IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of: Liechti, Matthias et al. Confirmation No.: 1014
Serial No.: 17/734,601 Group No.:
Filing or 371(c) Date: May 02, 2022 Examiner:
Entitled: LSD and Psilocybin Dose Equivalence Determination

THIRD-PARTY PRE-ISSUANCE SUBMISSION

Examiner:

The following documents, which are also identified in the Form PTO/SB/429 filed herewith, are submitted for your consideration as being of potential relevance to the examination of the present application:

1. ABRAMSON (1965) "Lysergic Acid Diethylamide (LSD-25). 38. Comparison with action of methysergide and psilocybin on text subjects." Vol. 3(1): 81-96. Journal of Asthma Research.
2. FUENTES (2020) "Therapeutic Use of LSD in Psychiatry: A Systematic Review of Randomized-Controlled Clinical Trials" Vol. 10. Frontiers in Psychiatry.
3. Intl. Pat. App. Pub No. 2021/211358 "LSD Dose Identification" (Published October 21, 2022)

Attached hereto is a claim chart providing a concise description of the relevance of each reference in the document list to the elements of the presently pending claims.

U.S.S.N. 17/734,601 Pending Claims	References
1. A method of treating a patient with a psychedelic, including the steps of: administering either a dose of LSD to the patient that is equivalent to a known dose of psilocybin with desired acute and therapeutic effects, or administering a dose of psilocybin to the patient that is equivalent to a known dose of LSD with desired acute and therapeutic effects; and treating the patient.	1. ABRAMSON (1965) "Lysergic Acid Diethylamide (LSD-25). 38. Comparison with action of methysergide and psilocybin on text subjects." Vol. 3(1): 81-96. Journal of Asthma Research. From Page 95 "Although it was found that differences in the rates of action and in the duration of action were observed, the effects of the drugs, as measured by the questionnaire, were strikingly similar at their respective dosages just above the threshold level and at 2 to 3 times above these levels**. One hundred and seventy mcg of methysergide and one hundred and thirty-five mcg of psilocybin are estimated to be equal to 1 mcg of LSD near the threshold level of dosage.**"
2. The method of claim 1 , wherein the patient is being treated for a condition chosen from the group consisting of	2. FUENTES (2020) "Therapeutic Use of LSD in Psychiatry: A Systematic Review of Randomized-Controlled Clinical Trials" Vol. 10. Frontiers in Psychiatry.

depression, anxiety, and addiction.	From Abstract "Lysergic acid diethylamide (LSD) was studied from the 1950s to the 1970s to evaluate behavioral and personality changes, as well as remission of psychiatric symptoms in various disorders**. LSD was used in the treatment of anxiety, depression, psychosomatic diseases and addiction**." Intl. Pat. App. Pub No. 2021/211358 "LSD Dose Identification" (Published October 21, 2022) From Claim 37 "The method of claim 36, wherein the individual has a condition chosen from the group consisting of **depression, anxiety, substance use disorder, addiction,** personality disorder, eating disorder, post-traumatic stress disorder, obsessive compulsive disorder, pain disorders, migraine, cluster headache, and requiring palliative care."
3. The method of claim 1 , further including the step of maximizing positive acute effects of the psychedelic wherein the positive subjective acute effects are chosen from the group consisting of good drug effect, drug liking, well-being, oceanic boundlessness, experience of unity, spiritual experience, blissful state, insightfulness, mystical-type experience positively experienced psychedelic effects, aspects of ego-dissolution, and combinations thereof.	Intl. Pat. App. Pub No. 2021/211358 "LSD Dose Identification" (Published October 21, 2022) From [00037] "Generally, the present invention provides for a method of dosing and treating patients with a psychedelic, by administering a psychedelic (such as LSD or a salt thereof) at a specific dose defined below such as a microdose, minidose, psychedelic dose, good effect dose, ego-dissolution dose, or cardiovascular safe dose, and producing **maximum positive subjective acute effects** that are known to be associated with more positive long-term outcomes and minimizing negative acute effects." From [00038] ""**Positive acute effects**" as used herein refers primarily to an increase in subjective rating of **"good drug effect" and may also include ratings of "drug liking", "well-being", "oceanic boundlessness", "experience of unity", "spiritual experience", "blissful state", "insightfulness", any "mystical-type experience" and positively experienced "psychedelic effects", and "aspects of ego-dissolution"** if experienced without anxiety. From Claim 5 "The method of claim 1, wherein the psychedelic is chosen from the group consisting of **LSD**, **psilocybin**, mescaline, dimethyltryptamine (DMT), 2,5-dimethoxy-4-iodoamphetamine (DOI), 2,5-dimethoxy-4-bromoamphetamie (DOB), salts thereof, tartrates thereof, analogs thereof, and homologues thereof."
4. The method of claim 1 , further including the step of minimizing negative acute effects chosen from the group consisting of bad drug effect, anxiety, fear, increased ratings of anxious ego-dissolution, or	Intl. Pat. App. Pub No. 2021/211358 "LSD Dose Identification" (Published October 21, 2022) From [00037] "Generally, the present invention provides for a method of dosing and treating patients with a psychedelic, by administering a psychedelic (such as LSD or a salt thereof) at a specific dose defined below such as a microdose, minidose, psychedelic dose, good effect dose, ego-dissolution dose, or cardiovascular safe dose, and producing maximum positive

