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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
18/053,648	11/08/2022	Judith BLUMSTOCK	55554-701.301	1222

21971 7590 04/24/2023

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EXAMINER
WELLS, LAUREN QUINLAN

ART UNIT	PAPER NUMBER
1622	

NOTIFICATION DATE	DELIVERY MODE
04/24/2023	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. 18/053,648	Applicant(s) BLUMSTOCK et al.	
	Examiner LAUREN WELLS	Art Unit 1622	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 4/12/2023.

☐ 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) 1-20 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) 1-20 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: _____.

-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.

DETAILED ACTION

This Office Action is in response to Applicant's Arguments and Amendment filed, 04/12/2023, wherein claims 1-7 were amended.

Claims 1-20 are pending.

REJECTIONS WITHDRAWN

The status for each rejection and/or objection in the previous Office Action is set out below.

Priority

Applicant's amendment to the instant claims is sufficient to overcome the objection to the priority of the instant claims. The instant claims are afforded a priority date of 01/30/2019.

Specification Objections

-Applicant's amendment to the title is sufficient to overcome the objection.

-Applicant's amendment to the specification is sufficient to overcome the objection.

REJECTIONS—NEW and MODIFIED

The below modified and new rejections are necessitated by Applicant's amendment to the claims. These rejections are over the same prior art references relied upon in the previous Office Action. New and modified rejections are bolded below.

Claim Rejections - 35 USC § 112

The following is a quotation of 35 U.S.C. 112(d):

> (d) REFERENCE IN DEPENDENT FORMS.—Subject to subsection (e), a claim in dependent form shall contain a reference to a claim previously set forth and then specify a further limitation of the subject matter claimed. A claim in dependent form shall be construed to incorporate by reference all the limitations of the claim to which it refers.

The following is a quotation of pre-AIA 35 U.S.C. 112, fourth paragraph:

> Subject to the following paragraph [i.e., the fifth paragraph of pre-AIA 35 U.S.C. 112], a claim in dependent form shall contain a reference to a claim previously set forth and then specify a further limitation of the subject matter claimed. A claim in dependent form shall be construed to incorporate by reference all the limitations of the claim to which it refers.

Claim 7 is rejected under 35 U.S.C. 112(d) or pre-AIA 35 U.S.C. 112, 4th paragraph, as being of improper dependent form for failing to further limit the subject matter of the claim upon which it depends, or for failing to include all the limitations of the claim upon which it depends.

Claim 7, which depends on claim 3, which depends on claim 1, recites a "The method of claim 3, wherein the improving the symptoms of the disorder involving cognitive function ameliorates the anxiety, cognitive or depressive disorder," However, claim 1, recites "A method of improving symptoms of a disorder involving cognitive function" and claim 3 recites "wherein the disorder is an anxiety, cognitive or depressive disorder." **As such, claim 7 does not further limit claim 3 since claim 3 is already directed toward a method of improving symptoms of an anxiety, cognitive or depressive disorder and since ameliorate is defined as to make something better.**

Applicant may cancel the claim(s), amend the claim(s) to place the claim(s) in proper dependent form, rewrite the claim(s) in independent form, or present a sufficient showing that the dependent claim(s) complies with the statutory requirements.

Claim Rejections - 35 USC § 102

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

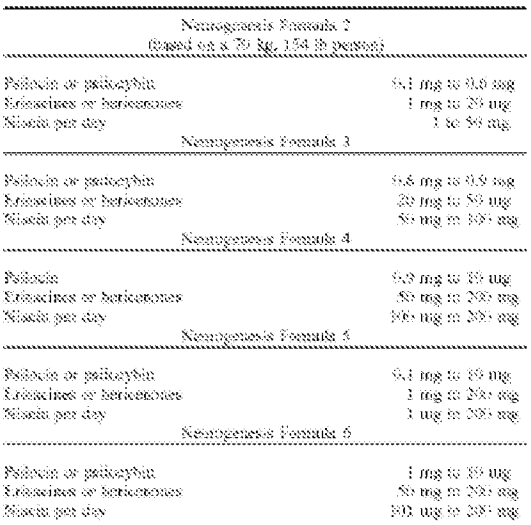
> A person shall be entitled to a patent unless –
>
> (a)(1) the claimed invention was patented, described in a printed publication, or in public use, on sale, or otherwise available to the public before the effective filing date of the claimed invention.
>
> (a)(2) the claimed invention was described in a patent issued under section 151, or in an application for patent published or deemed published under section 122(b), in which the patent or application, as the case may be, names another inventor and was effectively filed before the effective filing date of the claimed invention.

Claims 1-20 are rejected under 35 U.S.C. 102(a)(1) and 102(a)(2) as being anticipated by US 10,729,706 to Kucuksen (effectively filed 01/18/2017, IDS of 11/23/2022).

Kucuksen '706 teaches a method for preventing or treating a psychological disorder in a patient by administering psilocybin and/or psilocin in combination with a cannabinoid (Col. 13, claim 1). The compositions are taught as comprising pharmaceutically acceptable carriers (Col. 8, lines 34-49, Col. 9, lines 35-59, Col. 16, claim 19).

Depression, anxiety disorder such as generalized anxiety disorder, attention disorder, such as ADHD, and others are taught as psychological disorders (Col. 3, lines 62-Col. 5, line 5, Col. 10, line 45-Col. 12, line 35, Cols. 13-14, claim 2).

Exemplified is the treatment of depression, anxiety disorder, attention deficit syndrome, and more (Col. 12-13, Example 1).



Neurogenesis Formula 2 (based on a 70 kg, 154 lb person)	
Psilocin or psilocybin	0.1 mg to 0.6 mg
Ketamines or benzenones	1 mg to 20 mg
Niacin per day	1 to 50 mg
Neurogenesis Formula 3	
Psilocin or psilocybin	0.6 mg to 0.9 mg
Ketamines or benzenones	20 mg to 50 mg
Niacin per day	50 mg to 100 mg
Neurogenesis Formula 4	
Psilocin	0.9 mg to 10 mg
Ketamines or benzenones	50 mg to 200 mg
Niacin per day	100 mg to 200 mg
Neurogenesis Formula 5	
Psilocin or psilocybin	0.1 mg to 10 mg
Ketamines or benzenones	1 mg to 200 mg
Niacin per day	1 mg to 200 mg
Neurogenesis Formula 6	
Psilocin or psilocybin	1 mg to 10 mg
Ketamines or benzenones	50 mg to 200 mg
Niacin per day	100 mg to 200 mg

Exemplified are the following formulations: (paragraph 15).

Exemplified are oral doses (Example 1).

The quantity of active compound per unit dose may be varied according to the nature of the active compound and the intended dosage regime. Generally, an effective amount shall be used, which may be within the range of from 0.01mg to 5000 mg (Col. 10, lines 14-21).

The appropriate effective amount may be determined by one of ordinary skill in the art using only routine experimentation or prior knowledge in the art in view of the present disclosure. The effective ranges/dosages are not expected to be precisely the same for all compounds. Dosages may be optimized with each compound when the pharmokinetics are studies to see how each compound is metabolized, which may alter the dose ranges. This neuro-enhancing is best managed in consultation with a skilled medical professional (paragraph 11).

While Kucuksen does not explicitly teach "in an amount insufficient to provide a hallucinogenic experience," it is reasonable to assume that the composition comprising 0.1-0.6, 0.6-0.9 and 0.9-10mg of psilocybin or psilocin of Kucuksen would have the same property since it is administered for the same purpose (treating depression, anxiety, and ADHD) in the same dosage (0.1-6 mg), to the same population (subjects suffering from

depression, anxiety, and ADHD) as that taught by the instant specification and claims. Thus, while the prior art does not explicitly teach these properties, burden is on Applicant to show that the prior art does not have these properties.

