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EXAMINER	
COPPINS, JANET L	

ART UNIT	PAPER NUMBER
1628	

NOTIFICATION DATE	DELIVERY MODE
02/23/2023	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. 17/238,088	Applicant(s) LIECHTI, Matthias Emanuel	
	Examiner JANET L COPPINS	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 11/15/22.

☐ 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) 1-28 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5a) Of the above claim(s) _____ is/are withdrawn from consideration.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) See Continuation Sheet 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 5/27/21; 12/1/22.

3) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date _____.

4) ☑ Other: See Continuation Sheet.

Continuation of Disposition of Claims* 7) Claim(s) is/are rejected: 1-28

Continuation of Attachment(s) 4) Other: third party submissions (x3) dated 4/14/22

DETAILED ACTION

Election/Restrictions

1. Applicant's election **without** traverse of **Group I, claims 1-13, 20-24**, and **25-28,** drawn to a method of treatment/ a method of enhancing positive therapeutic effects of a psychedelic, and species elections of (1) the single specific empathogen/entactogen: **MDMA** (as recited in claim 5); (2) the single specific psychedelic: **LSD**; (3) the single psychiatric disorder: **depression**; (4) the single "bad drug effect": anxiety; and (5) the single "good drug effect": blissful state, in the reply filed on November 15, 2022 is acknowledged with appreciation.

2. **Claims 14-18**, drawn to Group II, are **withdrawn** from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim.

3. The remaining non-elected species of empathogen/entactogens **other than** MDMA; the remaining non-elected species of psychedelics **other than** LSD; and non-elected disorders **other than** depression are also withdrawn from consideration.

4. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Information Disclosure Statement

5. The information disclosure statements (IDS) submitted on May 27, 2021 and December 1, 2022, are in compliance with the provisions of 37 CFR 1.97. Accordingly, the information disclosure statements have been considered by the examiner, please refer to the signed copies of Applicant's PTO-1449 forms, attached herewith.

Claim Rejections - 35 USC § 112

6. 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.

7. **Claims 1-28 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.**

8. **Claim 1** recites a method of enhancing positive therapeutic effects of a psychedelic, including the steps of: inducing a positive psychological state in an individual with an empathogen/entactogen; administering a psychedelic to the individual; and enhancing a positive response to the psychedelic.

Claim 1 is unclear in the following aspects: First, it is unclear what steps are active, i.e., it is not clear from the claim itself how the individual is "enhanced," i.e. what

steps are actually performed, and Second, it is not clear how said individual displays "a positive psychological state" or what parameters define "a positive response," i.e., "positive" is a relative term that must be more clearly defined as Applicant has not set forth a basis for comparison/ Applicant has not defined a threshold. A claim is indefinite when it recites a result to be achieved without indicating the steps required to achieve it. Such a claim amounts to little more than a statement of intended results.

Third, the term "enhancing" is a relative term which renders the claim indefinite. The term "enhance" is not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention.

Therefore, the metes and bounds of the claim cannot be ascertained. Applying a broadest reasonable interpretation, claim 1 is construed to mean:

a method of treating a psychiatric disorder in an individual, comprising administering a synergistic amount of an empathogen/entactogen in combination with a synergistic amount of a psychedelic to an individual in need thereof, wherein the empathogen/entactogen enhances the positive response of the psychedelic in said individual.

9. **Claim 20** recites a method of enhancing positive therapeutic effects of a psychedelic, including the steps of: inducing the release of endogenous monoamines, and stimulating 5-HT_{2A} receptors.

Likewise, it is unclear what steps are active in claim 20, i.e., it is not clear from the claim itself how the endogenous monoamines are "induced," or how the 5-HT_{2A} receptors are "stimulated," i.e., the claim fails to recite any active administration steps to

an individual, and Second, it is not clear how said individual displays said release or what parameters define said stimulation, i.e., "stimulating" is a relative term that must be more clearly defined as Applicant has not set forth a basis for comparison/ Applicant has not defined a threshold. A claim is indefinite when it recites a result to be achieved without indicating the steps required to achieve it. Such a claim amounts to little more than a statement of intended results.

