## IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of: TURTLE BEAR HOLDINGS, LLCConfirmation No.:Serial No.: 18/115,966Group No.:Filing or 371(c) Date: March 01, 2023Examiner:Entitled: TRYPTAMINE COMPOSITIONS FOR ENHANCING NEURITE OUTGROWTH

## 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

- U.S. Pat. App. Pub. No. 2018/0021405 "Nutritional Approach to the Control of Anemia, Diabetes, and Other Diseases or Conditions and Prevention of Associated Comorbid States with the Use of Ergothioneine" (Published January 25, 2018)
- LENZ (2017) "Identification of ω-N-Methyl-4-hydroxytryptamine (Norpsilocin) as a Psilocybe Natural Product" Journal of Natural Products. 80:10(2835-2838)
- JULSON, "16 Foods That Are High in Niacin (Vitamin B3)" October 5, 2018; retrieved from WaybackMachine Internet Archive, Healthline. https://web.archive.org/web/20190507113644/https://www.healthline.com/nutrition/foodshigh-in-niacin, retrieved May 07, 2019
- 4. U.S. Pat. App. Pub. No. 2017/0035820 "Integrative Fungal Solutions For Protecting Bees And Overcoming Colony Collapse Disorder (CCD)" (Published February 09, 2017)
- 5. WILCOX (2014) "Psilocybin and Obsessive Compulsive Disorder" Journal of Psychoactive Drugs. 46:5(393-395)
- DRUGS.COM, "lovie... Taken for 1 to 6 months July 12, 2018" July 12, 2018; retrieved from Drugs.com comment. https://www.drugs.com/comments/niacin/for-depression.html, retrieved July 12, 2018
- J, "My Cognition Improves Tremendously: Mushrooms & Amphetamines (Adderall XR)" August 11, 2018; retrieved from Erowid. https://erowid.org/experiences/exp.php?ID=111984, retrieved August 11, 2018
- SAUL, "Treating ADHD with Vitamin B-3 (Niacinamide)" October 30, 2013; retrieved from Orthomolecular.org. http://orthomolecular.org/resources/omns/v09n23.shtml, retrieved on October 30, 2013

- 9. GARCIA-ROMEU (2015) "Psilocybin-occasioned Mystical Experiences in the Treatment of Tobacco Addiction" Current Drug Abuse Reviews. 7:3(157-164)
- 10. PSOOD0NYM, "4-Ho-NMT" 2007; retrieved from Bluelight.org comment. https://bluelight.org/xf/threads/4-ho-nmt.321417/, retrieved June 18, 2007
- 11. U.S. Pat. App. Pub. No. 2019/0142851 "Compositions Comprising a Psilocybin Derivative and a Cannabinoid" (Published May 16, 2019)
- 12. LAKE, "Some Vitamins and Minerals May Reduce Alcohol Toxicity: Promising findings for certain B vitamins, vitamin C, magnesium and zinc." January 29, 2019; retrieved from Psychology Today. https://www.psychologytoday.com/us/blog/integrative-mental-healthcare/201901/some-vitamins-and-minerals-may-reduce-alcohol-toxicity, retrieved January 29, 2019

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

U.S.S.N. 18/115,966	References
Pending Claims	
1. A method of treating	2. LENZ (2017) "Identification of ω-N-Methyl-4-
serotonin (5-	hydroxytryptamine (Norpsilocin) as a Psilocybe Natural
hydroxytryptamine, 5-HT)	Product" Journal of Natural Products. 80:10(2835-2838)
receptor disorders,	
neurological diseases, or	From <b>abstract</b> : "We report the <b>identification of ω-N-methyl-4-</b>
augmenting	hydroxytryptamine (norpsilocin, 1) from the carpophores of
neurogeneration in a	the hallucinogenic mushroom Psilocybe cubensis."
subject in need thereof, the	
method comprising	
administering to the	4. U.S. Pat. App. Pub. No. 2017/0035820 "Integrative Fungal
subject a pharmaceutical	Solutions For Protecting Bees And Overcoming Colony
composition comprising:	Collapse Disorder (CCD)" (Published February 09, 2017)
0.5-4 mg of norpsilocin or	
a salt or combinations	From [0292]: "Psilocybin and psilocybin-producing fungi,
thereof; and 0.5-4 mg of	including but not limited to species of Psilocybe, Panaeolus,
niacin.	Gymnopilus, Pluteus and Conocybe such as Psilocybe
	azurescens, Psilocybe cyanescens, Psilocybe allenii, Psilocybe
	cyanofibrillosa, Psilocybe cubensis, Psilocybe ovoideocystidiata,
	Psilocybe subaeruginosa, Copelandian Panaeoli (Copelandia
	cyanescens, Copelandia tropicalis, Copelandia bispora), Pluteus
	salicinus, Gymnopilus luteofolius, Gymnopilus spectabilis,
	Conocybe cyanopus and Conocybe smithii can trigger
	neurogenesis. (See Catlow et al., Effects of psilocybin on
	hippocampal neurogenesis and extinction of trace fear
	conditioning, Exp Brain Res (2013) 228:481-491 DOI
	10.1007/s00221-013-3579-0). Individually or in combination,
	mixtures of extracts of psilocybin mushroom and Hericium
	mushroom fruitbodies, or more preferably their mycelial
	extracts, could help repair neurons damaged by toxins,
	cholinergic pesticides, fungicides, herbicides, glyphosates,
	oxidation, old age, or other sources of neuro-damaging toxins.
	The net effect of ingesting these mixtures of nerve regenerating
	Hericium and psilocybin species would improve the
	neurological health of bees through neurogenesis and re-
	myelination, and indeed of animals, including humans.
	Another, improved form of "smart mycohoney" might
	incorporate these elements for the benefits of bees and
	people, improving cognition, preventing or repairing
	neuropatnies presenting themselves as diseases to numans
	within scope of the definitions for Alzneimer's, Parkinson's, Darkiganigma MS (multiple galaxis), or as yet
	rarkisonisms, IVIS (multiple scierosis), or as yet
	apprint and the second dimension of the second dimensi
	combinations could increase intelligence, sensory abilities,
	memory, renexes, reaction times, and problem solving abilities.

