

**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE**

In re Application of: BLUMSTOCK; Judith Confirmation No.: 6210

Serial No.: 17/427,037 Group No.:

Filing or 371(c) Date: January 29, 2020 Examiner:

Entitled: Methods and compositions comprising a 5ht receptor agonist for the treatment of psychological, cognitive, behavioral, and/or mood disorders

**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. South African Pat. App. Pub. No. ZA2000/02311 "5HT1 RECEPTOR AGONISTS AND EITHER A COX 2 INHIBITOR OR NSAID FOR THE TREATMENT OF MIGRAINE" (Published January 30, 2002)
2. Int'l Pat. App. Pub. No. WO/2016/138138 "5HT AGONISTS FOR TREATING DISORDERS" (Published September 1, 2016)
3. JOHNSTAD (2018) "Powerful substances in tiny amounts: An interview study of psychedelic microdosing" Nordic Studies on Alcohol and Drugs. 35(1):39-51.
4. SESSA (2015) "Underground MDMA-, LSD- and 2-CB-assisted individual and group psychotherapy in Zurich: Outcomes, implications and commentary" Drug Science, Policy and Law. 2(0):1-8.
5. RIJCKEVORSEL (2006) "Cognitive problems related to epilepsy syndromes, especially malignant epilepsies" Seizure. 15(4):227-234.
6. ARONSON (2014) Manson's Tropical Infectious Diseases (Twenty-Third Edition). ISBN: 9780702051012
7. U.S. App. Pub. No. US/2018/0021326 "Compositions and methods for enhancing neuroregeneration and cognition by combining mushroom extracts containing active ingredients psilocin or psilocybin with erinacines or hericenones enhanced with niacin" (Published January 25, 2018)
8. Int'l Pat. App. Pub. No. WO/2018/148605 "COMPOSITIONS AND METHODS COMPRISING A PSILOCYBIN DERIVATIVE" (Published August 16, 2018)
9. CARHART-HARRIS (2016) "Psilocybin with psychological support for treatment-resistant depression: an open label feasibility study" The Lancet Psychiatry. 3(7):619-627.
10. DOLDER (2015) "Pharmacokinetics and Concentration-Effect Relationship of Oral LSD in Humans" International Journal of Neuropsychopharmacology. 19(10):1-7.

11. Int'l Pat. App. Pub. No. WO/2019/079742 "METHODS AND SYSTEMS FOR ENHANCING SAFETY OF PSYCHEDELIC DRUG THERAPIES" (Published April 25, 2019)
12. Int'l Pat. App. Pub. No. WO/2014/140925 "TOPICAL COMPOSITIONS AND METHODS OF TREATMENT OF TOPICAL DISORDERS" (Published September 18, 2014)
13. Int'l Pat. App. Pub. No. WO/2018/135943 "Psilocybin and/or psilocin in combination with cannabinoids and/or terpenes" (Published July 26, 2018)
14. Int'l Pat. App. Pub. No. WO/2018/195455 "ASSESSING AND TREATING PSYCHEDELIC-RESPONSIVE SUBJECTS" (Published October 25, 2018)
15. LINDENBLATT (1998) "Quantitation of psilocin in human plasma by high-performance liquid chromatography and electrochemical detection: comparison of liquid-liquid extraction with automated on-line solid-phase extraction" *Journal of Chromatography B: Biomedical Sciences and Applications*. 209(2):255-263.
16. Kryptonite (2009) "A Glorious New Year LSD & MDMA (Ecstasy)" Erowid. Retrieved July 4th, 2010.  
<https://web.archive.org/web/20100704210848/https://www.erowid.org/experiences/exp.php?ID=58609>
17. CARHART-HARRIS (2018) "Psilocybin with psychological support for treatment-resistant depression: six-month follow-up" *Psychopharmacology (Berl)*. 235(2):399-408.
18. ANDERSSON (2017) "Psychoactive substances as a last resort - a qualitative study of self-treatment of migraine and cluster headaches" *Harm Reduction Journal*. 14(1):1-10.

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. 17/427,037 Pending Claims	References
<p><b>1.</b> A method of managing a neurological condition or one or more symptoms thereof in a subject in need thereof, comprising administering to the subject a pharmaceutical composition comprising:</p> <p>a) a therapeutically effective amount of one or more 5HT receptor agonist or a pharmaceutically acceptable salt, solvate, metabolite, derivative, or prodrug thereof; and</p> <p>b) a pharmaceutically acceptable excipient wherein the therapeutically effective amount of the 5HT receptor agonist or a pharmaceutically acceptable salt, solvate, metabolite, derivative, or prodrug thereof is provided to the subject in need thereof in an amount insufficient to provide an adverse side effect, such as hallucinogenic experience.</p>	<p>2. Int'l Pat. App. Pub. No. WO/2016/138138 "5HT AGONISTS FOR TREATING DISORDERS" (Published September 1, 2016)</p> <p>From <b>claim 1</b> "A method of <b>treating an epilepsy disorder</b>, said method comprising administering to a subject in need thereof a therapeutically <b>effective amount of a 5HT receptor agonist</b>, or a pharmaceutically acceptable salt thereof."</p> <p>From <b>claim 24</b> "The method of claim 1, wherein said <b>5HT receptor agonist</b> is administered to said subject at an <b>amount of about 0.1 mg to about 1000 mg per kg body weight.</b>"</p> <p>From <b>paragraph [0084]</b> "An example of an "<b>effective amount</b>" is an <b>amount of the 5-HT agonist</b> (including pharmaceutically acceptable salts thereof) which is <b>sufficient to contribute to the treatment, prevention, or reduction of a symptom or symptoms of a disease</b>, which could also be referred to as a "therapeutically effective amount.""</p> <p>7. U.S. App. Pub. No. US/2018/0021326 "Compositions and methods for enhancing neuroregeneration and cognition by combining mushroom extracts containing active ingredients psilocin or psilocybin with erinacines or hericenones enhanced with niacin" (Published January 25, 2018)</p> <p>From <b>claim 1</b> "A <b>method for improving neurological health</b> of an animal comprising: administering a therapeutically effective amount of a composition to an animal, wherein the composition comprises one or more of <b>psilocybin, psilocin</b>, baeocystin, norbaeocystin, salts thereof, or combinations thereof, one or more of erinacines, hericenones or combinations thereof, and niacin."</p> <p>From <b>claim 14</b> "A method for <b>improving neurological health comprising: administering</b> a daily dose of a composition for at least one month to a patient, wherein the composition comprises: one or more <b>of about 0.1 to 10 mg of psilocybin, psilocin</b>, baeocystin, norbaeocystin, or salts thereof, one or more of about <b>0.1 to 1 gram of psilocybin mushrooms</b>, or combinations thereof; about 0.1 to 200 mg of one or more of erinacines, hericenones, or combinations thereof; and about 1 to 200 mg of niacin."</p> <p>From paragraph <b>[0011]</b> "The term "effective amount" or "therapeutic amount" refers to an <b>amount sufficient to have neurogenerative activity</b>. This amount may vary to some degree depending on the mode of administration, but will be in the same general range. The <b>exact effective amount necessary could vary</b> from subject to subject, <b>depending on the</b></p>

	<p><b>compound, preventative treatment or condition being treated</b>, the mode of administration, etc.”</p> <p>3. JOHNSTAD (2018) “Powerful substances in tiny amounts: An interview study of psychedelic microdosing” <i>Nordic Studies on Alcohol and Drugs</i>. 35(1):39-51.</p> <p>From <b>page 39</b> “This article presents a qualitative interview study of people who <b>microdose with psychedelic drugs</b>, which means that the user takes about one tenth of an ordinary recreational dose.”</p> <p>From <b>page 44</b> “<b>For LSD, this amounted to somewhere between 10 and 25 mcg</b>, and for <i>Psilocybe cubensis</i> mushrooms to <b>0.1–0.3 g.</b>”</p> <p>6. ARONSON (2014) <i>Manson's Tropical Infectious Diseases (Twenty-Third Edition)</i>. ISBN: 9780702051012</p> <p>From <b>page 1146</b> “Psilocybin content varies based on such factors as species and preparation. The most commonly used mushroom is <i>Psilocybe cubensis</i>, which contains <b>10–12 mg of psilocybin per gram of dried mushrooms</b>”</p>
<p>2. A method of treating the symptoms of a neurological condition in a subject suffering from or susceptible to the neurological condition, comprising administering to the subject a pharmaceutical composition comprising:</p> <p>a) a therapeutically effective amount of one or more 5HT receptor agonist or a pharmaceutically acceptable salt, solvate, metabolite, derivative, or prodrug thereof; and</p>	<p>2. Int’l Pat. App. Pub. No. WO/2016/138138 “5HT AGONISTS FOR TREATING DISORDERS” (Published September 1, 2016)</p> <p>From <b>claim 1</b> “A method of <b>treating an epilepsy disorder</b>, said method comprising administering to a subject in need thereof a therapeutically <b>effective amount of a 5HT receptor agonist</b>, or a pharmaceutically acceptable salt thereof.”</p> <p>From <b>claim 24</b> “The method of claim 1, wherein said <b>5HT receptor agonist</b> is administered to said subject at an <b>amount of about 0.1 mg to about 1000 mg per kg body weight.</b>”</p> <p>From <b>paragraph [0084]</b> “An example of an “<b>effective amount</b>” is an <b>amount of the 5-HT agonist</b> (including pharmaceutically acceptable salts thereof) which is <b>sufficient to contribute to the treatment, prevention, or reduction of a symptom or symptoms of a disease</b>, which could also be referred to as a “therapeutically effective amount.””</p> <p>7. U.S. App. Pub. No. US/2018/0021326 “Compositions and methods for enhancing neuroregeneration and cognition by combining mushroom extracts containing active ingredients psilocin or psilocybin with erinacines or hericenones enhanced with niacin” (Published January 25, 2018)</p>

<p>b) a pharmaceutically acceptable excipient; wherein the therapeutically effective amount of the 5HT receptor agonist or a pharmaceutically acceptable salt, solvate, metabolite, derivative, or prodrug thereof is provided to the subject in need thereof in an amount insufficient to provide an adverse side effect, such as hallucinogenic experience.</p>	<p>From <b>claim 1</b> “A <b>method for improving neurological health</b> of an animal comprising: administering a therapeutically effective amount of a composition to an animal, wherein the composition comprises one or more of <b>psilocybin, psilocin</b>, baeocystin, norbaeocystin, salts thereof, or combinations thereof, one or more of erinacines, hericenones or combinations thereof, and niacin.”</p> <p>From <b>claim 14</b> “A method for <b>improving neurological health comprising: administering</b> a daily dose of a composition for at least one month to a patient, wherein the composition comprises: one or more of <b>about 0.1 to 10 mg of psilocybin, psilocin</b>, baeocystin, norbaeocystin, or salts thereof, one or more of <b>about 0.1 to 1 gram of psilocybin mushrooms</b>, or combinations thereof; about 0.1 to 200 mg of one or more of erinacines, hericenones, or combinations thereof; and about 1 to 200 mg of niacin.”</p> <p>From paragraph <b>[0011]</b> “The term “effective amount” or “therapeutic amount” refers to an <b>amount sufficient to have neurogenerative activity</b>. This amount may vary to some degree depending on the mode of administration, but will be in the same general range. The <b>exact effective amount necessary could vary</b> from subject to subject, <b>depending on the compound, preventative treatment or condition being treated</b>, the mode of administration, etc.”</p> <p>3. JOHNSTAD (2018) “Powerful substances in tiny amounts: An interview study of psychedelic microdosing” <i>Nordic Studies on Alcohol and Drugs</i>. 35(1):39-51.</p> <p>From <b>page 39</b> “This article presents a qualitative interview study of people who <b>microdose with psychedelic drugs</b>, which means that the user takes about one tenth of an ordinary recreational dose.”</p> <p>From <b>page 39</b> “To <b>microdose with a psychedelic drug means to take a dose small enough to provide no intoxication</b> or significant alteration of consciousness.”</p> <p>From <b>page 44</b> “<b>For LSD, this amounted to somewhere between 10 and 25 mcg</b>, and for <i>Psilocybe cubensis</i> mushrooms to <b>0.1–0.3 g</b>.”</p> <p>6. ARONSON (2014) <i>Manson's Tropical Infectious Diseases</i> (Twenty-Third Edition). ISBN: 9780702051012</p> <p>From <b>page 1146</b> “Psilocybin content varies based on such factors as species and preparation. The most commonly used mushroom is <i>Psilocybe cubensis</i>, which contains <b>10–12 mg of psilocybin per gram of dried mushrooms</b>”</p>
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3. The method of any one of the preceding claims, wherein the 5HT receptor agonist or a pharmaceutically acceptable salt, solvate, metabolite, derivative, or prodrug thereof is present in an amount of from about 0.1 mg to about 50 mg (e.g. about 0.1 mg to about 10 mg, about 0.2 mg to about 5 mg, about 10 mg to about 50 mg, or the like).