Therefore, the metes and bounds of the claim cannot be ascertained. Applying a broadest reasonable interpretation, claim 20 is construed to mean:

a method of treating a psychiatric disorder in an individual, comprising administering a synergistic amount of an empathogen/entactogen in combination with a synergistic amount of a psychedelic to an individual in need thereof, wherein said administration induces the release of endogenous monoamines, and stimulates the 5-HT$_{2A}$ receptor.

10. **Claim 25** recites a method of treating a patient including the step of: enhancing a mood of the patient prior to psychedelic treatment.

Likewise, it is unclear what steps are active in claim 25, i.e., it is not clear from the claim itself how the mood of the patient is "enhanced," i.e., the claim fails to recite any active administration steps to an individual, and Second, it is not clear how said patient displays said mood or what parameters define said enhanced mood, i.e., "enhancing" is a relative term that must be more clearly defined as Applicant has not set forth a basis for comparison/ Applicant has not defined a threshold. A claim is indefinite when it recites a result to be achieved without indicating the steps required to achieve it. Such a claim amounts to little more than a statement of intended results.

Therefore, the metes and bounds of the claim cannot be ascertained. Applying a broadest reasonable interpretation, claim 25 is construed to mean:

a method of treating a psychiatric disorder in an individual, comprising administering a synergistic amount of an empathogen/entactogen prior to administering a psychedelic to an individual in need thereof, wherein said administration enhances the mood of the patient prior to the administration of the psychedelic.

11. **Claims 2-19, 21-24 and 26-28** are rejected as being dependent on claims 1, 20 or 25 and not overcoming the indefiniteness issues cited above.

Claim Rejections - 35 USC § 102

12. 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.

13. **Claims 1, 2, 4, 6, 8, 10, 20-22 and 25-27 are rejected under 35 U.S.C. 102(a)(1) as being anticipated by *Schechter, M.D.*, European Journal of Pharmacology 1998, as evidenced by *Knapp et al.*, Journal of Immunology 2018.**

Claim 1 recites a method of enhancing positive therapeutic effects of a psychedelic, including the steps of:

(a) inducing a positive psychological state in an individual, (more specifically, an individual suffering from **depression** (**claim 10**)), with an empathogen/entactogen (more specifically, **MDMA** (**claim 4**));

(b) administering a psychedelic to the individual (more specifically, **LSD** (**claim 6**)), wherein the empathogen/entactogen is administered in a separate dosage form as the psychedelic (**claim 2**) but at the same time as the psychedelic (**claim 8**); and

(c) enhancing a positive response to the psychedelic.

As thus summarized, the invention reads on claims 1, 2, 4, 6, 8 and 10.

Schechter teaches the combined administration of **MDMA** and **LSD** in fawn-hooded rats wherein MDMA and LSD potentiated each other, i.e., "a sub-threshold discriminative dose of MDMA combined with a sub-threshold dose of LSD produce a large and significant increase in MDMA stimulus discrimination," (see page 133, right column, last paragraph). *Schechter* discusses that Fawn-Hooded rats have a serotonergic deficiency in the brain (page 131, right column, last paragraph), and as evidenced by *Knapp et al.*, "Fawn Hooded (FH/Wjd) rats have long been used as a model of depression based on their depressive-like behaviors, high basal corticosterone levels and altered serotonergic levels," (see abstract). Thus, the subject being treated by *Schechter* meets the limitation of a subject suffering from depression.

While *Schechter* does not explicitly disclose the limitation of "enhancing positive therapeutic effects of a psychedelic" or "inducing a positive psychological state" or "enhancing a positive response to the psychedelic/ enhancing a mood of the patient prior to psychedelic treatment," these limitations are functional limitations that

characterize intrinsic properties of the claimed composition, which is taught by *Schechter*. As recognized by MPEP § 2112.01(1D), "Products of identical chemical composition cannot have mutually exclusive properties." *In re Spada*, 911 F.2d 705, 709, 15 USPQ2d 1655, 1658 (Fed. Cir. 1990). A chemical composition and its properties are inseparable. Therefore, if the prior art teaches the identical chemical structure, the properties applicant discloses and/or claims are necessarily present. Id. (Applicant argued that the claimed composition was a pressure sensitive adhesive containing a tacky polymer while the product of the reference was hard and abrasion resistant. "The Board correctly found that the virtual identity of monomers and procedures sufficed to support a prima facie case of unpatentability of Spada's polymer latexes for lack of novelty.").

