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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|---|-------------|----------------------|---------------------|------------------|
| 16/249,275 | 01/16/2019 | Michael Soeberdt | 47TER10003VA | 9044 |
| 25006 | 7590 | 03/18/2020 | EXAMINER | |
| DINSMORE & SHOHL LLP 900 WILSHIRE DRIVE SUITE 300 TROY, MI 48084 | | | GARYU, LIANKO G | |
| | | | ART UNIT | PAPER NUMBER |
| | | | 1658 | |
| | | | NOTIFICATION DATE | DELIVERY MODE |
| | | | 03/18/2020 | ELECTRONIC |

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.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

MichiganPatTM@dinsmore.com

Office Action Summary

Application No.

16/249,275

Applicant(s)

Soeberdt et al.

Examiner

Lianko G Garyu

Art Unit

1658

AIA (FITF) Status

Yes

-- 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 MONTHS 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 19 December 2019.
 A declaration(s)/affidavit(s) under **37 CFR 1.130(b)** was/were filed on _____.
- 2a) This action is **FINAL**. 2b) This action is non-final.
- 3) An election was made by the applicant in response to a restriction requirement set forth during the interview on _____; the restriction requirement and election have been incorporated into this action.
- 4) 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*

- 5) Claim(s) 1-14 is/are pending in the application.
5a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 6) Claim(s) _____ is/are allowed.
- 7) Claim(s) 1-14 is/are rejected.
- 8) Claim(s) _____ is/are objected to.
- 9) Claim(s) _____ are subject to restriction and/or election requirement

* If any claims have been determined allowable, you may be eligible to benefit from the **Patent Prosecution Highway** program at a participating intellectual property office for the corresponding application. For more information, please see http://www.uspto.gov/patents/init_events/pph/index.jsp or send an inquiry to PPHfeedback@uspto.gov.

Application Papers

- 10) The specification is objected to by the Examiner.
- 11) 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).

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).

Certified copies:

- a) All b) Some** c) None of the:
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) Information Disclosure Statement(s) (PTO/SB/08a and/or PTO/SB/08b)
Paper No(s)/Mail Date _____
- 3) Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
- 4) Other: _____

DETAILED ACTION

Notice of Pre-AIA or AIA Status

The present application, filed on or after March 16, 2013, is being examined under the first inventor to file provisions of the AIA.

Status of Claims

Claims 1-14 are pending and under examination.

Claim Rejections - 35 USC § 112

Response to Arguments

The rejection of claim 8, 9 and 11- 14 under 35 U.S.C. 112(b) or 35 U.S.C. 112 (pre-AIA), second paragraph has been withdrawn as necessitated by amendment.

Claim Rejections - 35 USC § 103

In the event the determination of the status of the application as subject to AIA 35 U.S.C. 102 and 103 (or as subject to pre-AIA 35 U.S.C. 102 and 103) is incorrect, any correction of the statutory basis for the rejection will not be considered a new ground of rejection if the prior art relied upon, and the rationale supporting the rejection, would be the same under either status.

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

A patent for a claimed invention may not be obtained, notwithstanding that the claimed invention is not identically disclosed as set forth in section 102, if the differences between the claimed invention and the prior art are such that the claimed invention as a whole would have been obvious before the effective filing date of the claimed invention to a person having ordinary skill in the art to which the claimed invention pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims the examiner presumes that the subject matter of the various claims was commonly owned as of the effective filing date of the claimed invention(s) absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and effective filing dates of each claim that was not commonly owned as of the effective filing date of the later invention in order for the examiner to consider the applicability of 35 U.S.C. 102(b)(2)(C) for any potential 35 U.S.C. 102(a)(2) prior art against the later invention.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103 are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

The rejection basis is maintained.

Claims 1-12 and 14 are rejected under 35 U.S.C. 103 as being unpatentable over Ferreira et al. (US 5,389,615; 1995) and Brzoska et al. ("α-Melanocyte-Stimulating Hormone and Related Tripeptides: Biochemistry, Antiinflammatory and Protective Effects in Vitro and in Vivo, and Future Perspectives for the Treatment of Immune-Mediated Inflammatory Diseases", Endocrine Reviews, 2007;

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pp. 581-602) in view of Zomaro (US 5,718,882; 1998), Gentilucci et al. ("Chemical Modifications Designed to Improve Peptide Stability: Incorporation of Non-Natural Amino Acids, Pseudo-Peptide Bonds, and Cyclization", Current Pharmaceutical Design, 2010, pp. 3185-3203; cited in the IDS), Chatterjee et al. (N-Methylation of Peptides: A New Perspective in Medicinal Chemistry", Accounts of Chemical Research, 2008, pp. 1331-1342), and The National Center for Biotechnology Information ("6-Amino-2-(dimethylamino)hexanoic acid" (2007); "N-Methyl-L-valine" (2005) and "N-Methyl-L-threonine" (2006)).

Ferreira et al. teach the tripeptides Lys-Pro-Thr, Lys-D-Pro-Thr, Lys-Pro-Val and Lys-D-Pro-Val (see col. lines 46-48), medicaments comprising the tripeptides and methods of treating pain with the tripeptides thereof (see e.g., the abstract; col. 1, lines 30-51; col. 3, line 53-col. 5, line 3). Brzoska et al. teach the tripeptides are anti-inflammatory peptides (see e.g., Table 6, §8. α -MSH in experimentally induced acute pancreatitis sand §IV. Anti-inflammatory Effects of α -MSH-Related Tripeptides *in Vitro* and *in Vivo*) and further suggest administering the tripeptides to treat immune-mediated inflammatory diseases, e.g., pancreatitis, eczema (inflammatory disease of the skin), allergic asthma, rheumatoid arthritis (inflammatory disease of the joints), and inflammatory bowel disease because of the activity of the KPV tripeptide is very similar to α -MSH (see p. 596, right col.-1st para.-p. 597, right col. continuing paragraph).

The difference between the tripeptides of Ferreira et al. and Brzoska et al. and the peptides of claims 1-12 and 14 is the methylation of the N- and C-termini amino

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