Moreover, to the above mixture, vitamins can be added for further enhancement of beneficial properties. **The addition of** vitamin D—either from UV exposed fungal cells or from external sources, **with or without Vitamin B (niacin, nicotinic acid, or related congener), enhance neurogenesis and are preferred ingredients.** As such a smart nutraceutical in many forms are possible, including a 'smart mycohoney' or 'smart mycosyrup' both of which are anticipated to be within the scope of this invention. Such a mycosyrup can be reduced into solid or powdered form added to any food consumed by animals, or by any means known to pharmaceutical science."

10. PSOOD0NYM, "4-Ho-NMT" 2007; retrieved from Bluelight.org comment. https://bluelight.org/xf/threads/4-ho-nmt.321417/, retrieved June 18, 2007

From **Bluelight webpage comment #3**: "4-ho-NMT may be much more influential in combination with psilocin than it is alone. Manic energy and idiomotor effects were pronounced when I combined the two. Over the weekend I did psilocin alone (4mg IM, 6mg oral, 4mg insufflated over an hour) and found it to be much smoother and relaxing than the first time, even though I expected that the 4-ho-NMT had little to no influence on it. After the oral dose plateaued I IM'd 5mg of 4-ho-NMT to see what influence it would have, if any. After 10 minutes nothing had changed and I started to think my first experience was a fluke. The whole time I was waiting for the 4-ho-NMT to come on I was sitting down. Upon getting up and walking I began to feel compulsions to contort my arms, legs, and neck in strange jerking or rolling motions just like last time. The manic energy and idiomotor movement was not as pronouced as it was with 10mg oral and 5mgs insufflated 4-ho-NMT with just 8mg psilocin insufflated (at once, over an hour after the 4-ho-NMT), suggesting that the 4-ho-NMT requires psilocin to produce the effect, but is itself responsible for the brunt of it. (I'll also mention that during the first experience there was a reflexive swallowing effect whose speed and irresistibility was directly proportional to the coldness of the liquid I drank.) This continued for the next two or so hours, but would stop when I sat back down to watch a DVD. I don't think it was a placebo effect because the spastic movements (which were accompanied by an extremely giddy sensation) would occur even when I was immersed in thought with no expectation of the movements occurring, so long as I was already in motion. I'm interested to know if anyone else tried the combo and each alone, and noticed

similar effects. I've only done this twice and it's possible that the second time the idiomotor effects of the psilocin were simply delayed and just happened to coincide with the injection of 4-ho-NMT, or that the phenomenon is entirely idiosyncratic."
<ul> <li>JULSON, "16 Foods That Are High in Niacin (Vitamin B3)"</li> <li>October 5, 2018; retrieved from WaybackMachine Internet Archive, Healthline.</li> <li>https://web.archive.org/web/20190507113644/https://www.healt hline.com/nutrition/foods-high-in-niacin, retrieved May 07, 2019</li> </ul>
From webpage: "Mushrooms are one of the best vegetable sources of niacin, providing 2.5 mg per cup (70 grams) — that's 15% and 18% of the RDA for men and women, respectively (40)."
1. U.S. Pat. App. Pub. No. 2018/0021405 "Nutritional Approach to the Control of Anemia, Diabetes, and Other Diseases or Conditions and Prevention of Associated Comorbid States with the Use of Ergothioneine" (Published January 25, 2018)
From [0059]: "Any type of mushroom, mushroom part, component, fungi or even used substrate for cultivating mushrooms, with ergosterol present may be used. This includes all filamentous fungi where ergosterol has been shown to be present and includes the use of tissues such as the mycelia, spores or vegetative cells. This includes, but is not limited to, for example, Coprinus, Agrocybe, Hypholoma, Hypsizygus, Pholiota, Pleurotus, Stropharia, Ganoderma, Grifola, Trametes, Hericium, Tramella, <b>Psilocybe</b> , Agaricus, including for example Agaricus bisporus (e.g. white button mushrooms), Phytophthora achlya, Flammulina, Melanoleuca, Agrocybe, Morchella, Mastigomycotina, Auricularia, Gymnopilus, Mycena, Boletus, Gyromitra, Pholiota, Calvatia, Kuegneromyces, Phylacteria, Cantharellus, Lactarius, Pleurotus, Clitocybe, Lentinula (Lentinus), Stropharia, Coprinus, Lepiota, Tuber, Tremella, Drosophia, Leucocoprinus, Tricholoma, Dryphila, Marasmius, and Volvariella."
From <b>[0008]</b> : "These and other valuable health benefits of ET- enhanced mushrooms are disclosed in U.S. patent application Ser. Nos. 12/887,276 and 12/386,810, titled "Vitamin D2 Enriched Mushrooms and Fungi for Treatment of Oxidative

Stress, Alzheimer's Disease and Associated Disease States," and "Methods and Compositions for Improving the Nutritional Content of Mushrooms and Fungi," respectively, which are herein incorporated by reference in its entirety. Mushrooms are a valuable health food—low in calories, high in vegetable proteins, chitin, iron, zinc, fiber, essential amino acids, vitamins and minerals. They are also an excellent source of organic selenium compounds, riboflavin, pantothenic acid, copper, niacin, potassium and phosphorous. Selenium is needed for the proper function of the antioxidant system, which works to reduce the levels of damaging free radicals in the body. Selenium is a necessary cofactor of one of the body's most important internally produced antioxidants, glutathione peroxidase, and also works with vitamin E in numerous vital antioxidant systems throughout the body. Mushrooms are also a primary source of natural Vitamin D, in the form of D2, which is naturally present in very few foods. Most other natural food sources of Vitamin D, in the form Vitamin D3, are of animal, poultry or seafood origin."

From [0051]: "The term "treating" or "treatment" as used herein, refers to any indicia of success in the prevention or amelioration of an injury, pathology or condition, including any objective or subjective parameter such as abatement; remission; diminishing of symptoms or making the injury, pathology, or condition more tolerable to the patient; slowing in the rate of degeneration or decline; making the final point of degeneration less debilitating; or improving a subject's physical or mental well-being. The treatment or amelioration of symptoms can be based on objective or subjective parameters; including the results of a physical examination, neurological examination, and/or psychiatric evaluations."

