

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of: STAMETS; Paul E.

Confirmation No.:

Serial No.: 17/738,925

Group No.:

Filing or 371(c) Date: May 6, 2022

Examiner:

Entitled: FUNGAL COMPOUND COMPOSITIONS AND METHODS FOR MODULATING
INFLAMMATION

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. Priority Document of Int'l Pat. App. Pub. No. WO/2021/101926 "TRYPTAMINE COMPOSITIONS FOR ENHANCING NEURITE OUTGROWTH" (Priority date 9 April 2020)
2. NUZZO (2021) "Post-Acute COVID-19 Neurological Syndrome: A New Medical Challenge" *Journal of Clinical Medicine*. Vol 10(9):1947.
3. SZABO (2014) "Psychedelic N,N-Dimethyltryptamine and 5-Methoxy-N,N-Dimethyltryptamine Modulate Innate and Adaptive Inflammatory Responses through the Sigma-1 Receptor of Human Monocyte-Derived Dendritic Cells" *PLOS One*. Vol 9(8):1-8.
4. SHEU (2013) "Immunomodulatory effects of polysaccharides isolated from *Hericium erinaceus* on dendritic cells" *Process Biochemistry*. Vol 48(9):1402-1408.
5. DILING (2017) "Extracts from *Hericium erinaceus* relieve inflammatory bowel disease by regulating immunity and gut microbiota" *Oncotarget*. Vol 8:85838-85857.
6. Int'l Pat. App. Pub. No. WO/2020/212948 "METHODS OF TREATING NEUROCOGNITIVE DISORDERS, CHRONIC PAIN AND REDUCING INFLAMMATION" (Published 22 October 2020)
7. ASKIM (2016) "Epidemiology and outcome of sepsis in adult patients with *Streptococcus pneumoniae* infection in a Norwegian county 1993–2011: an observational study" *BMC Infectious Diseases*. Vol. 6(223):1-9.

8. ATARASHI (2017) “Ectopic colonization of oral bacteria in the intestine drives TH1 cell induction and inflammation” *Science*. Vol.358(6361):359-365.
9. ICEERS (2020) “Ayahuasca: Basic Info” Retrieved from 6 August 2020. URL: <https://web.archive.org/web/20200806102318/https://www.iceers.org/ayahuasca-basic-info/>
10. GOULART DA SILVA (2021) “Anti-inflammatory activity of ayahuasca: therapeutical implications in neurological and psychiatric diseases” *Behavioural Brain Research*. Vol.400:1-8.
11. CHEN (2021) “Cytokine Storm: The Primary Determinant for the Pathophysiological Evolution of COVID-19 Deterioration” *Frontiers in Immunology*. Vol.12:1-11.

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. 17/738,925 Pending Claims	References																					
<p>1. A composition comprising: one or more tryptamines, salts thereof, or combinations thereof; extracts or isolates from <i>Hericium erinaceus</i> mushroom species, erinacines, hericenones, or combinations thereof; and one or more monoamine oxidase inhibitors.</p>	<p>1. Priority Document of Int'l Pat. App. Pub. No. WO/2021/101926 "TRYPTAMINE COMPOSITIONS FOR ENHANCING NEURITE OUTGROWTH" (Priority date 9 April 2020)</p> <p>From page 26</p> <p>Table 1. Exemplary neurotropic or nootropic compositions</p> <table border="1"> <thead> <tr> <th>Component</th> <th>Example</th> <th>Dosage</th> </tr> </thead> <tbody> <tr> <td>Tryptamine neurotrophics, tryptamine derivatives, esters, or salts thereof, or extracts from fungi or plants; In addition to or alternatively, phenethylamines, amphetamines; derivatives thereof, extracts from fungi or plants</td> <td>Psilocybin, baeocystin, norbaeocystin, psilocin norpsilocin, 4-hydroxytryptamine, <i>N,N</i>-dimethyltryptamine, <i>N</i>-methyltryptamine, inter alia; In addition or alternatively, 3,4,5-trimethoxyphenethylamine (Mescaline), 2,4-dimethoxy-amphetamine (2,4-DMA), 3,4-dimethoxy-amphetamine (3,4-DMA), 3,4-methylenedioxy-amphetamine (MDA), 3-methoxy-4,5-methylenedioxy-amphetamine (MMDA), inter alia</td> <td>10 ng to 10 mg</td> </tr> <tr> <td>Optional secondary neurotrophic fungal or plant extracts, or purified compounds thereof</td> <td>Erinacines, hericenones, cannabidiol, cannabichromene, cannabigerol, Δ8-tetrahydrocannabinol, Δ9-tetrahydrocannabinol, cannabinal, tetrahydrocannabivarin, cannabidiol-2',6'-dimethyl ether, inter alia <i>Antrodia, Beauveria, Copelandia, Cordyceps, Fomitopsis, Ganoderma, Grifola, Hericium, Hypsizygos, Inonotus, Isaria, Panaeolus, Phellinus, Phellinus, Piptoporus, Pleurotus, Polyporus</i> or <i>Trametes</i> species or combinations thereof; <i>Bacopa monnien, Centella asiatica, Ginkgo biloba, Zingiber officinale, Ocimum sanctum, Polygonum cuspidatum, Origanum vulgare, Origanum onites, Rosmarinus officinalis, Rosmarinus eriocalyx, Curcuma longa, Camellia sinensis, Psychotria viridis</i>, inter alia</td> <td>10 ng to 500 mg</td> </tr> <tr> <td>Optional neurotropic or nootropic fungal or plant extracts, or other natural products, or purified compounds thereof</td> <td><i>Bacopa monnien, Centella asiatica, Ginkgo biloba, Zingiber officinale, Ocimum sanctum, Polygonum cuspidatum, Origanum vulgare, Origanum onites, Rosmarinus officinalis, Rosmarinus eriocalyx, Curcuma longa, Camellia sinensis, Psychotria viridis</i>, inter alia</td> <td>10 μg to 500 mg</td> </tr> <tr> <td>Optional MAO inhibitor compounds</td> <td>β-carbolines (e.g., harmine, harmine, nor harmine, peroloryne, harmol, cordysin, inter alia)</td> <td>10 ng to 10 mg</td> </tr> <tr> <td>Optional adersive</td> <td>Niacin, capsaicin, ipecac, apomorphine, bittering agents (e.g., denatonium benzoate) inter alia</td> <td>10 μg to 200 mg</td> </tr> <tr> <td>Optional pharmaceutical excipients</td> <td>Fillers, binders, diluents, vehicles, lubricants, preservatives, flavors, colors, etc.</td> <td>quantum sufficit</td> </tr> </tbody> </table>	Component	Example	Dosage	Tryptamine neurotrophics, tryptamine derivatives, esters, or salts thereof, or extracts from fungi or plants; In addition to or alternatively, phenethylamines, amphetamines; derivatives thereof, extracts from fungi or plants	Psilocybin, baeocystin, norbaeocystin, psilocin norpsilocin, 4-hydroxytryptamine, <i>N,N</i> -dimethyltryptamine, <i>N</i> -methyltryptamine, inter alia; In addition or alternatively, 3,4,5-trimethoxyphenethylamine (Mescaline), 2,4-dimethoxy-amphetamine (2,4-DMA), 3,4-dimethoxy-amphetamine (3,4-DMA), 3,4-methylenedioxy-amphetamine (MDA), 3-methoxy-4,5-methylenedioxy-amphetamine (MMDA), inter alia	10 ng to 10 mg	Optional secondary neurotrophic fungal or plant extracts, or purified compounds thereof	Erinacines, hericenones, cannabidiol, cannabichromene, cannabigerol, Δ 8-tetrahydrocannabinol, Δ 9-tetrahydrocannabinol, cannabinal, tetrahydrocannabivarin, cannabidiol-2',6'-dimethyl ether, inter alia <i>Antrodia, Beauveria, Copelandia, Cordyceps, Fomitopsis, Ganoderma, Grifola, Hericium, Hypsizygos, Inonotus, Isaria, Panaeolus, Phellinus, Phellinus, Piptoporus, Pleurotus, Polyporus</i> or <i>Trametes</i> species or combinations thereof; <i>Bacopa monnien, Centella asiatica, Ginkgo biloba, Zingiber officinale, Ocimum sanctum, Polygonum cuspidatum, Origanum vulgare, Origanum onites, Rosmarinus officinalis, Rosmarinus eriocalyx, Curcuma longa, Camellia sinensis, Psychotria viridis</i> , inter alia	10 ng to 500 mg	Optional neurotropic or nootropic fungal or plant extracts, or other natural products, or purified compounds thereof	<i>Bacopa monnien, Centella asiatica, Ginkgo biloba, Zingiber officinale, Ocimum sanctum, Polygonum cuspidatum, Origanum vulgare, Origanum onites, Rosmarinus officinalis, Rosmarinus eriocalyx, Curcuma longa, Camellia sinensis, Psychotria viridis</i> , inter alia	10 μ g to 500 mg	Optional MAO inhibitor compounds	β -carbolines (e.g., harmine, harmine, nor harmine, peroloryne, harmol, cordysin, inter alia)	10 ng to 10 mg	Optional adersive	Niacin, capsaicin, ipecac, apomorphine, bittering agents (e.g., denatonium benzoate) inter alia	10 μ g to 200 mg	Optional pharmaceutical excipients	Fillers, binders, diluents, vehicles, lubricants, preservatives, flavors, colors, etc.	quantum sufficit
Component	Example	Dosage																				
Tryptamine neurotrophics, tryptamine derivatives, esters, or salts thereof, or extracts from fungi or plants; In addition to or alternatively, phenethylamines, amphetamines; derivatives thereof, extracts from fungi or plants	Psilocybin, baeocystin, norbaeocystin, psilocin norpsilocin, 4-hydroxytryptamine, <i>N,N</i> -dimethyltryptamine, <i>N</i> -methyltryptamine, inter alia; In addition or alternatively, 3,4,5-trimethoxyphenethylamine (Mescaline), 2,4-dimethoxy-amphetamine (2,4-DMA), 3,4-dimethoxy-amphetamine (3,4-DMA), 3,4-methylenedioxy-amphetamine (MDA), 3-methoxy-4,5-methylenedioxy-amphetamine (MMDA), inter alia	10 ng to 10 mg																				
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Optional pharmaceutical excipients	Fillers, binders, diluents, vehicles, lubricants, preservatives, flavors, colors, etc.	quantum sufficit																				
<p>2. The composition of claim 1, wherein the one or more tryptamines are psilocybin, psilocin, norpsilocin, baeocystin, norbaeocystin, <i>N,N</i>-dimethyltryptamine (DMT), or combinations thereof.</p>	<p>1. Priority Document of Int'l Pat. App. Pub. No. WO/2021/101926 "TRYPTAMINE COMPOSITIONS FOR ENHANCING NEURITE OUTGROWTH" (Priority date 9 April 2020)</p> <p>From page 26</p>																					

