08933
United States of America

NOTIFICATION OF TRANSMITTAL OF
THE INTERNATIONAL SEARCH REPORT AND
THE WRITTEN OPINION OF THE INTERNATIONAL
SEARCHING AUTHORITY, OR THE DECLARATION

(PCT Rule 44.1)

Date of mailing (day/month/year)	13 JAN 2020
Applicant's or agent's file reference JBI6010WOPCT1	FOR FURTHER ACTION See paragraphs 1 and 4 below
International application No. PCT/IB19/58098	International filing date (day/month/year) 24 September 2019 (24.09.2019)
Applicant JANSSEN BIOTECH, INC.	

1. ☒ The applicant is hereby notified that the international search report and the written opinion of the International Searching Authority have been established and are transmitted herewith.

Filing of amendments and statement under Article 19:

The applicant is entitled, if he so wishes, to amend the claims of the international application (see Rule 46):

When? The time limit for filing such amendments is normally two months from the date of transmittal of the international search report.

How? Directly to the International Bureau preferably through ePCT, or on paper to:
The International Bureau of WIPO, 34, chemin des Colombettes, 1211 Geneva 20, Switzerland
(Facsimile No.: +41 22 338 82 70)

For more detailed instructions, see the *PCT Applicant's Guide*, International Phase, paragraphs 9.004 – 9.011.

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4. Reminders

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Name and mailing address of the ISA/US Mail Stop PCT, Attn: ISA/US Commissioner for Patents P.O. Box 1450, Alexandria, Virginia 22313-1450 Facsimile No. 571-273-8300	Authorized officer Shane Thomas Telephone No. PCT Helpdesk: 571-272-4300
---	--

Form PCT/ISA/220 (revised January 2019)

PATENT COOPERATION TREATY

From the INTERNATIONAL SEARCHING AUTHORITY

PCT

To: Joseph F. Shirtz
Johnson & Johnson
One Johnson & Johnson Plaza
New Brunswick, New Jersey 08933
United States of America

NOTIFICATION OF TRANSMITTAL OF
THE INTERNATIONAL SEARCH REPORT AND
THE WRITTEN OPINION OF THE INTERNATIONAL
SEARCHING AUTHORITY, OR THE DECLARATION

(PCT Rule 44.1)

RECEIVED
JAN 16 2020

Date of mailing
(day/month/year)

13 JAN 2020

Applicant's or agent's file reference

JB16010WOPCT1

FOR FURTHER ACTION See paragraphs 1 and 4 below

International application No.

PCT/IB19/58098

International filing date
(day/month/year)

24 September 2019 (24.09.2019)

Applicant

JANSSEN BIOTECH, INC.

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Mail Stop PCT, Attn: ISA/US
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Authorized officer

Shane Thomas

Telephone No. PCT Helpdesk: 571-272-4300

Form PCT/ISA/220 (revised January 2019)

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(PCT Rule 44.1)

Applicant's or agent's file reference JB16010WOPCT1	Date of mailing (day/month/year) FOR FURTHER ACTION See paragraphs 1 and 4 below
International application No. PCT/IB19/58098	International filing date (day/month/year) 24 September 2019 (24.09.2019)
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---	---

Form PCT/ISA/220 (revised January 2019)

PATENT COOPERATION TREATY

PCT

INTERNATIONAL SEARCH REPORT

(PCT Article 18 and Rules 43 and 44)

Applicant's or agent's file reference JEI6010WOPCT1		FOR FURTHER ACTION see Form PCT/ISA/220 as well as, where applicable, item 5 below.	
International application No. PCT/IB19/58098	International filing date (day/month/year) 24 September 2019 (24.09.2019)	(Earliest) Priority Date (day/month/year) 24 September 2018 (24.09.2018)	
Applicant JANSSEN BIOTECH, INC.			

This international search report has been prepared by this International Searching Authority and is transmitted to the applicant according to Article 18. A copy is being transmitted to the International Bureau.

This international search report consists of a total of 4 sheets.

☐ It is also accompanied by a copy of each prior art document cited in this report.

1. Basis of the report

a. With regard to the language, the international search was carried out on the basis of:

- ☒ the international application in the language in which it was filed.
☐ a translation of the international application into _____ which is the language of a translation furnished for the purposes of international search (Rules 12.3(a) and 23.1(b)).

b. ☐ This international search report has been established taking into account the rectification of an obvious mistake authorized by or notified to this Authority under Rule 91 (Rule 43.6bis(a)).

c. ☒ With regard to any nucleotide and/or amino acid sequence disclosed in the international application, see Box No. I.