While Kucuksen '706 does not explicitly teach maximum plasma concentrations, it is reasonable to assume that Kucuksen's compositions comprising 0.1mg-10mg of psilocybin for the treatment of psychological disorders such as depression, anxiety, and attention deficit syndrome would have the same properties since they are administered for the same purpose (treatment of cognitive/mood disorders), to the same population (patients with depression/anxiety/attention deficit), and in the same dosage amounts as that taught by the instant specification and claims. Thus, while the prior art does not explicitly teach these properties, burden is on Applicant to show that the prior art does not have these properties.

Applicants are reminded that the office does not have the facilities and resources to provide the factual evidence needed in order to establish that the product of the prior art does not possess the same material, structural and functional characteristics of the claimed product. In the absence of evidence to the contrary, the burden is on the applicant to prove that the claimed product is different from those taught by the prior art and to establish patentable differences. See In re Best 562F.2d 1252, 195 USPQ 430 (CCPA 1977) and Ex parte Gray 10 USPQ 2d 1922 (PTO Bd. Pat. App. & Int. 1989).

RESPONSE TO ARGUMENTS

In view of the newly applied rejection over Kucuksen, the instant arguments are moot. However, in view of compact prosecution, arguments pertinent to the above newly applied rejection, will be addressed below.

It is first noted that Applicant's assertion that "The office admits that Kucuksen fail to (1). . .(7). . .instant claims," is not correct. As seen in the previous Office Action, the office did not admit (1)-(7).

Applicant argues that none of the references suggest that a skilled artisan would have any reason to use or expectation of success in using a non-hallucinogenic amount of psilocybin or psilocin to treat any disorder.

This argument is not persuasive. As stated in the above rejection, Kucuksen exemplifies the following formulations:

Neurogenesis Formula 2 (based on a 70 kg, 154 lb person)	
Psilocin or psilocybin	0.1 mg to 6.6 mg
Ibrutinibs or derivatives	1 mg to 20 mg
Niacin per day	1 to 50 mg
Neurogenesis Formula 3	
Psilocin or psilocybin	0.6 mg to 0.9 mg
Ibrutinibs or derivatives	20 mg to 50 mg
Niacin per day	50 mg to 100 mg
Neurogenesis Formula 4	
Psilocin	0.9 mg to 10 mg
Ibrutinibs or derivatives	50 mg to 250 mg
Niacin per day	100 mg to 250 mg
Neurogenesis Formula 5	
Psilocin or psilocybin	0.1 mg to 10 mg
Ibrutinibs or derivatives	1 mg to 250 mg
Niacin per day	1 mg to 250 mg
Neurogenesis Formula 6	
Psilocin or psilocybin	1 mg to 10 mg
Ibrutinibs or derivatives	20 mg to 250 mg
Niacin per day	100 mg to 250 mg

(paragraph 15). Furthermore, while Kucuksen does not explicitly teach "in an amount insufficient to provide a hallucinogenic experience," it is reasonable to assume that the composition comprising 0.1-0.6, 0.6-0.9 and 0.9-10mg of psilocybin or psilocin of Kucuksen would have the same property since it is administered for the same purpose (treating depression, anxiety, and ADHD) in the same dosage (0.1-6 mg), to the same population (subjects suffering from depression, anxiety, and ADHD) as that taught by the instant specification and claims. Thus, while the prior art does not explicitly teach these properties, burden is on Applicant to show that the prior art does not have these properties.

Claims 1-5, 7-8, 12-20 are rejected under 35 U.S.C. 102(a)(1) and 102(a)(2) as being anticipated by US 10,947,257 to Londesbrough (effectively filed 10/09/2018, PTO-892).

Londesbrough '257 teaches a method of treating central nervous system disorders, such as major depressive disorder by administering an oral dosage form of psilocybin with a carrier (Col. 3, lines 46-55, Col. 69-70, claims 1 and 21).

1mg-40mg of psilocybin is taught (Col. 69, claim 2). 5mg is taught (Col. 69, claim 3).

While Londesbrough '257 does not explicitly teach "in an amount insufficient to provide a hallucinogenic experience," it is reasonable to assume that the composition comprising 5mg of psilocybin of Londesbrough would have the same property since it is administered for the same purpose (treating depression) in the same dosage (0.1-6 mg), to the same population (subjects suffering from depression) as that taught by the instant specification and claims. Thus, while the prior art does not explicitly teach these properties, burden is on Applicant to show that the prior art does not have these properties.

While Londesbrough '257 does not explicitly teach maximum plasma concentrations, it is reasonable to assume that Londesbrough's compositions comprising 5mg of psilocybin for the treatment of depression and anxiety would have the same properties since they are administered for the same purpose (treatment of cognitive/mood disorders), to the same population (patients with depression/anxiety), and in the same dosage as that taught by the instant specification and claims. Thus, while the prior art does not explicitly teach these properties, burden is on Applicant to show that the prior art does not have these properties.

Applicants are reminded that the office does not have the facilities and resources to provide the factual evidence needed in order to establish that the product of the prior art does not possess the same material, structural and functional characteristics of the claimed product. In the absence of evidence to the contrary, the burden is on the applicant to prove that the claimed product is different from those taught by the prior art and to establish patentable differences. See In re Best 562F.2d 1252, 195 USPQ 430 (CCPA 1977) and Ex parte Gray 10 USPQ 2d 1922 (PTO Bd. Pat. App. & Int. 1989).

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.

The factual inquiries 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.

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.

Claims 9-11 are rejected under 35 U.S.C. 103 as being unpatentable over US 10,947,257 to Londesbrough (effectively filed 10/09/2018, PTO-892), as applied to claims **1-5, 7-8, 12-20 above.**

Londesbrough is applied as discussed in the above 35 USC 102 rejection.

While Londesbrough '257 teaches a method of treating depression with psilocybin, it differs from that of the instantly claimed invention in that it does not exemplify the treatment of anxiety or exemplify 0.1 to 2.5mg amounts of psilocybin.

Londesbrough additionally teaches it methods for the treatment of generalized anxiety disorder (Col. 21, lines 44-59).

Administration of microdoses of psilocybin in the range of 0.05 to 2.5mg is taught (Col. 20, lines 41-67).

It would have been prima facie obvious to one of ordinary skill in the art, prior to the effective filing date of the instantly claimed invention, to apply a method of treating generalized anxiety disorder to the methods of Londesbrough '257, to arrive at the instantly claimed invention. One of ordinary skill in the art would have been motivated to apply a method of treating generalized anxiety disorder to the methods of Londesbrough '257, with a reasonable expectation of success, because Londesbrough '257 teaches its methods for the treatment of generalized anxiety disorder.

It would have been prima facie obvious to one of ordinary skill in the art, prior to the effective filing date of the instantly claimed invention, to modify the amount of psilocybin of Londesbrough `257 to 0.05 to 2.5mg, to arrive at the instantly claimed invention. One of ordinary skill in the art would have been motivated to modify the amount of psilocybin of Londesbrough `257 0.05 to 2.5mg, with a reasonable expectation of success, because Londesbrough teaches that microdoses of psilocybin can be administered in the range of 0.05mg to 2.5mg and "[W]here the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation." See MPEP 2144.05(II).

Claim 6 is rejected under 35 U.S.C. 103 as being unpatentable over US 10,947,257 to Londesbrough (effectively filed 10/09/2018, PTO-892), as applied to claims **1-5, 7-8, 12-20 above,** and further in view of US 10,729,706 to Kucuksen (effectively filed 01/18/2017, IDS of 11/23/2022).

Londesbrough '257 is applied as discussed in the above 35 USC 102 rejection.

