

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of: Barrow, Robert et al Confirmation No.: 2388

Serial No.: 17/877,521 Group No.:

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Entitled: Psychedelics for Treatment of Pain

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. Int'l Pat. App. Pub. No. WO/2021/175816 "Compounds for Use in a Method of Treating, Preventing, and/or Reducing the Symptoms of Pain" (Published September 10, 2021)
2. Int'l Pat. App. Pub. No. WO/2022/011350 "Method of Treatment for Psilocybin or Psilocin Infusion" (Published July 12, 2021)
3. Castellanos (2020) Chronic pain and psychedelics: a review and proposed mechanism of action Reg Anesth Pain Med. 45(7):486-494
4. Hutten (2019) "Self-Rated Effectiveness of Microdosing With Psychedelics for Mental and Physical Health Problems Among Microdosers" Front Psychiatry. 10:672
5. Int'l Pat. App. Pub. No. WO/2021/209815 "Transdermal Micro-Dosing Delivery of Psychedelics Derivatives" (Published October 21, 2021)
6. Int'l Pat. App. Pub. No. WO/2020/181194 "Compositions and Methods of Use Comprising Substances with Neural Plasticity Actions Administered at Non-Psychedelic/Psychotomimetic Dosages and Formulations" (Published September 10, 2020)
7. Int'l Pat. App. Pub. No. WO/2022/212854 "Methods and Compositions Relating to Psychedelics and Serotonin Receptor Modulators" (Published November 6, 2022)
8. Int'l Pat. App. Pub. No. WO/2022/225884 "Deuterated Derivatives of Psychedelic Compounds and Uses Thereof" (Published October 27, 2022)
9. Int'l Pat. App. Pub. No. WO/2020/212948 "Methods of Treating Neurocognitive Disorders, Chronic Pain and Reducing Inflammation" (Published October 22, 2020)
10. Int'l Pat. App. Pub. No. WO/2022/011350 "Method of Treatment for Psilocybin or Psilocin Infusion" (Published January 13, 2022)

<p>1. A method of treating pain, including the steps of: administering an effective amount of a psychedelic to an individual; and treating pain in the individual.</p>	<p>1. Int'l Pat. App. Pub. No. WO/2021/175816 "Compounds for Use in a Method of Treating, Preventing, and/or Reducing the Symptoms of Pain" (Published September 10, 2021)</p> <p>From Claim 1 "Compound for use in a method of treating, preventing or reducing the symptoms of pain, where in the compound is administered to a subject in an amount of 2 to 50 mcg per day, and the compound is a lysergamide or a pharmaceutically acceptable salt thereof"</p> <p>2. Int'l Pat. App. Pub. No. WO/2022/011350 "Method of Treatment for Psilocybin or Psilocin Infusion" (Published July 12, 2021)</p> <p>From Abstract "Methods for treatment for patients suffering from disease or condition are contemplated as including an administration of an intravenous infusion of a pharmaceutically effective amount of psilocybin or psilocin. The intravenous infusion of psilocybin or psilocin may include an additional compound such as a benzodiazepine, preferably lorazepam, administered via a continuous intravenous infusion. Such methods may be seen to better alleviate the symptoms of psychological conditions, neurological injuries, pain, or inflammatory condition, and may result in reduced need for other medications."</p>
<p>2. The method of claim 1, wherein the pain is a type chosen from the group consisting of acute, chronic, nociceptive, neuropathic, inflammatory, and functional.</p>	<p>3. Castellanos (2020) Chronic pain and psychedelics: a review and proposed mechanism of action Reg Anesth Pain Med. 45(7):486-494</p> <p>From Page 486 "There is also evidence that psychedelic drugs may possess antinociceptive effects in chronic pain conditions."</p>

1. Int'l Pat. App. Pub. No. WO/2021/175816
"Compounds for Use in a Method of Treating, Preventing, and/or Reducing the Symptoms of Pain" (Published September 10, 2021)

From **Claim 1** "Compound for use in a method of treating, preventing or reducing the symptoms of **pain**, where in the compound is administered to a subject in an amount of 2 to 50 pg per day, and the compound is a **lysergamide** or a pharmaceutically acceptable salt thereof"

From **Claim 2** "The compound for use according to claim 1, wherein the compound is **lysergic acid diethylamide (LSD)** or a pharmaceutically acceptable salt thereof."