Table 1. Exemplary neurotropic or nootropic compositions		
Component	Example	Dosage
Tryptamine neurotrophics, tryptamine derivatives, esters, or salts thereof, or extracts from fungi or plants; In addition to or alternatively, phenethylamines, amphetamines; derivatives thereof, extracts from fungi or plants	Psilocybin, baeocystin, norbaeocystin, psilocin norpsilocin, 4-hydroxytryptamine, <i>N,N</i> -dimethyltryptamine, <i>N</i> -methyltryptamine inter alia; In addition or alternatively, 3,4,5-trimethoxyphenethylamine (Mescaline), 2,4-dimethoxy-amphetamine (2,4-DMA), 3,4-dimethoxy-amphetamine (3,4-DMA), 3,4-methylenedioxy-amphetamine (MDA), 3-methoxy-4,5-methylenedioxy-amphetamine (MMDA), inter alia	10 ng to 10 mg
Optional secondary neurotrophic fungal or plant extracts, or purified compounds thereof	Erinacines, hericenones, cannabidiol, cannabichromene, cannabigerol, Δ 8-tetrahydrocannabinol, Δ 9-tetrahydrocannabinol, cannabinol, tetrahydrocannabivarin, cannabidiol-2',6'-dimethyl ether, inter alia <i>Antrodia</i> , <i>Beauveria</i> , <i>Copelandia</i> , <i>Cordyceps</i> , <i>Fomitopsis</i> , <i>Ganoderma</i> , <i>Grifola</i> , <i>Hericium</i> , <i>Hypsizygos</i> , <i>Inonotus</i> , <i>Isaria</i> , <i>Panaeolus</i> , <i>Phellinus</i> , <i>Phellinus</i> , <i>Piptoporus</i> , <i>Pleurotus</i> , <i>Polyporus</i> or <i>Trametes</i> species or combinations thereof; <i>Bacopa monnien</i> , <i>Centella asiatica</i> , <i>Gingko biloba</i> , <i>Zingiber officinale</i> , <i>Ocimum sanctum</i> , <i>Polygonum cuspidatum</i> , <i>Origanum vulgare</i> , <i>Origanum onites</i> , <i>Rosmarinus officinalis</i> , <i>Rosmarinus ericalyx</i> , <i>Curcuma longa</i> , <i>Camellia sinensis</i> , <i>Psychotria viridis</i> , inter alia	10 ng to 500 mg
Optional neurotropic or nootropic fungal or plant extracts, or other natural products, or purified compounds thereof	<i>Bacopa monnien</i> , <i>Centella asiatica</i> , <i>Gingko biloba</i> , <i>Zingiber officinale</i> , <i>Ocimum sanctum</i> , <i>Polygonum cuspidatum</i> , <i>Origanum vulgare</i> , <i>Origanum onites</i> , <i>Rosmarinus officinalis</i> , <i>Rosmarinus ericalyx</i> , <i>Curcuma longa</i> , <i>Camellia sinensis</i> , <i>Psychotria viridis</i> , inter alia	10 μ g to 500 mg
Optional MAO inhibitor compounds	β -carbolines (e.g., harmane, harmine, norharmine, perlolyrine, harmol, cordysin, inter alia)	10 ng to 10 mg
Optional adersive	Niacin, capsaicin, ipecac, apomorphine, bittering agents (e.g., denatonium benzoate) inter alia	10 μ g to 200 mg
Optional pharmaceutical excipients	Fillers, binders, diluents, vehicles, lubricants, preservatives, flavors, colors, etc.	quantum sufficit

<p>3. The composition of claim 1, wherein the composition comprises about 1 ng to about 10 mg, about 10 mg to about 100 mg, about 10 mg to about 20 mg, about 20 mg to about 50 mg, about 20 mg to about 100 mg, about 1 ng to about 20 mg, about 1 ng to about 50 mg, or about 1 ng to about 100 mg of the one or more tryptamines, salts thereof, or combinations thereof.</p>	<p>1. Priority Document of Int'l Pat. App. Pub. No. WO/2021/101926 "TRYPTAMINE COMPOSITIONS FOR ENHANCING NEURITE OUTGROWTH" (Priority date 9 April 2020)</p> <p>From page 26</p>
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Table 1. Exemplary neurotropic or nootropic compositions		
Component	Example	Dosage
Tryptamine neurotropics, tryptamine derivatives, esters, or salts thereof, or extracts from fungi or plants; In addition to or alternatively, phenethylamines, amphetamines; derivatives thereof, extracts from fungi or plants	Psilocybin, baecocystin, norbaecocystin, psilocin norpsilocin, 4-hydroxytryptamine, <i>N,N</i> -dimethyltryptamine, <i>N</i> -methyltryptamine, inter alia; In addition or alternatively, 3,4,5-trimethoxyphenethylamine (Mescaline), 2,4-dimethoxy-amphetamine (2,4-DMA), 3,4-dimethoxy-amphetamine (3,4-DMA), 3,4-methylenedioxy-amphetamine (MDA), 3-methoxy-4,5-methylenedioxy-amphetamine (MMDA), inter alia	10 ng to 10 mg
Optional secondary neurotrophic fungal or plant extracts, or purified compounds thereof	Erinacines, hericenones, cannabidiol, cannabichromene, cannabigerol, Δ 8-tetrahydrocannabinol, Δ 9-tetrahydrocannabinol, cannabinol, tetrahydrocannabivarin, cannabidiol-2',6'-dimethyl ether, inter alia <i>Antrodia</i> , <i>Beauveria</i> , <i>Copelandia</i> , <i>Cordyceps</i> , <i>Fomitopsis</i> , <i>Ganoderma</i> , <i>Grifola</i> , <i>Hericium</i> , <i>Hypsizygus</i> , <i>Inonotus</i> , <i>Isaria</i> , <i>Panaeolus</i> , <i>Phellinus</i> , <i>Phellinus</i> , <i>Piptoporus</i> , <i>Pleurotus</i> , <i>Polyporus</i> or <i>Trametes</i> species or combinations thereof; <i>Bacopa monnien</i> , <i>Centella asiatica</i> , <i>Gingko biloba</i> , <i>Zingiber officinale</i> , <i>Ocimum sanctum</i> , <i>Polygonum cuspidatum</i> , <i>Origanum vulgare</i> , <i>Origanum onites</i> , <i>Rosmarinus officinalis</i> , <i>Rosmarinus eriocalyx</i> , <i>Curcuma longa</i> , <i>Camellia sinensis</i> , <i>Psychotria viridis</i> , inter alia	10 ng to 500 mg
Optional neurotropic or nootropic fungal or plant extracts, or other natural products, or purified compounds thereof	<i>Bacopa monnien</i> , <i>Centella asiatica</i> , <i>Gingko biloba</i> , <i>Zingiber officinale</i> , <i>Ocimum sanctum</i> , <i>Polygonum cuspidatum</i> , <i>Origanum vulgare</i> , <i>Origanum onites</i> , <i>Rosmarinus officinalis</i> , <i>Rosmarinus eriocalyx</i> , <i>Curcuma longa</i> , <i>Camellia sinensis</i> , <i>Psychotria viridis</i> , inter alia	10 μ g to 500 mg
Optional MAO inhibitor compounds	β -carbolines (e.g., harmane, harmine, norharmine, perlolyrine, harmol, cordysin, inter alia)	10 ng to 10 mg
Optional adersive	Niacin, capsaicin, ipecac, apomorphine, bittering agents (e.g., denatonium benzoate) inter alia	10 μ g to 200 mg
Optional pharmaceutical excipients	Fillers, binders, diluents, vehicles, lubricants, preservatives, flavors, colors, etc.	quantum sufficit

<p>4. The composition of claim 21, wherein the composition comprises about 1 ng to about 2000 mg of the extracts or isolates from <i>Hericium erinaceus</i> mushroom species, erinacines, hericenones, or combinations thereof.</p>	<p>1. Priority Document of Int'l Pat. App. Pub. No. WO/2021/101926 "TRYPTAMINE COMPOSITIONS FOR ENHANCING NEURITE OUTGROWTH" (Priority date 9 April 2020)</p> <p>From page 26</p>
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Component	Example	Dosage
Tryptamine neurotrophics, tryptamine derivatives, esters, or salts thereof, or extracts from fungi or plants; In addition to or alternatively, phenethylamines, amphetamines; derivatives thereof, extracts from fungi or plants	Psilocybin, baeocystin, norbaeocystin, psilocin norpsilocin, 4-hydroxytryptamine, <i>N,N</i> -dimethyltryptamine, <i>N</i> -methyltryptamine, inter alia; In addition or alternatively, 3,4,5-trimethoxyphenethylamine (Mescaline), 2,4-dimethoxy-amphetamine (2,4-DMA), 3,4-dimethoxy-amphetamine (3,4-DMA), 3,4-methylenedioxy-amphetamine (MDA), 3-methoxy-4,5-methylenedioxy-amphetamine (MMDA), inter alia	10 ng to 10 mg
Optional secondary neurotrophic fungal or plant extracts, or purified compounds thereof	Erinacines, hericenones, cannabidiol, cannabichromene, cannabigerol, Δ 8-tetrahydrocannabinol, Δ 9-tetrahydrocannabinol, cannabinol, tetrahydrocannabivarin, cannabidiol-2',6'-dimethyl ether, inter alia <i>Antrodia, Beauveria, Copelandia, Cordyceps, Fomitopsis, Ganoderma, Grifola, Hericium, Hypsizygos, Inonotus, Isaria, Panaeolus, Phellinus, Phellinus, Piptoporus, Pleurotus, Polyporus</i> or <i>Trametes</i> species or combinations thereof; <i>Bacopa monnien, Centella asiatica, Ginkgo biloba, Zingiber officinale, Ocimum sanctum, Polygonum cuspidatum, Origanum vulgare, Origanum onites, Rosmarinus officinalis, Rosmarinus eriocalyx, Curcuma longa, Camellia sinensis, Psychotria viridis</i> , inter alia	10 ng to 500 mg
Optional neurotropic or nootropic fungal or plant extracts, or other natural products, or purified compounds thereof	<i>Niacin, capsaicin, ipecac, apomorphine,</i> bittering agents (e.g., denatonium benzoate) inter alia	10 μ g to 500 mg
Optional MAO inhibitor compounds	β -carbolines (e.g., harmane, harmine, nor harmine, perlolyrine, harmol, cordysin, inter alia)	10 ng to 10 mg
Optional adersive	Niacin, capsaicin, ipecac, apomorphine, bittering agents (e.g., denatonium benzoate) inter alia	10 μ g to 200 mg
Optional pharmaceutical excipients	Fillers, binders, diluents, vehicles, lubricants, preservatives, flavors, colors, etc.	quantum sufficiet
5. (canceled)		
6. The composition of claim 1, wherein the composition comprises about 70 mg to about 200 mg of the one or more monoamine oxidase inhibitors	1. Priority Document of Int'l Pat. App. Pub. No. WO/2021/101926 "TRYPTAMINE COMPOSITIONS FOR ENHANCING NEURITE OUTGROWTH" (Priority date 9 April 2020) From page 26	

