# PATENT COOPERATION TREATY

### **PCT**

#### THIRD PARTY OBSERVATION

### (PCT Administrative Instructions Part 8)

Applicant's or agent's file reference						
0614-00154						
International application number	International filing date (day/month/year)					
PCT/US2022/040636	17 Aug 2022 (17/08/2022)					
Applicant						
MIND MEDICINE, INC.						
Third party observation submitted by	Observation submitted on behalf of					
Sisi LI	Porta Sophia					
Date of submission(day/month/year)	Language of observation					
03 Aug 2023 (03/08/2023)	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: 6

Uploaded copies of documents: 6

3. Further explanations:

Uploaded copies of documents: 0

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

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Country code:	Publication num	ber:				Docu	ment kind code:
US	20200085	085816				A	.1
Patent Applicant/Patent Owner: Title of i			of invention:	M			
Eleusis Benefit C	orporation, Pl	3C	L	LSD FOR THE TREATMENT OF ALZHEIMER'S			
			ج.	ISEASE			
Link to document:				2)			
Publication Date: Filing Date:				Priority Date:			
19 Mar 2020 (19/03/2020) 19 Apr 2019 (19/04/20			19/04/201	19)			
Source of Abstract:	Accession	number:		Publication I	Date of Abstract: Retrieval Da		Retrieval Date of Abstract:
Most relevant passages or drawings:				Relevant to Claims:			
[0040], [0043], [0060], [0055], [0057], [0046], [0066], [0044				1-14, 17-20, 22			
], [0052], [0064], [0001], claim 47, [0003], [0013], [0002], [							
0065]	14(1)						

From [0040]: "The methods of the invention can include administration of lysergic acid diethylamide, or a pharmaceutically acceptable salt thereof, in a dosage form designed for immediate release. Such immediate release formulations can include for administration intravenously, intramuscularly, or subcutaneously, orally, sublingually, by inhalation, or by topical or transdermal application...etc" relevant to WO2023023182 claims 1, 2, 10

From [0043]: "Formulations for oral use include tablets containing the lysergic acid diethylamide, or a pharmaceutically acceptable salt thereof, in a mixture with non-toxic pharmaceutically acceptable excipients. These excipients may be, for example, inert diluents or fillers (e.g., sucrose, sorbitol, sugar, mannitol, microcrystalline cellulose, starches including potato starch, ... disintegrating agents (e.g., cellulose derivatives including microcrystalline cellulose, starches including potato starch, ... binding agents (e.g., ..., gelatin, starch, pregelatinized starch, microcrystalline cellulose, ... Other pharmaceutically acceptable excipients can be colorants, flavoring agents, plasticizers, humectants, buffering agents, and the like." relevant to WO2023023182 claims 1, 2, 3, 4, 5, 9, 10, 11, 12, 13, 14, 17

From [0060]: "In a membrane-moderated system, the lysergic acid diethylamide, or a pharmaceutically acceptable salt thereof, is present in a reservoir which is totally encapsulated in a shallow compartment molded from a drug-impermeable laminate, .... In the drug reservoir, the lysergic acid diethylamide, or a pharmaceutically acceptable salt thereof, substance may either be dispersed in a solid polymer matrix or suspended in a viscous liquid medium such as silicone fluid.. etc" relevant to WO2023023182 claims 1, 2, 8, 10, 11, 17

From [0055]: "Materials for use in the preparation of microspheres and/or microcapsules are, e.g., ... (e.g., dextrans), ...etc" relevant to WO2023023182 claims 2, 11

From [0057]: "Examples of emulsifying agents are naturally occurring gums (e.g., gum acacia or gum tragacanth) and naturally occurring phosphatides (e.g., soybean lecithin and sorbitan monooleate derivatives). Examples of antioxidants are butylated hydroxy anisole (BHA), ascorbic acid and derivatives thereof, tocopherol and derivatives thereof, butylated hydroxy anisole, and cysteine... Examples of penetration enhancers are propylene glycol, DMSO, ... Examples of chelating agents are sodium EDTA, citric acid, and phosphoric acid...etc" relevant to WO2023023182 claims 2, 4, 6, 7, 8, 11, 13, 14