From **Claim 5** "The compound for use according to any one of claims 1 to 4, wherein the pain is an **acute pain** or a **chronic pain**"

From **Claim 6** "6. The compound for use according to any one of claims 1 to 5, wherein the pain is selected from head pain such as cluster headache and migraine; visceral pain such as irritable bowel syndrome (IBS) and menstrual cramps; somatic pain such as postoperative pain; **neuropathic pain** such as fibromyalgia, central pain syndrome, complex regional pain syndrome, trigeminal neuralgia, posttraumatic neuralgia, peripheral neuropathy and herpetic/postherpetic neuralgia; **inflammatory pain** such as osteoarthritis, rheumatoid arthritis and atherosclerosis; **functional pain** such as psychogenic/psychosomatic pain and phantom limb pain; and pain in advanced and progressive diseases such as pain in acquired immune deficiency syndrome (AIDS), cancer, multiple sclerosis (MS) and Crohn's disease."

8. Int'l Pat. App. Pub. No. WO/2022/225884
"Deuterated Derivatives of Psychedelic Compounds and Uses Thereof" (Published October 27, 2022)

From **Paragraph [003]** “The present invention relates to compositions (e.g., pharmaceutical compositions) comprising deuterated derivatives of certain naturally-occurring and synthetic **psychedelic compounds.**”

From **Paragraph [00101]** “In certain embodiments, the disease is a painful condition. A “painful condition” includes **neuropathic pain** (e.g., peripheral neuropathic pain), central pain, deafferentation pain, **chronic pain** (e.g., chronic nociceptive pain, and other forms of chronic pain such as post-operative pain, e.g., pain arising after hip, knee, or other replacement surgery), pre-operative pain, stimulus of nociceptive receptors (**nociceptive pain**), **acute pain** (e.g., phantom and transient acute pain), noninflammatory pain, **inflammatory pain**, pain associated with cancer, wound pain, bum pain, postoperative pain, pain associated with medical procedures, pain resulting from pruritus, painful bladder syndrome, pain associated with premenstrual dysphoric disorder and/or premenstrual syndrome, pain associated with chronic fatigue syndrome, pain associated with pre-term labor, pain associated with withdrawal symptoms from drug addiction, joint pain, arthritic pain (e.g., pain associated with crystalline arthritis, osteoarthritis, psoriatic arthritis, gouty arthritis, reactive arthritis, rheumatoid arthritis or Reiter’s arthritis), lumbosacral pain, musculo-skeletal pain, headache, migraine, muscle ache, lower back pain, neck pain, toothache, dental/maxillofacial pain, visceral pain and the like.”

2. Int’l Pat. App. Pub. No. WO/2022/011350
“Method of Treatment for Psilocybin or Psilocin Infusion” (Published July 12, 2021)

	<p>From Claim 10 “A method of treating a disease or condition in a subject in need thereof, the method comprising intravenously administering to the subject a pharmacologically effective amount of (i) psilocybin or psilocin, or a pharmaceutically acceptable salt thereof, and (ii) a benzodiazepine, each in an amount that together is effective for the treatment of the disease or condition.”</p> <p>From Claim 46 “The method of any one of claims 1 -38, wherein the disease or condition is a neurological injury, an inflammatory condition, or pain.”</p> <p>From Claim 52 “The method of claim 46, wherein the disease or condition is chronic pain.”</p>
<p>3. The method of claim 1, wherein the pain is caused by a physical state in the individual's body.</p>	<p>3. Castellanos (2020) Chronic pain and psychedelics: a review and proposed mechanism of action Reg Anesth Pain Med. 45(7):486-494</p> <p>From Page 490 “The earliest published studies on psychedelics and analgesia are works from Dr Eric Kast in the mid-1960s on analgesic response to LSD for cancer pain. In these studies, LSD not only acutely outperformed 2mg of PO hydromorphone or 100 mg of PO meperidine but also produced analgesia that persisted for an average of 3 weeks after LSD administration.”</p> <p>1. Int’l Pat. App. Pub. No. WO/2021/175816 “Compounds for Use in a Method of Treating, Preventing, and/or Reducing the Symptoms of Pain” (Published September 10, 2021)</p> <p>From Claim 6 “The compound for use according to any one of claims 1 to 5, wherein the pain is selected from head pain such as</p>