From **[0118]**: "Applicants demonstrated that the combination of antioxidants, including phytonutrient turmeric and Ergothioneine, along with Vitamin D enriched mushrooms increase longevity in Drosophila kept under nutritionally deficient diet. These results represent a novel use of the compositions of the invention for **treating a variety of disease states associated with** inflammation and oxidative stress. According to the invention, Applicants have shown that the compositions increase survival and decrease biologic death in conditions associated with oxidative stress, which include disease states such as Alzheimer's disease and other associated diseases including those involving chronic markers of inflammation, such as **chronic depression**, traumatic brain

	injury and PTSD. Thus the supplements, food compositions and pharmaceutical compositions according to the invention, employing the Vitamin D enriched mushrooms, turmeric and Ergothioneine have surprising benefits for treatment of such disease states."
	From [0083]: "The therapeutically effective dosage of any specific compound will vary somewhat from compound to compound, patient to patient, and will depend upon the condition of the patient and the route of delivery. As a general proposition, a dosage from about 0.01 to about 50 mg/kg will have therapeutic efficacy, with still higher dosages potentially being employed for oral and/or aerosol administration. Toxicity concerns at the higher level may restrict intravenous dosages to a lower level such as up to about 10 mg/kg, all weights being calculated based upon the weight or volume of the enriched mushrooms, fractions thereof or compounds thereof of the present invention, including the cases where a salt is employed. In an aspect of the invention a pharmaceutical composition provided in 500 mg capsules may be dosed to a patient from 1 to 4 capsules a day, preferably 2 to 4 capsules a day."
2. The method of claim 1, wherein the composition further comprises an	4. U.S. Pat. App. Pub. No. 2017/0035820 "Integrative Fungal Solutions For Protecting Bees And Overcoming Colony Collapse Disorder (CCD)" (Published February 09, 2017)
extract of or isolate from <i>Hericium erinaceus</i> .	From [0292]: "Psilocybin and psilocybin-producing fungi, including but not limited to species of Psilocybe, Panaeolus, Gymnopilus, Pluteus and Conocybe such as Psilocybe azurescens, Psilocybe cyanescens, Psilocybe allenii, Psilocybe cyanofibrillosa, Psilocybe cubensis, Psilocybe ovoideocystidiata, Psilocybe subaeruginosa, Copelandian Panaeoli (Copelandia cyanescens, Copelandia tropicalis, Copelandia bispora), Pluteus salicinus, Gymnopilus luteofolius, Gymnopilus spectabilis, Conocybe cyanopus and Conocybe smithii can trigger neurogenesis. (See Catlow et al., Effects of psilocybin on hippocampal neurogenesis and extinction of trace fear conditioning, Exp Brain Res (2013) 228:481-491 DOI 10.1007/s00221-013-3579-0). Individually or in combination, mixtures of extracts of psilocybin mushroom and Hericium mushroom fruitbodies, or more preferably their mycelial extracts, could help repair neurons damaged by toxins, cholinergic pesticides, fungicides, herbicides, glyphosates, oxidation, old age, or other sources of neuro-damaging toxins. The net effect of ingesting these mixtures of nerve

regenerating Hericium and psilocybin species would improve the neurological health of bees through neurogenesis and remyelination, and indeed of animals, including humans. Another, improved form of "smart mycohoney" might incorporate these elements for the benefits of bees and people, improving cognition, preventing or repairing neuropathies presenting themselves as diseases to humans within scope of the definitions for Alzheimer's, Parkinson's, Parkisonisms, MS (multiple sclerosis), or as yet uncategorized forms of neurological impairment. Indeed such combinations could increase intelligence, sensory abilities, memory, reflexes, reaction times, and problem solving abilities. Moreover, to the above mixture, vitamins can be added for further enhancement of beneficial properties. The addition of vitamin D—either from UV exposed fungal cells or from external sources, with or without Vitamin B (niacin, nicotinic acid, or related congener), enhance neurogenesis and are preferred ingredients. As such a smart nutraceutical in many forms are possible, including a 'smart mycohoney' or 'smart mycosyrup' both of which are anticipated to be within the scope of this invention. Such a mycosyrup can be reduced into solid or powdered form added to any food consumed by animals, or by any means known to pharmaceutical science."

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From [0008]: "These and other valuable health benefits of ETenhanced mushrooms are disclosed in U.S. patent application Ser. Nos. 12/887,276 and 12/386,810, titled "Vitamin D2 Enriched Mushrooms and Fungi for Treatment of Oxidative Stress, Alzheimer's Disease and Associated Disease States," and "Methods and Compositions for Improving the Nutritional Content of Mushrooms and Fungi," respectively, which are herein incorporated by reference in its entirety. Mushrooms are a valuable health food—low in calories, high in vegetable proteins, chitin, iron, zinc, fiber, essential amino acids, vitamins and minerals. They are also an excellent source of organic selenium compounds, riboflavin, pantothenic acid, copper, **niacin**, potassium and phosphorous. Selenium is needed for the proper function of the antioxidant system, which works to reduce the levels of damaging free radicals in the body. Selenium is a necessary cofactor of one of the body's most important internally produced antioxidants, glutathione peroxidase, and also works with vitamin E in numerous vital antioxidant systems throughout the body. Mushrooms are also a primary source of natural Vitamin D, in the form of D2, which is naturally present in very few foods. Most other natural food sources of Vitamin D, in the form Vitamin D3, are of animal, poultry or seafood origin."

From [0051]: "The term "treating" or "treatment" as used herein, refers to any indicia of success in the prevention or amelioration of an injury, pathology or condition, including any objective or subjective parameter such as abatement; remission; diminishing of symptoms or making the injury, pathology, or condition more tolerable to the patient; slowing in the rate of degeneration or decline; making the final point of degeneration less debilitating; or improving a subject's physical or mental well-being. The treatment or amelioration of symptoms can be based on objective or subjective parameters; including the results of a physical examination, neurological examination, and/or psychiatric evaluations."