From [0046]: "Formulations for oral use may also be presented as chewable tablets, or as hard gelatin capsules wherein the lysergic acid diethylamide, ... is mixed with an inert solid diluent (... kaolin), ...etc" relevant to WQ2023023182 claims 3,12

From [0066]: "Povidone USP (PVP K29/32) is dissolved in distilled water and ethanol 96% mixture, and D-lysergic acid diethylamide tartrate is dissolved in the formed solution...etc" relevant to WO2023023182 claims 4, 13

From [0044]: "... The coating may be a sugar coating, ... cellulose acetate phthalate, hydroxypropyl methylcellulose phthalate, hydroxypropyl methylcellulose acetate succinate, polyvinyl acetate phthalate, ..." relevant to WO2023023182 claims 5, 9, 14

From [0052]: "... Furthermore, the composition may include suspending, solubilizing, stabilizing, pH-adjusting agents, and/or dispersing agents." relevant to WO2023023182 claims 7

From [0064]: "D-lysergic acid diethylamide tartrate is mixed with pharmaceutically suitable diluents (e.g., talc, silica, lactose) and placed into gelatin capsules... Immediate release LSD dosed at 1  $\mu$ g/kg can have an apparent plasma half-life of 5.1 hours, ..." relevant to WO2023023182 claims 11, 22

From [0001]: "This invention relates to the use of LSD for the treatment of Alzheimer's disease." relevant to WO2023023182 claims 17, 18, 20

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

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Country code:	Publication num	ber:				Docu	ıment kind code:
US	20210137	908				Α Α	<b>\1</b>
Patent Applicant/Patent Owner:			Title	Title of invention:			
Lophora ApS			5	5-HT2A AGONISTS FOR USE IN TREATMENT OF			
				EPRESSI	ON		
Link to document:							
Publication Date: Filing Date:			Pri		Priority D	ority Date:	
13 May 2021 (13/05/2021) 05 Nov 202			)20 (	05/11/20	20)		
Source of Abstract:	Accession	n number:		Publication	Date of A	bstract:	Retrieval Date of Abstract:
Most relevant passages or drawings:				Relevant to Claims:		s:	
[0344], [0340], [0	005], [0337]				1, 1	0, 19	



From [0344]: "The compounds according to the present invention may be used alone (i.e. in mono-therapy) or in combination with one or more known anti-depressants (i.e. in combination therapy). Thus, combination therapy may include but are not limited to combinations with other therapeutically active ingredients such as SSRIs, SNRIs, NDRIs, TCAs, benzodiazepines, atypical antipsychotics, stimulants such as amphetamines and methylphenidate, ketamine, classical psychedelics such as mescaline, lysergic acid diethylamide (LSD), psilocybin and N, N-dimethyltryptamine (DMT)...etc" relevant to WO2023023182 claims 1, 10, 19

From [0340]: "Another aspect of the invention relates to a pharmaceutical composition comprising a compound according to aspects 1-6 of the invention, a pharmaceutical acceptable carrier and optionally one or more pharmaceutically acceptable excipients. In the present context, a pharmaceutical composition should be understood as any conventional type of formulation intended for e.g. parental, oral, inhalation or topical administration. Parental formulations may be intended for intravenous, subcutaneous or intramuscular administration. Suitable oral formulations may include tablets, capsules, powders, solutions, suspensions or a sustained release formulation for oral administration. Other suitable formulations may include creams, ointments, gels, pastes or patches for topical administration. Suitable parental formulations may include liquids, lyophilized or spray dried powders for dissolution prior to parental administration...etc" relevant to WO2023023182 claims 1