cluster headache and migraine; **visceral pain** such as irritable bowel syndrome (IBS) and menstrual cramps; **somatic pain** such as postoperative pain; neuropathic pain such as fibromyalgia, central pain syndrome, complex regional pain syndrome, trigeminal neuralgia, posttraumatic neuralgia, peripheral neuropathy and herpetic/postherpetic neuralgia; inflammatory pain such as osteoarthritis, rheumatoid arthritis and atherosclerosis; functional pain such as psychogenic/psychosomatic pain and phantom limb pain; and pain in advanced and progressive diseases such as pain in acquired immune deficiency syndrome (AIDS), cancer, multiple sclerosis (MS) and Crohn's disease.”

8. Int'l Pat. App. Pub. No. WO/2022/225884
“Deuterated Derivatives of Psychedelic Compounds and Uses Thereof” (Published October 27, 2022)

From **Paragraph [00101]** “In certain embodiments, the disease is a painful condition. A “painful condition” includes neuropathic pain (e.g., peripheral neuropathic pain), central pain, deafferentation pain, chronic pain (e.g., chronic nociceptive pain, and other forms of chronic pain such as post-operative pain, e.g., **pain arising after hip, knee, or other replacement surgery**), pre-operative pain, stimulus of nociceptive receptors (nociceptive pain), acute pain (e.g., phantom and transient acute pain), noninflammatory pain, inflammatory pain, **pain associated with cancer, wound pain, bum pain**, postoperative pain, pain associated with medical procedures, **pain resulting from pruritus, painful bladder syndrome, pain associated with premenstrual dysphoric disorder and/or premenstrual syndrome**, pain associated with chronic fatigue syndrome, **pain associated with pre-term labor**, pain associated with withdrawal symptoms from drug addiction, **joint pain**,

	<p>arthritic pain (e.g., pain associated with crystalline arthritis, osteoarthritis, psoriatic arthritis, gouty arthritis, reactive arthritis, rheumatoid arthritis or Reiter’s arthritis), lumbosacral pain, musculo-skeletal pain, headache, migraine, muscle ache, lower back pain, neck pain, toothache, dental/maxillofacial pain, visceral pain and the like.”</p> <p>2. Int’l Pat. App. Pub. No. WO/2022/011350 “Method of Treatment for Psilocybin or Psilocin Infusion” (Published July 12, 2021)</p> <p>From Claim 10 “A method of treating a disease or condition in a subject in need thereof, the method comprising intravenously administering to the subject a pharmacologically effective amount of (i) psilocybin or psilocin, or a pharmaceutically acceptable salt thereof, and (ii) a benzodiazepine, each in an amount that together is effective for the treatment of the disease or condition.”</p> <p>From Claim 46 “The method of any one of claims 1 -38, wherein the disease or condition is a neurological injury, an inflammatory condition, or pain.”</p> <p>From Claim 53 “The method of claim 52, wherein the chronic pain results from post-operative pain, tension headaches, chronic lower back pain, fibromyalgia, nephropathy, multiple sclerosis, shingles, complex regional pain syndrome, cephalic pain, or sciatica.”</p>
<p>4. The method of claim 1, wherein the pain is caused by an emotional state in the individual's body.</p>	<p>3. Castellanos (2020) Chronic pain and psychedelics: a review and proposed mechanism of action Reg Anesth Pain Med. 45(7):486-494</p> <p>From Page 489 “Studies with single session administrations of LSD, psilocybin and MDMA have shown alleviation of anxiety</p>