While Londesbrough teaches a method of treating depression and anxiety by administering psilocybin, it differs from that of the instantly claimed invention in that it does not teach treating subjects with attention disorders.

Kucuksen '706 is discussed in the above 35 USC 102 rejection and incorporated herein.

In particular, Kucuksen '706 teaches the treatment of psychological disorders with psilocybin or psilocin and specifically teaches and exemplifies depression, anxiety disorder such as generalized anxiety disorder, and attention disorder, such as ADHD, as the psychological disorders (Col. 3, lines 62-Col. 5, line 5, Col. 10, line 45-Col. 12, line 35, Cols. 13-14, claim 2).

It would have been prima facie obvious to one of ordinary skill in the art, prior to the effective filing date of the instantly claimed invention, to modify the methods of Londesbrough to treat subjects with attention disorders, as taught by Kucuksen, to arrive at the instantly claimed invention. One of ordinary skill in the art would have been motivated to modify the methods of Londesbrough to treat subjects with attention disorders, with a reasonable expectation of success, because Londesbrough teaches methods of treating central nervous system disorders with compositions comprising psilocybin and Kucuksen teaches attention deficit syndrome as a psychological disorder that can be treated with compositions comprising psilocybin.

RESPONSE TO ARGUMENTS

In view of the newly applied rejection over Londesbrough, the instant arguments are moot. However, in view of compact prosecution, arguments pertinent to the above newly applied rejection, will be addressed below.

It is first noted that Applicant's assertion that "The office admits that Londesbrough fail to (1). . .(7). . .instant claims," is not correct. As seen in the previous Office Action, the office did not admit (1)-(7).

Applicant argues that none of the references suggest that a skilled artisan would have any reason to use or expectation of success in using a non-hallucinogenic amount of psilocybin or psilocin to treat any disorder.

Londesbrough '257 teaches a method of treating central nervous system disorders, such as major depressive disorder by administering an oral dosage form of psilocybin with a carrier (Col. 3, lines 46-55, Col. 69-70, claims 1 and 21) and administration of 5mg psilocybin is taught (Col. 69, claim 3).

While Londesbrough '257 does not explicitly teach "in an amount insufficient to provide a hallucinogenic experience," it is reasonable to assume that the composition comprising 5mg of psilocybin or psilocin of Londesbrough would have the same property since it is administered for the same purpose (treating depression) in the same dosage (5mg), to the same population (subjects suffering from depression) as that taught by the instant specification and claims. Thus, while the prior art does not explicitly teach these properties, burden is on Applicant to show that the prior art does not have these properties.

Applicant argues that because Londesbrough cites references that teach doses of psilocybin that result in hallucinogenic experiences that Londesbrough therefore teaches away from "in an amount insufficient to provide a hallucinogenic experience."

This argument is not persuasive. It is first noted that there are 21 pages of cited references. While these references are cited, they are not incorporated into the body of Londesbrough '257. As such, the teachings of these references have no bearing on the instant rejection.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on nonstatutory double patenting provided the reference application or patent either is shown to be commonly owned with the examined application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement. See MPEP § 717.02 for applications subject to examination under the first inventor to file provisions of the AIA as explained in MPEP § 2159. See MPEP § 2146 *et seq.* for applications not subject to examination under the first inventor to file provisions of the AIA. A terminal disclaimer must be signed in compliance with 37 CFR 1.321(b).

The USPTO Internet website contains terminal disclaimer forms which may be used. Please visit www.uspto.gov/patent/patents-forms. The filing date of the application in which the form is filed determines what form (e.g., PTO/SB/25, PTO/SB/26, PTO/AIA/25, or

PTO/AIA/26) should be used. A web-based eTerminal Disclaimer may be filled out completely online using web-screens. An eTerminal Disclaimer that meets all requirements is auto-processed and approved immediately upon submission. For more information about eTerminal Disclaimers, refer to www.uspto.gov/patents/process/file/efs/guidance/eTD-info-I.jsp.

Claims 1-20 are provisionally rejected on the ground of nonstatutory double patenting as being unpatentable over claims 1-38 of copending Application No. 18/102,268 (reference application). Although the claims at issue are not identical, they are not patentably distinct from each other.

‘268 claims a method for treating or managing a mental, behavioral or a neuropsychiatric condition in an individual who suffers from or susceptible to a mental, behavioral or neuropsychiatric condition, by administering a therapeutically effective amount of one or more 5-hydroxytryptamine (5HT) receptor agonist.

Cognitive disorders such as depression, anxiety and attention disorders are claimed.

A method for increasing motivation is claimed.

Administration of a therapeutically effective amount of a THT receptor agonist below a hallucinogenic threshold is claimed.

Plasma concentrations are claimed.

Psilocybin and psilocin are claimed as 5HT receptor agonists.

Oral formulations are claimed.

This is a provisional nonstatutory double patenting rejection because the patentably indistinct claims have not in fact been patented.

RESPONSE TO ARGUMENTS

Applicant argues that US 18/102,268 has a later effective filing date over the instant application and that he rejection should therefore be withdrawn.

This argument is not persuasive. The effective filing date of '268 or the instant application has no bearing on the Double Patenting Rejection.

Some commonality of inventorship or (deemed) ownership must exist between two or more patents or applications before consideration can be given to the issue of double patenting. For example, the patents or applications may have the same inventive entity. The patents or applications may also have at least one common (joint) inventor, which covers the situations where at least one patent or application names a sole inventor and the other patent(s) or application(s) names joint inventors and where all the patents or applications name joint inventors. For example, if one application names inventor A and the second application names joint inventors A and B, then the applications have one common (joint) inventor. As another example, if one application names joint inventors A and B and a second application names joint inventors A, B, and C, then the applications have two common joint inventors, and thus, have at least one common joint inventor. See 35 U.S.C. 100(f) for definition of "inventor" and 35 U.S.C. 100(g) for definition of "joint inventor". Alternatively, the patents or applications may have a common applicant, and/or be commonly assigned/owned or non-commonly assigned/owned but subject to a joint research agreement as set forth in 35 U.S.C. 102(c) or in pre-AIA 35 U.S.C. 103(c)(2) and (3). To determine if subject matter excepted as prior art under 35 U.S.C. 102(b)(2)(C) or disqualified as prior art under pre-AIA 35 U.S.C. 103(c) may be considered for double patenting issues, see MPEP § 804.03. See MPEP 804.

Conclusion

No claims are allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to LAUREN WELLS whose telephone number is (571)272-7316. The examiner can normally be reached M-F 7:00-4:30.

Examiner interviews are available via telephone, in-person, and video conferencing using a USPTO supplied web-based collaboration tool. To schedule an interview, applicant is encouraged to use the USPTO Automated Interview Request (AIR) at http://www.uspto.gov/interviewpractice.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brandon Fetterolf can be reached on 571-272-2919. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of published or unpublished applications may be obtained from Patent Center. Unpublished application information in Patent Center is available

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/L.Q.W./
Examiner, Art Unit 1622

/BRANDON J FETTEROLF/
Supervisory Patent Examiner, Art Unit 1622

AMENDMENTS TO THE CLAIMS

This listing of claims replaces all prior versions and listing of claims in the above-referenced patent application. The following amendments do not constitute an admission regarding the patentability of the amended subject matter and should not be so construed.

