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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
17/883,502	08/08/2022	Matthias Emanuel LIECHTI	0614.00169	9378

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KOHN & ASSOCIATES, PLLC
30500 NORTHWESTERN HWY.
SUITE 410
FARMINGTON HILLS, MI 48334-3179

EXAMINER	
KIRBERGER, MICHAEL PATRICK	

ART UNIT	PAPER NUMBER
1628	

NOTIFICATION DATE	DELIVERY MODE
03/16/2023	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):

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Office Action Summary	Application No. 17/883,502	Applicant(s) LIECHTI, Matthias Emanuel	
	Examiner MICHAEL P KIRBERGER	Art Unit 1628	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 08 August 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) 1-14 is/are pending in the application.

5a) Of the above claim(s) _____ is/are withdrawn from consideration.

6) ☐ Claim(s) _____ is/are allowed.

7) ☑ Claim(s) 1-14 is/are rejected.

8) ☐ Claim(s) _____ is/are objected to.

9) ☐ Claim(s) _____ are subject to restriction and/or election requirement

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

Application Papers

10)☐ The specification is objected to by the Examiner.

11)☑ The drawing(s) filed on 26 August 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 1-14 are pending in the instant application.

Priority

The instant application filed on 08/08/2022 is a Continuation of Application 17/675,894 filed on 02/18/2022 and claims benefit of US Provisional Application 63/153,318, filed 02/24/2021.

Information Disclosure Statement

The information disclosure statement (IDS) dated 08/08/2022 complies with the provisions of 37 CFR 1.97, 1.98 and MPEP § 609, except where noted. Accordingly, it has been placed in the application file and the information therein has been considered as to the merits.

Claim Rejections - 35 USC § 112

The following is a quotation of 35 U.S.C. 112(b):
(b) CONCLUSION.—The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the inventor or a joint inventor regards as the invention.

The following is a quotation of 35 U.S.C. 112 (pre-AIA), second paragraph:
The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 5 and 10 are rejected under 35 U.S.C. 112(b) or 35 U.S.C. 112 (pre-AIA), second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which the inventor or a joint inventor (or for applications subject to pre-AIA 35 U.S.C. 112, the applicant), regards as the invention.

Claim 5 recites the phrase "attenuated and prolonged response" in parentheses. In this case, it is not clear whether the parenthetical phrase is intended to further limit the phrase that immediately precedes it, or if it was intended to be exemplary language. Note that MPEP 2173.05(d) addresses examples of exemplary language, which may lead to confusion regarding the intended scope of the claims.

Claim 10 recites the following phrases in parentheses: "1-100 mg", "100-200 mg", "300-400 mg", "500 mg", and "800 mg". In each instance, it is not clear whether the parenthetical phrase is intended to further limit the phrase that immediately precedes it, or if it was intended to be exemplary language. Note that MPEP 2173.05(d) addresses examples of exemplary language, which may lead to confusion regarding the intended scope of the claims. Additionally, in claim 10, the ranges "1-100 mg" defined as a microdose, and "100-200 mg" defined as a low dose, are further indefinite in that they overlap, such that 100 mg is included in each described range, and it would not be clear whether 100 mg would be considered a microdose or a low dose.

Claim Rejections - 35 USC § 103

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.

Claims 1-2 and 5-7 are rejected under 35 U.S.C. 103 as being unpatentable over **Russ** et al. (WO 2018/195455 A1) in view of **Kovacic** et al (Oxid Med Cell Longev. 2009 Sep-Oct;2(4):181-90) and **Londesbrough** et al. (WO 2020/212952 A1).

Regarding instant claims 1-2 and 5-7, **Russ** teaches methods of identifying a subject as being likely to have a positive therapeutic response to a psychedelic agent, and the administration of a psychedelic agent to a subject to improve mental or physical well-being in the subject (e.g., by treating stress, anxiety, addiction, depression, compulsive behavior, by promoting weight loss, by improving mood, or by treating or preventing a condition (e.g., psychological disorder) (see abstract), and wherein the psychedelic agent is administered as an adjunctive therapy, wherein the subject is being treated with a psychotherapy (claim 79, P. 68), and wherein the psychotherapy comprises talk therapy (claim 82, P. 68). Russ also teaches that the psychedelic agent may be mescaline (P. 10, Line 37), and that a "psychedelic agent" refers to a compound capable of inducing an altered state of consciousness (P. 17, Line 10).