Table 1. Exemplary neurotropic or nootropic compositions

Component	Example	Dosage
Tryptamine neurotrophics, tryptamine derivatives, esters, or salts thereof, or extracts from fungi or plants; In addition to or alternatively, phenethylamines, amphetamines; derivatives thereof, extracts from fungi or plants	Psilocybin, baeocystin, norbaeocystin, psilocin norpsilocin, 4-hydroxytryptamine, <i>N,N</i> -dimethyltryptamine, <i>N</i> -methyltryptamine, inter alia; In addition or alternatively, 3,4,5-trimethoxyphenethylamine (Mescaline), 2,4-dimethoxy-amphetamine (2,4-DMA), 3,4-dimethoxy-amphetamine (3,4-DMA), 3,4-methylenedioxy-amphetamine (MDA), 3-methoxy-4,5-methylenedioxy-amphetamine (MMDA), inter alia	10 ng to 10 mg
Optional secondary neurotrophic fungal or plant extracts, or purified compounds thereof	Erinacines, hericenones, cannabidiol, cannabichromene, cannabigerol, Δ 8-tetrahydrocannabinol, Δ 9-tetrahydrocannabinol, cannabinalol, tetrahydrocannabivarin, cannabidiol-2',6'-dimethyl ether, inter alia <i>Antrodia</i> , <i>Beauveria</i> , <i>Copelandia</i> , <i>Cordyceps</i> , <i>Fomitopsis</i> , <i>Ganoderma</i> , <i>Grifola</i> , <i>Hericium</i> , <i>Hypsizygus</i> , <i>Inonotus</i> , <i>Isaria</i> , <i>Panaeolus</i> , <i>Phellinus</i> , <i>Phellinus</i> , <i>Piptoporus</i> , <i>Pleurotus</i> , <i>Polyporus</i> or <i>Trametes</i> species or combinations thereof; <i>Bacopa monnien</i> , <i>Centella asiatica</i> , <i>Gingko biloba</i> , <i>Zingiber officinale</i> , <i>Ocimum sanctum</i> , <i>Polygonum cuspidatum</i> , <i>Origanum vulgare</i> , <i>Origanum onites</i> , <i>Rosmarinus officinalis</i> , <i>Rosmarinus ericalyx</i> , <i>Curcuma longa</i> , <i>Camellia sinensis</i> , <i>Psychotria viridis</i> , inter alia	10 ng to 500 mg
Optional neurotropic or nootropic fungal or plant extracts, or other natural products, or purified compounds thereof	<i>Bacopa monnien</i> , <i>Centella asiatica</i> , <i>Gingko biloba</i> , <i>Zingiber officinale</i> , <i>Ocimum sanctum</i> , <i>Polygonum cuspidatum</i> , <i>Origanum vulgare</i> , <i>Origanum onites</i> , <i>Rosmarinus officinalis</i> , <i>Rosmarinus ericalyx</i> , <i>Curcuma longa</i> , <i>Camellia sinensis</i> , <i>Psychotria viridis</i> , inter alia	10 μ g to 500 mg
Optional MAO inhibitor compounds	β -carbolines (e.g., harmane, harmine, norharmine, perlolyrine, harmol, cordysin, inter alia)	10 ng to 10 mg
Optional adersive	Niacin, capsaicin, ipecac, apomorphine, bittering agents (e.g., denatonium benzoate) inter alia	10 μ g to 200 mg
Optional pharmaceutical excipients	Fillers, binders, diluents, vehicles, lubricants, preservatives, flavors, colors, etc.	quantum sufficit

From page 37 “One or more dosage forms of the compositions described herein can be administered, for example, 1x, 2x, 3x, 4x, 5x, 6x, or even more times per day.”

From paragraph [0041] of the application of interest (17/738,925): “The term “dosage” as used herein refers to the administering of a specific amount, number, and frequency of doses over a specified period of time, typically 1 day.”

7. The composition of claim 61, wherein the one or more monoamine oxidase inhibitors is Norharman, Harmine, 1,2,3,4-tetrahydro- β -carboline-3-carboxylic acid, 1-methyl-1,2,3,4-tetrahydro- β -carboline-3-carboxylic acid, 1-

1. Priority Document of Int’l Pat. App. Pub. No. WO/2021/101926 “TRYPTAMINE COMPOSITIONS FOR ENHANCING NEURITE OUTGROWTH” (Priority date 9 April 2020)

From page 26

<p>methyl-2,3,4,9-tetrahydro-1H-β-carboline-1,3-dicarboxylic acid, Harmaline, N-methoxy-1-vinyl-β-carboline, ethyl 9H-β-arboline-3-carboxylate, 1-furyl-β-carboline-3-carboxylic acid, 1-[5-(methoxymethyl)-2-furyl]-9H-β-carboline-3-carboxylic acid, 6-hydroxy-3-(6-hydroxy-1H-indol-3-yl)-9H-β-carboline-4-carboxylic acid, Strictosidine, (1S)-1-[(2S,3R,4S)-2-(β-L-glucopyranosyloxy)-5-(methoxycarbonyl)-3-vinyl-3,4-dihydro-2H-pyran-4-yl]methyl}-2,3,4,9-tetrahydro-1H-β-carboline-1,3-dicarboxylic acid, or combinations thereof.</p>	<p>Table 1. Exemplary neurotropic or nootropic compositions</p> <table border="1"> <thead> <tr> <th>Component</th> <th>Example</th> <th>Dosage</th> </tr> </thead> <tbody> <tr> <td>Tryptamine neurotrophics, tryptamine derivatives, esters, or salts thereof, or extracts from fungi or plants; In addition to or alternatively, phenethylamines, amphetamines; derivatives thereof, extracts from fungi or plants</td> <td>Psilocybin, baecocystin, norbaecocystin, psilocin norpsilocin, 4-hydroxytryptamine, <i>N,N</i>-dimethyltryptamine, <i>N</i>-methyltryptamine, inter alia; In addition or alternatively, 3,4,5-trimethoxyphenethylamine (Mescaline), 2,4-dimethoxy-amphetamine (2,4-DMA), 3,4-dimethoxy-amphetamine (3,4-DMA), 3,4-methylenedioxy-amphetamine (MDA), 3-methoxy-4,5-methylenedioxy-amphetamine (MMDA), inter alia</td> <td>10 ng to 10 mg</td> </tr> <tr> <td>Optional secondary neurotrophic fungal or plant extracts, or purified compounds thereof</td> <td>Erinacines, hericenones, cannabidiol, cannabichromene, cannabigerol, Δ8-tetrahydrocannabinol, Δ9-tetrahydrocannabinol, cannabinalol, tetrahydrocannabivarin, cannabidiol-2',6'-dimethyl ether, inter alia <i>Antrodia</i>, <i>Beauveria</i>, <i>Copelandia</i>, <i>Cordyceps</i>, <i>Fomitopsis</i>, <i>Ganoderma</i>, <i>Grifola</i>, <i>Hericium</i>, <i>Hypsizygus</i>, <i>Inonotus</i>, <i>Isaria</i>, <i>Panaeolus</i>, <i>Phellinus</i>, <i>Phellinus</i>, <i>Piptoporus</i>, <i>Pleurotus</i>, <i>Polyporus</i> or <i>Trametes</i> species or combinations thereof; <i>Bacopa monnien</i>, <i>Centella asiatica</i>, <i>Gingko biloba</i>, <i>Zingiber officinale</i>, <i>Ocimum sanctum</i>, <i>Polygonum cuspidatum</i>, <i>Origanum vulgare</i>, <i>Origanum onites</i>, <i>Rosmarinus officinalis</i>, <i>Rosmarinus eriocalyx</i>, <i>Curcuma longa</i>, <i>Camellia sinensis</i>, <i>Psychotria viridis</i>, inter alia</td> <td>10 ng to 500 mg</td> </tr> <tr> <td>Optional neurotropic or nootropic fungal or plant extracts, or other natural products, or purified compounds thereof</td> <td>β-carbolines (e.g., harmane, harmine, nor harmine, perfolyrine, harmol, cordysin, inter alia)</td> <td>10 μg to 500 mg</td> </tr> <tr> <td>Optional MAO inhibitor compounds</td> <td>Niacin, capsaicin, ipecac, apomorphine, bittering agents (e.g., denatonium benzoate) inter alia</td> <td>10 ng to 10 mg</td> </tr> <tr> <td>Optional adversive</td> <td>Fillers, binders, diluents, vehicles, lubricants, preservatives, flavors, colors, etc.</td> <td>10 μg to 200 mg</td> </tr> <tr> <td>Optional pharmaceutical excipients</td> <td></td> <td>quantum sufficiet</td> </tr> </tbody> </table>	Component	Example	Dosage	Tryptamine neurotrophics, tryptamine derivatives, esters, or salts thereof, or extracts from fungi or plants; In addition to or alternatively, phenethylamines, amphetamines; derivatives thereof, extracts from fungi or plants	Psilocybin, baecocystin, norbaecocystin, psilocin norpsilocin, 4-hydroxytryptamine, <i>N,N</i> -dimethyltryptamine, <i>N</i> -methyltryptamine, inter alia; In addition or alternatively, 3,4,5-trimethoxyphenethylamine (Mescaline), 2,4-dimethoxy-amphetamine (2,4-DMA), 3,4-dimethoxy-amphetamine (3,4-DMA), 3,4-methylenedioxy-amphetamine (MDA), 3-methoxy-4,5-methylenedioxy-amphetamine (MMDA), inter alia	10 ng to 10 mg	Optional secondary neurotrophic fungal or plant extracts, or purified compounds thereof	Erinacines, hericenones, cannabidiol, cannabichromene, cannabigerol, Δ 8-tetrahydrocannabinol, Δ 9-tetrahydrocannabinol, cannabinalol, tetrahydrocannabivarin, cannabidiol-2',6'-dimethyl ether, inter alia <i>Antrodia</i> , <i>Beauveria</i> , <i>Copelandia</i> , <i>Cordyceps</i> , <i>Fomitopsis</i> , <i>Ganoderma</i> , <i>Grifola</i> , <i>Hericium</i> , <i>Hypsizygus</i> , <i>Inonotus</i> , <i>Isaria</i> , <i>Panaeolus</i> , <i>Phellinus</i> , <i>Phellinus</i> , <i>Piptoporus</i> , <i>Pleurotus</i> , <i>Polyporus</i> or <i>Trametes</i> species or combinations thereof; <i>Bacopa monnien</i> , <i>Centella asiatica</i> , <i>Gingko biloba</i> , <i>Zingiber officinale</i> , <i>Ocimum sanctum</i> , <i>Polygonum cuspidatum</i> , <i>Origanum vulgare</i> , <i>Origanum onites</i> , <i>Rosmarinus officinalis</i> , <i>Rosmarinus eriocalyx</i> , <i>Curcuma longa</i> , <i>Camellia sinensis</i> , <i>Psychotria viridis</i> , inter alia	10 ng to 500 mg	Optional neurotropic or nootropic fungal or plant extracts, or other natural products, or purified compounds thereof	β -carbolines (e.g., harmane, harmine, nor harmine, perfolyrine, harmol, cordysin, inter alia)	10 μ g to 500 mg	Optional MAO inhibitor compounds	Niacin, capsaicin, ipecac, apomorphine, bittering agents (e.g., denatonium benzoate) inter alia	10 ng to 10 mg	Optional adversive	Fillers, binders, diluents, vehicles, lubricants, preservatives, flavors, colors, etc.	10 μ g to 200 mg	Optional pharmaceutical excipients		quantum sufficiet
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12. (canceled)																						
13. (canceled)																						
14. (canceled)																						
15. A method for treating or modulating an inflammatory response triggered by an infectious disease or condition, the method comprising: administering a composition to a subject in need thereof,	<p>1. Priority Document of Int'l Pat. App. Pub. No. WO/2021/101926 "TRYPTAMINE COMPOSITIONS FOR ENHANCING NEURITE OUTGROWTH" (Priority date 9 April 2020)</p> <p>From page 26</p>																					

the composition comprising: one or more tryptamines, salts thereof, or combinations thereof; extracts or isolates from *Hericum erinaceus* mushroom species, erinacines, hericenones, or combinations thereof; and one or more monoamine oxidase inhibitors.