Claim 20 recites a method of enhancing positive therapeutic effects of a psychedelic, including the steps of: inducing the release of endogenous monoamines, and stimulating 5-HT_{2A} receptors.

Applying a broadest reasonable interpretation, claim 20 is construed to mean:

a method of treating a psychiatric disorder in an individual, comprising administering a synergistic amount of an empathogen/entactogen (more specifically, ***MDMA*** *(**claim 21**)) in combination with a synergistic amount of a psychedelic (more specifically,* ***LSD*** *(**claim 22**)), to an individual in need thereof, wherein said administration induces the release of endogenous monoamines, and stimulates the 5-HT_{2A} receptor.*

Claim 25 recites a method of treating a patient including the step of: enhancing a mood of the patient prior to psychedelic treatment.

Applying a broadest reasonable interpretation, claim 25 is construed to mean:

a method of treating a psychiatric disorder in an individual, comprising administering a synergistic amount of an empathogen/entactogen prior (more specifically, ***MDMA*** *(**claim 26**)) to administering a psychedelic (more specifically,* ***LSD*** *(**claim 27**)) to an individual in need thereof, wherein said administration enhances the mood of the patient prior to the administration of the psychedelic.*

Claims 20-22 and **25-27** do not recite any additional limitations that have not been addressed in the rejection above; accordingly they are rejected under 35 USC 102(a)(1) for the same reasons as claims 1, 2, 4, 6, 8 and 10.

15. **Claims 3, 5, 9, 11-13, 23, 24 and 28 are rejected under 35 U.S.C. 103 as being unpatentable over *M. D. Schechter*, European Journal of Pharmacology, 1998), as evidenced by *Knapp et al.*, Journal of Immunology 2018, as applied to claims 1, 2, 6, 20, and 25 in the 35 USC 102(a)(1) rejections above.**

Claims 1 and 2 are addressed in detail in the 35 USC 102(a)(1) rejection above.

Claim 3 is drawn to claim 2, and limits wherein the empathogen/entactogen (more specifically, **MDMA**) and psychedelic (more specifically, **LSD**) are in the same dosage form and have different release profiles.

Schechter teaches the additive effects of the combined administration of **MDMA** and **LSD** in the same form of administration at the same time (i.e., saline solution for intraperitoneal injection) in an individual suffering from depression, but is silent to the limitation of the empathogen/entactogen and psychedelic having different release profiles.

Yet, claim 3 is drafted in terms of the intended outcome of the administration of the empathogen/entactogen and psychedelic: i.e., "...wherein the empathogen/ entactogen and psychedelic... have different release profiles." However, a claimed composition maybe obvious because it was suggested by, or structurally similar to, a prior art composition even though a particular benefit of the claimed composition asserted by patentee is not expressly disclosed in the prior art. It is the differences in fact in their respective properties which are determinative of nonobviousness. If the prior art composition does in fact possess a particular benefit, even though the benefit is not recognized in the prior art, Applicant's recognition of the benefit is not in itself sufficient to distinguish the claimed composition from the prior art, *In re Dillon,* 919 F.2d 688, 16 USPQ2d 1897 (Fed. Cir. 1991). In this case, the release profiles are considered latent properties of the combined administration of MDMA and LSD as previously disclosed by *Schechter*, and the alleged unexpected result does not confer patentability.

And, the limitation of different release profiles functional limitation that characterize intrinsic properties of the claimed composition, which is taught by *Schechter*. As recognized by MPEP § 2112.01(II), "Products of identical chemical composition cannot have mutually exclusive properties." *In re Spada,* 911 F.2d 705, 709, 15 USPQ2d 1655, 1658 (Fed. Cir. 1990). A chemical composition and its properties are inseparable. Therefore, if the prior art teaches the identical chemical structure, the properties applicant discloses and/or claims are necessarily present. *Id.* (Applicant argued that the claimed composition was a pressure sensitive adhesive containing a tacky polymer while the product of the reference was hard and abrasion resistant. "The Board correctly found that the virtual identity of monomers and procedures sufficed to

support a *prima facie* case of unpatentability of Spada's polymer latexes for lack of novelty.").