	<p>and depression which may persist for weeks, or even months.”</p> <p>From Claim 6 “The compound for use according to any one of claims 1 to 5, wherein the pain is selected from head pain such as cluster headache and migraine; visceral pain such as irritable bowel syndrome (IBS) and menstrual cramps; somatic pain such as postoperative pain; neuropathic pain such as fibromyalgia, central pain syndrome, complex regional pain syndrome, trigeminal neuralgia, posttraumatic neuralgia, peripheral neuropathy and herpetic/postherpetic neuralgia; inflammatory pain such as osteoarthritis, rheumatoid arthritis and atherosclerosis; functional pain such as psychogenic/psychosomatic pain and phantom limb pain; and pain in advanced and progressive diseases such as pain in acquired immune deficiency syndrome (AIDS), cancer, multiple sclerosis (MS) and Crohn's disease.”</p>
<p>5. The method of claim 1, wherein the psychedelic is chosen from the group consisting of lysergic acid diethylamide (LSD), psilocybin, psilocin, mescaline, 5-methoxy-N,N-dimethyltryptamine (5-MeO-DMT), dimethyltryptamine (DMT), 2,5-dimethoxy-4-iodoamphetamine (DOI), 2,5-dimethoxy-4-bromoamphetamine (DOB), salts thereof, tartrates thereof, solvates thereof, isomers thereof, analogs thereof, and homologues thereof.</p>	<p>1. Int’l Pat. App. Pub. No. WO/2021/175816 “Compounds for Use in a Method of Treating, Preventing, and/or Reducing the Symptoms of Pain” (Published September 10, 2021)</p> <p>From Claim 2 “The compound for use according to claim 1, wherein the compound is lysergic acid diethylamide (LSD) or a pharmaceutically acceptable salt thereof.”</p> <p>2. Int’l Pat. App. Pub. No. WO/2022/011350 “Method of Treatment for Psilocybin or Psilocin Infusion” (Published July 12, 2021)</p> <p>From Claim 10 “A method of treating a disease or condition in a subject in need thereof, the method comprising intravenously administering to the subject a pharmacologically effective amount of (i) psilocybin or psilocin, or a pharmaceutically</p>

	<p>acceptable salt thereof, and (ii) a benzodiazepine, each in an amount that together is effective for the treatment of the disease or condition.”</p> <p>From Claim 46 “The method of any one of claims 1 -38, wherein the disease or condition is a neurological injury, an inflammatory condition, or pain.”</p> <p>7. Int’l Pat. App. Pub. No. WO/2022/212854 “Methods and Compositions Relating to Psychedelics and Serotonin Receptor Modulators” (Published November 6, 2022)</p> <p>From Claim 4 “The composition of claim 1, wherein the psychedelic is selected from psilocybin, psilocin, baeocystin, norbaeocystin, lisurgide, LSD, dimethyltryptamine, carboxamindotryptamine, ibogaine, tabernanthalog, 3,4-methylenedioxy-methamphetamine (MDMA), 1-acetyl LSD, O-acetyl psilocin, mescaline (3,4,5-trimethoxy phenethylamine), ... or a pharmaceutically acceptable salt, solvate, metabolite, deuterated analogue, derivative, prodrug, or combinations thereof.”</p> <p>From Paragraph [0005] “In some embodiments, the psychedelic is a phenethylamine or a tryptamine, or a pharmaceutically acceptable salt, solvate, metabolite, deuterated analogue, derivative, or prodrug thereof. In some embodiments, the phenethylamine or the tryptamine is selected from the group consisting of... 2,5-dimethoxy-4-iodophenethylamine ... 2,5-dimethoxy-4-bromoamphetamine ... 5-meo-DMT ... or a pharmaceutically acceptable salt, solvate, metabolite, deuterated analogue, derivative, prodrug, or combinations thereof.”</p>
<p>6. The method of claim 1, wherein said treating step is further defined as providing a</p>	<p>4. Hutten (2019) “Self-Rated Effectiveness of Microdosing With Psychedelics for Mental</p>

