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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
16/773,641	01/27/2020	John Maloney	066859/543316	3992

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EXAMINER	
PACKARD, BENJAMIN J	

ART UNIT	PAPER NUMBER
1612	

NOTIFICATION DATE	DELIVERY MODE
07/23/2020	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):

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Office Action Summary	Application No. 16/773,641	Applicant(s) Maloney et al.	
	Examiner BENJAMIN J PACKARD	Art Unit 1612	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 6/2/2020.

☐ 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) 1-27 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) 1-27 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 7pgs (6/2/20), 2pgs (6/11/20).

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.

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 05/28/2020 has been entered.

Applicants' arguments, filed 05/28/2020, have been fully considered. Rejections and/or objections not reiterated from previous office actions are hereby withdrawn. The following rejections and/or objections are either reiterated or newly applied. They constitute the complete set presently being applied to the instant application.

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.

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 1-27 is/are rejected under 35 U.S.C. 103 as being unpatentable over Sandoz Label (2010) in view of Hernandez -Sanchez (*Aluminum in Parenteral Nutrition: A Systematic Review*, 67 Eur J Clinical Nutrition 230 (2013)), and Bohrer (*Influences of the Glass Packing on the Contamination of Pharmaecutical Products in Aluminum Part II: Amino Acids for Parenteral Nutrition*, 15 J Trace Elements Med & Bioloby 103 (2001), Nakayama et al (US 4,385,086), Asquith et al (Biochimica et Biophysica Acta, 345-357, 1696), and Waterman (*Stabilization of Pharmaceuticals to Oxidative Degradation*, 7 Pharmaceutical Dev. & Tech. 1 (2002)).

The Sandoz Label discloses L-Cysteine Hydrochloride injections, 50mg/mL, available in single-dose vials. Sandoz label notes the product contains water and air replaced with Nitrogen, with a pH 1.0-

2.5. The label further states the product contains no more than 5,000 mcg/L (5,000 ppb) of aluminum. Sandoz Label further discloses a warning about aluminum which suggest premature neonates should not receive levels of more than 4mcg to 5 mcg/kg/day accumulate aluminum levels.

Sandoz Label does not teach methods to remove aluminum contaminant.

Hernandez-Sanchez teaches manufacturers of parenteral compositions should limit the aluminum content in formulations to limit patients' exposure and to prevent cases of Al toxicity, especially in infants (pg 236 Discussion). Various steps to reduce aluminum content are discussed, but it is noted that few manufacturers have put the procedures into use (pg 237, Low-Al product options).

Hernandez-Sanchez does not teach the instantly claimed methods to remove aluminum contaminant by modifying the glass container.

Bohrer teaches it was known that cysteine, cystine, and aspartic acid release aluminum from standard glass containers when stored for a long period (pg 107, Conclusion).

Bohrer does not teach the application of L-cysteine formulations.

Nakayama et al teaches a method to prevent leaching of contaminants from the surface of glass by applying a coating of silicate (see for example claim 1 and Example 1).

Bohrer does not teach the application of L-cysteine formulations.

Asquith et al teaches cysteine was known to degrade in the presence of air (pg 347).

Waterman teaches preventing oxidative degradation by applying a nitrogen headspace to liquids (pg 27).

Based on the teachings of Sandoz Label, the skilled artisan would recognize that aluminum was a known contaminant of L-Cysteine parenteral formulations and that the aluminum content should be minimized. Hernandez-Sanchez provides motivation to develop lower aluminum content formulations and provides teachings on how to achieve the desired results. The skilled artisan would recognize the teaching of Bohrer as another cause of contamination levels and would solve the problem by using

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