From [0005]: "Recent research efforts have shown that classical psychedelics may be useful for the treatment of psychiatric disorders, e.g. major depression, severe depression, treatment-resistant depression, alcohol dependence, alcohol use disorder, nicotine dependence, cocaine-related disorders, heroin dependence, obsessive compulsive disorder, eating disorders, general anxiety, death-related anxiety in terminal cancer patients, PTSD, Alzheimer's disease, mild cognitive impairment, distress, grief, migraine headache, post traumatic headache, cluster headache, Parkinson's disease, and psychosis.1, 2 The psychedelics are a class of drugs whose primary action is to trigger psychedelic experiences via serotonin receptor agonism, producing thought and visual/auditory changes and an altered state of consciousness. Classical psychedelics include mescaline (the active constituent of the peyote cactus), lysergic acid diethylamide (LSD), psilocybin (the active constituent of psilocybin mushrooms commonly known as "magic mushrooms") and N, N-dimethyltryptamine (DMT) (the active component in ayahuasca)...etc" relevant to WO2023023182 claims 19

From [0337]: "Furthermore, 5-HT2A agonists, such as psilocybin, have shown to be useful in the treatment of a number of diseases, disorders and addictions besides the above depressive disorders. Thus, in another preferred embodiment the compounds according to aspects 4-6 are for use in the treatment of a disease, a disorder, an addiction or an abuse selected from the list consisting of Alzheimer's disease, Parkinson's disease, autism, general anxiety, existential anxiety, end of life anxiety, terminal cancer related end of life anxiety, epilepsy, sleep-wake disorders, neurocognitive disorders, obsessive compulsive disorder (OCD), attention deficit disorder (ADD), attention deficit hyperactivity disorder (ADHD), post-traumatic stress disorder (PTSD), stress, acute stress disorder, Horton's headache, chronic cluster headache, migraine, general local inflammation, muscle inflammation, joint inflammation, pulmonary inflammation, asthma, arthritis, smoking cessation, alcohol cessation, cocaine cessation, heroin cessation, opioid cessation, methamphetamine cessation, general addiction therapy, eating disorders such as compulsive eating disorders, anorexia nervosa, bulimia nervosa, binge eating disorder, Pica, Rumination disorder, avoidant/restrictive food intake disorder, night eating syndrome, other specified feeding or eating disorder (OSFED), body dysmorphic disorder, purging disorder, pain, chronic pain disorders, sleep wake disorders or physical rehabilitation. In a highly preferred embodiment, the compounds according to the aspects 4-6 are for use in the treatment of chronic cluster headache, bipolar type II disorder, body dysmorphic disorder." relevant to WO2023023182 claims 19

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

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Country code:	Publication number:					Docı	ument kind code:
US	20180228	20180228797					<b>A</b> 1
Patent Applicant/Patent 0	Patent Applicant/Patent Owner: Title of invention:						
CHARLESTON LABORATORIES, INC. PH			PHARMACEUTICAL COMPOSITIONS				
Link to document:							
Publication Date:	rublication Date: Filing Date:			Priority Date:		Date:	
16 Aug 2018 (16/08/2018) 11 Apr 2018 (1			11/04/20	18)			
Source of Abstract:	Accession	n number:		Publication	Date of A	Abstract:	Retrieval Date of Abstract:
Most relevant passages	or drawings:				Relevar	nt to Claim	is:
[0096], [0124], [0	139], [0125]				15,	16, 20,	21



From [0096]: "In some instances, a pharmaceutical composition disclosed herein comprises one or more serotonin receptor agonists. Exemplary serotonin receptor agonists include buspirone, mescaline, psilocybin, cisapride, lysergic acid diethylamide, or a pharmaceutically acceptable salt of any one of the foregoing, or any combination thereof." relevant to WO2023023182 claims 15, 16, 20 , 21

