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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
15/999,517	08/20/2018	Lance L. Gooberman	CU-73640 JPL	4474

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EXAMINER	
ZHANG, YANZHI	

ART UNIT	PAPER NUMBER
1617	

NOTIFICATION DATE	DELIVERY MODE
06/17/2019	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):

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Office Action Summary	Application No. 15/999,517	Applicant(s) Gooberman, Lance L.	
	Examiner YANZHI ZHANG	Art Unit 1617	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 05/29/19.

☐ 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) 1-20 is/are pending in the application.

5a) Of the above claim(s) 17-20 is/are withdrawn from consideration.

6) ☐ Claim(s) _____ is/are allowed.

7) ☑ Claim(s) 1-16 is/are rejected.

8) ☑ Claim(s) 17-20 is/are objected to.

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

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

Application Papers

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

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

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

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

Priority under 35 U.S.C. § 119

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

Certified copies:

a)☐ All b)☐ Some** c)☐ None of the:

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

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

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

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

Attachment(s)

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

2) ☐ Information Disclosure Statement(s) (PTO/SB/08a and/or PTO/SB/08b) Paper No(s)/Mail Date

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

4) ☐ Other: _____.

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.

Claim Status

This is in response to papers file on May 29, 2019. Claims 1, 4, 11, and 14.have been amended. No claim has been newly added or cancelled. Claims 17-20 have been withdrawn for the reason of record. Accordingly, claims 1-16 are under consideration on the merit.

Previous Rejections

Rejections and objections not reiterated from previous office actions are hereby withdrawn in view of amendments dated 05/29/19. The following rejections and/or objections are either reiterated or newly applied necessitated by amendments dated 05/29/19. They constitute the complete set presently being applied to the instant application.

Claim Objections

Claims 17-20 are objected to because of the following informalities:

The status of claims 17-20 should be "**withdrawn**", not "previous presented". As applicant confirmed (page 1 of remarks), claims 17-20 have been **withdrawn** from further consideration as a result of restriction.

Appropriate correction is required.

Claim Rejections - 35 USC § 112(b) (new)

The text of those sections of Title 35 of the U.S. Code not included in this action can be found in a prior Office action.

Claims 1-16 are rejected under 35 U.S.C. 112(b) or 35 U.S.C. 112 (pre-AIA), second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which the inventor or a joint inventor, or for pre-AIA the applicant regards as the invention.

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 1 recites a broad limitation by using the transitional phrase “comprising”, and the claim also recites a narrow limitation by using the transitional phrase “consisting of”. Therefore, claim is considered indefinite.

Appropriate action is required.

Claims 2-16 ultimately depend on the base claim, thus are included in the rejection.

In the interest of compact prosecution, claim 1 is search and examined as a composition for injection consisting of an opioid antagonist, a steroidal anti-inflammatory agent, and an

injection vehicle because the narrow transitional phrase controls the scope. The opioid antagonist and a polymeric binder are in the form of microparticles, while the steroid is either mixed with the vehicle (in the form of a solution) or encapsulated in the microparticles together with the opioid antagonist based on claim 3 and specification (e.g. [0018] and [0047]).

It is suggested that claim 1 is amended by adding "wherein the (or said) steroidal anti-inflammatory agent is either mixed with the vehicle (in the form of a solution) or encapsulated in the microparticles." at the end of claim 1.

Response to arguments

Applicant's arguments filed 05/29/2019 have been fully considered towards the previous 112(b) rejection, they are persuasive. Thus, the rejection has been withdrawn in view of amendments and arguments dated 05/29/19.

The above 112(b) rejection is newly applied due to amendments dated 05/29/19. The amendments and arguments dated 05/29/19 do not applied to the new rejection.

Claim Rejections - 35 USC § 112(d) (maintained)

The text of those sections of Title 35 of the U.S. Code not included in this action can be found in a prior Office action.

Claim 3 is rejected under 35 U.S.C. 112(d) or pre-AIA 35 U.S.C. 112, 4th paragraph, as being of improper dependent form for failing to further limit the subject matter of the claim upon which it depends, or for failing to include all the limitations of the claim upon which it depends. Claim 3 recites the limitation of "wherein steroidal anti-inflammatory agent is encapsulated in the microparticles". However, claim 1 uses the closed transitional phrase "consisting of", which

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