2. Int'l Pat. App. Pub. No. WO/2016/138138 "5HT AGONISTS FOR TREATING DISORDERS" (Published September 1, 2016)

From **claim 1** "A method of **treating an epilepsy disorder**, said method comprising administering to a subject in need thereof a therapeutically **effective amount of a 5HT receptor agonist**, or a pharmaceutically acceptable salt thereof."

From **claim 24** "The method of claim 1, wherein said **5HT receptor agonist** is administered to said subject at an **amount of about 0.1 mg to about 1000 mg per kg body weight.**"

7. U.S. App. Pub. No. US/2018/0021326 "Compositions and methods for enhancing neuroregeneration and cognition by combining mushroom extracts containing active ingredients psilocin or psilocybin with erinacines or hericenones enhanced with niacin" (Published January 25, 2018)

From **claim 1** "A **method for improving neurological health** of an animal comprising: administering a therapeutically effective amount of a composition to an animal, wherein the composition comprises one or more of **psilocybin, psilocin**, baeocystin, norbaeocystin, salts thereof, or combinations thereof, one or more of erinacines, hericenones or combinations thereof, and niacin."

From **claim 14** "A method for **improving neurological health comprising: administering** a daily dose of a composition for at least one month to a patient, wherein the composition comprises: one or more of **about 0.1 to 10 mg of psilocybin, psilocin**, baeocystin, norbaeocystin, or salts thereof, one or more of **about 0.1 to 1 gram of psilocybin mushrooms**, or combinations thereof; about 0.1 to 200 mg of one or more of erinacines, hericenones, or combinations thereof; and about 1 to 200 mg of niacin."

3. JOHNSTAD (2018) "Powerful substances in tiny amounts: An interview study of psychedelic microdosing" Nordic Studies on Alcohol and Drugs. 35(1):39-51.

From **page 39** "This article presents a qualitative interview study of people who **microdose with psychedelic drugs**, which means that the user takes about one tenth of an ordinary recreational dose."

From **page 39** "To **microdose with a psychedelic drug means to take a dose small enough to provide no intoxication** or significant alteration of consciousness."

From **page 44** "For LSD, this amounted to somewhere between **10 and 25 mcg**, and for *Psilocybe cubensis* mushrooms to **0.1–0.3 g.**"

	<p>6. ARONSON (2014) Manson's Tropical Infectious Diseases (Twenty-Third Edition). ISBN: 9780702051012</p> <p>From <b>page 1146</b> “Psilocybin content varies based on such factors as species and preparation. The most commonly used mushroom is <i>Psilocybe cubensis</i>, which contains <b>10–12 mg of psilocybin per gram of dried mushrooms</b>”</p>
<p><b>4.</b> The method of any one of the preceding claims, wherein the 5HT receptor agonist or a pharmaceutically acceptable salt, solvate, metabolite, derivative, or prodrug thereof is present in an amount of from about 0.1 mg to about 2 mg.</p>	<p>2. Int'l Pat. App. Pub. No. WO/2016/138138 “5HT AGONISTS FOR TREATING DISORDERS” (Published September 1, 2016)</p> <p>From <b>claim 1</b> “A method of <b>treating an epilepsy disorder</b>, said method comprising administering to a subject in need thereof a therapeutically <b>effective amount of a 5HT receptor agonist, or a pharmaceutically acceptable salt thereof.</b>”</p> <p>From <b>claim 24</b> “The method of claim 1, wherein said <b>5HT receptor agonist</b> is administered to said subject at an <b>amount of about 0.1 mg to about 1000 mg per kg body weight.</b>”</p> <p>7. U.S. App. Pub. No. US/2018/0021326 “Compositions and methods for enhancing neuroregeneration and cognition by combining mushroom extracts containing active ingredients psilocin or psilocybin with erinacines or hericenones enhanced with niacin” (Published January 25, 2018)</p> <p>From <b>claim 1</b> “A <b>method for improving neurological health</b> of an animal comprising: administering a therapeutically effective amount of a composition to an animal, wherein the composition comprises one or more of <b>psilocybin, psilocin</b>, baeocystin, norbaeocystin, salts thereof, or combinations thereof, one or more of erinacines, hericenones or combinations thereof, and niacin.”</p> <p>From <b>claim 14</b> “A method for <b>improving neurological health comprising: administering</b> a daily dose of a composition for at least one month to a patient, wherein the composition comprises: one or more of about <b>0.1 to 10 mg of psilocybin, psilocin</b>, baeocystin, norbaeocystin, or salts thereof, one or more of about <b>0.1 to 1 gram of psilocybin mushrooms</b>, or combinations thereof; about 0.1 to 200 mg of one or more of erinacines, hericenones, or combinations thereof; and about 1 to 200 mg of niacin.”</p> <p>3. JOHNSTAD (2018) “Powerful substances in tiny amounts: An interview study of psychedelic microdosing” Nordic Studies on Alcohol and Drugs. 35(1):39-51.</p>

	<p>From <b>page 39</b> “This article presents a qualitative interview study of people who <b>microdose with psychedelic drugs</b>, which means that the user takes about one tenth of an ordinary recreational dose.”</p> <p>From <b>page 44</b> “<b>For LSD, this amounted to somewhere between 10 and 25 mcg</b>, and for <i>Psilocybe cubensis</i> mushrooms to <b>0.1–0.3 g</b>.”</p> <p>6. ARONSON (2014) Manson's Tropical Infectious Diseases (Twenty-Third Edition). ISBN: 9780702051012</p> <p>From <b>page 1146</b> “Psilocybin content varies based on such factors as species and preparation. The most commonly used mushroom is <i>Psilocybe cubensis</i>, which contains <b>10–12 mg of psilocybin per gram of dried mushrooms</b>”</p>
<p><b>5.</b> The method of any one of the preceding claims, wherein the 5HT receptor agonist or a pharmaceutically acceptable salt, solvate, metabolite, derivative, or prodrug thereof is present in an amount of from about 1 mg to about 15 mg.</p>	<p>2. Int’l Pat. App. Pub. No. WO/2016/138138 “5HT AGONISTS FOR TREATING DISORDERS” (Published September 1, 2016)</p> <p>From <b>claim 1</b> “A method of <b>treating an epilepsy disorder</b>, said method comprising administering to a subject in need thereof a therapeutically <b>effective amount of a 5HT receptor agonist, or a pharmaceutically acceptable salt thereof.</b>”</p> <p>From <b>claim 24</b> “The method of claim 1, wherein said <b>5HT receptor agonist</b> is administered to said subject at an <b>amount of about 0.1 mg to about 1000 mg per kg body weight.</b>”</p> <p>7. U.S. App. Pub. No. US/2018/0021326 “Compositions and methods for enhancing neuroregeneration and cognition by combining mushroom extracts containing active ingredients psilocin or psilocybin with erinacines or hericenones enhanced with niacin” (Published January 25, 2018)</p> <p>From <b>claim 1</b> “A <b>method for improving neurological health</b> of an animal comprising: administering a therapeutically effective amount of a composition to an animal, wherein the composition comprises one or more of <b>psilocybin, psilocin</b>, baeocystin, norbaeocystin, salts thereof, or combinations thereof, one or more of erinacines, hericenones or combinations thereof, and niacin.”</p> <p>From <b>claim 14</b> “A method for <b>improving neurological health comprising: administering</b> a daily dose of a composition for at least one month to a patient, wherein the composition comprises: one or more of about <b>0.1 to 10 mg of psilocybin, psilocin</b>, baeocystin, norbaeocystin, or salts thereof, one or more of about <b>0.1 to 1 gram of psilocybin mushrooms</b>, or combinations</p>



	<p>thereof; about 0.1 to 200 mg of one or more of erinacines, hericenones, or combinations thereof; and about 1 to 200 mg of niacin.”</p> <p>6. ARONSON (2014) Manson's Tropical Infectious Diseases (Twenty-Third Edition). ISBN: 9780702051012</p> <p>From <b>page 1146</b> “Psilocybin content varies based on such factors as species and preparation. The most commonly used mushroom is <i>Psilocybe cubensis</i>, which contains 10–12 mg of psilocybin per gram of dried mushrooms”</p>
<p><b>6.</b> The method of any one of the preceding claims, wherein the pharmaceutical composition is a low-dose pharmaceutical composition.</p>	<p>2. Int’l Pat. App. Pub. No. WO/2016/138138 “5HT AGONISTS FOR TREATING DISORDERS” (Published September 1, 2016)</p> <p>From <b>claim 1</b> “A method of <b>treating an epilepsy disorder</b>, said method comprising administering to a subject in need thereof a therapeutically <b>effective amount of a 5HT receptor agonist</b>, or a pharmaceutically acceptable salt thereof.”</p> <p>From <b>claim 24</b> “The method of claim 1, wherein said <b>5HT receptor agonist</b> is administered to said subject at an <b>amount of about 0.1 mg to about 1000 mg per kg body weight.</b>”</p>
<p><b>7.</b> The method of any one of the preceding claims, wherein the pharmaceutical composition comprises a controlled release component.</p>	<p>2. Int’l Pat. App. Pub. No. WO/2016/138138 “5HT AGONISTS FOR TREATING DISORDERS” (Published September 1, 2016)</p> <p>From <b>paragraph [0104]</b> “As used herein, the term "administering" means oral administration, administration as a suppository, topical contact, intravenous, intraperitoneal, intramuscular, intralesional, intrathecal, intranasal or subcutaneous administration, or the implantation of a <b>slow-release device</b>, e.g., a mini-osmotic pump, to a subject. Administration is by any route, including parenteral and transmucosal (e.g., buccal, sublingual, palatal, gingival, nasal, vaginal, rectal, or transdermal). Parenteral administration includes, e.g., intravenous, intramuscular, intra-arteriole, intradermal, subcutaneous, intraperitoneal, intraventricular, and intracranial. Other modes of delivery include, but are not limited to, the use of liposomal formulations, intravenous infusion, transdermal patches, etc.”</p> <p>11. Int’l Pat. App. Pub. No. WO/2019/079742 “METHODS AND SYSTEMS FOR ENHANCING SAFETY OF PSYCHEDELIC DRUG THERAPIES” (Published April 25, 2019)</p> <p>From <b>page 38</b> “For example, the coating may be <b>adapted to release a psychedelic agent in a predetermined pattern</b> (e.g., in order to <b>achieve a controlled release formulation</b>) or it may be adapted not to release the psychedelic agent until after passage of the stomach (enteric coating).”</p>