From **[0118]**: "Applicants demonstrated that the combination of antioxidants, including phytonutrient turmeric and Ergothioneine, along with Vitamin D enriched mushrooms increase longevity in Drosophila kept under nutritionally deficient diet. These results represent a novel use of the compositions of the invention for **treating a variety of disease** 

states associated with inflammation and oxidative stress. According to the invention, Applicants have shown that the compositions increase survival and decrease biologic death in conditions associated with oxidative stress, which include disease states such as Alzheimer's disease and other associated diseases including those involving chronic markers of inflammation, such as <b>chronic depression</b> , traumatic brain injury and PTSD. Thus the supplements, food compositions and pharmaceutical compositions according to the invention, employing the Vitamin D enriched mushrooms, turmeric and Ergothioneine have surprising benefits for treatment of such disease states."
<ul> <li>11. U.S. Pat. App. Pub. No. 2019/0142851 "Compositions Comprising a Psilocybin Derivative and a Cannabinoid" (Published May 16, 2019)</li> <li>From [0002]: "This disclosure relates to psilocybin technology, which at the time of this disclosure is primarily concerned with mycology, mushroom cultivation, crude mushroom extracts, natural mushroom preparations, fruitbody extracts, mycelium preparations, and (in a few cases) the isolated compound psilocybin "</li> </ul>
<ul> <li>From claim 1: "A composition, comprising: a first purified psilocybin derivative; and a first purified cannabinoid."</li> <li>From [0023]: "Disclosed herein are new compositions comprising a first purified psilocybin derivative and a serotonergic drug. In one embodiment, the compositions disclosed herein comprise a first purified psilocybin derivative and a serotonergic drug present in purposefully engineered and unnaturally occurring molar ratios."</li> <li>From [0310]: "Some exemplary serotonergic drugs include the following molecules: 4-hydroxy-N-methyltryptamine (aka 3[2-(methylamino)ethyl]-1H-indol-4-ol), aeruginascin (aka [3-[2-(trimethylazaniumyl)ethyl]-1H-indol-4-yl] hydrogen phosphate), baeocystin (aka [3-[2-(trimethylazaniumypethyl]-1H-indol-5-olate), bufotenin (aka 3-[2-(dimethylamino)ethyl]-1H-indol-5-ol), ethocybin (aka [3-[2-(dimethylamino)ethyl]-1H-indol-4-yl] dihydrogen phosphate), norbaeocystin (aka [3-(2-aminoethyl)-1H-indol-4-yl] dihydrogen</li> </ul>

(dimethylamino)ethyl]-1H-indol-4-yl] dihydrogen phosphate),etc"
From [0022]: "In one embodiment, the methods disclosed herein comprise administering the compositions disclosed herein. In one embodiment, the methods disclosed herein comprise treating a psychological disorder, e.g., an anxiety disorder, a compulsive disorder, a depressive disorder, etc., with the compositions disclosed herein, e.g., a composition with one or more psilocybin derivatives, a composition with one or more cannabinoids, a composition with one or more terpenes, and/or a combination thereof. In one embodiment, the methods disclosed herein comprise treating a psychological disorder, e.g., an anxiety disorder, a compulsive disorder, a depressive disorder, etc., with the compositions disclosed herein and a neurotransmitter activity modulator, e.g., a serotonergic drug, a dopaminergic drug, etc"
2. LENZ (2017) "Identification of ω-N-Methyl-4- hydroxytryptamine (Norpsilocin) as a Psilocybe Natural Product" Journal of Natural Products. 80:10(2835-2838)
From abstract: "We report the identification of ω-N-methyl-4- hydroxytryptamine (norpsilocin, 1) from the carpophores of the hallucinogenic mushroom Psilocybe cubensis."
<ul> <li>3. JULSON, "16 Foods That Are High in Niacin (Vitamin B3)"</li> <li>October 5, 2018; retrieved from WaybackMachine Internet Archive, Healthline.</li> <li>https://web.archive.org/web/20190507113644/https://www.healt hline.com/nutrition/foods-high-in-niacin, retrieved May 07, 2019</li> </ul>
From webpage: "Mushrooms are one of the best vegetable sources of niacin, providing 2.5 mg per cup (70 grams) — that's 15% and 18% of the RDA for men and women, respectively (40)."
4. U.S. Pat. App. Pub. No. 2017/0035820 "Integrative Fungal Solutions For Protecting Bees And Overcoming Colony Collapse Disorder (CCD)" (Published February 09, 2017)
From [0292]: "Psilocybin and psilocybin-producing fungi, including but not limited to species of Psilocybe, Panaeolus,

	Gymnopilus, Pluteus and Conocybe such as Psilocybe azurescens, Psilocybe cyanescens, Psilocybe allenii, Psilocybe cyanofibrillosa, Psilocybe cubensis, Psilocybe allenii, Psilocybe subaeruginosa, Copelandia Panaeoli (Copelandia cyanescens, Copelandia tropicalis, Copelandia bispora), Pluteus salicinus, Gymnopilus luteofolius, Gymnopilus spectabilis, Conocybe cyanopus and Conocybe smithii <b>can trigger</b> <b>neurogenesis</b> . (See Catlow et al., Effects of psilocybin on hippocampal neurogenesis and extinction of trace fear conditioning, Exp Brain Res (2013) 228:481-491 DOI 10.1007/s00221-013-3579-0). Individually or in combination, mixtures of extracts of psilocybin mushroom and Hericium mushroom fruitbodies, or more preferably their mycelial extracts, could help repair neurons damaged by toxins, cholinergic pesticides, fungicides, herbicides, glyphosates, oxidation, old age, or other sources of neuro-damaging toxins. The net effect of ingesting these mixtures of nerve regenerating Hericium and <b>psilocybin species would improve the</b> <b>neurological health of bees through neurogenesis and re- myelination, and indeed of animals, including humans.</b> <b>Another, improved form of "smart mycohoney" might</b> <b>incorporate these elements for the benefits of bees and</b> <b>people, improving cognition, preventing or repairing</b> <b>neuropathies presenting themselves as diseases to humans</b> <b>within scope of the definitions for Alzheimer's, Parkison's,</b> <b>Parkisonisms, MS (multiple sclerosis), or as yet</b> <b>uncategorized forms of neurological impairment</b> . Indeed such combinations could increase intelligence, sensory abilities, memory, reflexes, reaction times, and problem solving abilities. Moreover, to the above mixture, vitamins can be added for further enhancement of beneficial properties. The addition of vitamin D—either from UV exposed fungal cells or from external sources, with or without Vitamin B (niacin, nicotinic acid, or related congener), enhance neurogenesis and are <b>preferred ingredients</b> . As such a smart nutraceutical in many forms are p
	mycosyrup' both of which are anticipated to be within the scope of this invention. Such a mycosyrup can be reduced into solid or powdered form added to any food consumed by animals, or by any means known to pharmaceutical science."
4. The method of claim 1, wherein the composition comprises one or more pharmaceutically acceptable excipients.	11. U.S. Pat. App. Pub. No. 2019/0142851 "Compositions Comprising a Psilocybin Derivative and a Cannabinoid" (Published May 16, 2019)

