IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of: Mind Medicine, Inc. Confirmation No.: 3296
Serial No.: 18/194,761 Group No.:
Filing or 371(c) Date: April 03, 3023 Examiner: MICHAEL J SCHMITT
Entitled: Lyophilized Orally Disintegrating Tablet Formulations of d-Lysergic Acid Diethylamide for Therapeutic Applications

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. U.S. Pat. App. Pub. No. 2020/0085816 "LSD for the Treatment of Alzheimer's Disease" (Published March 19, 2020)
2. U.S. Pat. App. Pub. No. 2021/0137908 "5-HT2A Agonists for Use in Treatment of Depression" (Published May 13, 2021)
3. U.S. Pat. App. Pub. No. 2018/0228797 "Pharmaceutical Composition" (Published August 16, 2018)
4. U.S. Pat. App. Pub. No. 2021/0015738 "Oral Dissolvable Film Containing Psychedelic Compound" (Published January 21, 2021)
5. U.S. Pat. App. Pub. No. 2020/0101041 "Methods and Compositions for Enhancing Health" (Published April 02, 2020)
6. NHS, "Swallowing Difficulties in Dementia" March 17, 2016; retrieved from NHS Hull University Teaching Hospitals NHS Trust. https://www.hey.nhs.uk/patient-leaflet/swallowing-difficulties-in-dementia/, retrieved March 17, 2016

Attached hereto is a claim chart providing a concise description of the relevance of each reference in the document list of the elements of the presently pending claims.

U.S.S.N. 18/194,761 Pending Claims	References
1. A composition of a solid oral immediate release formulation of LSD, comprising LSD contained within an immediate release dosage form of an orally disintegrating tablet, wherein said composition is produced by lyophilization of a feedstock in a pre-formed mold to form the orally disintegrating tablet.	1. U.S. Pat. App. Pub. No. 2020/0085816 "LSD for the Treatment of Alzheimer's Disease" (Published March 19, 2020) 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. For example, the lysergic acid diethylamide, or a pharmaceutically acceptable salt thereof, can be formulated as a lozenge, drop, or film placed under the tongue for sublingual administration of a rapidly acting dosage form." 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, calcium carbonate, sodium chloride, lactose, calcium phosphate, calcium sulfate, or sodium phosphate); granulating and disintegrating agents (e.g., cellulose derivatives including microcrystalline cellulose, starches including potato starch, croscarmellose sodium, alginates, or alginic acid); binding agents (e.g., sucrose, glucose, sorbitol, acacia, alginic acid, sodium alginate, gelatin, starch, pregelatinized starch, microcrystalline cellulose, magnesium aluminum silicate, carboxymethylcellulose sodium, methylcellulose, hydroxypropyl methylcellulose, ethylcellulose, polyvinylpyrrolidone, or polyethylene glycol); and lubricating agents, glidants, and antiadhesives (e.g., magnesium stearate, zinc stearate, stearic acid, silicas, hydrogenated vegetable oils, or talc). Other pharmaceutically acceptable excipients can be colorants, flavoring agents, plasticizers, humectants, buffering agents, and the like." 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**, such as a metallic plastic laminate, and a rate-controlling polymeric membrane such as a microporous or a non-porous polymeric membrane (e.g., ethylene-vinyl acetate copolymer). The lysergic acid

	diethylamide, or a pharmaceutically acceptable salt thereof, is only released through the rate-controlling polymeric membrane. 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. On the external surface of the polymeric membrane, a thin layer of an adhesive polymer is applied to achieve an intimate contact of the transdermal system with the skin surface. The adhesive polymer is preferably a hypoallergenic polymer that is compatible with the drug." 2. U.S. Pat. App. Pub. No. 2021/0137908 "5-HT2A Agonists for Use in Treatment of Depression" (Published May 13, 2021) 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). In case of combination therapy the other therapeutically active ingredients may be administered in separate dosage forms or as a single dosage form comprising one or more compounds according to the invention in combination with one or more other therapeutically active ingredients. In particular, due to the slow on-set of e.g. SSRI as described above, it might be beneficial in some instances to initiate the treatment with one or more compounds according to the invention together with or followed by e.g. a SSRI to avoid any delay in anti-depressant effect." 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"
2. The composition of claim 1, further including a non-gelling matrix former chosen from the group consisting of non-gelling gelatin, maltodextrin, modified starches, starch ethers, low molecular weight dextrans, and low to intermediate molecular weight cellulose gums.	1. U.S. Pat. App. Pub. No. 2020/0085816 "LSD for the Treatment of Alzheimer's Disease" (Published March 19, 2020) 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**, such as a metallic plastic laminate, and a rate-controlling polymeric membrane such as a microporous or a non-porous polymeric membrane (e.g., ethylene-vinyl acetate copolymer). The lysergic acid diethylamide, or a pharmaceutically acceptable salt thereof, is only released through the rate-controlling polymeric membrane. 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. On the external surface of the polymeric membrane, a thin layer of an adhesive polymer is applied to achieve an intimate contact of the transdermal system with the skin surface. The adhesive polymer is preferably a hypoallergenic polymer that is compatible with the drug." 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. For example, the lysergic acid diethylamide, or a pharmaceutically acceptable salt thereof, can be formulated as a lozenge, drop, or film placed under the tongue for sublingual administration of a rapidly acting dosage form." 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**, calcium carbonate, sodium chloride, lactose, calcium phosphate, calcium sulfate, or sodium phosphate); granulating and disintegrating agents

