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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/750,022	12/29/2000	Indu J. Isaacs	016777/0454	6419

7590                      09/16/2003  
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EXAMINER

KAM, CHIH MIN

ART UNIT                      PAPER NUMBER

1653

DATE MAILED: 09/16/2003

13

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b> 09/750,022	<b>Applicant(s)</b> ISAACS, INDU J.	
	<b>Examiner</b> Chih-Min Kam	<b>Art Unit</b> 1653	

-- 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 MONTH(S) 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 the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- 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 09 July 2003.
- 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) 1-55 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5)  Claim(s) 36,39 and 40 is/are allowed.
- 6)  Claim(s) 1-35,37,38 and 41-55 is/are rejected.
- 7)  Claim(s) \_\_\_\_\_ is/are objected to.
- 8)  Claim(s) \_\_\_\_\_ 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).
- 11)  The proposed drawing correction filed on \_\_\_\_\_ is: a)  approved b)  disapproved by the Examiner.  
If approved, corrected drawings are required in reply to this Office action.
- 12)  The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. §§ 119 and 120**

- 13)  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.
- 14)  Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a)  The translation of the foreign language provisional application has been received.
- 15)  Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

**Attachment(s)**

- |   |   |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)                   | 4) <input checked="" type="checkbox"/> Interview Summary (PTO-413) Paper No(s). <u>13</u> . |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)          | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)                 |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____. | 6) <input type="checkbox"/> Other:  |

**DETAILED ACTION**

***Status of the Claims***

1. Claims 1-55 are pending.

Applicants' amendment filed July 9, 2003 (Paper No. 12) is acknowledged. Applicants' response has been fully considered. Claims 1, 14, 15 and 32 have been amended, and new claim 55 has been added. Therefore, claims 1-55 are examined.

**Rejection Withdrawn**

***Claim Rejections - 35 USC § 103***

2. The previous rejection of claims 1-10, 22, and 49-54 under 35 U.S.C. 103(a) as being unpatentable over Knudsen *et al.* (WO 99/43361) in view of Makino *et al.* (U. S. Patent 4,985,244), is withdrawn in view of applicants' response at pages 3-5 in Paper No. 12.
3. The previous rejection of claims 11, 12 and 31 under 35 U.S.C. 103(a) as being unpatentable over Knudsen *et al.* in view of Makino *et al.* as applied to claims 1-10 above, further in view of Hora *et al.* (U. S. Patent 5,997,856), is withdrawn in view of applicants' response at page 5 in Paper No. 12.
4. The previous rejection of claims 13-15 and 17-20 under 35 U.S.C. 103(a) as being unpatentable over Knudsen *et al.* in view of Makino *et al.* as applied to claim 1 above, further in view of Drucker *et al.* (WO 97/39031), is withdrawn in view of applicants' response at page 6 in Paper No. 12.
5. The previous rejection of claims 16 and 21 under 35 U.S.C. 103(a) as being unpatentable over Knudsen *et al.* in view of Makino *et al.* as applied to claim 1 above, further in view of Thim

*et al.* (U.S. Patent 5,912,229), is withdrawn in view of applicants' response at page 6 in Paper No. 12.

6. The previous rejection of claims 43-46 under 35 U.S.C. 103(a) as being unpatentable over Knudsen *et al.* in view of Makino *et al.* as applied to claim 1 above, further in view of Drucker (U. S. Patent 5,952,301), is withdrawn in view of applicants' response at pages 6-7 in Paper No. 12.

#### ***Claim Objections***

7. Claim 1 is objected to because the amended claim in the amendment filed July 9, 2003 (Paper No. 12) is not based on the previously amended claim 1 filed November 27, 2002 (Paper No. 8).

#### ***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

8. Claims 2-4, 17, 23-30, 34, 35, 37, 38, 41, 42, 44, 45 and 47-54 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

9. Claims 2-4, 34, 35, 37, 38, 44, 45, 50 and 51 are indefinite because of the use of the term "greater than about 6.0" or "greater than about 5.5". The term "greater than about 6.0" or "greater than about 5.5" renders the claim indefinite, it is unclear whether the pH of the formulation is greater than pH 6.0 (or 5.5), or less than pH 6.0 (5.5) as to "about". Claims 3, 4, 35, 38, 45 and 51 are included in this rejection for being dependent on rejected claims and not correcting the deficiency of the claims from which they depend.

10. Claims 23-25, for example, are indefinite because of the use of the term “less than about 5%”, “for up to at least 6 months” or “less than about 3 to about 4%”. The term “less than about 5%”, “for up to at least 6 months” or “less than about 3 to about 4%” renders the claim indefinite, it is unclear whether the water content in the lyophilized formulation is less than 5% as to “less than”, or greater than 5% as to “about”, whether the GLP-2 formulation is stable less than 6 months as to “up to” or greater than 6 months as to “about”, and the percentage of degradation of GLP-2 is in the range of 3 to 4% as to “about...to about”, or less than 3% as to “less than”. See also claims 26-30, 41, 42 and 47.

11. Claim 42 is indefinite because of the use of the term “no more than about 2%”. The term “no more than about 2%” renders the claim indefinite, it is unclear whether the water content is less than 2% as to “no more than” or greater than 2% as to “about”.

12. Claim 48 is indefinite because of the use of the term “up to about 24 hours”. The term “up to about 24 hours” renders the claim indefinite, it is unclear the GLP-2 formulation is stable less than 24 hours as to “up to”, or more than 24 hours as to “about”.

13. Claim 17 is indefinite because of the use of the term “one or more amino acid substitutions, additions, deletions or modifications” or “biological activity”. The term “one or more amino acid substitutions, additions, deletions or modifications” or “biological activity” renders the claim indefinite, it is unclear which amino acids are modified, and what amino acids are used for modifications, and what the biological activity is.

14. Claims 49-54 are indefinite because of the use of the term “a disorder, disease or condition” or “gastrointestinal disease”. The term “a disorder, disease or condition” or “gastrointestinal disease” renders the claim indefinite, it is unclear what disease is being treated.

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