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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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EXAMINER	
KAM, CHIH MIN	

ART UNIT	PAPER NUMBER
1653	10

DATE MAILED: 02/05/2003

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

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Office Action Summary	Application No.	Applicant(s)	
	09/750,022	ISAACS, INDU J.	
	Examiner	Art Unit	
	Chih-Min Kam	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 *27 November 2002* .

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) *1-54* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☒ Claim(s) *36-42* is/are ~~allowed~~. free of prior art

6)☒ Claim(s) *1-22,31,43-46 and 49-54* is/are rejected.

7)☒ Claim(s) *23-30,32-35,47,48* 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) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

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DETAILED ACTION

Status of the Claims

1. Claims 1-54 are pending.

Applicants' amendment filed November 27, 2002 (Paper No. 8) is acknowledged. Applicants' response has been fully considered. Claims 1, 14, 15 and 32 have been amended, and claims 1-54 are examined.

Priority Document

2. The priority document (United Kingdom 9930882.7, filed December 30, 1999) is acknowledged (Paper No. 9).

Objection Withdrawn

3. The previous objection to claims 14, 15 and 32 is withdrawn in view of the amendment to the claim, and applicants' response at page 3 in Paper No. 8.

Rejection Withdrawn

Claim Rejections - 35 USC § 112

4. The previous rejection of claims 1-54, under 35 U.S.C.112, second paragraph, is withdrawn in view of applicants' amendment to the claims, and applicants' response at pages 3-5 in Paper No. 8.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

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5. Claims 1-10; 22, and 49-54 are rejected 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).

Knudsen *et al.* teach a pharmaceutical composition comprising a GLP-2 derivative or analog, an isotonic agent such as mannitol, a buffer of histidine or sodium phosphate, a pharmaceutical acceptable carrier, a preservative and a surfactant, where the solubility and stability of GLP-2 is improved and the pharmaceutical formulation has pH 6.9 if phosphate buffer is used (page 4, line 19-29; page 3, lines 24-25; claims 1-4 and 10). The reference also indicates the concentration of the GLP-2 derivative is more than 0.5 mg and less than 100 mg/ml (page 4, lines 9-12; page 13, lines 16-19; claims 5-8), the formulation can be obtained in lyophilized form (page 13, line 10; claim 22), and the pharmaceutical composition can be administered by injection or means of infusion pump to treat small bowl syndrome or intestinal inflammation (page 12, lines 13-16; page 13, 16-24, claims 49-54). However, Knudsen *et al.* do not disclose using histidine as a stabilizing agent. Makino *et al.* disclose using 5% (w/v%) of histidine as a stabilizing agent in a vaccine composition (column 1, lines 15-20), which is about 1% (claim 9). At the time the invention was made, it would have been obvious to a person of ordinary skill in the art to use the pharmaceutical composition of GLP-2 analogs as indicated by Knudsen *et al.* with the addition of a stabilizing agent taught by Makino *et al.* to treat a gastrointestinal disease because the addition of histidine can further improve the stability of the pharmaceutical formulation. Thus, the combined references result in the claimed invention and was, as a whole, prima facie obvious at the time the claimed invention was made.

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7. Claims 11, 12 and 31 are rejected 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).

Knudsen *et al.* teach a pharmaceutical composition comprising a GLP-2 derivative or analog, an isotonic agent such as mannitol, a buffer of histidine or sodium phosphate, a pharmaceutical acceptable carrier, a preservative and a surfactant, where the solubility and stability of GLP-2 is improved and the pharmaceutical formulation has pH 6.9 if phosphate buffer is used (page 4, line 19-29; page 3, lines 24-25; claims 1-4 and 10), the concentration of the GLP-2 derivative is more than 0.5 mg and less than 100 mg/ml (page 4, lines 9-12; page 13, lines 16-19; claims 5-8), and Makino *et al.* disclose using 5% (w/v%) of histidine as a stabilizing agent in a vaccine composition (column 1, lines 15-20), which is about 1% (claim 9). However, Knudsen *et al.* and Makino *et al.* do not disclose the concentration of mannitol in the pharmaceutical composition. Hora *et al.* disclose 1-5% mannitol is used as a bulking agent in a protein preparation (column 25, lines 7-14). At the time the invention was made, it would have been obvious to a person of ordinary skill in the art using the pharmaceutical formulation of GLP-2 analogs as indicated by Knudsen *et al.* and Makino *et al.* with a known concentration of mannitol taught by Hora *et al.* (claims 11, 12 and 31) to treat a gastrointestinal disease because the addition of a known concentration of mannitol can further improve the stability of the pharmaceutical composition. Thus, the combined references result in the claimed invention and was, as a whole, prima facie obvious at the time the claimed invention was made.

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