Listing of the Claims

1. **(Currently Amended)** A method of improving ~~motivation or~~ symptoms of a disorder involving cognitive function ~~engagement~~ in a subject in need thereof, the method comprising administering to the subject a pharmaceutical composition comprising:
   a) a therapeutically effective and non-hallucinogenic amount of psilocybin or psilocin, wherein the psilocybin or psilocin is in an amount of about 0.1 mg to about 6 mg; and
   b) a pharmaceutically acceptable excipient;
   wherein the therapeutically effective and non-hallucinogenic amount of the psilocybin or psilocin is provided to the subject in need thereof in an amount insufficient to provide a hallucinogenic experience.
2. **(Currently Amended)** The method of claim 1, wherein the disorder is ~~subject is suffering from~~ a mood or cognitive disorder.
3. **(Currently Amended)** The method of claim 1, wherein the disorder is ~~subject is suffering from~~ an anxiety, cognitive, or depression disorder.
4. **(Currently Amended)** The method of claim 3, wherein the disorder is ~~subject is suffering from~~ an anxiety disorder.
5. **(Currently Amended)** The method of claim 4, wherein the anxiety disorder is generalized anxiety disorder.
6. **(Currently Amended)** The method of claim 3, wherein ~~the subject is suffering from a cognitive disorder, and~~ the cognitive disorder is an attention disorder.
7. **(Currently Amended)** The method of claim 3, wherein the improving the symptoms of the disorder involving cognitive function ameliorates ~~method is for treating~~ the anxiety, cognitive, or depression disorder.
8. **(Original)** The method of claim 1, wherein the therapeutically effective and non-hallucinogenic amount of the psilocybin or psilocin is no more than 5 mg.

9. **(Original)** The method of claim 1, wherein the therapeutically effective and non-hallucinogenic amount of the psilocybin or psilocin is about 0.5 mg to about 4 mg.
10. **(Original)** The method of claim 1, wherein the therapeutically effective and non-hallucinogenic amount of the psilocybin or psilocin is no more than 3.5 mg.
11. **(Original)** The method of claim 1, wherein the therapeutically effective and non-hallucinogenic amount of the psilocybin or psilocin is about 0.5 mg to about 2.5 mg.
12. **(Original)** The method of claim 1, wherein the therapeutically effective and non-hallucinogenic amount of the psilocybin or psilocin is provided to the subject in need thereof in an amount and/or formulation to provide a maximum plasma concentration (C_{max}) of active form of the psilocybin or psilocin of about 0.5 ng/mL or more and less than 6 ng/mL.
13. **(Original)** The method of claim 1, wherein the therapeutically effective and non-hallucinogenic amount of the psilocybin or psilocin is provided to the subject in need thereof in an amount and/or formulation to provide a maximum plasma concentration (C_{max}) of active form of the psilocybin or psilocin of no more than 4.5 ng/mL.
14. **(Original)** The method of claim 1, wherein the therapeutically effective and non-hallucinogenic amount of the psilocybin or psilocin is provided to the subject in need thereof in an amount and/or formulation to provide a maximum plasma concentration (C_{max}) of active form of the psilocybin or psilocin of about 0.5 ng/mL to about 4.5 ng/mL.
15. **(Original)** The method of claim 1, wherein the therapeutically effective and non-hallucinogenic amount of the psilocybin or psilocin is provided to the subject in need thereof in an amount and/or formulation to provide a maximum plasma concentration (C_{max}) of active form of the psilocybin or psilocin of about 2 ng/mL to about 4.5 ng/mL.
16. **(Original)** The method of claim 1, wherein the therapeutically effective and non-hallucinogenic amount of the psilocybin or psilocin is provided to the subject in need thereof in an amount and/or formulation to provide a maximum plasma concentration (C_{max}) of active form of the psilocybin or psilocin of about 0.5 ng/mL to about 3 ng/mL.
17. **(Original)** The method of claim 1, wherein the therapeutically effective and non-hallucinogenic amount of the psilocybin or psilocin is provided to the subject in need thereof in an amount and/or formulation to provide a plasma concentration of active form of the psilocybin or psilocin of at least 0.1 ng/mL after at least 6 hours.

18. **(Original)** The method of claim 1, wherein the therapeutically effective and non-hallucinogenic amount of the psilocybin or psilocin is provided to the subject in need thereof in an amount and/or formulation to provide a plasma concentration of active form of the psilocybin or psilocin of at least 0.5 ng/mL after at least 6 hours.
19. **(Original)** The method of claim 1, wherein the pharmaceutical composition is administered orally.
20. **(Original)** The method of claim 1, wherein the psilocybin or psilocin is provided in an amount insufficient to provide a perturbation in the subject's sense of reality or perceptions.

REMARKS

Amendments to the Specification

Applicant provides herewith both a clean copy and a marked copy of a substitute specification, excluding claims, in compliance with 37 C.F.R. §§ 1.52, 1.121, and 1.125. Applicant respectfully requests that the specification of record be replaced with the substitute specification filed herewith. The specification has been amended to adjust the Title and Abstract, as required by the Office Action mailed 3/7/2023. No new matter is introduced by any amendment made herein.

Amendments to the Claims

Claims 1-7 have been amended. Upon entry of the proposed claims, claims 1-20 will be pending and under examination. Support for the amendments to the claims is found in the original claims and throughout the specification as filed, such as, for example, at least at [41], [199], and [255]. No new matter is introduced by any amendment made herein.

Priority

The Office alleged that claims 1, and 8-20 are afforded an effective filing date of 01/29/2020, and 2-7 are afforded an effective filing date of the instant application, 11/08/2022.

The office alleged,

> The provisional applications filed 01/30/2019, do not provide support for improving motivation or cognitive engagement. Additionally, neither the provisional applications nor PCT/IB2020/000052 or 17/427,037 provide support for a method of improving motivation or cognitive engagement *in a subject suffering from an anxiety or cognitive disorder* or improving cognitive engagement *in a subject suffering from depression disorder*. Paragraph 302 of WO2020/0157569 does provide support for a method of treating motivation in a patient with clinical depression. *Office Action page 2.*

Applicant respectfully disagrees. However, to expedite prosecution, Applicant has amended claims 1-7 to more closely resemble the language present in the priority document (US 62/798,998), with a filing date of 1/30/2019. Claim 1 has been amended to recite "symptoms of a disorder involving cognitive function" which has support at least at paragraph [0037] of US 62/798,998. Claims 2-7 find support at least at paragraphs [0167] and [0220] of US 62/798,998.

As such, Applicant respectfully submits that claims 1-20 be afforded an effective filing date of at least 1/30/2019.

Claim Rejections – 35 U.S.C. § 112

The Office rejected claim 7 under 35 U.S.C. § 112(d) as allegedly being of improper dependent form for allegedly being broader than claim 1 from which it depends. *See Office Action at page 4.* Specifically, the Office alleges, "claim 7 is broader than claim 1 since the patient population for the treatment of patients with anxiety, cognitive or depressive disorder is larger than the patent population for the treatment of patients with anxiety, cognitive or depressive disorder who also exhibit decreased motivation or cognitive engagement." *Office Action at page 4.*

Applicant respectfully disagrees. Specifically, Applicant notes that because claim 7 depends from claim 3, both features of claim 1 and 3 are required in claim 7. However, in an effort to expedite prosecution, Applicant amends claim 7 herein to more explicitly describe the presence of the features of both claim 1 and claim 3 in claim 7. As such, Applicant submits that the amended claims are clear and respectfully requests withdrawal of the rejection of claim 7.

Claim Rejections – 35 U.S.C. § 103

The Office rejected claims 1-5 and 7-20 as allegedly being unpatentable over US 10,947,257 ("Londesbrough") in view of Miller. Applicant respectfully disagrees.

