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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
10/04/2021	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):

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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 9/01/2021.

☐ 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) 1-2,5-13 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) 1-2,5-13 and 18-19 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 _____ 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 9/01/2021 (2 IDSs)

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.

Amendments

Applicant has amended claim 1 to limit the pegylated uricase to “pegadricase” and to specify that the composition comprising an anti-inflammatory therapeutic is administered “at least once at least one week prior” to the other two compositions. Claims 2 and 11-13 have also been amended, while claims 3-4 and 15 have been cancelled. No new matter has been added.

Claims 1-2, 5-13, and 18-19 are pending and have been considered on the merits.

Power of Attorney

Applicant is reminded that a Power of Attorney is missing.

Information Disclosure Statement

The information disclosure statements (IDSs) submitted on 9/01/2021 are in compliance with the provisions of 37 C.F.R. 1.97. Accordingly, all references listed in these IDSs have been fully considered.

Claim Objections

RE: Objection to claims

The minor informalities in claim 1 have been corrected, thereby obviating claim objections.

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.

Traversal of rejections is based on “pegadricase” (also known as pegsiticase) being different from Reinders *et al.*’s pegloticase. Referring to Garay *et al.*, Applicant points out that PEGylated uricase derived from *Candida utilis* has a short half-life of 8 hours whereas pegloticase has a half-life of 10-20 days. Thus, it is argued that teachings pertaining to pegloticase would not necessarily extend to pegadricase.

Applicant further asserts that the claimed method is unexpectedly found to be significantly better than other therapies (Table 4, page 61 of Specification).

All arguments have been fully considered but are deemed unpersuasive. First, the PEGylated uricase discussed by Garay *et al*. is indeed derived from *Candida utilis* like pegadricase. But upon reviewing the source of the information regarding its half-life (Davis *et al*., *The Lancet* 1981, Vol. 318, p. 281-283), it found that the former is synthesized by covalently attaching 5 kDa PEG to uricase (fourth par. in left column, p. 282). On the other hand, pegadricase has 20 kDa PEG molecules attached to said enzyme. It is therefore respectfully submitted that the *C. utilis* PEGylated uricase described by Garay *et al*. is not structurally the same as pegadricase and its shorter PEG groups may be the reason why the half-life is only 8 hours.

Second, the prior art rejections are based on Kishimoto *et al*. as the primary reference, which discloses a method comprising co-administering SVP-rapamycin and pegsiticase to a subject. Pegisticase is another name for pegadricase, hence Kishimoto *et al*. meets the new requirement that the pegylated uricase is “pegadricase”. Reinders *et al*. was only applied in the rejections as a secondary reference to show the obviousness of administering an anti-inflammatory agent (*i.e*., not for its use of pegloticase). According to Reinders *et al*., anti-inflammatory therapy helps reduce gout flare that occurs due to urate mobilization induced by urate-lowering agents. So even though Reinders *et al*. describes a study wherein an anti-inflammatory agent like colchicine or an NSAID was administered to patients receiving pegloticase and not pegadricase as claimed, a person with ordinary skill in the art would have recognized that pegadricase also functions as a urate-lowering agent like pegloticase and would

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