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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
17/940,950	09/08/2022	Scott Thompson	58907-714.301	2743
21971	7590	03/10/2023	EXAMINER	
WILSON SONSINI GOODRICH & ROSATI			CHONG, YONG SOO	
650 PAGE MILL ROAD			ART UNIT	
PALO ALTO, CA 94304-1050			PAPER NUMBER	
			1627	
			NOTIFICATION DATE	
			DELIVERY MODE	
			03/10/2023	
			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):

patentdocket@wsgr.com

# Office Action Summary

**Application No.**

17/940,950

**Applicant(s)**

Thompson, Scott

**Examiner**

Yong S Chong

**Art Unit**

1627

**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 2/21/23.

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) 25-44 is/are pending in the application.

5a) Of the above claim(s) 32,38 and 42-44 is/are withdrawn from consideration.

6)  Claim(s) \_\_\_\_\_ is/are allowed.

7)  Claim(s) 25-31,33-37 and 39-41 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](http://www.uspto.gov/patents/init_events/pph/index.jsp) or send an inquiry to [PPHfeedback@uspto.gov](mailto: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)

3)  Interview Summary (PTO-413)

Paper No(s)/Mail Date \_\_\_\_\_.

2)  Information Disclosure Statement(s) (PTO/SB/08a and/or PTO/SB/08b)

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 the Application***

Applicant's election of Group I, drawn to a method of treating depression in a subject in need thereof by administering a serotonin receptor 2A antagonist and a serotonin agonist, as well as the species, ketanserin and psilocybin, in the reply filed on 2/21/23 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.01(a)).

Claims 25-44 are pending. Claims 42-44 have been withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention, there being no allowable generic or linking claim. Claims 32 and 38 have been withdrawn from further consideration as being drawn to a non-elected species. Claims 25-31, 33-37, 39-41 are examined herein insofar as they read on the elected invention and species.

***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

Claims 25-31, 33, 36-37, 40-41 are rejected under 35 U.S.C. 102(a) as being anticipated by Perez et al. (WO 2019/081764 A1, of record).

Perez et al. teach a pharmaceutical combination of a compound of formula I and a 5-HT<sub>2A</sub> receptor antagonist (claim 1) for the use in the treatment of depression (claim 9). A preferred compound of formula I is psilocybin (page 18, line 25), which can be extracted from mushrooms (page 19, lines 15-16). A preferred 5-HT<sub>2A</sub> receptor antagonist is ketanserin (claim 4). The compound of formula I and 5-HT<sub>2A</sub> receptor antagonist can be administered together or separately (page 12, lines 24-25). The 5-HT<sub>2A</sub> receptor antagonist alleviates or removes the hallucinogenic side effects of the compound of formula I (abstract).

It is noted that the limitation regarding “wherein the serotonin receptor 2A antagonist increases locomotor activity” is considered inherent since this mechanism of action will necessarily occur in vivo when administered the serotonin receptor 2A antagonist.

***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.

The factual inquiries set forth in *Graham vs 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(a) 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.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 34-35, 39 are rejected under 35 U.S.C. 103(a) as being obvious over Perez et al. (WO 2019/081764 A1, of record), as applied to claims 25-31, 33, 36-37, 40-41, in view of Kucuksen (WO 2018/135943 A1, of record).

The instant claims are directed to a method of treating depression in a subject in need thereof by administering a serotonin receptor 2A antagonist and a serotonin agonist.

Perez et al. teach as discussed above, however, fail to teach the specifically claimed mushroom and depression.

Kucuksen teaches using psilocybin in combination with cannabinoids or terpenes for the treatment of psychological and brain disorders, such as depression (claims 1-2), and more specifically major depression (page 1, lines 33-34; and claim 2), psychotic depression (claim 2), or postpartum depression (claim 15). Kucuksen also teaches that psilocybin can be extracted from the following mushroom and/or truffle: Psilocybe, Gymnopilus, Panaeolus, Copelandia, Hypholoma, Pluteus, Inocybe, Conocybe, Panaeolina, Gerronema, Agrocybe, Galerina and/or Mycena, and more preferably P. azurescens, P. semilanceata, P. cyanescens, and/or P. cubensis, P. subcubensis, P. tampanensis, P. mexicana A, P. atlantis, and/or P. semilanceata (claim 10).

Therefore, it would have been prima facie obvious to a person of ordinary skill in the art, at the time the claimed invention was made, to have used psilocybin that has been extracted from the claimed mushroom and/or truffle in the method of treating major depression, psychotic depression, or postpartum depression, as taught by Kucuksen, by administering the pharmaceutical combination of the compound of formula I (psilocybin) and the 5-HT<sub>2A</sub> receptor antagonist (ketanserin), as taught by Perez.

A person of ordinary skill in the art would have been motivated to use psilocybin that has been extracted from the claimed mushroom and/or truffle because both Perez and Kucuksen teach that psilocybin is primarily found and extracted from these mushrooms and truffles. A person of ordinary skill in the art would have been motivated to treat major depression, psychotic depression, or postpartum depression because

Perez teaches that the treatment of depression, in general. Furthermore, both Perez and Kucusen teach that psilocybin is useful in the treatment of these specific types of depression. Therefore, one of ordinary skill in the art would have had a reasonable expectation of success in treating major depression, psychotic depression, or postpartum depression by administering pharmaceutical combination of psilocybin and ketanserin.

### ***Conclusion***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Yong S. Chong whose telephone number is (571)-272-8513. The examiner can normally be reached Monday to Friday: 9 am to 5 pm EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Kortney Klinkel, can be reached at (571)-270-5239. The fax phone number for the organization where this application or proceeding is assigned is (571)-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at (866)-217-9197 (toll-free).

/Yong S. Chong/  
Primary Examiner, Art Unit 1627