From [0124]: "In some instances, a pharmaceutical composition disclosed herein comprises a pharmaceutically active agent that can be in the form of its free base, its pharmaceutically acceptable salt, prodrug, analog, or complex. Exemplary pharmaceutically acceptable salts include metal salts, such as sodium salts, potassium salts, lithium salts; alkaline earth metals, such as calcium salts, magnesium salts; organic amine salts, such as triethylamine salts, pyridine salts, picoline salts, ethanolamine salts, triethanolamine salts, dicyclohexylamine salts, N,N'-dibenzylethylenediamine salts; inorganic acid salts such as hydrochloride salts, hydrobromide salts, sulfate salts, phosphate salts; organic acid salts such as formate salts, acetate salts, trifluoroacetate salts, maleate salts, tartrate salts; sulfonate salts such as methanesulfonate salts, benzenesulfonate salts, p-toluenesulfonate salts; and amino acid salts, such as arginate salts, asparginate salts, glutamate salts, or combinations thereof." relevant to WO2023023182 claims 15, 16, 20, 21

From [0139]: "In some instances, about 100% of a pharmaceutically active agent is capable of achieving dissolution from the immediate-release layer at about 40 minutes following oral administration. In another instance, about 100% to of a pharmaceutically active agent is capable of achieving dissolution from the immediate-release layer at about 40 minutes following contact with a dissolution fluid, such as the dissolution fluid described in Example 6 or as measured by any of the dissolution methods as described herein." relevant to WO2023023182 claims 15, 20

From [0125]: "In some instances, a pharmaceutically acceptable salt includes bitartrate, bitartrate hydrate, hydrochloride, p-toluenesulfonate, phosphate, sulfate, trifluoroacetate, bitartrato hemipentahydrate, pentafluoropropionate, hydropromide, mucate, oleate, phosphate dibasic, phosphate monobasic, acetate trihydrate, bis(heptafuorobutyrate), bis(pentafluoropropionate), bis( pyridine carboxylate), bis(trifluoroacetate), chlorhydrate, sulfate pentahydrate, or combinations thereof. In some instances, exemplary pharmaceutically acceptable salts include, e.g., water-soluble and water-insoluble salts, such as the acetate, amsonate(4,4-diaminostilbene-2,2disulfonate), benzenesulfonate, benzonate, bicarbonate, bisulfate, bitartrate, borate, butyrate, calcium edetate, camphorsulfonate, camsylate, carbonate, citrate, clavulariate, dihydrochloride, edetate, edisylate, estolate, esylate, flunarate, fumarate, gluceptate, gluconate, glutamate, glycollylarsanilate, hexafluorophosphate, hexylresorcinate, hydrabamine, hydrobromide, hydrochloride, hydroxynaphthoate, iodide, isothionate, lactate, lactobionate, laurate, malate, maleate, mandelate, mesylate, methylbromide, methylnitrate, methylsulfate, mucate, napsylate, nitrate, N-methylglucamine ammonium salt, 3-hydroxy-2-naphthoate, oleate, oxalate, palmitate, pamoate (1,1-methene-bis-2-hydroxy-3-naphthoate, einbonate), pantothenate, phosphate/ diphosphate, picrate, polygalacturonate, propionate, p-toluenesulfonate, salicylate, stearate, subacetate, succinate, sulfate, or combinations thereof. In some instances, a pharmaceutically acceptable salt includes bitartrate, bitartrate hydrate, hydrochloride, p-toluenesulfonate, phosphate, sulfate, trifluoroacetate, or bitartrato hemipentahydrate." relevant to WO2023023182 claims 16, 21

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

Country code:	Publication number:		Document kind code:		
US	20210015738		A1		
Patent Applicant/Pa	ent Owner:	Title of invention:			
Concept Matrix Solutions		ORAL DISSOLVABLE FILM CONTAINING			
		PSYCHEDELIC COMPOUND			
Link to document:		·			

Publication Date:		Filing Date:		Priority Date:		
21 Jan 2021 (21/01/2021) 14 Jul 2020		14 Jul 2020 (1	20 (14/07/2020)			
Source of Abstract:	Accession	n number:	Publication Date of Abstract		bstract:	Retrieval Date of Abstract:
Most relevant passages or drawings:				Relevant to Claims:		S:
[0002], [0014], [0023], [0091], [0104]				2, 1	11, 22	

