PATENT COOPERATION TREATY

PCT

THIRD PARTY OBSERVATION

(PCT Administrative Instructions Part 8)

| Applicant's or agent's file reference 0614-00114 | | | | | | |
|--|---|--|--|--|--|--|
| International application number PCT/US2022/026921 | International filing date (day/month/year) 29 Apr 2022 (29/04/2022) | | | | | |
| Applicant MIND MEDICINE, INC. | | | | | | |

| Third party observation submitted by | Observation submitted on behalf of | | | |
|--------------------------------------|--|--|--|--|
| Taylor KURTZWEIL | Porta Sophia Psychedelic Prior Art Library | | | |
| Date of submission(day/month/year) | Language of observation | | | |
| 28 Jun 2023 (28/06/2023) | English | | | |

Basis and contents of observation

- 1. The observation is made on the basis of the claims in the international application as filed.
- 2. The observation comprises:References to documents: 8Uploaded copies of documents: 2

3. Further explanations:

Uploaded copies of documents: 0



Citation # 1 (Patent/utility model) (# uploaded documents: 0):

| | | | | | | <u> </u> | | |
|-------------------------------------|-------------------|--------------|----------------------------|---|--|--------------------------|-----------------------------|--|
| Country code: | Publication num | ber: | | | | Docu | ment kind code: | |
| wo | 20211758 | 2021175816 | | | | _ A | .1 | |
| THE BECKLEY FOUND [GB] C | | | | Title of invention: COMPOUNDS FOR USE IN A METHOD OF TREATING, PREVENTING AND/OR REDUCING THE SYMPTOMS OF PAIN | | | | |
| Link to document: | Link to document: | | | | | | | |
| Publication Date: | | Filing Date: | Priority Date: | | | ate: | | |
| 10 Sep 2021 (10/ | (09/2021) | 9/2021) | | | | 03 Mar 2020 (03/03/2020) | | |
| Source of Abstract: | Accession | n number: | umber: Publication Date of | | | bstract: | Retrieval Date of Abstract: | |
| Most relevant passages or drawings: | | | | Relevant to Claims: | | s: | | |
| Claims 1, 2, 5, 6, | pg 14 | | | 1, 2, 3, 4, 5, 7 | | | , 7 | |

Brief explanation of relevance:

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" Relevant to WO202235500 Claims 1, 2,

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." Relevant to WO202235500 Claims 2, 5

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" Relevant to WO202235500 Claim 2

From Page 14, lines 6-12 "The routes for administration (delivery) include one or more of oral (e.g. tablet, capsule, ingestable 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." Relevant to WO202235500 Claim 7

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." Relevant to WO202235500 Claims 2, 3, 4

Citation # 2 (Patent/utility model) (# uploaded documents: 0):

| | | 3.3.7 (3.15. | | | | - / · | |
|-------------------------------------|-----------------|---------------|---|---------------------|------------------------|------------|-----------------------------|
| Country code: | Publication num | ber: | | | | Docu | ment kind code: |
| WO | 20220113 | 50 | | | | Δ | .1 |
| Patent Applicant/Patent Owner: | | | | Title of invention: | | | |
| ELEUSIS THERAPEUTICS US INC [US] | | | N | IETHOD C | F TREA | TMEN | FOR PSILOCYBIN OR |
| | | | F | PSILOCIN INFUSION | | | |
| Link to document: | | | | | | | |
| | | | | | | | |
| Publication Date: | | Filing Date: | | | | Priority D | ate: |
| 13 Jan 2022 (13/01/2022) | | | | | 10 Jul 2020 (10/07/202 | | |
| Source of Abstract: | Accession | n number: | | Publication | Date of Al | stract: | Retrieval Date of Abstract: |
| | | | | | | | |
| Most relevant passages or drawings: | | | | | Relevan | to Claim | S: |
| Abstract, Claims 10, 46, 52, 53 | | | | 1, 2, 3, 5 | | | |

Brief explanation of relevance:

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." Relevant to WO202235500 Claim 1

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." Relevant to WO202235500 Claims 2, 3, 5

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." Relevant to WO202235500 Claims 2, 3, 5

From Claim 52 "The method of claim 46, wherein the disease or condition is chronic pain." Relevant to WO202235500 Claim 2

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." Relevant to WO202235500 Claim 2