The Office alleges,

> Londesbrough '257 teaches a method of treating central nervous system disorders, such as major depressive disorder by administering an oral dosage form of psilocybin with a carrier.
>
> 1mg-40mg of psilocybin is taught.
>
> Generalized anxiety disorder is also taught as a condition that can be treated.
>
> Administration of microdoses of psilocybin in the range of 0.05 to 2.5mg is taught. *Office Action page 9 (internal citations omitted).*

The Office admits that Londesbrough fails to (1) "teach a method of improving motivation or cognitive engagement," and (2) "does not teach preferred ranges of psilocybin." *Office Action page 9.* Applicant submits that in addition to the noted deficiencies, the Office also

(3) fails to provide any reference to where Londesbrough describes or teaches the use of a non-hallucinogenic amount of psilocybin or psilocin, (4) fails to provide any reference to where Londesbrough describes or teaches the use of a therapeutically effective and non-hallucinogenic amount of psilocybin or psilocin, (5) fails to provide a reason for why the skilled artisan reading Londesbrough would have any expectation of success in treating any disorder using a therapeutically effective amount of psilocybin or psilocin that is non-hallucinogenic, (6) particularly when references cited in Londesbrough for supporting psychotherapy using plant based psychedelics suggest the need for a hallucinogenic effect in order to have therapeutic efficacy, (7) would not have any reason to treat the instantly claimed disorders with a non-hallucinogenic amount of psilocybin or psilocin, and (8) would not have any reason to expect that a non-hallucinogenic amount of psilocybin or psilocin would or could be efficacious in treating an indication of the instant claims.

The Office attempts to overcome these deficiencies in Londesbrough, arguing:

> It would have been prima facie obvious to one of ordinary skill in the art, prior to the effective filing date of the instantly claimed invention, to modify the amount of psilocybin in Londesbrough '257 to 0.1-6mg, to arrive at the instantly claimed invention. One of ordinary skill in the art would have been motivated to modify the amount of psilocybin of Londesbrough '257 to 0.1-6mg, with reasonable expectation of success, because [Londesbrough] teaches that microdoses of psilocybin can be administered in the range of 0.05mg to 2.5mg and "[W]here the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation. *Office action page 10.*

None of such allegations or references suggest that a skilled artisan would have any reason to use or any expectation of success in using a non-hallucinogenic amount of psilocybin or psilocin to treat any disorder, let alone a disorder instantly claimed.

While the primary reference Londesbrough generally teaches broad disclosures of "adult oral doses" in an amount, as alleged by the Office, of 1 mg to 40 mg, Londesbrough describes preferred doses as being 15 to 30 mg. Moreover, the disclosure fails to provide any suggestion that a single of any such "adult oral doses" are sufficient to provide a therapeutic effect.

Indeed, to demonstrate psychotherapy efficacy in the treatment of mood disorders and alcohol disorders, Londesbrough cites a number of references, which the skilled artisan would understand as explicitly requiring a hallucinogenic experience in order to provide a therapeutic benefit.

For example, Londesbrough cited reference Griffiths et al 2016; J Psychopharmacol 30 (12):1181-1197 (hereinafter "Griffiths"), which describes the use of psilocybin for the treatment of depression and anxiety. Griffiths describes in the abstract that, "[a] ***[m]ystical-type psilocybin experience*** on session day ***mediated the effect of psilocybin dose on therapeutic outcomes***" (emphasis added). Griffiths also states, "a mediation analysis further suggested that ***mystical-type experience has a mediating role in positive therapeutic response***." *Griffiths page 1195 (emphasis added)*. Furthermore, the skilled artisan would find it clear from the abstract of Griffiths that Griffiths describes a randomized, double-blind, cross-over trial which investigated the effects of an **inactive placebo dose** (1 or 3 mg/70 kg) and a **high dose** (22 or 30 mg/70 kg) of psilocybin. Applicant submits that the skilled artisan would not see Griffiths as describing the placebo dose of 1 or 3 mg/70 kg psilocybin as providing any therapeutic effect. Therefore, a skilled artisan, reading Griffiths, would understand that a hallucinogenic experience is required for achieving a therapeutic benefit described therein.

Similarly, Londesbrough cited reference Carhart-Harris et al 2016, Lancet Psychiatry 3(7): 619-627 (hereinafter "Carhart-Harris"), which describes administering a 10 mg safety dose of psilocybin (*see Carhart-Harris, page 620*). Following administration of the 10 mg safety dose, a 25 mg treatment dose is administered. It was the 25 mg treatment dose that was the focus of the studies of psilocybin to manage depression. Carhart-Harris describes that all patients in the study experienced "adverse events" associated with psilocybin (see e.g., the table on page 624) and states, "Psilocybin's ***acute psychedelic effects*** typically became detectable between 30 min and 60 min after dosing, peaked between 2 h and 3 h after dosing" *Carhart-Harris page 624 (emphasis added)*. Therefore, a skilled artisan, reading Carhart-Harris, would understand that a hallucinogenic effect is required for achieving a therapeutic effect.

Similarly, Londesbrough cited reference Ross et al 2016, J Psychopharmacol 30 (12):1165-1180, which describes administering a single dose of 0.3mg/kg psilocybin (equal to 21 mg psilocybin in a 70 kg subject) to patients with life-threatening cancer using a hallucinogenic treatment model (*see Ross, Abstract*). Following treatment, mystical experiences were scored 7 hours post-drug administration. Total mystical experience scores were correlated with change scores for 6 primary outcome measures (*see e.g., Figure 7*), with the authors concluding ***"The psilocybin-induced mystical experience mediated the therapeutic effect of psilocybin on anxiety and depression."*** (*see Ross page 1165, Abstract*) *(emphasis added)*.

Thus, the skilled artisan would understand Londesbrough as requiring the hallucinogenic effect (the "mystical type" experience or "acute psychedelic effect") of Ross, Griffiths, and Carhart-Harris to achieve any therapeutic benefit described therein. By contrast, the instant claims provide for achieving a therapeutic benefit with psilocybin or psilocin in the absence of such effects. Indeed, the skilled artisan would not have reason to reduce a dose below a hallucinogenic threshold because the skilled artisan would simply not expect such a dose to have any therapeutic effect, given the teachings of Ross, Griffiths, and Carhart-Harris, cited in the Londesbrough.

The Office points to page 9 of the Office Action that Londesbrough describes doses of psilocybin in the range of "1mg-40mg," but Londesbrough fails to suggest that such doses would themselves be effective at treating any particular disorder, let alone those instantly claimed. And, the skilled artisan would read the disclosure of such doses in the context of the state of the art, particularly in the context of the references cited therein (including Ross, Griffiths, and Carhart-Harris), which would suggest to the skilled artisan that a hallucinogenic experience would be required for the treatment of any disorder suggested therein.

The office rejected claims 1-20 as being allegedly unpatentable over US 10,729,706 ("Kucuksen") in view of Miller and claim 6 as allegedly being unpatentable over Londesbrough in view of Miller, as applied to claims 1-5 and 7-20 above, and in further view of Kucuksen. Applicant respectfully disagrees.