Regarding instant claims 6-7, Russ teaches that the altered state of consciousness can be described as a “mystical experience” (P. 15, Line 3), wherein a mystical experience is characterized by at least one of the following key dimensions set forth by Stace (Mysticism and Philosophy, Lippincott, Philadelphia, PA, 2006): noetic quality(i.e., intuitive thinking), or a feeling of insight with tremendous force of certainty (P. 15, Line 3). Thus, Russ teaches that inducing a mystical experience produces subjective insight in the subject. Russ further teaches that having a complete mystical

experience based on patient response was associated with significantly higher self-reported scores in positive change (e.g., gratitude, joy, trust, empathy, and social concern) and significantly lower scores in negative change (e.g., anxiety, fear, impatience) (P. 50, Line 3).

Russ does not teach inducing a psychedelic state in the individual while reducing the risk of nausea or vomiting within a psychedelic treatment session and reducing the risk of cardiovascular stimulation within a psychedelic treatment session, as recited in instant claim 1.

Regarding instant claims 1 and 5, **Kovacic** teaches that mescaline is about 1,000–3,000 times less potent than LSD and about 30 times less potent than psilocybin (P. 186, Col. 1, Paragraph 3, Line 1). Kovacic also teaches that an effective dose of the mescaline sulfate, 200–400 mg, causes hallucination lasting for about 10–12 h, compared with psilocybin (4–6 h) (P. 186, Col. 1, Paragraph 3, Line 08), and that mescaline has a delayed onset of the main behavioral changes in rats compared to other hallucinogens (P. 186, Col. 1, Paragraph 3, Line 14). Thus, Kovacic teaches that mescaline provides a more attenuated response, with a slower onset of the psychological, or physiological response of the psychedelic compared with other psychedelics (instant claim 5).

Londesbrough then teaches the use of psilocybin in psychedelic therapy, wherein side effects observed in subjects treated with psilocybin include irritability, restlessness, anxiety, and anxiety reactions, and "bad trips" that may include bizarre or frightening images, paranoia, and complete derealization, as well as transitory acute

effects that include: dizziness, nausea, gastrointestinal upset, muscle weakness and/or pain, shivers, tremors, mydriasis, hypertension, and tachycardia (P. 234, Line 27)

Thus, although Kovacic does not explicitly teach that the attenuated response of mescaline provides the effects of less nausea and vomiting and less cardiovascular stimulation (instant claim 1), it would be reasonable for a person having ordinary skill in the art to consider that the attenuation of effects and reduced potency of mescaline compared with other psychedelic drugs would also attenuate the common adverse side effects shared by psychedelic drugs psilocybin and mescaline, as identified with respect to psilocybin and taught by Londesbrough.

Therefore, regarding instant claims 1-2 and 5-7, it would have been *prima facie* obvious to one of ordinary skill in the art before the effective filing date of the claimed invention to consider the combined teachings of Russ, Kovacic, and Londesbrough, such that a person having ordinary skill in the art would be motivated to consider a method of inducing a psychedelic state in an individual by administering mescaline or a salt thereof, wherein the inducing step would increase feelings of trust and insight, and in lieu of other more potent psychedelic agents, with a reasonable expectation that the attenuated response of mescaline would have the effect of reducing nausea and vomiting and reducing cardiovascular stimulation.

Claims 3-4 are rejected under 35 U.S.C. 103 as being unpatentable over **Russ** et al. (WO 2018/195455 A1) in view of **Kovacic** et al. (Oxid Med Cell Longev. 2009 Sep-Oct;2(4):181-90) and **Londesbrough** et al. (WO 2020/212952 A1), as applied to claims 1-2 and 5-7, and further in view of **Weisler** et al. (J Clin Psychiatry 2010; 71; 21-26).

