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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

DATE MAILED: 10/04/2004

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 07 September 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) 1-54 and 58-78 is/are pending in the application.
  - 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5)  Claim(s) 31-42 is/are allowed.
- 6)  Claim(s) 1-8, 10-22, 43-46, 49-55, 58, 59, 63-71 and 73-78 is/are rejected.
- 7)  Claim(s) 9, 23-30, 47, 48 and 72 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)  Notice of References Cited (PTO-892)
- 2)  Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3)  Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_
- 4)  Interview Summary (PTO-413)  
Paper No(s)/Mail Date 0704.
- 5)  Notice of Informal Patent Application (PTO-152)
- 6)  Other: \_\_\_\_\_

**DETAILED ACTION**

1. The finality of the previous Office Action dated June 8, 2004 is withdrawn due to a new ground rejection.

***Status of the Claims***

2. Claims 1-54 and 58-78 are pending.

Applicants' amendment filed September 07, 2004 is acknowledged. Applicants' response has been fully considered. Claims 25-29, 42, 49 and 59 have been amended, claims 56 and 57 have been cancelled, and new claims 77 and 78 have been added. Therefore, claims 1-54 and 58-78 are examined.

**Objection Withdrawn**

3. The previous objection of claims 56, 57 and 59 is withdrawn in view of applicants' cancellation of the claim, applicants' amendment to the claim, and applicants' response at pages 13-14 in the amendment filed September 07, 2004.

**Rejection Withdrawn**

***Claim Rejections - 35 USC § 112***

4. The previous rejection of claims 2-4, 23-30, 34, 35, 37, 38, 41, 42, 44, 45, 47-54, 56, 57, 63, 65-67 are rejected under 35 U.S.C. 112, second paragraph under 35 U.S.C. 112, second paragraph, as being indefinite, is withdrawn in view of applicants' cancellation of the claim, applicants' amendment to the claim, and applicants' response at pages 14-17 in the amendment filed September 07, 2004.

***Claim Rejections - 35 USC § 112***

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

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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.

5. Claims 17 and 58-63 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.
6. Claims 17 and 58, 60-63 are indefinite because of the use of the term "one or more substitutions, additions, deletions, or modifications". The cited term renders the claim indefinite, it is not clear where the substitutions, additions, deletions, or modifications occur in the sequence and how many amino acids are substituted, added, deleted or modified, and what resulting sequence is.
7. Claim 59 is indefinite as to the claim recites amino acid substitutions at various positions without indicating "SEQ ID NO:" of the reference sequence, it is not clear what amino acid sequence these positions are referring to.

In response, applicants indicate the amino acid sequence of GLP-2 was well known in the art prior to the earlier priority date of the application, and further cite many patents and references to indicate various vertebrate forms of GLP-2 include, for example, rat GLP-2 and its homologues including ox GLP-2, porcine GLP-2, degu GLP-2, bovine GLP-2, guinea pig GLP-2, hamster GLP-2, human GLP-2, rainbow trout GLP-2, and chicken GLP-2, the sequences of which have been reported by many authors, and the practice of those skilled in the art was to indicate amino acid substitutions in the GLP-2 sequence by reciting, for example, "Lys<sup>20</sup>GLP-2" where the amino acid substitution, followed by the position number in superscript, precedes the peptide indicator GLP-2. The disclosure of the instant application conforms to this practice and

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describes GLP-2 as a 33 amino acid peptide (See e.g., page 6, lines 16-18 of the specification; pages 17-19 of the response).

The response has been considered, however, the argument is not found persuasive because there are sequence variations among different naturally occurring vertebrate GLP-2 peptides (see Fig. 2 of Buhl et al., J. Biol. Chem. 263, 8621-8624 (1988)) and synthetic GLP-2 peptides (e.g., Lys<sup>20</sup>Arg<sup>30</sup>GLP-2(1-33), Arg<sup>30</sup>Lys<sup>34</sup>GLP-2(1-35) in WO 99/43361, the reference has shown the parent sequence at page 7), thus, it is not clear which amino acid sequence is used for the substitution, and what resulting sequence the GLP-2 analog has, if only the position of substitution and amino acid residue substituted are given without a reference sequence. Furthermore, it is noted that both U. S. Patents 5,789,379 and 5,834,428 have "SEQ ID NO:" cited in the claims when there is a variation indicated in the sequence.

#### ***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 negated by the manner in which the invention was made.

8. Claims 1-8, 10, 22, 49-55, 58, 63-71, 73 and 78 are rejected under 35 U.S.C. 103(a) as being unpatentable over Knudsen *et al.* (WO 99/43361) in view of Kornfelt *et al.* (U. S. Patent 5,652,216, July 29, 1997).

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

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