<p><b>8.</b> The method of any one of the preceding claims, wherein the pharmaceutical composition comprises a controlled release component and an immediate release component.</p>	<p>11. Int’l Pat. App. Pub. No. WO/2019/079742 “METHODS AND SYSTEMS FOR ENHANCING SAFETY OF PSYCHEDELIC DRUG THERAPIES” (Published April 25, 2019)</p> <p>From <b>page 38</b> “For example, the coating may be <b>adapted to release a psychedelic agent in a predetermined pattern</b> (e.g., in order <b>to achieve a controlled release formulation</b>) or it may be adapted not to release the psychedelic agent until after passage of the stomach (enteric coating).”</p>
<p><b>9.</b> The method of any one of the preceding claims, wherein the therapeutically effective amount of 5HT receptor agonist or a pharmaceutically acceptable salt, solvate, metabolite, derivative, or prodrug thereof is provided to a subject in need thereof in an amount and/or formulation insufficient to provide a maximum plasma concentration (Cmax) of (e.g. active form of the) 5HT receptor agonist or a pharmaceutically acceptable salt, solvate, metabolite, derivative, or prodrug thereof of 6 ng/mL or more.</p>	<p>3. JOHNSTAD (2018) “Powerful substances in tiny amounts: An interview study of psychedelic microdosing” Nordic Studies on Alcohol and Drugs. 35(1):39-51.</p> <p>From <b>page 39</b> “This article presents a qualitative interview study of people who <b>microdose with psychedelic drugs</b>, which means that the user takes about <b>one tenth of an ordinary recreational dose.</b>”</p> <p>From <b>page 44</b> “<b>For LSD, this amounted to somewhere between 10 and 25 mcg, and for <i>Psilocybe cubensis</i> mushrooms to 0.1–0.3 g.</b>”</p> <p>6. ARONSON (2014) Manson's Tropical Infectious Diseases (Twenty-Third Edition). ISBN: 9780702051012</p> <p>From <b>page 1146</b> “Psilocybin content varies based on such factors as species and preparation. The most commonly used mushroom is <i>Psilocybe cubensis</i>, which contains <b>10–12 mg of psilocybin per gram of dried mushrooms</b>”</p> <p>15. LINDENBLATT (1998) “Quantitation of psilocin in human plasma by high-performance liquid chromatography and electrochemical detection: comparison of liquid–liquid extraction with automated on-line solid-phase extraction” Journal of Chromatography B: Biomedical Sciences and Applications. 209(2):255-263.</p> <p>From <b>page 261</b></p>

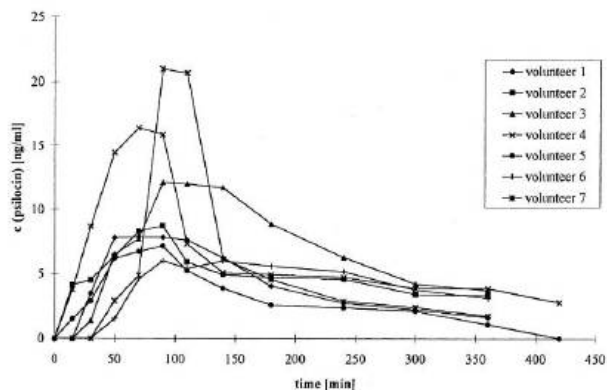


Fig. 4. Plasma concentration curves of psilocin (ng/ml) of volunteers 1, 2, 3, 4, 5, 6 and 7 after p.o. administration of 0.2 mg/kg psilocybin.

10. The method of any one of the preceding claims, wherein the therapeutically effective amount of 5HT receptor agonist or a pharmaceutically acceptable salt, solvate, metabolite, derivative, or prodrug thereof is provided to a subject in need thereof in an amount and/or formulation to provide a maximum plasma concentration (C<sub>max</sub>) of (e.g. active form of the) 5HT receptor agonist or a pharmaceutically acceptable salt, solvate, metabolite, derivative, or prodrug thereof of about 0.1 ng/mL or more and less than 6 ng/mL (e.g. at least 0.5 ng/mL and less than 6 ng/mL, about 1 ng/mL to about 5.5 ng/mL, about 2 ng/mL to about 5 ng/mL, or the like).

3. JOHNSTAD (2018) “Powerful substances in tiny amounts: An interview study of psychedelic microdosing” *Nordic Studies on Alcohol and Drugs*. 35(1):39-51.

From page 39 “This article presents a qualitative interview study of people who **microdose with psychedelic drugs**, which means that the user takes about **one tenth of an ordinary recreational dose.**”

From page 44 “**For LSD, this amounted to somewhere between 10 and 25 mcg, and for *Psilocybe cubensis* mushrooms to 0.1–0.3 g.**”

6. ARONSON (2014) *Manson's Tropical Infectious Diseases* (Twenty-Third Edition). ISBN: 9780702051012

From page 1146 “Psilocybin content varies based on such factors as species and preparation. The most commonly used mushroom is *Psilocybe cubensis*, which contains **10–12 mg of psilocybin per gram of dried mushrooms**”

15. LINDENBLATT (1998) “Quantitation of psilocin in human plasma by high-performance liquid chromatography and electrochemical detection: comparison of liquid–liquid extraction with automated on-line solid-phase extraction” *Journal of Chromatography B: Biomedical Sciences and Applications*. 209(2):255-263.

From page 261

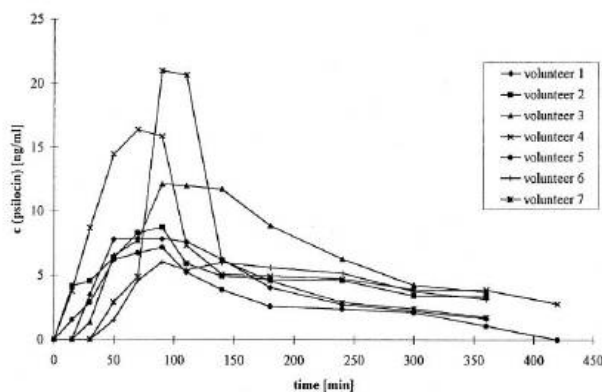


Fig. 4. Plasma concentration curves of psilocin (ng/ml) of volunteers 1, 2, 3, 4, 5, 6 and 7 after p.o. administration of 0.2 mg/kg psilocybin.

10. DOLDER (2015) “Pharmacokinetics and Concentration-Effect Relationship of Oral LSD in Humans” International Journal of Neuropsychopharmacology. 19(10):1-7.

From **page 1** “We characterized the pharmacokinetic profile, pharmacokinetic-pharmacodynamic relationship, and urine recovery of lysergic acid diethylamide and its main metabolite after administration of a single oral dose of **lysergic acid diethylamide (200 µg)** in 8 male and 8 female healthy subjects.”

From **page 1** “Plasma lysergic acid diethylamide concentrations were quantifiable (>0.1ng/mL) in all the subjects up to 12 hours after administration. **Maximal concentrations of lysergic acid diethylamide (mean±SD: 4.5±1.4ng/mL)** were reached (median, range) 1.5 (0.5–4) hours after administration.”

**11.** The method of any one of the preceding claims, wherein the therapeutically effective amount of 5HT receptor agonist or a pharmaceutically acceptable salt, solvate, metabolite, derivative, or prodrug thereof is provided to a subject in need thereof in an amount and/or formulation to provide a plasma concentration of (e.g. active form of the) 5HT receptor

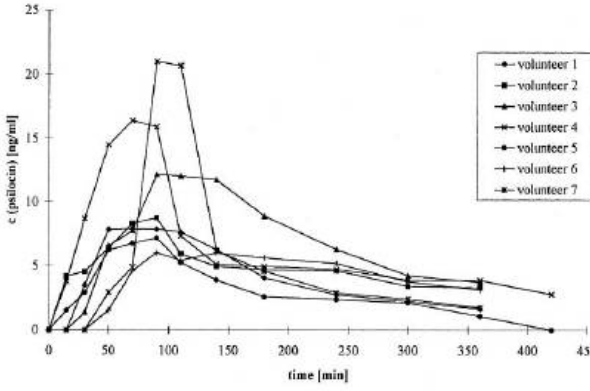
3. JOHNSTAD (2018) “Powerful substances in tiny amounts: An interview study of psychedelic microdosing” Nordic Studies on Alcohol and Drugs. 35(1):39-51.

From **page 39** “This article presents a qualitative interview study of people who **microdose with psychedelic drugs**, which means that the user takes about **one tenth of an ordinary recreational dose.**”

From **page 44** “**For LSD, this amounted to somewhere between 10 and 25 mcg**, and for *Psilocybe cubensis* mushrooms to **0.1–0.3 g.**”

6. ARONSON (2014) Manson's Tropical Infectious Diseases (Twenty-Third Edition). ISBN: 9780702051012

From **page 1146** “Psilocybin content varies based on such factors as species and preparation. The most commonly used mushroom is *Psilocybe*

<p>agonist or a pharmaceutically acceptable salt, solvate, metabolite, derivative, or prodrug thereof of at least 0.1 ng/mL (e.g. at least 0.2 ng/mL, at least 0.3 ng/mL, at least 0.5 ng/mL, or the like) after at least 6 hours (e.g. at least 12 hours, at least 24 hours, at least 36 hours, at least 48 hours, at least 72 hours, at least 96 hours, at least 120 hours, at least 144 hours, or the like).</p>	<p><i>cubensis</i>, which contains 10–12 mg of psilocybin per gram of dried mushrooms”</p> <p>15. LINDENBLATT (1998) “Quantitation of psilocin in human plasma by high-performance liquid chromatography and electrochemical detection: comparison of liquid–liquid extraction with automated on-line solid-phase extraction” <i>Journal of Chromatography B: Biomedical Sciences and Applications</i>. 209(2):255-263.</p> <p>From <b>page 261</b></p>  <p>Fig. 4. Plasma concentration curves of psilocin (ng/ml) of volunteers 1, 2, 3, 4, 5, 6 and 7 after p.o. administration of 0.2 mg/kg psilocybin.</p>
<p><b>12.</b> The method of any one of the preceding claims, wherein the 5HT receptor agonist is a 5HT2 receptor agonist.</p>	<p>2. Int’l Pat. App. Pub. No. WO/2016/138138 “5HT AGONISTS FOR TREATING DISORDERS” (Published September 1, 2016)</p> <p>From <b>claim 2</b> “The method of claim 1, wherein said <b>5HT receptor agonist is a 5HT2A receptor agonist or a 5HT2B receptor agonist.</b>”</p>
<p><b>13.</b> The method of any one of the preceding claims, wherein the 5HT receptor agonist is psilocybin or a pharmaceutically acceptable salt, solvate, metabolite, derivative, or prodrug thereof.</p>	<p>7. U.S. App. Pub. No. US/2018/0021326 “Compositions and methods for enhancing neuroregeneration and cognition by combining mushroom extracts containing active ingredients psilocin or psilocybin with erinacines or hericenones enhanced with niacin” (Published January 25, 2018)</p> <p>From <b>claim 1</b> “A <b>method for improving neurological health</b> of an animal comprising: administering a therapeutically effective amount of a composition to an animal, wherein the composition comprises one or more of <b>psilocybin, psilocin</b>, baeocystin, norbaeocystin, salts thereof, or combinations thereof, one or more of erinacines, hericenones or combinations thereof, and niacin.”</p> <p>From <b>claim 14</b> “A <b>method for improving neurological health comprising: administering a daily dose of a composition for at least one month</b> to a patient, wherein the composition comprises: one or more of about <b>0.1 to 10 mg of psilocybin, psilocin</b>, baeocystin, norbaeocystin, <b>or salts thereof</b>, one</p>