	(e.g., **cellulose** derivatives including microcrystalline **cellulose**, **starches including potato starch**, croscarmellose sodium, alginates, or alginic acid); binding agents (e.g., sucrose, glucose, sorbitol, acacia, alginic acid, sodium alginate, **gelatin, starch, pregelatinized starch**, microcrystalline **cellulose**, magnesium aluminum silicate, carboxymethylcellulose sodium, methylcellulose, hydroxypropyl methylcellulose, ethylcellulose, polyvinylpyrrolidone, or polyethylene glycol); and lubricating agents, glidants, and antiadhesives (e.g., magnesium stearate, zinc stearate, stearic acid, silicas, hydrogenated vegetable oils, or talc). Other pharmaceutically acceptable excipients can be colorants, flavoring agents, plasticizers, humectants, buffering agents, and the like." From **[0055]** "Materials for use in the preparation of microspheres and/or microcapsules are, e.g., biodegradable/bioerodible polymers such as polygalactin, poly-(isobutyl cyanoacrylate), poly(2-hydroxyethyl-L-glutamnine) and, poly(lactic acid). Biocompatible carriers that may be used when formulating a controlled release parenteral formulation are carbohydrates (e.g., **dextrans**), proteins (e.g., albumin), lipoproteins, or antibodies. Materials for use in implants can be non-biodegradable (e.g., polydimethyl siloxane) or biodegradable (e.g., poly(caprolactone), poly(lactic acid), poly(glycolic acid) or poly(ortho esters))." 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)...etc" 4. U.S. Pat. App. Pub. No. 2021/0015738 "Oral Dissolvable Film Containing Psychedelic Compound" (Published January 21, 2021) 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." 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." 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)."
3. The composition of claim 1, further including a filler chosen from the group consisting of lactose, mannitol, dicalcium phosphate, calcium sulfate, starch, cellulose, kaolin, sodium chloride, sorbitol, trehalose, and sucrose.	1. U.S. Pat. App. Pub. No. 2020/0085816 "LSD for the Treatment of Alzheimer's Disease" (Published March 19, 2020) 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, calcium carbonate, **sodium chloride**, **lactose, calcium phosphate, calcium sulfate,** or sodium phosphate); granulating and disintegrating agents (e.g., **cellulose derivatives including microcrystalline**

	cellulose, **starches including potato starch**, croscarmellose sodium, alginates, or alginic acid); binding agents (e.g., **sucrose**, glucose, **sorbitol**, acacia, alginic acid, sodium alginate, gelatin, starch, pregelatinized starch, microcrystalline cellulose, magnesium aluminum silicate, carboxymethylcellulose sodium, methylcellulose, hydroxypropyl methylcellulose, ethylcellulose, polyvinylpyrrolidone, or polyethylene glycol); and lubricating agents, glidants, and antiadhesives (e.g., magnesium stearate, zinc stearate, stearic acid, silicas, hydrogenated vegetable oils, or talc). Other pharmaceutically acceptable excipients can be colorants, flavoring agents, plasticizers, humectants, buffering agents, and the like." From **[0046]** "Formulations for oral use may also be presented as chewable tablets, or as hard gelatin capsules wherein the lysergic acid diethylamide, or a pharmaceutically acceptable salt thereof, is mixed with an inert solid diluent (e.g., potato starch, lactose, microcrystalline cellulose, calcium carbonate, calcium phosphate or **kaolin**), or as soft gelatin capsules wherein the lysergic acid diethylamide, or a pharmaceutically acceptable salt thereof, is mixed with water or an oil medium, for example, peanut oil, liquid paraffin, or olive oil. Powders and granulates may be prepared using the ingredients mentioned above under tablets and capsules in a conventional manner using, e.g., a mixer, a fluid bed apparatus or a spray drying equipment."
4. The composition of claim 1, further including a binder chosen from the group consisting of acacia gum, methylcellulose, hydroxypropyl methylcellulose, hydroxypropyl cellulose, tragacanth, polyvinyl pyrrolidone (PVP), and starch.	1. U.S. Pat. App. Pub. No. 2020/0085816 "LSD for the Treatment of Alzheimer's Disease" (Published March 19, 2020) 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**, calcium carbonate, sodium chloride, lactose, calcium phosphate, calcium sulfate, or sodium phosphate); granulating and disintegrating agents (e.g., cellulose derivatives including microcrystalline cellulose, **starches including potato starch**, croscarmellose sodium, alginates, or alginic acid); binding agents (e.g., sucrose, glucose, sorbitol, **acacia**, alginic acid, sodium alginate, gelatin, starch, pregelatinized starch, microcrystalline cellulose, magnesium aluminum silicate, **carboxymethylcellulose sodium, methylcellulose, hydroxypropyl methylcellulose**, ethylcellulose, polyvinylpyrrolidone, or polyethylene glycol); and lubricating