Table 1. Exemplary neurotropic or nootropic compositions

Component	Example	Dosage
Tryptamine neurotrophics, tryptamine derivatives, esters, or salts thereof, or extracts from fungi or plants; In addition to or alternatively, phenethylamines, amphetamines; derivatives thereof, extracts from fungi or plants	Psilocybin, baecocystin, norbaecocystin, psilocin norpsilocin, 4-hydroxytryptamine, <i>N,N</i> -dimethyltryptamine, <i>N</i> -methyltryptamine, inter alia; In addition or alternatively, 3,4,5-trimethoxyphenethylamine (Mescaline), 2,4-dimethoxy-amphetamine (2,4-DMA), 3,4-dimethoxy-amphetamine (3,4-DMA), 3,4-methylenedioxy-amphetamine (MDA), 3-methoxy-4,5-methylenedioxy-amphetamine (MMDA), inter alia	10 ng to 10 mg
Optional secondary neurotrophic fungal or plant extracts, or purified compounds thereof	Erinacines, hericenones, cannabidiol, cannabichromene, cannabigerol, Δ 8-tetrahydrocannabinol, Δ 9-tetrahydrocannabinol, cannabinol, tetrahydrocannabivarin, cannabidiol-2',6'-dimethyl ether, inter alia <i>Antrodia, Beauveria, Copelandia, Cordyceps, Fomitopsis, Ganoderma, Grifola, Hericum, Hypsizyugus, Inonotus, Isaria, Panaeolus, Phellinus, Phellinus, Piptoporus, Pleurotus, Polyporus</i> or <i>Trametes</i> species or combinations thereof; <i>Bacopa monnien, Centella asiatica, Gingko biloba, Zingiber officinale, Ocimum sanctum, Polygonum cuspidatum, Origanum vulgare, Origanum onites, Rosmarinus officinalis, Rosmarinus eriocalyx, Curcuma longa, Camellia sinensis, Psychotria viridis</i> , inter alia	10 ng to 500 mg
Optional neurotropic or nootropic fungal or plant extracts, or other natural products, or purified compounds thereof	<i>Bacopa monnien, Centella asiatica, Gingko biloba, Zingiber officinale, Ocimum sanctum, Polygonum cuspidatum, Origanum vulgare, Origanum onites, Rosmarinus officinalis, Rosmarinus eriocalyx, Curcuma longa, Camellia sinensis, Psychotria viridis</i> , inter alia	10 μ g to 500 mg
Optional MAO inhibitor compounds	β -carbolines (e.g., harmane, harmine, norharmine, perlolyrine, harmol, cordysin, inter alia)	10 ng to 10 mg
Optional adersive	Niacin, capsaicin, ipecac, apomorphine, bittering agents (e.g., denatonium benzoate) inter alia	10 μ g to 200 mg
Optional pharmaceutical excipients	Fillers, binders, diluents, vehicles, lubricants, preservatives, flavors, colors, etc.	quantum sufficiet

From **claim 18** “The composition of claim 1, wherein **the composition is effective to treat, alleviate, prevent or ameliorate...neuronal injuries or physical neurodegeneration** (e.g....neurotoxic viruses...)”

From **page 12** “In an embodiment, to **ameliorating the disease or disorder** (I.e., slowing or arresting or **reducing the development of the disease or at least one of the clinical symptoms thereof**).”

2. NUZZO (2021) “Post-Acute COVID-19 Neurological Syndrome: A New Medical Challenge” Journal of Clinical Medicine. Vol 10(9):1947.

From **abstract** “**Neurological complications after severe COVID-19 infection** might include delirium, **brain inflammation**, stroke, and nerve damage.”

From **page 4** “Furthermore, **high levels of inflammation (cytokine storm) and BBB lesions in the brain** are very likely to have long-term consequences on neurodegeneration.”

16. The method of claim 15, wherein the composition comprises about 1 ng to about 10 mg, about 10 mg to about 100 mg, about 10 mg to about 20 mg, about 20 mg to about 50 mg, about 20 mg to about 100 mg, about 1 ng to about 20 mg, about 1 ng to about 50 mg, or about 1 ng to about 100 mg of the one or more tryptamines, salts thereof, or combinations thereof.

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From page 26

Table 1. Exemplary neurotropic or nootropic compositions

Component	Example	Dosage
Tryptamine neurotropics, tryptamine derivatives, esters, or salts thereof, or extracts from fungi or plants; In addition to or alternatively, phenethylamines, amphetamines; derivatives thereof, extracts from fungi or plants	Psilocybin, baecocystin, norbaecocystin, psilocin norpsilocin, 4-hydroxytryptamine, <i>N,N</i> -dimethyltryptamine, <i>N</i> -methyltryptamine, inter alia; In addition or alternatively, 3,4,5-trimethoxyphenethylamine (Mescaline), 2,4-dimethoxy-amphetamine (2,4-DMA), 3,4-dimethoxy-amphetamine (3,4-DMA), 3,4-methylenedioxy-amphetamine (MDA), 3-methoxy-4,5-methylenedioxy-amphetamine (MMDA), inter alia	10 ng to 10 mg
Optional secondary neurotropic fungal or plant extracts, or purified compounds thereof	Erinacines, hericenones, cannabidiol, cannabichromene, cannabigerol, Δ 8-tetrahydrocannabinol, Δ 9-tetrahydrocannabinol, cannabinalol, tetrahydrocannabivarin, cannabidiol-2',6'-dimethyl ether, inter alia <i>Antrodia</i> , <i>Beauveria</i> , <i>Copelandia</i> , <i>Cordyceps</i> , <i>Fomitopsis</i> , <i>Ganoderma</i> , <i>Grifola</i> , <i>Hericium</i> , <i>Hypsizygus</i> , <i>Inonotus</i> , <i>Isaria</i> , <i>Panaeolus</i> , <i>Phellinus</i> , <i>Phellinus</i> , <i>Piptoporus</i> , <i>Pleurotus</i> , <i>Polyporus</i> or <i>Trametes</i> species or combinations thereof; <i>Bacopa monnien</i> , <i>Centella asiatica</i> , <i>Gingko biloba</i> , <i>Zingiber officinale</i> , <i>Ocimum sanctum</i> , <i>Polygonum cuspidatum</i> , <i>Origanum vulgare</i> , <i>Origanum onites</i> , <i>Rosmarinus officinalis</i> , <i>Rosmarinus eriocalyx</i> , <i>Curcuma longa</i> , <i>Camellia sinensis</i> , <i>Psychotria viridis</i> , inter alia	10 ng to 500 mg
Optional neurotropic or nootropic fungal or plant extracts, or other natural products, or purified compounds thereof	β -carbolines (e.g., harmine, harmine, nor harmine, perlolyrine, harmol, cordysin, inter alia)	10 μ g to 500 mg
Optional MAO inhibitor compounds	Niacin, capsaicin, ipecac, apomorphine, bittering agents (e.g., denatonium benzoate) inter alia	10 ng to 10 mg
Optional adversive	Fillers, binders, diluents, vehicles, lubricants, preservatives, flavors, colors, etc.	10 μ g to 200 mg
Optional pharmaceutical excipients		quantum sufficiet

From claim 18 "The composition of claim 1, wherein the composition is effective to treat, alleviate, prevent or ameliorate...neuronal injuries or physical neurodegeneration (e.g....neurotoxic viruses...)"

From page 12 "In an embodiment, to ameliorating the disease or disorder (I.e., slowing or arresting or reducing the development of the disease or at least one of the clinical symptoms thereof)."

2. NUZZO (2021) "Post-Acute COVID-19 Neurological Syndrome: A New Medical Challenge" Journal of Clinical Medicine. Vol 10(9):1947.

From abstract "Neurological complications after severe COVID-19 infection might include delirium, brain inflammation, stroke, and nerve damage."

From **page 4** “Furthermore, **high levels of inflammation (cytokine storm) and BBB lesions in the brain are very likely to have long-term consequences on neurodegeneration.**”

17. The method of claim 15, wherein the one or more tryptamines are psilocybin, psilocin, norpsilocin, baeocystin, norbaeocystin, N,N-dimethyltryptamine (DMT), or combinations thereof.

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From **page 26**

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Optional secondary neurotrophic fungal or plant extracts, or purified compounds thereof	Erinacines, hericenones, cannabidiol, cannabichromene, cannabigerol, Δ8-tetrahydrocannabinol, Δ9-tetrahydrocannabinol, cannabinal, tetrahydrocannabivarin, cannabidiol-2',6'-dimethyl ether, inter alia <i>Antrodia, Beauveria, Copelandia, Cordyceps, Fomitopsis, Ganoderma, Grifola, Hericium, Hypsizygos, Inonotus, Isaria, Panaeolus, Phellinus, Phellinus, Piptoporus, Pleurotus, Polyporus or Trametes species or combinations thereof; Bacopa monnien, Centella asiatica, Ginkgo biloba, Zingiber officinale, Ocimum sanctum, Polygonum cuspidatum, Origanum vulgare, Origanum onites, Rosmarinus officinalis, Rosmarinus eriocalyx, Curcuma longa, Camellia sinensis, Psychotria viridis, inter alia</i>	10 ng to 500 mg
Optional neurotropic or nootropic fungal or plant extracts, or other natural products, or purified compounds thereof	β-carbolines (e.g., harmine, harmine, norharmine, perlolyrine, harmol, cordysin, inter alia)	10 μg to 500 mg
Optional MAO inhibitor compounds	Niacin, capsaicin, ipecac, apomorphine, bittering agents (e.g., denatonium benzoate) inter alia	10 ng to 10 mg
Optional adversive	Fillers, binders, diluents, vehicles, lubricants, preservatives, flavors, colors, etc.	10 μg to 200 mg
Optional pharmaceutical excipients		quantum sufficiet

From **claim 18** “The composition of claim 1, wherein **the composition is effective to treat, alleviate, prevent or ameliorate...neuronal injuries or physical neurodegeneration (e.g....neurotoxic viruses...)**”

From **page 12** “In an embodiment, to ameliorating the disease or disorder (I.e., slowing or arresting or **reducing the development of the disease or at least one of the clinical symptoms thereof.**”

2. NUZZO (2021) “Post-Acute COVID-19 Neurological Syndrome: A New Medical Challenge” Journal of Clinical Medicine. Vol 10(9):1947.

From abstract “Neurological complications after severe COVID-19 infection might include delirium, brain inflammation, stroke, and nerve damage.”

From page 4 “Furthermore, high levels of inflammation (cytokine storm) and BBB lesions in the brain are very likely to have long-term consequences on neurodegeneration.”

18. The method of claim 15, wherein the composition comprises about 1 ng to about 2000 mg of the extracts or isolates from *Hericum erinaceus* mushroom species, erinacines, hericenones, or combinations thereof.