<p>psychological effect and a direct neural effect to the individual.</p>	<p>and Physical Health Problems Among Microdosers” Front Psychiatry. 10:672</p> <p>From Page 1 “As of the last few years, there has been an increasing visibility and interest in the use of low doses of psychedelics, such as lysergic acid diethylamide (LSD) and psilocybin, for beneficial health-related purposes. Referred to as “microdosing,” users report consuming about one tenth of a recreational dose, to enhance daily functions, without inducing a profound altered state of consciousness. While the primary motivation to microdose is indeed to enhance performance, including creativity and mental concentration, it is also reported to be used to alleviate psychological and physical symptoms, such as anxiety and headache.”</p>
<p>7. The method of claim 1, wherein said administering step is further defined as administering the psychedelic in a form chosen from the group consisting of transdermal patches, modified-release oral dosage forms, extended release injection, implanted titration device, intranasal delivery forms, and sublingual delivery forms.</p>	<p>1. Int’l Pat. App. Pub. No. WO/2021/175816 “Compounds for Use in a Method of Treating, Preventing, and/or Reducing the Symptoms of Pain” (Published September 10, 2021)</p> <p>From Page 14, lines 6-12 “The routes for administration (delivery) include one or more of oral (e.g. tablet, capsule, ingestible solution), topical, mucosal (e.g. nasal spray, aerosol for inhalation), nasal, parenteral (e.g. an injectable form), and sublingual. According to a preferred embodiment, the compound of the present invention is administered by topical administration, parenteral administration or mucosal administration, more preferably by mucosal administration such as intranasal administration, buccal administration or sublingual administration.”</p> <p>5. Int’l Pat. App. Pub. No. WO/2021/209815 “Transdermal Micro-Dosing Delivery of Psychedelics Derivatives” (Published October 21, 2021)</p>

From **Claim 1** “A **transdermal and/or topical pharmaceutical composition** comprising: about 0.1 % to about 20 % of an active agent selected from the group consisting of **psilocybin, psilocin, lysergic acid diethylamine (LSD)**, and/or **ibogaine**, derivatives of these compounds, and combinations thereof..”

From **Claim 7** “The pharmaceutical composition of any one of claims 1 to 6 which is formulated as a **transdermal patch**.”

6. Int’l Pat. App. Pub. No. WO/2020/181194
“Compositions and Methods of Use
Comprising Substances with Neural Plasticity
Actions Administered at Non-
Psychedelic/Psychotomimetic Dosages and
Formulations” (Published September 10,
2020)

From **Paragraph [0082]** “For the purpose of this disclosure, the present inventors define “neuroplastogen dose” and in particular “neuroplastogen dose of drugs classified as **5-HT2A agonists**”, as a dose, dosage, posology or formulation, including **modified release** formulations, of a substance with 5-HT2A agonist actions and actions on neural plasticity, including modulation of NMDARs, that is well tolerated, safe, when administered at doses, dosages, posology and or formulations, that does not cause clinically meaningful psychedelic/psychotomimetic effects.”

From **Claim 1** “A compound comprising a structural analogue to **psilocin**, norpsilocin, **psilocybin**, baeocystin, norbaeocystin or **N,N-dimethyltryptamine**, according to formula I...”

From **Claim 2** “A compound comprising a structural analogue to **2,5-Dimethoxy-4-**

iodoamphetamine, according to formula II...”

From **Claim 3** “A compound comprising a structural analogue to **Lysergic acid diethylamide**, according to formula III...”

From **Claim 4** “A compound comprising a structural analogue to **ibogaine**, according to formula IV...”

