IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of:	STAMETS; Paul Edward	Confirmation No.: 1619
Serial No.:	17/480,789	Group No.:
Filing or 371(c) Date:	September 21, 2021	Examiner:

Entitled: COMPOSITIONS AND METHODS FOR TREATING DEPRESSION

THIRD-PARTY PRE-ISSUANCE SUBMISSION

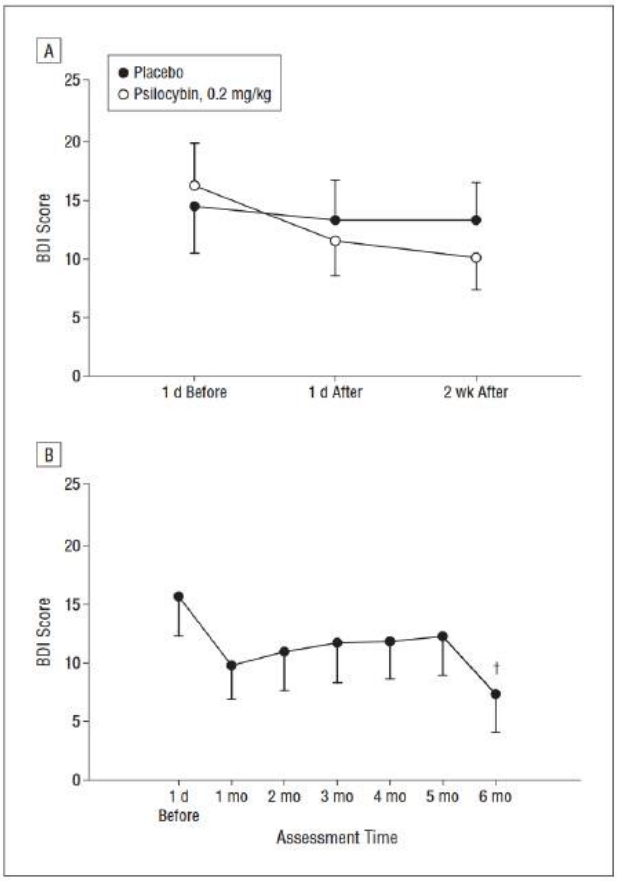
Examiner:

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:

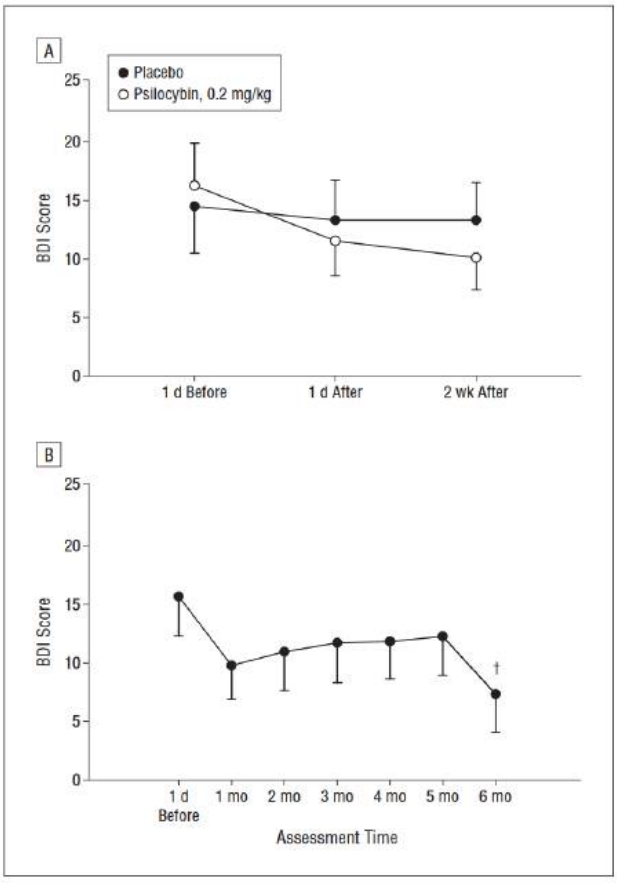
1. GROB (2011) "Pilot Study of Psilocybin Treatment for Anxiety in Patients With Advanced-Stage Cancer" Arch Gen Psychiatry. 68(1):71-78.
2. Int'l Pat. App. Pub. No. WO/2005/039546 "USE OF COMPOUNDS THAT ARE ABLE TO INCREASE THE SERUM IGF-1 LEVEL FOR THE PREPARATION OF A THERAPEUTICAL COMPOSITION FOR TREATMENT OF VARIOUS DISEASE STATES ASSOCIATED WITH A REDUCED IGF-1 SERUM LEVEL IN HUMANS AND ANIMALS" (Published May 6, 2005)
3. FRIEDMAN (2015) "Chemistry, Nutrition, and Health-Promoting Properties of *Hericium erinaceus* (Lion's Mane) Mushroom Fruiting Bodies and Mycelia and Their Bioactive Compounds" J. Agric. Food Chem. 63:7108-7123.
4. DMT-NEXUS (2013) "Known substance-interactions and their effects" DMT-Nexus. Retrieved January 25, 2013. https://web.archive.org/web/20130125065447/https://wiki.dmt-nexus.me/Known_substance-interactions_and_their_effects
5. LICHT (2012) "Simultaneous polysubstance use among Danish 3,4-methylenedioxymethamphetamine and hallucinogen users: combination patterns and proposed biological bases" Hum. Psychopharmacol. Clin. Exp. 27: 352–363.
6. U.S. Pat. App. Pub. No. US/2001/0008641 "NUTRITIONALLY ACTIVE COMPOSITION FOR BODYBUILDING" (Published July 19, 2001)

7. Int'l Pat. App. Pub. No. WO/2006/091988 "COMPOSITION FOR TREATING MENTAL HEALTH DISORDERS" (Published August 31, 2006)
8. Int'l Pat. App. Pub. No. WO/2016/001922 "METHODS, DEVICES AND SYSTEMS FOR PULMONARY DELIVERY OF ACTIVE AGENTS" (Published January 7, 2016)

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. 17/480,789 Pending Claims	References
1. A method for reducing symptoms of depression or anxiety in a subject in need thereof comprising: administering a therapeutically effective amount of a composition comprising psilocybin or psilocin sufficient to reduce the symptoms of depression or anxiety in the subject.	1. GROB (2011) "Pilot Study of Psilocybin Treatment for Anxiety in Patients With Advanced-Stage Cancer" Arch Gen Psychiatry. 68(1):71-78. From **page 75**  **Figure 3.** Beck Depression Inventory (BDI) scores. A, Mean (SEM) BDI scores 1 day before, 1 day after, and 2 weeks after administration of psilocybin or niacin placebo are shown. B, Six months of mean (SEM) BDI follow-up data are shown. The BDI was administered at monthly intervals for 6 months after the second treatment session, and the 6 sets of monthly follow-up data were compared with the scores obtained the first time the participants filled out the instruments (ie, 1 day before the first treatment session). †$P < .05$ for psilocybin vs the value from 1 day before the first treatment session (t tests were used to compare individual monthly follow-up values with values on the day before the first session).
2. The method of claim 1, where the composition further comprises an extract of *Hericium erinaceus.*	3. FRIEDMAN (2015) "Chemistry, Nutrition, and Health-Promoting Properties of *Hericium erinaceus* (Lion's Mane) Mushroom Fruiting Bodies and Mycelia and Their Bioactive Compounds" J. Agric. Food Chem. 63:7108-7123. From **page 7116** "Nagano et al. investigated the effect of *H. erinaceus* on depression, menopause, and sleep quality using epidemiological-based questionaires. (110) In a randomized, double-blind, placebo-control trial conducted over 4 weeks, 30 females aged 41.3 ± 5.6 years were randomly