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From page 26

Table 1. Exemplary neurotropic or nootropic compositions

Component	Example	Dosage
Tryptamine neurotrophics, tryptamine derivatives, esters, or salts thereof, or extracts from fungi or plants; In addition to or alternatively, phenethylamines, amphetamines; derivatives thereof, extracts from fungi or plants	Psilocybin, baeocystin, norbaeocystin, psilocin norpsilocin, 4-hydroxytryptamine, <i>N,N</i> -dimethyltryptamine, <i>N</i> -methyltryptamine, inter alia; In addition or alternatively, 3,4,5-trimethoxyphenethylamine (Mescaline), 2,4-dimethoxy-amphetamine (2,4-DMA), 3,4-dimethoxy-amphetamine (3,4-DMA), 3,4-methylenedioxy-amphetamine (MDA), 3-methoxy-4,5-methylenedioxy-amphetamine (MMDA), inter alia	10 ng to 10 mg
Optional secondary neurotrophic fungal or plant extracts, or purified compounds thereof	Erinacines, hericenones, cannabidiol, cannabichromene, cannabigerol, Δ 8-tetrahydrocannabinol, Δ 9-tetrahydrocannabinol, cannabinalol, tetrahydrocannabivarin, cannabidiol-2',6'-dimethyl ether, inter alia <i>Antrodia</i> , <i>Beauveria</i> , <i>Copelandia</i> , <i>Cordyceps</i> , <i>Fomitopsis</i> , <i>Ganoderma</i> , <i>Grifola</i> , <i>Hericum</i> , <i>Hyphozygus</i> , <i>Inonotus</i> , <i>Isaria</i> , <i>Panaeolus</i> , <i>Phellinus</i> , <i>Phellinus</i> , <i>Piptoporus</i> , <i>Pleurotus</i> , <i>Polyporus</i> or <i>Trametes</i> species or combinations thereof; <i>Bacopa monnien</i> , <i>Centella asiatica</i> , <i>Ginkgo biloba</i> , <i>Zingiber officinale</i> , <i>Ocimum sanctum</i> , <i>Polygonum cuspidatum</i> , <i>Onganum vulgare</i> , <i>Origanum onites</i> , <i>Rosmarinus officinalis</i> , <i>Rosmarinus eriocalyx</i> , <i>Curcuma longa</i> , <i>Camellia sinensis</i> , <i>Psychotria viridis</i> , inter alia	10 ng to 500 mg
Optional neurotropic or nootropic fungal or plant extracts, or other natural products, or purified compounds thereof	<i>Bacopa monnien</i> , <i>Centella asiatica</i> , <i>Ginkgo biloba</i> , <i>Zingiber officinale</i> , <i>Ocimum sanctum</i> , <i>Polygonum cuspidatum</i> , <i>Onganum vulgare</i> , <i>Origanum onites</i> , <i>Rosmarinus officinalis</i> , <i>Rosmarinus eriocalyx</i> , <i>Curcuma longa</i> , <i>Camellia sinensis</i> , <i>Psychotria viridis</i> , inter alia	10 μ g to 500 mg
Optional MAO inhibitor compounds	β -carbolines (e.g., harmane, harmine, norharmine, perlolyrine, harmol, cordysin, inter alia)	10 ng to 10 mg
Optional adversive	Niacin, capsaicin, ipecac, apomorphine, bittering agents (e.g., denatonium benzoate) inter alia	10 μ g to 200 mg
Optional pharmaceutical excipients	Fillers, binders, diluents, vehicles, lubricants, preservatives, flavors, colors, etc.	quantum sufficiet

From claim 18 “The composition of claim 1, wherein the composition is effective to treat, alleviate, prevent or ameliorate...neuronal injuries or physical neurodegeneration (e.g....neurotoxic viruses...)”

From page 12 “In an embodiment, to ameliorating the disease or disorder (I.e., slowing or arresting or reducing the development of the disease or at least one of the clinical symptoms thereof).”

2. NUZZO (2021) “Post-Acute COVID-19 Neurological Syndrome: A New Medical Challenge” Journal of Clinical Medicine. Vol 10(9):1947.

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From page 4 “Furthermore, high levels of inflammation (cytokine storm) and BBB lesions in the brain are very likely to have long-term consequences on neurodegeneration.”

19. (canceled)

20. The method of claim 15, wherein the composition comprises about 70 mg to about 200 mg of the one or more monoamine oxidase inhibitors.

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Component	Example	Dosage
Tryptamine neurotrophics, tryptamine derivatives, esters, or salts thereof, or extracts from fungi or plants; In addition to or alternatively, phenethylamines, amphetamines; derivatives thereof, extracts from fungi or plants	Psilocybin, baeocystin, norbaeocystin, psilocin norpsilocin, 4-hydroxytryptamine, <i>N,N</i> -dimethyltryptamine, <i>N</i> -methyltryptamine, inter alia; In addition or alternatively, 3,4,5-trimethoxyphenethylamine (Mescaline), 2,4-dimethoxy-amphetamine (2,4-DMA), 3,4-dimethoxy-amphetamine (3,4-DMA), 3,4-methylenedioxy-amphetamine (MDA), 3-methoxy-4,5-methylenedioxy-amphetamine (MMDA), inter alia	10 ng to 10 mg
Optional secondary neurotrophic fungal or plant extracts, or purified compounds thereof	Erinacines, hericenones, cannabidiol, cannabichromene, cannabigerol, Δ 8-tetrahydrocannabinol, Δ 9-tetrahydrocannabinol, cannabinalol, tetrahydrocannabivarin, cannabidiol-2',6'-dimethyl ether, inter alia <i>Antrodia</i> , <i>Beauveria</i> , <i>Copelandia</i> , <i>Cordyceps</i> , <i>Fomitopsis</i> , <i>Ganoderma</i> , <i>Grifola</i> , <i>Hericium</i> , <i>Hypsizyus</i> , <i>Inonotus</i> , <i>Isaria</i> , <i>Panaeolus</i> , <i>Phellinus</i> , <i>Phellinus</i> , <i>Piptoporus</i> , <i>Pleurotus</i> , <i>Polyporus</i> or <i>Trametes</i> species or combinations thereof; <i>Bacopa monnien</i> , <i>Centella asiatica</i> , <i>Gingko biloba</i> , <i>Zingiber officinale</i> , <i>Ocimum sanctum</i> , <i>Polygonum cuspidatum</i> , <i>Origanum vulgare</i> , <i>Origanum onites</i> , <i>Rosmarinus officinalis</i> , <i>Rosmarinus eriocalyx</i> , <i>Curcuma longa</i> , <i>Camellia sinensis</i> , <i>Psychotria viridis</i> , inter alia	10 ng to 500 mg
Optional neurotropic or nootropic fungal or plant extracts, or other natural products, or purified compounds thereof	<i>Antrodia</i> , <i>Beauveria</i> , <i>Copelandia</i> , <i>Cordyceps</i> , <i>Fomitopsis</i> , <i>Ganoderma</i> , <i>Grifola</i> , <i>Hericium</i> , <i>Hypsizyus</i> , <i>Inonotus</i> , <i>Isaria</i> , <i>Panaeolus</i> , <i>Phellinus</i> , <i>Phellinus</i> , <i>Piptoporus</i> , <i>Pleurotus</i> , <i>Polyporus</i> or <i>Trametes</i> species or combinations thereof; <i>Bacopa monnien</i> , <i>Centella asiatica</i> , <i>Gingko biloba</i> , <i>Zingiber officinale</i> , <i>Ocimum sanctum</i> , <i>Polygonum cuspidatum</i> , <i>Origanum vulgare</i> , <i>Origanum onites</i> , <i>Rosmarinus officinalis</i> , <i>Rosmarinus eriocalyx</i> , <i>Curcuma longa</i> , <i>Camellia sinensis</i> , <i>Psychotria viridis</i> , inter alia	10 μ g to 500 mg
Optional MAO inhibitor compounds	β -carbolines (e.g., harmane, harmine, nor harmine, perlolyrine, harmol, cordysin, inter alia)	10 ng to 10 mg
Optional adversive	Niacin, capsaicin, ipecac, apomorphine, bittering agents (e.g., denatonium benzoate) inter alia	10 μ g to 200 mg
Optional pharmaceutical excipients	Fillers, binders, diluents, vehicles, lubricants, preservatives, flavors, colors, etc.	quantum sufficiet

From claim 18 “The composition of claim 1, wherein the composition is effective to treat, alleviate, prevent or ameliorate...neuronal injuries or physical neurodegeneration (e.g....neurotoxic viruses...)”

	<p>From page 12 “In an embodiment, to ameliorating the disease or disorder (I.e., slowing or arresting or reducing the development of the disease or at least one of the clinical symptoms thereof).”</p> <p>From page 37 “One or more dosage forms of the compositions described herein can be administered, for example, 1x, 2x, 3x, 4x, 5x, 6x, or even more times per day.”</p> <p><i>From paragraph [0041] of the application of interest (17/738,925): “The term “dosage” as used herein refers to the administering of a specific amount, number, and frequency of doses over a specified period of time, typically 1 day.”</i></p> <p>2. NUZZO (2021) “Post-Acute COVID-19 Neurological Syndrome: A New Medical Challenge” Journal of Clinical Medicine. Vol 10(9):1947.</p> <p>From abstract “Neurological complications after severe COVID-19 infection might include delirium, brain inflammation, stroke, and nerve damage.”</p> <p>From page 4 “Furthermore, high levels of inflammation (cytokine storm) and BBB lesions in the brain are very likely to have long-term consequences on neurodegeneration.”</p>
<p>21. The method of claim 15, wherein the one or more monoamine oxidase inhibitors is Norharman, Harmine, 1,2,3,4-tetrahydro-β-carboline-3-carboxylic acid, 1-methyl-1,2,3,4-tetrahydro-β-carboline-3-carboxylic acid, 1-methyl-2,3,4,9-tetrahydro-1H-β-carboline-1,3-dicarboxylic acid, Harmaline, N-methoxy-1-vinyl-β-carboline, ethyl 9H-β-carboline-3-carboxylate, 1-furyl-β-carboline-3-carboxylic</p>	<p>1. Priority Document of Int’l Pat. App. Pub. No. WO/2021/101926 “TRYPTAMINE COMPOSITIONS FOR ENHANCING NEURITE OUTGROWTH” (Priority date 9 April 2020)</p> <p>From page 26</p>

acid, 1-[5-(methoxymethyl)-2-furyl]-9H-β-carboline-3-carboxylic acid, 6-hydroxy-3-(6-hydroxy-1H-indol-3-yl)-9H-β-carboline-4-carboxylic acid, Strictosidine, (1S)-1-[[[(2S,3R,4S)-2-(β-L-glucopyranosyloxy)-5-(methoxycarbonyl)-3-vinyl-3,4-dihydro-2H-pyran-4-yl]methyl]-2,3,4,9-tetrahydro-1H-β-carboline-1,3-dicarboxylic acid, or combinations thereof.