The Office alleges,

> Kucuksen '706 teaches a method for preventing or treating a psychological disorder in a patient by administering a psilocybin and/or psilocin in combination with a cannabinoid. The compositions are taught as comprising pharmaceutically acceptable carriers.
> Depression, anxiety disorders such as generalized anxiety disorder, attention disorder, such as ADHD, and others are taught as psychological disorders.
> Exemplified is the treatment of depression, anxiety disorder, attention deficit syndrome and more.
> …
> The quantity of active compound per unit dose may be varied according to the nature of the active compound and the intended dosage regime. Generally, an effective amount shall be used, which may be within the range from 0.01 mg to 5000 mg. *Office Action pages 6-7 (internal references omitted).*

The office admits that Kucuksen fails to (1) "teach a method of improving motivation or cognitive engagement" *Office Action page 7.* Applicant submits that in addition to the noted deficiency, the Office also (2) fails to provide any reference to where Kucuksen describes or teaches the use of a non-hallucinogenic amount of psilocybin or psilocin, (3) fails to provide any reference to where Kucuksen describes or teaches the use of a therapeutically effective and non-hallucinogenic amount of psilocybin or psilocin, (4) fails to provide a reason for why the skilled artisan reading Kucuksen would have any expectation of success in treating any disorder using a therapeutically effective amount of psilocybin or psilocin that is non-hallucinogenic, (5) particularly when Kucuksen describes the combined administration of psilocybin or psilocin "with at least one cannabinoid and/or at least one terpene" *Kucuksen claim 1* and describes that cannabinoids are associated with a "**psychoactive effect (the 'high')**" and that the "[t]erpenes can **correct** or enhance **the effect of the cannabinoids**." *See Kucuksen at Col. 8 Lines 49-56 (emphasis added)*, yet **provides no similar disclosure for "correcting" the "mind-altering effects" associated with psilocybin**, *see Kucuksen Col. 7 line 5*, (6) the skilled artisan reading Kucuksen would not have any reason to treat the instantly claimed disorders with a non-hallucinogenic amount of psilocybin or psilocin, and (7) would not have any reason to expect that a non-hallucinogenic amount of psilocybin or psilocin would or could be efficacious in treating an indication of the instant claims.

The Office attempts to overcome these deficiencies in Kucuksen by arguing:

> The appropriate effective amount may be determined by one of ordinary skill in the art using only routine experimentation or prior knowledge in the art in view of the present disclosure. The effective ranges/dosages are not expected to be precisely the same for all compounds. Dosages may be optimized with each compound when the pharmacokinetics are studies to see how each compound is metabolized, which may alter the dose ranges. This neuro-enhancing is best managed in consultation with a skilled medical professional. *Office Action page 7.*

None of the allegations or references suggest that a skilled artisan would have any reason to use or expectation of success in using a non-hallucinogenic amount of psilocybin or psilocin to treat any disorder, let alone a disorder instantly claimed.

The office alleged that it would have been prima facie obvious "to modify the amount of psilocybin in Londesbrough '257 to 0.1-6mg" *Office Action page 10* and "the appropriate effective amount may be determined by one of ordinary skilled in the art using only routine experimentation or prior knowledge in the art in view of [Kucuksen]" *Office Action page 7*. Applicant respectfully disagrees. Upon reading Londesbrough and Kucuksen, the skilled artisan would not be motivated to design into the ranges described in the two references and would especially not be motivated and have no expectation of success in designing into these ranges and providing a dose that is non-hallucinogenic. Furthermore, in view of Londesbrough and the art cited therein (e.g, Ross, Griffiths and Carhart-Harris), which describe the requirement of a hallucinogenic experience, and Kucuksen's description of the "mind-altering effects" of psilocybin, ***the skilled artisan would not have any reason to believe that a non-hallucinogenic amount of psilocybin or psilocin would or could be efficacious in treating an indication of the instant claims***.

Further, with respect to claim 6 (objected to under 35 U.S.C. 103 as being unpatentable over Londesbrough and Miller, further in view of Kucuksen), Kucuksen does not remedy the defects of the primary references. Mainly, as discussed herein, the skilled artisan reading Kucuksen or Londesbrough would not have any reason to use or expectation of success in using a non-hallucinogenic amount of psilocybin or psilocin to treat a subject suffering from an attention disorder. Miller does not cure the noted deficiencies of Londesbrough and Kucuksen as set forth above.

Accordingly, in view of the foregoing arguments, Applicant respectfully requests withdrawal of the obviousness rejections to claims 1-20.

Double Patenting

The Office provisionally rejected claims 1-20 on the ground of nonstatutory double patenting as allegedly being patentably indistinct over claims 1-38 of co-pending Application No. US 18/102,268. *See* Office Action at page 13. Applicant respectfully disagrees.

Applicant respectfully submits that claims 1-38 of co-pending Application No. US 18/102,268 have a later effective filing date than the claims of the instant application. Therefore,

Applicant requests the provisional nonstatutory double patenting rejection to claims 1-20 be withdrawn.

CONCLUSION

Applicants respectfully solicit the Examiner to expedite prosecution of this patent application to issuance. Should the Examiner have any questions, the Examiner is encouraged to telephone the undersigned attorney at (858) 350-2398. The Commissioner is hereby authorized to charge any fees that may be required, or credit any overpayment to Deposit Account No. 23-2415, referencing Attorney Docket No. 55554-701.301.

Respectfully submitted,

WILSON SONSINI GOODRICH & ROSATI
A Professional Corporation

Date: April 12, 2023 By: /Brian Brown/
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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
18/053,648	11/08/2022	Judith BLUMSTOCK	55554-701.301	1222

21971 7590 03/07/2023

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EXAMINER
WELLS, LAUREN QUINLAN

ART UNIT	PAPER NUMBER
1622	

NOTIFICATION DATE	DELIVERY MODE
03/07/2023	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. 18/053,648	Applicant(s) BLUMSTOCK et al.	
	Examiner LAUREN WELLS	Art Unit 1622	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 11/23/2022.

☐ 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) 1-20 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) 1-20 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 11/23/2022 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: _____.

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.

DETAILED ACTION

Claims 1-20 are pending.

Priority

The instant application is a continuation of 17/427,037, filed 07/29/2021, which is a 371 of PCT/IB2020/000052, filed 01/29/2020, which claims priority to provisional applications 62/798,998, filed 01/30/2019 and provisional application 62/799,010, filed 01/30/2019.

Applicant's claim for the benefit of a prior-filed application under 35 U.S.C. 119(e) or under 35 U.S.C. 120, 121, 365(c), or 386(c) is acknowledged. Applicant has not complied with one or more conditions for receiving the benefit of an earlier filing date under 35 U.S.C. 119(e) as follows:

The provisional applications filed 01/30/2019, do not provide support for improving motivation or cognitive engagement. Additionally, neither the provisional applications nor PCT/IB2020/000052 or 17/427,037 provide support for a method of improving motivation or cognitive engagement *in a subject suffering from an anxiety or cognitive disorder* or improving cognitive engagement *in a subject suffering from depression disorder*. Paragraph 302 of WO 2020/157569 does provide support for a method of treating motivation in a patient with clinical depression.

As such, the instant claims 1, and 8-20 are afforded an effective filing date of 01/29/2020.

Claims 2-7 are afforded an effective filing date of the instant application, 11/08/2022.

Information Disclosure Statement

The information disclosure statement (IDS) dated 11/23/2022, complies with the provisions of 37 CFR 1.97, 1.98 and MPEP §609. Accordingly, it has been placed in the application file and the information therein has been considered as to the merits, except where noted.

Title

The title of the invention is not descriptive. A new title is required that is clearly indicative of the invention to which the claims are directed.

Abstract

Applicant is reminded of the proper content of an abstract of the disclosure.

A patent abstract *is a concise statement of the technical disclosure of the patent and should include that which is new in the art to which the invention pertains*. The abstract should not refer to purported merits or speculative applications of the invention and should not compare the invention with the prior art.

If the patent is of a basic nature, the entire technical disclosure may be new in the art, and the abstract should be directed to the entire disclosure. If the patent is in the nature of an improvement in an old apparatus, process, product, or composition, the abstract should include the technical disclosure of the improvement. The abstract should also mention by way of example any preferred modifications or alternatives.

Where applicable, the abstract should include the following: (1) if a machine or apparatus, its organization and operation; (2) if an article, its method of making; (3) if a chemical compound, its identity and use; (4) *if a mixture, its ingredients*; (5) *if a process, the steps.*

Extensive mechanical and design details of an apparatus should not be included in the abstract. The abstract should be in narrative form and generally limited to a single paragraph within the range of 50 to 150 words in length.