2. ☐ Certain claims were found unsearchable (see Box No. II).

3. ☐ Unity of invention is lacking (see Box No. III).

4. With regard to the title,

- ☒ the text is approved as submitted by the applicant.
☐ the text has been established by this Authority to read as follows:

5. With regard to the abstract,

- ☒ the text is approved as submitted by the applicant.
☐ the text has been established, according to Rule 38.2, by this Authority as it appears in Box No. IV. The applicant may, within one month from the date of mailing of this international search report, submit comments to this Authority.

6. With regard to the drawings,

- a. the figure of the drawings to be published with the abstract is Figure No. 1
☒ as suggested by the applicant,
☐ as selected by this Authority, because the applicant failed to suggest a figure.
☐ as selected by this Authority, because this figure better characterizes the invention.
- b. ☐ none of the figures is to be published with the abstract.

INTERNATIONAL SEARCH REPORT

International application No.
PCT/IB19/58098

Box No. I Nucleotide and/or amino acid sequence(s) (Continuation of item 1.c of the first sheet)

1. With regard to any nucleotide and/or amino acid sequence disclosed in the international application, the international search was carried out on the basis of a sequence listing:
- a. ☒ forming part of the international application as filed:
☒ in the form of an Annex C/ST.25 text file.
☐ on paper or in the form of an image file.
- b. ☐ furnished together with the international application under PCT Rule 13ter.1(a) for the purposes of international search only in the form of an Annex C/ST.25 text file.
- c. ☐ furnished subsequent to the international filing date for the purposes of international search only:
☐ in the form of an Annex C/ST.25 text file (Rule 13ter.1(a)).
☐ on paper or in the form of an image file (Rule 13ter.1(b) and Administrative Instructions, Section 713).
2. ☐ In addition, in the case that more than one version or copy of a sequence listing has been filed or furnished, the required statements that the information in the subsequent or additional copies is identical to that forming part of the application as filed or does not go beyond the application as filed, as appropriate, were furnished.
3. Additional comments:

Form PCT/ISA/210 (continuation of first sheet (1)) (July 2019)

INTERNATIONAL SEARCH REPORT

International application No.

PCT/IB19/58098

A. CLASSIFICATION OF SUBJECT MATTER

IPC - A61K 39/395; C07K 16/244, 14/54 (2019.01)

CPC - A61K 39/395; C07K 16/244, 14/54

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

See Search History document

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

See Search History document

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)

See Search History document

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
Y	(JANSSEN RESEARCH & DEVELOPMENT, LLC) A Study to Evaluate the Safety and Efficacy of Ustekinumab Induction and Maintenance Therapy in Participants With Moderately to Severely Active Ulcerative Colitis (UNIFI). 13 August 2018; retrieved from the internet < https://clinicaltrials.gov/ct2/show/NCT02407238 > on 18 December 2019; pages 1-12; page 3/12, paragraph 2; 5/12, paragraphs 2-7	1-3, 4/1-3, 5/4/1-3, 6/4/1-3, 7/6/4/1-3, 8/7/6/4/1-3, 9/7/6/4/1-3, 10/9/7/6/4/1-3, 11/9/7/6/4/1-3, 12/8/7/6/4/1-3, 13/9/7/6/4/1-3, 14/9/7/6/4/1-3, 15/9/7/6/4/1-3, 16/9/7/6/4/1-3, 17/9/7/6/4/1-3, 18/9/7/6/4/1-3, 19-21, 22/19-21, 23/22/19-21, 24/19-21, 25/19-21, 26/19-21, 27/19-21, 28/19-21, 29/19-21, 30/19-21, 31/19-21, 32/19-21, 33-34
Y	US 2009/0181027 A1 (DAL MONTE, P et al.) 16 July 2009; paragraphs [0076]; claim 3	1-3, 4/1-3, 5/4/1-3, 6/4/1-3, 7/6/4/1-3, 8/7/6/4/1-3, 9/7/6/4/1-3, 10/9/7/6/4/1-3, 11/9/7/6/4/1-3, 12/8/7/6/4/1-3

☒ Further documents are listed in the continuation of Box C.☐ See patent family annex.

