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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
14/100,717	12/09/2013	Mary Jane Helenek	30015730-0065	2813

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EXAMINER	
LAU, JONATHAN S	
ART UNIT	PAPER NUMBER
1673	

MAIL DATE	DELIVERY MODE
02/07/2014	PAPER

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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Office Action Summary	Application No. 14/100,717	Applicant(s) HELENEK ET AL.	
	Examiner Jonathan S. Lau	Art Unit 1673	AIA (First Inventor to File) Status No

-- 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 Dec 2013*.

☐ 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5a) Of the above claim(s) _____ is/are withdrawn from consideration.

6)☐ Claim(s) _____ is/are allowed.

7)☒ Claim(s) *1-20* 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 _____.

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

4) ☐ Other: _____.

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DETAILED ACTION

The present application is being examined under the pre-AIA first to invent provisions.

This application is made special as a Track I application.

This application is a domestic application, filed 9 Dec 2013; and claims benefit as a CON of 13/847,254, filed 19 Mar 2013; which claims benefit as a CON of 12/787,283, issued as Patent 8,431,549, filed 25 May 2010; which claims benefit as a CON of 11/620,986, issued as Patent 7,754,702, filed 8 Jan 2007; which claims benefit of provisional application 60/757,119, filed 6 Jan 2006.

Claims 1-20 are pending in the current application and are examined on the merits herein.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of pre-AIA 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1, 3-5, 8, 13, 14 and 18 are rejected under pre-AIA 35 U.S.C. 102(b) as being anticipated by Geisser et al. (WIPO Publication WO 2004/037865 A1, published 6

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May 2004, cited in PTO-892, English language equivalent US Patent 7,612,109 provided, cited in PTO-892). As WO 2004/037865 A1 is not in English, US Patent 7,612,109 is provided as an English language equivalent and is cited as Geisser et al. hereafter.

Geisser et al. discloses an iron carbohydrate complex of iron and the oxidation product of maltodextrins as a medicament for treatment of iron deficiency conditions (abstract). Geisser et al. discloses the iron carbohydrate complex for treatment of iron deficiency anemia and especially useful for parenteral application (column 1, lines 15-20), meeting limitations of instant claims 4, 5 and 18. Geisser et al. discloses the complexes shall have reduced toxicity and shall avoid dangerous anaphylactic shocks which can be induced by dextran (column 1, lines 35-40), meeting limitations of instant claim 3. Geisser et al. discloses in the complexes theoretically it is assumed that the oxidation occurs mainly at the terminal aldehyde group (acetal or semiacetal group respectively) of the maltodextrin molecules (column 2, lines 25-30), implying the iron carbohydrate complex is an iron carboxymaltose complex, meeting limitations of instant claim 13. Geisser et al. discloses the complexes are prepared from an iron (III) salt and a strong base such as a potassium, calcium or magnesium hydroxide (column 3, lines 1-15), implying the iron carbohydrate complex is a polynuclear iron (III)-hydroxide carboxymaltose complex and implicitly meeting limitations of instant claim 14. Geisser et al. discloses the advantage that the LD_{50} lies at over 2000 mg Fe/kg and it is possible to apply the medicaments of the invention parenterally in the form of a single dose of,

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for example, 500 to 1000 mg iron; and it can be applied, for example, during the course of one hour (column 4, lines 50-65), meeting limitations of instant claim 1 and 8.

Claims 1-3, 7-12 and 18-20 are rejected under pre-AIA 35 U.S.C. 102(b) as being anticipated by Helenek et al. (US Patent Application Publication 2004/0180849 A1, published 16 Sep 2004, cited in PTO-892).

Helenek et al. discloses a method of treating restless leg syndrome by administering to a subject an iron complex (abstract), meeting limitations of instant claim 7. Helenek et al. discloses the iron carbohydrate complexes administered include iron polyisomaltose (iron dextran), iron polymaltose (iron dextrin), iron gluconate, iron sorbital and iron hydrogenated dextran (page 3, paragraph 0021), meeting limitations of instant claim 1. Helenek et al. discloses the iron carbohydrate complexes avoid the risks of anaphylaxis associated with IDI when administered intravenously due to antibodies against the dextran moiety not being present in other iron complexes (page 3, paragraph 0017), meeting limitations of instant claims 2 and 3. Helenek et al. discloses the appropriate dosage level will generally be about 10 mg to 1000 mg of elemental iron per dose, which can be administered in single or multiple doses, for example particularly at least 600.0, 750.0, 800.0, 900.0, 1000.0, and 2000.0 milligrams of elemental iron, and furthermore up to the maximal tolerated dose (MTD) per administration (page 5, paragraph 0051), meeting limitations of instant claims 1 and 8-10. Helenek et al. discloses the embodiments of 1000 mg of elemental iron administered in an injectable

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