See MPEP § 608.01(b) for guidelines for the preparation of patent abstracts.

Claim Rejections - 35 USC § 112

The following is a quotation of 35 U.S.C. 112(d):

> (d) REFERENCE IN DEPENDENT FORMS.—Subject to subsection (e), a claim in dependent form shall contain a reference to a claim previously set forth and then specify a further limitation of the subject matter claimed. A claim in dependent form shall be construed to incorporate by reference all the limitations of the claim to which it refers.

The following is a quotation of pre-AIA 35 U.S.C. 112, fourth paragraph:

> Subject to the following paragraph [i.e., the fifth paragraph of pre-AIA 35 U.S.C. 112], a claim in dependent form shall contain a reference to a claim previously set forth and then specify a further limitation of the subject matter claimed. A claim in dependent form shall be construed to incorporate by reference all the limitations of the claim to which it refers.

Claim 7 is rejected under 35 U.S.C. 112(d) or pre-AIA 35 U.S.C. 112, 4th paragraph, as being of improper dependent form for failing to further limit the subject matter of the claim upon which it depends, or for failing to include all the limitations of the claim upon which it depends.

Claim 7, which depends on claim 3, which depends on claim 1, recites a "the method for treating the anxiety, cognitive, or depression disorder," However, claim 1, recites "A method of improving motivation or cognitive engagement." As such, claim 7 is broader than claim 1 since the patient population for the treatment of patients with anxiety, cognitive or depressive disorder is larger than the patient population for the treatment of patients with anxiety, cognitive or depressive disorder who also exhibit decreased motivation or cognitive engagement.

Applicant may cancel the claim(s), amend the claim(s) to place the claim(s) in proper dependent form, rewrite the claim(s) in independent form, or present a sufficient showing that the dependent claim(s) complies with the statutory requirements.

Claim Interpretation

For the purpose of examination, claim 7 is interpreted as a method of improving motivation or cognitive engagement in a subject suffering from an anxiety, cognitive or depression disorder.

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.

The factual inquiries 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.

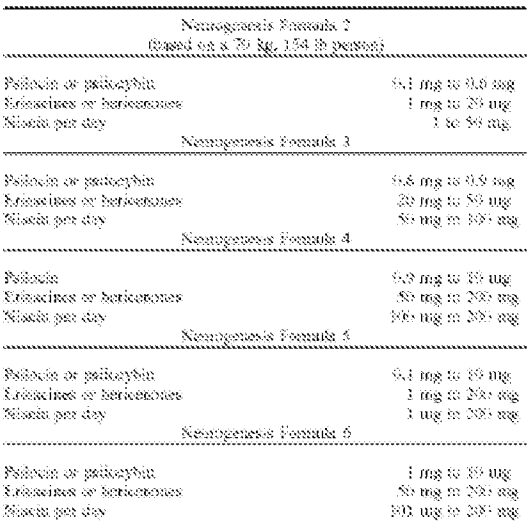
This application currently names joint inventors. In considering patentability of the claims the examiner presumes that the subject matter of the various claims was commonly owned as of the effective filing date of the claimed invention(s) absent any evidence to the contrary. Applicant is advised of 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.

Claims 1-20 are rejected under 35 U.S.C. 103 as being unpatentable over US 10,729,706 to Kucuksen (effectively filed 01/18/2017, IDS of 11/23/2022) in view of Miller (Everlywell, published 2019, PTO-892).

Kucuksen '706 teaches a method for preventing or treating a psychological disorder in a patient by administering psilocybin and/or psilocin in combination with a cannabinoid (Col. 13, claim 1). The compositions are taught as comprising pharmaceutically acceptable carriers (Col. 8, lines 34-49, Col. 9, lines 35-59, Col. 16, claim 19).

Depression, anxiety disorder such as generalized anxiety disorder, attention disorder, such as ADHD, and others are taught as psychological disorders (Col. 3, lines 62-Col. 5, line 5, Col. 10, line 45-Col. 12, line 35, Cols. 13-14, claim 2).

Exemplified is the treatment of depression, anxiety disorder, attention deficit syndrome, and more (Col. 12-13, Example 1).



Neurogenesis Formula 2 (based on a 70 kg, 154 lb person)	
Psilocin or psilocybin	0.1 mg to 0.6 mg
Ergocalciferol or hericenones	1 mg to 20 mg
Niacin per day	1 to 50 mg
Neurogenesis Formula 3	
Psilocin or psilocybin	0.6 mg to 0.9 mg
Ergocalciferol or hericenones	20 mg to 50 mg
Niacin per day	50 mg to 100 mg
Neurogenesis Formula 4	
Psilocin	0.9 mg to 10 mg
Ergocalciferol or hericenones	50 mg to 200 mg
Niacin per day	100 mg to 200 mg
Neurogenesis Formula 5	
Psilocin or psilocybin	0.1 mg to 10 mg
Ergocalciferol or hericenones	1 mg to 200 mg
Niacin per day	1 mg to 200 mg
Neurogenesis Formula 6	
Psilocin or psilocybin	1 mg to 10 mg
Ergocalciferol or hericenones	50 mg to 200 mg
Niacin per day	100 mg to 200 mg

Exemplified are the following formulations: (paragraph 15).

Exemplified are oral doses (Example 1).

The quantity of active compound per unit dose may be varied according to the nature of the active compound and the intended dosage regime. Generally, an effective amount shall be used, which may be within the range of from 0.01mg to 5000 mg (Col. 10, lines 14-21).

The appropriate effective amount may be determined by one of ordinary skill in the art using only routine experimentation or prior knowledge in the art in view of the present disclosure. The effective ranges/dosages are not expected to be precisely the same for all compounds. Dosages may be optimized with each compound when the pharmokinetics are studies to see how each compound is metabolized, which may alter the dose ranges. This neuro-enhancing is best managed in consultation with a skilled medical professional (paragraph 11).

While Kucuksen '706 teaches a method of treating depression, anxiety and attention deficit syndrome, it differs from that of the instantly claimed invention in that it does not teach a method of improving motivation or cognitive engagement.

Miller teaches that depression, anxiety or attention-deficit/hyperactivity disorder cause lack of motivation and trouble concentrating (pgs. 1-2).

It would have been prima facie obvious to one of ordinary skill in the art, prior to the effective filing date of the instantly claimed invention, to teach the methods of Kucuksen as improving motivation or cognitive engagement, as taught by Miller, to arrive at the instantly claimed invention. One of ordinary skill in the art would have been motivated to teach the methods of Kucuksen as improving motivation or cognitive engagement, with a reasonable expectation of success, because Kucuksen teaches treating depression, anxiety and attention disorders and Millers teaches these disorders as causing a lack of motivation and trouble concentrating.

While Kucuksen '706 does not explicitly teach maximum plasma concentrations, it is reasonable to assume that Kucuksen's compositions comprising 0.1mg-10mg of psilocybin for the treatment of psychological disorders such as depression, anxiety, and attention deficit syndrome would have the same properties since they are administered for the same purpose (treatment of cognitive/mood disorders), to the same population (patients with depression/anxiety/attention deficit), and in the same dosage amounts as that taught by the instant specification and claims. Thus, while the prior art does not explicitly teach these properties, burden is on Applicant to show that the prior art does not have these properties.

Applicants are reminded that the office does not have the facilities and resources to provide the factual evidence needed in order to establish that the product of the prior art does not possess the same material, structural and functional characteristics of the claimed product. In the absence of evidence to the contrary, the burden is on the applicant to prove that the claimed product is different from those taught by the prior art and to establish patentable differences. See In re Best 562F.2d 1252, 195 USPQ 430 (CCPA 1977) and Ex parte Gray 10 USPQ 2d 1922 (PTO Bd. Pat. App. & Int. 1989).