The teachings of Russ, Kovacic, and Londesbrough as applied to claims 1-2 and 5-7, and documented in the preceding 103 rejection, do not teach that an individual may have insufficient therapeutic response or adverse effects after the use of other psychedelics substances and said method is used as a second-line treatment as recited in instant claim 3, or that the individual has a need for a qualitatively different psychedelic response after the use of other psychedelics substances and said method is used as an alternative treatment option as recited in instant claim 4.

Regarding instant claims 3-4, **Russ** teaches that the psychedelic agent may LSD, psilocybin, or mescaline, among others (P. 4, Line 3), such that any one of the agents may be selected as a first-line therapy.

Kovacic teaches that mescaline is about 1,000–3,000 times less potent than LSD and about 30 times less potent than psilocybin (P. 186, Col. 1, Paragraph 3, Line 1). Kovacic also teaches that mescaline has a delayed onset of the main behavioral changes in rats compared to other hallucinogens (P. 186, Col. 1, Paragraph 3, Line 14). Thus, Kovacic teaches that mescaline provides a more attenuated response than other psychedelics.

Londesbrough teaches the use of psilocybin in psychedelic therapy, wherein side effects observed in subjects treated with psilocybin include irritability, restlessness, anxiety, and anxiety reactions, and "bad trips" that may include bizarre or frightening images, paranoia, and complete derealization, as well as transitory acute effects that include: dizziness, nausea, gastrointestinal upset, muscle weakness and/or pain, shivers, tremors, mydriasis, hypertension, and tachycardia (P. 234, Line 27).

Londesbrough also teaches a method of characterizing the influence of a psychedelic agent on the perception of a patient administered therewith (P. 5, Line 1), where the methods of screening provided herein may inform a determination that a patient undergoing psychedelic therapy is at risk of developing psychosis, hypomania, or mania (e.g., an elevated risk prior to an earlier time point, which may be indicative of pre-symptomatic development of psychosis, hypomania, or mania), in which instance a decision or recommendation can be made regarding continued therapy (e.g., whether to adjust dosage or suspend administration of the psychedelic therapy) (P. 17, Line 19). Thus, Londesbrough teaches that adverse responses in a subject to psychedelic therapy using psilocybin may inform changes to dosage or to suspend administration of psilocybin psychedelic therapy.

Regarding instant claims 3-4, **Weisler** teaches that, for clinicians dealing with major depressive disorders, second line treatments may be selected according to patients' symptom profiles, adverse event profiles, medical histories, and treatment preferences (P. 22, Column 1, Paragraph 2). Therefore, adverse effects from a first-line therapy would motivate a person skilled in the art to select a second-line therapy or an alternative therapy that would mitigate those effects.

Thus, regarding instant claims 3-4, it would have been *prima facie* obvious to one of ordinary skill in the art before the effective filing date of the claimed invention to consider the combined teachings of Russ, Kovacic, Londesbrough, and Weisler, such that a person having ordinary skill in the art would be motivated to consider the use of mescaline in psychedelic therapy as either: an alternative to the use of psilocybin in psychedelic therapy in the event that the user had a qualitatively different response to

another psychedelic (instant claim 4); or as a second-line treatment in the event that an individual had already participated in psychedelic therapy involving use of psilocybin, wherein the first-line therapy could be psilocybin as taught by Russ, and wherein that therapy could be discontinued as a result of the individual experiencing adverse side effects associated with the use of psilocybin (instant claim 3), and further wherein the attenuating effect of the mescaline could mitigate the adverse effects of the first-line therapy (instant claim 3).

Claim 8 is rejected under 35 U.S.C. 103 as being unpatentable over **Russ** et al. (WO 2018/195455 A1) in view of **Kovacic** et al (Oxid Med Cell Longev. 2009 Sep-Oct;2(4):181-90) and **Londesbrough** et al. (WO 2020/212952 A1), as applied to claims 1-2 and 5-7, and further in view of **Raz** et al. (WO 2019/079742 A1).