	agents, glidants, and antiadhesives (e.g., magnesium stearate, zinc stearate, stearic acid, silicas, hydrogenated vegetable oils, or talc). Other pharmaceutically acceptable excipients can be colorants, flavoring agents, plasticizers, humectants, buffering agents, and the like." 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)...etc" 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**. Talc extra fine is dispersed into the solution to form a uniform suspension, which is then coated onto sugar spheres of 600-710 μm using a fluid bed coater. In a separate container, a functional coating suspension is prepared by mixing Ethocel 45 cps (ethylcellulose; a release control polymer) in acetone and ethanol 96% mixture with polyethylene glycol (PEG) 4000 dissolved in distilled water to the form a coating mixture. The coating mixture is then coated onto the LSD-loaded pellets using a fluid bed coater."
5. The composition of claim 1, further including a buffer chosen from the group consisting of citrate, phosphate, and acetate.	1. U.S. Pat. App. Pub. No. 2020/0085816 "LSD for the Treatment of Alzheimer's Disease" (Published March 19, 2020) 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, calcium carbonate, sodium chloride, lactose, **calcium phosphate**, calcium sulfate, or **sodium phosphate**); granulating and disintegrating agents (e.g., cellulose derivatives including microcrystalline cellulose, starches including potato starch, croscarmellose sodium, alginates, or alginic acid); binding agents (e.g., sucrose, glucose, sorbitol, acacia, alginic acid, sodium alginate, gelatin, starch, pregelatinized starch, microcrystalline cellulose, magnesium aluminum silicate, carboxymethylcellulose sodium, methylcellulose, hydroxypropyl methylcellulose, ethylcellulose, polyvinylpyrrolidone, or polyethylene glycol); and lubricating agents, glidants, and antiadhesives (e.g., magnesium stearate, zinc stearate, stearic acid, silicas, hydrogenated vegetable oils, or talc). Other pharmaceutically acceptable excipients can be

	colorants, flavoring agents, plasticizers, humectants, buffering agents, and the like." From **[0044]** "The tablets may be uncoated or they may be coated by known techniques, optionally to delay disintegration and absorption in the gastrointestinal tract and thereby providing a sustained action over a longer period. The coating may be adapted to release the lysergic acid diethylamide, or a pharmaceutically acceptable salt thereof, in a predetermined pattern (e.g., in order to achieve a controlled release formulation) or it may be adapted not to release the lysergic acid diethylamide, or a pharmaceutically acceptable salt thereof, until after passage of the stomach (enteric coating). The coating may be a sugar coating, a film coating (e.g., based on hydroxypropyl methylcellulose, methylcellulose, methyl hydroxyethylcellulose, hydroxypropylcellulose, carboxymethylcellulose, acrylate copolymers, polyethylene glycols and/or polyvinylpyrrolidone), or an enteric coating (e.g., based on methacrylic acid copolymer, **cellulose acetate phthalate**, hydroxypropyl methylcellulose phthalate, **hydroxypropyl methylcellulose acetate succinate, polyvinyl acetate phthalate**, shellac, and/or ethylcellulose). Furthermore, a time delay material such as, e.g., glyceryl monostearate or glyceryl distearate may be employed." 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 preservatives are parabens, such as methyl or propyl p-hydroxybenzoate, and benzalkonium chloride. Examples of humectants are glycerin, propylene glycol, sorbitol, and urea. Examples of penetration enhancers are propylene glycol, DMSO, triethanolamine, N,N-dimethylacetamide, N,N-dimethylformamide, 2-pyrrolidone and derivatives thereof, tetrahydrofurfuryl alcohol, and AZONE™. Examples of chelating agents are sodium EDTA, **citric acid**, and phosphoric acid. Examples of gel forming agents are CARBOPOL™, cellulose derivatives, bentonite, alginates, gelatin and polyvinylpyrrolidone. Examples of ointment bases are beeswax, paraffin, cetyl palmitate, vegetable oils, sorbitan esters of fatty acids (Span), polyethylene glycols, and condensation products between sorbitan esters of fatty acids and ethylene oxide (e.g., polyoxyethylene sorbitan monooleate (TWEEN™))."

6. The composition of claim 1, further including an antioxidant chosen from the group consisting of ascorbic acid, butylated hydroxy anisole (BHA), and butylated hydroxyl toluene (BHT).	1. U.S. Pat. App. Pub. No. 2020/0085816 "LSD for the Treatment of Alzheimer's Disease" (Published March 19, 2020) 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 preservatives are parabens, such as methyl or propyl p-hydroxybenzoate, and benzalkonium chloride. Examples of humectants are glycerin, propylene glycol, sorbitol, and urea. Examples of penetration enhancers are propylene glycol, DMSO, triethanolamine, N,N-dimethylacetamide, N,N-dimethylformamide, 2-pyrrolidone and derivatives thereof, tetrahydrofurfuryl alcohol, and AZONE™. Examples of chelating agents are sodium EDTA, citric acid, and phosphoric acid. Examples of gel forming agents are CARBOPOL™, cellulose derivatives, bentonite, alginates, gelatin and polyvinylpyrrolidone. Examples of ointment bases are beeswax, paraffin, cetyl palmitate, vegetable oils, sorbitan esters of fatty acids (Span), polyethylene glycols, and condensation products between sorbitan esters of fatty acids and ethylene oxide (e.g., polyoxyethylene sorbitan monooleate (TWEEN™))."
7. The composition of claim 1, further including a photostabilization agent, a permeation enhancer chosen from the group consisting of sulphoxides, azones, pyrrolidones, alcohols, alkanols, glycols, surfactants, and terpenes, and coloring agents, sweeteners, and flavoring agents.	1. U.S. Pat. App. Pub. No. 2020/0085816 "LSD for the Treatment of Alzheimer's Disease" (Published March 19, 2020) From **[0052]** "Compositions for parenteral use may be provided in unit dosage forms (e.g., in single-dose ampoules), or in vials containing several doses and in which a suitable preservative may be added (see below). The composition may be in form of a solution, a suspension, an emulsion, an infusion device, or a delivery device for implantation, or it may be presented as a dry powder to be reconstituted with water or another suitable vehicle before use. Apart from the lysergic acid diethylamide, or a pharmaceutically acceptable salt thereof, the composition may include suitable parenterally acceptable carriers and/or excipients. The lysergic acid diethylamide, or a pharmaceutically acceptable salt thereof, may be incorporated into microspheres, microcapsules, nanoparticles, liposomes, or the like for controlled release. **Furthermore, the composition may include** suspending, solubilizing, **stabilizing**, pH-adjusting agents, and/or dispersing agents."

