

PATENT COOPERATION TREATY
PCT
THIRD PARTY OBSERVATION
(PCT Administrative Instructions Part 8)

Applicant's or agent's file reference ATAI-018-01WO	
International application number PCT/US2022/045336	International filing date (day/month/year) 30 Sep 2022 (30/09/2022)
Applicant ATAI LIFE SCIENCES AG	
Third party observation submitted by Shahin SHAMS	Observation submitted on behalf of Porta Sophia
Date of submission(day/month/year) 24 May 2023 (24/05/2023)	Language of observation 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: 6
Uploaded copies of documents: 6
3. Further explanations:
Uploaded copies of documents: 0

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

Country code: WO	Publication number: 2021/226416	Document kind code: A1
Patent Applicant/Patent Owner: PSILERA INC.	Title of invention: NOVEL COMPOSITIONS OF MATTER AND PHARMACEUTICAL COMPOSITIONS	
Link to document:		
Publication Date: 11 Nov 2021 (11/11/2021)	Filing Date: 07 May 2021 (07/05/2021)	Priority Date: 08 May 2020 (08/05/2020)
Source of Abstract:	Accession number:	Publication Date of Abstract: Retrieval Date of Abstract:
Most relevant passages or drawings: Pages: 21, 22, 28, 41, 52		Relevant to Claims:

Brief explanation of relevance:

Relevant to claims: 1, 2, 3, 4, 5, 6, 7, 8, 9, 10, 11, 21

From page 21 paragraph 3 “As used herein, and unless otherwise specified, the term “Neurological Disorder” refers to diseases of the central and peripheral nervous system e.g., the brain, spinal cord , cranial nerves, peripheral nerves, nerve roots, autonomic nervous system, neuromuscular junction , and muscles. These disorders include epilepsy, Alzheimer’s disease and other dementias, cerebrovascular diseases including stroke, migraine, cluster headaches and other headache disorders, multiple sclerosis, Parkinson's disease, neuroinfections, brain tumors, traumatic disorders of the nervous system due to head trauma, and traumatic disorders due to traumatic or terrifying experiences (Posttraumatic Stress Disorder e.g. PTSD) and neurological disorders as a result of malnutrition and substance abuse.”; Relevant to WO2023055992 claims 1, 2, 3, 4, 5, 6, 7, 8, 9, 10, 11, 21

From page 22, paragraph 2 “As used herein, and unless otherwise specified, the terms “prevent,” “preventing” and “prevention” refer to the prevention of the onset, recurrence or spread of a disease or disorder or of one or more symptoms thereof.”; Relevant to WO2023055992 claim 21

From page 28 paragraph 1 “In certain embodiments, the psilocybin analogue is 5-methoxy-N, N-dimethyltryptamine (5-MeO-DMT). In certain embodiments, the psilocybin analogue is bufotenin (5-OH-DMT).”; Relevant to WO2023055992 claims 1, 2, 3, 4, 5, 6, 7, 8, 9, 10, 11, 21

From page 41 paragraph 1 “In particular embodiments, the specific amount of the psilocybin analogue in the formulation is, e.g., at least about 1 mg, at least about 2 mg, at least about 3 mg, at least about 4 mg, at least about 5 mg, at least about 6 mg, at least about 7 mg, at least about 8 mg, at least about 9 mg, at least about 10 mg, at least about 11 mg, at least about 12 mg, at least about 13 mg, at least about 14 mg, at least about 15 mg, at least about 16 mg, at least about 17 mg, at least about 18 mg, at least about 19 mg, at least about 20 mg, at least about 21 mg, at least about 22 mg, at least about 23 mg, at least about 24 mg, at least about 25 mg, at least about 26 mg, at least about 27 mg, at least about 28 mg, at least about 29 mg, at least about 30 mg, at least about 31 mg, at least about 32 mg, at least about 33 mg, at least about 34 mg, at least about 35 mg, at least about 36 mg, at least about 37 mg, at least about 38 mg, at least about 39 mg, at least 40 mg, at least 45 mg, at least 50 mg, at least about 55 mg, at least about 60 mg, at least about 65 mg, at least about 70 mg, at least about 75 mg, at least about 80 mg, at least about 85 mg, at least about 90 mg, at least about 95 mg, or at least 100 mg.”; Relevant to WO2023055992 claims 5, 6, 7, 8, 9, 11