* Special categories of cited documents:

"A" document defining the general state of the art which is not considered to be of particular relevance

"D" document cited by the applicant in the international application

"E" earlier application or patent but published on or after the international filing date

"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)

"Q" document referring to an oral disclosure, use, exhibition or other means

"P" document published prior to the international filing date but later than the priority date claimed

"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention

"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone

"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art

"&" document member of the same patent family

Date of the actual completion of the international search

20 December 2019 (20.12.2019)

Date of mailing of the international search report

13 JAN 2020

Name and mailing address of the ISA/US

Mail Stop PCT, Attn: ISA/US, Commissioner for Patents
P.O. Box 1450, Alexandria, Virginia 22313-1450
Facsimile No. 571-273-8300

Authorized officer

Shane Thomas

Telephone No. PCT Helpdesk: 571-272-4300

Form PCT/ISA/210 (second sheet) (July 2019)

INTERNATIONAL SEARCH REPORT

International application No.

PCT/IB19/58098

C (Continuation). DOCUMENTS CONSIDERED TO BE RELEVANT		
Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
		13/9/7/6/4/1-3, 14/9/7/6/4/1-3, 15/9/7/6/4/1-3, 16/9/7/6/4/1-3, 17/9/7/6/4/1-3, 18/9/7/6/4/1-3, 19-21, 22/19-21, 23/22/19-21, 24/19-21, 25/19-21, 26/19-21, 27/19-21, 28/19-21, 29/19-21, 30/19-21, 31/19-21, 32/19-21, 33-34
Y	US 2018/0252728 A1 (AMGEN INC. et al.) 06 September 2018; paragraph [0189]	3, 4/3, 5/4/3, 6/4/3, 7/6/4/3, 8/7/6/4/3, 9/7/6/4/3, 10/9/7/6/4/3, 11/9/7/6/4/3, 12/8/7/6/4/3, 13/9/7/6/4/3, 14/9/7/6/4/3, 15/9/7/6/4/3, 16/9/7/6/4/3, 17/9/7/6/4/3, 18/9/7/6/4/3, 21, 22/21, 23/22/21, 24/21, 25/21, 26/21, 27/21, 28/21, 29/21, 30/21, 31/21, 32/21
Y	(JANSSEN RESEARCH & DEVELOPMENT, LLC) A Multicenter, Randomized, Double-blind, Placebo-controlled, Proof-of-Concept Study of Ustekinumab in Subjects with Active Systemic Lupus Erythematosus. 18 January 2017; retrieved from the internet < https://clinicaltrials.gov/ProvidedDocs/61/NCT02349061/Prot_000.pdf > on 19 December 2019; pages 1-148; page 8, paragraph 2; page 9, paragraph 2; page 12, paragraph 4; page 48, paragraph 1; page 49, paragraph 2; page 69, paragraphs 4, 7; page 70, paragraph 3	4/1-3, 5/4/1-3, 6/4/1-3, 7/6/4/1-3, 8/7/6/4/1-3, 9/7/6/4/1-3, 10/9/7/6/4/1-3, 11/9/7/6/4/1-3, 12/8/7/6/4/1-3, 13/9/7/6/4/1-3, 14/9/7/6/4/1-3, 15/9/7/6/4/1-3, 16/9/7/6/4/1-3, 17/9/7/6/4/1-3, 18/9/7/6/4/1-3, 19-21, 22/19-21, 23/22/19-21, 24/19-21, 25/19-21, 26/19-21, 27/19-21, 28/19-21, 29/19-21, 30/19-21, 31/19-21, 32/19-21, 33-34
Y	(GUDJONSSON, J) Efficacy and Safety of Ustekinumab, A Human Interleukin-12/23 Monoclonal Antibody, in Patients with Psoriasis: 52-Week Results from a Randomised, Double-Blind, Placebo-Controlled Trial (PHOENIX 2). 17 May 2008; retrieved from the internet < https://f1000.com/prime/1108987 > on 19 December 2019; pages 1-3; page 1/3, paragraph 2	10/9/7/6/4/1-3, 24/19-21, 25/19-21, 26/19-21, 27/19-21, 28/19-21, 29/19-21, 30/19-21, 31/19-21
Y	(ADEDOKUN, OJ et al.) Pharmacokinetics and Exposure Response Relationships of Ustekinumab in Patients with Crohn's Disease. Gastroenterology. 01 February 2018; Vol. 154, No. 6; pages 1660-1671; page 1664, column 2, paragraph 2; DOI: 10.1053/j.gastro.2018.01.043	17/9/7/6/4/1-3, 30/19-21

Form PCT/ISA/210 (continuation of second sheet) (July 2019)

PATENT COOPERATION TREATY

3 of 3

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NOTIFICATION OF TRANSMITTAL OF
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(PCT Rule 44.1)

Applicant's or agent's file reference JB16010WOPCT1	Date of mailing (day/month/year) 13 JAN 2020
International application No. PCT/IB19/58098	International filing date (day/month/year) 24 September 2019 (24.09.2019)
Applicant JANSSEN BIOTECH, INC.	