Regarding a dosage form comprising both the empathogen/ entactogen and the psychedelic, *Schechter* teaches the combined administration of MDMA and LSD, wherein both drugs are administered in the form of a saline solution, via intraperitoneal injection, at the same time (see page 132, left column).

As such, combining both MDMA and LSD into a single pharmaceutical composition for ease/ efficiency of administration to a patient in need thereof is recognized as within the ordinary capabilities of one skill in the art.

As such, **claim 3** is *prima facie* obvious.

Claim 4 is addressed in detail in the 35 USC 102(a)(1) rejection above.

Claim 5 is drawn to claim 4, wherein the empathogen/ entactogen is MDMA and is administered at a dose of 20-200 mg.

Schecter additionally teaches that MDMA is administered at a dose of from 0.0315 — 2.0 mg/kg, which overlaps the instantly recited dosage range of from 20-200 mg, assuming an average 62 kg human (see page 132, left column, last paragraph -right column, first paragraph). *Schecter* provides evidence that humans take the combination of LSD and MDMA, i.e., "the co-administration of LSD and MDMA has reached a prevalence that has allowed for the street terminology 'candyflipping' to describe the combination" (see abstract). Though *Schecter* does not disclose the exact claimed weight values, but does overlap: in such instances even a slight overlap in range establishes a *prima facie* case of obviousness, In re Peterson, 65 USPQ2d 1379,1382 (Fed. Cir. 2003).

As such, **claim 5** is *prima facie* obvious.

Claim 9 is drawn to claim 1, and limits wherein the psychedelic is a short-acting psychedelic, and the empathogen/entactogen is administered 1-2 hours before the short-acting psychedelic.

Schechter teaches the combined administration of MDMA and LSD in a subject, but do not explicitly teach wherein the MDMA is administered 1-2 hrs before the LSD.

Yet, order of administration is a result-effective variable. Since the recited method is well-known, optimization of variables of said process such as order of administration would be obvious to one skilled in the art. It would have been customary for one of skill in the art to determine the optimal time of administration of each drug in order to best achieve the desired results. Changing the weight, purity or other characteristic (i.e. temperature, pressure, etc) of an old process does not render the newer claimed form patentable where the difference in weight, purity or characteristic was inherent, please see *In re Cofer* (CCPA 1966) 354 F2d 664, 148 USPA 268.

As such, **claim 9** is *prima facie* obvious.

Claim 11 is drawn to claim 1, and limits wherein said enhancing step further includes the step of reducing bad drug effects chosen from the group consisting of anxiety, fear, fear of loss of body control, anxious-ego dissolution, disembodiment, fear of impaired thought control, paranoia, panic, negative thoughts, grooming, nadir effects, and combinations thereof (more specifically, **anxiety**). **Claim 12** is drawn to claim 1, wherein said enhancing step further includes the step of improving good drug effects chosen from the group consisting of drug linking, oceanic boundlessness, experience of

unity, spiritual experience, blissful state, insightfulness, connectedness, mystical experiences, mystical-type effects, positive mood, transcendence of time/space, ineffability, well-being, trust, feelings of love, feeling open, peak experience, and combinations thereof. **Claim 13** is drawn to claim 1, wherein the empathogen/ entactogen reduces anxiety up to 6 hours after administration.

Yet, claims 11-13 are drafted in terms of the intended outcome of the administration of the empathogen/entactogen and psychedelic of claim 1: i.e., wherein "bad drug effects" are reduced, or wherein "good drug effects" are improved, or wherein anxiety is reduced for up to 6 hours. However, a claimed composition maybe obvious because it was suggested by, or structurally similar to, a prior art composition even though a particular benefit of the claimed composition asserted by patentee is not expressly disclosed in the prior art. It is the differences in fact in their respective properties which are determinative of nonobviousness. If the prior art composition does in fact possess a particular benefit, even though the benefit is not recognized in the prior art, Applicant's recognition of the benefit is not in itself sufficient to distinguish the claimed composition from the prior art, *In re Dillon,* 919 F.2d 688, 16 USPQ2d 1897 (Fed. Cir. 1991). In this case, the recited outcome of reducing bad drug effects or improving good drug effects or reducing anxiety for up to 6 hours are considered latent properties of the combined administration of MDMA and LSD as previously disclosed by *Schechter*, and the alleged unexpected result does not confer patentability.