	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 preservatives are parabens, such as methyl or propyl p-hydroxybenzoate, and benzalkonium chloride. Examples of humectants are glycerin, **propylene glycol**, sorbitol, and urea. Examples of penetration enhancers are **propylene glycol**, **DMSO**, triethanolamine, N,N-dimethylacetamide, N,N-dimethylformamide, 2-pyrrolidone and derivatives thereof, tetrahydrofurfuryl alcohol, and AZONE™. Examples of chelating agents are sodium EDTA, citric acid, and phosphoric acid. Examples of gel forming agents are CARBOPOL™, cellulose derivatives, bentonite, alginates, gelatin and polyvinylpyrrolidone. Examples of ointment bases are beeswax, paraffin, cetyl palmitate, vegetable oils, sorbitan esters of fatty acids (Span), polyethylene glycols, and condensation products between sorbitan esters of fatty acids and ethylene oxide (e.g., polyoxyethylene sorbitan monooleate (TWEEN™))." 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, calcium carbonate, sodium chloride, lactose, calcium phosphate, calcium sulfate, or sodium phosphate); granulating and disintegrating agents (e.g., cellulose derivatives including microcrystalline cellulose, starches including potato starch, croscarmellose sodium, alginates, or alginic acid); binding agents (e.g., sucrose, glucose, sorbitol, acacia, alginic acid, sodium alginate, gelatin, starch, pregelatinized starch, microcrystalline cellulose, magnesium aluminum silicate, carboxymethylcellulose sodium, methylcellulose, hydroxypropyl methylcellulose, ethylcellulose, polyvinylpyrrolidone, or polyethylene glycol); and lubricating agents, glidants, and antiadhesives (e.g., magnesium stearate, zinc stearate, stearic acid, silicas, hydrogenated vegetable oils, or talc). **Other pharmaceutically acceptable excipients can be colorants, flavoring agents**, plasticizers, humectants, buffering agents, and the like." From **[0044]** "The tablets may be uncoated or they may be coated by known techniques, optionally to delay disintegration and absorption in the gastrointestinal tract and thereby

	providing a sustained action over a longer period. The coating may be adapted to release the lysergic acid diethylamide, or a pharmaceutically acceptable salt thereof, in a predetermined pattern (e.g., in order to achieve a controlled release formulation) or it may be adapted not to release the lysergic acid diethylamide, or a pharmaceutically acceptable salt thereof, until after passage of the stomach (enteric coating). **The coating may be a sugar coating,** a film coating (e.g., based on hydroxypropyl methylcellulose, methylcellulose, methyl hydroxyethylcellulose, hydroxypropylcellulose, carboxymethylcellulose, acrylate copolymers, polyethylene glycols and/or polyvinylpyrrolidone), or an enteric coating (e.g., based on methacrylic acid copolymer, cellulose acetate phthalate, hydroxypropyl methylcellulose phthalate, hydroxypropyl methylcellulose acetate succinate, polyvinyl acetate phthalate, shellac, and/or ethylcellulose). Furthermore, a time delay material such as, e.g., glyceryl monostearate or glyceryl distearate may be employed." 5. U.S. Pat. App. Pub. No. 2020/0101041 "Methods and Compositions for Enhancing Health" (Published April 02, 2020) 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." 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." 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." 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." 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."
8. A method of making a solid oral immediate release formulation of LSD, including the steps of: lyophilizing a flash frozen stock solution of LSD and excipients of a non-gelling matrix former, filler, binder, and buffer in a pre-formed mold; and forming an orally disintegrating tablet.	1. U.S. Pat. App. Pub. No. 2020/0085816 "LSD for the Treatment of Alzheimer's Disease" (Published March 19, 2020) 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. For example, the lysergic acid diethylamide, or a pharmaceutically acceptable salt thereof, can be formulated as a lozenge, drop, or film placed under the tongue for sublingual administration of a rapidly acting dosage form." 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, calcium carbonate, sodium chloride, lactose, calcium phosphate, calcium sulfate, or sodium phosphate); granulating and **disintegrating agents** (e.g., cellulose derivatives including microcrystalline cellulose, starches including potato starch, croscarmellose sodium, alginates, or alginic acid); **binding agents** (e.g., sucrose, glucose, sorbitol, acacia, alginic acid, sodium alginate, gelatin, starch, pregelatinized starch, microcrystalline cellulose, magnesium aluminum silicate, carboxymethylcellulose sodium, methylcellulose, hydroxypropyl methylcellulose, ethylcellulose, polyvinylpyrrolidone, or polyethylene glycol); and lubricating agents, glidants, and antiadhesives (e.g., magnesium stearate, zinc stearate, stearic acid, silicas, hydrogenated vegetable oils, or talc). **Other pharmaceutically acceptable excipients** can be colorants, flavoring agents, plasticizers, humectants, **buffering agents**, and the like." 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**, such as a metallic plastic laminate, and a rate-controlling polymeric membrane such as a microporous or a non-porous polymeric membrane (e.g., ethylene-vinyl acetate copolymer). The lysergic acid diethylamide, or a pharmaceutically acceptable salt thereof, is only released through the rate-controlling polymeric membrane. **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. On the external surface of the polymeric membrane, a thin layer of an adhesive polymer is applied to achieve an intimate contact of the transdermal system with the skin surface. The adhesive polymer is preferably a hypoallergenic polymer that is compatible with the drug." 2. U.S. Pat. App. Pub. No. 2021/0137908 "5-HT2A Agonists for Use in Treatment of Depression" (Published May 13, 2021) 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). In case of combination therapy the other therapeutically active ingredients may be administered in separate dosage forms or as a single dosage form comprising one or more compounds according to the invention in combination with one or more other therapeutically active ingredients. In particular, due to the slow on-set of e.g. SSRI as described above, it might be beneficial in some instances to initiate the treatment with one or more compounds according to the invention together with or followed by e.g. a SSRI to avoid any delay in anti-depressant effect."
9. The method of claim 8, wherein the non-gelling matrix former is chosen from the group consisting of non-gelling gelatin, maltodextrin, modified starches, starch ethers, low molecular weight dextrans, and low to intermediate molecular weight cellulose gums.	1. U.S. Pat. App. Pub. No. 2020/0085816 "LSD for the Treatment of Alzheimer's Disease" (Published March 19, 2020) 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, such as a metallic plastic laminate, and a rate-controlling polymeric membrane such as a microporous or a non-porous polymeric membrane (e.g., ethylene-vinyl acetate copolymer). The lysergic acid diethylamide, or a pharmaceutically acceptable salt thereof, is only released through the rate-controlling polymeric membrane. 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. On the external surface of the polymeric membrane, a thin layer of an adhesive polymer is applied to achieve an intimate contact of the transdermal system with the skin surface. The adhesive polymer is preferably a hypoallergenic polymer that is compatible with the drug." 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**, calcium carbonate, sodium chloride, lactose, calcium phosphate, calcium sulfate, or sodium phosphate); granulating and disintegrating agents (e.g., **cellulose** derivatives including microcrystalline **cellulose**, **starches including potato starch**, croscarmellose sodium, alginates, or alginic acid); binding agents (e.g., sucrose, glucose, sorbitol, acacia, alginic acid, sodium