	<p>or more of about 0.1 to 1 gram of psilocybin mushrooms, or combinations thereof; about 0.1 to 200 mg of one or more of erinacines, hericenones, or combinations thereof; and about 1 to 200 mg of niacin.”</p>
<p><b>14.</b> The method of any one of claims 1-12, wherein the 5HT receptor agonist is psilocin or a pharmaceutically acceptable salt, solvate, metabolite, derivative, or prodrug thereof.</p>	<p>7. U.S. App. Pub. No. US/2018/0021326 “Compositions and methods for enhancing neuroregeneration and cognition by combining mushroom extracts containing active ingredients psilocin or psilocybin with erinacines or hericenones enhanced with niacin” (Published January 25, 2018)</p> <p>From <b>claim 1</b> “A <b>method for improving neurological health</b> of an animal comprising: administering a therapeutically effective amount of a composition to an animal, wherein the composition comprises one or more of <b>psilocybin, psilocin</b>, baeocystin, norbaeocystin, salts thereof, or combinations thereof, one or more of erinacines, hericenones or combinations thereof, and niacin.”</p> <p>From <b>claim 14</b> “A method for <b>improving neurological health comprising: administering a daily dose of a composition for at least one month</b> to a patient, wherein the composition comprises: one or more of about <b>0.1 to 10 mg of psilocybin, psilocin</b>, baeocystin, norbaeocystin, <b>or salts thereof</b>, one or more of about 0.1 to 1 gram of psilocybin mushrooms, or combinations thereof; about 0.1 to 200 mg of one or more of erinacines, hericenones, or combinations thereof; and about 1 to 200 mg of niacin.”</p>
<p><b>15.</b> The method of any one of the preceding claims, wherein the pharmaceutical composition further comprises one or more agents selected from the group consisting of surfactants, preservatives, flavoring agents, sweetening agents, and antifoaming agents.</p>	<p>2. Int’l Pat. App. Pub. No. WO/2016/138138 “5HT AGONISTS FOR TREATING DISORDERS” (Published September 1, 2016)</p> <p>From <b>paragraph [0145]</b> “Preparation may include pharmaceutically acceptable carriers. The pharmaceutically acceptable carriers can be either solid or liquid. Solid form preparations include powders, tablets, pills, capsules, cachets, suppositories, and dispersible granules. A solid carrier may be one or more substance that may also act as diluents, <b>flavoring agents</b>, binders, <b>preservatives</b>, tablet disintegrating agents, or an encapsulating material.”</p> <p>From <b>paragraph [0158]</b> “Formulations may include a <b>surfactant</b> or other appropriate co-solvent in the composition.”</p>
<p><b>16.</b> The method of any one of the preceding claims, wherein the pharmaceutical composition is an oral formulation, a buccal formulation, a nasal</p>	<p>2. Int’l Pat. App. Pub. No. WO/2016/138138 “5HT AGONISTS FOR TREATING DISORDERS” (Published September 1, 2016)</p> <p>From <b>paragraph [0104]</b> “As used herein, the term "administering" means <b>oral</b> administration, administration as a suppository, topical contact, intravenous, intraperitoneal, intramuscular, intralesional, intrathecal, intranasal or subcutaneous administration, or the implantation of a slow-release device, e.g., a mini-osmotic pump, to a subject. Administration is by</p>

<p>formulation, or an inhalation formulation.</p>	<p>any route, including parenteral and transmucosal (e.g., <b>buccal</b>, sublingual, palatal, gingival, <b>nasal</b>, vaginal, rectal, or transdermal). Parenteral administration includes, e.g., intravenous, intramuscular, intra-arteriole, intradermal, subcutaneous, intraperitoneal, intraventricular, and intracranial. Other modes of delivery include, but are not limited to, the use of liposomal formulations, intravenous infusion, transdermal patches, etc.”</p>
<p><b>17.</b> The method of any one of the preceding claims, wherein the pharmaceutical composition is in a form selected from a spray, aerosol, mist, nebulae, ointment, cream, gel, paste, salve, solution, suspension, tincture, patch, and atomized vapor.</p>	<p>2. Int’l Pat. App. Pub. No. WO/2016/138138 “5HT AGONISTS FOR TREATING DISORDERS” (Published September 1, 2016)</p> <p>From <b>paragraph [0106]</b> “By "co-administer" it is meant that a composition described herein is administered at the same time, just prior to, or just after the administration of one or more additional therapies. The <b>5-HT agonist</b> (including pharmaceutically acceptable salts thereof) can be administered alone or can be co-administered to the patient. Co-administration is meant to include simultaneous or sequential administration of the compounds individually or in combination (more than one compound). Thus, the preparations can also be combined, when desired, with other active substances (e.g. to reduce metabolic degradation). The 5-HT agonist (including pharmaceutically acceptable salts thereof) can be delivered <b>transdermally</b>, by a topical route, or formulated as applicator sticks, solutions, suspensions, emulsions, <b>gels, creams, ointments, pastes</b>, jellies, paints, powders, and <b>aerosols</b>.”</p>
<p><b>18.</b> The method of any one of the preceding claims, wherein the pharmaceutical composition further comprises an effective amount of a second agent.</p>	<p>1. South African Pat. App. Pub. No. ZA2000/02311 “5HT1 RECEPTOR AGONISTS AND EITHER A COX 2 INHIBITOR OR NSAID FOR THE TREATMENT OF MIGRAINE” (Published January 30, 2002)</p> <p>From <b>claim 1</b> “A pharmaceutical composition for the <b>treatment of migraine</b> comprising a <b>5HT receptor agonist, with either a cyclooxygenase-2 inhibitor or a nonsteroidal antiinflammatory drug (NSAID)</b>, and a pharmaceutically acceptable carrier.”</p>
<p><b>19.</b> The method of claim 18, wherein the second agent is a vasodilator or vasoconstrictor.</p>	<p>7. U.S. App. Pub. No. US/2018/0021326 “Compositions and methods for enhancing neuroregeneration and cognition by combining mushroom extracts containing active ingredients psilocin or psilocybin with erinacines or hericenones enhanced with niacin” (Published January 25, 2018)</p> <p>From <b>paragraph [0005]</b> “As niacin activates nerve endings, the inventor suggests that the addition of <b>niacin contributes an added benefit by enhancing the neurogenic effects of psilocybin, psilocin</b>, erinacines and hericenones by helping these nootropics cross the blood brain barrier, and migrate throughout the nervous systems, and to its end points. Moreover, <b>niacin is a vasodilator</b> improving blood flow in the brain by relaxing constricted blood vessels.”</p>

<p><b>20.</b> The method of claim 19, wherein the vasoconstrictor is epinephrine, phenylephrine, methoxamine, norepinephrine, zolmitriptan, tetrahydrozoline, naphazoline, or combinations thereof.</p>	<p>8. Int'l Pat. App. Pub. No. WO/2018/148605 "COMPOSITIONS AND METHODS COMPRISING A PSILOCYBIN DERIVATIVE" (Published August 16, 2018)</p> <p>From <b>claim 82</b> "A method of modulating activity at a neurotransmitter receptor comprising administering a neurotransmitter activity modulator, and administering a first dosage formulation comprising a first purified <b>psilocybin</b> derivative to the person in need of treatment, wherein the first dosage formulation modulates activity at a neurotransmitter receptor."</p> <p>From <b>claim 86</b> "The method of claim 82, wherein the neurotransmitter receptor is chosen from a serotonin receptor, a cannabinoid receptor, an adrenergic receptor, a dopamine receptor, a GABAergic receptor, a glutaminergic receptor, a histaminergic receptor, a cholinergic receptor, an opioid receptor, or a glycinergic receptor."</p> <p>From <b>claim 90</b> "The method of claim 86, wherein the neurotransmitter receptor is an adrenergic receptor."</p> <p>From <b>claim 91</b> "The method of claim 90, wherein the neurotransmitter activity modulator is an adrenergic drug."</p> <p>From <b>claim 92</b> "The method of claim 91, wherein the adrenergic drug is chosen from adrenaline, agmatine, amoxapine, aptazapine, atomoxetine, bupropion, clonidine, doxepin, duloxetine, esmirtazpine, mianserin, mirabegron, mirtazapine, <b>norepinephrine</b>, phentolamine, <b>phenylephrine</b>, piperoxan, reserpine, ritodrine, setiptiline, tesofensine, timolol, trazodone, trimipramine, or xylazine."</p>
<p><b>21.</b> The method of claim 18, wherein the second agent is a stimulant, an antihistamine, an antiemetic, an antidepressant, an anti-inflammatory, a growth factor, a lithium compound, resveratrol, phosphatidylcholine, curcumin, magnesium, melatonin, pregnenolone, ginseng, lysergic acid diethylamide, or combinations thereof.</p>	<p>1. South African Pat. App. Pub. No. ZA2000/02311 "5HT1 RECEPTOR AGONISTS AND EITHER A COX 2 INHIBITOR OR NSAID FOR THE TREATMENT OF MIGRAINE" (Published January 30, 2002)</p> <p>From <b>claim 1</b> "A pharmaceutical composition for the treatment of migraine comprising a <b>5HT receptor agonist</b>, with either a cyclooxygenase-2 inhibitor or a nonsteroidal <b>antiinflammatory drug</b> (NSAID), and a pharmaceutically acceptable carrier."</p> <p>8. Int'l Pat. App. Pub. No. WO/2018/148605 "COMPOSITIONS AND METHODS COMPRISING A PSILOCYBIN DERIVATIVE" (Published August 16, 2018)</p> <p>From <b>claim 52</b> "A composition, comprising a first <b>purified psilocybin derivative</b> and a stabilizer."</p>



	<p>From <b>claim 54</b> “The composition of claim 52, wherein the stabilizer is an antioxidant.”</p> <p>From <b>claim 55</b> “The composition of claim 54, wherein the antioxidant comprises a compound chosen from ascorbic acid, lycopene, tocopherol, <b>melatonin</b>, retinol, astaxanthin, lutein, apigenin, carnosine, selenium, zinc, or <b>cucurmin</b>.”</p> <p>From <b>claim 102</b> “A method of treating a psychological disorder comprising identifying a person in need of treatment, and administering a first purified psilocybin derivative to the person in need of treatment, wherein the first purified <b>psilocybin</b> derivative modulates activity at a neurotransmitter receptor.”</p> <p>From <b>claim 117</b> “The method of claim 102, wherein the psychological disorder is an anxiety disorder.”</p> <p>From <b>claim 119</b> “The method of claim 117, comprising administering an anxiolytic drug.”</p> <p>From <b>claim 120</b> “The method of claim 119, wherein the anxiolytic drug is chosen from alprazolam, an alpha blocker, <b>an antihistamine</b>, a barbiturate, a beta blocker, bromazepam, a carbamate, chlordiazepoxide, clonazepam, clorazepate, diazepam, flurazepam, lorazepam, an opioid, oxazepam, temazepam, or triazolam.”</p> <p>From <b>claim 121</b> “The method of claim 102, wherein the psychological disorder is a depressive disorder.”</p> <p>From <b>claim 123</b> “The method of claim 121, comprising administering an <b>antidepressant</b>.”</p>
<p><b>22.</b> The method of claim 18, wherein the second agent is a 5HT receptor antagonist.</p>	<p>4. SESSA (2015) “Underground MDMA-, LSD- and 2-CB-assisted individual and group psychotherapy in Zurich: Outcomes, implications and commentary” Drug Science, Policy and Law. 2(0):1-8.</p> <p>From <b>page 3</b> “Most psycholytic sessions <b>began with MDMA, then LSD or 2-CB were added mid-way</b>. Sometimes sessions began with 2-CB or with LSD or on rare occasions other substances such as <b>ayahuasca or psilocybin</b> were used.”</p>
<p><b>23.</b> The method of claim 18, wherein the second agent is an anti-psychotic agent.</p>	<p>8. Int’l Pat. App. Pub. No. WO/2018/148605 “COMPOSITIONS AND METHODS COMPRISING A PSILOCYBIN DERIVATIVE” (Published August 16, 2018)</p> <p>From <b>claim 82</b> “A method of modulating activity at a neurotransmitter receptor comprising <b>administering a neurotransmitter activity</b></p>