The teachings of Russ, Kovacic, and Londesbrough as applied to claims 1-2 and 5-7, and documented in the preceding 103 rejection, do not teach inducing neuroregenerative processes beneficial in medical conditions chosen from the group consisting of Alzheimer's disease, dementia, predementia, and Parkinson's disease.

Raz teaches psychedelic therapy that can comprise administration of mescaline (P. 11, Line 36; P. 61, claim 196) as a psychedelic agent, wherein the psychedelic agent is capable of inducing an altered state of consciousness (P. 34, Line 24). Raz then teaches that the psychedelic therapy may be administered to a patient or candidate with a neurodegenerative disease (e.g., Alzheimer's disease) (P. 11, Line 18) as recited in instant claim 8.

Thus, regarding instant claim 8, it would have been *prima facie* obvious

to one of ordinary skill in the art before the effective filing date of the claimed invention that the psychedelic therapy taught by Russ, Kovacic, and Londesbrough, could be extended to neurodegenerative diseases as taught by Raz, with a reasonable expectation of success.

Claim 9 is rejected under 35 U.S.C. 103 as being unpatentable over **Russ** et al. (WO 2018/195455 A1) in view of **Kovacic** et al (Oxid Med Cell Longev. 2009 Sep-Oct;2(4):181-90) and **Londesbrough** et al. (WO 2020/212952 A1), as applied to claims 1-2 and 5-7, and further in view of **Young** et al. (US 2012/0108510 A1).

The teachings of Russ, Kovacic, and Londesbrough as applied to claims 1-2 and 5-7, and documented in the above 103 rejection, do not teach a composition administered in a dose of 1-800 mg.

Young teaches multiple dosage forms between 1-800 mg as recited in instant claim 9.

Thus, regarding instant claim 9, it would have been *prima facie* obvious to one of ordinary skill in the art before the effective filing date of the claimed invention that the psychedelic therapy taught by Russ, Kovacic, and Londesbrough, could be administered in a dosage range of 1-800 mg as taught by Young, with the expectation that the dosage would be effective for the intended therapy.

Claim 10 is rejected under 35 U.S.C. 103 as being unpatentable over **Russ** et al. (WO 2018/195455 A1) in view of **Kovacic** et al (Oxid Med Cell Longev. 2009 Sep-Oct;2(4):181-90) and **Londesbrough** et al. (WO 2020/212952 A1), as applied to claims

1-2 and 5-7, and further in view of **Young** et al. (US 2012/0108510 A1) as applied to claim 9, and **Wolbach** et al. (Psychopharmacologia 3, 219–223 (1962)).

The teachings of Russ, Kovacic, Londesbrough, and Young as applied to claims 1-2, 5-7, and 9, are documented in the above 103 rejection.

The teachings of Russ, Kovacic, Londesbrough, and Young, do not explicitly teach the use of mescaline hydrochloride as a mescaline salt, or the LSD base equivalents for the mescaline dosages recited. However, these equivalent values are defined in the Specification ([00047]) of the instant application.

Regarding instant claim 10, **Wolbach** explicitly teaches the use of the mescaline salt, mescaline chloride, in an early study comparing the objective and subjective effects of psilocin with psilocybin, mescaline, and LSD-25 (P. 219, Paragraph 2, Line 2), wherein the mescaline chloride was administered at a dose of 5.0 mg/Kg (P. 219, Paragraph 3, Line 3), which would be 350.0 mg for an average male subject weighing 70 Kg, corresponding to a moderate to medium dose inducing a moderate to medium strong psychedelic experience with mainly positive drug effects, as recited in instant claim 12.

Young then teaches that unit dosage forms of the active ingredient, which can be mescaline or mescaline salt, generally contain between from about 0.01 mg to about 1000 mg of the active ingredient, typically 0.01 mg, 0.05 mg, 0.25 mg, 1 mg, 5 mg, 25 mg, 50 mg, 100 mg, 200 mg, 300 mg, 400 mg, 500 mg, 600 mg, 800 mg or 1000 mg (P. 9, [0078]), which includes each of the dosage forms recited in instant claim 10.