Table 1. Exemplary neurotropic or nootropic compositions

Component	Example	Dosage
Tryptamine neurotrophics, tryptamine derivatives, esters, or salts thereof, or extracts from fungi or plants; In addition to or alternatively, phenethylamines, amphetamines; derivatives thereof, extracts from fungi or plants	Psilocybin, baecocystin, norbaecocystin, psilocin norpsilocin, 4-hydroxytryptamine, <i>N,N</i> -dimethyltryptamine, <i>N</i> -methyltryptamine, inter alia; In addition or alternatively, 3,4,5-trimethoxyphenethylamine (Mescaline), 2,4-dimethoxy-amphetamine (2,4-DMA), 3,4-dimethoxy-amphetamine (3,4-DMA), 3,4-methylenedioxy-amphetamine (MDA), 3-methoxy-4,5-methylenedioxy-amphetamine (MMDA), inter alia	10 ng to 10 mg
Optional secondary neurotrophic fungal or plant extracts, or purified compounds thereof	Erinacines, hericenones, cannabidiol, cannabichromene, cannabigerol, Δ8-tetrahydrocannabinol, Δ9-tetrahydrocannabinol, cannabinalol, tetrahydrocannabivarin, cannabidiol-2',6'-dimethyl ether, inter alia <i>Antrodia</i> , <i>Beauveria</i> , <i>Copelandia</i> , <i>Cordyceps</i> , <i>Fomitopsis</i> , <i>Ganoderma</i> , <i>Grifola</i> , <i>Hericium</i> , <i>Hypsizygus</i> , <i>Inonotus</i> , <i>Isaria</i> , <i>Panaeolus</i> , <i>Phellinus</i> , <i>Phellinus</i> , <i>Piptoporus</i> , <i>Pleurotus</i> , <i>Polyporus</i> or <i>Trametes</i> species or combinations thereof; <i>Bacopa monnien</i> , <i>Centella asiatica</i> , <i>Gingko biloba</i> , <i>Zingiber officinale</i> , <i>Ocimum sanctum</i> , <i>Polygonum cuspidatum</i> , <i>Origanum vulgare</i> , <i>Origanum onites</i> , <i>Rosmarinus officinalis</i> , <i>Rosmarinus ericalyx</i> , <i>Curcuma longa</i> , <i>Camellia sinensis</i> , <i>Psychotria viridis</i> , inter alia	10 ng to 500 mg
Optional neurotropic or nootropic fungal or plant extracts, or other natural products, or purified compounds thereof	β-carbolines (e.g., harmane, harmine, nor harmine, perfolyrine, harmol, cordysin, inter alia)	10 μg to 500 mg
Optional MAO inhibitor compounds	Niacin, capsaicin, ipecac, apomorphine, bittering agents (e.g., denatonium benzoate) inter alia	10 ng to 10 mg
Optional adversive	Fillers, binders, diluents, vehicles, lubricants, preservatives, flavors, colors, etc.	10 μg to 200 mg
Optional pharmaceutical excipients		quantum sufficit

From **claim 18** “The composition of claim 1, wherein **the composition is effective to treat, alleviate, prevent or ameliorate...neuronal injuries or physical neurodegeneration (e.g....neurotoxic viruses...)**”

From **page 12** “In an embodiment, to ameliorating the disease or disorder (I.e., slowing or arresting or **reducing the development of the disease or at least one of the clinical symptoms thereof**).”

From **page 37** “One or more **dosage forms of the compositions described herein can be administered, for example, 1x, 2x, 3x, 4x, 5x, 6x, or even more times per day.**”

2. NUZZO (2021) “Post-Acute COVID-19 Neurological Syndrome: A New Medical Challenge” Journal of Clinical Medicine. Vol 10(9):1947.

From **abstract** “**Neurological complications after severe COVID-19 infection** might include delirium, **brain inflammation**, stroke, and nerve damage.”

From **page 4** “Furthermore, **high levels of inflammation (cytokine storm) and BBB lesions in the brain are very likely to have long-term consequences on neurodegeneration.**”

22. The method of claim 15, wherein the inflammatory response is cytokine storm.

1. Priority Document of Int’l Pat. App. Pub. No. WO/2021/101926 “TRYPTAMINE COMPOSITIONS FOR ENHANCING NEURITE OUTGROWTH” (Priority date 9 April 2020)

From **page 26**

Table 1. Exemplary neurotropic or nootropic compositions

Component	Example	Dosage
<p>Tryptamine neurotrophics, tryptamine derivatives, esters, or salts thereof, or extracts from fungi or plants; In addition to or alternatively, phenethylamines, amphetamines; derivatives thereof, extracts from fungi or plants</p>	<p>Psilocybin, baecocystin, norbaecocystin, psilocin norpsilocin, 4-hydroxytryptamine, <i>N,N</i>-dimethyltryptamine, <i>N</i>-methyltryptamine, inter alia; In addition or alternatively, 3,4,5-trimethoxyphenethylamine (Mescaline), 2,4-dimethoxy-amphetamine (2,4-DMA), 3,4-dimethoxy-amphetamine (3,4-DMA), 3,4-methylenedioxy-amphetamine (MDA), 3-methoxy-4,5-methylenedioxy-amphetamine (MMDA), inter alia</p>	10 ng to 10 mg
<p>Optional secondary neurotrophic fungal or plant extracts, or purified compounds thereof</p>	<p>Erinacines, hericenones, cannabidiol, cannabichromene, cannabigerol, Δ8-tetrahydrocannabinol, Δ9-tetrahydrocannabinol, cannabinal, tetrahydrocannabivarin, cannabidiol-2',6'-dimethyl ether, inter alia <i>Antrodia, Beauveria, Copelandia, Cordyceps Fomitopsis, Ganoderma, Grifola, Hericium, Hypsizyugus, Inonotus, Isaria, Panaeolus, Phellinus, Phellinus, Piptoporus, Pleurotus, Polyporus</i> or <i>Trametes</i> species or combinations thereof; <i>Bacopa monnien, Centella asiatica, Ginkgo biloba, Zingiber officinale, Ocimum sanctum, Polygonum cuspidatum, Origanum vulgare, Origanum onites, Rosmarinus officinalis, Rosmarinus eriocalyx, Curcuma longa, Camellia sinensis, Psychotria viridis</i>, inter alia</p>	10 ng to 500 mg
<p>Optional neurotropic or nootropic fungal or plant extracts, or other natural products, or purified compounds thereof</p>	<p>β-carbolines (e.g., harmine, harmine, norharmine, perlolyrine, harmol, cordysin, inter alia)</p>	10 μ g to 500 mg
<p>Optional MAO inhibitor compounds</p>	<p>Niacin, capsaicin, ipecac, apomorphine, bittering agents (e.g., denatonium benzoate) inter alia</p>	10 ng to 10 mg
<p>Optional adversive</p>	<p>Fillers, binders, diluents, vehicles, lubricants, preservatives, flavors, colors, etc.</p>	10 μ g to 200 mg
<p>Optional pharmaceutical excipients</p>		quantum sufficet

From **claim 18** “The composition of claim 1, wherein **the composition is effective to treat, alleviate, prevent or ameliorate...neuronal injuries or physical neurodegeneration (e.g....neurotoxic viruses...)**”

From **page 12** “In an embodiment, to ameliorating the disease or disorder (I.e., slowing or arresting or **reducing the development of the disease or at least one of the clinical symptoms thereof.**”

From **page 37** “One or more **dosage forms of the compositions described herein can be administered, for example, 1x, 2x, 3x, 4x, 5x, 6x, or even more times per day.**”

2. NUZZO (2021) “Post-Acute COVID-19 Neurological Syndrome: A New Medical Challenge” Journal of Clinical Medicine. Vol 10(9):1947.

From abstract “Neurological complications after severe COVID-19 infection might include delirium, brain inflammation, stroke, and nerve damage.”

From page 4 “Furthermore, high levels of inflammation (cytokine storm) and BBB lesions in the brain are very likely to have long-term consequences on neurodegeneration.”

23. The method of claim 15, wherein the infectious disease or condition is a viral infection, a bacterial infection, or a parasitic infection.

1. Priority Document of Int’l Pat. App. Pub. No. WO/2021/101926 “TRYPTAMINE COMPOSITIONS FOR ENHANCING NEURITE OUTGROWTH” (Priority date 9 April 2020)

From page 26

Table 1. Exemplary neurotropic or nootropic compositions

Component	Example	Dosage
Tryptamine neurotrophics, tryptamine derivatives, esters, or salts thereof, or extracts from fungi or plants; In addition to or alternatively, phenethylamines, amphetamines, derivatives thereof, extracts from fungi or plants	Psilocybin, baeocystin, norbaeocystin, psilocin norpsilocin, 4-hydroxytryptamine, <i>N,N</i> -dimethyltryptamine, <i>N</i> -methyltryptamine, inter alia; In addition or alternatively, 3,4,5-trimethoxyphenethylamine (Mescaline), 2,4-dimethoxy-amphetamine (2,4-DMA), 3,4-dimethoxy-amphetamine (3,4-DMA), 3,4-methylenedioxy-amphetamine (MDA), 3-methoxy-4,5-methylenedioxy-amphetamine (MMDA), inter alia	10 ng to 10 mg
Optional secondary neurotrophic fungal or plant extracts, or purified compounds thereof	Erinacines, hericenones, cannabidiol, cannabichromene, cannabigerol, Δ 8-tetrahydrocannabinol, Δ 9-tetrahydrocannabinol, cannabinal, tetrahydrocannabivarin, cannabidiol-2',6'-dimethyl ether, inter alia <i>Antrodia, Beauveria, Copelandia, Cordyceps, Fomitopsis, Ganoderma, Grifola, Hericium, Hypsizygos, Inonotus, Isana, Panaeolus, Phellinus, Phellinus, Piptoporus, Pleurotus, Polyporus</i> or <i>Trametes</i> species or combinations thereof; <i>Bacopa monnien, Centella asiatica, Ginkgo biloba, Zingiber officinale, Ocimum sanctum, Polygonum cuspidatum, Origanum vulgare, Origanum onites, Rosmarinus officinalis, Rosmarinus eriocalyx, Curcuma longa, Camellia sinensis, Psychotria viridis</i> , inter alia	10 ng to 500 mg
Optional neurotropic or nootropic fungal or plant extracts, or other natural products, or purified compounds thereof	β -carbolines (e.g., harmane, harmine, norharmine, perlolyrine, harmol, cordysin, inter alia)	10 ng to 10 mg
Optional adversive	Niacin, capsaicin, ipecac, apomorphine, bittering agents (e.g., denatonium benzoate) inter alia	10 μ g to 200 mg
Optional pharmaceutical excipients	Fillers, binders, diluents, vehicles, lubricants, preservatives, flavors, colors, etc.	quantum sufficit

From claim 18 “The composition of claim 1, wherein the composition is effective to treat, alleviate, prevent or ameliorate...neuronal injuries or physical neurodegeneration (e.g....neurotoxic viruses...)”