From [0002]: "The present invention provides for an oral dissolvable film that includes: (i) a flowable water-soluble or water swellable film-forming matrix that includes a polymer, and (ii) psychedelic compound selected from the group consisting of psilocybin, psilocin, mescaline, lysergic acid diethylamide (LSD), ketamine, salvinorin A, ibotenic acid, muscimol, N,N-dimethyltryptamine (DMT), 3,4-methylenedioxymethamphetamine (MDMA), methyl diethanolamine, also known as N-methyl diethanolamine (MDEA), 3,4-methylenedioxy amphetamine (MDA), and combinations thereof." relevant to WO2023023182 claims 2, 11, 22

From [0014]: "It is appreciated that those of skill in the art understand that any substance employed in the slurry and/or oral dissolvable film can have multiple functions. However, unless the substance is otherwise indicated as having only a single function, reference to that substance as having a specified function is nonetheless appropriate and non-limiting, with the understanding that it may also have one or more additional functions. It is also appreciated that those of skill in the art understand that when feasible, the slurry and/or oral dissolvable film will preferably include substances that serve multiple desired purposes (e.g., possess multiple desired functions). In doing so, an oral dissolvable film can therefore be obtained that weighs less, dries quicker, disintegrates faster, and/or allows for a higher load of active ingredient." relevant to WO2023023182 claims 2, 11

From [0023]: "The term "binder" refers to a substance, typically a polymer, used to hold the ingredients together. Binders ensure that the oral dissolvable films can be formed with the requisite mechanical strength. The binders also provide the requisite volume to low amount of active present in dissolvable films. The presence of the binder also facilitates the formation of the cured film. As such, the binder includes those substances, which when present in the cast slurry and upon curing, will effectively provide for a cured film. The binder may also be referred to as a "film forming agent," or more specifically a "film forming polymer" when it is a polymer. The polymer can be a natural polymer or a synthetic polymer. Natural polymers include, e.g., pullulan, sodium alginate (Na alginate), pectin, gelatin, chitosan, and maltodextrin. Synthetic polymers include, e.g., hydroxpropyl cellulose (HPC), hydroxpropyl methylcellulose (HPMC), carboxymethyl cellulose (CMC), sodium carboxymethylcellulose (CMC-Na), microcrystalline cellulose (MCC), polyvinyl alcohol (PVA), polyethylene oxide (PEO), polyvinylpyrrolidone (PVP), and Kollicoat® (e.g., Kollicoat® Protect or Kollicoat® IR)." relevant to WO2023023182 claims 2, 11

From [0091]: "In specific embodiments, the psychedelic compound is present in up to 1 mg." relevant to WO2023023182 claims 22

From [0092]: "In specific embodiments, the psychedelic compound is present in up to 0.5 mg." relevant to WO2023023182 claims 22

From [0093]: "In specific embodiments, the psychedelic compound is present in up to 0.25 mg." relevant to WO2023023182 claims 22

From [0094]: "In specific embodiments, the psychedelic compound is present in 1-200 mg." relevant to WO2023023182 claims 22

From [0100]: "In specific embodiments, the psychedelic compound is present in 0.01-5 mg." relevant to WO2023023182 claims 22

From [0101]: "In specific embodiments, the psychedelic compound is present in 0.01-2.5 mg." relevant to WO2023023182 claims 22

From [0102]: "In specific embodiments, the psychedelic compound is present in 0.01-1 mg."

relevant to WO2023023182 claims 22

From [0103]: "In specific embodiments, the psychedelic compound is present in 0.01-0.5 mg." relevant to WO2023023182 claims 22

From [0104]: "In specific embodiments, the psychedelic compound is present in 0.01-0.25 mg." relevant to WO2023023182 claims 22

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

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US	20200101	041				/	<b>4</b> 1
Patent Applicant/Patent Owner:			Title of invention:				
Ojai Energetics P	BC		M	METHODS AND COMPOSITIONS FOR			
			E	NHANCIN	G HEA	LTH	
Link to document:							
Publication Date: Filing Date:			Pri		Priority D	iority Date:	
02 Apr 2020 (02/04/2020) 27 Sep 20			)19 (	27/09/20	19)		
Source of Abstract:	Accession	sion number: Publication			Publication Date of Abstract:		Retrieval Date of Abstract:
Most relevant passages or drawings:			Relevant to Claims:		ns:		
[0088], [0078], [0076], [0085], [0153], [0136			6]		8, 1	9	



