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16/746,028	01/17/2020	JOHN MALONEY	066859/542422	4075
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ALSTON & BIRD LLP BANK OF AMERICA PLAZA 101 SOUTH TRYON STREET SUITE 4000 CHARLOTTE, NC 28280-4000			PACKARD, BENJAMIN J	
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**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.

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PTOL-90A (Rev. 04/07)



**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and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114.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 Rejections and/or objections not reiterated from previous office actions are hereby withdrawn.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 Pharmaceutical Products in Aluminum Part II: Amino Acids for Parenteral Nutrition*, 15 J Trace Elements Med & Biology 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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