

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of: Pike Therapeutics Inc Confirmation No.:

Serial No.: 17/879,846 Group No.:

Filing or 371(c) Date: August 03, 2022 Examiner:

Entitled: TRANSDERMAL MICRO-DOSING DELIVERY OF PHARMACEUTICAL AGENTS

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. 2011/0111029 "Composition for transdermal delivery of cationic active agents" (Published 12 May 2011)
2. W.I.P.O. Pat. App. No. 2020/157569 "METHODS AND COMPOSITIONS COMPRISING A 5HT RECEPTOR AGONIST FOR THE TREATMENT OF PSYCHOLOGICAL, COGNITIVE, BEHAVIORAL, AND/OR MOOD DISORDERS" (Published August 6, 2020)
3. MADSEN (2019) "Psychedelic Effects of Psilocybin Correlate with Serotonin 2A Receptor Occupancy and Plasma Psilocin Levels" *Neuropsychopharmacology*. 44(7) 1328-1334
4. KAMATA (2006) "Direct detection of serum psilocin glucuronide by LC/MS and LC/MS/MS: time-courses of total and free (unconjugated) psilocin concentrations in serum specimens of a "magic mushroom" user" *Forensic Toxicology*. 24(1) 36-40
5. HOLZE (2021) "Pharmacokinetics and Pharmacodynamics of Lysergic Acid Diethylamide Microdoses in Healthy Participants" *Clinical Pharmacology & Therapeutics*. 109(3) 658-666
6. HENSTRA (2017) "Toxicokinetics of ibogaine and noribogaine in a patient with prolonged multiple cardiac arrhythmias after ingestion of internet purchased ibogaine" *Clinical Toxicology*. 55(6) 600-602
7. W.I.P.O. Pat. App. No. 2018/135943 "PSILOCYBIN AND/OR PSILOCIN IN COMBINATION WITH CANNABINOIDS AND/OR TERPENES" (Published July 26, 2018)
8. KUYPERS (2020) "The therapeutic potential of microdosing psychedelics in depression" *Therapeutic Advances in Psychopharmacology*. 10: 1-15
9. STRASSMAN (1984) "Adverse reactions to psychedelic drugs. A review of the literature" *The Journal of Nervous and Mental Disease*. 172(10):577-585

10. U.S. Pat. App. No. 2020/0085816 “LSD FOR THE TREATMENT OF ALZHEIMER'S DISEASE” (Published March 19, 2020)
11. W.I.P.O. Pat. App. No. 2020/123625 “Co-crystals, method and apparatus for forming the same” (Published June 18, 2020)
12. U.S. Patent App. No. 2013/0253449 “NORADRENERGIC AND SPECIFIC SEROTONERGIC ANTIDEPRESSANT-CONTAINING TRANSDERMAL PATCH” (Published September 26, 2013)
13. ASI, “Adhesives In Transdermal Drug Delivery Systems” 2005; retrieved <https://web.archive.org/web/20161005045648/https://www.adhesivesmag.com/articles/86012-adhesives-in-transdermal-drug-delivery-systems>, retrieved October 5, 2016
14. SINHA (2000) “Permeation Enhancers for Transdermal Drug Delivery” Drug Development and Industrial Pharmacy. 26(11) 1131-1140.
15. SMITH (1995) Percutaneous Penetration Enhancers. CRC-Press ISBN: 0849326052
16. GRODOWSKA (2010) “Organic solvents in the pharmaceutical industry” Acta Poloniae Pharmaceutica – Drug Research. 67(1) 3-12.
17. U.S. Pat. App. No. 2021/0069170 “TRYPTAMINE COMPOSITIONS FOR ENHANCING NEURITE OUTGROWTH” (Published March 11, 2021)
18. Priority Doc. of U.S. Pat. App. No. 2022/0017549 “PSILOCIN DERIVATIVES AS SEROTONERGIC PSYCHEDELIC AGENTS FOR THE TREATMENT OF CNS DISORDERS” provisional application (62/969,934) (Filing date: February 4, 2020)
19. VALENTA (2004) “The use of polymers for dermal and transdermal delivery” European Journal of Pharmaceutics and Biopharmaceutics. 58(2):279-289.
20. Priority Doc. of U.S. Pat. App. No. 2021/0322447 “TRANSDERMAL MICRO-DOSING DELIVERY OF PSYCHEDELICS DERIVATIVES” provisional application (63/010,924) (Filing date: April 16, 2020)

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

U.S.S.N. 17/879,846 Pending Claims	References
<p>1. A transdermal and/or topical pharmaceutical composition comprising: at least one active agent selected from the group consisting of: about 0.1% to about 50% of an active agent selected from the group consisting of tetrahydrocannabinol (THC), cannabidiol (CBD), psilocybin, psilocin, lysergic acid diethylamine (LSD), and/or ibogaine, the free base thereof, salts thereof, isomers thereof, amorphous forms thereof, crystalline forms thereof, co-crystalline forms thereof, prodrugs thereof, analogs thereof, derivatives thereof, synthetic forms thereof, naturally derived forms thereof, active metabolites thereof, polymorph thereof, solid solution thereof, coated form thereof, and combinations thereof, further wherein the pharmaceutical composition comprises: about 10% to about 99.9% of an adhesive and/or polymer; optionally, about 0.1% to about 99% of a permeation enhancer; optionally, about 0.1% to about 99% of a solvent, wherein said pharmaceutical composition will have no or minimal hallucinogenic or psychoactive effect in a patient to whom the pharmaceutical composition is applied.</p>	<p>20. Priority Doc. of U.S. Pat. App. No. 2021/0322447 “TRANSDERMAL MICRO-DOSING DELIVERY OF PSYCHEDELICS DERIVATIVES” provisional application (63/010,924) (Filing date: April 16, 2020)</p> <p>From provisional app. 63/010,924 claims 1 “1. A pharmaceutical composition comprising an active agent selected from the group consisting of psilocybin, lysergic acid diethylamide (LSD), and/or ibogaine, derivatives of these compounds, and combinations thereof, in a dosage form for transdermal delivery wherein said pharmaceutical composition will have no or minimal hallucinogenic effect in a patient to whom the pharmaceutical composition is applied.”</p> <p>From provisional app. 63/010,924 claims 2 “2. The pharmaceutical composition of claim 1 which comprises at least about 0.1 % to about 70% (w/w) of the active agent.”</p> <p>1. U.S. Pat. App. Pub. No. 2011/0111029 “Composition for transdermal delivery of cationic active agents” (Published 12 May 2011)</p> <p>From claim 1 “1. A composition for transdermal delivery of at least one cationic active agent or a salt thereof, comprising: said at least one cationic active agent or a salt thereof; at least one polyamine in the form of a polyamine salt, obtained by combining or reacting said at least one polyamine with a suitable acid; water or an aqueous solvent mixture; and optionally, one or more additives.”</p> <p>From claim 18 “18. The composition according to claim 1, wherein said at least one cationic active agent is selected from the group consisting of cationic indole compounds and salts thereof.”</p> <p>From claim 19 “19. The composition according to claim 18, wherein said cationic indole compounds comprise N-dimethyltryptamine and psilocin, and pharmacologically acceptable salts of said cationic indole compounds.”</p> <p>From claim 21 “21. The composition according to claim 1, wherein the total content of said at least one cationic active agent or a salt thereof amounts to 0.1-20%-wt. relative to the total weight of the composition.”</p>

From [0032] “The invention further encompasses the use of said composition as a component of a **transdermal patch** or as a component of an iontophoretic transdermal patch.”

From **claim 16** “16. The composition according to claim 1, wherein said composition is an **adhesive** composition.”

2. W.I.P.O. Pat. App. No. 2020/157569 “METHODS AND COMPOSITIONS COMPRISING A 5HT RECEPTOR AGONIST FOR THE TREATMENT OF PSYCHOLOGICAL, COGNITIVE, BEHAVIORAL, AND/OR MOOD DISORDERS” (Published August 6, 2020)

From **claim 1** “A method of managing a neurological condition or one or more symptoms thereof in a subject in need thereof, comprising administering to the subject a pharmaceutical composition comprising:
a) a therapeutically effective amount of one or more 5HT receptor agonist or a pharmaceutically acceptable salt, solvate, metabolite, derivative, or prodrug thereof; and
b) a pharmaceutically acceptable excipient wherein the therapeutically effective amount of the **5HT receptor agonist** or a pharmaceutically acceptable salt, solvate, metabolite, derivative, or prodrug thereof is provided to the subject in need thereof **in an amount insufficient to provide an adverse side effect, such as hallucinogenic experience.**”

From **claim 13** “The method of any one of the preceding claims, wherein the **5HT receptor agonist** is **psilocybin** or a pharmaceutically acceptable salt, solvate, metabolite, derivative, or prodrug thereof.”

From **claim 14** “The method of any one of claims 1-12, wherein the 5HT receptor agonist is **psilocin** or a pharmaceutically acceptable salt, solvate, metabolite, derivative, or prodrug thereof.”

From **claim 17** “The method of any one of the preceding claims, wherein the pharmaceutical composition is in a form selected from a spray, aerosol, mist, nebulae, **ointment, cream, gel, paste, salve**, solution, suspension, tincture, **patch**, and atomized vapor.”

From [0042] “In certain embodiments, the 5-HT_{2A} agonist provided herein is one of the following classes of 5-HT_{2A} agonists: the ergolines, **tryptamines** and phenethylamines. In specific embodiments, a 5HT (e.g.5HT_{2A}) receptor agonist utilized herein is an ergoline”

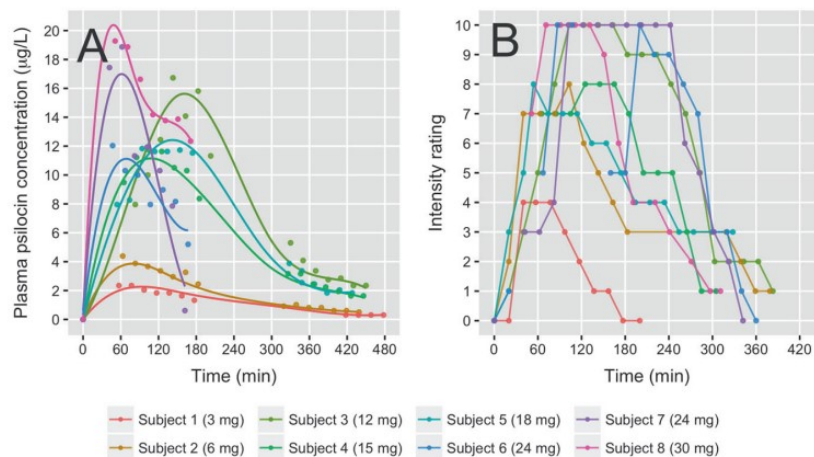
From [0047] “Examples of **tryptamines** include serotonin, melatonin, **psilocybin** and N,N-dimethyltryptamine. Additionally, the tryptamine

	<p>structure may comprise part of a more complex compound, for example: LSD, ibogaine, mitragynine, yohimbine, etc.”</p> <p>From [0112] “In some embodiments, a coating or layer (e.g. an immediate release or controlled release coating or layer) comprises an antiemetic. In some embodiments, the antiemetic is selected from the group consisting of aprepitant, dronabinol, perphenazine, palonosetron, trimethobenzamide, metoclopramide, domperidone, prochlorperazine, promethazine, chlorpromazine, trimethobenzamide, ondansetron, granisetron, hydroxyzine, acetylleucine monoethanolamine, alizapride, azasetron, benzquinamide, bictanautine, bromopride, buclizine, clebopride, cyclizine, dimenhydrinate, diphenidol, dolasetron, meclizine, methallatal, metopimazine, nabilone, oxyperndyl, pipamazine, scopolamine, sulphiride, tetrahydrocannabinol, thiethylperazine, thioproperazine, tropisetron, droperidol, haloperidol, prochlorperazine, metoclopramide, diphenhydramine, cannabis, midazolam, lorazepam, hyoscine, dexamethasone, emetrol, propofol, or a combination thereof.”</p>
<p>2. The pharmaceutical composition of claim 1, wherein the pharmaceutical composition provides a blood serum level of active agent selected from the group consisting of about 0.01 ng/mL, about 0.02 ng/mL, about 0.05 ng/mL, about 0.1 ng/mL, about 0.2 ng/mL, about 0.5 ng/mL, about 1 ng/mL, about 2 ng/mL, about 5 ng/mL, about 10 ng/mL, about 20 ng/mL, about 50 ng/mL, about 100 ng/mL, about 200 ng/mL, about 500 ng/mL, about 1 µg/mL, about 2 µg/mL, and about 5 µg/mL.</p>	<p>2. W.I.P.O. Pat. App. No. 2020/157569 “METHODS AND COMPOSITIONS COMPRISING A 5HT RECEPTOR AGONIST FOR THE TREATMENT OF PSYCHOLOGICAL, COGNITIVE, BEHAVIORAL, AND/OR MOOD DISORDERS” (Published August 6, 2020)</p> <p>From claim 1 “A method of managing a neurological condition or one or more symptoms thereof in a subject in need thereof, comprising administering to the subject a pharmaceutical composition comprising: a) a therapeutically effective amount of one or more 5HT receptor agonist or a pharmaceutically acceptable salt, solvate, metabolite, derivative, or prodrug thereof; and b) a pharmaceutically acceptable excipient wherein the therapeutically effective amount of the 5HT receptor agonist or a pharmaceutically acceptable salt, solvate, metabolite, derivative, or prodrug thereof is provided to the subject in need thereof in an amount insufficient to provide an adverse side effect, such as hallucinogenic experience.”</p> <p>From claim 17 “The method of any one of the preceding claims, wherein the pharmaceutical composition is in a form selected from a spray, aerosol, mist, nebulae, ointment, cream, gel, paste, salve, solution, suspension, tincture, patch, and atomized vapor.”</p> <p>From [0047] “Examples of tryptamines include serotonin, melatonin, psilocybin and N,N-dimethyltryptamine. Additionally, the tryptamine structure may comprise part of a more complex compound, for example: LSD, ibogaine, mitragynine, yohimbine, etc.”</p>

From [0019] “[19] In some embodiments, the therapeutically effective amount of **5HT receptor agonist** or a pharmaceutically acceptable salt, solvate, metabolite, derivative, or prodrug (e.g., **psilocybin**) thereof is provided to a subject in need thereof in an amount and/or formulation to provide a **maximum plasma concentration (Cmax)** of (e.g. active form of the) **5HT receptor agonist (e.g., psilocin)** or a pharmaceutically acceptable salt, solvate, metabolite, derivative, or prodrug thereof of about **0.1 ng/mL or more and less than 6 ng/mL (e.g. at least 0.5 ng/mL and less than 6 ng/mL, about 1 ng/mL to about 5.5 ng/mL, about 2 ng/mL to about 5 ng/mL, or the like).**”

3. MADSEN (2019) “Psychedelic Effects of Psilocybin Correlate with Serotonin 2A Receptor Occupancy and Plasma Psilocin Levels” *Neuropsychopharmacology*. 44(7) 1328-1334

From page 1330: “Fig. 1 Psilocin and intensity rating time course. a **Plasma psilocin levels**. Individual data points are **measured plasma psilocin concentrations**, fitted with spline fits. b Time course of subjective intensity ratings. Time = 0 indicates time of psilocybin ingestion”



4. KAMATA (2006) “Direct detection of serum psilocin glucuronide by LC/MS and LC/MS/MS: time-courses of total and free (unconjugated) psilocin concentrations in serum specimens of a “magic mushroom” user” *Forensic Toxicology*. 24(1) 36-40

From page 37: “**Serum PC** and PCG were monitored in the selected reaction monitoring (SRM) mode after the sample preparation described below”

From page 39: “The SRM technique showed good linearity in the range from **1 to 100 ng/ml serum.**”

Table 1 Concentrations of total and free psilocin (PC) in human serum specimens as a function of time after magic mushroom ingestion

Time after intake (h)	Total PC (ng/ml serum) ^a	Free PC (ng/ml serum) ^b	Proportion of free PC (%)
5	71	13	19
12	58	7.2	13
27	14	0.83	5.8
36	4.1	nd	—
52	2.2	nd	—

nd, Not detected

^aPC detected with hydrolysis

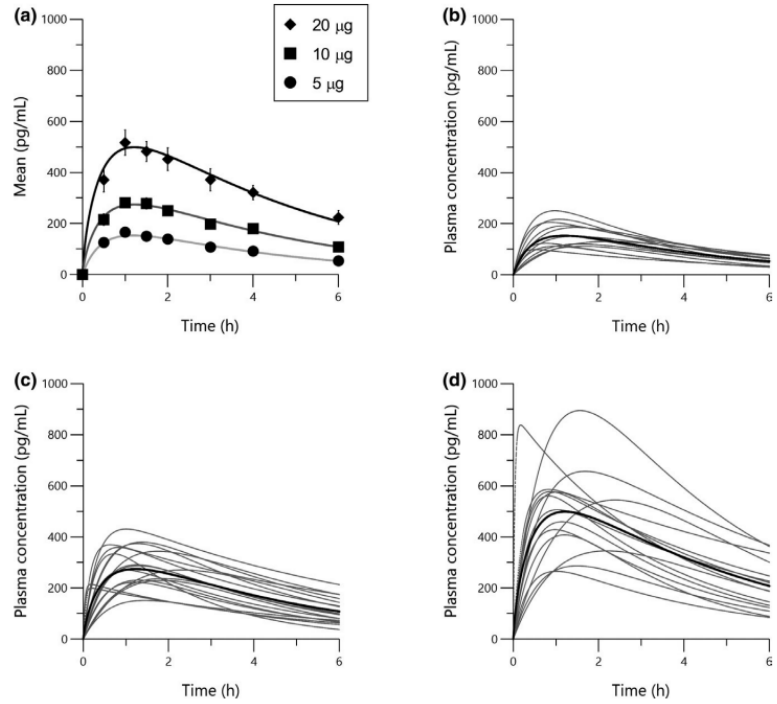
^bPC detected without hydrolysis

From **page 37**: “The specimens used in the present study were collected from a 16-year-old girl. She had allegedly taken approximately **9 g of dried MM** (containing 0.375 mg/g of PC and 11.2 mg/g of PB), which had been obtained through the Internet [15].”

5. HOLZE (2021) “Pharmacokinetics and Pharmacodynamics of Lysergic Acid Diethylamide Microdoses in Healthy Participants” *Clinical Pharmacology & Therapeutics*. 109(3) 658-666

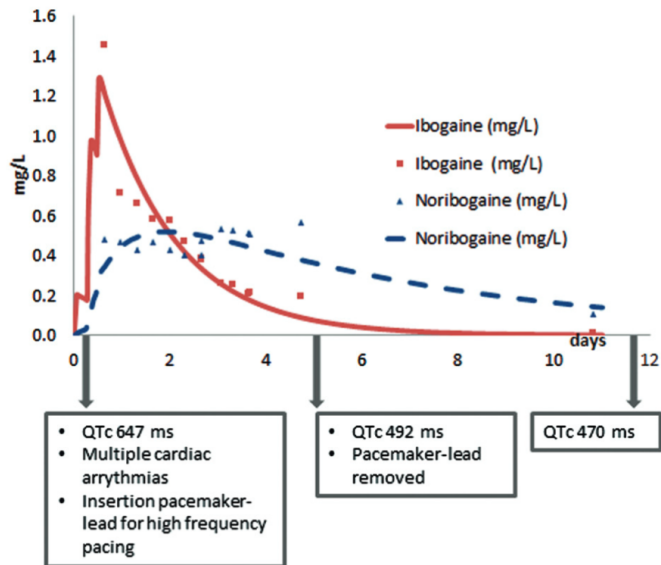
From **abstract**: “Single doses of **LSD base (5, 10, and 20 µg)** and placebo were administered in a double-blind, randomized, placebo-controlled crossover study in 23 healthy participants... Plasma levels of LSD and subjective effects were assessed up to 6 hours after administration... Mean (95% confidence interval) maximal LSD concentrations were 151 pg/mL (127–181), 279 pg/mL (243–320), and 500 pg/mL (413–607) after 5, 10, and 20 µg LSD administration, respectively. Maximal concentrations were reached after 1.1 hours. The mean elimination half-life was 2.7 hours (1.5–6.2). The 5 µg dose of LSD elicited no significant acute subjective effects.”

From **page 660**: “Figure 1 Pharmacokinetics of three very low doses of LSD, **5, 10, and 20 µg**, in 13, 18, and 15 subjects, respectively. (a) **Plasma LSD concentration**-time curves representing the mean of the individual pharmacokinetic model predictions. The observed data are expressed as symbols and the mean ± SEM. Dose-linear increases in LSD concentrations were observed. (b–d) Predicted individual plasma LSD concentration-time curves shown separately for each subject and the mean marked in bold and illustrating the between-subject variability of LSD concentrations after the administration of (b) 5 µg, (c) 10 µg, and (d) 20 µg LSD. LSD was administered at t = 0 hour. h, hours; LSD, lysergic acid diethylamide.”



6. HENSTRA (2017) “Toxicokinetics of ibogaine and noribogaine in a patient with prolonged multiple cardiac arrhythmias after ingestion of internet purchased ibogaine” *Clinical Toxicology*. 55(6) 600-602

From page 601: “Figure 1. Plasma-concentration versus time curve of ibogaine and noribogaine with important clinical interventions and observations.”



	<p>From page 600-601: “Case details A 46-year-old woman presented to our emergency department after being found unconscious by her spouse a few hours after repeated ingestion over a period of 12 h of inter-net-purchased ibogaine capsules with a total amount of 1400 mg.”</p>
<p>3. The pharmaceutical composition of claim 1, wherein the pharmaceutical formulation provides a dose of active agent to a patient equal to or greater than, for example, about 0.001 ng/day, 0.01 ng/day, 0.025 ng/day, 0.05 ng/day, 0.1 ng/day, 0.25 ng/day, 0.5 ng/day, 1 ng/day, 10 ng/day, 25 ng/day, 50 ng/day, 100 ng/day, 250 ng/day, 500 ng/day, 1000 ng/day, 0.001 microgram/day, 0.01 microgram/day, 0.025 microgram/day, 0.050 microgram/day, 0.1 microgram/day, 0.25 microgram/day, 0.5 microgram/day, 1 microgram/day, 2.5 microgram/day, 5 microgram/day, 10 microgram/day, 25 microgram/day, 50 microgram/day, 100 microgram/day, 250 microgram/day, 500 microgram/day, about 0.001 mg/day, 0.01 mg/day, 0.025 mg/day, 0.05 mg/day, 0.1 mg/day, 0.25 mg/day, 0.5 mg/day, 1 mg/day, 10 mg/day, or 25 mg/day.</p>	<p>7. W.I.P.O. Pat. App. No. 2018/135943 “PSILOCYBIN AND/OR PSILOCIN IN COMBINATION WITH CANNABINOIDS AND/OR TERPENES” (Published July 26, 2018)</p> <p>From page 14 paragraph 2 “Also encompassed are dosage forms for transdermal administration, including creams, lotions, aerosols and/or emulsions. These dosage forms may be included in transdermal patches of the matrix or reservoir type, which are generally known in the art. Pharmaceutical preparations dose (for the cannabinoid, terpene and/or the psilocybin/psilocin) may be conveniently prepared in unit dosage form, according to standard procedures of pharmaceutical formulation. The quantity of active compound(s) per unit dose may be varied according to the nature of the active compound and the intended dosage regime. Generally an effective amount shall be used, which may be within the range of from 0.01 mg to 5000 mg, preferably 0.01-4000 mg, 0.1-3000 mg, 1-2500, 5-1000, or 10-100 mg per unit dose (for the at least one cannabinoid and/or the at least one terpene and/or the at least one psilocybin and/or the at least one psilocin).”</p> <p>8. KUYPERS (2020) “The therapeutic potential of microdosing psychedelics in depression” Therapeutic Advances in Psychopharmacology. 10: 1-15</p> <p>Form page 2 “In general, a microdose is considered to be one tenth of a dose normally causing hallucinogenic effects. When taking the doses used in clinical research as a reference,^{2,4} a microdose then would be 10–20mcg of LSD and/or 0.3–0.5g of psilocybin-containing mushrooms.^{15,16} In a recent survey, users reported taking between 6 and 20mcg LSD and 0.2–0.5g of dried psilocybin mushrooms ^{13,17,18} with a microdosing frequency that ranges between 2 and 4 times a week, this for a few weeks, to months, or even years, although the latter is rare.”</p> <p>20. Priority Doc. of U.S. Pat. App. No. 2021/0322447 “TRANSDERMAL MICRO-DOSING DELIVERY OF PSYCHEDELICS DERIVATIVES” provisional application (63/010,924) (Filing date: April 16, 2020)</p> <p>From provisional app. 63/010,924 claims 1 “1. A pharmaceutical composition comprising an active agent selected from the group</p>

	<p>consisting of psilocybin, lysergic acid diethylamide (LSD), and/or ibogaine, derivatives of these compounds, and combinations thereof, in a dosage form for transdermal delivery wherein said pharmaceutical composition will have no or minimal hallucinogenic effect in a patient to whom the pharmaceutical composition is applied.”</p> <p>From provisional app. 63/010,924 claims 2 “2. The pharmaceutical composition of claim 1 which comprises at least about 0.1 % to about 70% (w/w) of the active agent.”</p> <p>From provisional app. 63/010,924 page 11 line 1-6 “...the dose of active agent is greater than, for example, about 0.001, 0.0025 0.005, 0.0075, 0.01, 0.025, 0.05, 0.075, 0.1, 0.25, 0.75, 1, 2, 3, 4, 5, 6, 7, 8, 9, 10, 15, 20, 25, 30, 35, 40, or 45 mg/kg/day. In certain embodiments, the dose of active agent is greater than, for example, about 0.001, 0.0025 0.005, 0.0075, 0.01, 0.025, 0.05, 0.075, 0.1, 0.25, 0.75, 1, 2, 3, 4, 5, 6, 7, 8, 9, 10, 15, 20, 25, 30, 35, 40, 45, 50, 55, 60, 65, 70, 75, 80, 85, 90, 95, 100, 125, 150,175,200,225,250, or 275 mg/day...”</p>
<p>4. The pharmaceutical composition of claim 1, wherein the THC is selected from the group comprising of free base thereof, salts thereof, isomers thereof, amorphous forms thereof, crystalline forms thereof, co-crystalline forms thereof, prodrugs thereof, analogs thereof, derivatives thereof, synthetic forms thereof, naturally derived forms thereof, active metabolites thereof, polymorph thereof, solid solution thereof, coated form thereof, stereoisomers thereof, solid solution thereof, ion-pair thereof, solution thereof, powder form thereof, liquid form thereof, alone or combinations thereof.</p>	<p>7. W.I.P.O. Pat. App. No. 2018/135943 “PSILOCYBIN AND/OR PSILOCIN IN COMBINATION WITH CANNABINOIDS AND/OR TERPENES” (Published July 26, 2018)</p> <p>From page 11 line 15 “Preferably the substantially pure cannabinoid used in the invention is substantially free of any other naturally occurring or synthetic cannabinoids, including cannabinoids that occur naturally in cannabis plants. In this context "substantially free" can be taken to mean that no cannabinoids other than the target cannabinoid are detectable by HPLC.</p> <p>Substantially pure cannabinoids can be prepared from a botanical drug substance. A technique has been established by the applicant and is described in GB2393721.</p> <p>In another aspect of the present invention the cannabinoid is in a synthetic form.”</p> <p>From page 10 line 24 “Preferably the one or more cannabinoids are taken from the group: cannabidiol (CBD); cannabidiolic acid (CBDA); tetrahydrocannbidivarin (THCV); tetrahydrocannbidivarinin acid (THCVA); cannabichromene (CBC); cannabichromenic acid (CBCA); cannabigerol (CBG) and cannabigerolic acid (CBGA).</p> <p>Preferably the plurality of phyto-cannabinoids are present in the form of a cannabis plant extract, which depending on the composition of the extract, may have all or a proportion of THC or THCA selectively removed.”</p>

	<p>From page 11 line 31 “The scope of the disclosure also extends to derivatives of cannabinoids that retain the desired activity. Derivatives that retain substantially the same activity as the starting material, or more preferably exhibit improved activity, may be produced according to standard principles of medicinal chemistry, which are well known in the art. Such derivatives may exhibit a lesser degree of activity than the starting material, so long as they retain sufficient activity to be therapeutically effective. Derivatives may exhibit improvements in other properties that are desirable in pharmaceutically active agents such as, for example, improved solubility, reduced toxicity, enhanced uptake, etc. Preferably, the cannabinoid combined with the psilocybin/psilocin is formulated as a pharmaceutical composition further comprising one or more pharmaceutically acceptable carriers, excipients or diluents.”</p> <p>From page 14 paragraph 2 “Also encompassed are dosage forms for transdermal administration, including creams, lotions, aerosols and/or emulsions. These dosage forms may be included in transdermal patches of the matrix or reservoir type, which are generally known in the art. Pharmaceutical preparations dose (for the cannabinoid, terpene and/or the psilocybin/psilocin) may be conveniently prepared in unit dosage form, according to standard procedures of pharmaceutical formulation. The quantity of active compound(s) per unit dose may be varied according to the nature of the active compound and the intended dosage regime. Generally an effective amount shall be used, which may be within the range of from 0.01 mg to 5000 mg, preferably 0.01-4000 mg, 0.1-3000 mg, 1-2500, 5-1000, or 10-100 mg per unit dose (for the at least one cannabinoid and/or the at least one terpene and/or the at least one psilocybin and/or the at least one psilocin).”</p>
<p>5. The pharmaceutical composition of claim 1, wherein the CBD is selected from the group comprising of free base thereof, salts thereof, isomers thereof, amorphous forms thereof, crystalline forms thereof, co-crystalline forms thereof, prodrugs thereof, analogs thereof, derivatives thereof, synthetic forms thereof, biosynthetic forms thereof, active metabolites thereof, polymorph thereof, solid</p>	<p>7. W.I.P.O. Pat. App. No. 2018/135943 “PSILOCYBIN AND/OR PSILOCIN IN COMBINATION WITH CANNABINOIDS AND/OR TERPENES” (Published July 26, 2018)</p> <p>From page 11 line 15 “Preferably the substantially pure cannabinoid used in the invention is substantially free of any other naturally occurring or synthetic cannabinoids, including cannabinoids that occur naturally in cannabis plants. In this context "substantially free" can be taken to mean that no cannabinoids other than the target cannabinoid are detectable by HPLC.</p> <p>Substantially pure cannabinoids can be prepared from a botanical drug substance. A technique has been established by the applicant and is described in GB2393721.</p>

<p>solution thereof, coated form thereof, ion-pairs thereof, stereoisomers thereof, solid solution thereof, solution thereof, powder form thereof, liquid form thereof, alone or combinations thereof.</p>	<p>In another aspect of the present invention the cannabinoid is in a synthetic form.”</p> <p>From page 10 line 24 “Preferably the one or more cannabinoids are taken from the group: cannabidiol (CBD); cannabidiolic acid (CBDA); tetrahydrocannbidivarin (THCV); tetrahydrocannbidivarinin acid (THCVA); cannabichromene (CBC); cannabichromenic acid (CBCA); cannabigerol (CBG) and cannabigerolic acid (CBGA).</p> <p>Preferably the plurality of phyto-cannabinoids are present in the form of a cannabis plant extract, which depending on the composition of the extract, may have all or a proportion of THC or THCA selectively removed.”</p> <p>From page 11 line 31 “The scope of the disclosure also extends to derivatives of cannabinoids that retain the desired activity. Derivatives that retain substantially the same activity as the starting material, or more preferably exhibit improved activity, may be produced according to standard principles of medicinal chemistry, which are well known in the art. Such derivatives may exhibit a lesser degree of activity than the starting material, so long as they retain sufficient activity to be therapeutically effective. Derivatives may exhibit improvements in other properties that are desirable in pharmaceutically active agents such as, for example, improved solubility, reduced toxicity, enhanced uptake, etc. Preferably, the cannabinoid combined with the psilocybin/psilocin is formulated as a pharmaceutical composition further comprising one or more pharmaceutically acceptable carriers, excipients or diluents.”</p> <p>From page 14 paragraph 2 “Also encompassed are dosage forms for transdermal administration, including creams, lotions, aerosols and/or emulsions. These dosage forms may be included in transdermal patches of the matrix or reservoir type, which are generally known in the art. Pharmaceutical preparations dose (for the cannabinoid, terpene and/or the psilocybin/psilocin) may be conveniently prepared in unit dosage form, according to standard procedures of pharmaceutical formulation. The quantity of active compound(s) per unit dose may be varied according to the nature of the active compound and the intended dosage regime. Generally an effective amount shall be used, which may be within the range of from 0.01 mg to 5000 mg, preferably 0.01-4000 mg, 0.1-3000 mg, 1-2500, 5-1000, or 10-100 mg per unit dose (for the at least one cannabinoid and/or the at least one terpene and/or the at least one psilocybin and/or the at least one psilocin).”</p>
<p>6. A pharmaceutical composition of claim 1</p>	<p>2. W.I.P.O. Pat. App. No. 2020/157569 “METHODS AND COMPOSITIONS COMPRISING A 5HT RECEPTOR AGONIST</p>