	<p><b>modulator, and administering a first dosage formulation comprising a first purified psilocybin derivative to the person in need of treatment,</b> wherein the first dosage formulation modulates activity at a neurotransmitter receptor.”</p> <p>From <b>claim 86</b> “The method of claim 82, wherein the neurotransmitter receptor is chosen from a serotonin receptor, a cannabinoid receptor, an adrenergic receptor, a dopamine receptor, a GABAergic receptor, a glutaminergic receptor, a histaminergic receptor, a cholinergic receptor, an opioid receptor, or a glycinergic receptor.”</p> <p>From <b>claim 93</b> “The method of claim 86, wherein the neurotransmitter receptor is a dopaminergic receptor.”</p> <p>From <b>claim 94</b> “The method of claim 93, wherein the neurotransmitter activity modulator is a dopaminergic drug.”</p> <p>From <b>claim 95</b> “The method of claim 94, wherein the dopaminergic drug is chosen from amineptine, apomorphine, benzylpiperazine, bromocriptine, cabergoline, <b>chlompromazine, clozapine</b>, dihydrexidine, domperidone, dopamine, fluphenazine, haloperidol, ketamine, loxapine, methamphetamine, <b>olanzapine</b>, pemoline, <b>perphenazine</b>, pergolide, phencyclidine, phenethylamine, phenmetrazine, pimozide, piribedil, a psychostimulant, reserpine, <b>risperidone</b>, ropinirole, tetrabenazine, or thioridazine.”</p>
<p><b>24.</b> The method of claim 23, wherein the anti-psychotic agent is olanzapine, clozapine, risperidone, paliperidone, aripiprazole, quetiapine, iloperidone, ziprasidone, asenapine, lurasidone, sertindole, amisulpride, clotiapine, mosapramine, perospirone, sulphiride, zotepine, haloperidol, benperidol, loxapine, molindone, pimozide, thioridazine, mesoridazine, thiothixene, chlorprothixene, fluphenazine,</p>	<p>8. Int’l Pat. App. Pub. No. WO/2018/148605 “COMPOSITIONS AND METHODS COMPRISING A PSILOCYBIN DERIVATIVE” (Published August 16, 2018)</p> <p>From <b>claim 82</b> “A method of modulating activity at a neurotransmitter receptor comprising <b>administering a neurotransmitter activity modulator, and administering a first dosage formulation comprising a first purified psilocybin derivative to the person in need of treatment,</b> wherein the first dosage formulation modulates activity at a neurotransmitter receptor.”</p> <p>From <b>claim 86</b> “The method of claim 82, wherein the neurotransmitter receptor is chosen from a serotonin receptor, a cannabinoid receptor, an adrenergic receptor, a dopamine receptor, a GABAergic receptor, a glutaminergic receptor, a histaminergic receptor, a cholinergic receptor, an opioid receptor, or a glycinergic receptor.”</p> <p>From <b>claim 93</b> “The method of claim 86, wherein the neurotransmitter receptor is a dopaminergic receptor.”</p>

<p>trifluoperazine, chlorpromazine, perphenazine, prochlorperazine, droperidol, and zuclopenthixol.</p>	<p>From <b>claim 94</b> “The method of claim 93, wherein the neurotransmitter activity modulator is a dopaminergic drug.”</p> <p>From <b>claim 95</b> “The method of claim 94, wherein the dopaminergic drug is chosen from amineptine, apomorphine, benzylpiperazine, bromocriptine, cabergoline, <b>chlorpromazine</b>, <b>clozapine</b>, dihydrexidine, domperidone, dopamine, fluphenazine, haloperidol, ketamine, loxapine, methamphetamine, <b>olanzapine</b>, pemoline, <b>perphenazine</b>, pergolide, phencyclidine, phenethylamine, phenmetrazine, pimoziide, piribedil, a psychostimulant, reserpine, <b>risperidone</b>, ropinirole, tetrabenazine, or thioridazine.”</p>
<p><b>25.</b> The method of claim 18, wherein the second agent is administered simultaneously, sequentially, or alternately with the pharmaceutical composition.</p>	<p>2. Int’l Pat. App. Pub. No. WO/2016/138138 “5HT AGONISTS FOR TREATING DISORDERS” (Published September 1, 2016)</p> <p>From <b>paragraph [0106]</b> “By "co-administer" it is meant that a composition described herein is <b>administered at the same time, just prior to, or just after the administration of one or more additional therapies</b>. The 5-HT agonist (including pharmaceutically acceptable salts thereof) can be administered alone or can be co-administered to the patient. Co-administration is meant to include <b>simultaneous or sequential administration of the compounds individually or in combination</b> (more than one compound).”</p>
<p><b>26.</b> The method of claim 25, wherein the second agent is administered simultaneously, sequentially, or alternately with the pharmaceutical composition.</p>	<p>2. Int’l Pat. App. Pub. No. WO/2016/138138 “5HT AGONISTS FOR TREATING DISORDERS” (Published September 1, 2016)</p> <p>From <b>paragraph [0106]</b> “By "co-administer" it is meant that a composition described herein is <b>administered at the same time, just prior to, or just after the administration of one or more additional therapies</b>. The 5-HT agonist (including pharmaceutically acceptable salts thereof) can be administered alone or can be co-administered to the patient. Co-administration is meant to include <b>simultaneous or sequential administration of the compounds individually or in combination</b> (more than one compound).”</p>
<p><b>27.</b> The method of claim 25, wherein the pharmaceutical composition is administered first and the second agent is administered at least once before the pharmaceutical composition is</p>	<p>16. Kryptonite (2009) “A Glorious New Year LSD &amp; MDMA (Ecstasy)” Erowid. Retrieved July 4th, 2010.  <a href="https://web.archive.org/web/20100704210848/https://www.erowid.org/experiences/exp.php?ID=58609">https://web.archive.org/web/20100704210848/https://www.erowid.org/experiences/exp.php?ID=58609</a></p>

administered a subsequent time.

https://www.erowid.org/experiences/exp.php?ID=58609

160 captures

4 Jul 2010 - 18 Oct 2010

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A Glorious New Year  
LSD & MDMA (Ecstasy)  
by Kryptonite

DOSE:	T+ 0:00	1 tablet	oral	MDMA	(pill / tablet)
	T+ 2:00	2 drops	oral	LSD	(liquid)
	T+ 2:00	1 tablet	oral	MDMA	(pill / tablet)
	T+ 4:00	1 tablet	oral	MDMA	(pill / tablet)
	T+ 6:00	1 tablet	oral	MDMA	(pill / tablet)
	T+ 7:30	4 drops	oral	LSD	(liquid)
	T+ 8:00	1 tablet	oral	MDMA	(pill / tablet)

17. CARHART-HARRIS (2018) “Psilocybin with psychological support for treatment-resistant depression: six-month follow-up” *Psychopharmacology (Berl)*. 235(2):399-408.

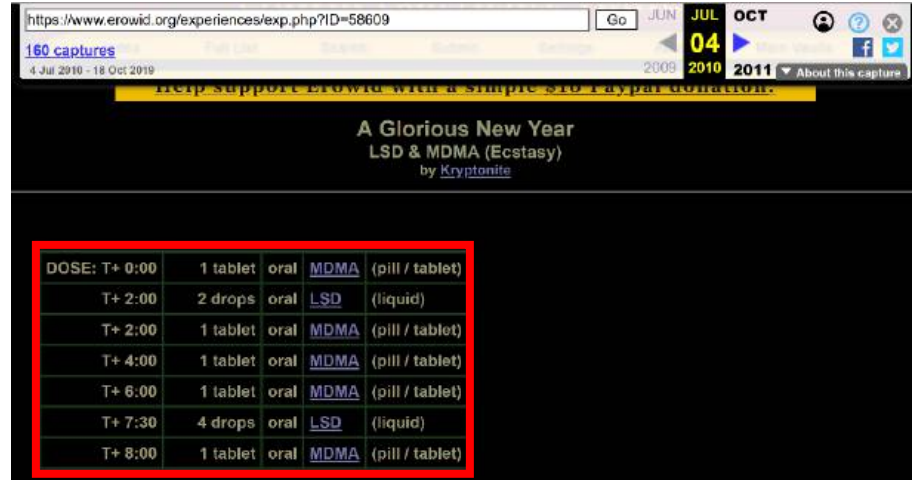
From page 402

Employment status	Illness duration (years)	QIDS-16	BDI	HAM-D	STAI	Past meds	Past psychotherapy
Employed	30	19	36	19	72	SSRI (two), SNRI (two), NDRI, NSSRI, MAOI	None
Unemployed	25	20	33	28	76	SSRI (two), SNRI, NDRI, NSSRI, Na + channel blocker (two), ketamine, TCA	CNT
Employed	17	22	22	18	63	SSRI (two), SNRI	CBT, GT
Studying	10	14	26	18	67	NDRI, NSSRI	CBT
Unemployed	12	19	38	25	71	SSRI (three), TCA	CBT, MBT
Unemployed	29	19	39	23	78	SSRI (four), SNRI, SARI	CS
Unemployed	27	18	33	22	57	TCA, SARI	CS, MBT
Employed	17	19	39	17	71	SSRI (two), TCA	CS
Unemployed	15	20	32	26	71	SSRI (three), SNRI	CS, CBT
Unemployed	8	21	47	28	75	SSRI (two), NSSRI	CS
Employed	15	18	24	16	72	SSRI (four), SNRI (two), NDRI, MAOI, Na + channel blocker, SARI, DRI	CBT
Employed	8	21	35	17	68	SSRI, TCA	CBT
Employed	7	18	29	26	55	SSRI, TCA, SARI, NDRI	CBT
Unemployed	30	23	36	29	70	SSRI (four), SNRI, TCA, NDRI	JA, GT
Unemployed	30	25	44	36	66	SSRI, SARI	CBT
Unemployed	22	17	45	29	69	SSRI (three), SARI (two), TCA	None
Unemployed	6	19	44	20	66	SSRI, SNRI	None
Part retired	10	16	28	28	61	SSRI (two), SARI	JA
Retired	15	17	42	24	74	SSRI (two), TCA, pregabalin	JA
Unemployed	20	14	27	28	68	SSRI (three), SARI, SNRI, Na + channel blocker, TCA, MAOI	CBT, MBT
11 Unemployed	17.7 (8.5)	19 (2.-7)	35 (-7-	23.9 (5.-4)	68.5 (6.-0)		17 psychotherapy

From p. 404-405 “Six began new courses of antidepressant medication after the 3-month time point.”

28. The method of claim 25, wherein the pharmaceutical composition is administered first and the second agent is administered more than once before the pharmaceutical composition is administered a subsequent time.

16. Kryptonite (2009) "A Glorious New Year LSD & MDMA (Ecstasy)" Erowid. Retrieved July 4th, 2010.  
<https://web.archive.org/web/20100704210848/https://www.erowid.org/experiences/exp.php?ID=58609>



29. The method of any one of the preceding claims, wherein the pharmaceutical composition is administered to a subject in need thereof no more frequently than once a day (e.g. no more frequently than once every other day, no more frequently than once every third day, no more frequently than twice a week, no more frequently than once a week, no more frequently than once every two weeks, or the like).

7. U.S. App. Pub. No. US/2018/0021326 "Compositions and methods for enhancing neuroregeneration and cognition by combining mushroom extracts containing active ingredients psilocin or psilocybin with erinacines or hericenones enhanced with niacin" (Published January 25, 2018)

From **claim 1** "A **method for improving neurological health** of an animal comprising: administering a therapeutically effective amount of a composition to an animal, wherein the composition comprises one or more of **psilocybin, psilocin**, baeocystin, norbaeocystin, salts thereof, or combinations thereof, one or more of erinacines, hericenones or combinations thereof, and niacin."

From **claim 14** "A **method for improving neurological health comprising: administering a daily dose** of a composition for at least one month to a patient, wherein the composition comprises: one or more of **about 0.1 to 10 mg of psilocybin, psilocin**, baeocystin, norbaeocystin, or salts thereof, one or more of about 0.1 to 1 gram of psilocybin mushrooms, or combinations thereof; about 0.1 to 200 mg of one or more of erinacines, hericenones, or combinations thereof; and about 1 to 200 mg of niacin."

9. CARHART-HARRIS (2016) "Psilocybin with psychological support for treatment-resistant depression: an open label feasibility study" The Lancet Psychiatry. 3(7):619-627.