Thus, regarding instant claim 10 it would have been *prima facie* obvious to one of ordinary skill in the art before the effective filing date of the claimed invention to utilize

mescaline hydrochloride as taught by Wolbach, within a composition taught by Russ, Kovacic, Londesbrough, and using the dosages for an active ingredient taught by Young, for the method of inducing a psychedelic state, and with the expectation that such a composition would produce the desired corresponding effects at the different dosages.

Claims 11-14 are rejected under 35 U.S.C. 103 as being unpatentable over **Young** et al. (US 2012/0108510 A1).

Regarding claims 11-14, **Young** teaches methods of using compounds that act to increase oxytocin release, including certain melanocortin receptor agonists, for treating or reducing the severity of psychotherapeutic or social disorders (Abstract), including depression and anxiety disorders (P. 2, [0022]). In certain embodiments, the method of treatment can include use of mescaline or mescaline salts as oxytocin releasing agent P. 3, ([0026], claim 13). Young also teaches that unit dosage forms of the active ingredient, which can be mescaline or mescaline salt, generally contain between from about 0.01 mg to about 1000 mg of the active ingredient, typically 0.01 mg, 0.05 mg, 0.25 mg, 1 mg, 5 mg, 25 mg, 50 mg, 100 mg, 200 mg, 300 mg, 400 mg, 500 mg, 600 mg, 800 mg or 1000 mg (P. 9, [0078]). Thus, Young teaches the specific dosage of 500mg recited in instant claim 12, wherein the dosage would correspond to a "good effect dose" as recited in instant claim 1a, and the specific dosage of 800 mg recited in instant claim 14, wherein the dosage would correspond to an "ego dissolution" dose as recited in instant claim 13.

It would therefore have been *prima facie* obvious to one of ordinary skill in the art before the effective filing date of the claimed invention to select such an embodiment taught by Young, particularly with the dosages recited for the active ingredient mescaline, with the expectation that the selected embodiment would produce the desired effects when administered to a subject.

Non-Statutory 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.

Claim 1-14 are provisionally rejected on the ground of nonstatutory double patenting as being unpatentable over claims 1-16 of copending Application No. **17/675,894** (reference application). Although the claims at issue are not identical, they are not patentably distinct from each other because copending Application No. **17/675,894** is drawn to a method of inducing a psychedelic state in an individual, including the steps of: administering a composition chosen from the group consisting of mescaline, a salt thereof, analogs thereof, and derivatives thereof to an individual; and inducing a psychedelic state in the individual (claim 1). Claim 2 limits claim 1 to treating a medical condition from the group consisting of anxiety disorder, anxiety associated

with life-threatening illness, depression, addiction including substance use disorder and impulse control disorder (behavioral addiction), personality disorder, compulsive-obsessive disorder, post-traumatic stress disorder, eating disorder, cluster headache, and migraine. Claim 3 limits the method of claim 1 to an individual having an insufficient therapeutic response or adverse effects after the use of other psychedelics substances and said method is used as a second-line treatment. Claim 4 limits the method of claim 1 to an individual having a need for a qualitatively different psychedelic response after the use of other psychedelics substances and said method is used as an alternative treatment option. Claim 5 limits the method of claim 1 to an individual having a need for a more attenuated response, with a slower onset of the psychological, or physiological response of the psychedelic (attenuated and prolonged response) compared with other psychedelics, while reducing the adverse side effects associated with psilocybin, and with a longer effect duration. Claim 6 limits the method of claim 1, wherein the inducing step is performed in the individual to reduce the risk of nausea or vomiting within a psychedelic treatment session. Claim 7 limits the method of claim 1 to reduce the risk of cardiovascular stimulation within a psychedelics treatment session. Claim 8 limits the method of claim 1, wherein said inducing step is performed in the individual to increase feelings of trust and openness beneficial in enhancing the therapeutic alliance and catalyze the effects of psychotherapy for any indication. Claim 9 limits the method of claim 1 to producing an inward oriented focus of attention and subjective insight to enhance psychotherapy. Claim 10 limits the method of claim 1 to inducing neuroregenerative processes beneficial in medical conditions chosen from the group consisting of Alzheimer's disease, dementia, predementia, and Parkinson's disease.