<p>comprising one or more active agent selected from the group consisting of tetrahydrocannabinol (THC), cannabidiol (CBD), psilocybin, psilocin, lysergic acid diethylamine (LSD), and/or ibogaine, the free base thereof, salts thereof, isomers thereof, amorphous forms thereof, crystalline forms thereof, co-crystalline forms thereof, prodrugs thereof, analogs thereof, derivatives thereof, synthetic forms thereof, biosynthetic forms thereof, active metabolites thereof, polymorph thereof, solid solution thereof, coated form thereof, and combinations thereof, in a dosage form for transdermal delivery.</p>	<p>FOR THE TREATMENT OF PSYCHOLOGICAL, COGNITIVE, BEHAVIORAL, AND/OR MOOD DISORDERS” (Published August 6, 2020)</p> <p>From [0229] “The term “5HT receptor agonist agent” refers to a 5HT receptor agonist as a free base or a derivative or analog thereof. Included in the term are salts, solvates, metabolites, prodrugs, isomers, tautomers, isotopic derivatives, and the like, of a 5HT receptor agonist. In some embodiments, the derivative, analogs, salts, solvates, metabolites, prodrugs, isomers, tautomers, isotopic derivatives, etc are pharmaceutically acceptable derivative, analogs, salts, solvates, metabolites, prodrugs, isomers, tautomers, isotopic derivatives of a 5HT receptor agonist.”</p> <p>From [0049] “Examples of synthetic substituted tryptamines include, by way of non-limiting example:...”</p> <p>From claim 1 “A method of managing a neurological condition or one or more symptoms thereof in a subject in need thereof, comprising administering to the subject a pharmaceutical composition comprising: a) a therapeutically effective amount of one or more 5HT receptor agonist or a pharmaceutically acceptable salt, solvate, metabolite, derivative, or prodrug thereof; and b) a pharmaceutically acceptable excipient wherein the therapeutically effective amount of the 5HT receptor agonist or a pharmaceutically acceptable salt, solvate, metabolite, derivative, or prodrug thereof is provided to the subject in need thereof in an amount insufficient to provide an adverse side effect, such as hallucinogenic experience.”</p> <p>From claim 13 “The method of any one of the preceding claims, wherein the 5HT receptor agonist is psilocybin or a pharmaceutically acceptable salt, solvate, metabolite, derivative, or prodrug thereof.”</p> <p>From claim 14 “The method of any one of claims 1-12, wherein the 5HT receptor agonist is psilocin or a pharmaceutically acceptable salt, solvate, metabolite, derivative, or prodrug thereof.”</p> <p>From claim 17 “The method of any one of the preceding claims, wherein the pharmaceutical composition is in a form selected from a spray, aerosol, mist, nebulae, ointment, cream, gel, paste, salve, solution, suspension, tincture, patch, and atomized vapor.”</p> <p>From [0042] “In certain embodiments, the 5-HT_{2A} agonist provided herein is one of the following classes of 5-HT_{2A} agonists: the ergolines, tryptamines and phenethylamines. In specific embodiments, a 5HT (e.g.5HT_{2A}) receptor agonist utilized herein is an ergoline”</p>
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	<p>From [0047] “Examples of tryptamines include serotonin, melatonin, psilocybin and N,N-dimethyltryptamine. Additionally, the tryptamine structure may comprise part of a more complex compound, for example: LSD, ibogaine, mitragynine, yohimbine, etc.”</p> <p>From [0112] “In some embodiments, a coating or layer (e.g. an immediate release or controlled release coating or layer) comprises an antiemetic. In some embodiments, the antiemetic is selected from the group consisting of aprepitant, dronabinol, perphenazine, palonosetron, trimethobenzamide, metoclopramide, domperidone, prochlorperazine, promethazine, chlorpromazine, trimethobenzamide, ondansetron, granisetron, hydroxyzine, acetylleucine monoethanolamine, alizapride, azasetron, benzquinamide, biantanautine, bromopride, buclizine, clebopride, cyclizine, dimenhydrinate, diphenidol, dolasetron, meclizine, methallatal, metopimazine, nabilone, oxyperndyl, pipamazine, scopolamine, sulpiride, tetrahydrocannabinol, thiethylperazine, thioproperazine, tropisetron, droperidol, haloperidol, prochlorperazine, metoclopramide, diphenhydramine, cannabis, midazolam, lorazepam, hyoscine, dexamethasone, emetrol, propofol, or a combination thereof.”</p>
<p>7. A pharmaceutical composition of claim 1 comprising one or more active agent selected from the group consisting of tetrahydrocannabinol (THC), cannabidiol (CBD), psilocybin, psilocin, lysergic acid diethylamine (LSD), and/or ibogaine, the free base thereof, salts thereof, isomers thereof, amorphous forms thereof, crystalline forms thereof, co-crystalline forms thereof, prodrugs thereof, analogs thereof, derivatives thereof, synthetic forms thereof, biosynthetic forms thereof, active metabolites thereof, polymorph thereof, solid solution thereof, coated form thereof, and combinations thereof, in a dosage form for topical delivery.</p>	<p>2. W.I.P.O. Pat. App. No. 2020/157569 “METHODS AND COMPOSITIONS COMPRISING A 5HT RECEPTOR AGONIST FOR THE TREATMENT OF PSYCHOLOGICAL, COGNITIVE, BEHAVIORAL, AND/OR MOOD DISORDERS” (Published August 6, 2020)</p> <p>From [0229] “The term “5HT receptor agonist agent” refers to a 5HT receptor agonist as a free base or a derivative or analog thereof. Included in the term are salts, solvates, metabolites, prodrugs, isomers, tautomers, isotopic derivatives, and the like, of a 5HT receptor agonist. In some embodiments, the derivative, analogs, salts, solvates, metabolites, prodrugs, isomers, tautomers, isotopic derivatives, etc are pharmaceutically acceptable derivative, analogs, salts, solvates, metabolites, prodrugs, isomers, tautomers, isotopic derivatives of a 5HT receptor agonist.”</p> <p>From [0049] “Examples of synthetic substituted tryptamines include, by way of non-limiting example:...”</p> <p>From claim 1 “A method of managing a neurological condition or one or more symptoms thereof in a subject in need thereof, comprising administering to the subject a pharmaceutical composition comprising: a) a therapeutically effective amount of one or more 5HT receptor agonist or a pharmaceutically acceptable salt, solvate, metabolite, derivative, or prodrug thereof; and</p>

	<p>b) a pharmaceutically acceptable excipient wherein the therapeutically effective amount of the 5HT receptor agonist or a pharmaceutically acceptable salt, solvate, metabolite, derivative, or prodrug thereof is provided to the subject in need thereof in an amount insufficient to provide an adverse side effect, such as hallucinogenic experience.”</p> <p>From claim 13 “The method of any one of the preceding claims, wherein the 5HT receptor agonist is psilocybin or a pharmaceutically acceptable salt, solvate, metabolite, derivative, or prodrug thereof.”</p> <p>From claim 14 “The method of any one of claims 1-12, wherein the 5HT receptor agonist is psilocin or a pharmaceutically acceptable salt, solvate, metabolite, derivative, or prodrug thereof.”</p> <p>From claim 17 “The method of any one of the preceding claims, wherein the pharmaceutical composition is in a form selected from a spray, aerosol, mist, nebulae, ointment, cream, gel, paste, salve, solution, suspension, tincture, patch, and atomized vapor.”</p> <p>From [0042] “In certain embodiments, the 5-HT2A agonist provided herein is one of the following classes of 5-HT2A agonists: the ergolines, tryptamines and phenethylamines. In specific embodiments, a 5HT (e.g.5HT2A) receptor agonist utilized herein is an ergoline”</p> <p>From [0047] “Examples of tryptamines include serotonin, melatonin, psilocybin and N,N-dimethyltryptamine. Additionally, the tryptamine structure may comprise part of a more complex compound, for example: LSD, ibogaine, mitragynine, yohimbine, etc.”</p> <p>From [0112] “In some embodiments, a coating or layer (e.g. an immediate release or controlled release coating or layer) comprises an antiemetic. In some embodiments, the antiemetic is selected from the group consisting of aprepitant, dronabinol, perphenazine, palonosetron, trimethobenzamide, metoclopramide, domperidone, prochlorperazine, promethazine, chlorpromazine, trimethobenzamide, ondansetron, granisetron, hydroxyzine, acetylleucine monoethanolamine, alizapride, azasetron, benzquinamide, biantanautine, bromopride, buclizine, clebopride, cyclizine, dimenhydrinate, diphenidol, dolasetron, meclizine, methallatal, metopimazine, nabilone, oxyperndyl, pipamazine, scopolamine, sulpiride, tetrahydrocannabinol, thiethylperazine, thioproperazine, tropisetron, droperidol, haloperidol, prochlorperazine, metoclopramide, diphenhydramine, cannabis, midazolam, lorazepam, hyoscine, dexamethasone, emetrol, propofol, or a combination thereof.”</p>
<p>8. The pharmaceutical composition of claim 1</p>	<p>2. W.I.P.O. Pat. App. No. 2020/157569 “METHODS AND COMPOSITIONS COMPRISING A 5HT RECEPTOR AGONIST</p>

wherein said CBD, THC, psilocybin, psilocin, lysergic acid diethylamine (LSD), and/or ibogaine, the free base thereof, salts thereof, isomers thereof, amorphous forms thereof, polymorphs thereof, stereoisomers thereof, ion-pairs thereof, coated forms thereof, crystalline forms thereof, co-crystalline forms thereof, prodrugs thereof, analogs thereof, derivatives thereof, synthetic forms thereof, biosynthetic forms thereof, active metabolites thereof, and combinations thereof, is produced by a natural route.

FOR THE TREATMENT OF PSYCHOLOGICAL, COGNITIVE, BEHAVIORAL, AND/OR MOOD DISORDERS” (Published August 6, 2020)

From [0048] “Examples of **naturally occurring substituted tryptamines** include, by way of non-limiting example:

Short/Common Name	Full Name	R ¹	R ²	R ³	R ⁴	R ⁵
Tryptamine	3-(2-aminoethyl)indole 2-(1H-indol-3-yl)ethanamine	H	H	H	H	H
Bufotenin	5-hydroxy- <i>N,N</i> -dimethyltryptamine	OH	H	H	CH ₃	CH ₃
Neo-Methylserotonin (norbufotenin)	5-hydroxy- <i>N</i> -methyltryptamine	OH	H	H	CH ₃	H
Serotonin	5-hydroxytryptamine	OH	H	H	H	H
NMT	<i>N</i> -methyltryptamine	H	H	H	H	CH ₃
5-MeO-NMT	5-methoxy- <i>N</i> -methyltryptamine	OCH ₃	H	H	CH ₃	H
DMT	<i>N,N</i> -dimethyltryptamine	H	H	H	CH ₃	CH ₃
5-Bromo-DMT	5-bromo- <i>N,N</i> -dimethyltryptamine	Br	H	H	CH ₃	CH ₃
5-MeO-DMT	5-methoxy- <i>N,N</i> -dimethyltryptamine	OCH ₃	H	H	CH ₃	CH ₃
Melatonin	5-methoxy- <i>N</i> -acetyltryptamine	OCH ₃	H	H	C(O)CH ₃	H
<i>N</i> -Acetylserotonin	5-hydroxy- <i>N</i> -acetyltryptamine	OH	H	H	C(O)CH ₃	H
Norbaecocystin	4-phosphoryloxy-tryptamine	H	OPO ₂ H ₂	H	H	H
Baecocystin	4-phosphoryloxy- <i>N</i> -methyltryptamine	H	OPO ₂ H ₂	H	CH ₃	H
Psilocybin	4-phosphoryloxy- <i>N,N</i> -dimethyltryptamine	H	PO ₄	H	CH ₃	CH ₃
Psilocin	4-hydroxy- <i>N,N</i> -dimethyltryptamine	H	OH	H	CH ₃	CH ₃
Tryptophan	α -carboxyltryptamine	H	H	COOH	H	H

”

From [0229] “The term “**5HT receptor agonist agent**” refers to a 5HT receptor agonist as a **free base** or a derivative or **analog** thereof. Included in the term are **salts**, solvates, metabolites, **prodrugs**, **isomers**, tautomers, isotopic derivatives, and the like, of a 5HT receptor agonist. In some embodiments, the derivative, analogs, salts, solvates, metabolites, prodrugs, isomers, tautomers, isotopic derivatives, etc are pharmaceutically acceptable derivative, analogs, salts, solvates, metabolites, prodrugs, isomers, tautomers, isotopic derivatives of a 5HT receptor agonist.”

From [0049] “Examples of **synthetic substituted tryptamines** include, by way of non-limiting example:...”

From **claim 1** “A method of managing a neurological condition or one or more symptoms thereof in a subject in need thereof, comprising administering to the subject a pharmaceutical composition comprising:
a) a therapeutically effective amount of one or more 5HT receptor agonist or a pharmaceutically acceptable salt, solvate, metabolite, derivative, or prodrug thereof; and

b) a pharmaceutically acceptable excipient wherein the therapeutically effective amount of the **5HT receptor agonist** or a pharmaceutically acceptable salt, solvate, metabolite, derivative, or prodrug thereof is provided to the subject in need thereof **in an amount insufficient to provide an adverse side effect, such as hallucinogenic experience.**”

From **claim 13** “The method of any one of the preceding claims, wherein the **5HT receptor agonist** is **psilocybin** or a pharmaceutically acceptable salt, solvate, metabolite, derivative, or prodrug thereof.”

From **claim 14** “The method of any one of claims 1-12, wherein the 5HT receptor agonist is **psilocin** or a pharmaceutically acceptable salt, solvate, metabolite, derivative, or prodrug thereof.”

From **claim 17** “The method of any one of the preceding claims, wherein the pharmaceutical composition is in a form selected from a spray, aerosol, mist, nebulae, **ointment, cream, gel, paste, salve,** solution, suspension, tincture, **patch,** and atomized vapor.”

From **[0042]** “In certain embodiments, the 5-HT_{2A} agonist provided herein is one of the following classes of 5-HT_{2A} agonists: the ergolines, **tryptamines** and phenethylamines. In specific embodiments, a 5HT (e.g.5HT_{2A}) receptor agonist utilized herein is an ergoline”

From **[0047]** “Examples of **tryptamines** include serotonin, melatonin, **psilocybin** and N,N-dimethyltryptamine. Additionally, the tryptamine structure may comprise part of a more complex compound, for example: **LSD, ibogaine,** mitragynine, yohimbine, etc.”

From **[0112]** “In some embodiments, a coating or layer (e.g. an immediate release or controlled release coating or layer) comprises an antiemetic. In some embodiments, the antiemetic is selected from the group consisting of aprepitant, dronabinol, perphenazine, palonosetron, trimethobenzamide, metoclopramide, domperidone, prochlorperazine, promethazine, chlorpromazine, trimethobenzamide, ondansetron, granisetron, hydroxyzine, acetylleucine monoethanolamine, alizapride, azasetron, benzquinamide, biantanautine, bromopride, buclizine, clebopride, cyclizine, dimenhydrinate, diphenidol, dolasetron, meclizine, methallatal, metopimazine, nabilone, oxyperndyl, pipamazine, scopolamine, sulpiride, **tetrahydrocannabinol,** thiethylperazine, thioproperazine, tropisetron, droperidol, haloperidol, prochlorperazine, metoclopramide, diphenhydramine, **cannabis,** midazolam, lorazepam, hyoscine, dexamethasone, emetrol, propofol, or a combination thereof.”

	<p>6. HENSTRA (2017) “Toxicokinetics of ibogaine and noribogaine in a patient with prolonged multiple cardiac arrhythmias after ingestion of internet purchased ibogaine” Clinical Toxicology. 55(6) 600-602</p> <p>From page 600: “Ibogaine is an alkaloid derived from the root of the Tabernanthe iboga-plant that possesses anti-addictive properties for drug dependence through reduction of craving induced by substance withdrawal.”</p> <p>7. W.I.P.O. Pat. App. No. 2018/135943 “PSILOCYBIN AND/OR PSILOCIN IN COMBINATION WITH CANNABINOIDS AND/OR TERPENES” (Published July 26, 2018)</p> <p>From page 11 line 15 “Preferably the substantially pure cannabinoid used in the invention is substantially free of any other naturally occurring or synthetic cannabinoids, including cannabinoids that occur naturally in cannabis plants. In this context "substantially free" can be taken to mean that no cannabinoids other than the target cannabinoid are detectable by HPLC.</p> <p>Substantially pure cannabinoids can be prepared from a botanical drug substance. A technique has been established by the applicant and is described in GB2393721.</p> <p>In another aspect of the present invention the cannabinoid is in a synthetic form.”</p>
<p>9. The pharmaceutical composition of claim 1 wherein said tetrahydrocannabinol (THC), cannabidiol (CBD), psilocybin, psilocin, lysergic acid diethylamine (LSD), and/or ibogaine, the free base thereof, salts thereof, isomers thereof, amorphous forms thereof, polymorphs thereof, stereoisomers thereof, ion-pairs thereof, coated forms thereof, crystalline forms thereof, co-crystalline forms thereof, prodrugs thereof, analogs thereof, derivatives thereof, synthetic forms thereof,</p>	<p>9. STRASSMAN (1984) “Adverse reactions to psychedelic drugs. A review of the literature” The Journal of Nervous and Mental Disease. 172(10):577-585</p> <p>From abstract: “The basic pharmacology of the major synthetic psychedelic compounds (primarily lysergic acid diethylamide [LSD]-25) is described and reference is made to their potentially beneficial psychological effects.”</p> <p>7. W.I.P.O. Pat. App. No. 2018/135943 “PSILOCYBIN AND/OR PSILOCIN IN COMBINATION WITH CANNABINOIDS AND/OR TERPENES” (Published July 26, 2018)</p> <p>From page 11 line 15 “Preferably the substantially pure cannabinoid used in the invention is substantially free of any other naturally occurring or synthetic cannabinoids, including cannabinoids that occur naturally in cannabis plants. In this context "substantially free" can be taken to mean that no cannabinoids other than the target cannabinoid are detectable by HPLC.</p>

<p>biosynthetic forms thereof, active metabolites thereof, and combinations thereof, is produced by a synthetic route.</p>	<p>Substantially pure cannabinoids can be prepared from a botanical drug substance. A technique has been established by the applicant and is described in GB2393721.</p> <p>In another aspect of the present invention the cannabinoid is in a synthetic form.”</p>
<p>10. The pharmaceutical composition of claim 1 formulated as transdermal liquid formulation, transdermal semisolid formulation, transdermal gel formulation, or transdermal polymer matrix formulation, transdermal adhesive matrix formulation, transdermal film forming gel, transdermal film forming formulation, a multilayer transdermal matrix system, or transdermal drug-in-adhesive matrix formulation.</p>	<p>10. U.S. Pat. App. No. 2020/0085816 “LSD FOR THE TREATMENT OF ALZHEIMER'S DISEASE” (Published March 19, 2020)</p> <p>From claim 40 “A transdermal delivery system comprising a pharmaceutically effective amount of a neuronal growth factor, 2 µg to 30 µg of lysergic acid diethylamide or a pharmaceutically acceptable salt thereof, and a naturally occurring gum.”</p> <p>From paragraph [0059] “There are several approaches for providing rate control over the release and transdermal permeation of a drug, including: membrane-moderated systems, adhesive diffusion-controlled systems, matrix dispersion-type systems, and microreservoir systems. A controlled release percutaneous and/or topical composition may be obtained by using a suitable mixture of the above-mentioned approaches.”</p> <p>From paragraph [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.”</p> <p>2. W.I.P.O. Pat. App. No. 2020/157569 “METHODS AND COMPOSITIONS COMPRISING A 5HT RECEPTOR AGONIST FOR THE TREATMENT OF PSYCHOLOGICAL, COGNITIVE,</p>

BEHAVIORAL, AND/OR MOOD DISORDERS” (Published August 6, 2020)

From **claim 1** “A method of managing a neurological condition or one or more symptoms thereof in a subject in need thereof, comprising administering to the subject a pharmaceutical composition comprising:
a) a therapeutically effective amount of one or more 5HT receptor agonist or a pharmaceutically acceptable salt, solvate, metabolite, derivative, or prodrug thereof; and
b) a pharmaceutically acceptable excipient wherein the therapeutically effective amount of the **5HT receptor agonist** or a pharmaceutically acceptable salt, solvate, metabolite, derivative, or prodrug thereof is provided to the subject in need thereof **in an amount insufficient to provide an adverse side effect, such as hallucinogenic experience.**”

From **claim 13** “The method of any one of the preceding claims, wherein the **5HT receptor agonist** is **psilocybin** or a pharmaceutically acceptable salt, solvate, metabolite, derivative, or prodrug thereof.”

From **claim 14** “The method of any one of claims 1-12, wherein the 5HT receptor agonist is **psilocin** or a pharmaceutically acceptable salt, solvate, metabolite, derivative, or prodrug thereof.”

From **claim 17** “The method of any one of the preceding claims, wherein the pharmaceutical composition is in a form selected from a spray, aerosol, mist, nebulae, **ointment, cream, gel, paste, salve**, solution, suspension, tincture, **patch**, and atomized vapor.”

From **[0042]** “In certain embodiments, the 5-HT_{2A} agonist provided herein is one of the following classes of 5-HT_{2A} agonists: the ergolines, **tryptamines** and phenethylamines. In specific embodiments, a 5HT (e.g. 5HT_{2A}) receptor agonist utilized herein is an ergoline”

From **[0047]** “Examples of **tryptamines** include serotonin, melatonin, **psilocybin** and N,N-dimethyltryptamine. Additionally, the tryptamine structure may comprise part of a more complex compound, for example: **LSD, ibogaine**, mitragynine, yohimbine, etc.”

From **[0112]** “In some embodiments, a coating or layer (e.g. an immediate release or controlled release coating or layer) comprises an antiemetic. In some embodiments, the antiemetic is selected from the group consisting of aprepitant, dronabinol, perphenazine, palonosetron, trimethobenzamide, metoclopramide, domperidone, prochlorperazine, promethazine, chlorpromazine, trimethobenzamide, ondansetron, granisetron, hydroxyzine, acetylleucine monoethanolamine, alizapride, azasetron, benzquinamide, bietanautine, bromopride, buclizine, clebopride, cyclizine, dimenhydrinate, diphenidol, dolasetron,

	<p>meclizine, methallatal, metopimazine, nabilone, oxyperndyl, pipamazine, scopolamine, sulpiride, tetrahydrocannabinol, thiethylperazine, thioproperazine, tropisetron, droperidol, haloperidol, prochloperazine, metoclopramide, diphenhydramine, cannabis, midazolam, lorazepam, hyoscine, dexamethasone, emetrol, propofol, or a combination thereof.”</p>
<p>11. The pharmaceutical composition of claim 1 formulated as a topical liquid formulation, topical semi solid formulation, topical gel formulation, topical polymer matrix formulation, topical adhesive matrix formulation, topical film forming gel formulation, or topical film forming spray formulation.</p>	<p>10. U.S. Pat. App. No. 2020/0085816 “LSD FOR THE TREATMENT OF ALZHEIMER'S DISEASE” (Published March 19, 2020)</p> <p>From claim 40 “A transdermal delivery system comprising a pharmaceutically effective amount of a neuronal growth factor, 2 µg to 30 µg of lysergic acid diethylamide or a pharmaceutically acceptable salt thereof, and a naturally occurring gum.”</p> <p>From paragraph [0059] “There are several approaches for providing rate control over the release and transdermal permeation of a drug, including: membrane-moderated systems, adhesive diffusion-controlled systems, matrix dispersion-type systems, and microreservoir systems. A controlled release percutaneous and/or topical composition may be obtained by using a suitable mixture of the above-mentioned approaches.”</p> <p>From paragraph [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.”</p> <p>2. W.I.P.O. Pat. App. No. 2020/157569 “METHODS AND COMPOSITIONS COMPRISING A 5HT RECEPTOR AGONIST FOR THE TREATMENT OF PSYCHOLOGICAL, COGNITIVE, BEHAVIORAL, AND/OR MOOD DISORDERS” (Published August 6, 2020)</p>

From **claim 1** “A method of managing a neurological condition or one or more symptoms thereof in a subject in need thereof, comprising administering to the subject a pharmaceutical composition comprising:
a) a therapeutically effective amount of one or more 5HT receptor agonist or a pharmaceutically acceptable salt, solvate, metabolite, derivative, or prodrug thereof; and
b) a pharmaceutically acceptable excipient wherein the therapeutically effective amount of the **5HT receptor agonist** or a pharmaceutically acceptable salt, solvate, metabolite, derivative, or prodrug thereof is provided to the subject in need thereof **in an amount insufficient to provide an adverse side effect, such as hallucinogenic experience.**”

From **claim 13** “The method of any one of the preceding claims, wherein the **5HT receptor agonist** is **psilocybin** or a pharmaceutically acceptable salt, solvate, metabolite, derivative, or prodrug thereof.”

From **claim 14** “The method of any one of claims 1-12, wherein the 5HT receptor agonist is **psilocin** or a pharmaceutically acceptable salt, solvate, metabolite, derivative, or prodrug thereof.”

From **claim 17** “The method of any one of the preceding claims, wherein the pharmaceutical composition is in a form selected from a spray, aerosol, mist, nebulae, **ointment, cream, gel, paste, salve,** solution, suspension, tincture, **patch,** and atomized vapor.”

From **[0042]** “In certain embodiments, the 5-HT_{2A} agonist provided herein is one of the following classes of 5-HT_{2A} agonists: the ergolines, **tryptamines** and phenethylamines. In specific embodiments, a 5HT (e.g.5HT_{2A}) receptor agonist utilized herein is an ergoline”

From **[0047]** “Examples of **tryptamines** include serotonin, melatonin, **psilocybin** and N,N-dimethyltryptamine. Additionally, the tryptamine structure may comprise part of a more complex compound, for example: **LSD, ibogaine,** mitragynine, yohimbine, etc.”

From **[0112]** “In some embodiments, a coating or layer (e.g. an immediate release or controlled release coating or layer) comprises an antiemetic. In some embodiments, the antiemetic is selected from the group consisting of aprepitant, dronabinol, perphenazine, palonosetron, trimethobenzamide, metoclopramide, domperidone, prochlorperazine, promethazine, chlorpromazine, trimethobenzamide, ondansetron, granisetron, hydroxyzine, acetylleucine monoethanolamine, alizapride, azasetron, benzquinamide, biantanautine, bromopride, buclizine, clebopride, cyclizine, dimenhydrinate, diphenidol, dolasetron, meclizine, methallatal, metopimazine, nabilone, oxyperndyl, pipamazine, scopolamine, sulpiride, **tetrahydrocannabinol,**

	<p>thiethylperazine, thioproperazine, tropisetron, droperidol, haloperidol, prochlorperazine, metoclopramide, diphenhydramine, cannabis, midazolam, lorazepam, hyoscine, dexamethasone, emetrol, propofol, or a combination thereof.”</p>
<p>12. The pharmaceutical composition of claim 1 which is formulated as a patch.</p>	<p>2. W.I.P.O. Pat. App. No. 2020/157569 “METHODS AND COMPOSITIONS COMPRISING A 5HT RECEPTOR AGONIST FOR THE TREATMENT OF PSYCHOLOGICAL, COGNITIVE, BEHAVIORAL, AND/OR MOOD DISORDERS” (Published August 6, 2020)</p> <p>From claim 1 “A method of managing a neurological condition or one or more symptoms thereof in a subject in need thereof, comprising administering to the subject a pharmaceutical composition comprising: a) a therapeutically effective amount of one or more 5HT receptor agonist or a pharmaceutically acceptable salt, solvate, metabolite, derivative, or prodrug thereof; and b) a pharmaceutically acceptable excipient wherein the therapeutically effective amount of the 5HT receptor agonist or a pharmaceutically acceptable salt, solvate, metabolite, derivative, or prodrug thereof is provided to the subject in need thereof in an amount insufficient to provide an adverse side effect, such as hallucinogenic experience.”</p> <p>From claim 13 “The method of any one of the preceding claims, wherein the 5HT receptor agonist is psilocybin or a pharmaceutically acceptable salt, solvate, metabolite, derivative, or prodrug thereof.”</p> <p>From claim 14 “The method of any one of claims 1-12, wherein the 5HT receptor agonist is psilocin or a pharmaceutically acceptable salt, solvate, metabolite, derivative, or prodrug thereof.”</p> <p>From claim 17 “The method of any one of the preceding claims, wherein the pharmaceutical composition is in a form selected from a spray, aerosol, mist, nebulae, ointment, cream, gel, paste, salve, solution, suspension, tincture, patch, and atomized vapor.”</p> <p>From [0047] “Examples of tryptamines include serotonin, melatonin, psilocybin and N,N-dimethyltryptamine. Additionally, the tryptamine structure may comprise part of a more complex compound, for example: LSD, ibogaine, mitragynine, yohimbine, etc.”</p> <p>From [0112] “In some embodiments, a coating or layer (e.g. an immediate release or controlled release coating or layer) comprises an antiemetic. In some embodiments, the antiemetic is selected from the group consisting of aprepitant, dronabinol, perphenazine, palonosetron, trimethobenzamide, metoclopramide, domperidone, prochlorperazine, promethazine, chlorpromazine, trimethobenzamide, ondansetron,</p>

	<p>granisetron, hydroxyzine, acetylleucine monoethanolamine, alizapride, azasetron, benzquinamide, bietanautine, bromopride, buclizine, clebopride, cyclizine, dimenhydrinate, diphenidol, dolasetron, meclizine, methallatal, metopimazine, nabilone, oxyperndyl, pipamazine, scopolamine, sulpiride, tetrahydrocannabinol, thiethylperazine, thioproperazine, tropisetron, droperidol, haloperidol, prochlorperazine, metoclopramide, diphenhydramine, cannabis, midazolam, lorazepam, hyoscine, dexamethasone, emetrol, propofol, or a combination thereof.”</p>
<p>13. The pharmaceutical composition of claim 1 which is formulated as two or more patches.</p>	<p>7. W.I.P.O. Pat. App. No. 2018/135943 “PSILOCYBIN AND/OR PSILOCIN IN COMBINATION WITH CANNABINOIDS AND/OR TERPENES” (Published July 26, 2018)</p> <p>From page 14 paragraph 2 “Also encompassed are dosage forms for transdermal administration, including creams, lotions, aerosols and/or emulsions. These dosage forms may be included in transdermal patches of the matrix or reservoir type, which are generally known in the art. Pharmaceutical preparations dose (for the cannabinoid, terpene and/or the psilocybin/psilocin) may be conveniently prepared in unit dosage form, according to standard procedures of pharmaceutical formulation.</p> <p>The quantity of active compound(s) per unit dose may be varied according to the nature of the active compound and the intended dosage regime. Generally an effective amount shall be used, which may be within the range of from 0.01 mg to 5000 mg, preferably 0.01-4000 mg, 0.1-3000 mg, 1-2500, 5-1000, or 10-100 mg per unit dose (for the at least one cannabinoid and/or the at least one terpene and/or the at least one psilocybin and/or the at least one psilocin).”</p> <p>11. W.I.P.O. Pat. App. No. 2020/123625 “Co-crystals, method and apparatus for forming the same” (Published June 18, 2020)</p> <p>From claim 14 “The method of any one of claims 1 -13, wherein the organic compound is selected from the group consisting of caffeine, carbamazepine, 5-methoxy sulfadiazine, ethenzamide, nalidixic acid, isoniazid, furosemide, sulfadimidine, celecoxib, temozolamide, piroxicam, tryptamine, chlorzoxazone, p-coumaric, itraconazole, fluoxetine, telaprevir, sildenafil, theophylline, aceclofenac, 5-nitrouracil, indomethacin, aripiprazole, and atorvastatin, or a mixture thereof.”</p> <p>From claim 38 “The method of any one of claims 1 -37, wherein the substrate is a medical device.”</p>