	alginate, **gelatin, starch, pregelatinized starch**, microcrystalline **cellulose**, magnesium aluminum silicate, carboxymethylcellulose sodium, methylcellulose, hydroxypropyl methylcellulose, ethylcellulose, polyvinylpyrrolidone, or polyethylene glycol); and lubricating agents, glidants, and antiadhesives (e.g., magnesium stearate, zinc stearate, stearic acid, silicas, hydrogenated vegetable oils, or talc). Other pharmaceutically acceptable excipients can be colorants, flavoring agents, plasticizers, humectants, buffering agents, and the like." From **[0055]** "Materials for use in the preparation of microspheres and/or microcapsules are, e.g., biodegradable/bioerodible polymers such as polygalactin, poly-(isobutyl cyanoacrylate), poly(2-hydroxyethyl-L-glutamnine) and, poly(lactic acid). Biocompatible carriers that may be used when formulating a controlled release parenteral formulation are carbohydrates (e.g., **dextrans**), proteins (e.g., albumin), lipoproteins, or antibodies. Materials for use in implants can be non-biodegradable (e.g., polydimethyl siloxane) or biodegradable (e.g., poly(caprolactone), poly(lactic acid), poly(glycolic acid) or poly(ortho esters))." 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)...etc" From **[0064]** "D-lysergic acid diethylamide tartrate is mixed with pharmaceutically suitable diluents (e.g., talc, silica, lactose) and placed into **gelatin** capsules. Formulated for immediate release, LSD's effects can typically last from 6-12 hours depending on dosage, tolerance, body weight and age. Immediate release LSD dosed at 1 μg/kg can have an apparent plasma half-life of 5.1 hours, with a peak plasma concentration of 5 ng/mL at 3 hours post-dose."
10. The method of claim 8, wherein the filler is chosen from the group consisting of lactose, mannitol, dicalcium phosphate, calcium sulfate, starch, cellulose, kaolin, sodium chloride, sorbitol, trehalose, and sucrose.	1. U.S. Pat. App. Pub. No. 2020/0085816 "LSD for the Treatment of Alzheimer's Disease" (Published March 19, 2020) 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, calcium carbonate, **sodium chloride**, **lactose, calcium phosphate, calcium sulfate,** or sodium phosphate); granulating and disintegrating agents (e.g., **cellulose derivatives including microcrystalline**