From <b>[0337]</b> : "In one embodiment, the methods and compositions disclosed herein comprise an <b>excipient</b> ."
From [0002]: "This disclosure relates to psilocybin technology, which at the time of this disclosure is primarily concerned with mycology, mushroom cultivation, crude mushroom extracts, natural mushroom preparations, fruitbody extracts, mycelium preparations, and (in a few cases) the isolated compound psilocybin."
From [0306]: "In one embodiment, a serotonergic drug is an antidepressant."
From <b>[0310]</b> : "Some exemplary serotonergic drugs include the following molecules: 4-hydroxy-N-methyltryptamine (aka 3[2-(methylamino)ethyl]-1H-indol-4-ol), aeruginascin (aka [3- [2-(trimethylazaniumyl)ethyl]-1H-indol-4-yl] hydrogen phosphate), baeocystin (aka [3-[2-(methylamino)ethyl]-1H- indol-4-yl] dihydrogen phosphate), bufotenidine (aka 3-[2- (trimethylazaniumypethyl]-1H-indol-5-olate), bufotenin (aka 3- [2-(dimethylamino)ethyl]-1H-indol-5-ol), ethocybin (aka [3-[2- (diethylamino)ethyl]-1H-indol-4-yl] dihydrogen phosphate), norbaeocystin (aka [3-(2-aminoethyl)-1H-indol-4-yl] dihydrogen phosphate), <b>norpsilocin</b> , psilocin (aka 3-[2- (dimethylamino)ethyl]-1H-indol-4-ol), psilocybin (aka [3-[2- (dimethylamino)ethyl]-1H-indol-4-yl] dihydrogen phosphate), <b>norpsilocin</b> , psilocin (aka 3-[2- (dimethylamino)ethyl]-1H-indol-4-yl] dihydrogen phosphate),etc"
From [0022]: "In one embodiment, the methods disclosed herein comprise administering the compositions disclosed herein. In one embodiment, the methods disclosed herein comprise treating a psychological disorder, e.g., an anxiety disorder, a compulsive disorder, a depressive disorder, etc., with the compositions disclosed herein, e.g., a composition with one or more psilocybin derivatives, a composition with one or more cannabinoids, a composition with one or more terpenes, and/or a combination thereof. In one embodiment, the methods disclosed herein comprise treating a psychological disorder, e.g., an anxiety disorder, a compulsive disorder, a depressive disorder, etc., with the compositions disclosed herein and a neurotransmitter activity modulator, e.g., a serotonergic drug, a dopaminergic drug, etc"

2 LENIZ (2017) "Identification of a NI Method 4
2. LENZ (2017) Identification of $\omega$ -N-Wethyl-4-
hydroxytryptamine (Norpsilocin) as a Psilocybe Natural
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From webpage: "Mushrooms are one of the best vegetable sources of niacin, providing 2.5 mg per cup (70 grams) — that's 15% and 18% of the RDA for men and women, respectively (40)."
4. U.S. Pat. App. Pub. No. 2017/0035820 "Integrative Fungal Solutions For Protecting Bees And Overcoming Colony Collapse Disorder (CCD)" (Published February 09, 2017)
From [0292]: "Psilocybin and psilocybin-producing fungi, including but not limited to species of Psilocybe, Panaeolus, Gymnopilus, Pluteus and Conocybe such as Psilocybe azurescens, Psilocybe cyanescens, Psilocybe allenii, Psilocybe cyanofibrillosa, Psilocybe cubensis, Psilocybe ovoideocystidiata, Psilocybe subaeruginosa, Copelandian Panaeoli (Copelandia cyanescens, Copelandia tropicalis, Copelandia bispora), Pluteus salicinus, Gymnopilus luteofolius, Gymnopilus spectabilis, Conocybe cyanopus and Conocybe smithii can trigger neurogenesis. (See Catlow et al., Effects of psilocybin on hippocampal neurogenesis and extinction of trace fear
conditioning, Exp Brain Res (2013) 228:481-491 DOI 10.1007/s00221-013-3579-0). Individually or in combination, mixtures of extracts of psilocybin mushroom and Hericium mushroom fruitbodies, or more preferably their mycelial extracts, could help repair neurons damaged by toxins, cholinergic pesticides, fungicides, herbicides, glyphosates, oxidation, old age, or other sources of neuro-damaging toxins. The net effect of ingesting these mixtures of nerve regenerating
Hericium and psilocybin species would improve the
neurological health of bees through neurogenesis and re-