	<p>From claim 39 “The method of claim 38, wherein the medical device is selected from the group consisting of a stent, needle, microneedle, probe, syringe, cannula, catheter, sponge, clip, mesh, bandage, gauze, dressing, tape, swab, burn dressing, staple, implant, contact lens, medical tubing, adhesive patches, artificial tissue, endoscopic device.”</p> <p>From [0073] “The disclosure also provides a co-crystal-coated needle (see e.g. FIG. 7) coating a needle or microneedle patch with a co-crystal prior to insertion into the skin, rather than direct injection, can enable a new route of treatment that does not require deep insertion, alleviating patient discomfort.”</p> <p>From [0077] “In various cases, the medical device is selected from the group consisting of a stent, needle, microneedle, syringe, cannula, catheter, sponge, clip, mesh, bandage, gauze, dressing, tape, swab, burn dressing, staple, implant, contact lens, medical tubing, adhesive patches, intraocular lens, endoscopic device, punctal plugs, buccal patches, lingual patches, sub-lingual patches, electrode patches, and combinations thereof.”</p>
<p>14. The pharmaceutical composition of claim 1 wherein the two or more patches each comprise the same active agent.</p>	<p>7. W.I.P.O. Pat. App. No. 2018/135943 “PSILOCYBIN AND/OR PSILOCIN IN COMBINATION WITH CANNABINOIDS AND/OR TERPENES” (Published July 26, 2018)</p> <p>From page 14 paragraph 2 “Also encompassed are dosage forms for transdermal administration, including creams, lotions, aerosols and/or emulsions. These dosage forms may be included in transdermal patches of the matrix or reservoir type, which are generally known in the art. Pharmaceutical preparations dose (for the cannabinoid, terpene and/or the psilocybin/psilocin) may be conveniently prepared in unit dosage form, according to standard procedures of pharmaceutical formulation.</p> <p>The quantity of active compound(s) per unit dose may be varied according to the nature of the active compound and the intended dosage regime. Generally an effective amount shall be used, which may be within the range of from 0.01 mg to 5000 mg, preferably 0.01-4000 mg, 0.1-3000 mg, 1-2500, 5-1000, or 10-100 mg per unit dose (for the at least one cannabinoid and/or the at least one terpene and/or the at least one psilocybin and/or the at least one psilocin.)”</p> <p>11. W.I.P.O. Pat. App. No. 2020/123625 “Co-crystals, method and apparatus for forming the same” (Published June 18, 2020)</p> <p>From claim 14 “The method of any one of claims 1 -13, wherein the organic compound is selected from the group consisting of caffeine, carbamazepine, 5-methoxy sulfadiazine, ethenzamide, nalidixic acid,</p>

	<p>isoniazid, furosemide, sulfadimidine, celecoxib, temozolamide, piroxicam, tryptamine, chlorzoxazone, p-coumaric, itraconazole, fluoxetine, telaprevir, sildenafil, theophylline, aceclofenac, 5-nitouracil, indomethacin, aripiprazole, and atorvastatin, or a mixture thereof.”</p> <p>From claim 38 “The method of any one of claims 1 -37, wherein the substrate is a medical device.”</p> <p>From claim 39 “The method of claim 38, wherein the medical device is selected from the group consisting of a stent, needle, microneedle, probe, syringe, cannula, catheter, sponge, clip, mesh, bandage, gauze, dressing, tape, swab, burn dressing, staple, implant, contact lens, medical tubing, adhesive patches, artificial tissue, endoscopic device.”</p> <p>From [0073] “The disclosure also provides a co-crystal-coated needle (see e.g. FIG. 7) coating a needle or microneedle patch with a co-crystal prior to insertion into the skin, rather than direct injection, can enable a new route of treatment that does not require deep insertion, alleviating patient discomfort.”</p> <p>From [0077] “In various cases, the medical device is selected from the group consisting of a stent, needle, microneedle, syringe, cannula, catheter, sponge, clip, mesh, bandage, gauze, dressing, tape, swab, burn dressing, staple, implant, contact lens, medical tubing, adhesive patches, intraocular lens, endoscopic device, punctal plugs, buccal patches, lingual patches, sub-lingual patches, electrode patches, and combinations thereof.”</p>
<p>15. The pharmaceutical composition of claim 1 wherein the two or more patches each comprise different active agents.</p>	<p>11. W.I.P.O. Pat. App. No. 2020/123625 “Co-crystals, method and apparatus for forming the same” (Published June 18, 2020)</p> <p>From claim 14 “The method of any one of claims 1 -13, wherein the organic compound is selected from the group consisting of caffeine, carbamazepine, 5-methoxy sulfadiazine, ethenzamide, nalidixic acid, isoniazid, furosemide, sulfadimidine, celecoxib, temozolamide, piroxicam, tryptamine, chlorzoxazone, p-coumaric, itraconazole, fluoxetine, telaprevir, sildenafil, theophylline, aceclofenac, 5-nitouracil, indomethacin, aripiprazole, and atorvastatin, or a mixture thereof.”</p> <p>From claim 38 “The method of any one of claims 1 -37, wherein the substrate is a medical device.”</p> <p>From claim 39 “The method of claim 38, wherein the medical device is selected from the group consisting of a stent, needle, microneedle, probe, syringe, cannula, catheter, sponge, clip, mesh, bandage, gauze,</p>

	<p>dressing, tape, swab, burn dressing, staple, implant, contact lens, medical tubing, adhesive patches, artificial tissue, endoscopic device.”</p> <p>From [0073] “The disclosure also provides a co-crystal-coated needle (see e.g. FIG. 7) coating a needle or microneedle patch with a co-crystal prior to insertion into the skin, rather than direct injection, can enable a new route of treatment that does not require deep insertion, alleviating patient discomfort.”</p> <p>From [0077] “In various cases, the medical device is selected from the group consisting of a stent, needle, microneedle, syringe, cannula, catheter, sponge, clip, mesh, bandage, gauze, dressing, tape, swab, burn dressing, staple, implant, contact lens, medical tubing, adhesive patches, intraocular lens, endoscopic device, punctal plugs, buccal patches, lingual patches, sub-lingual patches, electrode patches, and combinations thereof.”</p>
<p>16. The pharmaceutical composition of claim 1 wherein the two or more patches each comprise the same or different active agents.</p>	<p>11. W.I.P.O. Pat. App. No. 2020/123625 “Co-crystals, method and apparatus for forming the same” (Published June 18, 2020)</p> <p>From claim 14 “The method of any one of claims 1 -13, wherein the organic compound is selected from the group consisting of caffeine, carbamazepine, 5-methoxy sulfadiazine, ethenzamide, nalidixic acid, isoniazid, furosemide, sulfadimidine, celecoxib, temozolamide, piroxicam, tryptamine, chlorzoxazone, p-coumaric, itraconazole, fluoxetine, telaprevir, sildenafil, theophylline, aceclofenac, 5-nitouracil, indomethacin, aripiprazole, and atorvastatin, or a mixture thereof.”</p> <p>From claim 38 “The method of any one of claims 1 -37, wherein the substrate is a medical device.”</p> <p>From claim 39 “The method of claim 38, wherein the medical device is selected from the group consisting of a stent, needle, microneedle, probe, syringe, cannula, catheter, sponge, clip, mesh, bandage, gauze, dressing, tape, swab, burn dressing, staple, implant, contact lens, medical tubing, adhesive patches, artificial tissue, endoscopic device.”</p> <p>From [0073] “The disclosure also provides a co-crystal-coated needle (see e.g. FIG. 7) coating a needle or microneedle patch with a co-crystal prior to insertion into the skin, rather than direct injection, can enable a new route of treatment that does not require deep insertion, alleviating patient discomfort.”</p> <p>From [0077] “In various cases, the medical device is selected from the group consisting of a stent, needle, microneedle, syringe, cannula, catheter, sponge, clip, mesh, bandage, gauze, dressing, tape, swab, burn</p>

	<p>dressing, staple, implant, contact lens, medical tubing, adhesive patches, intraocular lens, endoscopic device, punctal plugs, buccal patches, lingual patches, sub-lingual patches, electrode patches, and combinations thereof.</p>
<p>17. The pharmaceutical composition of claim 1 which is formulated as a transdermal patch.</p>	<p>7. W.I.P.O. Pat. App. No. 2018/135943 “PSILOCYBIN AND/OR PSILOCIN IN COMBINATION WITH CANNABINOIDS AND/OR TERPENES” (Published July 26, 2018)</p> <p>From page 14 paragraph 2 “Also encompassed are dosage forms for transdermal administration, including creams, lotions, aerosols and/or emulsions. These dosage forms may be included in transdermal patches of the matrix or reservoir type, which are generally known in the art. Pharmaceutical preparations dose (for the cannabinoid, terpene and/or the psilocybin/psilocin) may be conveniently prepared in unit dosage form, according to standard procedures of pharmaceutical formulation.</p> <p>The quantity of active compound(s) per unit dose may be varied according to the nature of the active compound and the intended dosage regime. Generally an effective amount shall be used, which may be within the range of from 0.01 mg to 5000 mg, preferably 0.01-4000 mg, 0.1-3000 mg, 1-2500, 5-1000, or 10-100 mg per unit dose (for the at least one cannabinoid and/or the at least one terpene and/or the at least one psilocybin and/or the at least one psilocin.”</p>
<p>18. The pharmaceutical composition of claim 1 formulated as a transdermal patch, wherein the transdermal patch is selected from the group consisting of a reservoir patch, a microreservoir patch, a micro-dosing patch, a matrix patch, a drug in adhesive patch, a pressure sensitive adhesive patch, extended-release transdermal film a liquid reservoir system, a microreservoir patch, a mucoadhesive patch, multilayer transdermal matrix system, and combinations thereof.</p>	<p>10. U.S. Pat. App. No. 2020/0085816 “LSD FOR THE TREATMENT OF ALZHEIMER'S DISEASE” (Published March 19, 2020)</p> <p>From claim 40 “A transdermal delivery system comprising a pharmaceutically effective amount of a neuronal growth factor, 2 µg to 30 µg of lysergic acid diethylamide or a pharmaceutically acceptable salt thereof, and a naturally occurring gum.”</p> <p>From paragraph [0059] “There are several approaches for providing rate control over the release and transdermal permeation of a drug, including: membrane-moderated systems, adhesive diffusion-controlled systems, matrix dispersion-type systems, and microreservoir systems. A controlled release percutaneous and/or topical composition may be obtained by using a suitable mixture of the above-mentioned approaches.”</p> <p>From paragraph [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</p>

	<p>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.”</p>
<p>19. The pharmaceutical composition of claim 1, which is formulated as a topical patch.</p>	<p>2. W.I.P.O. Pat. App. No. 2020/157569 “METHODS AND COMPOSITIONS COMPRISING A 5HT RECEPTOR AGONIST FOR THE TREATMENT OF PSYCHOLOGICAL, COGNITIVE, BEHAVIORAL, AND/OR MOOD DISORDERS” (Published August 6, 2020)</p> <p>From claim 1 “A method of managing a neurological condition or one or more symptoms thereof in a subject in need thereof, comprising administering to the subject a pharmaceutical composition comprising: a) a therapeutically effective amount of one or more 5HT receptor agonist or a pharmaceutically acceptable salt, solvate, metabolite, derivative, or prodrug thereof; and b) a pharmaceutically acceptable excipient wherein the therapeutically effective amount of the 5HT receptor agonist or a pharmaceutically acceptable salt, solvate, metabolite, derivative, or prodrug thereof is provided to the subject in need thereof in an amount insufficient to provide an adverse side effect, such as hallucinogenic experience.”</p> <p>From claim 13 “The method of any one of the preceding claims, wherein the 5HT receptor agonist is psilocybin or a pharmaceutically acceptable salt, solvate, metabolite, derivative, or prodrug thereof.”</p> <p>From claim 14 “The method of any one of claims 1-12, wherein the 5HT receptor agonist is psilocin or a pharmaceutically acceptable salt, solvate, metabolite, derivative, or prodrug thereof.”</p> <p>From claim 17 “The method of any one of the preceding claims, wherein the pharmaceutical composition is in a form selected from a spray, aerosol, mist, nebulae, ointment, cream, gel, paste, salve, solution, suspension, tincture, patch, and atomized vapor.”</p> <p>From [0162] “In some embodiments, 5HT receptor agonists or pharmaceutical compositions or formulations described herein are administered to a subject by multiple administration routes, including but not limited to, oral, parenteral (e.g. intravenous,</p>

	<p>subcutaneous, intramuscular), intranasal, inhalation, buccal, topical, rectal, or transdermal administration routes”</p> <p>From [0042] “In certain embodiments, the 5-HT_{2A} agonist provided herein is one of the following classes of 5-HT_{2A} agonists: the ergolines, tryptamines and phenethylamines. In specific embodiments, a 5HT (e.g.5HT_{2A}) receptor agonist utilized herein is an ergoline”</p> <p>From [0047] “Examples of tryptamines include serotonin, melatonin, psilocybin and N,N-dimethyltryptamine. Additionally, the tryptamine structure may comprise part of a more complex compound, for example: LSD, ibogaine, mitragynine, yohimbine, etc.”</p> <p>From [0112] “In some embodiments, a coating or layer (e.g. an immediate release or controlled release coating or layer) comprises an antiemetic. In some embodiments, the antiemetic is selected from the group consisting of aprepitant, dronabinol, perphenazine, palonosetron, trimethobenzamide, metoclopramide, domperidone, prochlorperazine, promethazine, chlorpromazine, trimethobenzamide, ondansetron, granisetron, hydroxyzine, acetylleucine monoethanolamine, alizapride, azasetron, benzquinamide, bietanautine, bromopride, buclizine, clebopride, cyclizine, dimenhydrinate, diphenidol, dolasetron, meclizine, methallatal, metopimazine, nabilone, oxyperndyl, pipamazine, scopolamine, sulpiride, tetrahydrocannabinol, thiethylperazine, thioproperazine, tropisetron, droperidol, haloperidol, prochlorperazine, metoclopramide, diphenhydramine, cannabis, midazolam, lorazepam, hyoscine, dexamethasone, emetrol, propofol, or a combination thereof.”</p>
<p>20. The pharmaceutical composition of claim 1 formulated as a topical patch, wherein the topical patch is selected from the group consisting of a reservoir patch, a microreservoir patch, a matrix patch, a drug in adhesive patch, a pressure sensitive adhesive patch, extended-release transdermal film a liquid reservoir system, a microreservoir patch, a mucoadhesive patch, a micro-dosing patch, multilayer transdermal</p>	<p>2. W.I.P.O. Pat. App. No. 2020/157569 “METHODS AND COMPOSITIONS COMPRISING A 5HT RECEPTOR AGONIST FOR THE TREATMENT OF PSYCHOLOGICAL, COGNITIVE, BEHAVIORAL, AND/OR MOOD DISORDERS” (Published August 6, 2020)</p> <p>From claim 1 “A method of managing a neurological condition or one or more symptoms thereof in a subject in need thereof, comprising administering to the subject a pharmaceutical composition comprising:</p> <p>a) a therapeutically effective amount of one or more 5HT receptor agonist or a pharmaceutically acceptable salt, solvate, metabolite, derivative, or prodrug thereof; and</p> <p>b) a pharmaceutically acceptable excipient wherein the therapeutically effective amount of the 5HT receptor agonist or a pharmaceutically acceptable salt, solvate, metabolite, derivative, or prodrug thereof is provided to the subject in need thereof in an amount insufficient to provide an adverse side effect, such as hallucinogenic experience.”</p>

<p>matrix system, and combinations thereof.</p>	<p>From claim 13 “The method of any one of the preceding claims, wherein the 5HT receptor agonist is psilocybin or a pharmaceutically acceptable salt, solvate, metabolite, derivative, or prodrug thereof.”</p> <p>From claim 14 “The method of any one of claims 1-12, wherein the 5HT receptor agonist is psilocin or a pharmaceutically acceptable salt, solvate, metabolite, derivative, or prodrug thereof.”</p> <p>From claim 17 “The method of any one of the preceding claims, wherein the pharmaceutical composition is in a form selected from a spray, aerosol, mist, nebulae, ointment, cream, gel, paste, salve, solution, suspension, tincture, patch, and atomized vapor.”</p> <p>From [0162] “In some embodiments, 5HT receptor agonists or pharmaceutical compositions or formulations described herein are administered to a subject by multiple administration routes, including but not limited to, oral, parenteral (e.g. intravenous, subcutaneous, intramuscular), intranasal, inhalation, buccal, topical, rectal, or transdermal administration routes”</p> <p>From [0042] “In certain embodiments, the 5-HT_{2A} agonist provided herein is one of the following classes of 5-HT_{2A} agonists: the ergolines, tryptamines and phenethylamines. In specific embodiments, a 5HT (e.g.5HT_{2A}) receptor agonist utilized herein is an ergoline”</p> <p>From [0047] “Examples of tryptamines include serotonin, melatonin, psilocybin and N,N-dimethyltryptamine. Additionally, the tryptamine structure may comprise part of a more complex compound, for example: LSD, ibogaine, mitragynine, yohimbine, etc.”</p> <p>From [0112] “In some embodiments, a coating or layer (e.g. an immediate release or controlled release coating or layer) comprises an antiemetic. In some embodiments, the antiemetic is selected from the group consisting of aprepitant, dronabinol, perphenazine, palonosetron, trimethobenzamide, metoclopramide, domperidone, prochlorperazine, promethazine, chlorpromazine, trimethobenzamide, ondansetron, granisetron, hydroxyzine, acetylleucine monoethanolamine, alizapride, azasetron, benzquinamide, biantanautine, bromopride, buclizine, clebopride, cyclizine, dimenhydrinate, diphenidol, dolasetron, meclizine, methallatal, metopimazine, nabilone, oxyperndyl, pipamazine, scopolamine, sulpiride, tetrahydrocannabinol, thiethylperazine, thioproperazine, tropisetron, droperidol, haloperidol, prochlorperazine, metoclopramide, diphenhydramine, cannabis, midazolam, lorazepam, hyoscine, dexamethasone, emetrol, propofol, or a combination thereof.”</p>
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	<p>10. U.S. Pat. App. No. 2020/0085816 “LSD FOR THE TREATMENT OF ALZHEIMER'S DISEASE” (Published March 19, 2020)</p> <p>From claim 40 “A transdermal delivery system comprising a pharmaceutically effective amount of a neuronal growth factor, 2 µg to 30 µg of lysergic acid diethylamide or a pharmaceutically acceptable salt thereof, and a naturally occurring gum.”</p> <p>From paragraph [0059] “There are several approaches for providing rate control over the release and transdermal permeation of a drug, including: membrane-moderated systems, adhesive diffusion-controlled systems, matrix dispersion-type systems, and microreservoir systems. A controlled release percutaneous and/or topical composition may be obtained by using a suitable mixture of the above-mentioned approaches.”</p> <p>From paragraph [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.”</p>
<p>21. The pharmaceutical composition of claim 1 which is formulated as metered dose transdermal gel, metered dose transdermal spray, a film forming gel, a film forming spray, or a meter-dose aerosol.</p>	<p>2. W.I.P.O. Pat. App. No. 2020/157569 “METHODS AND COMPOSITIONS COMPRISING A 5HT RECEPTOR AGONIST FOR THE TREATMENT OF PSYCHOLOGICAL, COGNITIVE, BEHAVIORAL, AND/OR MOOD DISORDERS” (Published August 6, 2020)</p> <p>From claim 1 “A method of managing a neurological condition or one or more symptoms thereof in a subject in need thereof, comprising administering to the subject a pharmaceutical composition comprising: a) a therapeutically effective amount of one or more 5HT receptor agonist or a pharmaceutically acceptable salt, solvate, metabolite, derivative, or prodrug thereof; and</p>

b) a pharmaceutically acceptable excipient wherein the therapeutically effective amount of the **5HT receptor agonist** or a pharmaceutically acceptable salt, solvate, metabolite, derivative, or prodrug thereof is provided to the subject in need thereof **in an amount insufficient to provide an adverse side effect, such as hallucinogenic experience.**”

From **claim 13** “The method of any one of the preceding claims, wherein the **5HT receptor agonist** is **psilocybin** or a pharmaceutically acceptable salt, solvate, metabolite, derivative, or prodrug thereof.”

From **claim 14** “The method of any one of claims 1-12, wherein the 5HT receptor agonist is **psilocin** or a pharmaceutically acceptable salt, solvate, metabolite, derivative, or prodrug thereof.”

From **claim 17** “The method of any one of the preceding claims, wherein the pharmaceutical composition is in a form selected from a **spray, aerosol, mist, nebulae, ointment, cream, gel, paste, salve, solution, suspension, tincture, patch,** and atomized vapor.”

From **[0042]** “In certain embodiments, the 5-HT_{2A} agonist provided herein is one of the following classes of 5-HT_{2A} agonists: the ergolines, **tryptamines** and phenethylamines. In specific embodiments, a 5HT (e.g.5HT_{2A}) receptor agonist utilized herein is an ergoline”

From **[0047]** “Examples of **tryptamines** include serotonin, melatonin, **psilocybin** and N,N-dimethyltryptamine. Additionally, the tryptamine structure may comprise part of a more complex compound, for example: **LSD, ibogaine,** mitragynine, yohimbine, etc.”

From **[0112]** “In some embodiments, a coating or layer (e.g. an immediate release or controlled release coating or layer) comprises an antiemetic. In some embodiments, the antiemetic is selected from the group consisting of aprepitant, dronabinol, perphenazine, palonosetron, trimethobenzamide, metoclopramide, domperidone, prochlorperazine, promethazine, chlorpromazine, trimethobenzamide, ondansetron, granisetron, hydroxyzine, acetylleucine monoethanolamine, alizapride, azasetron, benzquinamide, biantanautine, bromopride, buclizine, clebopride, cyclizine, dimenhydrinate, diphenidol, dolasetron, meclizine, methallatal, metopimazine, nabilone, oxypendyl, pipamazine, scopolamine, sulpiride, **tetrahydrocannabinol,** thiethylperazine, thioproperazine, tropisetron, droperidol, haloperidol, prochlorperazine, metoclopramide, diphenhydramine, **cannabis,** midazolam, lorazepam, hyoscine, dexamethasone, emetrol, propofol, or a combination thereof.”

<p>22. The pharmaceutical composition of claim 1 formulated as microneedles.</p>	<p>11. W.I.P.O. Pat. App. No. 2020/123625 “Co-crystals, method and apparatus for forming the same” (Published June 18, 2020)</p> <p>From claim 14 “The method of any one of claims 1 -13, wherein the organic compound is selected from the group consisting of caffeine, carbamazepine, 5-methoxy sulfadiazine, ethenzamide, nalidixic acid, isoniazid, furosemide, sulfadimidine, celecoxib, temozolamide, piroxicam, tryptamine, chlorzoxazone, p-coumaric, itraconazole, fluoxetine, telaprevir, sildenafil, theophylline, aceclofenac, 5-nitrouracil, indomethacin, aripiprazole, and atorvastatin, or a mixture thereof.”</p> <p>From claim 38 “The method of any one of claims 1 -37, wherein the substrate is a medical device.”</p> <p>From claim 39 “The method of claim 38, wherein the medical device is selected from the group consisting of a stent, needle, microneedle, probe, syringe, cannula, catheter, sponge, clip, mesh, bandage, gauze, dressing, tape, swab, burn dressing, staple, implant, contact lens, medical tubing, adhesive patches, artificial tissue, endoscopic device.”</p> <p>From [0073] “The disclosure also provides a co-crystal-coated needle (see e.g. FIG. 7) coating a needle or microneedle patch with a co-crystal prior to insertion into the skin, rather than direct injection, can enable a new route of treatment that does not require deep insertion, alleviating patient discomfort.”</p> <p>From [0077] “In various cases, the medical device is selected from the group consisting of a stent, needle, microneedle, syringe, cannula, catheter, sponge, clip, mesh, bandage, gauze, dressing, tape, swab, burn dressing, staple, implant, contact lens, medical tubing, adhesive patches, intraocular lens, endoscopic device, punctal plugs, buccal patches, lingual patches, sub-lingual patches, electrode patches, and combinations thereof.”</p>
<p>23. The pharmaceutical composition of claim 1 formulated as a liquid formulation, transdermal semisolid formulation, or transdermal polymer matrix formulation, transdermal adhesive matrix formulation, film forming gel formulation, film forming spray formulation.</p>	<p>10. U.S. Pat. App. No. 2020/0085816 “LSD FOR THE TREATMENT OF ALZHEIMER'S DISEASE” (Published March 19, 2020)</p> <p>From claim 40 “A transdermal delivery system comprising a pharmaceutically effective amount of a neuronal growth factor, 2 µg to 30 µg of lysergic acid diethylamide or a pharmaceutically acceptable salt thereof, and a naturally occurring gum.”</p> <p>From paragraph [0059] “There are several approaches for providing rate control over the release and transdermal permeation of a drug, including: membrane-moderated systems, adhesive diffusion-controlled systems, matrix dispersion-type systems, and</p>

microreservoir systems. A controlled release percutaneous and/or topical composition may be obtained by using a suitable mixture of the above-mentioned approaches.”

From **paragraph [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. W.I.P.O. Pat. App. No. 2020/157569 “METHODS AND COMPOSITIONS COMPRISING A 5HT RECEPTOR AGONIST FOR THE TREATMENT OF PSYCHOLOGICAL, COGNITIVE, BEHAVIORAL, AND/OR MOOD DISORDERS” (Published August 6, 2020)

From **claim 1** “A method of managing a neurological condition or one or more symptoms thereof in a subject in need thereof, comprising administering to the subject a pharmaceutical composition comprising:
a) a therapeutically effective amount of one or more 5HT receptor agonist or a pharmaceutically acceptable salt, solvate, metabolite, derivative, or prodrug thereof; and
b) a pharmaceutically acceptable excipient wherein the therapeutically effective amount of the **5HT receptor agonist** or a pharmaceutically acceptable salt, solvate, metabolite, derivative, or prodrug thereof is provided to the subject in need thereof **in an amount insufficient to provide an adverse side effect, such as hallucinogenic experience.**”

From **claim 13** “The method of any one of the preceding claims, wherein the **5HT receptor agonist** is **psilocybin** or a pharmaceutically acceptable salt, solvate, metabolite, derivative, or prodrug thereof.”

	<p>From claim 14 “The method of any one of claims 1-12, wherein the 5HT receptor agonist is psilocin or a pharmaceutically acceptable salt, solvate, metabolite, derivative, or prodrug thereof.”</p> <p>From claim 17 “The method of any one of the preceding claims, wherein the pharmaceutical composition is in a form selected from a spray, aerosol, mist, nebulae, ointment, cream, gel, paste, salve, solution, suspension, tincture, patch, and atomized vapor.”</p> <p>From [0042] “In certain embodiments, the 5-HT_{2A} agonist provided herein is one of the following classes of 5-HT_{2A} agonists: the ergolines, tryptamines and phenethylamines. In specific embodiments, a 5HT (e.g.5HT_{2A}) receptor agonist utilized herein is an ergoline”</p> <p>From [0047] “Examples of tryptamines include serotonin, melatonin, psilocybin and N,N-dimethyltryptamine. Additionally, the tryptamine structure may comprise part of a more complex compound, for example: LSD, ibogaine, mitragynine, yohimbine, etc.”</p> <p>From [0112] “In some embodiments, a coating or layer (e.g. an immediate release or controlled release coating or layer) comprises an antiemetic. In some embodiments, the antiemetic is selected from the group consisting of aprepitant, dronabinol, perphenazine, palonosetron, trimethobenzamide, metoclopramide, domperidone, prochlorperazine, promethazine, chlorpromazine, trimethobenzamide, ondansetron, granisetron, hydroxyzine, acetylleucine monoethanolamine, alizapride, azasetron, benzquinamide, bietanautine, bromopride, buclizine, clebopride, cyclizine, dimenhydrinate, diphenidol, dolasetron, meclizine, methallatal, metopimazine, nabilone, oxyperndyl, pipamazine, scopolamine, sulpiride, tetrahydrocannabinol, thiethylperazine, thioproperazine, tropisetron, droperidol, haloperidol, prochlorperazine, metoclopramide, diphenhydramine, cannabis, midazolam, lorazepam, hyoscine, dexamethasone, emetrol, propofol, or a combination thereof.”</p>
<p>24. The pharmaceutical composition of claim 1 further comprising at least one additional active agent selected from the group consisting of THC, CBD, psilocybin, psilocin, lysergic acid diethylamine (LSD), and/or ibogaine, antidepressant drug, NSAIDS, anticonvulsants drug, corticosteroid drug, pain relievers, lidocaine,</p>	<p>2. W.I.P.O. Pat. App. No. 2020/157569 “METHODS AND COMPOSITIONS COMPRISING A 5HT RECEPTOR AGONIST FOR THE TREATMENT OF PSYCHOLOGICAL, COGNITIVE, BEHAVIORAL, AND/OR MOOD DISORDERS” (Published August 6, 2020)</p> <p>From [0025] “Also disclosed herein is a pharmaceutical composition comprising an oral dosage form, the oral dosage form comprising an immediate-release top layer and a controlled release core. In some embodiments, the immediate-release layer comprising (i) one or more 5HT receptor agonist or a pharmaceutically acceptable salt, solvate, metabolite, derivative, or prodrug thereof and (ii) one or more second agent. In some embodiments, the one or more second agent being a</p>

<p>menthol, capsaicin, methyl salicylate, lidocaine, capsaicin, Tricyclic Antidepressants, amitriptyline, imipramine, nortriptyline, desipramine, doxepin, SNRIs and SSRIs, duloxetine, venlafaxine, fluoxetine, milnacipran, diclofenac, aspirin, naproxen, ibuprofen, ketoprofen, celecoxib, meloxicam, acetaminophen, cox-2 inhibitors, celecoxib, anticonvulsants, carbamazepine, gabapentin, lamotrigine, pregabalin, oxcarbazepine, lamotrigine, valproic acid, menthol, camphor, methyl salicylate, salicylates, corticosteroid drugs, triamcinolone, methylprednisolone, cortisone, prednisone, dexamethasone, opioids, and combinations thereof.</p>	<p>stimulant, an antihistamine, an antiemetic, an antidepressant, an anti-inflammatory, a growth factor, a lithium compound, resveratrol, phosphatidylcholine, curcumin, magnesium, melatonin, pregnenolone, ginseng, or lysergic acid diethylamide.”</p> <p>From [0114] “In some embodiments, a coating or layer (e.g. immediate release or controlled release coating or layer) comprises an antidepressant. In some embodiments, the antidepressant is selected from the group consisting of Abilify (aripiprazole), Adapin (doxepin), Anafranil (clomipramine), Aplenzin (bupropion), Asendin (amoxapine), Aventyl HCl (nortriptyline), Celexa (citalopram), Cymbalta (duloxetine), Desyrel (trazodone), Effexor XR (venlafaxine), Emsam (selegiline), Etrafon (perphenazine and amitriptyline), Elavil (amitriptyline), Endep (amitriptyline), Fetzima (levomilnacipran), Khedezla (desvenlafaxine), Latuda (lurasidone), Lamictal (lamotrigine), Lexapro (escitalopram), Limbitrol (amitriptyline and chlordiazepoxide), Marplan (isocarboxazid), Nardil (phenelzine), Norpramin (desipramine), Oleptro (trazodone), Pamelor (nortriptyline), Parnate (tranylecypromine), Paxil (paroxetine), Pexeva (paroxetine), Prozac (fluoxetine), Pristiq (desvenlafaxine), Remeron (mirtazapine), Sarafem (fluoxetine), Seroquel XR (quetiapine), Serzone (nefazodone), Sinequan (doxepin), Surmontil (trimipramine), Symbyax (fluoxetine) and the atypical antipsychotic drug olanzapine), Tofranil (imipramine), Triavil (perphenazine and amitriptyline), Trintellix (vortioxetine), Viibryd (vilazodone), Vivactil (protriptyline), Wellbutrin (bupropion), Zoloft (sertraline), and Zyprexa (olanzapine). [115] In some embodiments, a coating or layer (e.g. immediate release or controlled release coating or layer) comprises an anti-inflammatory. In some embodiments, the anti-inflammatory is selected from the group consisting of Aceclofenac, Aspirin, Celecoxib, Diclofenac, Diflunisal, Etodolac, Etoricoxib, Fenoprofen, Flurbiprofen, Ibuprofen, Indomethacin, Ketoprofen, Ketorolac, Lornoxicam, Loxoprofen, Mefenamic acid, Meloxicam, Montelukast, Nabumetone, Naproxen, Oxaprozin, Phenylbutazone, Piroxicam, Pranlukast, Salsalate, Sulindac, Tenoxicam, Tiaprofenic acid, Tolmetin, Valdecoxib, Zafirlukast, and Zileuton.”</p>
<p>25. The pharmaceutical composition of claim 1 further comprising carriers or ingredients in effective amount selected from the group consisting of solvents, gelling agents, polymers, pressure sensitive adhesive polymers, penetration enhancers, emollients, skin irritation reducing agents, buffering agents, pH stabilizers, solubilizers, suspending agents,</p>	<p>1. U.S. Pat. App. Pub. No. 2011/0111029 “Composition for transdermal delivery of cationic active agents” (Published 12 May 2011)</p> <p>From claim 1 “1. A composition for transdermal delivery of at least one cationic active agent or a salt thereof, comprising: said at least one cationic active agent or a salt thereof; at least one polyamine in the form of a polyamine salt, obtained by combining or reacting said at least one polyamine with a suitable acid; water or an aqueous solvent mixture; and optionally, one or more additives.”</p> <p>From [0102] “The composition according to the present invention may optionally contain one or more further additives. Said additives</p>

