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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
15/917,742	03/11/2018	Lloyd Johnston	S1681.70093US01	6109

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EXAMINER	
PAGUIO FRISING, MICHELLE F	

ART UNIT	PAPER NUMBER
1651	

NOTIFICATION DATE	DELIVERY MODE
03/02/2021	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):

Patents_eOfficeAction@WolfGreenfield.com
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Office Action Summary	Application No. 15/917,742	Applicant(s) Johnston, Lloyd	
	Examiner MICHELLE F PAGUIO FRISING	Art Unit 1651	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 RCE filed 12/10/2020.

☐ 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) 1-13,15 and 18-19 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) 1-13,15 and 18-19 is/are rejected.

8) ☑ Claim(s) 1 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 12/11/2020; 12/11/2020

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.

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 12/10/2020 has been entered.

Amendments

Claim 1 has been amended to specify that the synthetic nanocarriers comprise “poly(D.L lactide) (PLA) and poly(D,L lactide) poly (ethylene glycol) (PLA-PEG)”, the immunosuppressant is “a rapalog”, and the uricase is “pegylated”. Consequently, claims 2, 11-13, 15, and 18 have also been amended. Claims 14, 16-17, and 50 have been canceled.

Election/Restrictions

With the cancelation of claim 50 (Invention II), claims 1-13, 15, and 18-19 remain pending and have been examined on the merits.

Power of Attorney

A Power of Attorney still has not yet been submitted.

Information Disclosure Statement

The two information disclosure statements (IDSs) filed on 12/11/2020 are in compliance with the provisions of 37 C.F.R. 1.97. All cited references have been fully considered.

Claim Objections

Claim 1 is objected to because of the following informalities: (i) the period in the term “poly(D.L lactide)” should have been a comma; (ii) a hyphen is missing between “D.L” and “lactide” in the term “poly(D,L lactide)”; (iii) a hyphen is missing between “D,L” and “lactide” as well as before the second “poly” in the term “poly(D,L lactide) poly (ethylene glycol)”; and (iv) there should be no space before the parenthesis in “poly (ethylene glycol)”.

To obviate these objections, the new limitation in lines 3-4 should be amended as “poly(D,L-lactide) (PLA) and poly(D,L-lactide)-poly(ethylene glycol) (PLA-PEG)”.

Claim Rejections - 35 USC § 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 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.

RE: Rejection of claims 1-19 under 35 U.S.C. 103 as being unpatentable over Kishimoto et al. in view of Reinders et al.

Applicant traverses the rejections because they allegedly stem from an improper application of hindsight reasoning and do not establish why the compositions of Reinders *et al.* would have been used with those of Kishimoto *et al.*. Applicant points out that the medical strategy by Reinders *et al.* is “merely conjecture” as said prior art does not show that administering an anti-inflammatory therapeutic would reliably reduce or eliminate infusion reactions (IR) and gout flares. The observed results during months 1-3 and months 4-6 supposedly indicate unpredictability of the combination treatment. It is asserted that the inventors of the present application were the ones who determined that the claimed method surprisingly resulted in better efficacy and gout flare reduction. In addition, Applicant argues that Reinders *et al.* only teaches administering pegylated

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