	<p>From page 12 “In an embodiment, to ameliorating the disease or disorder (I.e., slowing or arresting or reducing the development of the disease or at least one of the clinical symptoms thereof).”</p> <p>From page 37 “One or more dosage forms of the compositions described herein can be administered, for example, 1x, 2x, 3x, 4x, 5x, 6x, or even more times per day.”</p> <p>2. NUZZO (2021) “Post-Acute COVID-19 Neurological Syndrome: A New Medical Challenge” Journal of Clinical Medicine. Vol 10(9):1947.</p> <p>From abstract “Neurological complications after severe COVID-19 infection might include delirium, brain inflammation, stroke, and nerve damage.”</p> <p>From page 4 “Furthermore, high levels of inflammation (cytokine storm) and BBB lesions in the brain are very likely to have long-term consequences on neurodegeneration.”</p>
<p>24. The method of claim 23, wherein the viral infection is Paramyxoviridae (respiratory syncytial virus (RSV), parainfluenza virus (PIV), metapneumovirus (MPV), enteroviruses), Picomaviridae (Rhinovirus, RV), Coronaviridae (CoV), Adenoviridae (Adenovirus), Parvoviridae (HBoV), Orthomyxoviridae (influenza A, B, C, D, Isavirus, Thogotovirus, Quaranjavirus), Herpesviridae (human herpes viruses, Varicella zoster virus, Epstein-Barr virus, cytomegalovirus), avian influenza, smallpox, pandemic</p>	<p>1. Priority Document of Int’l Pat. App. Pub. No. WO/2021/101926 “TRYPTAMINE COMPOSITIONS FOR ENHANCING NEURITE OUTGROWTH” (Priority date 9 April 2020)</p> <p>From page 26</p>

influenza, or adult respiratory distress syndrome (ARDS).

Table 1. Exemplary neurotropic or nootropic compositions

Component	Example	Dosage
Tryptamine neurotrophics, tryptamine derivatives, esters, or salts thereof, or extracts from fungi or plants; In addition to or alternatively, phenethylamines, amphetamines; derivatives thereof, extracts from fungi or plants	Psilocybin, baecocystin, norbaecocystin, psilocin norpsilocin, 4-hydroxytryptamine, <i>N,N</i> -dimethyltryptamine, <i>N</i> -methyltryptamine, inter alia; In addition or alternatively, 3,4,5-trimethoxyphenethylamine (Mescaline), 2,4-dimethoxy-amphetamine (2,4-DMA), 3,4-dimethoxy-amphetamine (3,4-DMA), 3,4-methylenedioxy-amphetamine (MDA), 3-methoxy-4,5-methylenedioxy-amphetamine (MMDA), inter alia	10 ng to 10 mg
Optional secondary neurotrophic fungal or plant extracts, or purified compounds thereof	Erinacines, hericenones, cannabidiol, cannabichromene, cannabigerol, Δ 8-tetrahydrocannabinol, Δ 9-tetrahydrocannabinol, cannabinol, tetrahydrocannabivarin, cannabidiol-2',6'-dimethyl ether, inter alia <i>Antrodia, Beauveria, Copelandia, Cordyceps Fomitopsis, Ganoderma, Grifola, Hericium, Hypsizygos, Inonotus, Isaria, Panaeolus, Phellinus, Phellinus, Piptoporus, Pleurotus, Polyporus</i> or <i>Trametes</i> species or combinations thereof; <i>Bacopa monnien, Centella asiatica, Gingko biloba, Zingiber officinale, Ocimum sanctum, Polygonum cuspidatum, Origanum vulgare, Origanum onites, Rosmarinus officinalis, Rosmarinus eriocalyx, Curcuma longa, Camellia sinensis, Psychotria viridis</i> , inter alia	10 ng to 500 mg
Optional neurotropic or nootropic fungal or plant extracts, or other natural products, or purified compounds thereof	<i>Bacopa monnien, Centella asiatica, Gingko biloba, Zingiber officinale, Ocimum sanctum, Polygonum cuspidatum, Origanum vulgare, Origanum onites, Rosmarinus officinalis, Rosmarinus eriocalyx, Curcuma longa, Camellia sinensis, Psychotria viridis</i> , inter alia	10 μ g to 500 mg
Optional MAO inhibitor compounds	β -carbolines (e.g., harmane, harmine, nor harmine, perlolyrine, harmol, cordysin, inter alia)	10 ng to 10 mg
Optional adersive	Niacin, capsaicin, ipecac, apomorphine, bittering agents (e.g., denatonium benzoate) inter alia	10 μ g to 200 mg
Optional pharmaceutical excipients	Fillers, binders, diluents, vehicles, lubricants, preservatives, flavors, colors, etc.	quantum sufficit

From **claim 18** “The composition of claim 1, wherein **the composition is effective to treat, alleviate, prevent or ameliorate...neuronal injuries or physical neurodegeneration** (e.g....neurotoxic viruses...)”

From **page 12** “In an embodiment, to ameliorating the disease or disorder (I.e., slowing or arresting or **reducing the development of the disease or at least one of the clinical symptoms thereof**).”

2. NUZZO (2021) “Post-Acute COVID-19 Neurological Syndrome: A New Medical Challenge” Journal of Clinical Medicine. Vol 10(9):1947.

From **abstract** “**Neurological complications after severe COVID-19 infection** might include delirium, **brain inflammation**, stroke, and nerve damage.”

From **page 4** “Furthermore, **high levels of inflammation (cytokine storm) and BBB lesions in the brain** are very likely to have long-term consequences on neurodegeneration.”

	<p>11. CHEN (2021) “Cytokine Storm: The Primary Determinant for the Pathophysiological Evolution of COVID-19 Deterioration” <i>Frontiers in Immunology</i>. Vol.12:1-11.</p> <p>From page 6 “The cytokine storm is an important factor in the deterioration of some COVID-19 patients, and leads to abnormalities such as ARDS, MODS, and coagulation defects.”</p>
<p>25. The method of claim 23, wherein the bacterial infection is <i>Streptococcus pneumoniae</i>, <i>Mycobacterium tuberculosis</i>, <i>Bordetella pertussis</i>, <i>Haemophilus influenzae</i>, <i>Moraxella catarrhalis</i>, <i>Pseudomonas aeruginosa</i>, <i>Stenotrophomonas maltophilia</i>, <i>Staphylococcus aureus</i>, <i>Streptococcus pyogenes</i>, <i>Neisseria meningitidis</i>, <i>Klebsiella pneumoniae</i>, or Non-tuberculosis <i>Mycobacterium</i>.</p>	<p>6. Int’l Pat. App. Pub. No. WO/2020/212948 “METHODS OF TREATING NEUROCOGNITIVE DISORDERS, CHRONIC PAIN AND REDUCING INFLAMMATION” (Published 22 October 2020)</p> <p>From claim 47 “A method of reducing inflammation in a subject in need thereof, the method comprising administering to the subject a therapeutically effective amount of psilocybin or an active metabolite thereof.”</p> <p>From claim 48 “The method of claim 47, wherein administration of the psilocybin reduces the duration of the inflammation.”</p> <p>From claim 52 “The method of any one of claims 47-49, wherein reducing inflammation in the subject treats or prevents one or more of allergy, asthma, Alzheimer’s disease, diabetes, cardiovascular disease, sepsis, arthritis, joint disease, inflammatory bowel disease, or dermatitis in the subject.”</p> <p>From claim 56 “A method of treating Inflammatory Bowel Disease (IBD) in a subject in need thereof, the method comprising administering to the subject a therapeutically effective amount of psilocybin or an active metabolite thereof”</p> <p>From claim 57 “The method of claim 56, wherein the IBD is ulcerative colitis.”</p> <p>From page 110 paragraph 2 “In some embodiments, psilocybin is administered to the subject in combination with one or more additional therapies. In some embodiments, psilocybin is administered to the subject in combination with one or more anti-depressant or anti-anxiety drugs, such as SSRIs, tricyclic antidepressants (TCAs), monoamine oxidase inhibitors (MAOIs), or serotonin norepinephrine reuptake inhibitors (SNRIs).”</p> <p>7. ASKIM (2016) “Epidemiology and outcome of sepsis in adult patients with <i>Streptococcus pneumoniae</i> infection in a Norwegian county 1993–2011: an observational study” <i>BMC Infectious Diseases</i>. Vol. 6(223):1-9.</p>

	<p>Title “Epidemiology and outcome of sepsis in adult patients with <i>Streptococcus pneumoniae</i> infection in a Norwegian county 1993–2011: an observational study”</p> <p>8. ATARASHI (2017) “Ectopic colonization of oral bacteria in the intestine drives TH1 cell induction and inflammation” <i>Science</i>. Vol. 358(6361):359-365.</p> <p>From page 2 “Mining of our in-house data sets of 16S ribosomal RNA (rRNA) gene sequences revealed that several bacterial taxa—including species belonging to <i>Rothia</i>, <i>Streptococcus</i>, <i>Neisseria</i>, <i>Prevotella</i>, and <i>Gemella</i> (table S1A), all of which are aerotolerant and typically members of the oral microbiota—were significantly more abundant in the fecal microbiota of patients with ulcerative colitis (UC), primary sclerosing cholangitis (PSC), gastroesophageal reflux disease (GERD) being treated by long-term proton pump inhibitor therapy, and alcoholism, compared with that of healthy controls (Fig. 1A and table S1B).”</p> <p>From page 6 “In mouse models of IBD, such as T-bet^{-/-}Rag2^{-/-} mice, <i>K. pneumoniae</i> is known to proliferate and play an important role in triggering disease.”</p> <p>5. DILING (2017) “Extracts from <i>Hericium erinaceus</i> relieve inflammatory bowel disease by regulating immunity and gut microbiota” <i>Oncotarget</i>. Vol 8:85838-85857.</p> <p>From page 85838 “The proportion of Foxp3- and IL-10-positive cells in rats in the model group was significantly lower than that in the normal group (P < 0.05), while the levels of TNF-α and NF-κB p65 were significantly higher (P < 0.05). After treatment with <i>H. erinaceus</i> extracts, the proportion of Foxp3- and IL-10-positive cells significantly increased, especially in the alcoholic extracts (AE) (P < 0.05), compared with the model group. Nevertheless, the proportion of TNF-α- and NF-κB p65- positive cells was significantly reduced compared with the model group (P < 0.05). Cumulatively, these results suggested that <i>H. erinaceus</i> extracts had effective anti-inflammatory effects in IBD.”</p>
<p>26. The method of claim 23, wherein the parasitic infection is malaria.</p>	<p>1. Priority Document of Int’l Pat. App. Pub. No. WO/2021/101926 “TRYPTAMINE COMPOSITIONS FOR ENHANCING NEURITE OUTGROWTH” (Priority date 9 April 2020)</p> <p>From claim 8 “The composition as claimed in claim 4 wherein the active ingredient is selected from the group consisting of psilocybin, psilocin, norpsilocin...”</p>

From **claim 17** “The method of preventing, managing, or treating a subject in need thereof comprising administering to said subject an effective amount of transdermal delivery device as claimed in claim 4.”

From **page 32 paragraph 3** “The present invention provides for a composition as described for use in the treatment, management or prevention of neurological, mood and abuse disorders or diseases, wherein the disorder may be depression, central nervous system inflammation, addiction, headache or dementia, or disorders of cognition and memory.”

From **page 34 paragraph 2** “As used herein, and unless otherwise specified, the term “Neurological Disorder” refers to diseases of the central and peripheral nervous system...The disorders include....neuroinfections....parasitic (e.g., malaria, Chagas)...”