From **page 619** "In this open-label feasibility trial, 12 patients (six men, six women) with moderate-to-severe, unipolar, treatment-resistant major

	<p>depression received <b>two oral doses of psilocybin (10 mg and 25 mg, 7 days apart)</b> in a supportive setting.”</p>
<p><b>30.</b> The method of any one of the preceding claims, wherein the pharmaceutical composition is administered to a subject in need thereof once a day, every alternate day, three times a week, twice a week, once a week, every other week, two weeks per month, three weeks per month, once a month, twice a month or three times per month.</p>	<p>7. U.S. App. Pub. No. US/2018/0021326 “Compositions and methods for enhancing neuroregeneration and cognition by combining mushroom extracts containing active ingredients psilocin or psilocybin with erinacines or hericenones enhanced with niacin” (Published January 25, 2018)</p> <p>From <b>claim 1</b> “A <b>method for improving neurological health</b> of an animal comprising: administering a therapeutically effective amount of a composition to an animal, wherein the composition comprises one or more of <b>psilocybin, psilocin</b>, baeocystin, norbaeocystin, salts thereof, or combinations thereof, one or more of erinacines, hericenones or combinations thereof, and niacin.”</p> <p>From <b>claim 14</b> “A method for <b>improving neurological health comprising: administering a daily dose</b> of a composition for at least one month to a patient, wherein the composition comprises: one or more of <b>about 0.1 to 10 mg of psilocybin, psilocin</b>, baeocystin, norbaeocystin, or salts thereof, one or more of about 0.1 to 1 gram of psilocybin mushrooms, or combinations thereof; about 0.1 to 200 mg of one or more of erinacines, hericenones, or combinations thereof; and about 1 to 200 mg of niacin.”</p> <p>9. CARHART-HARRIS (2016) “Psilocybin with psychological support for treatment-resistant depression: an open label feasibility study” The Lancet Psychiatry. 3(7):619-627.</p> <p>From <b>page 619</b> “In this open-label feasibility trial, 12 patients (six men, six women) with moderate-to-severe, unipolar, treatment-resistant major depression received <b>two oral doses of psilocybin (10 mg and 25 mg, 7 days apart)</b> in a supportive setting.”</p>
<p><b>31.</b> The method of any one of the preceding claims, wherein the pharmaceutical composition is administered about once a day.</p>	<p>7. U.S. App. Pub. No. US/2018/0021326 “Compositions and methods for enhancing neuroregeneration and cognition by combining mushroom extracts containing active ingredients psilocin or psilocybin with erinacines or hericenones enhanced with niacin” (Published January 25, 2018)</p> <p>From <b>claim 1</b> “A <b>method for improving neurological health</b> of an animal comprising: administering a therapeutically effective amount of a composition to an animal, wherein the composition comprises one or more of <b>psilocybin, psilocin</b>, baeocystin, norbaeocystin, salts thereof, or combinations thereof, one or more of erinacines, hericenones or combinations thereof, and niacin.”</p> <p>From <b>claim 14</b> “A method for <b>improving neurological health comprising: administering a daily dose</b> of a composition for at least one month to a</p>

	<p>patient, wherein the composition comprises: one or more <b>of about 0.1 to 10 mg of psilocybin, psilocin</b>, baeocystin, norbaeocystin, or salts thereof, one or more of about 0.1 to 1 gram of psilocybin mushrooms, or combinations thereof; about 0.1 to 200 mg of one or more of erinacines, hericenones, or combinations thereof; and about 1 to 200 mg of niacin.”</p>
<p><b>32.</b> The method of any one of the preceding claims, wherein the pharmaceutical composition is administered about every alternate day.</p>	<p>12. Int’l Pat. App. Pub. No. WO/2014/140925 “TOPICAL COMPOSITIONS AND METHODS OF TREATMENT OF TOPICAL DISORDERS” (Published September 18, 2014)</p> <p>From <b>claim 1</b> “A topical composition comprising: at least one flexible film forming ingredient; at least one surfactant; at least 15% (w/w) water; at least one non-polar volatile siloxane solvent; and a therapeutically effective concentration of at least one pharmaceutical agent selected from the group consisting of pramoxine, phenylephrine, hydrocortisone, salicylic acid, nitroglycerine, sildenafil, nifedipine, verapamil, diltiazem, procaine, lidocaine, tetracaine, dibucaine, prilocaine, phenacaine, benzyl alcohol, benzocaine, diperodon, dyclonine, dimethisoquin, epinephrine, tetrahydrozoline hydrochloride, an amphetamine, an antihistamine, methylphenidate, mephedrone, oxymetazoline, pseudoephedrine, <b>psilocybin</b>, ephedrine sulphate, imiquimod, podophyllin, podophylotoxin, fluorouracil, sinecatechins, plant extracts, adapalene, benzoyl peroxide, tazarotene, azelaic acid, clidamycin, acyclovir, penciclovir, famciclovir, docosanol or their salts and combinations thereof, wherein the composition is sufficiently designed to dry within 60 seconds after application to a body surface to form a dried composition, and wherein the dried composition forms...”</p> <p>From <b>claim 21</b> “A method of treating a topical disorder comprising topically applying <b>once every other day</b> to a body surface of a subject in need of such treatment a therapeutically effective concentration of the composition of claim 1”</p>
<p><b>33.</b> The method of any one of the preceding claims, wherein the pharmaceutical composition is administered about once a week.</p>	<p>9. CARHART-HARRIS (2016) “Psilocybin with psychological support for treatment-resistant depression: an open label feasibility study” The Lancet Psychiatry. 3(7):619-627.</p> <p>From <b>page 619</b> “In this open-label feasibility trial, 12 patients (six men, six women) with moderate-to-severe, unipolar, treatment-resistant major depression received <b>two oral doses of psilocybin (10 mg and 25 mg, 7 days apart)</b> in a supportive setting.”</p>
<p><b>34.</b> The method of any one of the preceding claims, wherein the pharmaceutical composition is</p>	<p>18. ANDERSSON (2017) “Psychoactive substances as a last resort - a qualitative study of self-treatment of migraine and cluster headaches” Harm Reduction Journal. 14(1):1-10.</p> <p>From <b>page 5</b> “<b>Microdosing</b> was a related administration strategy fre-</p>

<p>administered about once every two weeks or more.</p>	<p>quently discussed and recommended.”</p> <p>From <b>page 7</b> “<b>Psilocybin</b> use was occasionally reported to cause anxiety or panic attacks. On the other hand, these adverse effects were also described as manageable by a more infrequent dosage interval by some of the same users: “I found that if I <b>didn’t take shrooms more than once a month</b>, I didn’t get anxiety.””</p>
<p><b>35.</b> The method of any one of the preceding claims, wherein the pharmaceutical composition is administered for at least 1 month, 2 months, 3 months, 4 months, 5 months, 6 months, 7 months, 8 months, 9 months, 10 months, 11 months, 12 months, 18 months, 2 years, or 3 years.</p>	<p>7. U.S. App. Pub. No. US/2018/0021326 “Compositions and methods for enhancing neuroregeneration and cognition by combining mushroom extracts containing active ingredients psilocin or psilocybin with erinacines or hericenones enhanced with niacin” (Published January 25, 2018)</p> <p>From <b>claim 1</b> “A <b>method for improving neurological health</b> of an animal comprising: administering a therapeutically effective amount of a composition to an animal, wherein the composition comprises one or more of <b>psilocybin, psilocin</b>, baeocystin, norbaeocystin, salts thereof, or combinations thereof, one or more of erinacines, hericenones or combinations thereof, and niacin.”</p> <p>From <b>claim 14</b> “A method for <b>improving neurological health comprising: administering</b> a daily dose of a composition <b>for at least one month</b> to a patient, wherein the composition comprises: one or more <b>of about 0.1 to 10 mg of psilocybin, psilocin</b>, baeocystin, norbaeocystin, or salts thereof, one or more of about 0.1 to 1 gram of psilocybin mushrooms, or combinations thereof; about 0.1 to 200 mg of one or more of erinacines, hericenones, or combinations thereof; and about 1 to 200 mg of niacin.”</p>
<p><b>36.</b> The method of any one of the preceding claims, wherein the neurological condition is a neurological disorder.</p>	<p>2. Int’l Pat. App. Pub. No. WO/2016/138138 “5HT AGONISTS FOR TREATING DISORDERS” (Published September 1, 2016)</p> <p>From <b>claim 1</b> “A method of <b>treating an epilepsy disorder</b>, said method comprising administering to a subject in need thereof a therapeutically <b>effective amount of a 5HT receptor agonist</b>, or a pharmaceutically acceptable salt thereof.”</p>
<p><b>37.</b> The method of any one of the preceding claims, wherein the neurological condition is a neurocognitive disorder.</p>	<p>2. Int’l Pat. App. Pub. No. WO/2016/138138 “5HT AGONISTS FOR TREATING DISORDERS” (Published September 1, 2016)</p> <p>From <b>claim 1</b> “A method of <b>treating an epilepsy disorder</b>, said method comprising administering to a subject in need thereof a therapeutically <b>effective amount of a 5HT receptor agonist</b>, or a pharmaceutically acceptable salt thereof.”</p> <p>5. RIJCKEVORSEL (2006) “Cognitive problems related to epilepsy syndromes, especially malignant epilepsies” <i>Seizure</i>. 15(4):227-234.</p>



	<p>From <b>page 227</b> “<b>Neurocognitive impairment is frequent in epilepsy patients.</b>”</p>
<p><b>38.</b> The method of any one of the preceding claims, wherein the symptoms of the neurological condition are physical, behavioral, emotional, mental or a combination thereof.</p>	<p>2. Int’l Pat. App. Pub. No. WO/2016/138138 “5HT AGONISTS FOR TREATING DISORDERS” (Published September 1, 2016)</p> <p>From <b>claim 1</b> “A method of <b>treating an epilepsy disorder</b>, said method comprising administering to a subject in need thereof a therapeutically <b>effective amount of a 5HT receptor agonist</b>, or a pharmaceutically acceptable salt thereof.”</p>
<p><b>39.</b> The method of any one of the preceding claims, wherein the neurological condition is an addictive disorder.</p>	<p>8. Int’l Pat. App. Pub. No. WO/2018/148605 “COMPOSITIONS AND METHODS COMPRISING A PSILOCYBIN DERIVATIVE” (Published August 16, 2018)</p> <p>From <b>claim 102</b> “A method of <b>treating a psychological disorder</b> comprising identifying a person in need of treatment, and administering a first purified <b>psilocybin</b> derivative to the person in need of treatment, wherein the first purified psilocybin derivative modulates activity at a neurotransmitter receptor.”</p> <p>From <b>claim 125</b> “The method of claim 102, wherein the psychological disorder is a compulsive disorder.”</p> <p>From <b>claim 126</b> “The method of claim 125, wherein the compulsive disorder is chosen from <b>addiction</b>, body dysmorphic disorder, excoriation disorder, hoarding disorder, obsessive compulsive disorder, and trichotillomania.”</p>
<p><b>40.</b> The method of claim 39, wherein the addictive disorder is alcohol abuse, substance abuse, smoking, or obesity.</p>	<p>14. Int’l Pat. App. Pub. No. WO/2018/195455 “ASSESSING AND TREATING PSYCHEDELIC-RESPONSIVE SUBJECTS” (Published October 25, 2018)</p> <p>From <b>claim 1</b> “A method of improving mental or physical well-being of a subject, the method comprising: (i) <b>providing a subject</b>, wherein based on a score of one or more predictors in the subject, the subject has been identified as likely to have a positive therapeutic response to a psychedelic agent; and (ii) following step (i), <b>administering to the subject the psychedelic agent.</b>”</p> <p>From <b>claim 3</b> “The method of claim 1 or 2, wherein <b>the subject is obese, and the method comprises promoting weight loss in the subject.</b>”</p> <p>From <b>claim 4</b> “The method of claim 1, wherein the method is for treating a condition in a subject, improving the mood of a subject, or enhancing the performance of a subject.”</p>