	myelination, and indeed of animals, including humans.
	Another, improved form of "smart mycohoney" might
	incorporate these elements for the benefits of bees and
	people, improving cognition, preventing or repairing
	neuropathies presenting themselves as diseases to humans
	within scope of the definitions for Alzheimer's, Parkinson's,
	Parkisonisms, MS (multiple sclerosis), or as yet
	uncategorized forms of neurological impairment. Indeed such combinations could increase intelligence, sensory abilities, memory, reflexes, reaction times, and problem solving abilities. Moreover, to the above mixture, vitamins can be added for further enhancement of beneficial properties. The addition of vitamin D—either from UV exposed fungal cells or from external sources, with or without Vitamin B (niacin, nicotinic acid, or related congener), enhance neurogenesis and are preferred ingredients. As such a smart nutraceutical in many forms are possible, including a 'smart mycohoney' or 'smart mycosyrup' both of which are anticipated to be within the scope of this invention. Such a mycosyrup can be reduced into solid or powdered form added to any food consumed by animals, or by any means known to pharmaceutical science."
<b>5</b> . The method of claim 1, wherein the composition is a powder admixture, liquid, suspension, or emulsion.	4. U.S. Pat. App. Pub. No. 2017/0035820 "Integrative Fungal Solutions For Protecting Bees And Overcoming Colony Collapse Disorder (CCD)" (Published February 09, 2017) From <b>[0216]</b> : "Example 17
	Preferred liquid sprays include aqueous solutions, emulsifiable concentrates, emulsions such as oil-in-water and water-in-oil emulsions, dispersions, suspoemulsions, microemulsions, water-dispersible granules, wettable powders, microcapsules, etc. Wettable powders are formulations that are typically uniformly dispersible in water and also contain surface active agents (surfactants) such as wetting agents, emulsifiers and dispersing agents. Emulsifiable concentrates are prepared with organic solvents and/or one or more emulsifiers. Sticking agents such as oils, gelatin, gums, tackifiers and adhesives may be used to improve the adhesion of the spray. Humectants may also be used to decrease the rate of evaporation, including for example glycols having from 3 to 10 carbon atoms and glycerin and solutes such as salts or sugars in water."
	From [0209]: "A liquid extract of the mycelium, or a precipitate from such extract, or a concentrated extract from which all or part of the solvent has been removed, containing

these active principles can be added to the honey, to honeyenriched water, to sugar water or bee candy, to pollen, to pollen substitutes, or to other substances in other manners obvious to those skilled in the art of apiary science or commercial practices. The extract can be used as an adjunct to other remedies making them more effective. The extracts can be in liquid, frozen, freeze dried, air dried, vacuum desiccated, refractance window dehydrated, sonically dehydrated, or partially purified forms, in amounts sufficient to have the effect of attracting bees and/or benefiting bee health, honey production and pollinations. Moreover, these derivative forms of extracts will be useful for human consumption as they are palatable, high in antioxidants, and in other properties beneficial to people and other animals, including bees."

From [0292]: "Psilocybin and psilocybin-producing fungi, including but not limited to species of Psilocybe, Panaeolus, Gymnopilus, Pluteus and Conocybe such as Psilocybe azurescens, Psilocybe cyanescens, Psilocybe allenii, Psilocybe cyanofibrillosa, Psilocybe cubensis, Psilocybe ovoideocystidiata, Psilocybe subaeruginosa, Copelandian Panaeoli (Copelandia cyanescens, Copelandia tropicalis, Copelandia bispora), Pluteus salicinus, Gymnopilus luteofolius, Gymnopilus spectabilis, Conocybe cyanopus and Conocybe smithii can trigger neurogenesis. (See Catlow et al., Effects of psilocybin on hippocampal neurogenesis and extinction of trace fear conditioning, Exp Brain Res (2013) 228:481-491 DOI 10.1007/s00221-013-3579-0). Individually or in combination, mixtures of extracts of psilocybin mushroom and Hericium mushroom fruitbodies, or more preferably their mycelial extracts, could help repair neurons damaged by toxins, cholinergic pesticides, fungicides, herbicides, glyphosates, oxidation, old age, or other sources of neuro-damaging toxins. The net effect of ingesting these mixtures of nerve regenerating Hericium and psilocybin species would improve the neurological health of bees through neurogenesis and re-myelination, and indeed of animals, including humans. Another, improved form of "smart mycohoney" might incorporate these elements for the benefits of bees and people, improving cognition, preventing or repairing neuropathies presenting themselves as diseases to humans within scope of the definitions for Alzheimer's, Parkinson's, Parkisonisms, MS (multiple sclerosis), or as yet uncategorized forms of neurological impairment. Indeed such combinations could increase intelligence, sensory abilities, memory, reflexes, reaction times, and problem solving abilities. Moreover, to the above mixture,

	vitamins can be added for further enhancement of beneficial
	properties. The addition of vitamin D—either from UV exposed
	fungal cells or from external sources, with or without Vitamin
	B (niacin, nicotinic acid, or related congener), enhance
	neurogenesis and are preferred ingredients. As such a smart
	nutraceutical in many forms are possible including a 'smart
	mycohoney' or 'smart mycosyrun' both of which are anticipated
	to be within the scope of this invention. Such a mycosyrup can
	be reduced into solid or powdered form added to any food
	consumed by animals, or by any means known to
	nharmaceutical science "
	From [0150]: "Additional pharmaceutical excipients useful for the compositions as described herein include, for example, the following:
	the following: Carbon dioxide sorbents (barium hydroxide
	lime, soda lime); Stiffening agents (hydrogenated castor oil,
	cetostearyl alconol, cetyl alconol, cetyl esters wax, hard fat,
	paratitin, polyeutytene excipient, stearyt alconol, enuisitying
	increasing agents (accession agent alginic acid aluminum
	monostearate bentonite purified bentonite magma bentonite
	carbomer, carboxymethylcellulose calcium
	carboyymethylcellulose sodium carboyymethylcellulose sodium
	12 carrageenan microcrystalline and carboxymethylcellulose
	sodium cellulose dextrin gelatin guar gum hydroxyethyl
	cellulose hydroxypronyl cellulose hydroxypronyl
	methylcellulose magnesium aluminum silicate methylcellulose
	netty icentitose, magnesiam arannam sineate, methy icentitose,
	alginate silicon dioxide colloidal silicon dioxide sodium
	alginate, sincon dioxide, conordal sincon dioxide, sourain
<b>6</b> . The method of claim 1.	1. U.S. Pat. App. Pub. No. 2018/0021405 "Nutritional Approach
wherein the serotonin (5-	to the Control of Anemia, Diabetes, and Other Diseases or
hvdroxytryptamine, 5-HT)	Conditions and Prevention of Associated Comorbid States with
receptor disorder	the Use of Ergothioneine" (Published January 25, 2018)
comprises depression.	
anxiety, major depressive	From [0059]: "Any type of mushroom, mushroom part,
disorder, treatment	component, fungi or even used substrate for cultivating
resistant depression,	mushrooms, with ergosterol present may be used. This
persistent depression,	includes all filamentous fungi where ergosterol has been shown
manic depression, bipolar	to be present and includes the use of tissues such as the mycelia.
disorder, depressive	spores or vegetative cells. This includes, but is not limited to, for
psychosis, perinatal	example, Coprinus, Agrocybe, Hypholoma, Hypsizygus,
depression, premenstrual	Pholiota, Pleurotus, Stropharia, Ganoderma, Grifola, Trametes,
dysphoric disorder,	Hericium, Tramella, Psilocybe, Agaricus, including for example
seasonal depressions,	Agaricus bisporus (e.g. white button mushrooms), Phytophthora