	assigned to either H. erinaceus or placebo groups and fed *H. erinaceus* cookies containing 0.5 g of the powdered fruiting body 4 times a day for 4 weeks or placebo cookies for the same regimen. The mean standard scores at the end of the test were lower for the *H. erinaceus* than for the placebo group, suggesting that orally consumed ***H. erinaceus* has the potential to reduce depression and anxiety** in women but this is by a different, and as yet unknown, mechanism from the NGF-enhancing effect by the mushroom extracts and hericenones mentioned above."
3. The method of claim 1, where the composition further comprises niacin.	2. Int'l Pat. App. Pub. No. WO/2005/039546 "USE OF COMPOUNDS THAT ARE ABLE TO INCREASE THE SERUM IGF-1 LEVEL FOR THE PREPARATION OF A THERAPEUTICAL COMPOSITION FOR TREATMENT OF VARIOUS DISEASE STATES ASSOCIATED WITH A REDUCED IGF-1 SERUM LEVEL IN HUMANS AND ANIMALS" (Published May 6, 2005) From **claim 1** "Use of **one or more compounds** that are capable of activating the hypothalamus in an individual to increase the serum level of Growth Hormone Releasing Hormone (GHRH) which in turn leads to an increase in the secretion of growth hormone (GH) and the subsequent rise of the serum level of insulin-like growth factor 1 (IGF-1) for the preparation of a therapeutical composition for the treatment of serious fatigue and exhaustion symptoms, burn-out, chronic fatigue syndrome, **depression**, Alzheimer disease, irritated bowel syndrome, osteoporosis, type 2 diabetes, or for anti-aging therapy, immune therapy and for stimulating recovery after physical exercise in humans or for stimulating growth and the immune system in animals." From **claim 5** "Use as claimed in claim 1, wherein **the compound is** a precursor of indole acetic acid selected from the group consisting of tryptophan, 4-hydroxytryptophan, 4-methoxy-tryptophan, 5-hydroxytryptophan, 5-methoxytryptophan, 6-hydroxytryptophan, 6-methoxytryptophan, 7-hydroxy-tryptophan, 7-methoxytryptophan, hypaphorine, tryptamine, 4-hydroxytryptamine, 4-methoxytryptamine, **psilocin** (4-hydroxy, dimethyl tryptamine), **psilocybin** (4-phosphate, dimethyl-tryptamine), baeocystin, serotonin (5 hydroxytryptamine), 5-methoxytryptamine, bufotenine (dimethylserotonine), O-methylbufotenine, melatonin, 6-hydroxytryptamine, 6-methoxy-tryptamine, 7-hydroxytryptamine, 7-methoxytryptamine, indole butyric acid and indole-3-pyruvate." From **claim 6** "Use as claimed in claim 1, wherein **the compound is** an analogue of the compounds listed in claim 3 or a metabolite of indole acetic acid that can be converted back into a compound as listed in claim 3, and selected from the group consisting of indole, indole-3-acetaldehyde, indole-3-ethanol, indole-3-aldehyde, indol-3-methanol, indole-3-carboxylic acid, 3-methylindole (skatole); indole-3-acetaldoxime, 3-aminomethylindole, N-

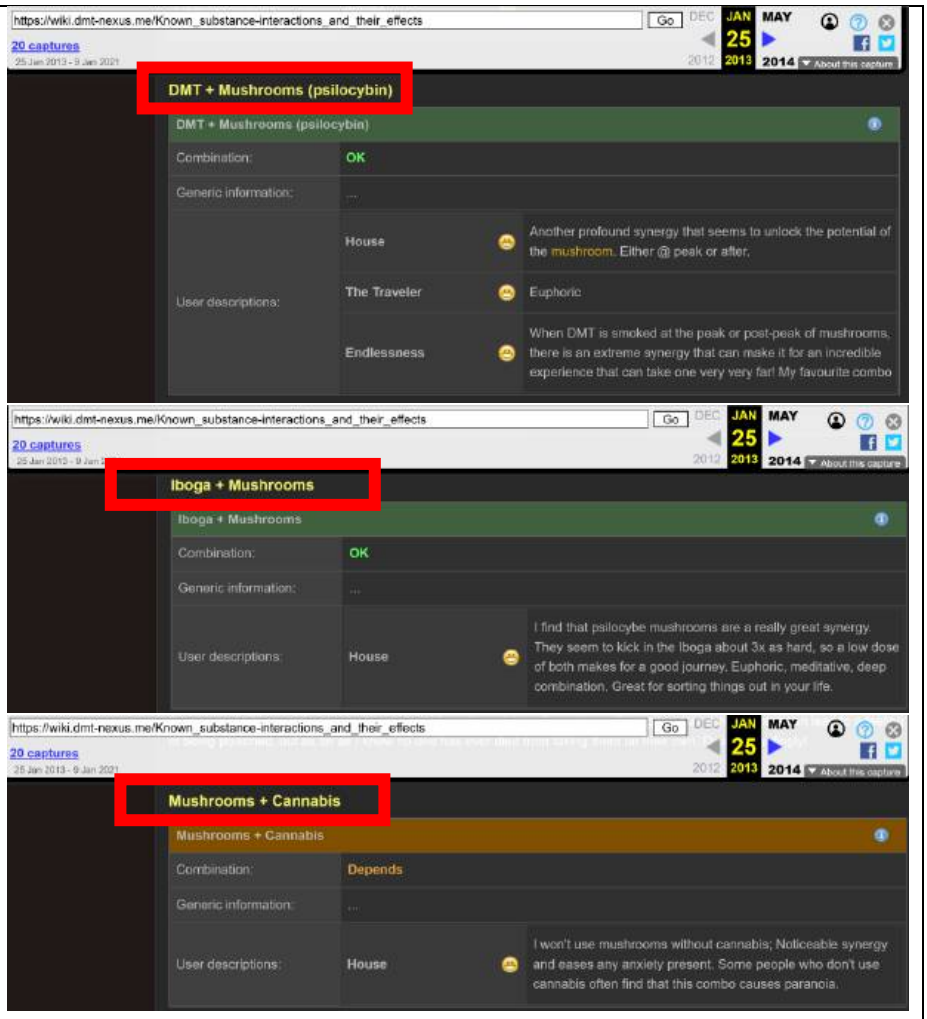
	methylaminomethylindole, gramine (N-dimethylaminomethylindole), indoxyls (indicans), indoleninones, 3-methylene-2-oxindole, abrine, isotan B, isatin, indican, indigo, indurubin, indigotins, 3-indolylmethyl (skatolyl), **niacin,** 2-oxindole-3-acetic acid, 3-methylene-2-oxindole, oxindole-3-methanol, oxindole-3-aldehyde, oxindole-3-carboxylic acid and 3-methyloxindole."
4. The method of claim 1, wherein the composition comprises 0.1 mg to 10 mg; 0.1 mg to 0.6 mg; 0.6 mg to 0.9 mg; 0.9 mg to 10 mg; or 1 mg to 10 mg of psilocybin or psilocin per 70 kg of the subject's body mass.	1. GROB (2011) "Pilot Study of Psilocybin Treatment for Anxiety in Patients With Advanced-Stage Cancer" Arch Gen Psychiatry. 68(1):71-78. From **page 75**  **Figure 3.** Beck Depression Inventory (BDI) scores. A, Mean (SEM) BDI scores 1 day before, 1 day after, and 2 weeks after administration of psilocybin or niacin placebo are shown. B, Six months of mean (SEM) BDI follow-up data are shown. The BDI was administered at monthly intervals for 6 months after the second treatment session, and the 6 sets of monthly follow-up data were compared with the scores obtained the first time the participants filled out the instruments (ie, 1 day before the first treatment session). †$P<.05$ for psilocybin vs the value from 1 day before the first treatment session (t tests were used to compare individual monthly follow-up values with values on the day before the first session). 2. Int'l Pat. App. Pub. No. WO/2005/039546 "USE OF COMPOUNDS THAT ARE ABLE TO INCREASE THE SERUM IGF-1 LEVEL FOR THE PREPARATION OF A THERAPEUTICAL COMPOSITION FOR TREATMENT OF VARIOUS DISEASE STATES ASSOCIATED WITH

	A REDUCED IGF-1 SERUM LEVEL IN HUMANS AND ANIMALS" (Published May 6, 2005) From **claim 1** "Use of **one or more compounds** that are capable of activating the hypothalamus in an individual to increase the serum level of Growth Hormone Releasing Hormone (GHRH) which in turn leads to an increase in the secretion of growth hormone (GH) and the subsequent rise of the serum level of insulin-like growth factor 1 (IGF-1) for the preparation of a therapeutical composition for the treatment of serious fatigue and exhaustion symptoms, burn-out, chronic fatigue syndrome, **depression**, Alzheimer disease, irritated bowel syndrome, osteoporosis, type 2 diabetes, or for anti-aging therapy, immune therapy and for stimulating recovery after physical exercise in humans or for stimulating growth and the immune system in animals." From **claim 5** "Use as claimed in claim 1, wherein **the compound is** a precursor of indole acetic acid selected from the group consisting of tryptophan, 4-hydroxytryptophan, 4-methoxy-tryptophan, 5-hydroxytryptophan, 5-methoxytryptophan, 6-hydroxytryptophan, 6-methoxytryptophan, 7-hydroxy-tryptophan, 7-methoxytryptophan, hypaphorine, tryptamine, 4-hydroxytryptamine, 4-methoxytryptamine, **psilocin** (4-hydroxy, dimethyl tryptamine), **psilocybin** (4-phosphate, dimethyl-tryptamine), baeocystin, serotonin (5 hydroxytryptamine), 5-methoxytryptamine, bufotenine (dimethylserotonine), O-methylbufotenine, melatonin, 6-hydroxytryptamine, 6-methoxy-tryptamine, 7-hydroxytryptamine, 7-methoxytryptamine, indole butyric acid and indole-3-pyruvate." From **claim 14** "Use as claimed in any one of the claims 1-13, wherein the composition comprises **1 to 100 mg,** preferably 10 to 90 mg, more preferably 40 mg of the active ingredient."
5. The method of claim 1, wherein the composition comprises 1 mg to 200 mg of niacin per 70 kg of the subject's body mass.	2. Int'l Pat. App. Pub. No. WO/2005/039546 "USE OF COMPOUNDS THAT ARE ABLE TO INCREASE THE SERUM IGF-1 LEVEL FOR THE PREPARATION OF A THERAPEUTICAL COMPOSITION FOR TREATMENT OF VARIOUS DISEASE STATES ASSOCIATED WITH A REDUCED IGF-1 SERUM LEVEL IN HUMANS AND ANIMALS" (Published May 6, 2005) From **claim 1** "Use of **one or more compounds** that are capable of activating the hypothalamus in an individual to increase the serum level of Growth Hormone Releasing Hormone (GHRH) which in turn leads to an increase in the secretion of growth hormone (GH) and the subsequent rise of the serum level of insulin-like growth factor 1 (IGF-1) for the preparation of a therapeutical composition for the treatment of serious fatigue and exhaustion symptoms, burn-out, chronic fatigue syndrome, **depression**, Alzheimer disease, irritated bowel syndrome, osteoporosis, type 2 diabetes,