	cellulose, **starches including potato starch**, croscarmellose sodium, alginates, or alginic acid); binding agents (e.g., **sucrose**, glucose, **sorbitol**, acacia, alginic acid, sodium alginate, gelatin, starch, pregelatinized starch, microcrystalline cellulose, magnesium aluminum silicate, carboxymethylcellulose sodium, methylcellulose, hydroxypropyl methylcellulose, ethylcellulose, polyvinylpyrrolidone, or polyethylene glycol); and lubricating agents, glidants, and antiadhesives (e.g., magnesium stearate, zinc stearate, stearic acid, silicas, hydrogenated vegetable oils, or talc). Other pharmaceutically acceptable excipients can be colorants, flavoring agents, plasticizers, humectants, buffering agents, and the like." From **[0046]** "Formulations for oral use may also be presented as chewable tablets, or as hard gelatin capsules wherein the lysergic acid diethylamide, or a pharmaceutically acceptable salt thereof, is mixed with an inert solid diluent (e.g., potato starch, lactose, microcrystalline cellulose, calcium carbonate, calcium phosphate or **kaolin**), or as soft gelatin capsules wherein the lysergic acid diethylamide, or a pharmaceutically acceptable salt thereof, is mixed with water or an oil medium, for example, peanut oil, liquid paraffin, or olive oil. Powders and granulates may be prepared using the ingredients mentioned above under tablets and capsules in a conventional manner using, e.g., a mixer, a fluid bed apparatus or a spray drying equipment."
11. The method of claim 8, wherein the binder is chosen from the group consisting of acacia gum, methylcellulose, hydroxypropyl methylcellulose, hydroxypropyl cellulose, tragacanth, polyvinyl pyrrolidone (PVP), and starch.	1. U.S. Pat. App. Pub. No. 2020/0085816 "LSD for the Treatment of Alzheimer's Disease" (Published March 19, 2020) 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**, calcium carbonate, sodium chloride, lactose, calcium phosphate, calcium sulfate, or sodium phosphate); granulating and disintegrating agents (e.g., cellulose derivatives including microcrystalline cellulose, **starches including potato starch**, croscarmellose sodium, alginates, or alginic acid); binding agents (e.g., sucrose, glucose, sorbitol, **acacia**, alginic acid, sodium alginate, gelatin, starch, pregelatinized starch, microcrystalline cellulose, magnesium aluminum silicate, **carboxymethylcellulose sodium, methylcellulose, hydroxypropyl methylcellulose**, ethylcellulose, polyvinylpyrrolidone, or polyethylene glycol); and lubricating agents, glidants, and antiadhesives (e.g., magnesium stearate,

	zinc stearate, stearic acid, silicas, hydrogenated vegetable oils, or talc). Other pharmaceutically acceptable excipients can be colorants, flavoring agents, plasticizers, humectants, buffering agents, and the like." 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)...etc" 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**. Talc extra fine is dispersed into the solution to form a uniform suspension, which is then coated onto sugar spheres of 600-710 μm using a fluid bed coater. In a separate container, a functional coating suspension is prepared by mixing Ethocel 45 cps (ethylcellulose; a release control polymer) in acetone and ethanol 96% mixture with polyethylene glycol (PEG) 4000 dissolved in distilled water to the form a coating mixture. The coating mixture is then coated onto the LSD-loaded pellets using a fluid bed coater."
12. The method of claim 8, wherein the buffer is chosen from the group consisting of citrate, phosphate, and acetate.	1. U.S. Pat. App. Pub. No. 2020/0085816 "LSD for the Treatment of Alzheimer's Disease" (Published March 19, 2020) 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, calcium carbonate, sodium chloride, lactose, **calcium phosphate**, calcium sulfate, or **sodium phosphate**); granulating and disintegrating agents (e.g., cellulose derivatives including microcrystalline cellulose, starches including potato starch, croscarmellose sodium, alginates, or alginic acid); binding agents (e.g., sucrose, glucose, sorbitol, acacia, alginic acid, sodium alginate, gelatin, starch, pregelatinized starch, microcrystalline cellulose, magnesium aluminum silicate, carboxymethylcellulose sodium, methylcellulose, hydroxypropyl methylcellulose, ethylcellulose, polyvinylpyrrolidone, or polyethylene glycol); and lubricating agents, glidants, and antiadhesives (e.g., magnesium stearate, zinc stearate, stearic acid, silicas, hydrogenated vegetable oils, or talc). Other pharmaceutically acceptable excipients can be colorants, flavoring agents, plasticizers, humectants, buffering agents, and the like."

	From **[0044]** "The tablets may be uncoated or they may be coated by known techniques, optionally to delay disintegration and absorption in the gastrointestinal tract and thereby providing a sustained action over a longer period. The coating may be adapted to release the lysergic acid diethylamide, or a pharmaceutically acceptable salt thereof, in a predetermined pattern (e.g., in order to achieve a controlled release formulation) or it may be adapted not to release the lysergic acid diethylamide, or a pharmaceutically acceptable salt thereof, until after passage of the stomach (enteric coating). The coating may be a sugar coating, a film coating (e.g., based on hydroxypropyl methylcellulose, methylcellulose, methyl hydroxyethylcellulose, hydroxypropylcellulose, carboxymethylcellulose, acrylate copolymers, polyethylene glycols and/or polyvinylpyrrolidone), or an enteric coating (e.g., based on methacrylic acid copolymer, **cellulose acetate phthalate**, hydroxypropyl methylcellulose phthalate, **hydroxypropyl methylcellulose acetate succinate, polyvinyl acetate phthalate**, shellac, and/or ethylcellulose). Furthermore, a time delay material such as, e.g., glyceryl monostearate or glyceryl distearate may be employed." 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 preservatives are parabens, such as methyl or propyl p-hydroxybenzoate, and benzalkonium chloride. Examples of humectants are glycerin, propylene glycol, sorbitol, and urea. Examples of penetration enhancers are propylene glycol, DMSO, triethanolamine, N,N-dimethylacetamide, N,N-dimethylformamide, 2-pyrrolidone and derivatives thereof, tetrahydrofurfuryl alcohol, and AZONE™. Examples of chelating agents are sodium EDTA, **citric acid**, and phosphoric acid. Examples of gel forming agents are CARBOPOL™, cellulose derivatives, bentonite, alginates, gelatin and polyvinylpyrrolidone. Examples of ointment bases are beeswax, paraffin, cetyl palmitate, vegetable oils, sorbitan esters of fatty acids (Span), polyethylene glycols, and condensation products between sorbitan esters of fatty acids and ethylene oxide (e.g., polyoxyethylene sorbitan monooleate (TWEEN™))."
13. The method of claim 8, wherein the LSD is in a form chosen from free base and salt.	3. U.S. Pat. App. Pub. No. 2018/0228797 "Pharmaceutical Composition" (Published August 16, 2018) 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." 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." 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."
14. The method of claim 8, wherein the LSD is in a salt form and the salt is chosen from the group consisting of hydrochloride, hydrobromide, maleate, tartrate, citrate, phosphate, fumarate, sulfate, mesylate, acetate, and oxalate.	3. U.S. Pat. App. Pub. No. 2018/0228797 "Pharmaceutical Composition" (Published August 16, 2018) 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." 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." From **[0125]** "**In some instances, a pharmaceutically acceptable salt includes** bitartrate, bitartrate hydrate, hydrochloride, p-toluenesulfonate, phosphate, sulfate, trifluoroacetate, bitartrato hemipentahydrate, pentafluoropropionate, hydrobromide, 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-2,2-disulfonate), 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."
15. A method of treating an individual, including the steps of: administering a solid oral immediate release formulation of LSD of an	1. U.S. Pat. App. Pub. No. 2020/0085816 "LSD for the Treatment of Alzheimer's Disease" (Published March 19, 2020)