7. Int’l Pat. App. Pub. No. WO/2022/212854 “Methods and Compositions Relating to Psychedelics and Serotonin Receptor Modulators” (Published November 6, 2022)\

From **Claim 4** “The composition of claim 1, wherein the **psychedelic** is selected from psilocybin, psilocin, baeocystin, norbaeocystin, lisurgide, LSD, dimethyltryptamine, carboxamindotryptamine, ibogaine, tabemanthalog, 3,4-methylenedioxy-methamphetamine (MDMA), 1-acetyl LSD, O-acetyl psilocin, mescaline (3,4,5-trimethoxy phenethylamine), proscaline (2-(3,5-dimethoxy-4-propoxyphenyl)ethanamine), metaescaline (2-(3-ethoxy-4, 5-dimethoxyphenyl)ethanamine), allylescaline (4-Allyloxy-3,5-dimethoxy phenylethylamine), methallylescaline (4-Methallyloxy-3,5 dimethoxyphenethylamine), and asymbescaline (3,4-Diethoxy-5-methoxyphenethylamine), or a pharmaceutically acceptable salt, solvate, metabolite, deuterated analogue, derivative, prodrug, or combinations thereof.”

From **Paragraph [00376]** “In some embodiments, the compositions described herein are administered **orally**, **intravenously**, subcutaneously, by inhalation, or by an **injection**. In some embodiments, the compositions described herein are administered orally. In some embodiments,

	<p>the compositions described herein are administered orally via a pill, ampoule, vial, or tablet.”</p> <p>From Paragraph [00377] “As used herein, the term "modified release" coating encompasses coatings that delay release, sustain release, extended release, prevent release, minimize release and/or otherwise prolong the release of a drug relative to formulations lacking such coatings which release a drug relatively quickly (i.e., "immediate release" compositions).”</p>
<p>8. The method of claim 1, further including the step of treating inflammation in the individual.</p>	<p>9. Int’l Pat. App. Pub. No. WO/2020/212948 “Methods of Treating Neurocognitive Disorders, Chronic Pain and Reducing Inflammation” (Published October 22, 2020)</p> <p>From Claim 47 “A method of reducing inflammation in a subject in need thereof, the method comprising administering to the subject a therapeutically effective amount of psilocybin or an active metabolite thereof.”</p> <p>From Claim 53 “The method of any one of claims 47-52, wherein reducing inflammation in the subject treats or prevents one or more of chronic pain, neuropathic pain, and inflammatory pain in the subject.”</p>
<p>9. The method of claim 8, further including the step of changing the levels of biomarkers of inflammation in the individual.</p>	<p>9. Int’l Pat. App. Pub. No. WO/2020/212948 “Methods of Treating Neurocognitive Disorders, Chronic Pain and Reducing Inflammation” (Published October 22, 2020)</p> <p>From Page 97 lines 3-4 “In some embodiments, administration of the psilocybin reduces the level of at least one inflammatory biomarker or indicator in a biological sample of the subject.”</p>
<p>10. The method of claim 9, wherein the biomarkers are chosen from the group consisting of IL-1, IL-6, TNF-alpha, IFN-</p>	<p>9. Int’l Pat. App. Pub. No. WO/2020/212948 “Methods of Treating Neurocognitive Disorders, Chronic Pain and Reducing Inflammation” (Published October 22, 2020)</p>