<p>dispersing agents, stabilizers, plasticizers, tackifiers, diluents, bulking agents, surfactants, antioxidants, oxidants, and combinations thereof in the range of 0.1%-99.5% w/w or w/v.</p>	<p>include, but are not limited to, additives selected from the group comprising solubility enhancers, skin permeation enhancers, preservatives and antimicrobial agents.”</p> <p>From paragraph [0101] “Generally, it is preferred to adjust and maintain the pH in said water-containing compositions such they do not substantially affect the ph of the skin, when the compositions are applied to the skin (e.g. during transdermal or iontophoretic administration). In a further embodiment, the pH of the skin changes about ± 4.0 or less, about ± 3.5 or less, about ± 3.0 or less, about ± 2.5 or less, about ± 2.0 or less, about ± 1.5 or less, about ± 1.0 or less, or about ± 0.5 or less. Substances and buffers suitable for pH adjustment are known to the skilled person.”</p> <p>2. W.I.P.O. Pat. App. No. 2020/157569 “METHODS AND COMPOSITIONS COMPRISING A 5HT RECEPTOR AGONIST FOR THE TREATMENT OF PSYCHOLOGICAL, COGNITIVE, BEHAVIORAL, AND/OR MOOD DISORDERS” (Published August 6, 2020)</p> <p>From paragraph [0079] “In some embodiments, the pharmaceutically acceptable excipient is selected from the group consisting of fillers, binders, suspending agents, disintegrants, lubricants, and combinations thereof.”</p> <p>From paragraph [0149] “In some instances, the pharmaceutical formulations further include diluent which are used to stabilize a 5HT receptor agonist or a pharmaceutically acceptable salt, solvate, metabolite, derivative, or prodrug thereof because they provide a more stable environment.”</p> <p>From paragraph [0153] “Plasticizers include compounds used to soften the microencapsulation material or film coatings to make them less brittle. Suitable plasticizers include, e.g. PEGs such as PEG 300, PEG 400, PEG 600, PEG 1450, PEG 3350, and PEG 800, stearic acid, propylene glycol, oleic acid, triethyl cellulose and triacetin. Plasticizers also function as dispersing agents or wetting agents.”</p> <p>From paragraph [0155] “Stabilizers include compounds such as any antioxidation agents, buffers, acids, preservatives and any combination thereof.”</p> <p>From page [0157] “Surfactants include compounds such as sodium lauryl sulfate, sodium docusate, Tween 60 or 80, triacetin, vitamin E TPGS, sorbitan monooleate, polyoxyethylene sorbitan monooleate, polysorbates, polaxomers, bile salts, glyceryl monostearate,</p>
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	<p>copolymers of ethylene oxide and propylene oxide, e.g. Pluronic® (BASF), and any combination thereof. Additional surfactants include polyoxyethylene fatty acid glycerides and vegetable oils, e.g. polyoxyethylene (60) hydrogenated castor oil; and polyoxyethylene alkylethers and alkylphenyl ethers, e.g. octoxynol 10, octoxynol 40. Sometimes, surfactants are included to enhance physical stability or for other purposes.”</p> <p>12. U.S. Patent App. No. 2013/0253449 “NORADRENERGIC AND SPECIFIC SEROTONERGIC ANTIDEPRESSANT-CONTAINING TRANSDERMAL PATCH” (Published September 26, 2013)</p> <p>From paragraph [0037] “If desired, the transdermal patch of the invention may contain any other additional ingredients such as a plasticizer, a crosslinking agent, a colorant, a UV absorbent, a tackifier, etc.</p>
<p>26. The pharmaceutical composition of claim 1 wherein the adhesive is selected from the group consisting of pressure sensitive adhesives, silicone polymers, bio psa 4302, bio-psa 4202, acrylic pressure sensitive adhesives, duro-tak 87-2156, duro-tak 387-2287, duro-tak 87-9301, duro-tak 387-2051, polyisobutylene, polyisobutylene low molecular weight, polyisobutylene medium molecular weight, polyisobutylene 35000 mw, acrylic copolymers, rubber based adhesives, hot melt adhesives, styrene-butadiene copolymers, bentonite, all water and/or organic solvent swellable polymers and combinations thereof.</p>	<p>1. U.S. Pat. App. Pub. No. 2011/0111029 “Composition for transdermal delivery of cationic active agents” (Published 12 May 2011)</p> <p>From paragraph [0052] “Preferably, the polyamine compounds to be used in accordance with the compositions of the invention are present in the form of polyamine salts, particularly water-soluble polyamine salts. Suitable salts are obtainable by combining or reacting the above-mentioned polyamines with suitable acids, preferably organic acids, by standard procedures.”</p> <p>From paragraph [0112] “Adhesiveness can be obtained by incorporating one or more adhesive polymers into said compositions. Adhesive polymers suitable for this purpose are generally known to the skilled person. Preferably, a polyamine or polyamine salt having adhesive properties is used as said adhesive polymer(s).</p> <p>From paragraph [0144] “The anodic reservoir (3) was prepared by applying a solution of said cationic active agent (4%-wt.) in polyamine (acrylic copolymer; EUDRAGIT® E 100) onto a non-woven viscose material (coating weight per unit area: 0.1 g/cm²).”</p> <p>2. W.I.P.O. Pat. App. No. 2020/157569 “METHODS AND COMPOSITIONS COMPRISING A 5HT RECEPTOR AGONIST FOR THE TREATMENT OF PSYCHOLOGICAL, COGNITIVE, BEHAVIORAL, AND/OR MOOD DISORDERS” (Published August 6, 2020)</p>

From **claim 1** “A method of managing a neurological condition or one or more symptoms thereof in a subject in need thereof, comprising administering to the subject a pharmaceutical composition comprising:
a) a therapeutically effective amount of one or more 5HT receptor agonist or a pharmaceutically acceptable salt, solvate, metabolite, derivative, or prodrug thereof; and
b) a pharmaceutically acceptable excipient wherein the therapeutically effective amount of the **5HT receptor agonist** or a pharmaceutically acceptable salt, solvate, metabolite, derivative, or prodrug thereof is provided to the subject in need thereof **in an amount insufficient to provide an adverse side effect, such as hallucinogenic experience.**”

From **claim 17** “The method of any one of the preceding claims, wherein the pharmaceutical composition is in a form selected from a spray, aerosol, mist, nebulae, **ointment, cream, gel, paste, salve,** solution, suspension, tincture, **patch,** and atomized vapor.”

From **paragraph [0132]** “In one non-limiting example, a **mucoadhesive** agent can be, by way of non-limiting example, at least two particulate components selected from titanium dioxide, silicon dioxide, and clay. In some embodiments, when the composition is not further diluted with any liquid prior to administration, the level of silicon dioxide is from about 3% to about 15%, by weight of the composition. In certain embodiments, silicon dioxide is selected from, by way of non-limiting example, fumed silicon dioxide, precipitated silicon dioxide, coacervated silicon dioxide, gel silicon dioxide, and mixtures thereof. In some embodiments, clay is selected from, by way of non-limiting example, kaolin minerals, serpentine minerals, smectites, illite or mixtures thereof. In certain embodiments, clay is selected from, by way of non-limiting example, laponite, **bentonite,** hectorite, saponite, montmorillonites or mixtures thereof.”

From **paragraph [0420]** “[420] Embodiment 107 is the pharmaceutical composition of any one of embodiments 1-38, wherein the composition comprises a patch comprising (i) a support layer and (ii) an adhesive agent layer, wherein the adhesive agent layer comprises
(a) a **5HT receptor agonist** or a pharmaceutically acceptable salt, solvate, metabolite, derivative, or prodrug thereof, and
(b) a **rubber-based adhesive agent** and/or a **silicone-based adhesive agent**

13. ASI, “Adhesives In Transdermal Drug Delivery Systems” 2005; retrieved

<https://web.archive.org/web/20161005045648/https://www.adhesivesmag.com/articles/86012-adhesives-in-transdermal-drug-delivery-systems>, retrieved October 5, 2016

	<p>“With many prescription and OTC products already available, there is a steady demand for bioadhesives. Currently there are three prevalent types of pressure-sensitive bioadhesives in use in the U.S. TDD system market: polyacrylate copolymers (acrylics), polysiloxanes (silicones) and polyisobutylenes (PIBs).”</p> <p>12. U.S. Patent App. No. 2013/0253449 “NORADRENERGIC AND SPECIFIC SEROTONERGIC ANTIDEPRESSANT-CONTAINING TRANSDERMAL PATCH” (Published September 26, 2013)</p> <p>From paragraph [0026] “The rubber-type adhesive ingredient includes one or more selected from styrene-isoprene-styrene block copolymer, styrene-butadiene-styrene block copolymer, styrene-butadiene rubber, polyisobutylene, polybutene, butyl rubber, natural rubber and isoprene rubber; and any of these may be used here.”</p> <p>From paragraph [0027] “The acrylic polymer includes, though not defined thereto, polymers or copolymers containing, as the monomer unit thereof, at least one (meth)acrylate of typically 2-ethylhexyl acrylate, methyl acrylate, butyl acrylate, 2-hydroxyethyl acrylate, 2-ethylhexyl methacrylate or the like. For example, herein usable are adhesives of acrylic polymers and the like that contain acrylic acid/octyl acrylate copolymer, 2-ethylhexyl acrylate/N-vinyl-2-pyrrolidone/1,6-hexaneglycol dimethacrylate copolymer, 2-ethylhexyl acrylate/vinyl acetate copolymer, 2-ethylhexyl acrylate/vinyl acetate/acrylic acid copolymer, 2-ethylhexyl acrylate/2-ethylhexyl methacrylate/dodecyl methacrylate copolymer, methyl acrylate/2-ethylhexyl acrylate copolymer resin emulsion, or acrylic resin alkanolamine liquid; and for example, usable are commercially-available DURO-TAK™ acrylic adhesive series (available from Henkel Technologies Japan), GELVA™ acrylic adhesive series (by Monsanto), SK-DYNE MATRIDERM (by Soken Chemical), EUDRAGIT™ series (by Higuchi Shokai), etc.”</p>
<p>27. The pharmaceutical composition of claim 1 wherein said polymer is present and is selected from the group consisting of natural polymers, polysaccharides, agar, alginic acid and derivatives, <i>Cassia tora</i>, collagen, gelatin, gellum gum, guar gum, pectin, potassium carageenan, sodium carageenan,</p>	<p>1. U.S. Pat. App. Pub. No. 2011/0111029 “Composition for transdermal delivery of cationic active agents” (Published 12 May 2011)</p> <p>From paragraph [0094] “In a further embodiment, the hydrogel compositions may comprise additional gel-forming polymers which may be selected e.g. from the group consisting of polyacrylates or cellulose derivatives such as hydroxypropylmethyl cellulose, hydroxypropyl cellulose or hydroxyethyl cellulose.”</p> <p>From paragraph [0144] “The anodic reservoir (3) was prepared by applying a solution of said cationic active agent (4%-wt.) in polyamine</p>

<p>tragacanth, xanthan, gum copal, chitosan, resin, semisynthetic polymers, cellulose, methylcellulose, ethyl cellulose, carboxymethyl cellulose, hydroxylpropyl cellulose, hydroxylpropylmethyl cellulose, synthetic polymers, carboxyvinyl polymers, carbomers, carbopol 940, carbopol 934, carbopol 971p NF, polyethylene, clays, silicates, bentonite, silicon dioxide, polyvinyl alcohol, acrylic polymers (eudragit), acrylic acid esters, polyacrylate copolymers, polyacrylamide, polyvinyl pyrrolidone homopolymer, polyvinyl pyrrolidone copolymers, PVP, Kollidon 30, poloxamer, isobutylene, ethyl vinyl acetate copolymers, natural rubber, synthetic rubber, and combinations thereof.</p>	<p>(acrylic copolymer; EUDRAGIT® E 100) onto a non-woven viscose material (coating weight per unit area: 0.1 g/cm²).”</p> <p>19. VALENTA (2004) “The use of polymers for dermal and transdermal delivery” European Journal of Pharmaceutics and Biopharmaceutics. 58(2):279-289.</p> <p>From page 279 “The use of polymers for skin preparations is manifold. Requirements of such polymers are dependent on the formulation types. The most applied polymers on skin belong to various classes, for example to cellulose derivatives, chitosan, carageenan, polyacrylates, polyvinylalcohol, polyvinylpyrrolidone and silicones.”</p> <p>From page 283 “Another sponge-type was an absorbable sponge, composed of gelatine and alginate.”</p> <p>From page 283 “Collagen is a natural substrate for cellular attachment, growth and differentiation and promotes cellular proliferation. Recently, in an excellent review the effects of collagen matrices on dermal wound healing including a cellular and cell-containing products were discussed in detail.”</p> <p>From page 283 “The most important and already well-known polymers for forming hydrogels are polyacrylic acid derivatives like Carbomers®, different cellulose derivatives like hydroxyethyl cellulose, hydroxypropyl cellulose and croscarmellose-sodium.”</p> <p>From page 280 “The novel polymer displayed the lowest incompatibility with multivalent cations as well as with ethanol, and exhibited significantly the best swelling properties among several tested polymers like HPMC, NaCMC, Carbopol® and polycarbophil.”</p> <p>From page 283 “Another synthetic polymer poly(n-vinylpyrrolidone) was used in a tropical environment. To achieve the thickness, additional additives like agar or polyethylene glycol were used.”</p> <p>From page 280 “As drug, kojic acid, an antimelanogenic agent was incorporated in different preparations like cream bases of mineral oil with caprylic capric triglyceride (MultiCream) and hydrophilic polymers such as chitosan (ChitoGel), Carbopol®, and poloxamer (Pluronic®). Pluronic®-based gels (PluGel) and Carbopol®-based gels (CarboGel) revealed controlled release of drug to some extent, followed by the square root-time kinetics.”</p>
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From **page 281** “One approach is the improvement of the adhesiveness on skin by combining different polymers or by polymer derivatisation. The effect of a combination of the adhesive polymethyl methacrylate (PMMA) with cellulose ethers or **polyvinylpyrrolidone (PVP)** was evaluated by a peel adhesion test.”

12. U.S. Patent App. No. 2013/0253449 “NORADRENERGIC AND SPECIFIC SEROTONERGIC ANTIDEPRESSANT-CONTAINING TRANSDERMAL PATCH” (Published September 26, 2013)

From **paragraph [0026]** “The rubber-type adhesive ingredient includes one or more selected from styrene-isoprene-styrene block copolymer, styrene-butadiene-styrene block copolymer, styrene-butadiene rubber, **polyisobutylene**, polybutene, **butyl rubber**, **natural rubber and isoprene rubber**; and any of these may be used here.”

From **paragraph [0027]** “The acrylic polymer includes, though not defined thereto, polymers or copolymers containing, as the monomer unit thereof, at least one (meth)acrylate of typically 2-ethylhexyl acrylate, methyl acrylate, butyl acrylate, 2-hydroxyethyl acrylate, 2-ethylhexyl methacrylate or the like. For example, herein usable are adhesives of acrylic polymers and the like that contain acrylic acid/octyl acrylate copolymer, 2-ethylhexyl acrylate/N-vinyl-2-pyrrolidone/1,6-hexaneglycol dimethacrylate copolymer, 2-ethylhexyl acrylate/vinyl acetate copolymer, 2-ethylhexyl acrylate/vinyl acetate/acrylic acid copolymer, 2-ethylhexyl acrylate/2-ethylhexyl methacrylate/dodecyl methacrylate copolymer, methyl acrylate/2-ethylhexyl **acrylate copolymer resin emulsion, or acrylic resin alkanolamine liquid**; and for example, usable are commercially-available DURO-TAK™ acrylic adhesive series (available from Henkel Technologies Japan), GELVA™ acrylic adhesive series (by Monsanto), SK-DYNE MATRIDERM (by Soken Chemical), EUDRAGIT™ series (by Higuchi Shokai), etc.”

From **paragraph [0042]** “The tackifier includes rosin derivatives such as rosin, rosin glycerin ester, hydrogenated rosin, hydrogenated rosin glycerin ester, etc.; alicyclic saturated hydrocarbon resins, alicyclic hydrocarbon resins, terpene resins, aliphatic saturated hydrocarbon resins, aliphatic hydrocarbon resins, resin maleate, carnauba wax, sodium carmellose, xanthane gum, **chitosan**, glycerin, **magnesium aluminium silicate**, light anhydrous silicic acid, benzyl acetate, talc, hydroxyethyl cellulose, hydroxypropyl cellulose, hypromellose, polyacrylic acid, sodium polyacrylate, partially-neutralized polyacrylic acid, polyvinyl alcohol, etc.”

	<p>From paragraph [0043] “As the support of the transdermal patch of the invention, a drug-impervious elastic or nonelastic support may be used. The support of the type includes, for example, synthetic resin films or sheets or their laminates of polyethylene, polypropylene, polybutadiene, ethylene-vinyl acetate copolymer, polyvinyl chloride, polyester (polyethylene terephthalate, etc.), nylon, polyurethane, etc.; porous substances, foams, papers, woven fabrics, nonwoven fabrics, etc.”</p>
<p>28. The pharmaceutical composition of claim 1 wherein said permeation enhancer is present, and is selected from the group consisting of dimethylsulfoxide, dimethyl acetamide, dimethylformamide, decymethylsulfoxide, dimethylisobutylamine, azone, pyrrolidones, N-methyl-2-pyrrolidone, 2-pyrrolidone, esters, fatty acid esters, propylene glycol monolaurate, butyl ethanoate, ethyl ethanoate, isopropyl myristate, isopropyl palmitate, methyl ethanoate, lauryl lactate, ethyl oleate decyl oleate, glycerol monooleate, glycerol monolaurate, lauryl laurate, fatty acids, capric acid, caprylic acid, lauric acid, oleic acid, myristic acid, linoleic acid, stearic acid, palmitic acid, alcohols, fatty alcohols, glycols, oleyl alcohol, nathanol, dodecanol, propylene glycol, glycerol, ethers, alcohol, diethylene glycol monoethyl ether, urea, triglycerides, triacetin, polyoxyethylene fatty alcohol ethers, polyoxyethylene fatty acid esters, esters of fatty alcohols, essential oils, surfactant type enhancers, brij, sodium lauryl sulfate,</p>	<p>1. U.S. Pat. App. Pub. No. 2011/0111029 “Composition for transdermal delivery of cationic active agents” (Published 12 May 2011)</p> <p>From paragraph [0084] “Fatty acids that may be used in accordance with the present invention include, for instance, hexanoic acid, decanoic acid, lauric acid, myristic acid, palmitic acid, caprylic acid and stearic acid; lauric acid being preferred.”</p> <p>From paragraph [0106] “Examples of permeation enhancers include, but are not limited to, dimethylsulfoxide (DMSO), N,N-dimethylacetamide (DMA), decylmethylsulfoxide (C10 MSO), polyethylene glycol monolaurate (PEGML), propylene glycol (PG), propylene glycol monolaurate (PGML), glycerol monolaurate (GML), lecithin, the 1-substituted alkyl-azacycloalkyl-2-ones, particularly 1-n-dodecylazacycloheptan-2-one, alcohols, and the like. The permeation enhancer may also be selected from vegetable oils, e.g. safflower oil, cotton seed oil, or corn oil.”</p> <p>14. SINHA (2000) “Permeation Enhancers for Transdermal Drug Delivery” Drug Development and Industrial Pharmacy. 26(11) 1131-1140.</p> <p>From page 1132 “The effect of three essential oils (eucalyptus, peppermint, turpentine oil) on the permeation of 5-fluorouracil (5-FU) were studied using excised rat skin. Although all three oils enhanced the permeation of drug, their effect was less than that of azone.”</p> <p>From page 1132 “TERPENES, TERPENOIDS, ESSENTIAL OILS: Terpenes and terpenoids are usually the constituents of volatile oil.”</p> <p>From page 1132 “Permeation of haloperidol was increased by both cineole and d-limonene; α-pinene provided no change in its permeation profile. Coapplication of terpenes (1,8-cineole, menthone, limonene, nerolidol) with 5-FU, both at saturation, in a propylene glycol (PG)/water cosolvent system increased drug flux significantly (9).”</p>

<p>tween, polysorbate, terpene, terpenoids, and combinations thereof.</p>	<p>From page 1133 “2-Pyrrolidone and NMP were assessed in enhancing the topical bioavailability of a model steroid betamethasone-17-benzoate, using dimethylisosorbide (DMI) as the standard solvent.”</p> <p>From page 1133 “Pyrrolidones and their derivatives have great potential to be used as transdermal permeation enhancers. The most common N-methyl-2-pyrrolidone (NMP) has been used widely to enhance the skin absorption of many drugs, for example, insulin (19), ibuprofen, and flurbiprofen (20).”</p> <p>From page 1133 “In general, 2-pyrrolidone enhances the transdermal permeation of caffeine through polar routes of skin by increasing its diffusivity and reduces the passage through the nonpolar route by decreasing diffusivity and partitioning (28). One of its derivatives, N-dodecyl-2-pyrrolidone, has been shown to increase the permeability coefficient of hydrophilic methyl paraben about seven times while decreasing that of butyl paraben. Perturbation of stratum corneum lipid lamellae seems to be related to the enhancement of absorption of hydrophilic paraben (4). Fatty acid esters of N-(2-hydroxyethyl)-2-pyrrolidone (HEP) produced a twofold increase in permeation of hydrocortisone through mouse skin (29).”</p> <p>From page 1134 “Azone (1-dodecylazacycloheptan-2-one) (Fig. 1) forms one of the major classes of percutaneous permeation enhancers.”</p> <p>From page 1134 “Azone (2%) in PG promoted the absorption of 5- FU by almost 100-fold, but in combination with Tween 20, the effect was less pronounced (33).”</p> <p>From page 1134 “Azone is less effective than oleic acid in increasing the transdermal permeation of amino acids through hairless mouse skin (39). But, in the case of insulin, the enhancement is almost double that produced by dodecyl-l-pyroglutamate (19). Compared with terpenes, azone is the most effective penetration enhancer for low molecular weight heparin across human skin. The enhancing power of enhancers decreased in the order laurocapram. nerolidol. eucalyptol (11).”</p> <p>From page 1135 “A large number of fatty acids and their esters have been used as permeation enhancers.”</p> <p>From page 1135 “Capric acid, lauric acid, and neodecanoic acid were tested for their activity on naloxone, testosterone, benzoic acid, indomethacin, 5-FU, and methotrexate (53). All three fatty acids increased the skin diffusivity of naloxone, testosterone, indomethacin, and 5-FU through human skin. Capric acid also increased the</p>
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diffusivity of PG, suggesting that increased solvent penetration could also be involved as a mechanism for increased skin absorption of the drug.”

From **page 1135** “Oleic acid was found to be the most efficient enhancer for piroxicam, followed by **linoleic acid** (50). Sodium oleate was found to be a better **permeation enhancer** than oleyl oleate when tested on indomethacin and urea (10).”

From **page 1136** “Urea analogues were effective in **enhancing the permeation** of 5-FU only when PG was used as a vehicle (68).”

From **page 1136** “ALCOHOLS, GLYCOLS, AND GLYCERIDES”

From **page 1136** “Of the **fatty alcohols** tested, lauryl alcohol increased the transdermal permeation of propranolol hydrochloride, timolol maleate, ibuprofen, acetaminophen, and 5-FU (50,71,72).”

From **page 1136** “Various compounds of category N,N-dimethylamides also possess **penetration-enhancing** power and are also structurally related to sulfoxides. **N,N-Dimethylformamide** promotes absorption through the polar route by increasing both the diffusion and the partitioning of drug.”

From **page 1137** “Short-chain glycerides are also effective as **permeation enhancers** (e.g., TCP). For instance, glycerin tricaprylate (caprylic acid **triglyceride**) in combination with ethanol is used as a solvent system (22,52)”

12. U.S. Patent App. No. 2013/0253449 “NORADRENERGIC AND SPECIFIC SEROTONERGIC ANTIDEPRESSANT-CONTAINING TRANSDERMAL PATCH” (Published September 26, 2013)

From **paragraph [0031]** “For improving the transdermal absorption of the active ingredient, if desired, a transdermal absorption promoter may be incorporated. The transdermal absorption promoter may be any compound that has heretofore been recognized to exhibit an absorption-promoting effect in transdermal administration, and includes, for example, alkanolamines such as diisopropanolamine, triisopropanolamine, etc., fatty acids or their esters such as lauric acid, oleic acid, **isopropyl myristate**, octyldodecyl myristate, oleic acid glycerol monoester, hexadecyl isostearate, etc.; **alcohols or their esters or ethers** such as **oleyl alcohol**, propylene glycol, propylene glycol monocaprylate, polyethylene glycol monooleate, etc.; sorbitan esters or ethers such as sorbitan monolaurate, sorbitan monooleate,

etc.; polyoxyethylene sorbitan fatty acid esters such as polyoxyethylene sorbitan monooleate, polyoxyethylene sorbitan monopalmitate, etc.; phenol ethers such as polyoxyethylene nonylphenyl ether, polyoxyethylene octylphenyl ether, etc.; castor oil or hardened castor oil; ionic surfactants such as oleoyl sarcosine, lauryldimethylaminoacetate betaine, sodium laurylsulfate, etc.; nonionic surfactants such as polyoxyethylene oleyl ether, polyoxyethylene lauryl ether, dimethyl laurylamine oxide, etc.; alkylmethyl sulfoxides such as dimethyl sulfoxide, decylmethyl sulfoxide, etc.; pyrrolidones such as **2-pyrrolidone**, 1-methyl-2-pyrrolidone, etc.; azacycloalkanes such as 1-dodecylazacycloheptan-2-one, 1-geranylazacycloheptan-2-one, etc.; terpenes such as menthol, camphor, limonene, etc. Of those, preferred are myristates such as isopropyl myristate, sebacates such as diisopropyl sebacate, etc.; menthol, polyoxyethylene oleyl ether or **Polysorbate 80™**.”

From **paragraph [0038]** “The plasticizer includes petroleum oils such as paraffinic process oil, naphthenic process oil, aromatic process oil, etc.; liquid fatty acid esters such as **isopropyl myristate**, hexyl laurate, diethyl sebacate, diisopropyl sebacate, isopropyl linoleate, etc.; vegetable oils such as olive oil, camellia oil, castor oil, tall oil, peanut oil, etc.; glycerin, chlorobutanol, vinyl acetate resin, dimethylpolysiloxane-silicon dioxide mixture, D-sorbitol, middle-chain fatty acid triglyceride, **triacetin**, 2-pyrrolidone, phytosterol, propylene glycol, polyethylene glycol, Polysorbate 80™, glycerin monostearate, etc.”

15. SMITH (1995) Percutaneous Penetration Enhancers. CRC-Press
ISBN: 0849326052

From **page 7**

Table 1 Chemical Penetration Enhancers

Chemical Class	Examples	Ref.
Sulfoxides	Dimethylsulfoxide, decylmethylsulfoxide	17, 18
Alcohols	Alkanol: ethanol, propanol, butanol, pentanol, hexanol, octanol, nonanol, decanol, 2-butanol, 2-pentanol, benzyl alcohol	19, 20
	Fatty alcohol: caprylic, decyl, lauryl, 2-lauryl, myristyl, cetyl, stearyl, oleyl, linoleyl, linolenyl alcohol	21
Fatty acids	Linear: valeric, heptanoic, pelagonic, caproic, capric, lauric, myristic, stearic, oleic, caprylic	21, 22
	Branched: isovaleric, neopentanoic, neoheptanoic, neononanoic, trimethyl hexanoic, neodecanoic, isostearic	21, 22
Fatty acid esters	Aliphatic-isopropyl <i>n</i> -butyrate, isopropyl <i>n</i> -hexanoate, isopropyl <i>n</i> -decanoate, isopropyl myristate, isopropyl palmitate, octyldodecyl myristate	23
	Alkyl: ethyl acetate, butyl acetate, methyl acetate, methylvalerate, methylpropionate, diethyl sebacate, ethyl oleate	24
Polyols	Propylene glycol, polyethylene glycol, ethylene glycol, diethylene glycol, triethylene glycol, dipropylene glycol, glycerol, propanediol, butanediol, pentanediol, hexanetriol	25
Amides	Urea, dimethylacetamide, diethyltoluamide, dimethylformamide, dimethyloctamide, dimethyldecamide	21, 26
	Biodegradable cyclic urea: 1-alkyl-4-imidazolin-2-one	27
	Pyrrolidone derivatives: 1-methyl-2-pyrrolidone, 2-pyrrolidone, 1-lauryl-2-pyrrolidone, 1-methyl-4-carboxy-2-pyrrolidone, 1-hexyl-4-carboxy-2-pyrrolidone, 1-lauryl-4-carboxy-2-pyrrolidone, 1-methyl-4-methoxycarbonyl-2-pyrrolidone, 1-hexyl-4-methoxycarbonyl-2-pyrrolidone, 1-lauryl-4-methoxycarbonyl-2-pyrrolidone, <i>N</i> -cyclohexylpyrrolidone, <i>N</i> -dimethylaminopropylpyrrolidone, <i>N</i> -cocoalkylpyrrolidone, <i>N</i> -tallowalkylpyrrolidone	21, 28
	Biodegradable pyrrolidone derivatives: Fatty acid esters of <i>N</i> -(2-hydroxyethyl)-2-pyrrolidone	14
	Cyclic amides: 1-dodecylazacycloheptane-2-one (Azone®), 1-geranylazacycloheptan-2-one, 1-farnesylazacycloheptan-2-one, 1-geranylgeranylazacycloheptan-2-one, 1-(3,7-dimethyloctyl)azacycloheptan-2-one, 1-(3,7,11-trimethyldodecyl)azacycloheptan-2-one, 1-geranylazacyclohexane-2-one, 1-geranylazacyclopentan-2,5-dione, 1-farnesylazacyclopentan-2-one	29, 30
	Hexamethylenelauramide and its derivatives	31
	Diethanolamine, triethanolamine	25
Surfactants	Anionic: Sodium laurate, sodium lauryl sulfate	32, 33
	Cationic: Cetyltrimethyl ammonium bromide, tetradecyltrimethylammonium bromide, benzalkonium chloride, octadecyltrimethylammonium chloride, cetylpyridinium chloride, dodecyltrimethylammonium chloride, hexadecyltrimethylammonium chloride	33–35
	Nonionics: Poloxamer (231, 182, 184), Brij (30, 93, 96, 99), Span (20, 40, 60, 80, 85), Tween (20, 40, 60, 80), Myrj (45, 51, 52), Miglyol 840	21, 36, 37
	Bile salts: Sodium cholate, sodium salts of taurocholic, glycholic, desoxycholic acids	38
	Lecithin	39

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Table 1 (continued) Chemical Penetration Enhancers		
Chemical Class	Examples	Ref.
Terpenes	Hydrocarbons: β -Limonene, α -pinene, β -carene Alcohols: α -Terpineol, terpinen-4-ol, carvol Ketones: Carvone, pulegone, piperitone, menthone Oxides: Cyclohexene oxide, limonene oxide, α -pinene oxide, cyclopentene oxide, 1,8-cineole Oils: Ylang ylang, anise, chenopodium, eucalyptus	40, 41
Alkanones	<i>N</i> -heptane, <i>N</i> -octane, <i>N</i> -nonane, <i>N</i> -decane, <i>N</i> -undecane, <i>N</i> -dodecane, <i>N</i> -tridecane, <i>N</i> -tetradecane, <i>N</i> -hexadecane	41
Organic acids	Salicylic acid and salicylates (including their methyl, ethyl, and propyl glycol derivatives), citric and succinic acid	42

<p>29. The pharmaceutical composition of claim 1 wherein said solvent is present, and is selected from the group consisting of methanol, ethanol, isopropyl alcohol, butanol, propanol, polyhydric alcohols, glycols, propylene glycol, polyethylene glycol, dipropylene glycol, hexylene glycol, butylene glycol, glycerine, derivative of glycols, pyrrolidone, N methyl 2-pyrrolidone, 2 pyrrolidone, sulfoxides, dimethyl sulfoxide, decymethylsulfoxide, dimethylisorbide, mineral oils, vegetable oils, sesame oil water, polar solvents, semi polar solvents, non polar solvents, volatile chemicals, ethanol, propanol, ethyl acetate, acetone, methanol, dichloromethane, chloroform, toluene, IPA, hexane, acids, acetic acid, lactic acid, levulinic acid, bases, pentane, dimethylformamide, butane, lipids, and combinations thereof.</p>	<p>1. U.S. Pat. App. Pub. No. 2011/0111029 “Composition for transdermal delivery of cationic active agents” (Published 12 May 2011)</p> <p>From paragraph [0042] “The term ‘aqueous solvent mixture’ generally includes liquid mixtures containing water and at least one further solvent which is generally selected from polar, water-miscible solvents such as, for instance, alcohols (e.g. ethanol, isopropanol, glycerol).”</p> <p>From paragraph [0042] “Alternatively, the solubility of the active agent can be achieved by changing its crystal modification. Examples of solubility enhancers include, without limitation, water; diols such as propylene glycol and glycerol; monoalcohols such as ethanol, propanol and higher alcohols; dimethylsulfoxide (DMSO), dimethylformamide, N,N-dimethylacetamide, N-substituted alkyl-azacycloalkyl-2-ones.”</p> <p>12. U.S. Patent App. No. 2013/0253449 “NORADRENERGIC AND SPECIFIC SEROTONERGIC ANTIDEPRESSANT-CONTAINING TRANSDERMAL PATCH” (Published September 26, 2013)</p> <p>From paragraph [0031] “For improving the transdermal absorption of the active ingredient, if desired, a transdermal absorption promoter may be incorporated. The transdermal absorption promoter may be any compound that has heretofore been recognized to exhibit an absorption-promoting effect in transdermal administration, and includes, for example, alkanolamines such as diisopropanolamine, triisopropanolamine, etc., fatty acids or their esters such as lauric acid, oleic acid, isopropyl myristate, octyldodecyl myristate, oleic acid glycerol monoester, hexadecyl isostearate, etc.; alcohols or their esters or ethers such as oleyl alcohol, propylene glycol, propylene glycol monocaprylate, polyethylene glycol monooleate, etc.; sorbitan esters or ethers such as sorbitan monolaurate, sorbitan monooleate, etc.; polyoxyethylene sorbitan fatty acid esters such as polyoxyethylene</p>
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sorbitan monooleate, polyoxyethylene sorbitan monopalmitate, etc.; phenol ethers such as polyoxyethylene nonylphenyl ether, polyoxyethylene octylphenyl ether, etc.; castor oil or hardened castor oil; ionic surfactants such as oleoyl sarcosine, lauryldimethylaminoacetate betaine, sodium laurylsulfate, etc.; nonionic surfactants such as polyoxyethylene oleyl ether, polyoxyethylene lauryl ether, dimethyl laurylamine oxide, etc.; alkylmethyl sulfoxides such as dimethyl sulfoxide, decylmethyl sulfoxide, etc.; **pyrrolidones** such as 2-pyrrolidone, 1-methyl-2-pyrrolidone, etc.; azacycloalkanes such as 1-dodecylazacycloheptan-2-one, 1-geranylazacycloheptan-2-one, etc.; terpenes such as menthol, camphor, limonene, etc. Of those, preferred are myristates such as isopropyl myristate, sebacates such as diisopropyl sebacate, etc.; menthol, polyoxyethylene oleyl ether or Polysorbate 80™.”