orally disintegrating tablet, wherein the composition is produced by lyophilization of a feedstock in a pre-formed mold to form the orally disintegrating tablet; and treating the individual.	From **[0001]** "This invention relates to the use of **LSD for the treatment of Alzheimer's disease.**" 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. For example, the lysergic acid diethylamide, or a pharmaceutically acceptable salt thereof, can be formulated as a lozenge, drop, or film placed under the tongue for sublingual administration of a rapidly acting dosage form." 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, calcium carbonate, sodium chloride, lactose, calcium phosphate, calcium sulfate, or sodium phosphate); granulating and disintegrating agents (e.g., cellulose derivatives including microcrystalline cellulose, starches including potato starch, croscarmellose sodium, alginates, or alginic acid); binding agents (e.g., sucrose, glucose, sorbitol, acacia, alginic acid, sodium alginate, gelatin, starch, pregelatinized starch, microcrystalline cellulose, magnesium aluminum silicate, carboxymethylcellulose sodium, methylcellulose, hydroxypropyl methylcellulose, ethylcellulose, polyvinylpyrrolidone, or polyethylene glycol); and lubricating agents, glidants, and antiadhesives (e.g., magnesium stearate, zinc stearate, stearic acid, silicas, hydrogenated vegetable oils, or talc). Other pharmaceutically acceptable excipients can be colorants, flavoring agents, plasticizers, humectants, buffering agents, and the like." 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**, such as a metallic plastic laminate, and a rate-controlling polymeric membrane such as a microporous or a non-porous polymeric membrane (e.g., ethylene-vinyl acetate copolymer). The lysergic acid diethylamide, or a pharmaceutically acceptable salt thereof, is only released through the rate-controlling polymeric membrane. 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. On the external surface of the polymeric membrane, a thin layer of an adhesive polymer is applied to achieve an intimate contact of the transdermal system with the skin surface. The adhesive polymer is preferably a hypoallergenic polymer that is compatible with the drug."
16. The method of claim 15, wherein the individual has trouble swallowing, is elderly, or has dementia.	1. U.S. Pat. App. Pub. No. 2020/0085816 "LSD for the Treatment of Alzheimer's Disease" (Published March 19, 2020) From **[0001]** "This invention relates to the use of **LSD for the treatment of Alzheimer's disease.**" From **claim 47** "The method claim 43, wherein the subject has Alzheimer's disease with comorbid **dementia.**" From **[0003]** "**The onset of Alzheimer's disease typically occurs after the age of 62 years**. As the world population and human longevity increase, so do the numbers of people affected by Alzheimer's disease globally. The estimated worldwide costs of dementia, of which Alzheimer's disease accounts for up to 80% of cases, was US$604 billion in 2010, which was greater than 1% of US GDP (VVimo and Prince 2010 World Alzheimer Report 2010: The Global Economic Impact of Dementia 1-93). The cost of caring for Alzheimer patients in the US is expected to increase from US$172 million in 2010, to US$1.07 trillion in 2050 (Alzheimer's Association. "Changing the Trajectory of Alzheimer's Disease: A National Imperative (2010)")." 6. NHS, "Swallowing Difficulties in Dementia" March 17, 2016; retrieved from NHS Hull University Teaching Hospitals NHS Trust. https://www.hey.nhs.uk/patient-leaflet/swallowing-difficulties-in-dementia/, retrieved March 17, 2016 From **webpage** "**Dysphagia is a swallowing difficulty. It is very common for individuals with dementia to have difficulties with feeding, eating, drinking and swallowing**"
17. The method of claim 15, wherein said treating step is further defined as treating a condition or disease chosen from the group consisting of anxiety disorders, depression, headache disorder, obsessive compulsive disorder (OCD), personality disorders, stress disorders, drug	1. U.S. Pat. App. Pub. No. 2020/0085816 "LSD for the Treatment of Alzheimer's Disease" (Published March 19, 2020) From **[0013]** "By "reducing the severity of an AD-associated neuropsychiatric condition" is meant to reduce one or more symptoms of an AD-associated neuropsychiatric condition, such as **depression, anxiety**, apathy, agitation, irritability, or