Claim 11 limits the method of claim 1 to a composition administered in a dose of 1-800 mg. Claim 12 limits the method of claim 1, further defining sub-sets of dosages from 1-800mg based on microdose, low dose, moderate to medium dose, medium to high dose, and high dose, with associated qualitative descriptions of each dose based on psychedelic effects. Claim 13 is drawn to administering an intermediate "good effect dose" of mescaline and inducing positive acute drug effects, while claim 14 defines "good effect dose" as 500 mg of the composition. Claim 15 is drawn to a method of therapy administering an "ego-dissolution" dose of a composition of mescaline, while claim 16 defines the “ego-dissolution” dose as 800 mg of the composition.

Instant claim 1 is drawn to a method of inducing a psychedelic state in an individual, including the steps of: administering a composition chosen from the group consisting of mescaline, a salt thereof, analogs thereof, and derivatives thereof to an individual; and inducing a psychedelic state in the individual while reducing the risk of nausea or vomiting within a psychedelic treatment session and reducing the risk of cardiovascular stimulation within a psychedelic treatment session. Instant claim 2 limits the method of instant claim 1 to treating a medical condition chosen from the group that includes anxiety disorder, depression, addiction, personality disorder, compulsive-obsessive disorder, post-traumatic stress disorder, and eating disorder. Instant claim 3 limits the method of instant claim 1 to an individual who has had an insufficient therapeutic response or adverse effects after the use of other psychedelic substances and said method is used as a second-line treatment. Instant claim 4 limits the method of instant claim 1, wherein the individual has a need for a qualitatively different psychedelic response after the use of other psychedelics substances and said method is used as an

alternative treatment option. Instant claim 5 limits the method of instant claim 1 to an individual having a need for a more attenuated response, with a slower onset of the psychological, or physiological response of the psychedelic (attenuated and prolonged response) compared with other psychedelics, while reducing the adverse side effects associated with psilocybin, and with a longer effect duration. Instant claim 6 limits the method of instant claim 1 wherein said inducing step is performed in the individual to increase feelings of trust and openness. Instant claim 7 limits the method of instant claim 1, wherein said inducing step is performed in the individual to produce an inward oriented focus of attention and subjective insight to enhance psychotherapy. Instant claim 8 limits the method of instant claim 1 wherein the inducing step is performed in the individual to induce neuroregenerative processes beneficial in medical conditions chosen from the group consisting of Alzheimer's disease, dementia, predementia, and Parkinson's disease. Instant claim 9 limits the method of instant claim 1 to a composition administered in a dose of 1-800 mg. Instant claim 10 limits the method of instant claim 1, further defining sub-sets of dosages from 1-800mg based on microdose, low dose, moderate to medium dose, medium to high dose, and high dose, with associated qualitative descriptions of each dose based on psychedelic effects. Instant claim 11 is drawn to administering an intermediate "good effect dose" of mescaline and inducing positive acute drug effects, while instant claim 12 defines "good effect dose" as 500 mg of the composition. Instant claim 13 is drawn to a method of therapy administering an "ego-dissolution" dose of a composition of mescaline, while instant claim 14 defines the “ego-dissolution” dose as 800 mg of the composition.

Thus, claims 1-16 of copending Application No. **17/675,894** anticipate all of the elements recited in instant claims 1-14.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to MICHAEL PATRICK KIRBERGER whose telephone number is (571)272-7710. The examiner can normally be reached M - F 7:00am - 4:00pm EST.

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, Wu-Cheng Winston Shen can be reached on (571)272-3157. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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/M.P.K./
Examiner, Art Unit 1628

/WU CHENG W SHEN/
Supervisory Patent Examiner, Art Unit 1628