From **paragraph [0038]** “The plasticizer includes petroleum oils such as paraffinic process oil, naphthenic process oil, aromatic process oil, etc.; liquid fatty acid esters such as isopropyl myristate, hexyl laurate, diethyl sebacate, diisopropyl sebacate, isopropyl linoleate, etc.; **vegetable oils such as olive oil, camellia oil, castor oil, tall oil, peanut oil, etc.**; **glycerin**, chlorobutanol, vinyl acetate resin, dimethylpolysiloxane-silicon dioxide mixture, **D-sorbitol**, middle-chain fatty acid triglyceride, triacetin, 2-pyrrolidone, phytosterol, propylene glycol, polyethylene glycol, Polysorbate 80™, glycerin monostearate, etc.”

From **paragraph [0045]** “There is no specific limitation on the transdermal patch of the invention and it can be produced according to any known production method. Preferred known production methods for the transdermal patch of the invention include a method that comprises, for example, dissolving an active ingredient and an adhesive and optionally a transdermal absorption promoter in an organic solvent of **ethyl acetate, hexane**, toluene or a mixed solvent thereof, then spreading the dissolved matter onto a release liner or a support, evaporating away the solvent from the dissolved matter to form a drug-containing layer, and thereafter sticking a support or a release liner thereto to give a transdermal patch; a method that comprises melting an active ingredient and an adhesive and optionally a transdermal absorption promoter under heat, then spreading the resulting melt onto a release liner or a support to form a drug-containing layer thereon, and thereafter sticking a support or a release liner thereto to give a transdermal patch, etc.”

16. GRODOWSKA (2010) “Organic solvents in the pharmaceutical industry” Acta Poloniae Pharmaceutica – Drug Research. 67(1)3-12.

From page 5

Table 2. Class 2 solvents (2)

Solvent	PDE (mg/day)	Concentration limit (ppm)
Acetonitrile	4.1	410
Chlorobenzene	3.6	360
Chloroform	0.6	60
Cyclohexane	38.8	3880
1,2-Dichloroethene	18.7	1870
Dichloromethane	6.0	600
1,2-Dimethoxyethane	1.0	100
N,N-Dimethylacetamide	10.9	1090
N,N-Dimethylformamide	8.8	880
1,4-Dioxane	3.8	380
2-Ethoxyethanol	1.6	160
Ethylene glycol	6.2	620
Formamide	2.2	220
Hexane	2.9	290
Methanol	20.0	2000
2-Methoxyethanol	0.5	50
Methylbutylketone	0.5	50
Methylcyclohexane	11.8	1180
N-methylpyrrolidone	48.4	4840
Nitromethane	0.5	50
Pyridine	2.0	200
Sulfolane	1.6	160
Tetralin	1.0	100
Toluene	8.9	890
1,1,2-Trichloroethylene	0.8	80
Xylene	21.7	2170

From page 6

Table 3. Solvents commonly used in chemical industry (6, 7)

Alcohols	Ketones	Halogenated solvents
Ethanol Butanol 2-Ethylhexanol Isobutanol Isopropanol Methanol Propanol Propylene glycol	Acetone Methyl ethyl ketone Methyl isobutyl ketone Methyl isopropyl ketone Mesityl oxide Trichloroethylene	Ethylene bromide Chloroform Ethylene chloride Dichloromethane Tetrachloroethylene Carbon tetrachloride
Amide	Ethers	Sulfur containing
Dimethylformamide	1,4-Dioxane Butyl ether Ethyl ether Diisopropyl ether Tetrahydrofuran <i>tert</i> -Butyl methyl ether	Dimethyl sulfoxide
Amine	Nitriles	Esters
Pyridine	Acetonitrile	Ethyl acetate
Aliphatic hydrocarbons	Water	Aromatic hydrocarbons
Cyclohexane Hexane		Toluene Xylene

30. The pharmaceutical composition of claim 1 which is formulated as a

10. U.S. Pat. App. No. 2020/0085816 “LSD FOR THE TREATMENT OF ALZHEIMER'S DISEASE” (Published March 19, 2020)

<p>transdermal formulation which can be administered in a dosage regimen selected from the group consisting of once daily, twice daily, three times a day, once in 1-8 hrs, once in 1-24 hrs, once in two days, once in three days, once in four days, once in five days, once in six days, once in a week, once in a 8 to about 13 days, once in two weeks, and once in 15 days to about 30 days.</p>	<p>From claim 40 “A transdermal delivery system comprising a pharmaceutically effective amount of a neuronal growth factor, 2 µg to 30 µg of lysergic acid diethylamide or a pharmaceutically acceptable salt thereof, and a naturally occurring gum.”</p> <p>From claim 52 “The method of claim 43, wherein said lysergic acid diethylamide, or a pharmaceutically acceptable salt thereof, is administered in a dosing regimen from once daily to once weekly.”</p> <p>2. W.I.P.O. Pat. App. No. 2020/157569 “METHODS AND COMPOSITIONS COMPRISING A 5HT RECEPTOR AGONIST FOR THE TREATMENT OF PSYCHOLOGICAL, COGNITIVE, BEHAVIORAL, AND/OR MOOD DISORDERS” (Published August 6, 2020)</p> <p>From claim 1 “A method of managing a neurological condition or one or more symptoms thereof in a subject in need thereof, comprising administering to the subject a pharmaceutical composition comprising: a) a therapeutically effective amount of one or more 5HT receptor agonist or a pharmaceutically acceptable salt, solvate, metabolite, derivative, or prodrug thereof; and b) a pharmaceutically acceptable excipient wherein the therapeutically effective amount of the 5HT receptor agonist or a pharmaceutically acceptable salt, solvate, metabolite, derivative, or prodrug thereof is provided to the subject in need thereof in an amount insufficient to provide an adverse side effect, such as hallucinogenic experience.”</p> <p>From claim 30 “The method of any one of the preceding claims, wherein the pharmaceutical composition is administered to a subject in need thereof once a day, every alternate day, three times a week, twice a week, once a week, every other week, two weeks per month, three weeks per month, once a month, twice a month or three times per month.</p> <p>From claim 31 “The method of any one of the preceding claims, wherein the pharmaceutical composition is administered about once a day.”</p> <p>From paragraph [0138] “These pharmaceutical compositions might also be formulated for transmucosal administration, buccal administration, for administration by inhalation, for parental administration, for transdermal administration, and rectal administration”</p>
<p>31. The pharmaceutical composition of claim 1</p>	<p>2. W.I.P.O. Pat. App. No. 2020/157569 “METHODS AND COMPOSITIONS COMPRISING A 5HT RECEPTOR AGONIST</p>

<p>which is formulated as a topical formulation which can be administered in a dosage regimen selected from the group consisting of once daily, twice daily, three times a day, four times a day, five times a day, six times a day, once in 1-8 hrs, once in 1-24 hrs, once in two days, once in three days, once in four days, once in five days, once in six days, once in a week, once in 8 to about 13 days, once in two weeks, and once in 15 days to about 30 days.</p>	<p>FOR THE TREATMENT OF PSYCHOLOGICAL, COGNITIVE, BEHAVIORAL, AND/OR MOOD DISORDERS” (Published August 6, 2020)</p> <p>From claim 1 “A method of managing a neurological condition or one or more symptoms thereof in a subject in need thereof, comprising administering to the subject a pharmaceutical composition comprising: a) a therapeutically effective amount of one or more 5HT receptor agonist or a pharmaceutically acceptable salt, solvate, metabolite, derivative, or prodrug thereof; and b) a pharmaceutically acceptable excipient wherein the therapeutically effective amount of the 5HT receptor agonist or a pharmaceutically acceptable salt, solvate, metabolite, derivative, or prodrug thereof is provided to the subject in need thereof in an amount insufficient to provide an adverse side effect, such as hallucinogenic experience.”</p> <p>From claim 30 “The method of any one of the preceding claims, wherein the pharmaceutical composition is administered to a subject in need thereof once a day, every alternate day, three times a week, twice a week, once a week, every other week, two weeks per month, three weeks per month, once a month, twice a month or three times per month.</p> <p>From claim 31 “The method of any one of the preceding claims, wherein the pharmaceutical composition is administered about once a day.”</p> <p>From paragraph [0138] “These pharmaceutical compositions might also be formulated for transmucosal administration, buccal administration, for administration by inhalation, for parental administration, for transdermal administration, and rectal administration”</p> <p>From [0162] “In some embodiments, 5HT receptor agonists or pharmaceutical compositions or formulations described herein are administered to a subject by multiple administration routes, including but not limited to, oral, parenteral (e.g. intravenous, subcutaneous, intramuscular), intranasal, inhalation, buccal, topical, rectal, or transdermal administration routes.”</p>
<p>32. The pharmaceutical composition of claim 1 co-administered with at least one additional an active agent selected from the group consisting of: medications administered for treatment and/or</p>	<p>17. U.S. Pat. App. No. 2021/0069170 “TRYPTAMINE COMPOSITIONS FOR ENHANCING NEURITE OUTGROWTH” (Published March 11, 2021)</p> <p>From [0007] “One embodiment described herein is a composition comprising norpsilocin or a salt or hydrate thereof or combinations thereof combined with one or more erinacines or hericenones in pure</p>

management and/or prevention and/or control of symptoms associated with neuropathic pain, peripheral neuropathic pain, inflammatory pain, musculoskeletal pain, pain due to muscle spasms, pain due to increased muscle tone, osteoarthritic pain, muscular headache, tension-type headache, migraine, cluster headache, atypical facial pain, referred pain, vulvodinia, proctodynia, adjustment disorder, prolonged grief disorder (PGD), and any combination thereof.

form, extracts or isolates from *Herichium* mushroom species, or combinations thereof... In another aspect, the **cannabinoids** comprise one or more of **Δ 8-tetrahydrocannabinol (THC)**, **Δ 9-tetrahydrocannabinol**, **tetrahydrocannabinolic acid (THCA)**, **cannabidiol (CBD)**, ... In another aspect, the composition is effective to treat, alleviate, prevent or ameliorate psychiatric and mood disorders comprising serotonin (5-hydroxytryptamine, 5-HT) receptor disorders, depression, anxiety, major depressive disorder, treatment resistant depression, persistent depression, manic depression or bipolar disorder, depressive psychosis, perinatal depression, premenstrual dysphoric disorder, seasonal depressions, situational depression, panic disorder, obsessive compulsive disorder, post-traumatic stress disorder, attention deficit/hyperactivity disorder, sleep disorders, eating disorders, schizophrenia, personality disorders, substance abuse disorders (drug abuse, addiction, alcoholism); neuronal injuries or physical neurodegeneration (e.g., physical injury, head trauma, spinal cord trauma, concussion, peripheral neuron trauma, paralysis, ischemia, hypoxia, stroke; organophosphates, lead, heavy metals, nerve agents, other toxic compounds, prions, amyloid plaque, neurotoxic viruses, stress); neurodegenerative diseases (e.g., Alzheimer's disease, Parkinson's disease, amyotrophic lateral sclerosis, multiple sclerosis, frontotemporal dementia, Huntington's disease, adrenal leukodystrophy, Alexander's disease, Alper's disease, Alzheimer's disease, amyotrophic lateral sclerosis, balo concentric sclerosis, Canavan disease, Charcot-Marie-Tooth disease, childhood ataxia with central nervous system hypomyelination, chronic idiopathic peripheral neuropathy, frontotemporal dementia, Huntington's disease, Krabbe disease, monomelic amyotrophy, multiple sclerosis (MS), neurodegeneration, neuromyelitis optica, **neuropathic pain**, neurosarcoidosis, Parkinson's disease, Pelizaeus-Merzbacher disease, primary lateral sclerosis, progressive supranuclear palsy, **radicular pain**, **radiculopathic pain**, Schilder's disease, **sciatic pain**, sciatica, subacute necrotizing myelopathy, transverse myelitis, or Zellweger syndrome); congenital or organic cognitive impairment, learning disabilities, autism spectrum disorder; cognitive enhancement, intelligence enhancement, creativity enhancement, memory improvement, learning enhancement and improvement, spiritual enhancement, "mind expansion," IQ improvement, EQ improvement, balance enhancement, athleticism, motor skill enhancement, special navigation, clairvoyance, psychic enhancement, or general improvement of mental health."

From [0003] "Serotonin (5-hydroxytryptamine, 5-HT) plays a significant role in influencing many central and peripheral processes. 5-HT-selective pharmacotherapies have been developed to treat a wide variety of medical problems including depression, anxiety, schizophrenia, **migraine**, emesis, and appetite control. 5-HT exerts its influence through activation of fourteen distinct receptor subtypes in seven separate families. There is interest in the three receptor subtypes of the 5-HT.sub.2 family, 5-HT.sub.2A, 5-HT.sub.2B, and 5-HT.sub.2C. Modulation of the 5-HT.sub.2C receptor subtype has been

	<p>shown to play a role in numerous human diseases including obesity, obsessive-compulsive disorder (OCD), sexual dysfunction, epilepsy, schizophrenia, anxiety disorders, among a variety of other psychiatric disorders.”</p> <p>From [0165] “In another embodiment, the tryptamine comprises: ..., 12-methoxyibogamine (Ibogaine), N,N-diethyl-lysergic acid (LSD)...”</p> <p>From [0108] “The pharmaceutically acceptable compositions of this disclosure may also be administered topically, especially when the target of treatment includes areas or organs readily accessible by topical application, including diseases of the eye, the skin, or the lower intestinal tract. Suitable topical formulations are readily prepared for each of these areas or organs. Topical application for the lower intestinal tract can be administered using a rectal suppository formulation (see above) or a suitable enema formulation. Topically transdermal patches may also be used.”</p>
<p>33. The pharmaceutical composition of claim 1 indicated for the treatment and/or prevention and/or control of chronic pain, multiple sclerosis, severe depression (treatment resistant), major depressive disorder, obsessive-compulsive disorder, post-traumatic stress disorder, quitting smoking, alcohol addiction, cocaine addiction, opioid addiction, anxiety (stress), adjustment disorder, prolonged grief disorder (PGD), adult ADHD, cluster headaches, and cancer related or other end-of-life psychological distress in a patient.</p>	<p>17. U.S. Pat. App. No. 2021/0069170 “TRYPTAMINE COMPOSITIONS FOR ENHANCING NEURITE OUTGROWTH” (Published March 11, 2021)</p> <p>From [0007] “One embodiment described herein is a composition comprising norpsilocin or a salt or hydrate thereof or combinations thereof combined with one or more erinacines or hericenones in pure form, extracts or isolates from <i>Herichium</i> mushroom species, or combinations thereof...In another aspect, the cannabinoids comprise one or more of Δ8-tetrahydrocannabinol (THC), Δ9-tetrahydrocannabinol, tetrahydrocannabinolic acid (THCA), cannabidiol (CBD), ... In another aspect, the composition is effective to treat, alleviate, prevent or ameliorate psychiatric and mood disorders comprising serotonin (5-hydroxytryptamine, 5-HT) receptor disorders, depression, anxiety, major depressive disorder, treatment resistant depression, persistent depression, manic depression or bipolar disorder, depressive psychosis, perinatal depression, premenstrual dysphoric disorder, seasonal depressions, situational depression, panic disorder, obsessive compulsive disorder, post-traumatic stress disorder, attention deficit/hyperactivity disorder, sleep disorders, eating disorders, schizophrenia, personality disorders, substance abuse disorders (drug abuse, addiction, alcoholism); neuronal injuries or physical neurodegeneration (e.g., physical injury, head trauma, spinal cord trauma, concussion, peripheral neuron trauma, paralysis, ischemia, hypoxia, stroke; organophosphates, lead, heavy metals, nerve agents, other toxic compounds, prions, amyloid plaque, neurotoxic viruses, stress); neurodegenerative diseases (e.g., Alzheimer's disease, Parkinson's disease, amyotrophic lateral sclerosis, multiple sclerosis, frontotemporal dementia, Huntington's disease, adrenal leukodystrophy, Alexander's disease, Alper's disease, Alzheimer's disease, amyotrophic lateral sclerosis, balo concentric sclerosis, Canavan disease, Charcot-Marie-Tooth disease, childhood ataxia with</p>

	<p>central nervous system hypomyelination, chronic idiopathic peripheral neuropathy, frontotemporal dementia, Huntington's disease, Krabbe disease, monomelic amyotrophy, multiple sclerosis (MS), neurodegeneration, neuromyelitis optica, neuropathic pain, neurosarcoidosis, Parkinson's disease, Pelizaeus-Merzbacher disease, primary lateral sclerosis, progressive supranuclear palsy, radicular pain, radiculopathic pain, Schilder's disease, sciatic pain, sciatica, subacute necrotizing myelopathy, transverse myelitis, or Zellweger syndrome); congenital or organic cognitive impairment, learning disabilities, autism spectrum disorder; cognitive enhancement, intelligence enhancement, creativity enhancement, memory improvement, learning enhancement and improvement, spiritual enhancement, “mind expansion,” IQ improvement, EQ improvement, balance enhancement, athleticism, motor skill enhancement, special navigation, clairvoyance, psychic enhancement, or general improvement of mental health.”</p> <p>From [0003] “Serotonin (5-hydroxytryptamine, 5-HT) plays a significant role in influencing many central and peripheral processes. 5-HT-selective pharmacotherapies have been developed to treat a wide variety of medical problems including depression, anxiety, schizophrenia, migraine, emesis, and appetite control. 5-HT exerts its influence through activation of fourteen distinct receptor subtypes in seven separate families. There is interest in the three receptor subtypes of the 5-HT.sub.2 family, 5-HT.sub.2A, 5-HT.sub.2B, and 5-HT.sub.2C. Modulation of the 5-HT.sub.2C receptor subtype has been shown to play a role in numerous human diseases including obesity, obsessive-compulsive disorder (OCD), sexual dysfunction, epilepsy, schizophrenia, anxiety disorders, among a variety of other psychiatric disorders.”</p> <p>From [0165] “In another embodiment, the tryptamine comprises: ..., 12-methoxyibogamine (Ibogaine), N,N-diethyl-lysergic acid (LSD)...”</p> <p>From [0108] “The pharmaceutically acceptable compositions of this disclosure may also be administered topically, especially when the target of treatment includes areas or organs readily accessible by topical application, including diseases of the eye, the skin, or the lower intestinal tract. Suitable topical formulations are readily prepared for each of these areas or organs. Topical application for the lower intestinal tract can be administered using a rectal suppository formulation (see above) or a suitable enema formulation. Topically transdermal patches may also be used.”</p>
<p>34. The pharmaceutical composition of claim 1 wherein the pharmaceutical composition provides a continuous, sustained delivery of the</p>	<p>18. Priority Doc. of U.S. Pat. App. No. 2022/0017549 “PSILOCIN DERIVATIVES AS SEROTONERGIC PSYCHEDELIC AGENTS FOR THE TREATMENT OF CNS DISORDERS” provisional application (62/969,934) (Filing date: February 4, 2020)</p>

<p>pharmaceutical composition to mitigate peak and valley pharmacokinetic behavior of the active agent.</p>	<p>From provisional 62/969,934 page 80 line 20 “...Parenteral administration includes systemic delivery routes other than the gastrointestinal (GI) tract, and includes, for example intravenous, intra-arterial, intraperitoneal, subcutaneous, intramuscular, transepithelial, nasal, intrapulmonary (for example, by use of an aerosol), intrathecal, rectal and topical (including the use of a patch or other transdermal delivery device) modes of administration. Parenteral administration may be by continuous infusion over a selected period of time.”</p> <p>From provisional 62/969,934 page 81 line 4 “In some embodiments, a compound of the application is orally administered, for example, with an inert diluent or with an assimilable edible carrier, or it is enclosed in hard or soft shell gelatin capsules, or it is compressed into tablets, or it is incorporated directly with the food of the diet. In some embodiments, the compound is incorporated with excipient and used in the form of ingestible tablets, buccal tablets, troches, capsules, caplets, pellets, granules, lozenges, chewing gum, powders, syrups, elixirs, wafers, aqueous solutions and suspensions, and the like. In the case of tablets, carriers that are used include lactose, com starch, sodium citrate and salts of phosphoric acid. Pharmaceutically acceptable excipients include binding agents (e.g., pregelatinized maize starch, polyvinylpyrrolidone or hydroxypropyl methylcellulose); fillers (e.g., lactose, microcrystalline cellulose or calcium phosphate); lubricants (e.g., magnesium stearate, talc or silica); disintegrants (e.g., potato starch or sodium starch glycolate); or wetting agents (e.g., sodium lauryl sulphate), or solvents (e.g. medium chain triglycerides, ethanol, water). In embodiments, the tablets are coated by methods well known in the art. In the case of tablets, capsules, caplets, pellets or granules for oral administration, pH sensitive enteric coatings, such as Eudragits TM designed to control the release of active ingredients are optionally used. Oral dosage forms also include modified release, for example immediate release and timed-release, formulations. Examples of modifiedrelease formulations include, for example, sustained-release (SR), extended-release (ER, XR, or XL), time-release or timed-release, controlled-release (CR), or continuous- release (CR or Cantin), employed...”</p>
<p>35. The pharmaceutical composition of claim 1 wherein the pharmaceutical composition provides a continuous, sustained delivery of the pharmaceutical composition via administration to the patient by a route selected from the group consisting of parenteral, intravenous, subcutaneous, intramuscular, intrathecal, oral, buccal,</p>	<p>18. Priority Doc. of U.S. Pat. App. No. 2022/0017549 “PSILOPIN DERIVATIVES AS SEROTONERGIC PSYCHEDELIC AGENTS FOR THE TREATMENT OF CNS DISORDERS” provisional application (62/969,934) (Filing date: February 4, 2020)</p> <p>From provisional 62/969,934 page 80 line 20 “...Parenteral administration includes systemic delivery routes other than the gastrointestinal (GI) tract, and includes, for example intravenous, intra-arterial, intraperitoneal, subcutaneous, intramuscular, transepithelial, nasal, intrapulmonary (for example, by use of an aerosol), intrathecal, rectal and topical (including the use of a patch or other transdermal delivery device) modes of administration.</p>

<p>mucosal, intranasal, rectal, vaginal, transdermal, implantable, topical, and combinations thereof.</p>	<p>Parenteral administration may be by continuous infusion over a selected period of time.”</p> <p>From provisional 62/969,934 page 81 line 4 “In some embodiments, a compound of the application is orally administered, for example, with an inert diluent or with an assimilable edible carrier, or it is enclosed in hard or soft shell gelatin capsules, or it is compressed into tablets, or it is incorporated directly with the food of the diet. In some embodiments, the compound is incorporated with excipient and used in the form of ingestible tablets, buccal tablets, troches, capsules, caplets, pellets, granules, lozenges, chewing gum, powders, syrups, elixirs, wafers, aqueous solutions and suspensions, and the like. In the case of tablets, carriers that are used include lactose, com starch, sodium citrate and salts of phosphoric acid. Pharmaceutically acceptable excipients include binding agents (e.g., pregelatinized maize starch, polyvinylpyrrolidone or hydroxypropyl methylcellulose); fillers (e.g., lactose, microcrystalline cellulose or calcium phosphate); lubricants (e.g., magnesium stearate, talc or silica); disintegrants (e.g., potato starch or sodium starch glycolate); or wetting agents (e.g., sodium lauryl sulphate), or solvents (e.g. medium chain triglycerides, ethanol, water). In embodiments, the tablets are coated by methods well known in the art. In the case of tablets, capsules, caplets, pellets or granules for oral administration, pH sensitive enteric coatings, such as Eudragits TM designed to control the release of active ingredients are optionally used. Oral dosage forms also include modified release, for example immediate release and timed-release, formulations. Examples of modified release formulations include, for example, sustained-release (SR), extended-release (ER, XR, or XL), time-release or timed-release, controlled-release (CR), or continuous- release (CR or Cantin), employed...”</p>
<p>36. The pharmaceutical composition of claim 1 wherein the pharmaceutical composition provides a continuous, sustained delivery of the pharmaceutical composition via intravenous or subcutaneous infusion.</p>	<p>18. Priority Doc. of U.S. Pat. App. No. 2022/0017549 “PSILOCIN DERIVATIVES AS SEROTONERGIC PSYCHEDELIC AGENTS FOR THE TREATMENT OF CNS DISORDERS” provisional application (62/969,934) (Filing date: February 4, 2020)</p> <p>From provisional 62/969,934 page 80 line 20 “...Parenteral administration includes systemic delivery routes other than the gastrointestinal (GI) tract, and includes, for example intravenous, intra-arterial, intraperitoneal, subcutaneous, intramuscular, transepithelial, nasal, intrapulmonary (for example, by use of an aerosol), intrathecal, rectal and topical (including the use of a patch or other transdermal delivery device) modes of administration. Parenteral administration may be by continuous infusion over a selected period of time.”</p>
<p>37. A method for the treatment and/or prevention and/or control of severe depression (treatment resistant), major depressive</p>	<p>17. U.S. Pat. App. No. 2021/0069170 “TRYPTAMINE COMPOSITIONS FOR ENHANCING NEURITE OUTGROWTH” (Published March 11, 2021)</p>

disorder, obsessive-compulsive disorder, post-traumatic stress disorder, quitting smoking, alcohol addiction, cocaine addiction, opioid addiction, anxiety (stress), adult ADHD, cluster headaches, adjustment disorder, prolonged grief disorder (PGD), and cancer related or other end-of-life psychological distress in a patient comprising: selecting a patient in need of treatment and/or prevention and/or control of severe depression (treatment resistant), major depressive disorder, obsessive-compulsive disorder, quitting smoking, alcohol addiction, cocaine addiction, opioid addiction, anxiety (stress), adult ADHD, cluster headaches, adjustment disorder, prolonged grief disorder (PGD), and cancer related or other end-of-life psychological distress; topically applying the pharmaceutical composition of claim 1, thereby treating and/or preventing and/or controlling severe depression (treatment resistant), major depressive disorder, obsessive-compulsive disorder, quitting smoking, alcohol addiction, cocaine addiction, opioid addiction, anxiety (stress), adult ADHD, cluster headaches, adjustment disorder, prolonged grief disorder (PGD), and cancer related or other end-of-life psychological distress in said patient, wherein said

From [0007] “One embodiment described herein is a composition comprising **norpsilocin** or a salt or hydrate thereof or combinations thereof combined with one or more erinacines or hericenones in pure form, extracts or isolates from *Herichium* mushroom species, or combinations thereof... In another aspect, the **cannabinoids** comprise one or more of **Δ 8-tetrahydrocannabinol (THC)**, **Δ 9-tetrahydrocannabinol**, **tetrahydrocannabinolic acid (THCA)**, **cannabidiol (CBD)**, ... In another aspect, the composition is effective to treat, alleviate, prevent or ameliorate psychiatric and mood disorders comprising serotonin (5-hydroxytryptamine, 5-HT) receptor disorders, **depression**, anxiety, major depressive disorder, **treatment resistant depression**, **persistent depression**, **manic depression** or bipolar disorder, depressive psychosis, perinatal depression, premenstrual dysphoric disorder, **seasonal depressions**, **situational depression**, panic disorder, **obsessive compulsive disorder**, **post-traumatic stress disorder**, **attention deficit/hyperactivity disorder**, sleep disorders, eating disorders, schizophrenia, personality disorders, **substance abuse disorders (drug abuse, addiction, alcoholism)**; neuronal injuries or physical neurodegeneration (e.g., physical injury, head trauma, spinal cord trauma, concussion, peripheral neuron trauma, paralysis, ischemia, hypoxia, stroke; organophosphates, lead, heavy metals, nerve agents, other toxic compounds, prions, amyloid plaque, neurotoxic viruses, stress); neurodegenerative diseases (e.g., Alzheimer's disease, Parkinson's disease, amyotrophic lateral sclerosis, multiple sclerosis, frontotemporal dementia, Huntington's disease, adrenal leukodystrophy, Alexander's disease, Alper's disease, Alzheimer's disease, amyotrophic lateral sclerosis, balo concentric sclerosis, Canavan disease, Charcot-Marie-Tooth disease, childhood ataxia with central nervous system hypomyelination, chronic idiopathic peripheral neuropathy, frontotemporal dementia, Huntington's disease, Krabbe disease, monomelic amyotrophy, multiple sclerosis (MS), neurodegeneration, neuromyelitis optica, **neuropathic pain**, neurosarcoidosis, Parkinson's disease, Pelizaeus-Merzbacher disease, primary lateral sclerosis, progressive supranuclear palsy, **radicular pain**, **radiculopathic pain**, Schilder's disease, **sciatic pain**, sciatica, subacute necrotizing myelopathy, transverse myelitis, or Zellweger syndrome); congenital or organic cognitive impairment, learning disabilities, autism spectrum disorder; cognitive enhancement, intelligence enhancement, creativity enhancement, memory improvement, learning enhancement and improvement, spiritual enhancement, “mind expansion,” IQ improvement, EQ improvement, balance enhancement, athleticism, motor skill enhancement, special navigation, clairvoyance, psychic enhancement, or general improvement of mental health.”