acute paranoia, states of panic, and combinations thereof.	subjective acute effects that are known to be associated with more positive long-term outcomes and **minimizing negative acute effects**." From [00039] ""**Negative acute effects**" as used herein refers primarily to subjective ratings of **"bad drug effect" and "anxiety" and "fear" and may additionally include increased ratings of "anxious ego-dissolution", or descriptions of acute paranoia or states of panic** an anxiety as observed by others."
5. The method of claim 1 , wherein the dose of LSD is 1 - 200 mcg.	Intl. Pat. App. Pub No. 2021/211358 "LSD Dose Identification" (Published October 21, 2022) From Claim 5 "The method of claim 1, wherein the psychedelic is chosen from the group consisting of **LSD**, psilocybin, mescaline, dimethyltryptamine (DMT), 2,5-dimethoxy-4-iodoamphetamine (DOI), 2,5-dimethoxy-4-bromoamphetamie (DOB), salts thereof, tartrates thereof, analogs thereof, and homologues thereof." From Claim 6 "The method of claim 1, wherein the dose is a microdose of **1 -20 mcg**" From Claim 7 "The method of claim 1, wherein the dose is a minidose of **21 -29 mcg**." From Claim 8 "The method of claim 1, wherein the dose is a psychedelic dose of **greater than 30 mcg**. From Claim 9 "The method of claim 1, wherein the dose is a good effect dose of **30-100 mcg**." From Claim 10 "The method of claim 1, wherein the dose is an ego-dissolution dose of **greater than 100 mcg**" From Claim 11 "The method of claim 1, wherein the dose is a cardiovascular safe dose of **50-200 mcg**."
6. The method of claim 1 , wherein the dose of psilocybin is 1 -30 mg.	Intl. Pat. App. Pub No. 2021/211358 "LSD Dose Identification" (Published October 21, 2022) From Claim 5 "The method of claim 1, wherein the psychedelic is chosen from the group consisting of LSD, **psilocybin**, mescaline, dimethyltryptamine (DMT), 2,5-dimethoxy-4-iodoamphetamine (DOI), 2,5-dimethoxy-4-bromoamphetamie (DOB), salts thereof, tartrates thereof, analogs thereof, and homologues thereof." From Claim 10 "The method of claim 1, wherein the dose is an ego-dissolution dose of **greater than 100 mcg**"

7. A method of treating a patient with LSD, including the steps of: administering a dose of LSD to the patient equivalent to those of psilocybin known to be associated with positive long-term therapeutic outcomes.	Intl. Pat. App. Pub No. 2021/211358 "LSD Dose Identification" (Published October 21, 2022) From [00037] "Generally, the present invention provides for **a method of dosing and treating patients with a psychedelic, by administering a psychedelic (such as LSD or a salt thereof) at a specific dose** defined below such as a microdose, minidose, psychedelic dose, good effect dose, ego-dissolution dose, or cardiovascular safe dose, and **producing maximum positive subjective acute effects that are known to be associated with more positive long-term outcomes** and minimizing negative acute effects." From Claim 5 "The method of claim 1, wherein the psychedelic is chosen from the group consisting of **LSD, psilocybin,** mescaline, dimethyltryptamine (DMT), 2,5-dimethoxy-4-iodoamphetamine (DOI), 2,5-dimethoxy-4-bromoamphetamie (DOB), salts thereof, tartrates thereof, analogs thereof, and homologues thereof."
8. A method of determining a dose of a psychedelic or the dose-equivalence to another psychedelic to be administered to an individual, including the steps of: administering a dose of a psychedelic to an individual; determining positive acute effects and negative acute effects in the individual; adjusting the dose to provide more positive acute effects than negative acute effects in the individual; and equating the dose to an equivalent dose of a second psychedelic.	Intl. Pat. App. Pub No. 2021/211358 "LSD Dose Identification" (Published October 21, 2022) From [00037] "Generally, the present invention provides for a **method of dosing and treating patients with a psychedelic, by administering a psychedelic (such as LSD or a salt thereof) at a specific dose defined below such as a microdose, minidose, psychedelic dose, good effect dose, ego-dissolution dose, or cardiovascular safe dose, and producing maximum positive subjective acute effects that are known to be associated with more positive long-term outcomes and minimizing negative acute effects."** From Claim 5 "The method of claim 1, wherein the psychedelic is chosen from the group consisting of **LSD, psilocybin,** mescaline, dimethyltryptamine (DMT), 2,5-dimethoxy-4-iodoamphetamine (DOI), 2,5-dimethoxy-4-bromoamphetamie (DOB), salts thereof, tartrates thereof, analogs thereof, and homologues thereof."
9. The method of claim 8, wherein the individual is healthy and further including the step of predicting doses for unhealthy individuals.	Intl. Pat. App. Pub No. 2021/211358 "LSD Dose Identification" (Published October 21, 2022) From [00015] "The present invention provides for a method of **defining therapeutic doses of a psychedelic in clinical trials, by administering a dose of a psychedelic to a healthy individual** in a

	phase 1 study of a microdose, minidose, psychedelic dose, good effect dose, ego-dissolution dose, or cardiovascular safe dose, determining positive acute effects and negative acute effects in the individual, adjusting the dose to provide more positive acute effects than negative acute effects in the individual, and using the adjusted dose for a phase 2 or phase 3 study in patients." From [00058] **"The individual can be healthy, and the method can be used to predict doses for unhealthy individuals."**
10. The method of claim 8, further including the step of determining long term dosing and dose schedules for the psychedelic.	Intl. Pat. App. Pub No. 2021/211358 "LSD Dose Identification" (Published October 21, 2022) From [0058] "This method can be used to **determine long term dosing and dose schedules.**"

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2	Third-Party Submission Under 37 CFR 1.290	Third-party-preissuance-submission.pdf	57298 385f5a4121b53c046d17d453c266a3c58776eed3	no	3
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