	or for anti-aging therapy, immune therapy and for stimulating recovery after physical exercise in humans or for stimulating growth and the immune system in animals." From **claim 6** "Use as claimed in claim 1, wherein **the compound is** an analogue of the compounds listed in claim 3 or a metabolite of indole acetic acid that can be converted back into a compound as listed in claim 3, and selected from the group consisting of indole, indole-3-acetaldehyde, indole-3-ethanol, indole-3-aldehyde, indol-3-methanol, indole-3-carboxylic acid, 3-methylindole (skatole); indole-3-acetaldoxime, 3-aminomethylindole, N-methylaminomethylindole, gramine (N-dimethylaminomethylindole), indoxyls (indicans), indoleninones, 3-methylene-2-oxindole, abrine, isotan B, isatin, indican, indigo, indurubin, indigotins, 3-indolylmethyl (skatolyl), **niacin,** 2-oxindole-3-acetic acid, 3-methylene-2-oxindole, oxindole-3-methanol, oxindole-3-aldehyde, oxindole-3-carboxylic acid and 3-methyloxindole." From **claim 14** "Use as claimed in any one of the claims 1-13, wherein the composition comprises **1 to 100 mg**, preferably 10 to 90 mg, more preferably 40 mg **of the active ingredient.**" 7. Int'l Pat. App. Pub. No. WO/2006/091988 "COMPOSITION FOR TREATING MENTAL HEALTH DISORDERS" (Published August 31, 2006) From **claim 15** "A method of treating **depression**, comprising administering to a subject in need thereof an effective amount of a composition of any of claims 1-12." From **claim 23** "The method of claim 21, further comprising administering to the subject a daily dosage of vitamin C 20-2000 mg or a daily dosage of **vitamin B3 1-200 mg**."
6. The method of claim 1, wherein the composition further comprises one or more pharmaceutically acceptable excipients.	2. Int'l Pat. App. Pub. No. WO/2005/039546 "USE OF COMPOUNDS THAT ARE ABLE TO INCREASE THE SERUM IGF-1 LEVEL FOR THE PREPARATION OF A THERAPEUTICAL COMPOSITION FOR TREATMENT OF VARIOUS DISEASE STATES ASSOCIATED WITH A REDUCED IGF-1 SERUM LEVEL IN HUMANS AND ANIMALS" (Published May 6, 2005) From **claim 17** "Therapeutical composition comprising a suitable diluent, carrier or **excipient** and one or more compounds as listed in claims 3-12."
7. The method of claim 1, wherein the composition is	2. Int'l Pat. App. Pub. No. WO/2005/039546 "USE OF COMPOUNDS THAT ARE ABLE TO INCREASE THE SERUM IGF-1 LEVEL FOR THE PREPARATION OF A THERAPEUTICAL COMPOSITION FOR

administered in a capsule.	TREATMENT OF VARIOUS DISEASE STATES ASSOCIATED WITH A REDUCED IGF-1 SERUM LEVEL IN HUMANS AND ANIMALS" (Published May 6, 2005) From **claim 15** "Use as claimed in any one of the claims 1-14, wherein the composition is in the form of a **capsule**."
8. The method of claim 1, wherein 500 mg to 1000 mg of the composition is administered once to three times per day.	2. Int'l Pat. App. Pub. No. WO/2005/039546 "USE OF COMPOUNDS THAT ARE ABLE TO INCREASE THE SERUM IGF-1 LEVEL FOR THE PREPARATION OF A THERAPEUTICAL COMPOSITION FOR TREATMENT OF VARIOUS DISEASE STATES ASSOCIATED WITH A REDUCED IGF-1 SERUM LEVEL IN HUMANS AND ANIMALS" (Published May 6, 2005) From **claim 14** "Use as claimed in any one of the claims 1-13, wherein the **composition comprises 1 to 100 mg**, preferably 10 to 90 mg, more preferably 40 mg of the active ingredient." From **page 4, paragraph 4** "The invention also relates to the use of **precursors from which IAA and analogues as listed above could be formed**, such as tryptophan, 4-hydroxytryptophan, 4-methoxytryptophan, 5-hydroxytryptophan, 5-methoxytryptophan, 6-hydroxytryptophan, 6-methoxytryptophan, 7-hydroxytryptophan 7-methoxytryptophan, hypaphorine, tryptamine, 4-hydroxytryptamine, 4-methoxytryptamine, **psilocin** (4-hydroxy, dimethyl tryptamine), **psilocybin** (4-phosphate, dimethyl tryptamine), baeocystin, serotonin (5 hydroxytryptamine), 5-methoxytryptamine, bufotenine (dimethylserotonine), O-methylbufotenine, melatonin (5-methoxy, acetamide function on tryptamine NH2), 6-hydroxytryptamine, 6-methoxytryptamine, 7-hydroxytryptamine, 7-methoxytryptamine. From **page 19, paragraph 3** "The patients took **1000 mg/day** (corresponding to 40 mg IAA and 960 mg salt and WPC 70) **of the composition** of the invention for 4 weeks. After this the dosage was reduced by 250 mg (corresponding to 10 mg IAA) every 2 weeks to 750 mg/day, 500 mg/day 250 mg/day respectively."
9. The method of claim 1, wherein the composition further comprises: Bacopa species (Bacopa monnieri), Gotu kola (Centella asiatica), Gingko (Gingko biloba), Ginger (Zingiber officinale),	4. DMT-NEXUS (2013) "Known substance-interactions and their effects" DMT-Nexus. Retrieved January 25, 2013. https://web.archive.org/web/20130125065447/https://wiki.dmt-nexus.me/Known_substance-interactions_and_their_effects

Holy Basil (Ocimum sanctum), Hu Zhang (Polygonum cuspid atum), Oregano (Origanum vulgare, Origanum onites), Rosemary (Rosmarinus officinalis, Rosmarinus eriocalyx, Rosmarinus species), Turmeric (Curcuma longa), Green Tea (Camellia sinensis), lavender (Lavandula spica and Lavandula species), skullcap (Scutellaria lateriflora), oat straw (Avena sativa and Avena byzantine), Diviner's Sage (Salvia divinorum), ayahuasca (Banisteriopsis caapi and Psychotria species), Tabemanthe iboga, Voacanga africana, Tabemaemontana undulate, peyote (Lophophora williamsii), morning glory (Ipomoea tricolor, Argyreia nervosa), Cannabis sativa, Cannabis indica or Cannabis ruderalis, extracts thereof, or combinations thereof.



5. LICHT (2012) “Simultaneous polysubstance use among Danish 3,4-methylenedioxymethamphetamine and hallucinogen users: combination patterns and proposed biological bases” Hum. Psychopharmacol. Clin. Exp. 27: 352–363.

From **page 355** “The most prevalent observations were **cannabis enhancing the effects of hallucinogens** (n = 17) and MDMA (n = 7), MDMA and hallucinogens enhancing each other (n = 11), **hallucinogens enhancing each other** (n = 6), amphetamines (n = 8) and cocaine (n = 6) counteracting hallucinogens, and cocaine counteracting the effects of MDMA (n = 7).”