From [0003] “Serotonin (5-hydroxytryptamine, 5-HT) plays a significant role in influencing many central and peripheral processes. 5-HT-selective pharmacotherapies have been developed to treat a wide variety of medical problems including depression, anxiety, schizophrenia, **migraine**, emesis, and appetite control. 5-HT exerts its influence through activation of fourteen distinct receptor subtypes in

<p>patient experiences no or minimal psychoactive or hallucinogenic effects from said transdermal pharmaceutical composition.</p>	<p>seven separate families. There is interest in the three receptor subtypes of the 5-HT.sub.2 family, 5-HT.sub.2A, 5-HT.sub.2B, and 5-HT.sub.2C. Modulation of the 5-HT.sub.2C receptor subtype has been shown to play a role in numerous human diseases including obesity, obsessive-compulsive disorder (OCD), sexual dysfunction, epilepsy, schizophrenia, anxiety disorders, among a variety of other psychiatric disorders.”</p> <p>From [0165] “In another embodiment, the tryptamine comprises: ..., 12-methoxyibogamine (Ibogaine), N,N-diethyl-lysergic acid (LSD)...”</p> <p>From [0108] “The pharmaceutically acceptable compositions of this disclosure may also be administered topically, especially when the target of treatment includes areas or organs readily accessible by topical application, including diseases of the eye, the skin, or the lower intestinal tract. Suitable topical formulations are readily prepared for each of these areas or organs. Topical application for the lower intestinal tract can be administered using a rectal suppository formulation (see above) or a suitable enema formulation. Topically transdermal patches may also be used.”</p> <p>From [0006] “The combination of sub-hallucinogenic “microdoses” of tryptamines, phenethylamines, or amphetamines with other neurogenic compounds such as the erinacines and hericenones, cannabinoids and other neurogenic or nootropic natural products can be used to treat a variety of neuronal disorders or enhance cognition and sensory motor neuron functioning. There is a need for such neurogenic and nootropic compositions.”</p>
<p>38. The method of claim 37 wherein the topical application of a pharmaceutical composition for the treatment and/or prevention and/or control of severe depression (treatment resistant), major depressive disorder, obsessive-compulsive disorder, post-traumatic stress disorder, quitting smoking, alcohol addiction, cocaine addiction, opioid addiction, anxiety (stress), adult ADHD, cluster headaches, adjustment disorder, prolonged grief disorder (PGD), and cancer related or other end-of-life psychological distress in a</p>	<p>17. U.S. Pat. App. No. 2021/0069170 “TRYPTAMINE COMPOSITIONS FOR ENHANCING NEURITE OUTGROWTH” (Published March 11, 2021)</p> <p>From [0007] “One embodiment described herein is a composition comprising norpsilocin or a salt or hydrate thereof or combinations thereof combined with one or more erinacines or hericenones in pure form, extracts or isolates from <i>Herichium</i> mushroom species, or combinations thereof. . . In another aspect, the cannabinoids comprise one or more of Δ8-tetrahydrocannabinol (THC), Δ9-tetrahydrocannabinol, tetrahydrocannabinolic acid (THCA), cannabidiol (CBD), . . . In another aspect, the composition is effective to treat, alleviate, prevent or ameliorate psychiatric and mood disorders comprising serotonin (5-hydroxytryptamine, 5-HT) receptor disorders, depression, anxiety, major depressive disorder, treatment resistant depression, persistent depression, manic depression or bipolar disorder, depressive psychosis, perinatal depression, premenstrual dysphoric disorder, seasonal depressions, situational depression, panic disorder, obsessive compulsive disorder, post-traumatic stress disorder, attention deficit/hyperactivity disorder, sleep disorders, eating disorders, schizophrenia, personality disorders, substance abuse</p>

patient, wherein the transdermal patch is applied at a time period selected from the group consisting of once in a day, once in two days, once in three days, once in four days, once in five days, once in six days, once in a week, once in ten days, and once in fifteen days.

disorders (drug abuse, addiction, alcoholism); neuronal injuries or physical neurodegeneration (e.g., physical injury, head trauma, spinal cord trauma, concussion, peripheral neuron trauma, paralysis, ischemia, hypoxia, stroke; organophosphates, lead, heavy metals, nerve agents, other toxic compounds, prions, amyloid plaque, neurotoxic viruses, stress); neurodegenerative diseases (e.g., Alzheimer's disease, Parkinson's disease, amyotrophic lateral sclerosis, multiple sclerosis, frontotemporal dementia, Huntington's disease, adrenal leukodystrophy, Alexander's disease, Alper's disease, Alzheimer's disease, amyotrophic lateral sclerosis, balo concentric sclerosis, Canavan disease, Charcot-Marie-Tooth disease, childhood ataxia with central nervous system hypomyelination, chronic idiopathic peripheral neuropathy, frontotemporal dementia, Huntington's disease, Krabbe disease, monomelic amyotrophy, multiple sclerosis (MS), neurodegeneration, neuromyelitis optica, **neuropathic pain**, neurosarcoidosis, Parkinson's disease, Pelizaeus-Merzbacher disease, primary lateral sclerosis, progressive supranuclear palsy, **radicular pain, radiculopathic pain**, Schilder's disease, **sciatic pain**, sciatica, subacute necrotizing myelopathy, transverse myelitis, or Zellweger syndrome); congenital or organic cognitive impairment, learning disabilities, autism spectrum disorder; cognitive enhancement, intelligence enhancement, creativity enhancement, memory improvement, learning enhancement and improvement, spiritual enhancement, "mind expansion," IQ improvement, EQ improvement, balance enhancement, athleticism, motor skill enhancement, special navigation, clairvoyance, psychic enhancement, or general improvement of mental health."

From [0003] "Serotonin (5-hydroxytryptamine, 5-HT) plays a significant role in influencing many central and peripheral processes. 5-HT-selective pharmacotherapies have been developed to treat a wide variety of medical problems including depression, anxiety, schizophrenia, **migraine**, emesis, and appetite control. 5-HT exerts its influence through activation of fourteen distinct receptor subtypes in seven separate families. There is interest in the three receptor subtypes of the 5-HT.sub.2 family, 5-HT.sub.2A, 5-HT.sub.2B, and 5-HT.sub.2C. Modulation of the 5-HT.sub.2C receptor subtype has been shown to play a role in numerous human diseases including obesity, obsessive-compulsive disorder (OCD), sexual dysfunction, epilepsy, schizophrenia, anxiety disorders, among a variety of other psychiatric disorders."

From [0165] "In another embodiment, the **tryptamine comprises: ..., 12-methoxyibogamine (Ibogaine), N,N-diethyl-lysergic acid (LSD)...**"

From [0108] "The pharmaceutically acceptable compositions of this disclosure may also be **administered topically**, especially when the target of treatment includes areas or organs readily accessible by topical application, including diseases of the eye, the skin, or the lower intestinal tract. Suitable topical formulations are readily prepared for

	<p>each of these areas or organs. Topical application for the lower intestinal tract can be administered using a rectal suppository formulation (see above) or a suitable enema formulation. Topically transdermal patches may also be used.”</p> <p>From [0006] “The combination of sub-hallucinogenic “microdoses” of tryptamines, phenethylamines, or amphetamines with other neurogenic compounds such as the erinacines and hericenones, cannabinoids and other neurogenic or nootropic natural products can be used to treat a variety of neuronal disorders or enhance cognition and sensory motor neuron functioning. There is a need for such neurogenic and nootropic compositions.”</p> <p>From [0158] “One or more dosage forms of the compositions described herein can be administered, for example, 1×, 2×, 3×, 4×, 5×, 6×, or even more times per day. One or more dosage forms can be administered, for example, for 1, 2, 3, 4, 5, 6, 7 days, or even longer. One or more dosage forms can be administered, for example, for 1, 2, 3, 4 weeks, or even longer. One or more dosage forms can be administered, for example, for 1, 2, 3, 4, 5, 6, 7, 8, 9, 10, 11, 12 months, 1 year, 2, years, 3 years, 4 years, 5 years, over 5 years, a decade, multiple decades, or even longer. One or more dosage forms can be administered at a regular interval until the subject or subject in need thereof, does not require treatment, prophylaxis, or amelioration of any disease or condition including but not limited to a neurological or neurodegenerative disease or disorder.”</p>
<p>39. The method of claim 37 wherein the pharmaceutical composition is applied to the patient separately, sequentially, or simultaneously.</p>	<p>17. U.S. Pat. App. No. 2021/0069170 “TRYPTAMINE COMPOSITIONS FOR ENHANCING NEURITE OUTGROWTH” (Published March 11, 2021)</p> <p>From [0127] “Another embodiment is a pharmaceutical combination comprising one or more of a tryptamine, an erinacine, a hericenone, a cannabinoid, or a pharmaceutically acceptable salt, hydrate, solvate, prodrug, stereoisomer, or tautomer thereof, a combination thereof, and one or more additional therapeutic agent(s) for simultaneous, separate or sequential use in therapy for neuronal injuries, neurodegeneration, neurological diseases, congenital or organic cognitive impairment, learning disabilities, autism spectrum disorder, psychiatric and mood disorders, cognitive enhancement, physical or motor neuron enhancement, or general improvement of mental health. In one embodiment, the additional therapeutic agent is selected from the group consisting of: an antiproliferative agent, anticancer agent, immunomodulatory agent, an anti-inflammatory agent, a neurological treatment agent, an anti-viral agent, an anti-fungal agent, anti-parasitic agent, an antibiotic, and a general anti-infective agent.”</p>
<p>40. The method of claim 37 further providing a constant rate of delivery of the active</p>	<p>20. Priority Doc. of U.S. Pat. App. No. 2021/0322447 “TRANSDERMAL MICRO-DOSING DELIVERY OF</p>

<p>components of the transdermal patch over a time period selected from the group consisting of once in a day, once in two days, once in three days, once in four days, once in five days, once in six days, once in a week, once in ten days, and once in fifteen days.</p>	<p>PSYCHEDELICS DERIVATIVES” provisional application (63/010,924) (Filing date: April 16, 2020)</p> <p>From provisional app. 63/010,924 claims 1 “1. A pharmaceutical composition comprising an active agent selected from the group consisting of psilocybin, lysergic acid diethylamide (LSD), and/or ibogaine, derivatives of these compounds, and combinations thereof, in a dosage form for transdermal delivery wherein said pharmaceutical composition will have no or minimal hallucinogenic effect in a patient to whom the pharmaceutical composition is applied.”</p> <p>From provisional app. 63/010,924 claims 2 “2. The pharmaceutical composition of claim 1 which comprises at least about 0.1 % to about 70% (w/w) of the active agent.”</p> <p>From provisional app. 63/010,924 page 37 line 23 “In some embodiments, the transdermal patches provide for a constant rate of delivery of the active components of the transdermal patch over a predetermined time period. In some embodiments, the predetermined time period is 24 hours, 48 hours, 72 hours, 96 hours, 120 hours, 144 hours, 7 days, 8 to 13 day, two weeks, or 15 day.”</p>
<p>41. The method of claim 37 further providing a steady absorption rates of the active components of the transdermal patch over a time period selected from the group consisting of once in a day, once in two days, once in three days, once in four days, once in five days, once in six days, once in a week, once in ten days, and once in fifteen days.</p>	<p>20. Priority Doc. of U.S. Pat. App. No. 2021/0322447 “TRANSDERMAL MICRO-DOSING DELIVERY OF PSYCHEDELICS DERIVATIVES” provisional application (63/010,924) (Filing date: April 16, 2020)</p> <p>From provisional app. 63/010,924 claims 1 “1. A pharmaceutical composition comprising an active agent selected from the group consisting of psilocybin, lysergic acid diethylamide (LSD), and/or ibogaine, derivatives of these compounds, and combinations thereof, in a dosage form for transdermal delivery wherein said pharmaceutical composition will have no or minimal hallucinogenic effect in a patient to whom the pharmaceutical composition is applied.”</p> <p>From provisional app. 63/010,924 claims 2 “2. The pharmaceutical composition of claim 1 which comprises at least about 0.1 % to about 70% (w/w) of the active agent.”</p> <p>From provisional app. 63/010,924 page 38 line 1 “In yet further embodiments, the transdermal patches described herein provide a steady absorption rate of the active components of the transdermal patches by the patient over a predetermined time. In one embodiments, the predetermined time period is 24 hours, 48 hours, 72 hours, 96 hours, 120 hours, 144 hours, 7 days, 8 to 13 days, two weeks, or 15 days.”</p>

<p>42. The method of claim 37 further achieving a constant blood serum levels of the active components of the transdermal patch over a time period selected from the group consisting of once in a day, once in two days, once in three days, once in four days, once in five days, once in six days, once in a week, once in ten days, and once in fifteen days.</p>	<p>20. Priority Doc. of U.S. Pat. App. No. 2021/0322447 “TRANSDERMAL MICRO-DOSING DELIVERY OF PSYCHEDELICS DERIVATIVES” provisional application (63/010,924) (Filing date: April 16, 2020)</p> <p>From provisional app. 63/010,924 claims 1 “1. A pharmaceutical composition comprising an active agent selected from the group consisting of psilocybin, lysergic acid diethylamide (LSD), and/or ibogaine, derivatives of these compounds, and combinations thereof, in a dosage form for transdermal delivery wherein said pharmaceutical composition will have no or minimal hallucinogenic effect in a patient to whom the pharmaceutical composition is applied.”</p> <p>From provisional app. 63/010,924 claims 2 “2. The pharmaceutical composition of claim 1 which comprises at least about 0.1 % to about 70% (w/w) of the active agent.”</p> <p>From provisional app. 63/010,924 page 38 line 5 “In yet further embodiments, the transdermal patches described herein provide a constant blood serum level of the active component of the transdermal patches in a patient over a predetermined time. In some embodiments, the predetermined time period is 24 hours, 48 hours, 72 hours, 96 hours, 120 hours, 144 hours, 7 days, 8 to 13 days, two weeks, or 15 days.”</p>
<p>43. The method of claim 37 further achieving a reduced variability in dosage of the active components of the transdermal patches over a time period selected from the group consisting of once in a day, once in two days, once in three days, once in four days, once in five days, once in six days, once in a week, once in ten days, and once in fifteen days.</p>	<p>20. Priority Doc. of U.S. Pat. App. No. 2021/0322447 “TRANSDERMAL MICRO-DOSING DELIVERY OF PSYCHEDELICS DERIVATIVES” provisional application (63/010,924) (Filing date: April 16, 2020)</p> <p>From provisional app. 63/010,924 claims 1 “1. A pharmaceutical composition comprising an active agent selected from the group consisting of psilocybin, lysergic acid diethylamide (LSD), and/or ibogaine, derivatives of these compounds, and combinations thereof, in a dosage form for transdermal delivery wherein said pharmaceutical composition will have no or minimal hallucinogenic effect in a patient to whom the pharmaceutical composition is applied.”</p> <p>From provisional app. 63/010,924 claims 2 “2. The pharmaceutical composition of claim 1 which comprises at least about 0.1 % to about 70% (w/w) of the active agent.”</p> <p>From provisional app. 63/010,924 page 38 line 13 “In yet further embodiments, the transdermal patches described herein allow for reduced variability in dosage of active components in a patient over a predetermined time. In some embodiment , the predetermined time period is 24 hours, 48 hours, 72 hour , 96 hour , 120 hour , 144 hours, 7 days, 8 to 13 days, two weeks, or 15 days.”</p>

<p>44. The method of claim 37 further providing a plasma concentration of the active components of the transdermal patch in a therapeutic range over a time period selected from the group consisting of once in a day, once in two days, once in three days, once in four days, once in five days, once in six days, once in a week, once in ten days, and once in fifteen days.</p>	<p>20. Priority Doc. of U.S. Pat. App. No. 2021/0322447 “TRANSDERMAL MICRO-DOSING DELIVERY OF PSYCHEDELICS DERIVATIVES” provisional application (63/010,924) (Filing date: April 16, 2020)</p> <p>From provisional app. 63/010,924 claims 1 “1. A pharmaceutical composition comprising an active agent selected from the group consisting of psilocybin, lysergic acid diethylamide (LSD), and/or ibogaine, derivatives of these compounds, and combinations thereof, in a dosage form for transdermal delivery wherein said pharmaceutical composition will have no or minimal hallucinogenic effect in a patient to whom the pharmaceutical composition is applied.”</p> <p>From provisional app. 63/010,924 claims 2 “2. The pharmaceutical composition of claim 1 which comprises at least about 0.1 % to about 70% (w/w) of the active agent.”</p> <p>From provisional app. 63/010,924 page 38 line 9 “In yet further embodiments, the transdermal patches described herein provide a plasma concentration of the active components of the trans dermal patches in a therapeutic range in a patient over a predetermined time. In some embodiment , the predetermined time period is 24 hours, 48 hours, 72 hours, 96 hours, 120 hours, 144 hours, 7 days, 8 to 13 days, two weeks, or 15 days.”</p>
<p>45. The method of claim 37 further providing a plasma concentration of the active components of the transdermal patch in a therapeutic range of about 0.01 ng/mL to about 500 ng/mL.</p>	<p>20. Priority Doc. of U.S. Pat. App. No. 2021/0322447 “TRANSDERMAL MICRO-DOSING DELIVERY OF PSYCHEDELICS DERIVATIVES” provisional application (63/010,924) (Filing date: April 16, 2020)</p> <p>From provisional app. 63/010,924 claims 1 “1. A pharmaceutical composition comprising an active agent selected from the group consisting of psilocybin, lysergic acid diethylamide (LSD), and/or ibogaine, derivatives of these compounds, and combinations thereof, in a dosage form for transdermal delivery wherein said pharmaceutical composition will have no or minimal hallucinogenic effect in a patient to whom the pharmaceutical composition is applied.”</p> <p>From provisional app. 63/010,924 claims 2 “2. The pharmaceutical composition of claim 1 which comprises at least about 0.1 % to about 70% (w/w) of the active agent.”</p> <p>From provisional app. 63/010,924 page 38 line 17 “In yet further embodiments, the transdermal patches described herein provide a plasma concentration of the active components of the transdermal patches in a therapeutic range in a patient over a predetermined time. In exemplary embodiment as di clo ed herein, the tran dermal patch</p>

provides a blood serum level of active agent of, for example, about 0.01 ng/mL, about 0.02 ng/mL, about 0.05 ng/mL, about **0.1 ng/mL**, **about 0.2 ng/mL**, **about 0.5 ng/mL**, **about 1 ng/mL**, **about 2 ng/mL**, **about 5 ng/mL**, **about 10 ng/mL**, **about 20 ng/mL**, **about 50 ng/mL**, **about 100 ng/mL**, **about 200 ng/mL**, **about 500 ng/mL**, **about 1 µg/mL**, **about 2 µg/mL**, **about 5 µg/mL**, **about 10 µg/mL**, **about 20 µg/mL**, **about 50 µg/mL**, , and ranges thereof.”

2. W.I.P.O. Pat. App. No. 2020/157569 “METHODS AND COMPOSITIONS COMPRISING A 5HT RECEPTOR AGONIST FOR THE TREATMENT OF PSYCHOLOGICAL, COGNITIVE, BEHAVIORAL, AND/OR MOOD DISORDERS” (Published August 6, 2020)

From **claim 1** “A method of managing a neurological condition or one or more symptoms thereof in a subject in need thereof, comprising administering to the subject a pharmaceutical composition comprising:
a) a therapeutically effective amount of one or more 5HT receptor agonist or a pharmaceutically acceptable salt, solvate, metabolite, derivative, or prodrug thereof; and
b) a pharmaceutically acceptable excipient wherein the therapeutically effective amount of the **5HT receptor agonist** or a pharmaceutically acceptable salt, solvate, metabolite, derivative, or prodrug thereof is provided to the subject in need thereof **in an amount insufficient to provide an adverse side effect, such as hallucinogenic experience.**”

From **claim 17** “The method of any one of the preceding claims, wherein the pharmaceutical composition is in a form selected from a spray, aerosol, mist, nebulae, **ointment, cream, gel, paste, salve**, solution, suspension, tincture, **patch**, and atomized vapor.”

From **[0047]** “Examples of **tryptamines** include serotonin, melatonin, **psilocybin** and N,N-dimethyltryptamine. Additionally, the tryptamine structure may comprise part of a more complex compound, for example: **LSD, ibogaine**, mitragynine, yohimbine, etc.”

From **[0019]** “In some embodiments, the therapeutically effective amount of **5HT receptor agonist** or a pharmaceutically acceptable salt, solvate, metabolite, derivative, or prodrug (e.g., **psilocybin**) thereof is provided to a subject in need thereof in an amount and/or formulation to provide a **maximum plasma concentration (C_{max})** of (e.g. active form of the) **5HT receptor agonist (e.g., psilocin)** or a pharmaceutically acceptable salt, solvate, metabolite, derivative, or prodrug thereof of about **0.1 ng/mL or more and less than 6 ng/mL (e.g. at least 0.5 ng/mL and less than 6 ng/mL, about 1 ng/mL to about 5.5 ng/mL, about 2 ng/mL to about 5 ng/mL, or the like).**”

<p>46. The method of claim 37 wherein the pharmaceutical composition provides a continuous, sustained delivery of the pharmaceutical composition to mitigate peak and valley pharmacokinetic behavior of the active agent.</p>	<p>18. Priority Doc. of U.S. Pat. App. No. 2022/0017549 “PSILOCIN DERIVATIVES AS SEROTONERGIC PSYCHEDELIC AGENTS FOR THE TREATMENT OF CNS DISORDERS” provisional application (62/969,934) (Filing date: February 4, 2020)</p> <p>From provisional 62/969,934 page 80 line 20 “...Parenteral administration includes systemic delivery routes other than the gastrointestinal (GI) tract, and includes, for example intravenous, intra-arterial, intraperitoneal, subcutaneous, intramuscular, transepithelial, nasal, intrapulmonary (for example, by use of an aerosol), intrathecal, rectal and topical (including the use of a patch or other transdermal delivery device) modes of administration. Parenteral administration may be by continuous infusion over a selected period of time.”</p> <p>From provisional 62/969,934 page 81 line 4 “In some embodiments, a compound of the application is orally administered, for example, with an inert diluent or with an assimilable edible carrier, or it is enclosed in hard or soft shell gelatin capsules, or it is compressed into tablets, or it is incorporated directly with the food of the diet. In some embodiments, the compound is incorporated with excipient and used in the form of ingestible tablets, buccal tablets, troches, capsules, caplets, pellets, granules, lozenges, chewing gum, powders, syrups, elixirs, wafers, aqueous solutions and suspensions, and the like. In the case of tablets, carriers that are used include lactose, com starch, sodium citrate and salts of phosphoric acid. Pharmaceutically acceptable excipients include binding agents (e.g., pregelatinized maize starch, polyvinylpyrrolidone or hydroxypropyl methylcellulose); fillers (e.g., lactose, microcrystalline cellulose or calcium phosphate); lubricants (e.g., magnesium stearate, talc or silica); disintegrants (e.g., potato starch or sodium starch glycolate); or wetting agents (e.g., sodium lauryl sulphate), or solvents (e.g. medium chain triglycerides, ethanol, water). In embodiments, the tablets are coated by methods well known in the art. In the case of tablets, capsules, caplets, pellets or granules for oral administration, pH sensitive enteric coatings, such as Eudragits TM designed to control the release of active ingredients are optionally used. Oral dosage forms also include modified release, for example immediate release and timed-release, formulations. Examples of modifiedrelease formulations include, for example, sustained-release (SR), extended-release (ER, XR, or XL), time-release or timed-release, controlled-release (CR), or continuous- release (CR or Cantin), employed...”</p>
<p>47. The method of claim 37 wherein the pharmaceutical composition provides a continuous, sustained delivery of the pharmaceutical composition via administration to the patient by a route selected</p>	<p>18. Priority Doc. of U.S. Pat. App. No. 2022/0017549 “PSILOCIN DERIVATIVES AS SEROTONERGIC PSYCHEDELIC AGENTS FOR THE TREATMENT OF CNS DISORDERS” provisional application (62/969,934) (Filing date: February 4, 2020)</p> <p>From provisional 62/969,934 page 80 line 20 “...Parenteral administration includes systemic delivery routes other than the gastrointestinal (GI) tract, and includes, for example intravenous,</p>

<p>from the group consisting of parenteral, intravenous, subcutaneous, intramuscular, intrathecal, oral, buccal, mucosal, intranasal, rectal, vaginal, transdermal, implantable, topical, and combinations thereof.</p>	<p>intra-arterial, intraperitoneal, subcutaneous, intramuscular, transepithelial, nasal, intrapulmonary (for example, by use of an aerosol), intrathecal, rectal and topical (including the use of a patch or other transdermal delivery device) modes of administration. Parenteral administration may be by continuous infusion over a selected period of time.”</p> <p>From provisional 62/969,934 page 81 line 4 “In some embodiments, a compound of the application is orally administered, for example, with an inert diluent or with an assimilable edible carrier, or it is enclosed in hard or soft shell gelatin capsules, or it is compressed into tablets, or it is incorporated directly with the food of the diet. In some embodiments, the compound is incorporated with excipient and used in the form of ingestible tablets, buccal tablets, troches, capsules, caplets, pellets, granules, lozenges, chewing gum, powders, syrups, elixirs, wafers, aqueous solutions and suspensions, and the like. In the case of tablets, carriers that are used include lactose, com starch, sodium citrate and salts of phosphoric acid. Pharmaceutically acceptable excipients include binding agents (e.g., pregelatinized maize starch, polyvinylpyrrolidone or hydroxypropyl methylcellulose); fillers (e.g., lactose, microcrystalline cellulose or calcium phosphate); lubricants (e.g., magnesium stearate, talc or silica); disintegrants (e.g., potato starch or sodium starch glycolate); or wetting agents (e.g., sodium lauryl sulphate), or solvents (e.g. medium chain triglycerides, ethanol, water). In embodiments, the tablets are coated by methods well known in the art. In the case of tablets, capsules, caplets, pellets or granules for oral administration, pH sensitive enteric coatings, such as Eudragits TM designed to control the release of active ingredients are optionally used. Oral dosage forms also include modified release, for example immediate release and timed-release, formulations. Examples of modifiedrelease formulations include, for example, sustained-release (SR), extended-release (ER, XR, or XL), time-release or timed-release, controlled-release (CR), or continuous- release (CR or Cantin), employed...”</p>
<p>48. The method of claim 37 wherein the pharmaceutical composition provides a continuous, sustained delivery of the pharmaceutical composition via intravenous or subcutaneous infusion.</p>	<p>18. Priority Doc. of U.S. Pat. App. No. 2022/0017549 “PSILOICIN DERIVATIVES AS SEROTONERGIC PSYCHEDELIC AGENTS FOR THE TREATMENT OF CNS DISORDERS” provisional application (62/969,934) (Filing date: February 4, 2020)</p> <p>From provisional 62/969,934 page 80 line 20 “...Parenteral administration includes systemic delivery routes other than the gastrointestinal (GI) tract, and includes, for example intravenous, intra-arterial, intraperitoneal, subcutaneous, intramuscular, transepithelial, nasal, intrapulmonary (for example, by use of an aerosol), intrathecal, rectal and topical (including the use of a patch or other transdermal delivery device) modes of administration. Parenteral administration may be by continuous infusion over a selected period of time.”</p>

	<p>From provisional 62/969,934 page 81 line 4 “In some embodiments, a compound of the application is orally administered, for example, with an inert diluent or with an assimilable edible carrier, or it is enclosed in hard or soft shell gelatin capsules, or it is compressed into tablets, or it is incorporated directly with the food of the diet. In some embodiments, the compound is incorporated with excipient and used in the form of ingestible tablets, buccal tablets, troches, capsules, caplets, pellets, granules, lozenges, chewing gum, powders, syrups, elixirs, wafers, aqueous solutions and suspensions, and the like. In the case of tablets, carriers that are used include lactose, com starch, sodium citrate and salts of phosphoric acid. Pharmaceutically acceptable excipients include binding agents (e.g., pregelatinized maize starch, polyvinylpyrrolidone or hydroxypropyl methylcellulose); fillers (e.g., lactose, microcrystalline cellulose or calcium phosphate); lubricants (e.g., magnesium stearate, talc or silica); disintegrants (e.g., potato starch or sodium starch glycolate); or wetting agents (e.g., sodium lauryl sulphate), or solvents (e.g. medium chain triglycerides, ethanol, water). In embodiments, the tablets are coated by methods well known in the art. In the case of tablets, capsules, caplets, pellets or granules for oral administration, pH sensitive enteric coatings, such as Eudragits™ designed to control the release of active ingredients are optionally used. Oral dosage forms also include modified release, for example immediate release and timed-release, formulations. Examples of modified release formulations include, for example, sustained-release (SR), extended-release (ER, XR, or XL), time-release or timed-release, controlled-release (CR), or continuous- release (CR or Cantin), employed...”</p>
<p>49. A method for the treatment and/or prevention and/or control of chronic pain in a patient comprising: selecting a patient in need of treatment and/or prevention and/or control of chronic pain; topically applying the pharmaceutical composition of claim 1, thereby treating, preventing and/or controlling chronic pain in the patient, wherein said patient experiences no or minimal psychoactive or hallucinogenic effects from said transdermal pharmaceutical composition.</p>	<p>2. W.I.P.O. Pat. App. No. 2020/157569 “METHODS AND COMPOSITIONS COMPRISING A 5HT RECEPTOR AGONIST FOR THE TREATMENT OF PSYCHOLOGICAL, COGNITIVE, BEHAVIORAL, AND/OR MOOD DISORDERS” (Published August 6, 2020)</p> <p>From claim 1 “A method of managing a neurological condition or one or more symptoms thereof in a subject in need thereof, comprising administering to the subject a pharmaceutical composition comprising: a) a therapeutically effective amount of one or more 5HT receptor agonist or a pharmaceutically acceptable salt, solvate, metabolite, derivative, or prodrug thereof; and b) a pharmaceutically acceptable excipient wherein the therapeutically effective amount of the 5HT receptor agonist or a pharmaceutically acceptable salt, solvate, metabolite, derivative, or prodrug thereof is provided to the subject in need thereof in an amount insufficient to provide an adverse side effect, such as hallucinogenic experience.”</p> <p>From claim 30 “The method of any one of the preceding claims, wherein the pharmaceutical composition is administered to a subject in need thereof once a day, every alternate day, three times a week,</p>

	<p>twice a week, once a week, every other week, two weeks per month, three weeks per month, once a month, twice a month or three times per month.</p> <p>From claim 31 “The method of any one of the preceding claims, wherein the pharmaceutical composition is administered about once a day.”</p> <p>From [0138] “These pharmaceutical compositions might also be formulated for transmucosal administration, buccal administration, for administration by inhalation, for parental administration, for transdermal administration, and rectal administration”</p> <p>From [0076] “In some embodiments, the neurological condition is a neurological disorder. In some embodiments, the neurological condition is a neurocognitive disorder. In some embodiments, the symptoms of the neurological condition are physical, behavioral, emotional, mental or a combination thereof. In some embodiments, the neurological condition is an addictive disorder. In some embodiments, the addictive disorder is alcohol abuse, substance abuse, smoking, or obesity. In some embodiments, the neurological condition is an eating disorder or an auditory disorder. In some embodiments, the neurological condition is pain (e.g. chronic pain).”</p>
<p>50. The method of claim 49, wherein the chronic pain is selected from the group consisting of neuropathic pain, peripheral neuropathic pain, inflammatory pain, musculoskeletal pain, pain due to muscle spasms, pain due to increased muscle tone, osteoarthritic pain, muscular headache, tension-type headache, migraine, cluster headache, atypical facial pain, referred pain, vulvodinia, proctodynia, and any combination thereof.</p>	<p>2. W.I.P.O. Pat. App. No. 2020/157569 “METHODS AND COMPOSITIONS COMPRISING A 5HT RECEPTOR AGONIST FOR THE TREATMENT OF PSYCHOLOGICAL, COGNITIVE, BEHAVIORAL, AND/OR MOOD DISORDERS” (Published August 6, 2020)</p> <p>From claim 1 “A method of managing a neurological condition or one or more symptoms thereof in a subject in need thereof, comprising administering to the subject a pharmaceutical composition comprising: a) a therapeutically effective amount of one or more 5HT receptor agonist or a pharmaceutically acceptable salt, solvate, metabolite, derivative, or prodrug thereof; and b) a pharmaceutically acceptable excipient wherein the therapeutically effective amount of the 5HT receptor agonist or a pharmaceutically acceptable salt, solvate, metabolite, derivative, or prodrug thereof is provided to the subject in need thereof in an amount insufficient to provide an adverse side effect, such as hallucinogenic experience.”</p> <p>From claim 30 “The method of any one of the preceding claims, wherein the pharmaceutical composition is administered to a subject in need thereof once a day, every alternate day, three times a week, twice a week, once a week, every other week, two weeks per month, three weeks per month, once a month, twice a month or three times per month.</p>