From page 52 paragraph 1 “Provided herein are methods of preventing, managing, and treating neurological, mood or addictive disorders including post-treatment Lyme disease syndrome, dementias, Alzheimer’s disease, post-traumatic stress disorder, anorexia nervosa, depression, anxiety, addiction, substance abuse including but not limited to opioid addiction, alcohol addiction, nicotine addiction, cannabinoid addiction, headache, central nervous system inflammation, dementia, cognition and memory by administering psilocybin analogues transdermally, intranasally, or orally.”; Relevant to WO2023055992 claims 1, 2, 3, 4, 5, 6, 7, 8, 9, 10, 11, 21

Citation # 2 (Patent/utility model) (# uploaded documents: 1):

Country code: WO	Publication number: 2022/246572	Document kind code: A1	
Patent Applicant/Patent Owner: MINDSET PHARMA INC.		Title of invention: HALLUCINOGEN-FATTY ACID COMBINATION	
Link to document:			
Publication Date: 01 Dec 2022 (01/12/2022)	Filing Date: 26 May 2022 (26/05/2022)	Priority Date: 26 May 2021 (26/05/2021)	
Source of Abstract:	Accession number:	Publication Date of Abstract:	Retrieval Date of Abstract:
Most relevant passages or drawings: Paragraphs [0098], [00121], [0141], [00155]		Relevant to Claims:	
<p>Brief explanation of relevance:</p> <p>Relevant to claims: 12, 13, 14, 16, 17, 18, 19, 22</p> <p>***Priority document of WO/2021/226416 (PCT/CA2022/050858 which was published on 26 May 2022): U.S. Doc Number 63/202,081; Filed 26 May 2021; Available through WIPO interface.***</p> <p>From paragraph [0098] “in some embodiments, the one or more psychedelics are selected from psilocybin, psilocin, dimethyltryptamine (DMT), 5-methoxy-dimethyltryptamine (5-MeO-DMT)...”; Relevant to WO2023055992 claims 12, 13, 14, 16, 17, 18, 19, 22</p> <p>From paragraph [00121] “The one or more hallucinogens...are administered to a subject or are used in a variety of forms depending on the selected route of administration, as will be understood by those skilled in the art...the hallucinogens...are administered by oral, inhalation, parenteral, buccal, sublingual, insufflation, epidurally, nasal, rectal, vaginal, patch, pump, minipump, topical or transdermal administration, and the pharmaceutical compositions formulated accordingly.”; Relevant to WO2023055992 claims 12, 13, 14, 16, 17, 18</p> <p>From paragraph [0141] “In some embodiments, the disease, disorder, or condition that is treated by activation of a serotonin receptor comprises cognitive impairment; ischemia including stroke; neurodegeneration; refractory substance use disorder; sleep disorders; pain, such as social pain, acute pain, cancer pain, chronic pain, breakthrough pain, bone pain, soft tissue pain, nerve pain, referred pain, phantom pain, neuropathic pain, cluster headaches or migraine; obesity or eating disorders; epilepsies or seizure disorders; neuronal cell death; excitotoxic cell death; or a combination thereof.”; Relevant to WO2023055992 claims 12, 13, 14, 16, 17, 18, 19, 22</p> <p>From paragraph [00155] “Treatment methods comprise administering to a subject the one or more hallucinogens, or a salt, prodrug and/or solvate thereof, and the one or more fatty acids, or a salt, prodrug and/or solvate thereof, and optionally consists of a single administration, or alternatively comprises a series of administrations.”; Relevant to WO2023055992 claim 19</p>			

Citation # 3 (Patent/utility model) (# uploaded documents: 1):