6. U.S. Pat. App. Pub. No. US/2001/0008641 “NUTRITIONALLY ACTIVE COMPOSITION FOR BODYBUILDING” (Published July 19, 2001)

	From **claim 24** "The composition of claim 4 wherein said substituent (C) is selected from the group consisting of red rice yeast, damiana, ephedra, ginger, ginseng, goto kola, lobelia, ma huang, maraba and **psilocybin**." From **paragraph [0017]** "The invention further provides such compositions that additionally contain at least one additional substituent (C) that provides long term psychological feedback substituent and/or at least one additional substituent (D) that provides short term psychological feedback; wherein the substituent (C) that provides the long term psychological feedback is selected from the group consisting of: an anandamide, 5-hydroxytryptophan, 5-fluoro-A-methyltryptamine, 5-fluorotryptophan, 6-fluorotryptophan, tryptophan, allocryptine, caffeine, theophylline, theobromine, California poppy, calcium, chromium picolinate, chromium polynicotinate, chicalote extract, cocoa, chocolate, Damiana (Turnera diffusa), DL-phenylalanine, ephedra, ephedrine, epinephrine, GABA, **ginger**, ginseng, L-glutamine, **green tea**, guarana, kava kava, lactuca virosa, L-tyrosine, lobelia, magnesium, maraba, protopine, pseudophedrine, pseudo-epinephrine, pyridoxal-5-phosphate, red rice yeast, serotonin, sucrose, fructose, glucose, high fructose corn syrup, and St. Johnswort, and is present in an amount sufficient to provide a long term feeling of well-being or calmness; and the substituent (D) that provides the short term psychological feedback is selected from the group consisting of: an anandamide, an alcohol enhancer, angelica root, balm, bitter orange (Auranti pericarpium), bogbean, boldo, calamus, California poppy, capsaicum, caraway, cayenne, chamomile, cinchona bark, quinine, chocolate, cinnamon, clove, cocoa, condurango, dandelion, elecampane, GABA, gentian, ginger, ginseng, holy thistle, hops, horehound, dried lemon peel (Citri pericardium), mugwort, unripe orange, peppermint, quassia, red sage, **rosemary,** star anise, thyme, **tumeric**, wormwood, yarrow, and zinc, and is present in an amount sufficient to provide a short term sensation of warmth, tingling, excitement, tranquility and well-being, or a distinctive, intense, bitter or unusual taste. From **paragraph [0079]** "The compositions of the present invention provide a nutritionally beneficial substituent to an individual in a manner accompanied by a reinforcing psychological feedback sensation. The psychological feedback sensation imparts an immediate physiological recognition of the composition (such as a feeling of warmth, or a flush feeling) as well as a long term psychological feedback (such as a **counter-depressive effect** or a sense of well-being)."
10. The method of claim 1, wherein the composition further comprises: mycelia, fruitbodies, or extracts thereof of Antrodia, Beauveria, Copelandia,	8. Int'l Pat. App. Pub. No. WO/2016/001922 "METHODS, DEVICES AND SYSTEMS FOR PULMONARY DELIVERY OF ACTIVE AGENTS" (Published January 7, 2016) From **claim 1** "A method of pulmonary delivering to a subject at least a first pharmacologically active agent and a second pharmacologically active agent, **at least one of which being in at least one plant material,** the

Cordyceps, Ganoderma, Grifola, Hericium, Inonotus, Isaria, Panaeolus, Phellinus or combinations thereof.	method comprising independently delivering the agents to the subject using a metered dose inhaler device configured to vaporize at least a first pre-determined vaporized amount of said first agent and at least a second pre-determined vaporized amount of said second agent upon controllably heating said at least one plant material, wherein said heating is effected such that said first pre-determined vaporized amount is delivered to the subject successively, concomitantly and/or at least partially overlapping with said second pre-determined vaporized amount, and wherein each of said pre-determined vaporized amounts of each of said agents induces in the subject independently at least one pharmacokinetic effect and/or at least one pharmacodynamic effect." From **claim 47** "The method of any one of claims 42-46, wherein said desired effect corresponds to a symptom, said symptom being selected from the group consisting of pain, migraine, **depression**, cognitive function deficit, attention deficit, hyperactivity, anxiety disorders, diarrhea, nausea, vomiting, insomnia, delirium, appetite variations, sexual dysfunction, spasticity, increased intra ocular pressure, bladder dysfunction, tics, Tourette symptoms, post-traumatic stress disorder (PTSD) symptoms, inflammatory bowel disease (IBD) symptoms, irritable bowel syndrome (IBS) symptoms, hyper tension, hemorrhagic symptoms, septic and cardiogenic shock, drug addiction and craving, withdrawal symptoms, tremors and other movement disorders." From **claim 51** "The method of any one of claims 1-2 and 26-50, wherein said **at least one plant is selected from the group consisting of** Cannabis sativa, Cannabis indica, Cannabis ruderalis, Acacia spp, Amanita muscaria, Yage, Atropa belladonna, Areca catechu, Brugmansia spp., Brunfelsia latifolia, Desmanthus illinoensis, Banisteriopsis caapi, Trichocereus spp., Theobroma cacao, Capsicum spp., Cestrum spp., Erythroxylum coca, Solenostemon scutellarioides, Arundo donax, Coffea arabica, Datura spp., Desfontainia spp., Diplopterys cabrerana, Ephedra sinica, Claviceps purpurea, Paullinia cupana, Argyreia nervosa, Hyoscyamus niger, Tabernanthe iboga, Lagochilus inebriens, Justicia pectoralis, Sceletium tortuosum, Piper methysticum, Catha edulis, Mitragyna speciosa, Leonotis leonurus, Nymphaea spp., Nelumbo spp., Sophora secundiflora, Mucuna pruriens, Mandragora officinarum, Mimosa tenuiflora, Ipomoea violacea, **Psilocybe spp., Panaeolus spp.**, Myristica fragrans, Turbina corymbosa, Passiflora incarnata, Lophophora williamsii, Phalaris spp., Duboisia hopwoodii, Papaver somniferum, Psychotria viridis, spp., Salvia divinorum, Combretum quadrangulare, Trichocereus pachanoi, Heimia salicifolia, Stipa robusta, Solandra spp., Hypericum perforatum, Peganum harmala, Tabernaemontanaspp, Camellia sinensis, Nicotiana tabacum, rusticum, Virola theidora, Voacanga africana, Lactuca virosa, Artemisia absinthium, Ilex paraguariensis, Anadenanthera spp., Corynanthe yohimbe, Calea zacatechichi, Coffea spp. (Rubiaceae), a Sapindaceae, Camellia spp., Malvaceae spp., Aquifoliaceae spp., Hoodia, spp. Chamomilla recutita,

	Passiflora incarnate, Camellia sinensis, Mentha piperita, Mentha spicata, Rubus idaeus, Eucalyptus globulus, Lavandula officinalis, Thymus vulgaris, Melissa officinalis, Aloe Vera, Angelica, Anise, Ayahuasca (Banisteriopsis caapi), Barberry, Black Horehound, Blue Lotus, Burdock, Camomille/Chamomile, Caraway, Cat's Claw, Clove, Comfrey, Corn Silk, Couch Grass, Damiana, Damiana, Dandelion, Ephedra, Eucalyptus, Evening Primrose, Fennel, Feverfew, Fringe Tree, Garlic, Ginger, Ginkgo, Ginseng, Goldenrod, Goldenseal, Gotu Kola, Green Tea, Guarana, Hawthorn, Hops, Horsetail, Hyssop, Kola Nut, Kratom, Lavender, Lemon Balm, Licorice, Lion's Tail (Wild Dagga), Maca Root, Marshmallow, Meadowsweet, Milk Thistle, Motherwort, Passion Flower, Passionflower, Peppermint, Prickly Poppy, Purslane, Raspberry Leaf, Red Poppy, Sage, Saw Palmetto, Sida Cordifolia, Sinicuichi (Mayan Sun Opener), Spearmint, Sweet Flag, Syrian Rue (Peganum harmala), Thyme, Turmeric, Valerian, Wild Yam, Wormwood, Yarrow, Yerba Mate, Yohimbe, and any part and any combination thereof." From **page 41** "According to some embodiments, the substance that contains at least one vaporizable active agent is, for example, a plant material. In some embodiments, the active agent is a naturally occurring agent, namely the agent occurs (produced) naturally in the plant. Alternatively, the substance is an organic material which contains, or consists of, for example, one or more natural plant materials, or a synthetic material which may comprise at least one vaporizable active agent. In some embodiments, the solid form of a substance comprises a plurality of vaporizable **active agents derived or extracted from** natural or organic sources, such as plants, **fungi,** bacteria and the likes."
11. A method for reducing symptoms of depression or anxiety in a subject in need thereof comprising: administering a composition comprising 0.1 mg to 10 mg of psilocybin or psilocin per 70 kg of the subject's body mass sufficient to reduce the symptoms of depression or anxiety in the subject.	1. GROB (2011) "Pilot Study of Psilocybin Treatment for Anxiety in Patients With Advanced-Stage Cancer" Arch Gen Psychiatry. 68(1):71-78. From **page 75**