situational depression, panic disorder, obsessive compulsive disorder, posttraumatic stress disorder, attention deficit/hyperactivity disorder, substance abuse disorders or combinations thereof. achlya, Flammulina, Melanoleuca, Agrocybe, Morchella, Mastigomycotina, Auricularia, Gymnopilus, Mycena, Boletus, Gyromitra, Pholiota, Calvatia, Kuegneromyces, Phylacteria, Cantharellus, Lactarius, Pleurotus, Clitocybe, Lentinula (Lentinus), Stropharia, Coprinus, Lepiota, Tuber, Tremella, Drosophia, Leucocoprinus, Tricholoma, Dryphila, Marasmius, and Volvariella."

From [0008]: "These and other valuable health benefits of ETenhanced mushrooms are disclosed in U.S. patent application Ser. Nos. 12/887,276 and 12/386,810, titled "Vitamin D2 Enriched Mushrooms and Fungi for Treatment of Oxidative Stress, Alzheimer's Disease and Associated Disease States," and "Methods and Compositions for Improving the Nutritional Content of Mushrooms and Fungi," respectively, which are herein incorporated by reference in its entirety. Mushrooms are a valuable health food—low in calories, high in vegetable proteins, chitin, iron, zinc, fiber, essential amino acids, vitamins and minerals. They are also an excellent source of organic selenium compounds, riboflavin, pantothenic acid, copper, **niacin**, potassium and phosphorous. Selenium is needed for the proper function of the antioxidant system, which works to reduce the levels of damaging free radicals in the body. Selenium is a necessary cofactor of one of the body's most important internally produced antioxidants, glutathione peroxidase, and also works with vitamin E in numerous vital antioxidant systems throughout the body. Mushrooms are also a primary source of natural Vitamin D, in the form of D2, which is naturally present in very few foods. Most other natural food sources of Vitamin D, in the form Vitamin D3, are of animal, poultry or seafood origin."

From [0051]: "The term "treating" or "treatment" as used herein, refers to any indicia of success in the prevention or amelioration of an injury, pathology or condition, including any objective or subjective parameter such as abatement; remission; diminishing of symptoms or making the injury, pathology, or condition more tolerable to the patient; slowing in the rate of degeneration or decline; making the final point of degeneration less debilitating; or improving a subject's physical or mental well-being. The treatment or amelioration of symptoms can be based on objective or subjective parameters; including the results of a physical examination, neurological examination, and/or psychiatric evaluations." From [0118]: "Applicants demonstrated that the combination of antioxidants, including phytonutrient turmeric and Ergothioneine, along with Vitamin D enriched mushrooms increase longevity in Drosophila kept under nutritionally deficient diet. These results represent a novel use of the compositions of the invention for treating a variety of disease states associated with inflammation and oxidative stress. According to the invention, Applicants have shown that the compositions increase survival and decrease biologic death in conditions associated with oxidative stress, which include disease states such as Alzheimer's disease and other associated diseases including those involving chronic markers of inflammation, such as chronic depression, traumatic brain injury and PTSD. Thus the supplements, food compositions and pharmaceutical compositions according to the invention, employing the Vitamin D enriched mushrooms, turmeric and Ergothioneine have surprising benefits for treatment of such disease states."

5. WILCOX (2014) "Psilocybin and Obsessive Compulsive Disorder" Journal of Psychoactive Drugs. 46:5(393-395)

From **page 394**: "...In desperation, he looked for herbal remedies and found no relief until a friend gave him "magic mushrooms" he had grown at home from a spore sample, labeled as "psilocybin cubensis." The patient reported that he consumed three of these mushrooms in his apartment with a friend watching over him. The subject found the immediate experience of mushrooms to be unpleasant and anxietyprovoking; however, the next day, his intrusive thoughts were significantly reduced. The subject denied actual hallucinations or strong psychedelic effects, but did report a feel of disassociation for four hours post-ingestion. He related that the next day his intrusive thoughts were significantly reduced. Several months later, when he appeared for an appointment at the clinic, the patient reported that he had found ongoing relief from his anxiety, intrusive thoughts, and rituals. This individual reported that each time he ingested approximately two grams of psilocybin mushrooms, he experienced about three weeks of relief from his intrusive thoughts and anxiety. The patient said that he did this about every three weeks to keep symptoms away...etc"

6. DRUGS.COM, "lovie Taken for 1 to 6 months July 12,
2018" July 12. 2018: retrieved from Drugs.com comment.
https://www.drugs.com/comments/niacin/for-depression.html.
retrieved July 12, 2018
From webpage: "lovie Taken for 1 to 6 months. July 12,
2018
"I can't recommend this vitamin enough! For the last couple of years my mind was plagued with lots of intrusive thoughts (OCD). It started with one thing and from then the cycle went on and on and on. Each time I got very anxious and later on even to the point that I got more and more depressed. My doctor recommended to take an SSRI, but somehow I didn't like that. So I've looked up for natural supplements and finally read more about Niacin. So I've ordered it online and it works! I'm so happy!! I also sleep way much better than since a long time and the intrusive thoughts have been reduced. Sometimes they are there, but that constant feeling of sadness and regret is gone! Everyone who has mental health issues should try this! I've started with 100 gram (I've been using Solgar's Niacin) and I've been upgrading the dosage each time (currently I take
500 on a daily basis).""
· ,
7. J, "My Cognition Improves Tremendously: Mushrooms & Amphetamines (Adderall XR)" August 11, 2018; retrieved from Erowid. https://erowid.org/experiences/exp.php?ID=111984, retrieved August 11, 2018
From <b>website</b> : "Boring Story, Psilocybin mushroom/Adderall XR
My friend and I split a <b>1/8 of Psilocybin mushrooms</b> , not knowing that it wasn't enough to get us high. After a couple hours, I went home, feeling completely sober. I was about to go to bed when I experienced a pleasant sensation of profound WAKEFULNESS. I cleaned my room, which was in a terrible state, and I experienced for the first time in recent memory being 'done' with a task 'before I knew it.' My room became orderly - as if an intelligence and benign presence had manifested there.
This may not seem to be a big deal to many but I have the
Inattentive subtype of ADHD and was diagnosed with Major
<b>Depressive Disorder four years ago.</b> This means that for the
most part, I experience life as kind of a half-person, slow to