	<p>From claim 31 “The method of any one of the preceding claims, wherein the pharmaceutical composition is administered about once a day.”</p> <p>From [0138] “These pharmaceutical compositions might also be formulated for transmucosal administration, buccal administration, for administration by inhalation, for parental administration, for transdermal administration, and rectal administration”</p> <p>From [0076] “In some embodiments, the neurological condition is a neurological disorder. In some embodiments, the neurological condition is a neurocognitive disorder. In some embodiments, the symptoms of the neurological condition are physical, behavioral, emotional, mental or a combination thereof. In some embodiments, the neurological condition is an addictive disorder. In some embodiments, the addictive disorder is alcohol abuse, substance abuse, smoking, or obesity. In some embodiments, the neurological condition is an eating disorder or an auditory disorder. In some embodiments, the neurological condition is pain (e.g. chronic pain).”</p> <p>From [0198] “Paraphilic disorders (sexual perversion, sexual deviation) which may involve sexual interest in atypical objects, situations, fantasies, behaviors, or individuals. Examples include but are not limited to sexual sadism disorder, voyeuristic disorder, and pedophilic disorder. [199] Further examples of the disorders, conditions and symptoms which may be managed or treated include by way of non-limiting example, Fragile X syndrome, Down syndrome, migraine headache, cluster headache...”</p>
<p>51. The method of claim 49 wherein the topical application of a pharmaceutical composition is for the treatment and/or prevention and/or control of chronic pain in a patient, and wherein the transdermal patch is applied at a time period selected from the group consisting of once in a day, once in two days, once in three days, once in four days, once in five days, once in six days, once in a week, and once in ten days, and once in fifteen days.</p>	<p>2. W.I.P.O. Pat. App. No. 2020/157569 “METHODS AND COMPOSITIONS COMPRISING A 5HT RECEPTOR AGONIST FOR THE TREATMENT OF PSYCHOLOGICAL, COGNITIVE, BEHAVIORAL, AND/OR MOOD DISORDERS” (Published August 6, 2020)</p> <p>From claim 1 “A method of managing a neurological condition or one or more symptoms thereof in a subject in need thereof, comprising administering to the subject a pharmaceutical composition comprising: a) a therapeutically effective amount of one or more 5HT receptor agonist or a pharmaceutically acceptable salt, solvate, metabolite, derivative, or prodrug thereof; and b) a pharmaceutically acceptable excipient wherein the therapeutically effective amount of the 5HT receptor agonist or a pharmaceutically acceptable salt, solvate, metabolite, derivative, or prodrug thereof is provided to the subject in need thereof in an amount insufficient to provide an adverse side effect, such as hallucinogenic experience.”</p>

	<p>From claim 30 “The method of any one of the preceding claims, wherein the pharmaceutical composition is administered to a subject in need thereof once a day, every alternate day, three times a week, twice a week, once a week, every other week, two weeks per month, three weeks per month, once a month, twice a month or three times per month.</p> <p>From claim 31 “The method of any one of the preceding claims, wherein the pharmaceutical composition is administered about once a day.”</p> <p>From [0138] “These pharmaceutical compositions might also be formulated for transmucosal administration, buccal administration, for administration by inhalation, for parental administration, for transdermal administration, and rectal administration”</p> <p>From [0076] “In some embodiments, the neurological condition is a neurological disorder. In some embodiments, the neurological condition is a neurocognitive disorder. In some embodiments, the symptoms of the neurological condition are physical, behavioral, emotional, mental or a combination thereof. In some embodiments, the neurological condition is an addictive disorder. In some embodiments, the addictive disorder is alcohol abuse, substance abuse, smoking, or obesity. In some embodiments, the neurological condition is an eating disorder or an auditory disorder. In some embodiments, the neurological condition is pain (e.g. chronic pain).”</p>
<p>52. The method of claim 49 wherein the pharmaceutical compositions are applied to the patient separately, sequentially or simultaneously.</p>	<p>17. U.S. Pat. App. No. 2021/0069170 “TRYPTAMINE COMPOSITIONS FOR ENHANCING NEURITE OUTGROWTH” (Published March 11, 2021)</p> <p>From [0127] “Another embodiment is a pharmaceutical combination comprising one or more of a tryptamine, an erinacine, a hericenone, a cannabinoid, or a pharmaceutically acceptable salt, hydrate, solvate, prodrug, stereoisomer, or tautomer thereof, a combination thereof, and one or more additional therapeutic agent(s) for simultaneous, separate or sequential use in therapy for neuronal injuries, neurodegeneration, neurological diseases, congenital or organic cognitive impairment, learning disabilities, autism spectrum disorder, psychiatric and mood disorders, cognitive enhancement, physical or motor neuron enhancement, or general improvement of mental health. In one embodiment, the additional therapeutic agent is selected from the group consisting of: an antiproliferative agent, anticancer agent, immunomodulatory agent, an anti-inflammatory agent, a neurological treatment agent, an anti-viral agent, an anti-fungal agent, anti-parasitic agent, an antibiotic, and a general anti-infective agent.”</p>

<p>53. The method of claim 49 wherein the pharmaceutical composition provides a continuous, sustained delivery of the pharmaceutical composition to mitigate peak and valley pharmacokinetic behavior of the active agent.</p>	<p>18. Priority Doc. of U.S. Pat. App. No. 2022/0017549 “PSILOCIN DERIVATIVES AS SEROTONERGIC PSYCHEDELIC AGENTS FOR THE TREATMENT OF CNS DISORDERS” provisional application (62/969,934) (Filing date: February 4, 2020)</p> <p>From provisional 62/969,934 page 80 line 20 “...Parenteral administration includes systemic delivery routes other than the gastrointestinal (GI) tract, and includes, for example intravenous, intra-arterial, intraperitoneal, subcutaneous, intramuscular, transepithelial, nasal, intrapulmonary (for example, by use of an aerosol), intrathecal, rectal and topical (including the use of a patch or other transdermal delivery device) modes of administration. Parenteral administration may be by continuous infusion over a selected period of time.”</p> <p>From provisional 62/969,934 page 81 line 4 “In some embodiments, a compound of the application is orally administered, for example, with an inert diluent or with an assimilable edible carrier, or it is enclosed in hard or soft shell gelatin capsules, or it is compressed into tablets, or it is incorporated directly with the food of the diet. In some embodiments, the compound is incorporated with excipient and used in the form of ingestible tablets, buccal tablets, troches, capsules, caplets, pellets, granules, lozenges, chewing gum, powders, syrups, elixirs, wafers, aqueous solutions and suspensions, and the like. In the case of tablets, carriers that are used include lactose, com starch, sodium citrate and salts of phosphoric acid. Pharmaceutically acceptable excipients include binding agents (e.g., pregelatinized maize starch, polyvinylpyrrolidone or hydroxypropyl methylcellulose); fillers (e.g., lactose, microcrystalline cellulose or calcium phosphate); lubricants (e.g., magnesium stearate, talc or silica); disintegrants (e.g., potato starch or sodium starch glycolate); or wetting agents (e.g., sodium lauryl sulphate), or solvents (e.g. medium chain triglycerides, ethanol, water). In embodiments, the tablets are coated by methods well known in the art. In the case of tablets, capsules, caplets, pellets or granules for oral administration, pH sensitive enteric coatings, such as Eudragits TM designed to control the release of active ingredients are optionally used. Oral dosage forms also include modified release, for example immediate release and timed-release, formulations. Examples of modifiedrelease formulations include, for example, sustained-release (SR), extended-release (ER, XR, or XL), time-release or timed-release, controlled-release (CR), or continuous- release (CR or Cantin), employed...”</p>
<p>54. The method of claim 49 wherein the pharmaceutical composition provides a continuous, sustained delivery of the pharmaceutical composition via administration to the patient by a route selected</p>	<p>18. Priority Doc. of U.S. Pat. App. No. 2022/0017549 “PSILOCIN DERIVATIVES AS SEROTONERGIC PSYCHEDELIC AGENTS FOR THE TREATMENT OF CNS DISORDERS” provisional application (62/969,934) (Filing date: February 4, 2020)</p> <p>From provisional 62/969,934 page 80 line 20 “...Parenteral administration includes systemic delivery routes other than the gastrointestinal (GI) tract, and includes, for example intravenous,</p>

<p>from the group consisting of parenteral, intravenous, subcutaneous, intramuscular, intrathecal, oral, buccal, mucosal, intranasal, rectal, vaginal, transdermal, implantable, topical, and combinations thereof.</p>	<p>intra-arterial, intraperitoneal, subcutaneous, intramuscular, transepithelial, nasal, intrapulmonary (for example, by use of an aerosol), intrathecal, rectal and topical (including the use of a patch or other transdermal delivery device) modes of administration. Parenteral administration may be by continuous infusion over a selected period of time.”</p> <p>From provisional 62/969,934 page 81 line 4 “In some embodiments, a compound of the application is orally administered, for example, with an inert diluent or with an assimilable edible carrier, or it is enclosed in hard or soft shell gelatin capsules, or it is compressed into tablets, or it is incorporated directly with the food of the diet. In some embodiments, the compound is incorporated with excipient and used in the form of ingestible tablets, buccal tablets, troches, capsules, caplets, pellets, granules, lozenges, chewing gum, powders, syrups, elixirs, wafers, aqueous solutions and suspensions, and the like. In the case of tablets, carriers that are used include lactose, com starch, sodium citrate and salts of phosphoric acid. Pharmaceutically acceptable excipients include binding agents (e.g., pregelatinized maize starch, polyvinylpyrrolidone or hydroxypropyl methylcellulose); fillers (e.g., lactose, microcrystalline cellulose or calcium phosphate); lubricants (e.g., magnesium stearate, talc or silica); disintegrants (e.g., potato starch or sodium starch glycolate); or wetting agents (e.g., sodium lauryl sulphate), or solvents (e.g. medium chain triglycerides, ethanol, water). In embodiments, the tablets are coated by methods well known in the art. In the case of tablets, capsules, caplets, pellets or granules for oral administration, pH sensitive enteric coatings, such as Eudragits™ designed to control the release of active ingredients are optionally used. Oral dosage forms also include modified release, for example immediate release and timed-release, formulations. Examples of modified release formulations include, for example, sustained-release (SR), extended-release (ER, XR, or XL), time-release or timed-release, controlled-release (CR), or continuous- release (CR or Cantin), employed...”</p>
<p>55. The method of claim 49 wherein the pharmaceutical composition provides a continuous, sustained delivery of the pharmaceutical composition via intravenous or subcutaneous infusion.</p>	<p>18. Priority Doc. of U.S. Pat. App. No. 2022/0017549 “PSILOICIN DERIVATIVES AS SEROTONERGIC PSYCHEDELIC AGENTS FOR THE TREATMENT OF CNS DISORDERS” provisional application (62/969,934) (Filing date: February 4, 2020)</p> <p>From provisional 62/969,934 page 80 line 20 “...Parenteral administration includes systemic delivery routes other than the gastrointestinal (GI) tract, and includes, for example intravenous, intra-arterial, intraperitoneal, subcutaneous, intramuscular, transepithelial, nasal, intrapulmonary (for example, by use of an aerosol), intrathecal, rectal and topical (including the use of a patch or other transdermal delivery device) modes of administration. Parenteral administration may be by continuous infusion over a selected period of time.”</p>

	<p>From provisional 62/969,934 page 81 line 4 “In some embodiments, a compound of the application is orally administered, for example, with an inert diluent or with an assimilable edible carrier, or it is enclosed in hard or soft shell gelatin capsules, or it is compressed into tablets, or it is incorporated directly with the food of the diet. In some embodiments, the compound is incorporated with excipient and used in the form of ingestible tablets, buccal tablets, troches, capsules, caplets, pellets, granules, lozenges, chewing gum, powders, syrups, elixirs, wafers, aqueous solutions and suspensions, and the like. In the case of tablets, carriers that are used include lactose, com starch, sodium citrate and salts of phosphoric acid. Pharmaceutically acceptable excipients include binding agents (e.g., pregelatinized maize starch, polyvinylpyrrolidone or hydroxypropyl methylcellulose); fillers (e.g., lactose, microcrystalline cellulose or calcium phosphate); lubricants (e.g., magnesium stearate, talc or silica); disintegrants (e.g., potato starch or sodium starch glycolate); or wetting agents (e.g., sodium lauryl sulphate), or solvents (e.g. medium chain triglycerides, ethanol, water). In embodiments, the tablets are coated by methods well known in the art. In the case of tablets, capsules, caplets, pellets or granules for oral administration, pH sensitive enteric coatings, such as Eudragits™ designed to control the release of active ingredients are optionally used. Oral dosage forms also include modified release, for example immediate release and timed-release, formulations. Examples of modifiedrelease formulations include, for example, sustained-release (SR), extended-release (ER, XR, or XL), time-release or timed-release, controlled-release (CR), or continuous- release (CR or Cantin), employed...”</p>
<p>56. A method for the treatment and/or prevention and/or control of adjustment disorder in a patient comprising: selecting a patient in need of treatment and/or prevention and/or control of adjustment disorder; topically applying the pharmaceutical composition of claim 1, thereby treating and/or preventing and/or controlling adjustment disorder in the patient, wherein said patent experiences no or minimal psychoactive or hallucinogenic effects from said transdermal pharmaceutical composition.</p>	<p>18. Priority Doc. of U.S. Pat. App. No. 2022/0017549 “PSILOCIN DERIVATIVES AS SEROTONERGIC PSYCHEDELIC AGENTS FOR THE TREATMENT OF CNS DISORDERS” provisional application (62/969,934) (Filing date: February 4, 2020)</p> <p>From provisional 62/969,934 page 89 line 8 “In yet another embodiment, the compounds general formula (I) are directed towards a method for preventing, treating, and/or reducing the severity of a mental illness disorder and/or condition in a subject. For example, the illness disorder comprises anxiety disorders include generalized anxiety disorder, panic disorder, social anxiety disorder, and specific phobias; depression such as, hopelessness, loss of pleasure, fatigue, and suicidal thoughts; mood disorders, such as depression, anxiety, and cyclothymic depression, bipolar disorder, cancer-related disorder; psychotic disorders, such as hallucinations and delusions, chizophrenia; eating disorders e.g. anorexia nervosa, bulimia nervosa, and binge eating disorder; impulse control and addiction disorders e.g. Pyromania (starting fires), kleptomania (stealing), and compulsive gambling; alcohol addiction; drug addiction including opioid addiction; personality disorders include antisocial personality disorder, obsessive-compulsive personality disorder, and paranoid personality disorder; obsessive-compulsive disorder (OCD) e.g. thoughts or fears that cause them to perform certain rituals or routines; post-traumatic stress</p>

disorder (PTSD); **stress response syndromes (formerly called adjustment disorders)**; dissociative disorders, formerly called multiple personality disorder, or "split personality," and depersonalization disorder are examples of dissociative disorders; factitious disorders; sexual and gender disorders e.g. sexual dysfunction, gender identity disorder, and the paraphilia's; somatic symptom disorders ,formerly known as a psychosomatic disorder or somatoform disorder; attentional disorders including attentional deficit disorder, attentional deficit hyperactivity disorder and attentional deficits seen in other disorders included here; tic disorders: People with tic disorders such as, Tourette's syndrome; and other diseases or conditions, including various sleep-related problems and many forms of dementia, including Alzheimer's disease, Lewy body dementia, Parkinson's dementia and frontotemporal dementia. In embodiments, the condition comprises cognitive impairment, ischemia including stroke, neurodegeneration, refractory substance use disorders, sleep disorders, , pain, e.g. surgical pain, social pain, acute pain, cancer pain, chronic pain, breakthrough pain, bone pain, soft tissue pain, nerve pain, referred pain, phantom pain, neuropathic pain, cluster headaches and migraine, obesity and eating disorders, epilepsies and seizures, neuronal cell death, excitotoxic cell death, or a combination thereof.”

From **provisional 62/969,934 page 80 line 20** “...**Parenteral administration includes** systemic delivery routes other than the gastrointestinal (GI) tract, and includes, for example **intravenous**, intra-arterial, intraperitoneal, **subcutaneous**, **intramuscular**, transepithelial, **nasal**, intrapulmonary (for example, by use of an aerosol), **intrathecal**, **rectal** and **topical (including the use of a patch or other transdermal delivery device) modes of administration. Parenteral administration may be by continuous infusion over a selected period of time.**”

From **provisional 62/969,934 page 81 line 4** “In some embodiments, a compound of the application is orally administered, for example, with an inert diluent or with an assimilable edible carrier, or it is enclosed in hard or soft shell gelatin capsules, or it is compressed into tablets, or it is incorporated directly with the food of the diet. In some embodiments, the compound is incorporated with excipient and used in the form of ingestible tablets, buccal tablets, troches, capsules, caplets, pellets, granules, lozenges, chewing gum, powders, syrups, elixirs, wafers, aqueous solutions and suspensions, and the like. In the case of tablets, carriers that are used include lactose, com starch, sodium citrate and salts of phosphoric acid. Pharmaceutically acceptable excipients include binding agents (e.g., pregelatinized maize starch, polyvinylpyrrolidone or hydroxypropyl methylcellulose); fillers (e.g., lactose, microcrystalline cellulose or calcium phosphate); lubricants (e.g., magnesium stearate, talc or silica); disintegrants (e.g., potato starch or sodium starch glycolate); or wetting agents (e.g., sodium lauryl sulphate), or solvents (e.g. medium chain triglycerides, ethanol, water). In embodiments, the tablets are coated by methods well known in the art. In the case of tablets, capsules, caplets, pellets or granules for

	<p>oral administration, pH sensitive enteric coatings, such as EudragitsTM designed to control the release of active ingredients are optionally used. Oral dosage forms also include modified release, for example immediate release and timed-release, formulations. Examples of modified release formulations include, for example, sustained-release (SR), extended-release (ER, XR, or XL), time-release or timed-release, controlled-release (CR), or continuous- release (CR or Cantin), employed...”</p> <p>From provisional 62/969,934 page 33 line 19 “...However, in another embodiment, the compounds are administered to the subject from about one time per two weeks, three weeks or one month. In another embodiment, the compounds are administered about one time per week to about once daily. In another embodiment, the compounds are administered 1, 2, 3, 4, 5 or 6 times daily...”</p>
<p>57. The method of claim 56 wherein the topical application of a pharmaceutical composition for the treatment and/or prevention and/or control of adjustment disorder, wherein the transdermal patch is applied at a time period selected from the group consisting of once in a day, once in two days, once in three days, once in four days, once in five days, once in six days, once in a week, once in ten days, and once in fifteen days.</p>	<p>18. Priority Doc. of U.S. Pat. App. No. 2022/0017549 “PSILOICIN DERIVATIVES AS SEROTONERGIC PSYCHEDELIC AGENTS FOR THE TREATMENT OF CNS DISORDERS” provisional application (62/969,934) (Filing date: February 4, 2020)</p> <p>From provisional 62/969,934 page 89 line 8 “In yet another embodiment, the compounds general formula (I) are directed towards a method for preventing, treating, and/or reducing the severity of a mental illness disorder and/or condition in a subject. For example, the illness disorder comprises anxiety disorders include generalized anxiety disorder, panic disorder, social anxiety disorder, and specific phobias; depression such as, hopelessness, loss of pleasure, fatigue, and suicidal thoughts; mood disorders, such as depression, anxiety, and cyclothymic depression, bipolar disorder, cancer-related disorder; psychotic disorders, such as hallucinations and delusions, chizophrenia; eating disorders e.g. anorexia nervosa, bulimia nervosa, and binge eating disorder; impulse control and addiction disorders e.g. Pyromania (starting fires), kleptomania (stealing), and compulsive gambling; alcohol addiction; drug addiction including opioid addiction; personality disorders include antisocial personality disorder, obsessive-compulsive personality disorder, and paranoid personality disorder; obsessive-compulsive disorder (OCD) e.g. thoughts or fears that cause them to perform certain rituals or routines; post-traumatic stress disorder (PTSD); stress response syndromes (formerly called adjustment disorders); dissociative disorders, formerly called multiple personality disorder, or "split personality," and depersonalization disorder are examples of dissociative disorders; factitious disorders; sexual and gender disorders e.g. sexual dysfunction, gender identity disorder, and the paraphilia's; somatic symptom disorders ,formerly known as a psychosomatic disorder or somatoform disorder; attentional disorders including attentional deficit disorder, attentional deficit hyperactivity disorder and attentional deficits seen in other disorders included here; tic disorders: People with tic disorders such as, Tourette's syndrome; and other diseases or</p>

conditions, including various sleep-related problems and many forms of dementia, including Alzheimer's disease, Lewy body dementia, Parkinson's dementia and frontotemporal dementia. In embodiments, the condition comprises cognitive impairment, ischemia including stroke, neurodegeneration, refractory substance use disorders, sleep disorders, , pain, e.g. surgical pain, social pain, acute pain, cancer pain, chronic pain, breakthrough pain, bone pain, soft tissue pain, nerve pain, referred pain, phantom pain, neuropathic pain, cluster headaches and migraine, obesity and eating disorders, epilepsies and seizures, neuronal cell death, excitotoxic cell death, or a combination thereof.”

From **provisional 62/969,934 page 80 line 20** “...**Parenteral administration includes** systemic delivery routes other than the gastrointestinal (GI) tract, and includes, for example **intravenous, intra-arterial, intraperitoneal, subcutaneous, intramuscular, transepithelial, nasal, intrapulmonary** (for example, by use of an aerosol), **intrathecal, rectal and topical (including the use of a patch or other transdermal delivery device) modes of administration. Parenteral administration may be by continuous infusion over a selected period of time.**”

From **provisional 62/969,934 page 81 line 4** “In some embodiments, a compound of the application is orally administered, for example, with an inert diluent or with an assimilable edible carrier, or it is enclosed in hard or soft shell gelatin capsules, or it is compressed into tablets, or it is incorporated directly with the food of the diet. In some embodiments, the compound is incorporated with excipient and used in the form of ingestible tablets, buccal tablets, troches, capsules, caplets, pellets, granules, lozenges, chewing gum, powders, syrups, elixirs, wafers, aqueous solutions and suspensions, and the like. In the case of tablets, carriers that are used include lactose, com starch, sodium citrate and salts of phosphoric acid. Pharmaceutically acceptable excipients include binding agents (e.g., pregelatinized maize starch, polyvinylpyrrolidone or hydroxypropyl methylcellulose); fillers (e.g., lactose, microcrystalline cellulose or calcium phosphate); lubricants (e.g., magnesium stearate, talc or silica); disintegrants (e.g., potato starch or sodium starch glycolate); or wetting agents (e.g., sodium lauryl sulphate), or solvents (e.g. medium chain triglycerides, ethanol, water). In embodiments, the tablets are coated by methods well known in the art. In the case of tablets, capsules, caplets, pellets or granules for oral administration, pH sensitive enteric coatings, such as Eudragits™ designed to control the release of active ingredients are optionally used. Oral dosage forms also include modified release, for example immediate release and timed-release, formulations. Examples of modified release formulations include, for example, **sustained-release (SR)**, extended-release (ER, XR, or XL), time-release or timed-release, controlled-release (CR), or **continuous- release (CR or Cantin)**, employed...”

From **provisional 62/969,934 page 33 line 19** “...However, in another embodiment, the compounds are administered to the subject from

	<p>about one time per two weeks, three weeks or one month. In another embodiment, the compounds are administered about one time per week to about once daily. In another embodiment, the compounds are administered 1, 2, 3, 4, 5 or 6 times daily..."</p>
<p>58. The method of claim 56 further providing a constant rate of delivery of the active components of the transdermal patch over a time period selected from the group consisting of once in a day, once in two days, once in three days, once in four days, once in five days, once in six days, once in a week, once in ten days, and once in fifteen days.</p>	<p>18. Priority Doc. of U.S. Pat. App. No. 2022/0017549 "PSILOPIN DERIVATIVES AS SEROTONERGIC PSYCHEDELIC AGENTS FOR THE TREATMENT OF CNS DISORDERS" provisional application (62/969,934) (Filing date: February 4, 2020)</p> <p>From provisional 62/969,934 page 89 line 8 "In yet another embodiment, the compounds general formula (I) are directed towards a method for preventing, treating, and/or reducing the severity of a mental illness disorder and/or condition in a subject. For example, the illness disorder comprises anxiety disorders include generalized anxiety disorder, panic disorder, social anxiety disorder, and specific phobias; depression such as, hopelessness, loss of pleasure, fatigue, and suicidal thoughts; mood disorders, such as depression, anxiety, and cyclothymic depression, bipolar disorder, cancer-related disorder; psychotic disorders, such as hallucinations and delusions, schizophrenia; eating disorders e.g. anorexia nervosa, bulimia nervosa, and binge eating disorder; impulse control and addiction disorders e.g. Pyromania (starting fires), kleptomania (stealing), and compulsive gambling; alcohol addiction; drug addiction including opioid addiction; personality disorders include antisocial personality disorder, obsessive-compulsive personality disorder, and paranoid personality disorder; obsessive-compulsive disorder (OCD) e.g. thoughts or fears that cause them to perform certain rituals or routines; post-traumatic stress disorder (PTSD); stress response syndromes (formerly called adjustment disorders); dissociative disorders, formerly called multiple personality disorder, or "split personality," and depersonalization disorder are examples of dissociative disorders; factitious disorders; sexual and gender disorders e.g. sexual dysfunction, gender identity disorder, and the paraphilia's; somatic symptom disorders ,formerly known as a psychosomatic disorder or somatoform disorder; attentional disorders including attentional deficit disorder, attentional deficit hyperactivity disorder and attentional deficits seen in other disorders included here; tic disorders: People with tic disorders such as, Tourette's syndrome; and other diseases or conditions, including various sleep-related problems and many forms of dementia, including Alzheimer's disease, Lewy body dementia, Parkinson's dementia and frontotemporal dementia. In embodiments, the condition comprises cognitive impairment, ischemia including stroke, neurodegeneration, refractory substance use disorders, sleep disorders, , pain, e.g. surgical pain, social pain, acute pain, cancer pain, chronic pain, breakthrough pain, bone pain, soft tissue pain, nerve pain, referred pain, phantom pain, neuropathic pain, cluster headaches and migraine, obesity and eating disorders, epilepsies and seizures, neuronal cell death, excitotoxic cell death, or a combination thereof."</p>

	<p>From provisional 62/969,934 page 80 line 20 “...Parenteral administration includes systemic delivery routes other than the gastrointestinal (GI) tract, and includes, for example intravenous, intra-arterial, intraperitoneal, subcutaneous, intramuscular, transepithelial, nasal, intrapulmonary (for example, by use of an aerosol), intrathecal, rectal and topical (including the use of a patch or other transdermal delivery device) modes of administration. Parenteral administration may be by continuous infusion over a selected period of time.”</p> <p>From provisional 62/969,934 page 81 line 4 “In some embodiments, a compound of the application is orally administered, for example, with an inert diluent or with an assimilable edible carrier, or it is enclosed in hard or soft shell gelatin capsules, or it is compressed into tablets, or it is incorporated directly with the food of the diet. In some embodiments, the compound is incorporated with excipient and used in the form of ingestible tablets, buccal tablets, troches, capsules, caplets, pellets, granules, lozenges, chewing gum, powders, syrups, elixirs, wafers, aqueous solutions and suspensions, and the like. In the case of tablets, carriers that are used include lactose, com starch, sodium citrate and salts of phosphoric acid. Pharmaceutically acceptable excipients include binding agents (e.g., pregelatinized maize starch, polyvinylpyrrolidone or hydroxypropyl methylcellulose); fillers (e.g., lactose, microcrystalline cellulose or calcium phosphate); lubricants (e.g., magnesium stearate, talc or silica); disintegrants (e.g., potato starch or sodium starch glycolate); or wetting agents (e.g., sodium lauryl sulphate), or solvents (e.g. medium chain triglycerides, ethanol, water). In embodiments, the tablets are coated by methods well known in the art. In the case of tablets, capsules, caplets, pellets or granules for oral administration, pH sensitive enteric coatings, such as Eudragits™ designed to control the release of active ingredients are optionally used. Oral dosage forms also include modified release, for example immediate release and timed-release, formulations. Examples of modifiedrelease formulations include, for example, sustained-release (SR), extended-release (ER, XR, or XL), time-release or timed-release, controlled-release (CR), or continuous- release (CR or Cantin), employed...”</p> <p>From provisional 62/969,934 page 33 line 19 “...However, in another embodiment, the compounds are administered to the subject from about one time per two weeks, three weeks or one month. In another embodiment, the compounds are administered about one time per week to about once daily. In another embodiment, the compounds are administered 1, 2, 3, 4, 5 or 6 times daily...”</p>
<p>59. The method of claim 56 further providing a steady absorption rates of the active components of the transdermal patch over a time period selected from</p>	<p>18. Priority Doc. of U.S. Pat. App. No. 2022/0017549 “PSILOCIN DERIVATIVES AS SEROTONERGIC PSYCHEDELIC AGENTS FOR THE TREATMENT OF CNS DISORDERS” provisional application (62/969,934) (Filing date: February 4, 2020)</p>

<p>the group consisting of once in a day, once in two days, once in three days, once in four days, once in five days, once in six days, once in a week, once in ten days, and once in fifteen days.</p>	<p>From provisional 62/969,934 page 89 line 8 “In yet another embodiment, the compounds general formula (I) are directed towards a method for preventing, treating, and/or reducing the severity of a mental illness disorder and/or condition in a subject. For example, the illness disorder comprises anxiety disorders include generalized anxiety disorder, panic disorder, social anxiety disorder, and specific phobias; depression such as, hopelessness, loss of pleasure, fatigue, and suicidal thoughts; mood disorders, such as depression, anxiety, and cyclothymic depression, bipolar disorder, cancer-related disorder; psychotic disorders, such as hallucinations and delusions, chizophrenia; eating disorders e.g. anorexia nervosa, bulimia nervosa, and binge eating disorder; impulse control and addiction disorders e.g. Pyromania (starting fires), kleptomania (stealing), and compulsive gambling; alcohol addiction; drug addiction including opioid addiction; personality disorders include antisocial personality disorder, obsessive-compulsive personality disorder, and paranoid personality disorder; obsessive-compulsive disorder (OCD) e.g. thoughts or fears that cause them to perform certain rituals or routines; post-traumatic stress disorder (PTSD); stress response syndromes (formerly called adjustment disorders); dissociative disorders, formerly called multiple personality disorder, or "split personality," and depersonalization disorder are examples of dissociative disorders; factitious disorders; sexual and gender disorders e.g. sexual dysfunction, gender identity disorder, and the paraphilia's; somatic symptom disorders ,formerly known as a psychosomatic disorder or somatoform disorder; attentional disorders including attentional deficit disorder, attentional deficit hyperactivity disorder and attentional deficits seen in other disorders included here; tic disorders: People with tic disorders such as, Tourette's syndrome; and other diseases or conditions, including various sleep-related problems and many forms of dementia, including Alzheimer's disease, Lewy body dementia, Parkinson's dementia and frontotemporal dementia. In embodiments, the condition comprises cognitive impairment, ischemia including stroke, neurodegeneration, refractory substance use disorders, sleep disorders, , pain, e.g. surgical pain, social pain, acute pain, cancer pain, chronic pain, breakthrough pain, bone pain, soft tissue pain, nerve pain, referred pain, phantom pain, neuropathic pain, cluster headaches and migraine, obesity and eating disorders, epilepsies and seizures, neuronal cell death, excitotoxic cell death, or a combination thereof.”</p> <p>From provisional 62/969,934 page 80 line 20 “...Parenteral administration includes systemic delivery routes other than the gastrointestinal (GI) tract, and includes, for example intravenous, intra-arterial, intra-peritoneal, subcutaneous, intramuscular, transepithelial, nasal, intrapulmonary (for example, by use of an aerosol), intrathecal, rectal and topical (including the use of a patch or other transdermal delivery device) modes of administration. Parenteral administration may be by continuous infusion over a selected period of time.”</p>
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	<p>From provisional 62/969,934 page 81 line 4 “In some embodiments, a compound of the application is orally administered, for example, with an inert diluent or with an assimilable edible carrier, or it is enclosed in hard or soft shell gelatin capsules, or it is compressed into tablets, or it is incorporated directly with the food of the diet. In some embodiments, the compound is incorporated with excipient and used in the form of ingestible tablets, buccal tablets, troches, capsules, caplets, pellets, granules, lozenges, chewing gum, powders, syrups, elixirs, wafers, aqueous solutions and suspensions, and the like. In the case of tablets, carriers that are used include lactose, com starch, sodium citrate and salts of phosphoric acid. Pharmaceutically acceptable excipients include binding agents (e.g., pregelatinized maize starch, polyvinylpyrrolidone or hydroxypropyl methylcellulose); fillers (e.g., lactose, microcrystalline cellulose or calcium phosphate); lubricants (e.g., magnesium stearate, talc or silica); disintegrants (e.g., potato starch or sodium starch glycolate); or wetting agents (e.g., sodium lauryl sulphate), or solvents (e.g. medium chain triglycerides, ethanol, water). In embodiments, the tablets are coated by methods well known in the art. In the case of tablets, capsules, caplets, pellets or granules for oral administration, pH sensitive enteric coatings, such as Eudragits™ designed to control the release of active ingredients are optionally used. Oral dosage forms also include modified release, for example immediate release and timed-release, formulations. Examples of modified release formulations include, for example, sustained-release (SR), extended-release (ER, XR, or XL), time-release or timed-release, controlled-release (CR), or continuous- release (CR or Cantin), employed...”</p> <p>From provisional 62/969,934 page 33 line 19 “...However, in another embodiment, the compounds are administered to the subject from about one time per two weeks, three weeks or one month. In another embodiment, the compounds are administered about one time per week to about once daily. In another embodiment, the compounds are administered 1, 2, 3, 4, 5 or 6 times daily...”</p>
<p>60. The method of claim 56 further achieving a constant blood serum levels of the active components of the transdermal patch over a time period selected from the group consisting of once in a day, once in two days, once in three days, once in four days, once in five days, once in six days, once in a week, once in ten days, and once in fifteen days.</p>	<p>18. Priority Doc. of U.S. Pat. App. No. 2022/0017549 “PSILOCIN DERIVATIVES AS SEROTONERGIC PSYCHEDELIC AGENTS FOR THE TREATMENT OF CNS DISORDERS” provisional application (62/969,934) (Filing date: February 4, 2020)</p> <p>From provisional 62/969,934 page 89 line 8 “In yet another embodiment, the compounds general formula (I) are directed towards a method for preventing, treating, and/or reducing the severity of a mental illness disorder and/or condition in a subject. For example, the illness disorder comprises anxiety disorders include generalized anxiety disorder, panic disorder, social anxiety disorder, and specific phobias; depression such as, hopelessness, loss of pleasure, fatigue, and suicidal thoughts; mood disorders, such as depression, anxiety, and cyclothymic depression, bipolar disorder, cancer-related disorder; psychotic disorders, such as hallucinations and delusions, chizophrenia; eating disorders e.g. anorexia nervosa, bulimia nervosa, and binge</p>

eating disorder; impulse control and addiction disorders e.g. Pyromania (starting fires), kleptomania (stealing), and compulsive gambling; alcohol addiction; drug addiction including opioid addiction; personality disorders include antisocial personality disorder, obsessive-compulsive personality disorder, and paranoid personality disorder; obsessive-compulsive disorder (OCD) e.g. thoughts or fears that cause them to perform certain rituals or routines; post-traumatic stress disorder (PTSD); **stress response syndromes (formerly called adjustment disorders)**; dissociative disorders, formerly called multiple personality disorder, or "split personality," and depersonalization disorder are examples of dissociative disorders; factitious disorders; sexual and gender disorders e.g. sexual dysfunction, gender identity disorder, and the paraphilia's; somatic symptom disorders, formerly known as a psychosomatic disorder or somatoform disorder; attentional disorders including attentional deficit disorder, attentional deficit hyperactivity disorder and attentional deficits seen in other disorders included here; tic disorders: People with tic disorders such as, Tourette's syndrome; and other diseases or conditions, including various sleep-related problems and many forms of dementia, including Alzheimer's disease, Lewy body dementia, Parkinson's dementia and frontotemporal dementia. In embodiments, the condition comprises cognitive impairment, ischemia including stroke, neurodegeneration, refractory substance use disorders, sleep disorders, , pain, e.g. surgical pain, social pain, acute pain, cancer pain, chronic pain, breakthrough pain, bone pain, soft tissue pain, nerve pain, referred pain, phantom pain, neuropathic pain, cluster headaches and migraine, obesity and eating disorders, epilepsies and seizures, neuronal cell death, excitotoxic cell death, or a combination thereof.”