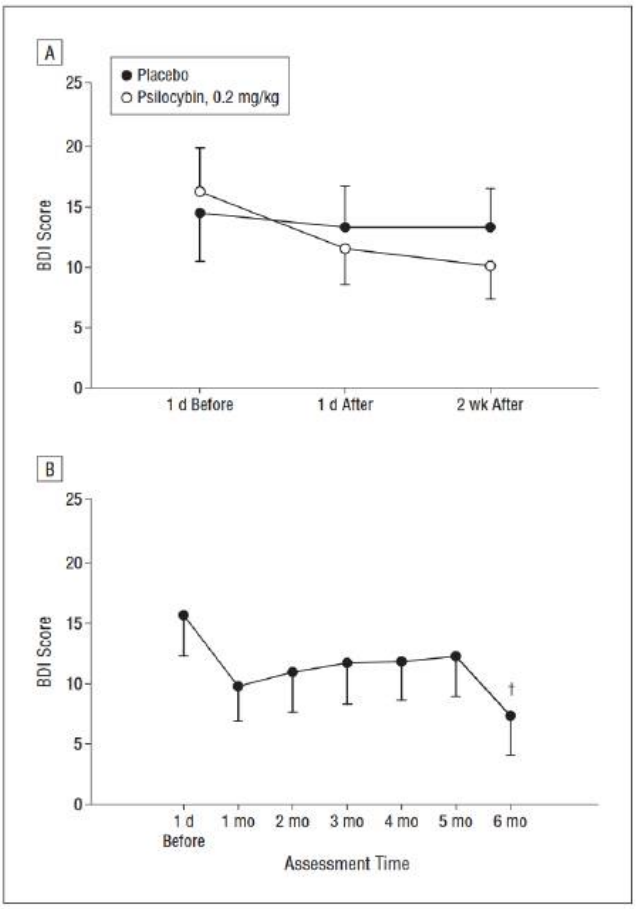


Figure 3. Beck Depression Inventory (BDI) scores. A, Mean (SEM) BDI scores 1 day before, 1 day after, and 2 weeks after administration of psilocybin or niacin placebo are shown. B, Six months of mean (SEM) BDI follow-up data are shown. The BDI was administered at monthly intervals for 6 months after the second treatment session, and the 6 sets of monthly follow-up data were compared with the scores obtained the first time the participants filled out the instruments (ie, 1 day before the first treatment session). †$P<.05$ for psilocybin vs the value from 1 day before the first treatment session (t tests were used to compare individual monthly follow-up values with values on the day before the first session).

2. Int'l Pat. App. Pub. No. WO/2005/039546 "USE OF COMPOUNDS THAT ARE ABLE TO INCREASE THE SERUM IGF-1 LEVEL FOR THE PREPARATION OF A THERAPEUTICAL COMPOSITION FOR TREATMENT OF VARIOUS DISEASE STATES ASSOCIATED WITH A REDUCED IGF-1 SERUM LEVEL IN HUMANS AND ANIMALS" (Published May 6, 2005)

From **claim 1** "Use of **one or more compounds** that are capable of activating the hypothalamus in an individual to increase the serum level of Growth Hormone Releasing Hormone (GHRH) which in turn leads to an increase in the secretion of growth hormone (GH) and the subsequent rise of the serum level of insulin-like growth factor 1 (IGF-1) for the preparation of a therapeutical composition **for the treatment of** serious fatigue and

	exhaustion symptoms, burn-out, chronic fatigue syndrome, **depression**, Alzheimer disease, irritated bowel syndrome, osteoporosis, type 2 diabetes, or for anti-aging therapy, immune therapy and for stimulating recovery after physical exercise in humans or for stimulating growth and the immune system in animals." From **claim 5** "Use as claimed in claim 1, wherein **the compound is** a precursor of indole acetic acid selected from the group consisting of tryptophan, 4-hydroxytryptophan, 4-methoxy-tryptophan, 5-hydroxytryptophan, 5-methoxytryptophan, 6-hydroxytryptophan, 6-methoxytryptophan, 7-hydroxy-tryptophan, 7-methoxytryptophan, hypaphorine, tryptamine, 4-hydroxytryptamine, 4-methoxytryptamine, **psilocin** (4-hydroxy, dimethyl tryptamine), **psilocybin** (4-phosphate, dimethyl-tryptamine), baeocystin, serotonin (5 hydroxytryptamine), 5-methoxytryptamine, bufotenine (dimethylserotonine), O-methylbufotenine, melatonin, 6-hydroxytryptamine, 6-methoxy-tryptamine, 7-hydroxytryptamine, 7-methoxytryptamine, indole butyric acid and indole-3-pyruvate." From **claim 14** "Use as claimed in any one of the claims 1-13, wherein the composition comprises **1 to 100 mg**, preferably 10 to 90 mg, more preferably 40 mg of the active ingredient."
12. The method of claim 11, where the composition further comprises an extract of *Hericium erinaceus.*	3. FRIEDMAN (2015) "Chemistry, Nutrition, and Health-Promoting Properties of Hericium erinaceus (Lion's Mane) Mushroom Fruiting Bodies and Mycelia and Their Bioactive Compounds" J. Agric. Food Chem. 63:7108-7123. From **page 7116** "Nagano et al. investigated the effect of *H. erinaceus* on depression, menopause, and sleep quality using epidemiological-based questionaires. (110) In a randomized, double-blind, placebo-control trial conducted over 4 weeks, 30 females aged 41.3 ± 5.6 years were randomly assigned to either H. erinaceus or placebo groups and fed *H. erinaceus* cookies containing 0.5 g of the powdered fruiting body 4 times a day for 4 weeks or placebo cookies for the same regimen. The mean standard scores at the end of the test were lower for the *H. erinaceus* than for the placebo group, **suggesting that orally consumed *H. erinaceus* has the potential to reduce depression and anxiety** in women but this is by a different, and as yet unknown, mechanism from the NGF-enhancing effect by the mushroom extracts and hericenones mentioned above."
13. The method of claim 11, where the composition further comprises niacin.	2. Int'l Pat. App. Pub. No. WO/2005/039546 "USE OF COMPOUNDS THAT ARE ABLE TO INCREASE THE SERUM IGF-1 LEVEL FOR THE PREPARATION OF A THERAPEUTICAL COMPOSITION FOR TREATMENT OF VARIOUS DISEASE STATES ASSOCIATED WITH A REDUCED IGF-1 SERUM LEVEL IN HUMANS AND ANIMALS" (Published May 6, 2005)

	From **claim 1** "Use of **one or more compounds** that are capable of activating the hypothalamus in an individual to increase the serum level of Growth Hormone Releasing Hormone (GHRH) which in turn leads to an increase in the secretion of growth hormone (GH) and the subsequent rise of the serum level of insulin-like growth factor 1 (IGF-1) for the preparation of a therapeutical composition for the treatment of serious fatigue and exhaustion symptoms, burn-out, chronic fatigue syndrome, **depression**, Alzheimer disease, irritated bowel syndrome, osteoporosis, type 2 diabetes, or for anti-aging therapy, immune therapy and for stimulating recovery after physical exercise in humans or for stimulating growth and the immune system in animals." From **claim 5** "Use as claimed in claim 1, wherein **the compound is** a precursor of indole acetic acid selected from the group consisting of tryptophan, 4-hydroxytryptophan, 4-methoxy-tryptophan, 5-hydroxytryptophan, 5-methoxytryptophan, 6-hydroxytryptophan, 6-methoxytryptophan, 7-hydroxy-tryptophan, 7-methoxytryptophan, hypaphorine, tryptamine, 4-hydroxytryptamine, 4-methoxytryptamine, **psilocin** (4-hydroxy, dimethyl tryptamine), **psilocybin** (4-phosphate, dimethyl-tryptamine), baeocystin, serotonin (5 hydroxytryptamine), 5-methoxytryptamine, bufotenine (dimethylserotonine), O-methylbufotenine, melatonin, 6-hydroxytryptamine, 6-methoxy-tryptamine, 7-hydroxytryptamine, 7-methoxytryptamine, indole butyric acid and indole-3-pyruvate." From **claim 6** "Use as claimed in claim 1, wherein **the compound is** an analogue of the compounds listed in claim 3 or a metabolite of indole acetic acid that can be converted back into a compound as listed in claim 3, and selected from the group consisting of indole, indole-3-acetaldehyde, indole-3-ethanol, indole-3-aldehyde, indol-3-methanol, indole-3-carboxylic acid, 3-methylindole (skatole); indole-3-acetaldoxime, 3-aminomethylindole, N-methylaminomethylindole, gramine (N-dimethylaminomethylindole), indoxyls (indicans), indoleninones, 3-methylene-2-oxindole, abrine, isotan B, isatin, indican, indigo, indurubin, indigotins, 3-indolylmethyl (skatolyl), **niacin,** 2-oxindole-3-acetic acid, 3-methylene-2-oxindole, oxindole-3-methanol, oxindole-3-aldehyde, oxindole-3-carboxylic acid and 3-methyloxindole."
14. The method of claim 11, wherein the composition comprises 0.1 mg to 10 mg; 0.1 mg to 0.6 mg; 0.6 mg to 0.9 mg; 0.9 mg to 10 mg; or 1 mg to 10 mg of psilocybin or	1. GROB (2011) "Pilot Study of Psilocybin Treatment for Anxiety in Patients With Advanced-Stage Cancer" Arch Gen Psychiatry. 68(1):71-78. From **page 75**

psilocin per 70 kg of the subject's body mass.