Country code: WO	Publication number: 2022/235514	Document kind code: A1	
Patent Applicant/Patent Owner: MIND MEDICINE, INC.		Title of invention: LIPOSOME DELIVERY OF PSYCHEDELICS	
Link to document:			
Publication Date: 10 Nov 2022 (10/11/2022)	Filing Date: 29 Apr 2022 (29/04/2022)	Priority Date: 04 May 2021 (04/05/2021)	
Source of Abstract:	Accession number:	Publication Date of Abstract:	Retrieval Date of Abstract:
Most relevant passages or drawings: Paragraph [00012], [00013], [00018], [00025]		Relevant to Claims: 15	
<p>Brief explanation of relevance:</p> <p>*** Priority document of WO/2022/235514 (PCT/US2022/027008 which was published on 29 April 2022): U.S. Doc Number 63/184,000; Filed 04 May 2021; Available through WIPO interface.***</p> <p>From paragraph [00012] "The present invention provides for a composition of a psychedelic in a liposome formulation. The composition can be used in methods of preferentially distributing psychedelics at the CNS."; Relevant to WO2023055992 claim 15</p> <p>From paragraph [00013] "The psychedelics in the present invention can be, but are not limited to, ibogaine, noribogaine, lysergic acid diethylamide (LSD), psilocybin, psilocin, mescaline, 5-methoxy-N,N-dimethyltryptamine (5-MeO-DMT),..."; Relevant to WO2023055992 claim 15</p> <p>From paragraph [00018] "The compounds can be administered orally, transcutaneously, subcutaneously, or parenterally including intravenous, intramuscular, and intranasal administration." ; Relevant to WO2023055992 claim 15</p> <p>From paragraph [00025] "The condition or disease being treated can include, but is not limited to, anxiety disorders (including anxiety in advanced stage illness e.g. cancer, as well as generalized anxiety disorder), depression (including post partum depression, major depressive disorder, and treatment-resistant depression), headache disorder (including cluster headaches and migraine headaches),..."; Relevant to WO2023055992 claim 15</p>			

Citation # 4 (Patent/utility model) (# uploaded documents: 1):

Country code: WO	Publication number: 2022/235529	Document kind code: A1	
Patent Applicant/Patent Owner: MIND MEDICINE, INC.		Title of invention: METHOD OF TITRATING DOSE OF PSYCHEDELICS	
Link to document:			
Publication Date: 10 Nov 2022 (10/11/2022)	Filing Date: 01 May 2022 (01/05/2022)	Priority Date: 03 May 2021 (03/05/2021)	
Source of Abstract:	Accession number:	Publication Date of Abstract:	Retrieval Date of Abstract:
Most relevant passages or drawings: Paragraphs [00012], [00014], [00018], [00029]		Relevant to Claims: 20	
Brief explanation of relevance: <p>*** Priority document of WO/2022/235529 (PCT/US2022/027179 which was published on 01 May 2022): U.S. Doc Number 63/183,579; Filed 03 May 2021; Available through WIPO interface.***</p> <p>From paragraph [00012] "More specifically, the titrating dosage regimen can include administering a starting dose to the individual, and at a set amount of time, increasing the dose a set amount and administering the increased dose to the individual, and repeating these steps over a period of time that the individual is being treated and until a maximum desired dose is achieved."; Relevant to WO2023055992 claim 20</p> <p>From paragraph [00014] "The time period can be hours, days, weeks, months, or years."; Relevant to WO2023055992 claim 20</p> <p>From paragraph [00018] "The psychedelics in the present invention can be, but are not limited to, lysergic acid diethylamide (LSD), psilocybin, mescaline, 5-methoxy-N,N-dimethyltryptamine (5-MeO-DMT)..."; Relevant to WO2023055992 claim 20</p> <p>From paragraph [00029] "The condition or disease being treated with the methods of the present invention can include, but is not limited to, anxiety disorders (including anxiety in advanced stage illness e.g. cancer, as well as generalized anxiety disorder), depression (including post partum depression, major depressive disorder and treatment resistant depression), headache disorder (including cluster headaches and migraine headaches)..."; Relevant to WO2023055992 claim 20</p>			

Citation # 5 (Patent/utility model) (# uploaded documents: 1):

Country code: US	Publication number: 2021/0363104	Document kind code: A1	
Patent Applicant/Patent Owner: CYBIN IRL LIMITED		Title of invention: DEUTERATED TRYPTAMINE DERIVATIVES AND METHODS OF USE	
Link to document:			
Publication Date: 25 Nov 2021 (25/11/2021)	Filing Date: 04 Aug 2021 (04/08/2021)	Priority Date: 03 May 2021 (03/05/2021)	

Source of Abstract:	Accession number:	Publication Date of Abstract:	Retrieval Date of Abstract:
Most relevant passages or drawings: Paragraphs [0001], [0200], [0202], [0320], [0322]		Relevant to Claims: 2, 21	

Brief explanation of relevance:

From paragraph [0001] "The present disclosure relates generally to chemical compounds and, in some embodiments, to serotonin 5-HT₂ receptor agonists and uses in the treatment of diseases associated with a 5-HT₂ receptor."; Relevant to WO2023055992 claim 2

From paragraph [0200] "In some embodiments, the disease or disorder may include central nervous system (CNS) disorders, for example, post-traumatic stress disorder (PTSD), major depressive disorder (MDD), treatment-resistant depression (TRD), suicidal ideation, suicidal behavior, major depressive disorder with suicidal ideation or suicidal behavior, nonsuicidal self-injury disorder (NSSID), bipolar and related disorders (including but not limited to bipolar I disorder, bipolar II disorder, cyclothymic disorder), obsessive-compulsive disorder (OCD), generalized anxiety disorder (GAD), social anxiety disorder, substance use disorders (including but not limited to alcohol use disorder, opioid use disorder, amphetamine use disorder, nicotine use disorder, and cocaine use disorder), anorexia nervosa, bulimia nervosa, Alzheimer's disease, cluster headache and migraine, attention deficit hyperactivity disorder (ADHD), pain and neuropathic pain, aphantasia, childhood-onset fluency disorder, major neurocognitive disorder, mild neurocognitive disorder, sexual dysfunction, and obesity. In some embodiments, the disease or disorder is alcohol use disorder. In some embodiments, the disease or disorder may include conditions of the autonomic nervous system (ANS). In some embodiments, the disease or disorder may include pulmonary disorders (e.g., asthma and chronic obstructive pulmonary disorder (COPD)). In some embodiments, the disease or disorder may include cardiovascular disorders (e.g., atherosclerosis)."; Relevant to WO2023055992 claim 2

From paragraph [0202] "Also disclosed herein is a single-layer orally administered tablet composition comprising a tryptamine derivative, such as DMT, 5-MeO-DMT, psilocybin, and psilocin, or any of the compounds described herein, or a pharmaceutically acceptable salt thereof, and a polymer."; Relevant to WO2023055992 claim 2

From paragraph [0320] "The term "treating" or "treatment" as used herein means the treating or treatment of a disease or medical condition in a patient, such as a mammal (particularly a human) that includes: ameliorating the disease or medical condition, such as, eliminating or causing regression of the disease or medical condition in a patient; suppressing the disease or medical condition, for example by, slowing or arresting the development of the disease or medical condition in a patient; or alleviating a symptom of the disease or medical condition in a patient. In an embodiment, prophylactic treatment can result in preventing the disease or medical condition from occurring, in a subject."; Relevant to WO2023055992 claim 2

From paragraph [0322] "As used herein, and unless otherwise specified, the terms "prevent," "preventing" and "prevention" refer to the prevention of the onset, recurrence or spread of a disease, disorder, or condition, or of one or more symptoms thereof. The terms encompass the inhibition or reduction of a symptom of the particular disease, disorder, or condition. Subjects with familial history of a disease, disorder, or condition, in particular, are candidates for preventive regimens in certain embodiments. In addition, subjects who have a history of recurring symptoms are also potential candidates for the prevention. In this regard, the term "prevention" may be interchangeably used with the term "prophylactic treatment.""; Relevant to WO2023055992 claims 2, 21

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

Author: Alan K Davis	Title of article: The epidemiology of 5-Methoxy-N, N-Dimethyltryptamine (5-MeO-DMT) use: Benefits, consequences, patterns of use, subjective effects, and reasons for consumption	Title of Periodical: Journal of Psychopharmacology	Publication Date: 30 Apr 2018 (30/04/ 2018)
Issue Number of Periodical: Volume 32 / Issue 7	Publisher of Periodical:	Place of publication:	
Page range of article within periodical:	ISBN:	ISSN:	
DOI:			
Most relevant passages or drawings: Page 781		Relevant to Claims: 20	
Brief explanation of relevance: From page 781 "Published studies of human self-experiments describe a range of subjective effects of 5-MeO-DMT that vary depending on the dose and route of administration (Ott, 2001; Shulgin & Shulgin, 1997). Such effects include auditory, visual, and time perception distortions, emotional experiences, as well as memory impairment, with peak effects between 35–40 minutes after insufflation or within seconds-to-minutes when smoked (Ott, 2001; Shulgin & Shulgin, 1997)."; Relevant to WO2023055992 claim 20			