Claims 1-5 and 7-20 are rejected under 35 U.S.C. 103 as being unpatentable over US 10,947,257 to Londesbrough (effectively filed 10/09/2018, PTO-892) in view of Miller (Everlywell, published 2019, PTO-892).

Londesbrough '257 teaches a method of treating central nervous system disorders, such as major depressive disorder by administering an oral dosage form of psilocybin with a carrier (Col. 3, lines 46-55, Col. 69-70, claims 1 and 21).

1mg-40mg of psilocybin is taught (Col. 69, claim 2).

Generalized anxiety disorder is also taught as a condition that can be treated (Col. 21, lines 44-59).

Administration of microdoses of psilocybin in the range of 0.05 to 2.5mg is taught.

While Londesbrough '257 teaches a method of treating depression and anxiety, it differs from that of the instantly claimed invention in that it does not teach a method of improving motivation or cognitive engagement, and does not teach preferred ranges of psilocybin.

Miller teaches that depression, anxiety or attention-deficit/hyperactivity disorder cause lack of motivation and trouble concentrating (pgs. 1-2).

It would have been prima facie obvious to one of ordinary skill in the art, prior to the effective filing date of the instantly claimed invention, to teach the methods of Londesbrough '257 as improving motivation or cognitive engagement, as taught by Miller, to arrive at the instantly claimed invention. One of ordinary skill in the art would have been motivated to teach the methods of Londesbrough '257 as improving motivation or cognitive engagement, with a

reasonable expectation of success, because Londesbrough '257 teaches treating depression, and anxiety, and Miller teaches these disorders as causing a lack of motivation and trouble concentrating.

It would have been prima facie obvious to one of ordinary skill in the art, prior to the effective filing date of the instantly claimed invention, to modify the amount of psilocybin of Londesbrough '257 to 0.1-6mg, to arrive at the instantly claimed invention. One of ordinary skill in the art would have been motivated to modify the amount of psilocybin of Londesbrough '257 to 0.1-6mg, with a reasonable expectation of success, because Kucuksen teaches that microdoses of psilocybin can be administered in the range of 0.05mg to 2.5mg and "[W]here the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation." See MPEP 2144.05(II).

While Londesbrough '257 does not explicitly teach maximum plasma concentrations, it is reasonable to assume that Londesbrough's compositions comprising 0.05mg to 2.5mg of psilocybin for the treatment of depression and anxiety would have the same properties since they are administered for the same purpose (treatment of cognitive/mood disorders), to the same population (patients with depression/anxiety), and in the same dosage as that taught by the instant specification and claims. Thus, while the prior art does not explicitly teach these properties, burden is on Applicant to show that the prior art does not have these properties.

Applicants are reminded that the office does not have the facilities and resources to provide the factual evidence needed in order to establish that the product of the prior art does not possess the same material, structural and functional characteristics of the claimed product. In the absence of evidence to the contrary, the burden is on the applicant to prove that the claimed product is different from those taught by the prior art and to establish patentable differences. See

In re Best 562F.2d 1252, 195 USPQ 430 (CCPA 1977) and Ex parte Gray 10 USPQ 2d 1922 (PTO Bd. Pat. App. & Int. 1989).

Claim 6 is rejected under 35 U.S.C. 103 as being unpatentable over US 10,947,257 to Londesbrough (effectively filed 10/09/2018, PTO-892) and Miller (Everlywell, published 2019, PTO-892) as applied to claims 1-5, 7-20 above, and further in view of US 10,729,706 to Kucuksen (effectively filed 01/18/2017, IDS of 11/23/2022).

Londesbrough '257 is applied as discussed in the above 35 USC 102 rejection.

While Londesbrough teaches a method of treating cognitive disorders such as depression and anxiety by administering psilocybin, it differs from that of the instantly claimed invention in that it does not teach treating subjects with attention disorders.

Kucuksen '706 is discussed in the above 35 USC 103 rejection and incorporated herein. In particular, Kucuksen '706 teaches the treatment of psychological disorders with psilocybin or psilocin and specifically teaches and exemplifies depression, anxiety disorder such as generalized anxiety disorder, and attention disorder, such as ADHD, as the psychological disorders (Col. 3, lines 62-Col. 5, line 5, Col. 10, line 45-Col. 12, line 35, Cols. 13-14, claim 2).

It would have been prima facie obvious to one of ordinary skill in the art, prior to the effective filing date of the instantly claimed invention, to modify the combined methods of Londesbrough and Miller to treat subjects with attention disorders, as taught by Kucuksen, to arrive at the instantly claimed invention. One of ordinary skill in the art would have been motivated to modify the combined methods of Londesbrough and Miller to treat subjects with attention disorders, with a reasonable expectation of success, because Londesbrough teaches methods of treating central nervous system disorders with compositions comprising psilocybin

and Kucuksen teaches attention deficit syndrome as a psychological disorder that can be treated with compositions comprising psilocybin.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on nonstatutory double patenting provided the reference application or patent either is shown to be commonly owned with the examined application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement. See MPEP § 717.02 for applications subject to examination under the first inventor to file provisions of the AIA as explained in MPEP § 2159. See MPEP § 2146 *et seq.* for applications not subject to examination under the first inventor to file provisions of the AIA. A terminal disclaimer must be signed in compliance with 37 CFR 1.321(b).

The USPTO Internet website contains terminal disclaimer forms which may be used. Please visit www.uspto.gov/patent/patents-forms. The filing date of the application in which the form is filed determines what form (e.g., PTO/SB/25, PTO/SB/26, PTO/AIA/25, or PTO/AIA/26) should be used. A web-based eTerminal Disclaimer may be filled out completely online using web-screens. An eTerminal Disclaimer that meets all requirements is auto-processed and approved immediately upon submission. For more information about eTerminal Disclaimers, refer to www.uspto.gov/patents/process/file/efs/guidance/eTD-info-I.jsp.

Claims 1-20 are provisionally rejected on the ground of nonstatutory double patenting as being unpatentable over claims 1-38 of copending Application No. 18/102,268 (reference application). Although the claims at issue are not identical, they are not patentably distinct from each other.

‘268 claims a method for treating or managing a mental, behavioral or a neuropsychiatric condition in an individual who suffers from or susceptible to a mental, behavioral or neuropsychiatric condition, by administering a therapeutically effective amount of one or more 5-hydroxytryptamine (5HT) receptor agonist.

Cognitive disorders such as depression, anxiety and attention disorders are claimed.

A method for increasing motivation is claimed.

Administration of a therapeutically effective amount of a THT receptor agonist below a hallucinogenic threshold is claimed.

Plasma concentrations are claimed.

Psilocybin and psilocin are claimed as 5HT receptor agonists.

Oral formulations are claimed.

This is a provisional nonstatutory double patenting rejection because the patentably indistinct claims have not in fact been patented.

Conclusion

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to LAUREN WELLS whose telephone number is (571)272-7316. The examiner can normally be reached M-F 7:00-4:30.

Examiner interviews are available via telephone, in-person, and video conferencing using a USPTO supplied web-based collaboration tool. To schedule an interview, applicant is encouraged to use the USPTO Automated Interview Request (AIR) at http://www.uspto.gov/interviewpractice.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brandon Fetterolf can be reached on 571-272-2919. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of published or unpublished applications may be obtained from Patent Center. Unpublished application information in Patent Center is available to registered users. To file and manage patent submissions in Patent Center, visit: https://patentcenter.uspto.gov. Visit https://www.uspto.gov/patents/apply/patent-center for more information about Patent Center and https://www.uspto.gov/patents/docx for information about filing in DOCX format. For additional questions, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/L.Q.W./
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