Citation # 3(Periodical article) (# uploaded documents:1):

| | , , . | | | |
|--------------------------------|--------------------------|-------------------|------------------|--------------------|
| Author: | Title of article: | Title of Periodic | al: | Publication Date: |
| JP Castellanos et al | Chronic pain and Regiona | | Anesthesia | Jul 2020 (07/2020) |
| | psychedelics: a | and Pain I | | |
| | review and proposed | | | |
| | mechanism of action | | | |
| Issue Number of Periodical: | Publisher of Periodical: | | Place of publica | ation: |
| Volume 45 issue 7 | | | | |
| Page range of article within | ISBN: | | ISSN: | |
| periodical: | | | | |
| 486-494 | | | | |
| DOI: | | | | |
| | | | | |
| Most relevant passages or drav | vings: | | Relevant t | o Claims: |
| Pgs 486, 489, 490, | | | 2, 3, 4 | 4 |

Brief explanation of relevance:

From Page 486 "There is also evidence that psychedelic drugs may possess antinociceptive effects in chronic pain conditions." Relevant to WO202235500 Claim 2

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." Relevant to WO202235500 Claim 3

From Page 489 "Studies with single session administrations of LSD, psilocybin and MDMA have shown alleviation of anxiety and depression which may persist for weeks, or even months." Relevant to WO202235500 Claim 4

Citation # 4 (Patent/utility model) (# uploaded documents: 0):

| | , | <i>,</i> , , | | | | , | |
|--------------------------------|-----------------|--------------|---|---------------------------------------|------------|------------|-----------------------------|
| Country code: | Publication num | ber: | | | | Docu | ment kind code: |
| wo | 20222258 | 84 | | | | A | .1 |
| Patent Applicant/Patent Owner: | | | | Title of invention: | | | |
| LENNHAM PHARMACEUTICALS INC [| | | | DEUTERATED DERIVATIVES OF PSYCHEDELIC | | | |
| US] | | | С | COMPOUNDS AND USES THEREOF | | | THEREOF |
| Link to document: | | | | | | | |
| | | | | | | | |
| Publication Date: | | Filing Date: | | | | Priority D | ate: |
| 27 Oct 2022 (27/ | 10/2022) | | | | | 22 A | pr 2021 (22/04/2021) |
| Source of Abstract: | Accession | number: | | Publication | Date of Al | ostract: | Retrieval Date of Abstract: |
| | | | | | | | |
| Most relevant passages of | or drawings: | | | | Relevan | to Claim | S: |
| Pgphs 0003, 001 | 01 | | | | 2, 3 | | |

Brief explanation of relevance:

From Paragraph [0003] "The present invention relates to compositions (e.g., pharmaceutical compositions) comprising deuterated derivatives of certain naturally-occurring and synthetic psychedeliccompounds." Relevant to WO202235500 Claim 2

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." Relevant to WO202235500 Claims 2, 3

Citation # 5 (Patent/utility model) (# uploaded documents: 0):

| Country code: | Publication num | ber: | | | | Docu | ment kind code: |
|--|-----------------|--------------|--|---------------------|------------|---------|-----------------------------|
| WO | 20222128 | 54 | | | | Δ | .1 |
| Patent Applicant/Patent Owner: TERRAN BIOSCIENCES INC [US] | | | Title of invention: METHODS AND COMPOSITIONS RELATING TO PSYCHEDELICS AND SEROTONIN RECEPTOR MODULATORS | | | | |
| Link to document: | | | | | | | |
| Publication Date: | | Filing Date: | Priority Date: | | | ate: | |
| 06 Oct 2022 (06/10/2022) | | | 01 Apr 2021 (01/04/202 | | | | pr 2021 (01/04/2021) |
| Source of Abstract: | Accession | n number: | | Publication | Date of Al | stract: | Retrieval Date of Abstract: |
| Most relevant passages or drawings: | | | | Relevant to Claims: | | s: | |
| Claim 4, pgphs 0005 00376, 00377 | | | | 5, 7 | | | |

Brief explanation of relevance:

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), ... or a pharmaceutically acceptable salt, solvate, metabolite, deuterated analogue, derivative, prodrug, or combinations thereof." Relevant to WO2022235500 Claims 5, 7

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." Relevant to WO2022235500 Claim 5

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, the compositions described herein are administered orally via a pill, ampoule, vial, or tablet." Relevant to WO2022235500 Claim 7

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)." Relevant to WO2022235500 Claim 7

