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Table with 5 columns: APPLICATION NO., FILING DATE, FIRST NAMED INVENTOR, ATTORNEY DOCKET NO., CONFIRMATION NO.

11/620,986 01/08/2007 Mary Jane Helenek 30015730-0043 1325

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SONNENSCHN NATH & ROSENTHAL LLP
P.O. BOX 061080
WACKER DRIVE STATION, SEARS TOWER
CHICAGO, IL 60606-1080

Table with 1 column: EXAMINER

LAU, JONATHAN S

Table with 2 columns: ART UNIT, PAPER NUMBER

1623

Table with 2 columns: MAIL DATE, DELIVERY MODE

10/23/2008

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.

<b>Office Action Summary</b>	<b>Application No.</b> 11/620,986	<b>Applicant(s)</b> HELENEK ET AL.	
	<b>Examiner</b> Jonathan S. Lau	<b>Art Unit</b> 1623	

**-- 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 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, 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 \_\_\_\_\_.
- 2a)  This action is **FINAL**.                      2b)  This action is non-final.
- 3)  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**

- 4)  Claim(s) 1-60 is/are pending in the application.
  - 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5)  Claim(s) \_\_\_\_\_ is/are allowed.
- 6)  Claim(s) \_\_\_\_\_ is/are rejected.
- 7)  Claim(s) \_\_\_\_\_ is/are objected to.
- 8)  Claim(s) 1-60 are subject to restriction and/or election requirement.

**Application Papers**

- 9)  The specification is objected to by the Examiner.
- 10)  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).
- 11)  The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**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).
    - a)  All    b)  Some \*    c)  None of:
    - 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)**

- |  |   |
|--|---|
| <ul style="list-style-type: none"> <li>1) <input type="checkbox"/> Notice of References Cited (PTO-892)</li> <li>2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)</li> <li>3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br/>Paper No(s)/Mail Date _____.</li> </ul> | <ul style="list-style-type: none"> <li>4) <input type="checkbox"/> Interview Summary (PTO-413)<br/>Paper No(s)/Mail Date. _____.</li> <li>5) <input type="checkbox"/> Notice of Informal Patent Application</li> <li>6) <input type="checkbox"/> Other: _____.</li> </ul> |
|--|---|

## DETAILED ACTION

### *Election of Species Requirement*

This application contains claims directed to the following patentably distinct **First** species of disease, disorder or condition; **Second** species of iron carbohydrate complex and **Third** species of route of administration. The species are independent or distinct because claims to the different species recite the mutually exclusive characteristics of such species. In addition, these species are not obvious variants of each other based on the current record.

Examples of a **First** specie of disease, disorder or condition are:

- 1a) chronic blood loss, disclosed in claim 4,
- 1b) surgery or acute trauma, disclosed in claim 4,
- 1c) inflammatory bowel disease, disclosed in claim 6, and
- 1d) restless leg syndrome, disclosed in claim 9.

Examples of a **Second** specie of iron carbohydrate complex are:

- 2a) iron mannitol complex, disclosed in claim 25,
- 2b) iron polymaltose complex, disclosed in claim 25,
- 2c) iron carboxymaltose complex, disclosed in claims 25 and 26, and
- 2d) iron polyglucose sorbitol carboxymethyl ether complex, disclosed in claim 31.

Examples of a **Third** specie of route of administration are:

- 3a) parenterally, disclosed in claim 44,
- 3b) intravenously infused, disclosed in claim 46, and
- 3c) intravenously injected as a bolus, disclosed in claim 50.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, all claims are generic to the First specie of disease, disorder or condition, claims 1-25 and 33-57 are generic to the Second specie of iron carbohydrate complex and claims 1-43 and 57-60 are generic to the Third specie of route of administration.

There is an examination and search burden for these patentably distinct species due to their mutually exclusive characteristics. The species require a different field of search (e.g., searching different classes/subclasses or electronic resources, or employing different search queries); and/or the prior art applicable to one species would not likely be applicable to another species; and/or the species are likely to raise different non-prior art issues under 35 U.S.C. 101 and/or 35 U.S.C. 112, first paragraph.

**Applicant is advised that the reply to this requirement to be complete must include (i) an election of a species to be examined** even though the requirement may be traversed (37 CFR 1.143) **and (ii) identification of the claims encompassing the elected species**, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

The election of the species may be made with or without traverse. To preserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the election of species requirement, the election shall be treated as an election without traverse. Traversal must be presented at the time of election in order to be considered timely. Failure to timely traverse the requirement will result in the loss of right to petition under 37 CFR 1.144. If claims are added after the election, applicant must indicate which of these claims are readable on the elected species.

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the species unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other species.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which depend from or otherwise require all the limitations of an allowable generic claim as provided by 37 CFR 1.141.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

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