RECEIVED

JAN 18 2020
 J&J PATENT DOCKET SECTION

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Form PCT/ISA/220 (revised January 2019)

PATENT COOPERATION TREATY

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United States of America

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4. Reminders

The applicant may submit comments on an informal basis on the written opinion of the International Searching Authority to the International Bureau. These comments will be made available to the public after international publication. The International Bureau will send a copy of such comments to all designated Offices unless an international preliminary examination report has been or is to be established.

Shortly after the expiration of 18 months from the priority date, the international application will be published by the International Bureau. If the applicant wishes to avoid or postpone publication, a notice of withdrawal of the international application, or of the priority claim, must reach the International Bureau before the completion of the technical preparations for international publication (Rules 90bis.1 and 90bis.3).

Within 19 months from the priority date, but only in respect of some designated Offices, a demand for international preliminary examination must be filed if the applicant wishes to postpone the entry into the national phase until 30 months from the priority date (in some Offices even later); otherwise, the applicant must, within 20 months from the priority date, perform the prescribed acts for entry into the national phase before those designated Offices. In respect of other designated Offices, the time limit of 30 months (or later) will apply even if no demand is filed within 19 months. For details about the applicable time limits, Office by Office, see www.wipo.int/pct/en/texts/time_limits.html and the *PCT Applicant's Guide*, National Chapters.

Within 22 months from the priority date, the applicant may request that a supplementary international search be carried out by a different International Searching Authority that offers this service (Rule 45bis.1). The procedure for requesting supplementary international search is described in the *PCT Applicant's Guide*, International Phase, paragraphs 8.006–8.032.

Name and mailing address of the ISA/IS Mail Stop PCT, Attn: ISA/US Commissioner for Patents P.O. Box 1450, Alexandria, Virginia 22313-1450 Facsimile No. 571-273-8300	Authorized officer Shane Thomas Telephone No. PCT Helpdesk: 571-272-4300
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Form PCT/ISA/220 (revised January 2019)

Electronic Patent Application Fee Transmittal				
Application Number:		16580509		
Filing Date:		24-Sep-2019		
Title of Invention:		Safe and Effective Method of Treating Ulcerative Colitis with Anti-IL12/IL23 Antibody		
First Named Inventor/Applicant Name:		Jewel Johans		
Filer:		Eric Dichter/Deborah Pishock		
Attorney Docket Number:		JBI6010USNP1		
Filed as Large Entity				
Filing Fees for Utility under 35 USC 111(a)				
Description	Fee Code	Quantity	Amount	Sub-Total in USD(\$)
Basic Filing:				
Pages:				
Claims:				
Miscellaneous-Filing:				
Petition:				
Patent-Appeals-and-Interference:				
Post-Allowance-and-Post-Issuance:				
Extension-of-Time:				

Description	Fee Code	Quantity	Amount	Sub-Total in USD(\$)
Miscellaneous:				
SUBMISSION- INFORMATION DISCLOSURE STMT	1806	1	260	260
Total in USD (\$)				260

Electronic Acknowledgement Receipt

EFS ID:	40865379
Application Number:	16580509
International Application Number:	
Confirmation Number:	7810
Title of Invention:	Safe and Effective Method of Treating Ulcerative Colitis with Anti-IL12/IL23 Antibody
First Named Inventor/Applicant Name:	Jewel Johans
Customer Number:	27777
Filer:	Eric Dichter/Deborah Pishock
Filer Authorized By:	Eric Dichter
Attorney Docket Number:	JBIG010USNP1
Receipt Date:	16-OCT-2020
Filing Date:	24-SEP-2019
Time Stamp:	15:56:33
Application Type:	Utility under 35 USC 111(a)

Payment information:

Submitted with Payment	yes
Payment Type	DA
Payment was successfully received in RAM	\$ 260
RAM confirmation Number	E20200FF57041504
Deposit Account	100750
Authorized User	Deborah Pishock

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36		ResptoOA01.pdf	165279 24e3febb99b3efd348bd90954895b8e3d1f bce10	yes	10
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	Claims		2	7	
	Applicant Arguments/Remarks Made in an Amendment		1	1	
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