Citation # 6(Periodical article) (# uploaded documents:1):

| | , · · · | | , | |
|--------------------------------|--------------------------|-------------------|-----------------|---------------------|
| Author: | Title of article: | Title of Periodic | al: | Publication Date: |
| Nadia Hutten et al | Self-Rated | Frontiers | in | 13 Sep 2019 (13/09/ |
| | Effectiveness of | Psychiatr | y | 2019) |
| | Microdosing With | | | |
| | Psychedelics for | Psychedelics for | | |
| | Mental and Physical | | | |
| | Health Problems | | | |
| | Among Microdosers | | | |
| Issue Number of Periodical: | Publisher of Periodical: | | Place of public | ation: |
| Volume 10 | | | | |
| Page range of article within | ISBN: | | ISSN: | |
| periodical: | | | | |
| DOI: | | | | |
| | | | | |
| Most relevant passages or drav | wings: | Relevant to | | o Claims: |
| Page 1 | | 6 | | |

Brief explanation of relevance:

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." Relevant to WO2022235500 Claim 6

Citation # 7 (Patent/utility model) (# uploaded documents: 0):

| Country code: | Publication number: | | | Document kind code: | | | |
|--|---------------------|-----------------|--------------|------------------------------------|--|--|--|
| WO | 2021209815 | | | A1 | | | |
| Patent Applicant/Patent Owner: Title of invention: | | | | | | | |
| PIKE THERAPE | JTICS INC [CA] | TRANSDE | RMAL MIC | CRO-DOSING DELIVERY OF | | | |
| | ~ (C | PSYCHED | ELICS DEI | RIVATIVES | | | |
| Link to document: | | | | | | | |
| Publication Date: | Filing | Date: | Pri | riority Date: | | | |
| 21 Oct 2021 (21/ | 10/2021) | | | 16 Apr 2020 (16/04/2020) | | | |
| Source of Abstract: | Accession number | er: Publication | Date of Abst | tract: Retrieval Date of Abstract: | | | |
| Most relevant passages | or drawings: | | Relevant to | o Claims: | | | |
| Claims 1, 7 | | | 7 | | | | |

Brief explanation of relevance:

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.." Relevant to WO202235500 Claim 7

From Claim 7 "The pharmaceutical composition of any one of claims 1 to 6 which is formulated as a transdermal patch." Relevant to WO202235500 Claim 7

Citation # 8 (Patent/utility model) (# uploaded documents: 0):

| | | <i>,</i> , . | | | | , | |
|-------------------------------------|-----------------|---------------------------------|--------------------------|---------------|-----------|---------------|-----------------------------|
| Country code: | Publication num | ber: | | | | Docu | ment kind code: |
| wo | 20201811 | 94 | | | | A | .1 |
| Patent Applicant/Patent Owner: | | | Title | of invention: | | | |
| UNIV OF PADO\ | /A [IT] | | C | OMPOSIT | TONS A | AND ME | THODS OF USE |
| | | | c | OMPRISI | NG SUE | BSTANC | ES WITH NEURAL |
| | | P | LASTICIT | Y ACTI | ONS AD | MINISTERED AT | |
| | | NON-PSYCHEDELIC/PSYCHOTOMIMETIC | | | | | |
| | | | DOSAGES AND FORMULATIONS | | | | |
| Link to document: | | | | | | | |
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| Publication Date: | | Filing Date: | | | | Priority Da | ate: |
| 10 Sep 2020 (10 | /09/2020) | | | | | 07 M | ar 2019 (07/03/2019) |
| Source of Abstract: | Accession | number: | | Publication | Date of A | bstract: | Retrieval Date of Abstract: |
| | | | | | | | |
| Most relevant passages or drawings: | | | Relevant to Claims: | | S: | | |
| Pgph 0082, Claims 1, 2, 3, 4 | | | | 7 | | | |
| | | | | | | | |

Brief explanation of relevance:

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." Relevant to WO202235500 Claim 7

From Claim 1 "A compound comprising a structural analogue to psilocin, norpsilocin, psilocybin, baeocystin, norbaeocystin or N,N-dimethyltryptamine, according to formula I..." Relevant to WO202235500 Claim 7

From Claim 2 "A compound comprising a structural analogue to 2,5-Dimethoxy-4-iodoamphetamine, according to formula II. Relevant to WO202235500 Claim 7

From Claim 3 "A compound comprising a structural analogue to Lysergic acid diethylamide, according to formula III..." Relevant to WO202235500 Claim 7

From Claim 4 "A compound comprising a structural analogue to ibogaine, according to formula IV... " Relevant to WO202235500 Claim 7