As such, **claims 11-13** are *prima facie* obvious.

Claim 23 is drawn to claim 20, further including the step of improving good drug effects and reducing bad drug effects; more specifically wherein the good drug

effects are chosen from the group consisting of drug linking, oceanic boundlessness, experience of unity, spiritual experience, blissful state, insightfulness, connectedness, mystical experiences, mystical-type effects, positive mood, transcendence of time/space, ineffability, well-being, trust, feelings of love, feeling open, peak experience, and combinations thereof, and the bad drug effects are chosen from the group consisting of anxiety, fear, fear of loss of body control, anxious-ego dissolution, disembodiment, fear of impaired thought control, paranoia, panic, negative thoughts, grooming, nadir effects, and combinations thereof (**claim 24**).

Yet, claims 23 and 24 are drafted in terms of the intended outcome of the administration of the empathogen/entactogen and psychedelic of claim 20: i.e., "...including the step of improving good drug effects and reducing bad drug effects." However, a claimed composition maybe obvious because it was suggested by, or structurally similar to, a prior art composition even though a particular benefit of the claimed composition asserted by patentee is not expressly disclosed in the prior art. It is the differences in fact in their respective properties which are determinative of nonobviousness. If the prior art composition does in fact possess a particular benefit, even though the benefit is not recognized in the prior art, Applicant's recognition of the benefit is not in itself sufficient to distinguish the claimed composition from the prior art, *In re Dillon,* 919 F.2d 688, 16 USPQ2d 1897 (Fed. Cir. 1991). In this case, the recited outcome of "improving good drug effects" and "reducing bad drug effects" are considered latent properties of the combined administration of MDMA and LSD as previously disclosed by *Schechter*, and the alleged unexpected result(s) do not confer patentability.

As such, **claims 23 and 24** are *prima facie* obvious.

Claim 28 is drawn to claim 25, wherein said enhancing a mood step is further defined as increasing positive acute effects chosen from the group consisting of good drug effect, drug liking, well-being, trust, feelings of love, openness, oceanic boundlessness, experience of unity, spiritual experience, blissful state, insightfulness, mystical-type experience, and positively experienced psychedelic effects, aspects of ego-dissolution, and combinations thereof, and decreasing negative acute effects chosen from the group consisting of bad drug effect, anxiety, fear, increased ratings of anxious ego-dissolution, descriptions of acute paranoia, states of panic and anxiety, and combinations thereof.

Yet, claim 28 is drafted in terms of the intended outcome of the administration of the empathogen/entactogen and psychedelic of claim 25: i.e., wherein "positive acute effects" are increased. However, a claimed composition maybe obvious because it was suggested by, or structurally similar to, a prior art composition even though a particular benefit of the claimed composition asserted by patentee is not expressly disclosed in the prior art. It is the differences in fact in their respective properties which are determinative of nonobviousness. If the prior art composition does in fact possess a particular benefit, even though the benefit is not recognized in the prior art, Applicant's recognition of the benefit is not in itself sufficient to distinguish the claimed composition from the prior art, *In re Dillon,* 919 F.2d 688, 16 USPQ2d 1897 (Fed. Cir. 1991). In this case, the recited outcome of "increasing positive acute effects" is considered a latent property of the combined administration of MDMA and LSD as

previously disclosed by *Schechter*, and the alleged unexpected result(s) do not confer patentability.

As such, **claim 28** is *prima facie* obvious.

16. **Claim 7 is rejected under 35 U.S.C. 103 as being unpatentable over *M. D. Schechter*, European Journal of Pharmacology, 1998), as evidenced by *Knapp et al.*, Journal of Immunology 2018, as applied to claims 1 and 6, above, further in view of *Sessa and Fischer*, Drug Science 2015.**

Claims 1 and 6 are addressed in detail in the 35 USC 102(a)(1) rejection, above.

Claim 7 is drawn to claim 6, and limits wherein the LSD is administered at a dose of 0.05-0.3 mg.

Schechter teaches the combined administration of MDMA and LSD to a subject in need thereof, wherein LSD is administered at a range of 0.02 - 0.12 mg/kg (see page 132, left column, last paragraph-right column, first paragraph), but do not explicitly teach the recited dosage range of LSD of 0.05-0.3 mg.