	<p>From <b>claim 5</b> “The method of claim 4, wherein the condition is a psychological disorder.”</p> <p>From <b>claim 38</b> “The method of any one of claims 5-37, wherein the psychological disorder is selected from the group consisting of a depressive disorder, an anxiety disorder, an addiction, or a compulsive behavior disorder.”</p> <p>From <b>claim 44</b> “The method of claim 38, wherein the psychological disorder is an <b>addiction</b>.”</p> <p>From <b>claim 45</b> “The method of claim 44, wherein the <b>addiction is substance abuse</b> or an eating disorder.”</p>
<p><b>41.</b> The method of any one of claims 1-38, wherein the neurological condition is an eating disorder or an auditory disorder.</p>	<p>13. Int’l Pat. App. Pub. No. WO/2018/135943 “Psilocybin and/or psilocin in combination with cannabinoids and/or terpenes” (Published July 26, 2018)</p> <p>From <b>claim 15</b> “<b>Psilocybin and/or psilocin</b> in combination with at least one cannabinoid and/or at least one terpene for use in the prevention and/or treatment of ADHD, ADD, <b>anorexia nervosa</b>, antisocial personality disorder, autism, addiction, avoidant personality disorder, bipolar disorder, <b>bulimia nervosa</b>, borderline personality disorder, catatone schizophrenia, chronic motor or vocal tic disorder, conversion disorder, cyclothymia, dependent personality disorder, delier, dementia, depersonalization disorder, depression, Dhat syndrome, dissociative amnesia, dissociative fugue, dissociative identity disorder, dissociative disorder, dissociative disorder, not otherwise specified, dysthymic disorder, Da Costa's syndrome, ephobophilia, exhibitionism, generalized anxiety disorder, grandiose delusions, hypochondria, hoarding disorder, intermittent explosive disorder, jealousy, kleptomania, KICiver-Bucy syndrome, maternity psychosis, mental retardation, monomania, MCinchhausen syndrome, misophony, narcissistic personality disorder, obsessive-compulsive disorder, oniomania, organic personality disorder, phobia, paranoid personality disorder, paranoid delusions, passive-aggressive personality, pathological gambling, pathological lying, personality disorder not otherwise defined (PDNOS), pervasive developmental disorder, pica, pain disorder, post encephalitic syndrome, postpartum depression, posttraumatic stress disorder, psychosis, psychotic disorder due to substance use, pyromania, querulant delusions, ruminational disorder, schizophrenia, schizoaffective disorder, schizoid personality disorder, schizotypal personality disorder, separation anxiety, social phobia, somatisation disorder, somatic delusion, somatoform disorder, syndrome of Capgras, syndrome of Cotard, syndrome of Ganser, syndrome of Gilles de la Tourette, selective mutism, theatrical personality disorder, trichotillomania, or undifferentiated somatoform disorder.”</p>

<p><b>42.</b> The method of any one of claims 1-38, wherein the neurological condition is pain (e.g. chronic pain).</p>	<p>13. Int'l Pat. App. Pub. No. WO/2018/135943 "Psilocybin and/or psilocin in combination with cannabinoids and/or terpenes" (Published July 26, 2018)</p> <p>From <b>claim 15</b> "Psilocybin and/or psilocin in combination with at least one cannabinoid and/or at least one terpene for use in the prevention and/or treatment of ADHD, ADD, anorexia nervosa, antisocial personality disorder, autism, addiction, avoidant personality disorder, bipolar disorder, bulimia nervosa, borderline personality disorder, catatone schizophrenia, chronic motor or vocal tic disorder, conversion disorder, cyclothymia, dependent personality disorder, delier, dementia, depersonalization disorder, depression, Dhat syndrome, dissociative amnesia, dissociative fugue, dissociative identity disorder, dissociative disorder, dissociative disorder, not otherwise specified, dysthymic disorder, Da Costa's syndrome, ephophobia, exhibitionism, generalized anxiety disorder, grandiose delusions, hypochondria, hoarding disorder, intermittent explosive disorder, jealousy, kleptomania, KICiver-Bucy syndrome, maternity psychosis, mental retardation, monomania, MCinchhausen syndrome, misophony, narcissistic personality disorder, obsessive-compulsive disorder, oniomania, organic personality disorder, phobia, paranoid personality disorder, paranoid delusions, passive-aggressive personality, pathological gambling, pathological lying, personality disorder not otherwise defined (PDNOS), pervasive developmental disorder, pica, <b>pain disorder</b>, post encephalitic syndrome, postpartum depression, posttraumatic stress disorder, psychosis, psychotic disorder due to substance use, pyromania, querulant delusions, ruminational disorder, schizophrenia, schizoaffective disorder, schizoid personality disorder, schizotypal personality disorder, separation anxiety, social phobia, somatisation disorder, somatic delusion, somatoform disorder, syndrome of Capgras, syndrome of Cotard, syndrome of Ganser, syndrome of Gilles de la Tourette, selective mutism, theatrical personality disorder, trichotillomania, or undifferentiated somatoform disorder."</p>
<p><b>43.</b> The method of any one of claims 1-38, wherein the neurological condition is depression, bipolar disorder, anxiety, social anxiety, post-traumatic stress disorder (PTSD), panic disorder, phobia, schizophrenia, psychopathy, or antisocial personality disorder.</p>	<p>8. Int'l Pat. App. Pub. No. WO/2018/148605 "COMPOSITIONS AND METHODS COMPRISING A PSILOCYBIN DERIVATIVE" (Published August 16, 2018)</p> <p>From <b>claim 102</b> "A method of treating a psychological disorder comprising identifying a person in need of treatment, and administering a first purified <b>psilocybin</b> derivative to the person in need of treatment, wherein the first purified psilocybin derivative modulates activity at a neurotransmitter receptor."</p> <p>From <b>claim 117</b> "The method of claim 102, wherein the psychological disorder is an anxiety disorder."</p> <p>From <b>claim 118</b> "The method of claim 1 17, wherein the anxiety disorder is chosen from acute stress disorder, anxiety due to a medical condition, generalized anxiety disorder, <b>panic disorder</b>, panic attack, <b>phobia</b>, <b>post</b></p>

	<p><b>traumatic stress disorder</b>, separation anxiety disorder, social anxiety disorder, substance-induced anxiety disorder, or selective mutism.”</p>
<p><b>44.</b> The method of any one of claims 1-38, wherein the neurological condition is an impulsive disorder.</p>	<p>13. Int’l Pat. App. Pub. No. WO/2018/135943 “Psilocybin and/or psilocin in combination with cannabinoids and/or terpenes” (Published July 26, 2018)</p> <p>From <b>claim 14</b> “<b>Psilocybin and/or psilocin</b> in combination with at least one cannabinoid and/or at least one terpene for use in the prevention and/or treatment of developmental disorders, delirium, dementia, amnesic disorders and other cognitive disorders, psychiatric disorders due to a somatic condition, drug-related disorders, schizophrenia and other psychotic disorders, mood disorders, anxiety disorders, somatoform disorders, factitious disorders, dissociative disorders, eating disorders, sleep disorders, <b>impulse control disorders</b>, adjustment disorders, or personality disorders.”</p>
<p><b>45.</b> The method of claim 44, wherein the impulsive disorder is attention deficit hyperactivity disorder (ADHD), attention deficit disorder (ADD), Tourette's syndrome or autism.</p>	<p>13. Int’l Pat. App. Pub. No. WO/2018/135943 “Psilocybin and/or psilocin in combination with cannabinoids and/or terpenes” (Published July 26, 2018)</p> <p>From <b>claim 15</b> “<b>Psilocybin and/or psilocin</b> in combination with at least one cannabinoid and/or at least one terpene for use in the prevention and/or treatment of <b>ADHD, ADD</b>, anorexia nervosa, antisocial personality disorder, <b>autism</b>, addiction, avoidant personality disorder, bipolar disorder, bulimia nervosa, borderline personality disorder, catatone schizophrenia, chronic motor or vocal tic disorder, conversion disorder, cyclothymia, dependent personality disorder, delier, dementia, depersonalization disorder, depression, Dhat syndrome, dissociative amnesia, dissociative fugue, dissociative identity disorder, dissociative disorder, dissociative disorder, not otherwise specified, dysthymic disorder, Da Costa's syndrome, ephophobia, exhibitionism, generalized anxiety disorder, grandiose delusions, hypochondria, hoarding disorder, intermittent explosive disorder, jealousy, kleptomania, KICiver-Bucy syndrome, maternity psychosis, mental retardation, monomania, MCinchhausen syndrome, misophony, narcissistic personality disorder, obsessive-compulsive disorder, oniomania, organic personality disorder, phobia, paranoid personality disorder, paranoid delusions, passive-aggressive personality, pathological gambling, pathological lying, personality disorder not otherwise defined (PDNOS), pervasive developmental disorder, pica, pain disorder, post encephalitic syndrome, postpartum depression, posttraumatic stress disorder, psychosis, psychotic disorder due to substance use, pyromania, querulant delusions, ruminational disorder, schizophrenia, schizoaffective disorder, schizoid personality disorder, schizotypal personality disorder, separation anxiety, social phobia, somatisation disorder, somatic delusion, somatoform disorder, syndrome of Capgras, syndrome of Cotard, syndrome of Ganser, <b>syndrome of Gilles de la Tourette</b>, selective mutism, theatrical personality disorder, trichotillomania, or undifferentiated somatoform disorder.”</p>

<p>46. The method of any one of claims 1-38, wherein the neurological condition is a compulsive disorder.</p>	<p>8. Int'l Pat. App. Pub. No. WO/2018/148605 "COMPOSITIONS AND METHODS COMPRISING A PSILOCYBIN DERIVATIVE" (Published August 16, 2018)</p> <p>From <b>claim 102</b> "A method of <b>treating a psychological disorder</b> comprising identifying a person in need of treatment, and administering a first purified <b>psilocybin</b> derivative to the person in need of treatment, wherein the first purified psilocybin derivative modulates activity at a neurotransmitter receptor."</p> <p>From <b>claim 125</b> "The method of claim 102, wherein the psychological disorder is a compulsive disorder."</p> <p>From <b>claim 126</b> "The method of claim 125, wherein the compulsive disorder is chosen from addiction, body dysmorphic disorder, excoriation disorder, hoarding disorder, <b>obsessive compulsive disorder</b>, and trichotillomania."</p> <p>13. Int'l Pat. App. Pub. No. WO/2018/135943 "Psilocybin and/or psilocin in combination with cannabinoids and/or terpenes" (Published July 26, 2018)</p> <p>From <b>claim 15</b> "<b>Psilocybin and/or psilocin</b> in combination with at least one cannabinoid and/or at least one terpene for use in the prevention and/or treatment of ADHD, ADD, anorexia nervosa, antisocial personality disorder, autism, addiction, avoidant personality disorder, bipolar disorder, bulimia nervosa, borderline personality disorder, catatone schizophrenia, chronic motor or vocal tic disorder, conversion disorder, cyclothymia, dependent personality disorder, delier, dementia, depersonalization disorder, depression, Dhat syndrome, dissociative amnesia, dissociative fugue, dissociative identity disorder, dissociative disorder, dissociative disorder, not otherwise specified, dysthymic disorder, Da Costa's syndrome, ephophobia, exhibitionism, generalized anxiety disorder, grandiose delusions, hypochondria, hoarding disorder, intermittent explosive disorder, jealousy, kleptomania, KICiver-Bucy syndrome, maternity psychosis, mental retardation, monomania, MCinchhausen syndrome, misophony, narcissistic personality disorder, <b>obsessive-compulsive disorder</b>, oniomania, organic personality disorder, phobia, paranoid personality disorder, paranoid delusions, passive-aggressive personality, pathological gambling, pathological lying, personality disorder not otherwise defined (PDNOS), pervasive developmental disorder, pica, pain disorder, post encephalitic syndrome, postpartum depression, posttraumatic stress disorder, psychosis, psychotic disorder due to substance use, pyromania, querulant delusions, ruminational disorder, schizophrenia, schizoaffective disorder, schizoid personality disorder, schizotypal personality disorder, separation anxiety, social phobia, somatisation disorder, somatic delusion, somatoform disorder, syndrome of Capgras, syndrome of Cotard, syndrome</p>
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	<p>of Ganser, syndrome of Gilles de la Tourette, selective mutism, theatrical personality disorder, trichotillomania, or undifferentiated somatoform disorder.”</p>
<p><b>47.</b> The method of claim 46, wherein the compulsive disorder is obsessive compulsive disorder (OCD), gambling, or aberrant sexual behavior.</p>	<p>8. Int’l Pat. App. Pub. No. WO/2018/148605 “COMPOSITIONS AND METHODS COMPRISING A PSILOCYBIN DERIVATIVE” (Published August 16, 2018)</p> <p>From <b>claim 102</b> “A method of <b>treating a psychological disorder</b> comprising identifying a person in need of treatment, and administering a first purified <b>psilocybin</b> derivative to the person in need of treatment, wherein the first purified psilocybin derivative modulates activity at a neurotransmitter receptor.”</p> <p>From <b>claim 125</b> “The method of claim 102, wherein the psychological disorder is a compulsive disorder.”</p> <p>From <b>claim 126</b> “The method of claim 125, wherein the compulsive disorder is chosen from <b>addiction</b>, body dysmorphic disorder, excoriation disorder, hoarding disorder, <b>obsessive compulsive disorder</b>, and trichotillomania.”</p>
<p><b>48.</b> The method of any one of claims 1-38, wherein the neurological condition is a personality disorder.</p>	<p>13. Int’l Pat. App. Pub. No. WO/2018/135943 “Psilocybin and/or psilocin in combination with cannabinoids and/or terpenes” (Published July 26, 2018)</p> <p>From <b>claim 15</b> “<b>Psilocybin and/or psilocin</b> in combination with at least one cannabinoid and/or at least one terpene for use in the prevention and/or treatment of ADHD, ADD, anorexia nervosa, <b>antisocial personality disorder</b>, autism, addiction, avoidant personality disorder, bipolar disorder, bulimia nervosa, borderline personality disorder, catatone schizophrenia, chronic motor or vocal tic disorder, conversion disorder, cyclothymia, dependent personality disorder, delier, dementia, depersonalization disorder, depression, Dhat syndrome, dissociative amnesia, dissociative fugue, dissociative identity disorder, dissociative disorder, dissociative disorder, not otherwise specified, dysthymic disorder, Da Costa's syndrome, ephophobia, exhibitionism, generalized anxiety disorder, grandiose delusions, hypochondria, hoarding disorder, intermittent explosive disorder, jealousy, kleptomania, KICiver-Bucy syndrome, maternity psychosis, mental retardation, monomania, MCinchhausen syndrome, misophony, narcissistic personality disorder, obsessive-compulsive disorder, oniomania, organic personality disorder, phobia, paranoid personality disorder, paranoid delusions, passive-aggressive personality, pathological gambling, pathological lying, <b>personality disorder not otherwise defined (PDNOS)</b>, pervasive developmental disorder, pica, pain disorder, post encephalitic syndrome, postpartum depression, posttraumatic stress disorder, psychosis, psychotic disorder due to substance use, pyromania, querulant delusions, ruminational disorder, schizophrenia, schizoaffective disorder, <b>schizoid</b></p>