disorders, gambling disorder, eating disorders, body dysmorphic disorder, pain, neurodegenerative disorders, autism spectrum disorder, and neurological disorders.	aggression in comparison to the performance of the subject prior to receiving the treatment. The symptoms of the AD-associated neuropsychiatric condition can be evaluated using any of a variety of tests known in the art." From **[0002]** "**Alzheimer's disease (hereinafter "Alzheimer's disease" or "AD") is a neurodegenerative disease** and the most common cause of dementia. This disease manifests as a gradual but progressive decline in memory, thinking skills and behavior that is accelerated relative to normal aging (Reitz et al. 2011 Nat Rev Neurol 7: 137-152). Eventually, patients are unable to recognize familiar people or carry out the simplest task. Alzheimer's disease is, at this time, among the leading causes of death in the United States (US). There are two predominant forms of the disease: Familial Alzheimer's disease is typically caused by dominant genetic mutations. This form of the disease is a rare and devastating illness with onset occurring in mid-life. The second and far more common form of the disease is Sporadic or Late onset Alzheimer's disease." 2. U.S. Pat. App. Pub. No. 2021/0137908 "5-HT2A Agonists for Use in Treatment of Depression" (Published May 13, 2021) 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). Most classical psychedelic drugs fall into one of three families: the tryptamines, phenethylamines or ergolines. Although ergolines constitute their own group, they are in fact both tryptamines and phenethylamines."

	From **[0344]** "**The compounds according to the present invention may be used alone (i.e. in mono-therapy) or in combination w**ith 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). In case of combination therapy the other therapeutically active ingredients may be administered in separate dosage forms or as a single dosage form comprising one or more compounds according to the invention in combination with one or more other therapeutically active ingredients. In particular, due to the slow on-set of e.g. SSRI as described above, it might be beneficial in some instances to initiate the treatment with one or more compounds according to the invention together with or followed by e.g. a SSRI to avoid any delay in anti-depressant effect." 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."**

	5. U.S. Pat. App. Pub. No. 2020/0101041 "Methods and Compositions for Enhancing Health" (Published April 02, 2020) 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."
18. The method of claim 15, wherein the LSD is in a form chosen from free base and salt.	3. U.S. Pat. App. Pub. No. 2018/0228797 "Pharmaceutical Composition" (Published August 16, 2018) 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." 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." 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."
19. The method of claim 15, wherein the LSD is in a salt form and the salt is chosen from the group consisting of hydrochloride, hydrobromide, maleate, tartrate, citrate, phosphate, fumarate, sulfate, mesylate, acetate, and oxalate.	3. U.S. Pat. App. Pub. No. 2018/0228797 "Pharmaceutical Composition" (Published August 16, 2018) 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." 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." From **[0125]** "**In some instances, a pharmaceutically acceptable salt includes** bitartrate, bitartrate hydrate, hydrochloride, p-toluenesulfonate, phosphate, sulfate, trifluoroacetate, bitartrato hemipentahydrate, pentafluoropropionate, hydrobromide, 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-2,2-disulfonate), 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."
20. The method of claim 15, wherein said administering step is further defined as administering 0.01-1 mg of LSD.	1. U.S. Pat. App. Pub. No. 2020/0085816 "LSD for the Treatment of Alzheimer's Disease" (Published March 19, 2020) From **[0064]** "D-lysergic acid diethylamide tartrate is mixed with pharmaceutically suitable diluents (e.g., talc, silica, lactose) and placed into gelatin capsules. Formulated for immediate release, LSD's effects can typically last from 6-12 hours depending on dosage, tolerance, body weight and age. **Immediate release LSD dosed at 1 µg/kg** can have an apparent plasma half-life of 5.1 hours, with a peak plasma concentration of 5 ng/mL at 3 hours post-dose." From **[0065]** "Capsules containing **5 µg, 10 µg, 15 µg, and 20 µg D-lysergic acid diethylamide** tartrate can be useful in the methods of the invention." 4. U.S. Pat. App. Pub. No. 2021/0015738 "Oral Dissolvable Film Containing Psychedelic Compound" (Published January 21, 2021) 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."

	From **[0091]** "In specific embodiments, the psychedelic compound is present in up to **1 mg."** From **[0092]** "In specific embodiments, the psychedelic compound is present in up to **0.5 mg."** From **[0093]** "In specific embodiments, the psychedelic compound is present in up to **0.25 mg."** From **[0094]** "In specific embodiments, the psychedelic compound is present in **1-200 mg."** From **[0100]** "In specific embodiments, the psychedelic compound is present in **0.01-5 mg."** From **[0101]** "In specific embodiments, the psychedelic compound is present in **0.01-2.5 mg."** From **[0102]** "In specific embodiments, the psychedelic compound is present in **0.01-1 mg."** From **[0103]** "In specific embodiments, the psychedelic compound is present in **0.01-0.5 mg."** From **[0104]** "In specific embodiments, the psychedelic compound is present in **0.01-0.25 mg."**

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First Named Inventor/Applicant Name:	Peter MACK
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10	Concise Description of Relevance	Claims_Chart.pdf	359477 789088e8d3277d70a46d02da9876bc26cd359815	no	29
Warnings:					
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11	Fee Worksheet (SB06)	fee-info.pdf	37414 6a59ae314ec28998e6cc9fd032cca0ae7d32d831	no	2
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