Yet, *Sessa and Fischer* teach that LSD is commonly employed at a dosage of 50-200 μg (i.e., 0.05-0.200 mg), (page 3, left column, under "The choice of and dosages of substances used for the sessions").

Thus, the range of 0.05-0.3 mg required by claim 7 is reasonably suggested by 0.05-0.200 mg as taught by *Schechter*. The prior art does not disclose the exact claimed weight values, but does overlap: in such instances even a slight overlap in range establishes a *prima facie* case of obviousness. See *In re Peterson*. 65 USPQ2d 1379,1382 (Fed. Cir. 2003). And, the optimization of result effect parameters (e.g., dosage range) is obvious as being within the skill of the artisan. The optimization of known effective

amounts of known active agents to be administered, is considered well in the competence level of an ordinary skilled artisan in pharmaceutical science, involving merely routine skill in the art. It has been held that it is within the skill in the art to select optimal parameters, such as amounts of ingredients, in a composition in order to achieve a beneficial effect. See *In re Boesch*, 205 USPQ 215 (CCPA 1980). It is also noted that "[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 optimization with a reasonable expectation of success.

As such, **claim 7** is *prima facie* obvious.

Double Patenting

17. 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.

18. **Claims 1-13 and 20-28 are rejected on the ground of nonstatutory double patenting as being unpatentable over the claims of U.S. Patent No. 11,364,221.**

Although the claims at issue are not identical, they are not patentably distinct from each other because instant Claim 1 recites a method of enhancing positive therapeutic effects of a psychedelic, including the steps of: inducing a positive psychological state in an individual with an empathogen/entactogen (more specifically,

MDMA administered at a dose of 20-200 mg (**instant claim 5**)); administering a psychedelic to the individual; and enhancing a positive response to the psychedelic. **Instant Claim 2** is drawn to claim 1, and limits wherein the empathogen/entactogen are administered in the same dosage form or in separate dosage forms as the psychedelic**. Instant Claim 3** is drawn to claim 2, and limits wherein the empathogen/entactogen (more specifically, MDMA) and psychedelic (more specifically, LSD) are in the same dosage form and have different release profiles. **Instant Claim 4** is drawn to claim 1, and limits wherein the empathogen/ entactogen is chosen from the group consisting of 3,4-methylenedioxy-methamphetamine (MDMA), 3,4-methylendioxy-amphetamine (MDA), 3,4,-methylene-dioxyethylamphetamine (MDEA), 5,6-methylene-dioxy-2-aminoindane (MDAI), mephedrone, methylone, 3-MMC, homologues thereof, analogues thereof, and prodrugs thereof. **Instant Claim 6** is drawn to claim 1, and limits wherein the psychedelic is chosen from the group consisting of psilocybin, psilocin, lysergic acid diethylamide (LSD), mescaline, dimethyltryptamine (DMT), 2,5-dimethoxy-4-iodoamphetamine (DOI), 2,5-dimethoxy-4-bromoamphetamie (DOB), phenethylamine or tryptamine psychedelics, salts thereof, analogs thereof, prodrugs thereof, and homologues thereof. **Instant Claim 7** is drawn to claim 6, and limits wherein the LSD is administered at a dose of 0.05-0.3 mg.

Instant Claim 8 is drawn to claim 1, and limits wherein the empathogen/entactogen is administered at a time chosen from the group consisting of before administering the psychedelic, **at the same time as** administering the psychedelic, after administering the psychedelic, and before and after administering the psychedelic. **Instant Claim 9** is drawn to claim 1, and limits wherein the psychedelic is a short-acting psychedelic, and the empathogen/entactogen is administered 1-2 hours