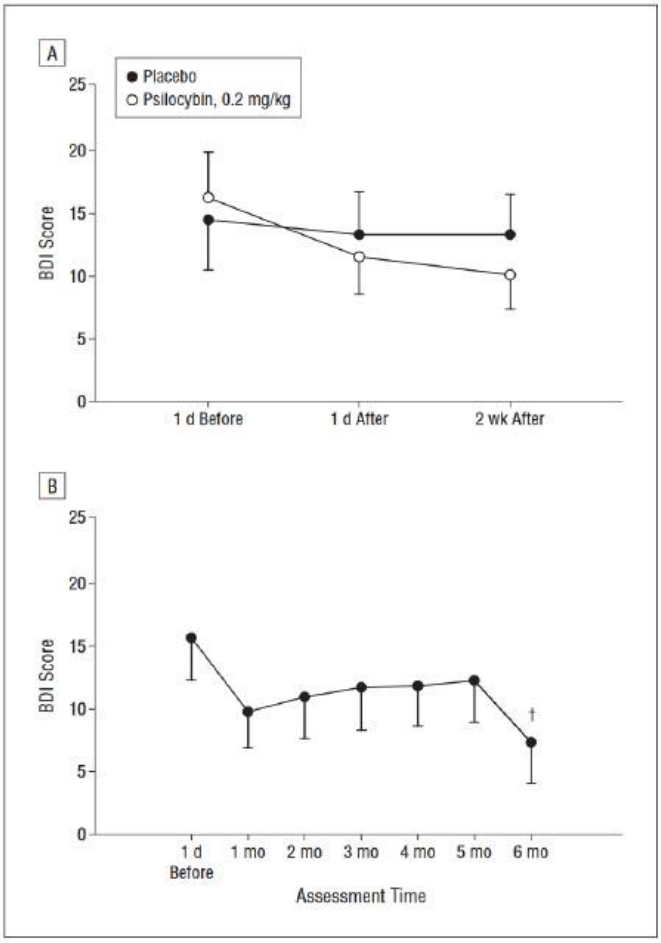


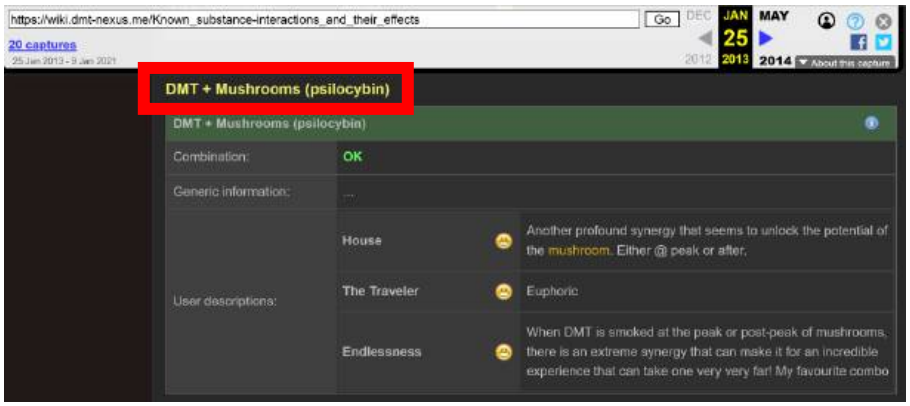
Figure 3. Beck Depression Inventory (BDI) scores. A, Mean (SEM) BDI scores 1 day before, 1 day after, and 2 weeks after administration of psilocybin or niacin placebo are shown. B, Six months of mean (SEM) BDI follow-up data are shown. The BDI was administered at monthly intervals for 6 months after the second treatment session, and the 6 sets of monthly follow-up data were compared with the scores obtained the first time the participants filled out the instruments (ie, 1 day before the first treatment session). †$P<.05$ for psilocybin vs the value from 1 day before the first treatment session (t tests were used to compare individual monthly follow-up values with values on the day before the first session).

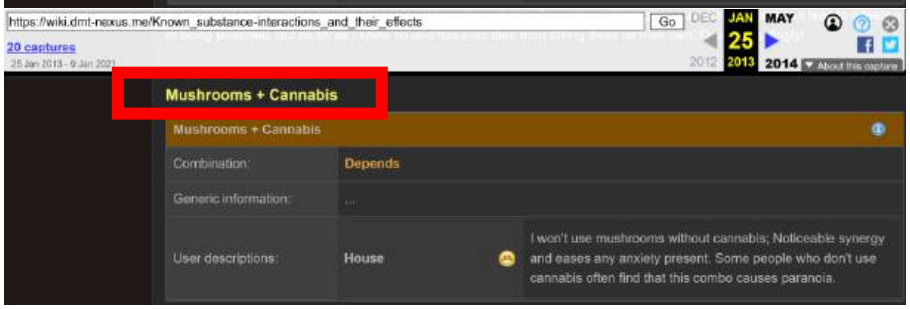
2. Int'l Pat. App. Pub. No. WO/2005/039546 "USE OF COMPOUNDS THAT ARE ABLE TO INCREASE THE SERUM IGF-1 LEVEL FOR THE PREPARATION OF A THERAPEUTICAL COMPOSITION FOR TREATMENT OF VARIOUS DISEASE STATES ASSOCIATED WITH A REDUCED IGF-1 SERUM LEVEL IN HUMANS AND ANIMALS" (Published May 6, 2005)

From **claim 1** "Use of **one or more compounds** that are capable of activating the hypothalamus in an individual to increase the serum level of Growth Hormone Releasing Hormone (GHRH) which in turn leads to an increase in the secretion of growth hormone (GH) and the subsequent rise of the serum level of insulin-like growth factor 1 (IGF-1) for the preparation of

	a therapeutical composition **for the treatment of** serious fatigue and exhaustion symptoms, burn-out, chronic fatigue syndrome, **depression**, Alzheimer disease, irritated bowel syndrome, osteoporosis, type 2 diabetes, or for anti-aging therapy, immune therapy and for stimulating recovery after physical exercise in humans or for stimulating growth and the immune system in animals." From **claim 5** "Use as claimed in claim 1, wherein **the compound is** a precursor of indole acetic acid selected from the group consisting of tryptophan, 4-hydroxytryptophan, 4-methoxy-tryptophan, 5-hydroxytryptophan, 5-methoxytryptophan, 6-hydroxytryptophan, 6-methoxytryptophan, 7-hydroxy-tryptophan, 7-methoxytryptophan, hypaphorine, tryptamine, 4-hydroxytryptamine, 4-methoxytryptamine, **psilocin** (4-hydroxy, dimethyl tryptamine), **psilocybin** (4-phosphate, dimethyl-tryptamine), baeocystin, serotonin (5 hydroxytryptamine), 5-methoxytryptamine, bufotenine (dimethylserotonine), O-methylbufotenine, melatonin, 6-hydroxytryptamine, 6-methoxy-tryptamine, 7-hydroxytryptamine, 7-methoxytryptamine, indole butyric acid and indole-3-pyruvate." From **claim 14** "Use as claimed in any one of the claims 1-13, wherein the composition comprises **1 to 100 mg,** preferably 10 to 90 mg, more preferably 40 mg of the **active ingredient**."
15. The method of claim 11, wherein the composition comprises 1 mg to 200 mg of niacin per 70 kg of the subject's body mass.	2. Int'l Pat. App. Pub. No. WO/2005/039546 "USE OF COMPOUNDS THAT ARE ABLE TO INCREASE THE SERUM IGF-1 LEVEL FOR THE PREPARATION OF A THERAPEUTICAL COMPOSITION FOR TREATMENT OF VARIOUS DISEASE STATES ASSOCIATED WITH A REDUCED IGF-1 SERUM LEVEL IN HUMANS AND ANIMALS" (Published May 6, 2005) From **claim 1** "Use of **one or more compounds** that are capable of activating the hypothalamus in an individual to increase the serum level of Growth Hormone Releasing Hormone (GHRH) which in turn leads to an increase in the secretion of growth hormone (GH) and the subsequent rise of the serum level of insulin-like growth factor 1 (IGF-1) for the preparation of a therapeutical composition **for the treatment of** serious fatigue and exhaustion symptoms, burn-out, chronic fatigue syndrome, **depression**, Alzheimer disease, irritated bowel syndrome, osteoporosis, type 2 diabetes, or for anti-aging therapy, immune therapy and for stimulating recovery after physical exercise in humans or for stimulating growth and the immune system in animals." From **claim 6** "Use as claimed in claim 1, wherein **the compound is** an analogue of the compounds listed in claim 3 or a metabolite of indole acetic acid that can be converted back into a compound as listed in claim 3, and selected from the group consisting of indole, indole-3-acetaldehyde, indole-