From [0088]: "In some cases, a cannabinoid composition as described herein may be used in combination with psychedelic compounds, such as 3,4-methylenedioxymethamphetamine (MDMA), psilocybin, lysergic acid diethylamide (LSD). In some cases, a cannabinoid composition may be used in combination with psychedelic assisted therapeutic programs, and may assist in overall efficacy." relevant to WO2023023182 claims 8

From [0078]: "Binders suitable for use in dosage forms include, but are not limited to, corn starch, potato starch, or other starches, gelatin, natural and synthetic gums such as acacia, sodium alginate, alginic acid, other alginates, powdered tragacanth, guar gum, cellulose and its derivatives (e.g., ethyl cellulose, cellulose acetate, carboxymethyl cellulose calcium, sodium carboxymethyl cellulose), polyvinyl pyrrolidone, methyl cellulose, pre-gelatinized starch, hydroxypropyl methyl cellulose, microcrystalline cellulose, and mixtures thereof." relevant to WO2023023182 claims 8

From [0076]: "An ingredient described herein can be combined in an intimate admixture with a pharmaceutical carrier according to conventional pharmaceutical compounding techniques. The carrier can take a wide variety of forms depending on the form of preparation desired for administration. In preparing the compositions for an oral dosage form, pharmaceutical media can be employed as carriers, such as, for example, water, glycols, oils, alcohols, flavoring agents, preservatives, coloring agents, in the case of oral liquid preparations (such as suspensions, solutions, and elixirs) or aerosols; or carriers such as starches, sugars, micro-crystalline cellulose, diluents, granulating agents, lubricants, binders, and disintegrating agents can be used in the case of oral solid preparations, with or without employing the use of lactose. For example, suitable carriers include powders, capsules, and tablets, with the solid oral preparations. If desired, tablets can be coated by standard aqueous or nonaqueous techniques." relevant to WO2023023182 claims

From [0085]: "In one embodiment, the composition can include a solubilizer to ensure good solubilization and/or dissolution of the compound of the present disclosure and to minimize precipitation of the compound of the present disclosure. This can be especially important for compositions for non-oral use, e.g., compositions for injection. A solubilizer can also be added to increase the solubility of the hydrophilic drug and/or other components, such as surfactants, or to maintain the composition as a stable or homogeneous solution or dispersion." relevant to WO2023023182 claims 8

From [0153]: "Alternatively, a composition may be administered based on standard testing for targeted treatment protocols, wherein cannabinoids and terpenes in the composition may prevent and/or treat risk factors or disease states." relevant to WO2023023182 claims 8

From [0136]: "A composition of the current disclosure may be used to treat psychiatric disorders, including, but not limited to, sleep disorder, anxiety disorders, panic disorders, obsessive-compulsive disorder, bipolar disorder, depression, mood disorders, personality disorders, psychotic disorders, such as schizophrenia or delusional disorder. A composition may be used to treat a bipolar episode, wherein a symptom may include an unusual shift in mood, energy, activity level, and the inability to carry out day-to-day tasks." relevant to WO2023023182 claims 19

### Citation # 6(Web page) (# uploaded documents:1):

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Author:		Title of Page Or Article:			
	Swallowing Difficulties in Dementia				
URL:					
https://www.hey.nhs.uk/patient-leaflet/swallowing-difficulties-in-dementia/					
DOI:					
Name of Website:	Publication Date:		Retrieval Date:		
	18 Mar 2016 (18/03/2016)		03 Aug 2023 (03/08/2023)		
Most relevant passages or drawings:		Relevant to Claims:			
Quote from webpage		18			
Brief explanation of relevance:					
From webpage: "Dysphagia is a swallowing difficulty. It is very common for individuals with					
dementia to have difficulties with feeding, eating, drinking and swallowing" relevant to					
WO2023023182 claims 18					