<p>gamma, IL-4, IL-10, IL-12, IL-13, MCP-1, GM-CSF, YKL-40, CRP, or TGF-beta.</p>	<p>From Page 97 lines 7-13 “In some embodiments, the inflammatory biomarker is a pro-inflammatory cytokine. In some embodiments, the pro-inflammatory cytokine is interleukin-1 (IL-1), tumor necrosis factor (TNF), gamma-interferon (IFN-g), IL-1 b, IL-6, IL-10, IL-12, IL-18, granulocyte-macrophage colony stimulating factor (GMCSF), C-X-C chemokine ligand 1 (CXCL1) or CXCL9. In some embodiments, the pro-inflammatory cytokine is TNF-a, IL-6, I L-1 b, or IL-10. In some embodiments, the pro-inflammatory cytokine is CXCL1 or CXCL9. In some embodiments, the inflammatory biomarker is C-Reactive Protein (CRP), homocysteine, or hemoglobin A1 c (HbA1 c).”</p>
<p>11. The method of claim 1, further including the step of administering an anti-inflammatory/anti-pain agent chosen from the group consisting of non-steroidal anti-inflammatory drugs (NSAIDS), steroids, immune selective anti-inflammatory derivatives (ImSAIDs), narcotics, analgesics, biologic agents, and combinations thereof.</p>	<p>1. Int’l Pat. App. Pub. No. WO/2021/175816 “Compounds for Use in a Method of Treating, Preventing, and/or Reducing the Symptoms of Pain” (Published September 10, 2021)</p> <p>From Page 5 lines 14-20 “The compound for use according to any one of items 1 to 7 or the composition for use according to item 8, wherein the compound or composition is administered concurrently with, before and/or after one or more active agents selected from nonsteroidal anti-inflammatory drugs (NSAIDs), COX-2 inhibitors (COXIBs) such as acetaminophen, cannabinoids, NMDA receptor antagonists such as ketamine, magnesium, trigger point injection (TPI), and botulinum toxin.”</p> <p>10. Int’l Pat. App. Pub. No. WO/2022/011350 “Method of Treatment for Psilocybin or Psilocin Infusion” (Published January 13, 2022)</p> <p>From Page 3 lines 3-6 “In some embodiments, the method further includes administering to the patient a preparation including a pharmacologically effective</p>

	<p>amount of an anti-inflammatory agent. In particular embodiments, the administration of the preparation is an intravenous infusion of ketorolac or pharmaceutically acceptable salt thereof.”</p>
<p>12. The method of claim 11, wherein said step of administering an anti-inflammatory/anti-pain is performed before, during, or after said administering the psychedelic step.</p>	<p>1. Int’l Pat. App. Pub. No. WO/2021/175816 “Compounds for Use in a Method of Treating, Preventing, and/or Reducing the Symptoms of Pain” (Published September 10, 2021)</p> <p>From Page 5 lines 14-20 “The compound for use according to any one of items 1 to 7 or the composition for use according to item 8, wherein the compound or composition is administered concurrently with, before and/or after one or more active agents selected from nonsteroidal anti-inflammatory drugs (NSAIDs), COX-2 inhibitors (COXIBs) such as acetaminophen, cannabinoids, NMDA receptor antagonists such as ketamine, magnesium, trigger point injection (TPI), and botulinum toxin.”</p>
<p>13. The method of claim 11, wherein the psychedelic and anti-inflammatory/anti-pain agent are in the same single dosage form or different dosage forms.</p>	<p>10. Int’l Pat. App. Pub. No. WO/2022/011350 “Method of Treatment for Psilocybin or Psilocin Infusion” (Published January 13, 2022)</p> <p>From Page 3 lines 3-6 “In some embodiments, the method further includes administering to the patient a preparation including a pharmacologically effective amount of an anti-inflammatory agent. In particular embodiments, the administration of the preparation is an intravenous infusion of ketorolac or pharmaceutically acceptable salt thereof.”</p>
<p>14. A method of treating a pain syndrome, including the steps of: administering an effective amount of a psychedelic to an individual; and providing a central effect, an effect on depression and anxiety, and an anti-inflammatory effect.</p>	<p>9. Int’l Pat. App. Pub. No. WO/2020/212948 “Methods of Treating Neurocognitive Disorders, Chronic Pain and Reducing Inflammation” (Published October 22, 2020)</p> <p>From Claim 47 “A method of reducing inflammation in a subject in need thereof, the</p>