From **provisional 62/969,934 page 80 line 20** “...**Parenteral administration includes** systemic delivery routes other than the gastrointestinal (GI) tract, and includes, for example **intravenous, intra-arterial, intraperitoneal, subcutaneous, intramuscular, transepithelial, nasal, intrapulmonary** (for example, by use of an aerosol), **intrathecal, rectal and topical (including the use of a patch or other transdermal delivery device) modes of administration. Parenteral administration may be by continuous infusion over a selected period of time.**”

From **provisional 62/969,934 page 81 line 4** “In some embodiments, a compound of the application is orally administered, for example, with an inert diluent or with an assimilable edible carrier, or it is enclosed in hard or soft shell gelatin capsules, or it is compressed into tablets, or it is incorporated directly with the food of the diet. In some embodiments, the compound is incorporated with excipient and used in the form of ingestible tablets, buccal tablets, troches, capsules, caplets, pellets, granules, lozenges, chewing gum, powders, syrups, elixirs, wafers, aqueous solutions and suspensions, and the like. In the case of tablets, carriers that are used include lactose, com starch, sodium citrate and salts of phosphoric acid. Pharmaceutically acceptable excipients include binding agents (e.g., pregelatinized maize starch,

	<p>polyvinylpyrrolidone or hydroxypropyl methylcellulose); fillers (e.g., lactose, microcrystalline cellulose or calcium phosphate); lubricants (e.g., magnesium stearate, talc or silica); disintegrants (e.g., potato starch or sodium starch glycolate); or wetting agents (e.g., sodium lauryl sulphate), or solvents (e.g. medium chain triglycerides, ethanol, water). In embodiments, the tablets are coated by methods well known in the art. In the case of tablets, capsules, caplets, pellets or granules for oral administration, pH sensitive enteric coatings, such as Eudragits™ designed to control the release of active ingredients are optionally used. Oral dosage forms also include modified release, for example immediate release and timed-release, formulations. Examples of modified release formulations include, for example, sustained-release (SR), extended-release (ER, XR, or XL), time-release or timed-release, controlled-release (CR), or continuous- release (CR or Cantin), employed...”</p> <p>From provisional 62/969,934 page 33 line 19 “...However, in another embodiment, the compounds are administered to the subject from about one time per two weeks, three weeks or one month. In another embodiment, the compounds are administered about one time per week to about once daily. In another embodiment, the compounds are administered 1, 2, 3, 4, 5 or 6 times daily...”</p>
<p>61. The method of claim 56 further achieving a reduced variability in dosage of the active components of the transdermal patches over a time period selected from the group consisting of once in a day, once in two days, once in three days, once in four days, once in five days, once in six days, once in a week, once in ten days, and once in fifteen days.</p>	<p>18. Priority Doc. of U.S. Pat. App. No. 2022/0017549 “PSILOPIN DERIVATIVES AS SEROTONERGIC PSYCHEDELIC AGENTS FOR THE TREATMENT OF CNS DISORDERS” provisional application (62/969,934) (Filing date: February 4, 2020)</p> <p>From provisional 62/969,934 page 89 line 8 “In yet another embodiment, the compounds general formula (I) are directed towards a method for preventing, treating, and/or reducing the severity of a mental illness disorder and/or condition in a subject. For example, the illness disorder comprises anxiety disorders include generalized anxiety disorder, panic disorder, social anxiety disorder, and specific phobias; depression such as, hopelessness, loss of pleasure, fatigue, and suicidal thoughts; mood disorders, such as depression, anxiety, and cyclothymic depression, bipolar disorder, cancer-related disorder; psychotic disorders, such as hallucinations and delusions, schizophrenia; eating disorders e.g. anorexia nervosa, bulimia nervosa, and binge eating disorder; impulse control and addiction disorders e.g. Pyromania (starting fires), kleptomania (stealing), and compulsive gambling; alcohol addiction; drug addiction including opioid addiction; personality disorders include antisocial personality disorder, obsessive-compulsive personality disorder, and paranoid personality disorder; obsessive-compulsive disorder (OCD) e.g. thoughts or fears that cause them to perform certain rituals or routines; post-traumatic stress disorder (PTSD); stress response syndromes (formerly called adjustment disorders); dissociative disorders, formerly called multiple personality disorder, or "split personality," and depersonalization disorder are examples of dissociative disorders; factitious disorders; sexual and gender disorders e.g. sexual</p>

dysfunction, gender identity disorder, and the paraphilia's; somatic symptom disorders ,formerly known as a psychosomatic disorder or somatoform disorder; attentional disorders including attentional deficit disorder, attentional deficit hyperactivity disorder and attentional deficits seen in other disorders included here; tic disorders: People with tic disorders such as, Tourette's syndrome; and other diseases or conditions, including various sleep-related problems and many forms of dementia, including Alzheimer's disease, Lewy body dementia, Parkinson's dementia and frontotemporal dementia. In embodiments, the condition comprises cognitive impairment, ischemia including stroke, neurodegeneration, refractory substance use disorders, sleep disorders, , pain, e.g. surgical pain, social pain, acute pain, cancer pain, chronic pain, breakthrough pain, bone pain, soft tissue pain, nerve pain, referred pain, phantom pain, neuropathic pain, cluster headaches and migraine, obesity and eating disorders, epilepsies and seizures, neuronal cell death, excitotoxic cell death, or a combination thereof.”

From **provisional 62/969,934 page 80 line 20** “...**Parenteral administration includes** systemic delivery routes other than the gastrointestinal (GI) tract, and includes, for example **intravenous, intra-arterial, intraperitoneal, subcutaneous, intramuscular, transepithelial, nasal, intrapulmonary** (for example, by use of an aerosol), **intrathecal, rectal and topical (including the use of a patch or other transdermal delivery device) modes of administration. Parenteral administration may be by continuous infusion over a selected period of time.**”

From **provisional 62/969,934 page 81 line 4** “In some embodiments, a compound of the application is orally administered, for example, with an inert diluent or with an assimilable edible carrier, or it is enclosed in hard or soft shell gelatin capsules, or it is compressed into tablets, or it is incorporated directly with the food of the diet. In some embodiments, the compound is incorporated with excipient and used in the form of ingestible tablets, buccal tablets, troches, capsules, caplets, pellets, granules, lozenges, chewing gum, powders, syrups, elixirs, wafers, aqueous solutions and suspensions, and the like. In the case of tablets, carriers that are used include lactose, com starch, sodium citrate and salts of phosphoric acid. Pharmaceutically acceptable excipients include binding agents (e.g., pregelatinized maize starch, polyvinylpyrrolidone or hydroxypropyl methylcellulose); fillers (e.g., lactose, microcrystalline cellulose or calcium phosphate); lubricants (e.g., magnesium stearate, talc or silica); disintegrants (e.g., potato starch or sodium starch glycolate); or wetting agents (e.g., sodium lauryl sulphate), or solvents (e.g. medium chain triglycerides, ethanol, water). In embodiments, the tablets are coated by methods well known in the art. In the case of tablets, capsules, caplets, pellets or granules for oral administration, pH sensitive enteric coatings, such as Eudragits™ designed to control the release of active ingredients are optionally used. Oral dosage forms also include modified release, for example immediate release and timed-release, formulations. Examples of modified release formulations include, for example, **sustained-release**

	<p>(SR), extended-release (ER, XR, or XL), time-release or timed-release, controlled-release (CR), or continuous- release (CR or Cantin), employed...”</p> <p>From provisional 62/969,934 page 33 line 19 “...However, in another embodiment, the compounds are administered to the subject from about one time per two weeks, three weeks or one month. In another embodiment, the compounds are administered about one time per week to about once daily. In another embodiment, the compounds are administered 1, 2, 3, 4, 5 or 6 times daily...”</p>
<p>62. The method of claim 56 further providing a plasma concentration of the active components of the transdermal patch in a therapeutic range over a time period selected from the group consisting of once in a day, once in two days, once in three days, once in four days, once in five days, once in six days, once in a week, once in ten days, and once in fifteen days.</p>	<p>18. Priority Doc. of U.S. Pat. App. No. 2022/0017549 “PSILOPIN DERIVATIVES AS SEROTONERGIC PSYCHEDELIC AGENTS FOR THE TREATMENT OF CNS DISORDERS” provisional application (62/969,934) (Filing date: February 4, 2020)</p> <p>From provisional 62/969,934 page 89 line 8 “In yet another embodiment, the compounds general formula (I) are directed towards a method for preventing, treating, and/or reducing the severity of a mental illness disorder and/or condition in a subject. For example, the illness disorder comprises anxiety disorders include generalized anxiety disorder, panic disorder, social anxiety disorder, and specific phobias; depression such as, hopelessness, loss of pleasure, fatigue, and suicidal thoughts; mood disorders, such as depression, anxiety, and cyclothymic depression, bipolar disorder, cancer-related disorder; psychotic disorders, such as hallucinations and delusions, schizophrenia; eating disorders e.g. anorexia nervosa, bulimia nervosa, and binge eating disorder; impulse control and addiction disorders e.g. Pyromania (starting fires), kleptomania (stealing), and compulsive gambling; alcohol addiction; drug addiction including opioid addiction; personality disorders include antisocial personality disorder, obsessive-compulsive personality disorder, and paranoid personality disorder; obsessive-compulsive disorder (OCD) e.g. thoughts or fears that cause them to perform certain rituals or routines; post-traumatic stress disorder (PTSD); stress response syndromes (formerly called adjustment disorders); dissociative disorders, formerly called multiple personality disorder, or "split personality," and depersonalization disorder are examples of dissociative disorders; factitious disorders; sexual and gender disorders e.g. sexual dysfunction, gender identity disorder, and the paraphilia's; somatic symptom disorders ,formerly known as a psychosomatic disorder or somatoform disorder; attentional disorders including attentional deficit disorder, attentional deficit hyperactivity disorder and attentional deficits seen in other disorders included here; tic disorders: People with tic disorders such as, Tourette's syndrome; and other diseases or conditions, including various sleep-related problems and many forms of dementia, including Alzheimer's disease, Lewy body dementia, Parkinson's dementia and frontotemporal dementia. In embodiments, the condition comprises cognitive impairment, ischemia including stroke, neurodegeneration, refractory substance use disorders, sleep</p>

disorders, , pain, e.g. surgical pain, social pain, acute pain, cancer pain, chronic pain, breakthrough pain, bone pain, soft tissue pain, nerve pain, referred pain, phantom pain, neuropathic pain, cluster headaches and migraine, obesity and eating disorders, epilepsies and seizures, neuronal cell death, excitotoxic cell death, or a combination thereof.”

From **provisional 62/969,934 page 80 line 20** “...**Parenteral administration includes** systemic delivery routes other than the gastrointestinal (GI) tract, and includes, for example **intravenous, intra-arterial, intraperitoneal, subcutaneous, intramuscular, transepithelial, nasal, intrapulmonary** (for example, by use of an aerosol), **intrathecal, rectal and topical (including the use of a patch or other transdermal delivery device) modes of administration. Parenteral administration may be by continuous infusion over a selected period of time.**”

From **provisional 62/969,934 page 81 line 4** “In some embodiments, a compound of the application is orally administered, for example, with an inert diluent or with an assimilable edible carrier, or it is enclosed in hard or soft shell gelatin capsules, or it is compressed into tablets, or it is incorporated directly with the food of the diet. In some embodiments, the compound is incorporated with excipient and used in the form of ingestible tablets, buccal tablets, troches, capsules, caplets, pellets, granules, lozenges, chewing gum, powders, syrups, elixirs, wafers, aqueous solutions and suspensions, and the like. In the case of tablets, carriers that are used include lactose, com starch, sodium citrate and salts of phosphoric acid. Pharmaceutically acceptable excipients include binding agents (e.g., pregelatinized maize starch, polyvinylpyrrolidone or hydroxypropyl methylcellulose); fillers (e.g., lactose, microcrystalline cellulose or calcium phosphate); lubricants (e.g., magnesium stearate, talc or silica); disintegrants (e.g., potato starch or sodium starch glycolate); or wetting agents (e.g., sodium lauryl sulphate), or solvents (e.g. medium chain triglycerides, ethanol, water). In embodiments, the tablets are coated by methods well known in the art. In the case of tablets, capsules, caplets, pellets or granules for oral administration, pH sensitive enteric coatings, such as EudragitsTM designed to control the release of active ingredients are optionally used. Oral dosage forms also include modified release, for example immediate release and timed-release, formulations. Examples of modified release formulations include, for example, **sustained-release (SR)**, extended-release (ER, XR, or XL), time-release or timed-release, controlled-release (CR), or **continuous- release (CR or Cantin)**, employed...”

From **provisional 62/969,934 page 33 line 19** “...However, in another embodiment, the compounds are administered to the subject from about one time per two weeks, three weeks or one month. In another embodiment, the compounds are administered about one time per week to about once daily. In another embodiment, the compounds are **administered 1, 2, 3, 4, 5 or 6 times daily...**”

<p>63. The method of claim 56 wherein the pharmaceutical compositions are applied to the patient separately, sequentially, or simultaneously.</p>	<p>17. U.S. Pat. App. No. 2021/0069170 “TRYPTAMINE COMPOSITIONS FOR ENHANCING NEURITE OUTGROWTH” (Published March 11, 2021)</p> <p>From [0127] “Another embodiment is a pharmaceutical combination comprising one or more of a tryptamine, an erinacine, a hericenone, a cannabinoid, or a pharmaceutically acceptable salt, hydrate, solvate, prodrug, stereoisomer, or tautomer thereof, a combination thereof, and one or more additional therapeutic agent(s) for simultaneous, separate or sequential use in therapy for neuronal injuries, neurodegeneration, neurological diseases, congenital or organic cognitive impairment, learning disabilities, autism spectrum disorder, psychiatric and mood disorders, cognitive enhancement, physical or motor neuron enhancement, or general improvement of mental health. In one embodiment, the additional therapeutic agent is selected from the group consisting of: an antiproliferative agent, anticancer agent, immunomodulatory agent, an anti-inflammatory agent, a neurological treatment agent, an anti-viral agent, an anti-fungal agent, anti-parasitic agent, an antibiotic, and a general anti-infective agent.”</p>
<p>64. The method of claim 56 further providing a plasma concentration of the active components of the transdermal patch in a therapeutic range of about 0.01 ng/mL to about 500 ng/mL.</p>	<p>2. W.I.P.O. Pat. App. No. 2020/157569 “METHODS AND COMPOSITIONS COMPRISING A 5HT RECEPTOR AGONIST FOR THE TREATMENT OF PSYCHOLOGICAL, COGNITIVE, BEHAVIORAL, AND/OR MOOD DISORDERS” (Published August 6, 2020)</p> <p>From claim 1 “A method of managing a neurological condition or one or more symptoms thereof in a subject in need thereof, comprising administering to the subject a pharmaceutical composition comprising: a) a therapeutically effective amount of one or more 5HT receptor agonist or a pharmaceutically acceptable salt, solvate, metabolite, derivative, or prodrug thereof; and b) a pharmaceutically acceptable excipient wherein the therapeutically effective amount of the 5HT receptor agonist or a pharmaceutically acceptable salt, solvate, metabolite, derivative, or prodrug thereof is provided to the subject in need thereof in an amount insufficient to provide an adverse side effect, such as hallucinogenic experience.”</p> <p>From claim 17 “The method of any one of the preceding claims, wherein the pharmaceutical composition is in a form selected from a spray, aerosol, mist, nebulae, ointment, cream, gel, paste, salve, solution, suspension, tincture, patch, and atomized vapor.”</p> <p>From [0047] “Examples of tryptamines include serotonin, melatonin, psilocybin and N,N-dimethyltryptamine. Additionally, the tryptamine structure may comprise part of a more complex compound, for example: LSD, ibogaine, mitragynine, yohimbine, etc.”</p>

	<p>From [0019] “In some embodiments, the therapeutically effective amount of 5HT receptor agonist or a pharmaceutically acceptable salt, solvate, metabolite, derivative, or prodrug (e.g., psilocybin) thereof is provided to a subject in need thereof in an amount and/or formulation to provide a maximum plasma concentration (C_{max}) of (e.g. active form of the) 5HT receptor agonist (e.g., psilocin) or a pharmaceutically acceptable salt, solvate, metabolite, derivative, or prodrug thereof of about 0.1 ng/mL or more and less than 6 ng/mL (e.g. at least 0.5 ng/mL and less than 6 ng/mL, about 1 ng/mL to about 5.5 ng/mL, about 2 ng/mL to about 5 ng/mL, or the like).”</p>
<p>65. The method of claim 56 wherein the pharmaceutical composition provides a continuous, sustained delivery of the pharmaceutical composition to mitigate peak and valley pharmacokinetic behavior of the active agent.</p>	<p>18. Priority Doc. of U.S. Pat. App. No. 2022/0017549 “PSILOCIN DERIVATIVES AS SEROTONERGIC PSYCHEDELIC AGENTS FOR THE TREATMENT OF CNS DISORDERS” provisional application (62/969,934) (Filing date: February 4, 2020)</p> <p>From provisional 62/969,934 page 80 line 20 “...Parenteral administration includes systemic delivery routes other than the gastrointestinal (GI) tract, and includes, for example intravenous, intra-arterial, intraperitoneal, subcutaneous, intramuscular, transepithelial, nasal, intrapulmonary (for example, by use of an aerosol), intrathecal, rectal and topical (including the use of a patch or other transdermal delivery device) modes of administration. Parenteral administration may be by continuous infusion over a selected period of time.”</p> <p>From provisional 62/969,934 page 81 line 4 “In some embodiments, a compound of the application is orally administered, for example, with an inert diluent or with an assimilable edible carrier, or it is enclosed in hard or soft shell gelatin capsules, or it is compressed into tablets, or it is incorporated directly with the food of the diet. In some embodiments, the compound is incorporated with excipient and used in the form of ingestible tablets, buccal tablets, troches, capsules, caplets, pellets, granules, lozenges, chewing gum, powders, syrups, elixirs, wafers, aqueous solutions and suspensions, and the like. In the case of tablets, carriers that are used include lactose, com starch, sodium citrate and salts of phosphoric acid. Pharmaceutically acceptable excipients include binding agents (e.g., pregelatinized maize starch, polyvinylpyrrolidone or hydroxypropyl methylcellulose); fillers (e.g., lactose, microcrystalline cellulose or calcium phosphate); lubricants (e.g., magnesium stearate, talc or silica); disintegrants (e.g., potato starch or sodium starch glycolate); or wetting agents (e.g., sodium lauryl sulphate), or solvents (e.g. medium chain triglycerides, ethanol, water). In embodiments, the tablets are coated by methods well known in the art. In the case of tablets, capsules, caplets, pellets or granules for oral administration, pH sensitive enteric coatings, such as Eudragits™ designed to control the release of active ingredients are optionally used. Oral dosage forms also include modified release, for example immediate release and timed-release, formulations. Examples of modified release formulations include, for example, sustained-release</p>

	<p>(SR), extended-release (ER, XR, or XL), time-release or timed-release, controlled-release (CR), or continuous- release (CR or Cantin), employed...”</p>
<p>66. The method of claim 56 wherein the pharmaceutical composition provides a continuous, sustained delivery of the pharmaceutical composition via administration to the patient by a route selected from the group consisting of parenteral, intravenous, subcutaneous, intramuscular, intrathecal, oral, buccal, mucosal, intranasal, rectal, vaginal, transdermal, implantable, topical, and combinations thereof.</p>	<p>18. Priority Doc. of U.S. Pat. App. No. 2022/0017549 “PSILOCIN DERIVATIVES AS SEROTONERGIC PSYCHEDELIC AGENTS FOR THE TREATMENT OF CNS DISORDERS” provisional application (62/969,934) (Filing date: February 4, 2020)</p> <p>From provisional 62/969,934 page 80 line 20 “...Parenteral administration includes systemic delivery routes other than the gastrointestinal (GI) tract, and includes, for example intravenous, intra-arterial, intraperitoneal, subcutaneous, intramuscular, transepithelial, nasal, intrapulmonary (for example, by use of an aerosol), intrathecal, rectal and topical (including the use of a patch or other transdermal delivery device) modes of administration. Parenteral administration may be by continuous infusion over a selected period of time.”</p> <p>From provisional 62/969,934 page 81 line 4 “In some embodiments, a compound of the application is orally administered, for example, with an inert diluent or with an assimilable edible carrier, or it is enclosed in hard or soft shell gelatin capsules, or it is compressed into tablets, or it is incorporated directly with the food of the diet. In some embodiments, the compound is incorporated with excipient and used in the form of ingestible tablets, buccal tablets, troches, capsules, caplets, pellets, granules, lozenges, chewing gum, powders, syrups, elixirs, wafers, aqueous solutions and suspensions, and the like. In the case of tablets, carriers that are used include lactose, com starch, sodium citrate and salts of phosphoric acid. Pharmaceutically acceptable excipients include binding agents (e.g., pregelatinized maize starch, polyvinylpyrrolidone or hydroxypropyl methylcellulose); fillers (e.g., lactose, microcrystalline cellulose or calcium phosphate); lubricants (e.g., magnesium stearate, talc or silica); disintegrants (e.g., potato starch or sodium starch glycolate); or wetting agents (e.g., sodium lauryl sulphate), or solvents (e.g. medium chain triglycerides, ethanol, water). In embodiments, the tablets are coated by methods well known in the art. In the case of tablets, capsules, caplets, pellets or granules for oral administration, pH sensitive enteric coatings, such as Eudragits™ designed to control the release of active ingredients are optionally used. Oral dosage forms also include modified release, for example immediate release and timed-release, formulations. Examples of modifiedrelease formulations include, for example, sustained-release (SR), extended-release (ER, XR, or XL), time-release or timed-release, controlled-release (CR), or continuous- release (CR or Cantin), employed...”</p>
<p>67. The method of claim 56 wherein the pharmaceutical composition provides a continuous, sustained</p>	<p>18. Priority Doc. of U.S. Pat. App. No. 2022/0017549 “PSILOCIN DERIVATIVES AS SEROTONERGIC PSYCHEDELIC AGENTS FOR THE TREATMENT OF CNS DISORDERS” provisional application (62/969,934) (Filing date: February 4, 2020)</p>

<p>delivery of the pharmaceutical composition via intravenous or subcutaneous infusion.</p>	<p>From provisional 62/969,934 page 80 line 20 "...Parenteral administration includes systemic delivery routes other than the gastrointestinal (GI) tract, and includes, for example intravenous, intra-arterial, intraperitoneal, subcutaneous, intramuscular, transepithelial, nasal, intrapulmonary (for example, by use of an aerosol), intrathecal, rectal and topical (including the use of a patch or other transdermal delivery device) modes of administration. Parenteral administration may be by continuous infusion over a selected period of time."</p>
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Electronic Acknowledgement Receipt

EFS ID:	48087192
Application Number:	17879846
International Application Number:	
Confirmation Number:	2695
Title of Invention:	TRANSDERMAL MICRO-DOSING DELIVERY OF PHARMACEUTICAL AGENTS
First Named Inventor/Applicant Name:	Fotios M. Plakogiannis
Customer Number:	137713
Filer:	Sisi Li
Filer Authorized By:	
Attorney Docket Number:	4782-0018US01
Receipt Date:	01-JUN-2023
Filing Date:	03-AUG-2022
Time Stamp:	13:45:02
Application Type:	

Payment information:

Submitted with Payment	yes
Payment Type	CARD
Payment was successfully received in RAM	\$72
RAM confirmation Number	E202361D44595854
Deposit Account	
Authorized User	

The Director of the USPTO is hereby authorized to charge indicated fees and credit any overpayment as follows:

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File Listing:

Document Number	Document Description	File Name	File Size(Bytes)/ Message Digest	Multi Part /.zip	Pages (if appl.)
1	Concise Description of Relevance	Concise-description-generated.pdf	46729 c67b1db801487842f9e28289db03852c3ea0d66b	no	8

Warnings:

Information:

2	Third-Party Submission Under 37 CFR 1.290	Third-party-preissuance-submission.pdf	72083 c9b6b51d586682afe364886595acb331554382f	no	4
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Warnings:

Information:

3	Request for Notification of Non-compliant Third-Party Submission	Third-party-notification-request.pdf	23614 89b05f7a1087f77ae739892d76684b74697d6991	no	1
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Warnings:

Information:

4	Concise Description of Relevance	Claims_Chart.pdf	1899453 491d05c4232574b37bb59613f9989238e854060c	no	91
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Warnings:

Information:

5	Non Patent Literature	MADSEN.pdf	1189006 007def6b43167f29c16a9bf58675de804df69233	no	7
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Warnings:

Information:

6	Non Patent Literature	KAMATA.pdf	239607 7a23a67c66bb02991844752ffeb981c3feac45f	no	5
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7	Non Patent Literature	HOLZE.pdf	607627	no	9
			df23ef00582a0eff1e6c96c37746743ef7fb96da		
Warnings:					
Information:					
8	Non Patent Literature	HENSTRA.pdf	930586	no	4
			66e3d5a2f9d34639c6bb654b224466b5a5d79bda		
Warnings:					
Information:					
9	Non Patent Literature	KUYPERS.pdf	615221	no	15
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Information:					
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Warnings:					
Information:					
11	Fee Worksheet (SB06)	fee-info.pdf	37411	no	2
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Information:					
Total Files Size (in bytes):			8539309		

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New Applications Under 35 U.S.C. 111

If a new application is being filed and the application includes the necessary components for a filing date (see 37 CFR 1.53(b)-(d) and MPEP 506), a Filing Receipt (37 CFR 1.54) will be issued in due course and the date shown on this Acknowledgement Receipt will establish the filing date of the application.

National Stage of an International Application under 35 U.S.C. 371

If a timely submission to enter the national stage of an international application is compliant with the conditions of 35 U.S.C. 371 and other applicable requirements a Form PCT/DO/EO/903 indicating acceptance of the application as a national stage submission under 35 U.S.C. 371 will be issued in addition to the Filing Receipt, in due course.

New International Application Filed with the USPTO as a Receiving Office

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Electronic Acknowledgement Receipt

EFS ID:	48087658
Application Number:	17879846
International Application Number:	
Confirmation Number:	2695
Title of Invention:	TRANSDERMAL MICRO-DOSING DELIVERY OF PHARMACEUTICAL AGENTS
First Named Inventor/Applicant Name:	Fotios M. Plakogiannis
Customer Number:	137713
Filer:	Sisi Li
Filer Authorized By:	
Attorney Docket Number:	4782-0018US01
Receipt Date:	01-JUN-2023
Filing Date:	03-AUG-2022
Time Stamp:	14:20:57
Application Type:	

Payment information:

Submitted with Payment	yes
Payment Type	CARD
Payment was successfully received in RAM	\$72
RAM confirmation Number	E202361E20538103
Deposit Account	
Authorized User	

The Director of the USPTO is hereby authorized to charge indicated fees and credit any overpayment as follows:

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File Listing:

Document Number	Document Description	File Name	File Size(Bytes)/ Message Digest	Multi Part /.zip	Pages (if appl.)
1	Concise Description of Relevance	Concise-description-generated.pdf	47976	no	9
			78ce3668b724c96dc7cca04d544d1577953140e3		

Warnings:

Information:

2	Third-Party Submission Under 37 CFR 1.290	Third-party-preissuance-submission.pdf	70779	no	4
			c7ca8ed57a07d086bb24f036ed99b938cfd67ebf		

Warnings:

Information:

3	Request for Notification of Non-compliant Third-Party Submission	Third-party-notification-request.pdf	23616	no	1
			d9efcee0af0b4f2382e4e256701e0b74d0f26721		

Warnings:

Information:

4	Concise Description of Relevance	Claims_Chart.pdf	1899453	no	91
			491d05c4232574b37bb59613f9989238e854060c		

Warnings:

Information:

5	Non Patent Literature	ASI.pdf	2007150	no	8
			290e4a654fb37ab8ef06b7e87aecbf761ee6f848		

Warnings:

Information:

6	Non Patent Literature	SINHA.pdf	302880	no	12
			c39d0acb1091e2bc00e724a74417b209a6a5b2b9		

Warnings:

Information:

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7	Non Patent Literature	SMITH.pdf	1041919	no	7
			cf9bb41e2c1c69583317ccdd64c91f2bb3bf34a		
Warnings:					
Information:					
8	Non Patent Literature	GRODOWSKA.pdf	9372353	no	10
			6e9116f8ed33986701dd672331c2cc1694a36f2e		
Warnings:					
Information:					
9	Non Patent Literature	62969934.pdf	5361836	no	133
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Warnings:					
Information:					
10	Non Patent Literature	63010924.pdf	3742424	no	55
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Warnings:					
Information:					
11	Non Patent Literature	VALENTA.pdf	286271	no	11
			d89d3d712ddc18ceca1e51ae7f5998d99f81ae3a		
Warnings:					
Information:					
12	Fee Worksheet (SB06)	fee-info.pdf	37411	no	2
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Information:					
Total Files Size (in bytes):				24194068	

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