before the short-acting psychedelic. **Instant Claim 10** is drawn to claim 1, and limits wherein the individual has a psychiatric disorder chosen from the group consisting of depression, anxiety, anxiety related to life-threatening disease, obsessive-compulsive disorder, personality disorder, and addiction. **Instant Claim 11** is drawn to claim 1, and limits wherein said enhancing step further includes the step of reducing bad drug effects chosen from the group consisting of anxiety, fear, fear of loss of body control, anxious-ego dissolution, disembodiment, fear of impaired thought control, paranoia, panic, negative thoughts, grooming, nadir effects, and combinations thereof. **Instant Claim 12** is drawn to claim 1, wherein said enhancing step further includes the step of improving good drug effects chosen from the group consisting of drug linking, oceanic boundlessness, experience of unity, spiritual experience, blissful state, insightfulness, connectedness, mystical experiences, mystical-type effects, positive mood, transcendence of time/space, ineffability, well-being, trust, feelings of love, feeling open, peak experience, and combinations thereof. **Instant Claim 13** is drawn to claim 1, wherein the empathogen/ entactogen reduces anxiety up to 6 hours after administration. **Instant Claim 20** recites a method of enhancing positive therapeutic effects of a psychedelic, including the steps of: inducing the release of endogenous monoamines, and stimulating 5-HT_{2A} receptors. **Instant Claim 21** is drawn to claim 20, wherein said inducing step is accomplished by administering an empathogen/ entactogen chosen from the group consisting of 3,4-methylenedioxymethamphetamine (MDMA), 3,4-methylendioxyamphetamine (MDA), 3,4-methylenedioxyethyl-amphetamine (MDEA), 5,6-methylenedioxy-2-aminoindane (MDAI), mephedrone, methylone, 3-MMC, homologues thereof, analogues thereof, and prodrugs thereof. **Instant Claim 22** is drawn to claim 20, wherein said stimulating step is accomplished

by administering a psychedelic chosen from the group consisting of psilocybin, psilocin, lysergic acid diethylamide (LSD), mescaline, dimethyltryptamine (DMT), 2,5-dimethoxy-4-iodoamphetamine (DOI), 2,5-dimethoxy-4-bromoamphetamie (DOB), phenethylamine or tryptamine psychedelics, salts thereof, analogs thereof, prodrugs thereof, and homologues thereof. **Instant Claim 23** is drawn to claim 20, further including the step of improving good drug effects, more specifically wherein the good drug effects are chosen from the group consisting of drug linking, oceanic boundlessness, experience of unity, spiritual experience, blissful state, insightfulness, connectedness, mystical experiences, mystical-type effects, positive mood, transcendence of time/space, ineffability, well-being, trust, feelings of love, feeling open, peak experience, and combinations thereof. **Instant claim 24** is drawn to claim 20, further including the step of reducing bad drug effects; and the bad drug effects are chosen from the group consisting of anxiety, fear, fear of loss of body control, anxious-ego dissolution, disembodiment, fear of impaired thought control, paranoia, panic, negative thoughts, grooming, nadir effects, and combinations thereof. **Instant Claim 25** recites a method of treating a patient including the step of: enhancing a mood of the patient prior to psychedelic treatment. **Instant Claim 25** recites a method of treating a patient including the step of: enhancing a mood of the patient prior to psychedelic treatment. **Instant Claim 26** is drawn to claim 25, wherein said enhancing step is further defined as administering an empathogen/ entactogen chosen from the group consisting of 3,4-methylenedioxymethamphetamine (MDMA), 3,4-methylendioxy-amphetamine (MDA), 3,4-methylenedioxyethyl-amphetamine (MDEA), 5,6-methylenedioxy-2-aminoindane (MDAI), mephedrone, methylone, 3-MMC, homologues thereof, analogues thereof, and prodrugs thereof. **Instant Claim 27** is

drawn to claim 25, and limits wherein the psychedelic is chosen from the group consisting of psilocybin, psilocin, lysergic acid diethylamide (LSD), mescaline, dimethyltryptamine (DMT), 2,5-dimethoxy-4-iodoamphetamine (DOI), 2,5-dimethoxy-4-bromoamphetamie (DOB), phenethylamine or tryptamine psychedelics, salts thereof, analogs thereof, prodrugs thereof, and homologues thereof**. Instant Claim 28** is drawn to claim 25, wherein said enhancing a mood step is further defined as increasing positive acute effects chosen from the group consisting of good drug effect, drug liking, well-being, trust, feelings of love, openness, oceanic boundlessness, experience of unity, spiritual experience, blissful state, insightfulness, mystical-type experience, and positively experienced psychedelic effects, aspects of ego-dissolution, and combinations thereof, and decreasing negative acute effects chosen from the group consisting of bad drug effect, anxiety, fear, increased ratings of anxious ego-dissolution, descriptions of acute paranoia, states of panic and anxiety, and combinations thereof.