	3-ethanol, indole-3-aldehyde, indol-3-methanol, indole-3-carboxylic acid, 3-methylindole (skatole); indole-3-acetaldoxime, 3-aminomethylindole, N-methylaminomethylindole, gramine (N-dimethylaminomethylindole), indoxyls (indicans), indoleninones, 3-methylene-2-oxindole, abrine, isotan B, isatin, indican, indigo, indurubin, indigotins, 3-indolylmethyl (skatolyl), **niacin,** 2-oxindole-3-acetic acid, 3-methylene-2-oxindole, oxindole-3-methanol, oxindole-3-aldehyde, oxindole-3-carboxylic acid and 3-methyloxindole." From **claim 14** "Use as claimed in any one of the claims 1-13, wherein the composition comprises **1 to 100 mg**, preferably 10 to 90 mg, more preferably 40 mg of the active ingredient." 7. Int'l Pat. App. Pub. No. WO/2006/091988 "COMPOSITION FOR TREATING MENTAL HEALTH DISORDERS" (Published August 31, 2006) From **claim 15** "A method of treating **depression**, comprising administering to a subject in need thereof an effective amount of a composition of any of claims 1-12." From **claim 23** "The method of claim 21, further comprising administering to the subject a daily dosage of vitamin C 20-2000 mg or a daily dosage of **vitamin B3 1-200 mg**."
16. The method of claim 11, wherein the composition further comprises one or more pharmaceutically acceptable excipients.	2. Int'l Pat. App. Pub. No. WO/2005/039546 "USE OF COMPOUNDS THAT ARE ABLE TO INCREASE THE SERUM IGF-1 LEVEL FOR THE PREPARATION OF A THERAPEUTICAL COMPOSITION FOR TREATMENT OF VARIOUS DISEASE STATES ASSOCIATED WITH A REDUCED IGF-1 SERUM LEVEL IN HUMANS AND ANIMALS" (Published May 6, 2005) From **claim 17** "Therapeutical composition comprising a suitable diluent, carrier or **excipient** and one or more compounds as listed in claims 3-12."
17. The method of claim 11, wherein the composition is administered in a capsule.	2. Int'l Pat. App. Pub. No. WO/2005/039546 "USE OF COMPOUNDS THAT ARE ABLE TO INCREASE THE SERUM IGF-1 LEVEL FOR THE PREPARATION OF A THERAPEUTICAL COMPOSITION FOR TREATMENT OF VARIOUS DISEASE STATES ASSOCIATED WITH A REDUCED IGF-1 SERUM LEVEL IN HUMANS AND ANIMALS" (Published May 6, 2005) From **claim 15** "Use as claimed in any one of the claims 1-14, wherein the composition is in the form of a **capsule**."

18. The method of claim 11, wherein 500 mg to 1000 mg of the composition is administered once to three times per day.	2. Int'l Pat. App. Pub. No. WO/2005/039546 "USE OF COMPOUNDS THAT ARE ABLE TO INCREASE THE SERUM IGF-1 LEVEL FOR THE PREPARATION OF A THERAPEUTICAL COMPOSITION FOR TREATMENT OF VARIOUS DISEASE STATES ASSOCIATED WITH A REDUCED IGF-1 SERUM LEVEL IN HUMANS AND ANIMALS" (Published May 6, 2005) From **claim 14** "Use as claimed in any one of the claims 1-13, wherein the **composition comprises 1 to 100 mg**, preferably 10 to 90 mg, more preferably 40 mg **of the active ingredient.**" From **page 4, paragraph 4** "The invention also relates to the use of **precursors from which IAA and analogues as listed above could be formed**, such as tryptophan, 4-hydroxytryptophan, 4-methoxytryptophan, 5-hydroxytryptophan, 5-methoxytryptophan, 6-hydroxytryptophan, 6-methoxytryptophan, 7-hydroxytryptophan 7-methoxytryptophan, hypaphorine, tryptamine, 4-hydroxytryptamine, 4-methoxytryptamine, **psilocin** (4-hydroxy, dimethyl tryptamine), **psilocybin** (4-phosphate, dimethyl tryptamine), baeocystin, serotonin (5 hydroxytryptamine), 5-methoxytryptamine, bufotenine (dimethylserotonine), O-methylbufotenine, melatonin (5-methoxy, acetamide function on tryptamine NH2), 6-hydroxytryptamine, 6-methoxytryptamine, 7-hydroxytryptamine, 7-methoxytryptamine. From **page 19, paragraph 3** "The patients took **1000 mg/day** (corresponding to 40 mg IAA and 960 mg salt and WPC 70) **of the composition** of the invention for 4 weeks. After this the dosage was reduced by 250 mg (corresponding to 10 mg IAA) every 2 weeks to 750 mg/day, 500 mg/day 250 mg/day respectively."
19. The method of claim 11, wherein the composition further comprises: Bacopa species (Bacopa monnieri), Gotu kola (Centella asiatica), Gingko (Gingko biloba), Ginger (Zingiber officinale), Holy Basil (Ocimum sanctum), Hu Zhang (Polygonum cuspid atum), Oregano (Origanum vulgare, Origanum onites), Rosemary (	4. DMT-NEXUS (2013) "Known substance-interactions and their effects" DMT-Nexus. Retrieved January 25, 2013. https://web.archive.org/web/20130125065447/https://wiki.dmt-nexus.me/Known_substance-interactions_and_their_effects 

Rosmarinus officinalis, Rosmarinus eriocalyx, Rosmarinus species), Turmeric (Curcuma longa), Green Tea (Camellia sinensis), lavender (Lavandula spica and Lavandula species), skullcap (Scutellaria lateriflora), oat straw (Avena sativa and Avena byzantine), Diviner's Sage (Salvia divinorum), ayahuasca (Banisteriopsis caapi and Psychotria species), Tabemanthe iboga, Voacanga africana, Tabemaemontana undulate, peyote (Lophophora williamsii), morning glory (Ipomoea tricolor, Argyreia nervosa), Cannabis sativa, Cannabis indica or Cannabis ruderalis, extracts thereof, or combinations thereof.	  5. LICHT (2012) “Simultaneous polysubstance use among Danish 3,4-methylenedioxymethamphetamine and hallucinogen users: combination patterns and proposed biological bases” Hum. Psychopharmacol. Clin. Exp. 27: 352–363. From **page 355** “The most prevalent observations were **cannabis enhancing the effects of hallucinogens** (n = 17) and MDMA (n = 7), MDMA and hallucinogens enhancing each other (n = 11), **hallucinogens enhancing each other** (n = 6), amphetamines (n = 8) and cocaine (n = 6) counteracting hallucinogens, and cocaine counteracting the effects of MDMA (n = 7).” 6. U.S. Pat. App. Pub. No. US/2001/0008641 “NUTRITIONALLY ACTIVE COMPOSITION FOR BODYBUILDING” (Published July 19, 2001) From **claim 24** “The composition of claim 4 wherein said substituent (C) is selected from the group consisting of red rice yeast, damiana, ephedra, ginger, ginseng, goto kola, lobelia, ma huang, maraba and **psilocybin**.” From **paragraph [0017]** “The invention further provides such compositions that additionally contain at least one additional substituent (C) that provides long term psychological feedback substituent and/or at least one additional substituent (D) that provides short term psychological feedback; wherein the substituent (C) that provides the long term psychological feedback is selected from the group consisting of: an anandamide, 5-hydroxytryptophan, 5-fluoro-A-methyltryptamine, 5-fluorotryptophan, 6-fluorotryptophan,