complete tasks and difficult to motivate. <b>On even a sub-optimal</b> <b>dose of mushrooms, however, my cognition improves</b> <b>tremendously.</b> I really love who I am on Mushrooms. I really love who I am on Mushrooms. I feel like I'm the person I was 'meant' to be - positive, sharp and solution-oriented."
8. SAUL, "Treating ADHD with Vitamin B-3 (Niacinamide)" October 30, 2013; retrieved from Orthomolecular.org. http://orthomolecular.org/resources/omns/v09n23.shtml, retrieved on October 30, 2013
From <b>website</b> : "FOR IMMEDIATE RELEASE Orthomolecular Medicine News Service, October 30, 2013
<b>Treating ADHD with Vitamin B-3 (Niacinamide)</b> by Andrew W. Saul, Editor
(OMNS Oct 30, 2013) ADHD is not caused by a drug deficiency. But it may indeed be caused by profound nutrient deficiency, more accurately termed nutrient dependency. Although all nutrients are important, the one that an ADHD child is most likely in greatest need of is vitamin B-3, niacinamide.
Over 60 years ago, niacinamide therapy pioneer William Kaufman, M.D., Ph.D, wrote:
"Some patients have a response to niacinamide therapy which seems to be the clinical equivalent of 'decreased running' observed in experimental animals. When these animals are deprived experimentally of certain essential nutriments, they display 'excessive running,' or hyperkinesis. When these deficient animals receive the essential nutriments in sufficient amounts for a sufficient period of time, there is exhibited a marked 'decrease in running.""
9. GARCIA-ROMEU (2015) "Psilocybin-occasioned Mystical Experiences in the Treatment of Tobacco Addiction" Current Drug Abuse Reviews. 7:3(157-164)
From <b>abstract</b> : "Psilocybin-occasioned mystical experiences have been linked to persisting effects in healthy volunteers including positive changes in behavior, attitudes, and values, and increases in the personality domain of openness. <b>In an open-</b>

label pilot-study of psilocybin-facilitated smoking addiction treatment, 15 smokers received 2 or 3 doses of psilocybin in the context of cognitive behavioral therapy (CBT) for smoking cessation. Twelve of 15 participants (80%) demonstrated biologically verified smoking abstinence at 6month follow-up. Participants who were abstinent at 6 months (n=12) were compared to participants still smoking at 6 months (n=3) on measures of subjective effects of psilocybin. Abstainers scored significantly higher on a measure of psilocybin-occasioned mystical experience. No significant differences in general intensity of drug effects were found between groups, suggesting that mystical-type subjective effects, rather than overall intensity of drug effects, were responsible for smoking cessation. Nine of 15 participants (60%) met criteria for "complete" mystical experience. Smoking cessation outcomes were significantly correlated with measures of mystical experience on session days, as well as retrospective ratings of personal meaning and spiritual significance of psilocybin sessions. These results suggest a mediating role of mystical experience in psychedelic-facilitated addiction treatment." 12. LAKE, "Some Vitamins and Minerals May Reduce Alcohol Toxicity: Promising findings for certain B vitamins, vitamin C, magnesium and zinc." January 29, 2019; retrieved from Psychology Today. https://www.psychologytoday.com/us/blog/integrative-mentalhealth-care/201901/some-vitamins-and-minerals-may-reducealcohol-toxicity, retrieved January 29, 2019 From webpage: "Some B-vitamins and Vitamin C may decrease craving, increase alcohol clearance from the blood, and reduce the severity of hangovers Animal studies suggest that low serum thiamin levels are associated with increased alcohol craving (Zimatkin 1996). There is evidence that the B vitamin niacin in the form of nicotinamide dosed at 1.25 grams taken with a meal before drinking may protect the liver against the acute toxic effects of alcohol in individuals who have relapsed or are unable to

abstain (Volpi 1997). Niacin in the form of nicotinic acid may reduce the risk of developing alcohol dependence by interfering with the synthesis of a morphine-like substance that is formed when acetaldehyde—a metabolite of alcohol condenses with dopamine (Davis 1970)."

Electronic Acknowledgement Receipt			
EFS ID:	48390002		
Application Number:	18115966		
International Application Number:			
Confirmation Number:	9636		
Title of Invention:	TRYPTAMINE COMPOSITIONS FOR ENHANCING NEURITE OUTGROWTH		
First Named Inventor/Applicant Name:	Paul Edward STAMETS		
Customer Number:	23409		
Filer:	Sisi Li		
Filer Authorized By:			
Attorney Docket Number:	888690-9002-US19		
Receipt Date:	03-AUG-2023		
Filing Date:	01-MAR-2023		
Time Stamp:	12:55:24		
Application Type:			

# Payment information:

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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:	48390046			
Application Number:	18115966			
International Application Number:				
Confirmation Number:	9636			
Title of Invention:	TRYPTAMINE COMPOSITIONS FOR ENHANCING NEURITE OUTGROWTH			
First Named Inventor/Applicant Name:	Paul Edward STAMETS			
Customer Number:	23409			
Filer:	Sisi Li			
Filer Authorized By:				
Attorney Docket Number:	888690-9002-US19			
Receipt Date:	03-AUG-2023			
Filing Date:	01-MAR-2023			
Time Stamp:	12:58:36			
Application Type:				

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Submitted wi	th Payment		no			
File Listing:						
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2	Third-Party Submission Under 37 CFR 1.290	Third-party-preissuance- submission.pdf	53236 676055cd54c7296304598521a626fddec35 2daea	no	2
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