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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

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Stephen A. Bent
FOLEY & LARDNER
Washington Harbour
3000 K Street, N.W., Suite 500
Washington, DC 20007-5109

EXAMINER

KAM, CHIH MIN

ART UNIT PAPER NUMBER

1653

DATE MAILED: 06/08/2004

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

Office Action Summary	Application No. 09/750,022	Applicant(s) ISAACS, INDU J.	
	Examiner Chih-Min Kam	Art Unit 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 16 March 2004.
- 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) 1-76 is/are pending in the application.
4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) Claim(s) 1,5-22,31-33,36,39,40,43,46,55,58,60-62,64 and 68-76 is/are allowed.
- 6) Claim(s) 2-4,23-30,34,35,37,38,41,42,44,45,47-54,56,57,59,63 and 65-67 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).
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)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 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 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Status of the Claims

1. Claims 1-76 are pending.

Applicants' amendment filed March 16, 2004 is acknowledged. Applicants' response has been fully considered. Claims 1, 25 and 52 have been amended, and new claims 56-76 have been added. Therefore, claims 1-76 are examined.

Rejection Withdrawn

Claim Rejections - 35 USC § 112

2. The previous rejection of claim 17 under 35 U.S.C. 112, second paragraph, as being indefinite, is withdrawn in view of applicants' response at page 14 in the amendment filed March 16, 2004, and applicant's response at page 4 in Paper No. 8.

Claim Rejections - 35 USC § 103

3. The previous rejection of claims 1-10, 22, and 49-55 under 35 U.S.C. 103(a) as being unpatentable over Knudsen *et al.* (WO 99/43361) in view of Yamazaki *et al.* (U. S. Patent 6,120,761), is withdrawn in view of applicants' response at pages 14-18 in the amendment filed March 16, 2004.
4. The previous rejection of claims 11, 12, 31 and 33 under 35 U.S.C. 103(a) as being unpatentable over Knudsen *et al.* (WO 99/43361) in view of Yamazaki *et al.* as applied to claims 1-10, further in view of Hora *et al.* (U. S. Patent 5,997,856), is withdrawn in view of applicants' response at pages 18-19 in the amendment filed March 16, 2004.
5. The previous rejection of claims 13-15, 17-20 and 32 under 35 U.S.C. 103(a) as being unpatentable over Knudsen *et al.* (WO 99/43361) in view of Yamazaki *et al.* and

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Hora *et al.*, as applied to claim 1, further in view of Drucker *et al.* (WO 97/39031), is withdrawn in view of applicants' response at page 19 in the amendment filed March 16, 2004.

6. The previous rejection of claims 16 and 21 under 35 U.S.C. 103(a) as being unpatentable over Knudsen *et al.* (WO 99/43361) in view of Yamazaki *et al.* as applied to claim 1, further in view of Thim *et al.* (U.S. Patent 5,912,229), is withdrawn in view of applicants' response at pages 19-20 in the amendment filed March 16, 2004.

7. The previous rejection of claims 43-46 under 35 U.S.C. 103(a) as being unpatentable over Knudsen *et al.* (WO 99/43361) in view of Yamazaki *et al.* as applied to claim 1, further in view of Drucker (U. S. Patent 5,952,301), is withdrawn in view of applicants' response at page 20 in the amendment filed March 16, 2004.

Claim Objections

8. Bracketing or underlining are commonly used to indicate amendments or changes in the claims as provided in 37 CFR 1.121(a)(2)(ii) and are normally not intended to be printed in the published patent. For example, in claims 56 and 57, applicant has used "h[Gly²]GLP-2" in such a manner that appears that the instant brackets would indicate deleted material and is thus, confusing as to whether the GLP-2 peptide in claims 56 and 57 would include "Gly²" or not. The applicant can only amend by cancellation and presentation of a new claim. See also changes to 37 CFR 1.121 in Amendment rules package (Final Rule published on 8 Sep. 2000 (65 Fed. Reg. 54603), see also O. G. of 19 Sep. 2000 (1238 Off. Gaz. Pat. Office 77)).

9. Claim 59 is objected to because of the use of terms "glu" and "PO₃-Tyr²". Use of "Glu" and "PO₃-Tyr" is suggested.

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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.

10. Claims 2-4, 23-30, 34, 35, 37, 38, 41, 42, 44, 45, 47-54, 56, 57, 59, 63, 65-67 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.

11. Claims 2-4, 34, 35, 37, 38, 44, 45, 50, 51, 56, 57, 65-67 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 higher than pH 6.0 (or 5.5) as to “greater than”, or, is less than pH 6.0 (5.5) as to “about”. Claims 3, 4, 35, 38, 45, 50, 51, 56, 57 and 65-67 are included in this rejection for being dependent on rejected claims and not correcting the deficiency of the claims from which they depend.

12. 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 is greater than 5% as to “about”, whether the GLP-2 formulation is stable less than 6 months as to “up to”, or, is 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, is less than 3% as to “less than”. See also claims 26-30, 41, 42 and 47.

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