CLAIM 1 of **U.S. Pat. No. 11,364,221** recites a method of enhancing positive therapeutic effects of a psychedelic, including the steps of: administering an empathogen/ entactogen and a psychedelic in a same single oral dosage form to an individual, wherein the empathogen/entactogen induces a positive psychological state in the individual and is administered in a dose of 20-200 mg; and enhancing a positive response to the psychedelic. **CLAIM 2** recites the method of claim 1, wherein the empathogen/entactogen and psychedelic have different release profiles. **CLAIM 3** recites the method of claim 1, wherein the psychedelic is chosen from the group consisting of psilocybin, psilocin, lysergic acid diethylamide (LSD), mescaline, dimethyltryptamine (DMT), 2,5-dimethoxy-4-iodoamphetamine (DOI), 2,5-dimethoxy-

4-bromo-amphetamine (DOB), phenethylamine or tryptamine psychedelics, salts thereof, analogs thereof, prodrugs thereof, and homologues thereof. **CLAIM 4** recites the method of claim 1, wherein the psychedelic is LSD and is administered in a dose of 0.05-0.3 mg. **CLAIM 5** recites the method of claim 1, wherein the empathogen/ entactogen is chosen from the group consisting of 3,4-methylenedioxymeth-amphetamine (MDMA), 3,4-methylen-dioxyamphetamine (MDA), 3,4,-methylene-dioxyethylamphetamine (MDEA), 5,6-methylenedioxy-2-aminoindane (MDAI), mephedrone, methylone, 3-methylmeth-cathinone (3-MMC), homologues thereof, analogues thereof, and prodrugs thereof. **CLAIM 6** recites the method of claim 1, wherein the psychedelic is a short-acting psychedelic. **CLAIM 7** recites the method of claim 1, wherein the individual has a psychiatric disorder chosen from the group consisting of depression, anxiety, anxiety related to life-threatening disease, obsessive-compulsive disorder, personality disorder, and addiction. **CLAIM 8** recites the method of claim 1, wherein said enhancing step further includes the step of reducing bad drug effects chosen from the group consisting of anxiety, fear, fear of loss of body control, anxious-ego dissolution, disembodiment, fear of impaired thought control, paranoia, panic, negative thoughts, grooming, nadir effects, and combinations thereof. **CLAIM 9** recites the method of claim 1, wherein said enhancing step further includes the step of improving good drug effects chosen from the group consisting of drug linking, oceanic boundlessness, experience of unity, spiritual experience, blissful state, insightfulness, connectedness, mystical experiences, mystical-type effects, positive mood, transcendence of time/space, ineffability, well-being, trust, feelings of love, feeling open, peak experience, and combinations thereof. **CLAIM 10** recites the method of claim 1, wherein the empathogen/entactogen reduces anxiety up to 6 hours after administration.

Thus, the subject matter claimed in the instant application is fully disclosed in the patent and is covered by the patent since the patent and the application are claiming common subject matter, as follows:

Both the claims of the '221 patent and instant claim 5 recite a method of enhancing positive therapeutic effects of a psychedelic, comprising administering an empathogen/ entactogen and a psychedelic to an individual, wherein the empathogen/ entactogen induces a positive psychological state in the individual, wherein the empathogen/ entactogen is MDMA and is administered at a dose of 20-200 mg. The '221 patent recites the same genus of psychedelics administered at the same dosage range, for the treatment of the same subgenus of psychiatric disorders.

Thus, it would be obvious to one skilled in the art to pick and choose from the limited genus of empathogens/ entactogens recited in claim 5 of the '221 patent and select MDMA, in the same method of enhancing positive therapeutic effects of a psychedelic comprising administering an empathogen/ entactogen and a psychedelic to an individual in need thereof.

Conclusion

19. Claims 1-28 are pending in the application. Claims 14-19 are presently withdrawn as directed to a nonelected invention. Claims 1-13 and 20-28 are currently rejected. No claim is presently allowed.

Correspondence

Any inquiry concerning this communication or earlier communications from the examiner should be directed to JANET L COPPINS whose telephone number is

(571)272-0680. The examiner can normally be reached Monday-Friday 8:30AM-5PM 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 W 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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