	<p>method comprising administering to the subject a therapeutically effective amount of psilocybin or an active metabolite thereof.”</p> <p>From Claim 53 “The method of any one of claims 47-52, wherein reducing inflammation in the subject treats or prevents one or more of chronic pain, neuropathic pain, and inflammatory pain in the subject.”</p> <p>From Claim 75 “The method of claim 74, wherein the administration of psilocybin alleviates depression in the subject.”</p> <p>From Page 109 Lines 3-5 “In some embodiments, the subject has one or more comorbidities. For example, the comorbidity may be conduct disorder, depression, or anxiety. In some embodiments, psilocybin ameliorates at least one sign or symptom of the comorbidity.”</p>
<p>15. The method of claim 14, wherein the psychedelic is chosen from the group consisting of lysergic acid diethylamide (LSD), psilocybin, psilocin, mescaline, 5-methoxy-N,N-dimethyltryptamine (5-MeO-DMT), dimethyltryptamine (DMT), 2,5-dimethoxy-4-iodoamphetamine (DOI), 2,5-dimethoxy-4-bromoamphetamine (DOB), desoxyscalines, salts thereof, tartrates thereof, solvates thereof, isomers thereof, analogs thereof, and homologues thereof.</p>	<p>9. Int’l Pat. App. Pub. No. WO/2020/212948 “Methods of Treating Neurocognitive Disorders, Chronic Pain and Reducing Inflammation” (Published October 22, 2020)</p> <p>From Claim 47 “A method of reducing inflammation in a subject in need thereof, the method comprising administering to the subject a therapeutically effective amount of psilocybin or an active metabolite thereof.”</p>
<p>16. The method of claim 14, further including the step of administering an anti-inflammatory/anti-pain agent chosen from the group consisting of non-steroidal anti-inflammatory drugs (NSAIDS), steroids, immune selective anti-inflammatory derivatives (ImSAIDs), narcotics, analgesics, biologic agents, and combinations thereof.</p>	<p>10. Int’l Pat. App. Pub. No. WO/2022/011350 “Method of Treatment for Psilocybin or Psilocin Infusion” (Published January 13, 2022)</p> <p>From Page 3 lines 3-6 “In some embodiments, the method further includes administering to the patient a preparation including a pharmacologically effective amount of an anti-inflammatory agent. In particular embodiments, the administration of the preparation is an intravenous infusion of</p>

	ketorolac or pharmaceutically acceptable salt thereof.”
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Electronic Acknowledgement Receipt

EFS ID:	48124312
Application Number:	17877521
International Application Number:	
Confirmation Number:	2388
Title of Invention:	PSYCHEDELICS FOR TREATMENT OF PAIN
First Named Inventor/Applicant Name:	Robert BARROW
Customer Number:	48924
Filer:	Taylor Kurtzweil
Filer Authorized By:	
Attorney Docket Number:	0614.00144
Receipt Date:	08-JUN-2023
Filing Date:	29-JUL-2022
Time Stamp:	16:14:20
Application Type:	

Payment information:

Submitted with Payment	yes
Payment Type	CARD
Payment was successfully received in RAM	\$72
RAM confirmation Number	E202368G14175521
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	43908 5eae4d840e6ea3853ccc16390401390f26e58a2b	no	5

Warnings:

Information:

2	Third-Party Submission Under 37 CFR 1.290	Third-party-preissuance-submission.pdf	77276 83cfbbb3cbeb23f36e29aef138e232f40d10093d	no	3
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Warnings:

Information:

3	Request for Notification of Non-compliant Third-Party Submission	Third-party-notification-request.pdf	23740 106896cd7d39754402e20ea9f02d32f49a26a8b5	no	1
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Warnings:

Information:

4	Evidence of Publication	Castellanos2020.pdf	1137851 f3bce247e20dfabdd3a6e71187479165d7a170d7	no	9
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Warnings:

Information:

5	Evidence of Publication	Hutten2019.pdf	980643 7580aa8d332c4f81c942977c369cd9a7dc426d08	no	9
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Warnings:

Information:

6	Concise Description of Relevance	20220362237_Claims_Chart.pdf	284662 6bffa361a0cc71957eb489227674c4f5de8a5ab3	no	17
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Warnings:

Information:

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7	Fee Worksheet (SB06)	fee-info.pdf	37588 af25911bfc530ea09db00d42202538a2460 ee657	no	2
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Warnings:

Information:

Total Files Size (in bytes):	2585668
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