	<p><b>personality disorder</b>, schizotypal personality disorder, separation anxiety, social phobia, somatisation disorder, somatic delusion, somatoform disorder, syndrome of Capgras, syndrome of Cotard, syndrome of Ganser, syndrome of Gilles de la Tourette, selective mutism, <b>theatrical personality disorder</b>, trichotillomania, or undifferentiated somatoform disorder.”</p>
<p><b>49.</b> The method of claim 48, wherein the personality disorder is conduct disorder, antisocial personality, or aggressive behavior.</p>	<p>13. Int’l Pat. App. Pub. No. WO/2018/135943 “Psilocybin and/or psilocin in combination with cannabinoids and/or terpenes” (Published July 26, 2018)</p> <p>From <b>claim 15</b> “<b>Psilocybin and/or psilocin</b> in combination with at least one cannabinoid and/or at least one terpene for use in the prevention and/or treatment of ADHD, ADD, anorexia nervosa, <b>antisocial personality disorder</b>, autism, addiction, avoidant personality disorder, bipolar disorder, bulimia nervosa, borderline personality disorder, catatone schizophrenia, chronic motor or vocal tic disorder, conversion disorder, cyclothymia, dependent personality disorder, delier, dementia, depersonalization disorder, depression, Dhat syndrome, dissociative amnesia, dissociative fugue, dissociative identity disorder, dissociative disorder, dissociative disorder, not otherwise specified, dysthymic disorder, Da Costa's syndrome, ephobophilia, exhibitionism, generalized anxiety disorder, grandiose delusions, hypochondria, hoarding disorder, intermittent explosive disorder, jealousy, kleptomania, KICiver-Bucy syndrome, maternity psychosis, mental retardation, monomania, MCinchhausen syndrome, misophony, narcissistic personality disorder, obsessive-compulsive disorder, oniomania, organic personality disorder, phobia, paranoid personality disorder, paranoid delusions, passive-aggressive personality, pathological gambling, pathological lying, <b>personality disorder not otherwise defined (PDNOS)</b>, pervasive developmental disorder, pica, pain disorder, post encephalitic syndrome, postpartum depression, posttraumatic stress disorder, psychosis, psychotic disorder due to substance use, pyromania, querulant delusions, ruminational disorder, schizophrenia, schizoaffective disorder, <b>schizoid personality disorder</b>, schizotypal personality disorder, separation anxiety, social phobia, somatisation disorder, somatic delusion, somatoform disorder, syndrome of Capgras, syndrome of Cotard, syndrome of Ganser, syndrome of Gilles de la Tourette, selective mutism, <b>theatrical personality disorder</b>, trichotillomania, or undifferentiated somatoform disorder.”</p>

## Electronic Acknowledgement Receipt

<b>EFS ID:</b>	46253653
<b>Application Number:</b>	17427037
<b>International Application Number:</b>	
<b>Confirmation Number:</b>	6210
<b>Title of Invention:</b>	METHODS AND COMPOSITIONS COMPRISING A 5HT RECEPTOR AGONIST FOR THE TREATMENT OF PSYCHOLOGICAL, COGNITIVE, BEHAVIORIAL, AND/OR MOOD DISORDERS
<b>First Named Inventor/Applicant Name:</b>	Judith BLUMSTOCK
<b>Customer Number:</b>	21971
<b>Filer:</b>	Shahin Shams
<b>Filer Authorized By:</b>	
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<b>Receipt Date:</b>	22-JUL-2022
<b>Filing Date:</b>	29-JUL-2021
<b>Time Stamp:</b>	15:51:02
<b>Application Type:</b>	

### Payment information:

Submitted with Payment	yes
Payment Type	CARD
Payment was successfully received in RAM	\$90
RAM confirmation Number	E20227LF50593919
Deposit Account	
Authorized User	

The Director of the USPTO is hereby authorized to charge indicated fees and credit any overpayment as follows:



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**File Listing:**

Document Number	Document Description	File Name	File Size(Bytes)/ Message Digest	Multi Part /.zip	Pages (if appl.)
1	Concise Description of Relevance	Concise-description-generated.pdf	46494 a9edb4c20dae31368983d969c575799300403535	no	8

**Warnings:**

**Information:**

2	Third-Party Submission Under 37 CFR 1.290	Third-party-preissuance-submission.pdf	72994 7b4c0076150911070ec24e9a0dda0a2722f25d07	no	4
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**Warnings:**

**Information:**

3	Request for Notification of Non-compliant Third-Party Submission	Third-party-notification-request.pdf	23720 9c6eb38f0071df798c9ea983d60e221b386138c3	no	1
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**Warnings:**

**Information:**

4	Evidence of Publication	1-ZA20000231.pdf	1026802 20328e09f634de25e8979ecf17b36e2fb8535cd	no	19
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**Warnings:**

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5	Evidence of Publication	2-WO2016138138A1.pdf	6199686 d872da5845bcaba78f89db7ba85ff1a6907c934a	no	100
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**Warnings:**

**Information:**

6	Evidence of Publication	3-JOHNSTAD.pdf	225979 e14d4f7dce3d3b11254b22c7c973dbae646cf79f	no	13
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**Warnings:**

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7	Evidence of Publication	4-SESSA.pdf	142333	no	8
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8	Evidence of Publication	5-RIJCKEVORSEL.pdf	208580	no	8
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<b>Warnings:</b>					
<b>Information:</b>					
9	Evidence of Publication	6-ARONSON.pdf	13367882	no	29
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<b>Information:</b>					
10	Evidence of Publication	7-US20180021326A1.pdf	1286444	no	9
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12	Evidence of Publication	9-CARHART.pdf	483912	no	9
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13	Evidence of Publication	10-DOLDER.pdf	1161455	no	7
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14	Concise Description of Relevance	US20220096504ClaimChartCom mp.pdf	360517	no	31
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**Warnings:**

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15	Fee Worksheet (SB06)	fee-info.pdf	37509	no	2
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**Warnings:**

**Information:**

<b>Total Files Size (in bytes):</b>	28562446
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**New Applications Under 35 U.S.C. 111**

**If a new application is being filed and the application includes the necessary components for a filing date (see 37 CFR 1.53(b)-(d) and MPEP 506), a Filing Receipt (37 CFR 1.54) will be issued in due course and the date shown on this Acknowledgement Receipt will establish the filing date of the application.**

**National Stage of an International Application under 35 U.S.C. 371**

**If a timely submission to enter the national stage of an international application is compliant with the conditions of 35 U.S.C. 371 and other applicable requirements a Form PCT/DO/EO/903 indicating acceptance of the application as a national stage submission under 35 U.S.C. 371 will be issued in addition to the Filing Receipt, in due course.**

**New International Application Filed with the USPTO as a Receiving Office**

**If a new international application is being filed and the international application includes the necessary components for an international filing date (see PCT Article 11 and MPEP 1810), a Notification of the International Application Number and of the International Filing Date (Form PCT/RO/105) will be issued in due course, subject to prescriptions concerning national security, and the date shown on this Acknowledgement Receipt will establish the international filing date of the application.**

## Electronic Acknowledgement Receipt

<b>EFS ID:</b>	46254085
<b>Application Number:</b>	17427037
<b>International Application Number:</b>	
<b>Confirmation Number:</b>	6210
<b>Title of Invention:</b>	METHODS AND COMPOSITIONS COMPRISING A 5HT RECEPTOR AGONIST FOR THE TREATMENT OF PSYCHOLOGICAL, COGNITIVE, BEHAVIORIAL, AND/OR MOOD DISORDERS
<b>First Named Inventor/Applicant Name:</b>	Judith BLUMSTOCK
<b>Customer Number:</b>	21971
<b>Filer:</b>	Shahin Shams
<b>Filer Authorized By:</b>	
<b>Attorney Docket Number:</b>	55554-701.831
<b>Receipt Date:</b>	22-JUL-2022
<b>Filing Date:</b>	29-JUL-2021
<b>Time Stamp:</b>	16:20:46
<b>Application Type:</b>	

### Payment information:

Submitted with Payment	yes
Payment Type	CARD
Payment was successfully received in RAM	\$90
RAM confirmation Number	E20227LG20434425
Deposit Account	
Authorized User	

The Director of the USPTO is hereby authorized to charge indicated fees and credit any overpayment as follows:

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**File Listing:**

Document Number	Document Description	File Name	File Size(Bytes)/ Message Digest	Multi Part /.zip	Pages (if appl.)
1	Concise Description of Relevance	Concise-description-generated.pdf	44247 ccac9c0a65ac0fd1c4b71d6e35014fecf5bd9685	no	6

**Warnings:**

**Information:**

2	Third-Party Submission Under 37 CFR 1.290	Third-party-preissuance-submission.pdf	72454 ebfdffb791070eea34580bd2abec2152cd5b5b84	no	4
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**Warnings:**

**Information:**

3	Request for Notification of Non-compliant Third-Party Submission	Third-party-notification-request.pdf	23719 5b7c531ea38a4b6bef2a314175bc903de683d36b	no	1
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**Warnings:**

**Information:**

4	Evidence of Publication	11-WO2019079742-PriorityDoc.pdf	4210583 e0acb42f7e95410dac4a9320ad1ea81fbaa42d3e	no	83
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**Warnings:**

**Information:**

5	Evidence of Publication	12-WO2014140925A2.pdf	3583088 cd7e2d72cdb713003e8a7027b658349162de3f0c	no	68
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**Warnings:**

**Information:**

6	Evidence of Publication	13-WO2018135943A1.pdf	1174843 7be41e8ee3a588b58c4729f4a536b00efe932323	no	26
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**Warnings:**

**Information:**

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7	Evidence of Publication	14-WO2018195455A1.pdf	4482794	no	77
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<b>Warnings:</b>					
<b>Information:</b>					
8	Evidence of Publication	15-LINDENBLATT.pdf	135096	no	9
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<b>Warnings:</b>					
<b>Information:</b>					
9	Evidence of Publication	16-Kryptonite.pdf	419379	no	1
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11	Evidence of Publication	18-Andersson.pdf	454783	no	10
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<b>Warnings:</b>					
<b>Information:</b>					
12	Concise Description of Relevance	US20220096504ClaimChartComp.pdf	360517	no	31
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13	Fee Worksheet (SB06)	fee-info.pdf	37509	no	2
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<b>Total Files Size (in bytes):</b>			15617418		

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