	tryptophan, allocryptine, caffeine, theophylline, theobromine, California poppy, calcium, chromium picolinate, chromium polynicotinate, chicalote extract, cocoa, chocolate, Damiana (Turnera diffusa), DL-phenylalanine, ephedra, ephedrine, epinephrine, GABA, **ginger**, ginseng, L-glutamine, **green tea**, guarana, kava kava, lactuca virosa, L-tyrosine, lobelia, magnesium, maraba, protopine, pseudophedrine, pseudo-epinephrine, pyridoxal-5-phosphate, red rice yeast, serotonin, sucrose, fructose, glucose, high fructose corn syrup, and St. Johnswort, and is present in an amount sufficient to provide a long term feeling of well-being or calmness; and the substituent (D) that provides the short term psychological feedback is selected from the group consisting of: an anandamide, an alcohol enhancer, angelica root, balm, bitter orange (Auranti pericarpium), bogbean, boldo, calamus, California poppy, capsaicum, caraway, cayenne, chamomile, cinchona bark, quinine, chocolate, cinnamon, clove, cocoa, condurango, dandelion, elecampane, GABA, gentian, ginger, ginseng, holy thistle, hops, horehound, dried lemon peel (Citri pericardium), mugwort, unripe orange, peppermint, quassia, red sage, **rosemary,** star anise, thyme, **tumeric**, wormwood, yarrow, and zinc, and is present in an amount sufficient to provide a short term sensation of warmth, tingling, excitement, tranquility and well-being, or a distinctive, intense, bitter or unusual taste. From **paragraph [0079]** "The compositions of the present invention provide a nutritionally beneficial substituent to an individual in a manner accompanied by a reinforcing psychological feedback sensation. The psychological feedback sensation imparts an immediate physiological recognition of the composition (such as a feeling of warmth, or a flush feeling) as well as a long-term psychological feedback (such as a **counter-depressive effect** or a sense of well-being)."
20. The method of claim 11, wherein the composition further comprises: mycelia, fruitbodies, or extracts thereof of Antrodia, Beauveria, Copelandia, Cordyceps, Ganoderma, Grifola, Hericium, Inonotus, Isaria, Panaeolus, Phellinus or combinations thereof.	8. Int'l Pat. App. Pub. No. WO/2016/001922 "METHODS, DEVICES AND SYSTEMS FOR PULMONARY DELIVERY OF ACTIVE AGENTS" (Published January 7, 2016) From **claim 1** "A method of pulmonary delivering to a subject at least a first pharmacologically active agent and a second pharmacologically active agent, **at least one of which being in at least one plant material,** the method comprising independently delivering the agents to the subject using a metered dose inhaler device configured to vaporize at least a first pre-determined vaporized amount of said first agent and at least a second pre-determined vaporized amount of said second agent upon controllably heating said at least one plant material, wherein said heating is effected such that said first pre-determined vaporized amount is delivered to the subject successively, concomitantly and/or at least partially overlapping with said second pre-determined vaporized amount, and wherein each of said pre-determined vaporized amounts of each of said agents induces in the subject independently at least one pharmacokinetic effect and/or at least one pharmacodynamic effect."

	From **claim 47** "The method of any one of claims 42-46, wherein said desired effect corresponds to a symptom, said symptom being selected from the group consisting of pain, migraine, **depression**, cognitive function deficit, attention deficit, hyperactivity, anxiety disorders, diarrhea, nausea, vomiting, insomnia, delirium, appetite variations, sexual dysfunction, spasticity, increased intra ocular pressure, bladder dysfunction, tics, Tourette symptoms, post traumatic stress disorder (PTSD) symptoms, inflammatory bowel disease (IBD) symptoms, irritable bowel syndrome (IBS) symptoms, hyper tension, hemorrhagic symptoms, septic and cardiogenic shock, drug addiction and craving, withdrawal symptoms, tremors and other movement disorders." From **claim 51** "The method of any one of claims 1-2 and 26-50, wherein said **at least one plant is selected from the group consisting of** Cannabis sativa, Cannabis indica, Cannabis ruderalis, Acacia spp, Amanita muscaria, Yage, Atropa belladonna, Areca catechu, Brugmansia spp., Brunfelsia latifolia, Desmanthus illinoensis, Banisteriopsis caapi, Trichocereus spp., Theobroma cacao, Capsicum spp., Cestrum spp., Erythroxylum coca, Solenostemon scutellarioides, Arundo donax, Coffea arabica, Datura spp., Desfontainia spp., Diplopterys cabrerana, Ephedra sinica, Claviceps purpurea, Paullinia cupana, Argyreia nervosa, Hyoscyamus niger, Tabernanthe iboga, Lagochilus inebriens, Justicia pectoralis, Sceletium tortuosum, Piper methysticum, Catha edulis, Mitragyna speciosa, Leonotis leonurus, Nymphaea spp., Nelumbo spp., Sophora secundiflora, Mucuna pruriens, Mandragora officinarum, Mimosa tenuiflora, Ipomoea violacea, **Psilocybe spp., Panaeolus spp.**, Myristica fragrans, Turbina corymbosa, Passiflora incarnata, Lophophora williamsii, Phalaris spp., Duboisia hopwoodii, Papaver somniferum, Psychotria viridis, spp., Salvia divinorum, Combretum quadrangulare, Trichocereus pachanoi, Heimia salicifolia, Stipa robusta, Solandra spp., Hypericum perforatum, Peganum harmala, Tabernaemontanaspp, Camellia sinensis, Nicotiana tabacum, rusticum, Virola theidora, Voacanga africana, Lactuca virosa, Artemisia absinthium, Ilex paraguariensis, Anadenanthera spp., Corynanthe yohimbe, Calea zacatechichi, Coffea spp. (Rubiaceae), a Sapindaceae, Camellia spp., Malvaceae spp., Aquifoliaceae spp., Hoodia, spp. Chamomilla recutita, Passiflora incarnate, Camellia sinensis, Mentha piperita, Mentha spicata, Rubus idaeus, Eucalyptus globulus, Lavandula officinalis, Thymus vulgaris, Melissa officinalis, Aloe Vera, Angelica, Anise, Ayahuasca (Banisteriopsis caapi), Barberry, Black Horehound, Blue Lotus, Burdock, Camomille/Chamomile, Caraway, Cat's Claw, Clove, Comfrey, Corn Silk, Couch Grass, Damiana, Damiana, Dandelion, Ephedra, Eucalyptus, Evening Primrose, Fennel, Feverfew, Fringe Tree, Garlic, Ginger, Ginkgo, Ginseng, Goldenrod, Goldenseal, Gotu Kola, Green Tea, Guarana, Hawthorn, Hops, Horsetail, Hyssop, Kola Nut, Kratom, Lavender, Lemon Balm, Licorice, Lion's Tail (Wild Dagga), Maca Root, Marshmallow, Meadowsweet, Milk Thistle, Motherwort, Passion Flower, Passionflower, Peppermint, Prickly

	Poppy, Purslane, Raspberry Leaf, Red Poppy, Sage, Saw Palmetto, Sida Cordifolia, Sinicuichi (Mayan Sun Opener), Spearmint, Sweet Flag, Syrian Rue (Peganum harmala), Thyme, Turmeric, Valerian, Wild Yam, Wormwood, Yarrow, Yerba Mate, Yohimbe, and any part and any combination thereof." From **page 41** "According to some embodiments, the substance that contains at least one vaporizable active agent is, for example, a plant material. In some embodiments, the active agent is a naturally occurring agent, namely the agent occurs (produced) naturally in the plant. Alternatively, the substance is an organic material which contains, or consists of, for example, one or more natural plant materials, or a synthetic material which may comprise at least one vaporizable active agent. In some embodiments, the solid form of a substance comprises a plurality of **vaporizable active agents derived or extracted from** natural or organic sources, such as plants, **fungi,** bacteria and the likes."

Electronic Acknowledgement Receipt

EFS ID:	45770626
Application Number:	17480789
International Application Number:	
Confirmation Number:	1619
Title of Invention:	COMPOSITIONS AND METHODS FOR TREATING DEPRESSION
First Named Inventor/Applicant Name:	Paul Edward STAMETS
Customer Number:	23409
Filer:	Shahin Shams
Filer Authorized By:	
Attorney Docket Number:	215261-9002-US13
Receipt Date:	20-MAY-2022
Filing Date:	21-SEP-2021
Time Stamp:	20:52:39
Application Type:	

Payment information:

Submitted with Payment	yes
Payment Type	CARD
Payment was successfully received in RAM	$90
RAM confirmation Number	E20225JK52364195
Deposit Account	
Authorized User	

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Document Number	Document Description	File Name	File Size(Bytes)/ Message Digest	Multi Part /.zip	Pages (if appl.)
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Warnings:					
Information:					
2	Third-Party Submission Under 37 CFR 1.290	Third-party-preissuance-submission.pdf	67319 b08257de949df87ae05580a8f27d445e3572f674	no	3
Warnings:					
Information:					
3	Request for Notification of Non-compliant Third-Party Submission	Third-party-notification-request.pdf	23723 4a8355296c18087b361f0dd273b8e6b0eae64d9a	no	1
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9	Non Patent Literature	5-LICHT.pdf	136346 22874ebddec35f5930e1b8ebb483e1fb071c4783	no	12
Warnings:					
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10	Evidence of Publication	6-US20010008641A1.pdf	1517451 e53f92fb36d4f9b46530ef4f9d86e08e124dc1fe	no	16
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11	Evidence of Publication	7-WO2006091988A1.pdf	808934 d69b67c80f7c256a2095ee498e6a2e88a9b1c11f	no	18
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12	Evidence of Publication	8-WO2016001922A1.pdf	10275797 9d2e6759c1a2b853196115a8da0ea70f4ae3c4bc	no	184
Warnings:					
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13	Fee Worksheet (SB06)	fee-info.pdf	37543 9221a5d63e4c89e2d3cc229d21393af9944d5dd8	no	2
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