27. The method of claim 15, wherein inflammation is reduced and neuroregeneration is induced in the subject.

1. Priority Document of Int’l Pat. App. Pub. No. WO/2021/101926 “TRYPTAMINE COMPOSITIONS FOR ENHANCING NEURITE OUTGROWTH” (Priority date 9 April 2020)

From **page 26**

Table 1. Exemplary neurotropic or nootropic compositions		
Component	Example	Dosage
Tryptamine neurotrophics, tryptamine derivatives, esters, or salts thereof, or extracts from fungi or plants; In addition to or alternatively, phenethylamines, amphetamines; derivatives thereof, extracts from fungi or plants	Psilocybin, baeocystin, norbaeocystin, psilocin norpsilocin, 4-hydroxytryptamine, N,N-dimethyltryptamine, N-methyltryptamine, inter alia; In addition or alternatively, 3,4,5-trimethoxyphenethylamine (Mescaline), 2,4-dimethoxy-amphetamine (2,4-DMA), 3,4-dimethoxy-amphetamine (3,4-DMA), 3,4-methylenedioxy-amphetamine (MDA), 3-methoxy-4,5-methylenedioxy-amphetamine (MMDA), inter alia	10 ng to 10 mg
Optional secondary neurotrophic fungal or plant extracts, or purified compounds thereof	Erinacines, hericenones, cannabidiol, cannabichromene, cannabigerol, Δ8-tetrahydrocannabinol, Δ9-tetrahydrocannabinol, cannabinal, tetrahydrocannabivarin, cannabidiol-2',6'-dimethyl ether, inter alia <i>Antrodia, Beauveria, Copelandia, Cordyceps Fomitopsis, Ganoderma, Grifola, Hericium, Hypsizygos, Inonotus, Isaria, Panaeolus, Phellinus, Phellinus, Piptoporus, Pleurotus, Polyporus or Trametes species or combinations thereof, Bacopa monnien, Centella asiatica, Ginkgo biloba, Zingiber officinale, Ocimum sanctum, Polygonum cuspidatum, Origanum vulgare, Origanum onites, Rosmarinus officinalis, Rosmarinus eriocalyx, Curcuma longa, Camellia sinensis, Psychotria viridis, inter alia</i>	10 ng to 500 mg
Optional neurotropic or nootropic fungal or plant extracts, or other natural products, or purified compounds thereof	β-carbolines (e.g., harmaline, harmine, nor harmine, perlolyrine, harmol, cordysin, inter alia)	10 μg to 500 mg
Optional MAO inhibitor compounds	Niacin, capsaicin, ipecac, apomorphine, bittering agents (e.g., denatonium benzoate) inter alia	10 ng to 10 mg
Optional adersive	Fillers, binders, diluents, vehicles, lubricants, preservatives, flavors, colors, etc.	10 μg to 200 mg
Optional pharmaceutical excipients		quantum sufficit

Title “TRYPTAMINE COMPOSITIONS FOR ENHANCING NEURITE OUTGROWTH”

From **claim 18** “The composition of claim 1, wherein **the composition is effective to treat, alleviate, prevent or ameliorate...neuronal injuries or physical neurodegeneration** (e.g....**neurotoxic viruses...**)”

From **page 12** “In an embodiment, to ameliorating the disease or disorder (I.e., slowing or arresting or **reducing the development of the disease or at least one of the clinical symptoms thereof.**”

28. The method of claim 27, wherein neuroregeneration comprises neurite outgrowth.

1. Priority Document of Int’l Pat. App. Pub. No. WO/2021/101926 “TRYPTAMINE COMPOSITIONS FOR ENHANCING NEURITE OUTGROWTH” (Priority date 9 April 2020)

From **page 26**

Table 1. Exemplary neurotropic or nootropic compositions

Component	Example	Dosage
Tryptamine neurotrophics, tryptamine derivatives, esters, or salts thereof, or extracts from fungi or plants; In addition to or alternatively, phenethylamines, amphetamines; derivatives thereof, extracts from fungi or plants	Psilocybin, baecocystin, norbaecocystin, psilocin norpsilocin, 4-hydroxytryptamine, <i>N,N</i> -dimethyltryptamine, <i>N</i> -methyltryptamine, inter alia; In addition or alternatively, 3,4,5-trimethoxyphenethylamine (Mescaline), 2,4-dimethoxy-amphetamine (2,4-DMA), 3,4-dimethoxy-amphetamine (3,4-DMA), 3,4-methylenedioxy-amphetamine (MDA), 3-methoxy-4,5-methylenedioxy-amphetamine (MMDA), inter alia	10 ng to 10 mg
Optional secondary neurotrophic fungal or plant extracts, or purified compounds thereof	Erinacines, hericenones, cannabidiol, cannabichromene, cannabigerol, Δ 8-tetrahydrocannabinol, Δ 9-tetrahydrocannabinol, cannabinol, tetrahydrocannabivarin, cannabidiol-2',6'-dimethyl ether, inter alia <i>Antrodia, Beauveria, Copelandia, Cordyceps Fomitopsis, Ganoderma, Grifola, Hericium, Hypsizygos, Inonotus, Isana, Panaeolus, Phellinus, Phellinus, Piptoporus, Pleurotus, Polyporus</i> or <i>Trametes</i> species or combinations thereof; <i>Bacopa monnien, Centella asiatica, Ginkgo biloba, Zingiber officinale, Ocimum sanctum, Polygonum cuspidatum, Origanum vulgare, Origanum onites, Rosmarinus officinalis, Rosmarinus eriocalyx, Curcuma longa, Camellia sinensis, Psychotria viridis</i> , inter alia	10 ng to 500 mg
Optional neurotropic or nootropic fungal or plant extracts, or other natural products, or purified compounds thereof	β -carbolines (e.g., harmine, harmine, nor harmine, perfolyrine, harmol, cordysinine, inter alia)	10 μ g to 500 mg
Optional MAO inhibitor compounds	Niacin, capsaicin, ipecac, apomorphine, bittering agents (e.g., denatonium benzoate) inter alia	10 ng to 10 mg
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Title “TRYPTAMINE COMPOSITIONS FOR ENHANCING NEURITE OUTGROWTH”

	<p>From claim 18 “The composition of claim 1, wherein the composition is effective to treat, alleviate, prevent or ameliorate...neuronal injuries or physical neurodegeneration (e.g....neurotoxic viruses...)”</p> <p>From page 12 “In an embodiment, to ameliorating the disease or disorder (I.e., slowing or arresting or reducing the development of the disease or at least one of the clinical symptoms thereof.)”</p>
<p>29. (canceled)</p>	
<p>30. A method for inducing expression of an anti-inflammatory cytokine, the method comprising administering a composition to a subject in need thereof, the composition comprising: one or more tryptamines, salts thereof, or combinations thereof; extracts or isolates from <i>Hericium erinaceus</i> mushroom species, erinacines, hericenones, or combinations thereof; and one or more monoamine oxidase inhibitors.</p>	<p>9. ICEERS (2020) “Ayahuasca: Basic Info” Retrieved 6 August 2020. URL: https://web.archive.org/web/20200806102318/https://www.iceers.org/ayahuasca-basic-info/</p> <p>From Beta-carbolines section, paragraph 3 “Analysis of ayahuasca brews have found harmine at quantities of about 158mg per dose, which would be equivalent to a dose of about 2mg/kg for a person weighing around 70kg. This amount is sufficient to cause the inhibitory effects of monoamine oxidase, which allows the DMT to be orally effective. In their bioassays, Jonathan Ott and other authors found that the minimum amount of harmine needed to induce the oral activity of DMT was about 70mg to 150mg, or around 1mg/kg to 2mg/kg.”</p> <p>10. GOULART DA SILVA (2021) “Anti-inflammatory activity of ayahuasca: therapeutical implications in neurological and psychiatric diseases” Behavioural Brain Research. Vol.400:1-8.</p> <p>From page 1 “Thus, the current scientific evidence, mainly in humans, make the ayahuasca a pioneer between classic psychedelics, because it has pointed its anti-inflammatory activity.”</p> <p>3. SZABO (2014) “Psychedelic N,N-Dimethyltryptamine and 5-Methoxy-N,N-Dimethyltryptamine Modulate Innate and Adaptive Inflammatory Responses through the Sigma-1 Receptor of Human Monocyte-Derived Dendritic Cells” PLOS One. Vol 9(8):1-12.</p> <p>From page 11 “We conclude that the function of dimethyltryptamines may extend the central nervous system activity and may play a more universal role in immune regulation. Here we demonstrate for the first time that NN-DMT and 5-MeO-DMT have potent immunomodulatory effects on the functional activities of human dendritic cells operating through the sigma-1 receptor. We also show that DMT-mediated sigmar-1 activation can interfere with both innate and adaptive immune responses. On the one hand, it strongly decreases the levels of pro-inflammatory cytokines and chemokines such as IL-1β, IL-6, TNFα and IL8, while upregulates the production of the anti-inflammatory cytokine IL-10.”</p>

	<p>5. DILING (2017) “Extracts from <i>Hericium erinaceus</i> relieve inflammatory bowel disease by regulating immunity and gut microbiota” <i>Oncotarget</i>. Vol 8:85838-85857.</p> <p>From page 85838 “The proportion of Foxp3- and IL-10-positive cells in rats in the model group was significantly lower than that in the normal group ($P < 0.05$), while the levels of TNF-α and NF-κB p65 were significantly higher ($P < 0.05$). After treatment with <i>H. erinaceus</i> extracts, the proportion of Foxp3- and IL-10-positive cells significantly increased, especially in the alcoholic extracts (AE) ($P < 0.05$), compared with the model group. Nevertheless, the proportion of TNF-α- and NF-κB p65- positive cells was significantly reduced compared with the model group ($P < 0.05$). Cumulatively, these results suggested that <i>H. erinaceus</i> extracts had effective anti-inflammatory effects in IBD.”</p> <p>4. SHEU (2013) “Immunomodulatory effects of polysaccharides isolated from <i>Hericium erinaceus</i> on dendritic cells” <i>Process Biochemistry</i>. Vol 48(9):1402-1408.</p> <p>From page 1402 “<i>Hericium erinaceus</i> (<i>H. erinaceus</i>; HE) polysaccharides (HE-PS) have been shown to have immunomodulatory activity. We found that the bioactive components of β-glucan derivatives consisted of 20% in HE-PS. We used an analytic platform for investigating the effects of HE-PS on the maturation of rat dendritic cells (DCs), which are derived from rat bone marrow hematopoietic cells (BMHCs). The results showed that treatment with 50 μg/mL HE-PS changed the morphology of the DCs to an active form in parallel with a significant two fold increase in MHC class II and CD80/86 surface antigens compared to the control. Furthermore, endocytosis by the DCs was significantly reduced at the same dosage. IL-12, IFN-γ and IL-10 cytokine secretion was significantly increased by 2.7, 1.5 and 1.6-fold, respectively, compared to the control after treatment with 50 μg/mL of HE-PS.”</p>
<p>31. The method of claim 30, wherein the composition comprises about 1 ng to about 10 mg, about 10 mg to about 100 mg, about 10 mg to about 20 mg, about 20 mg to about 50 mg, about 20 mg to about 100 mg, about 1 ng to about 20 mg,</p>	<p>9. ICEERS (2020) “Ayahuasca: Basic Info” Retrieved 6 August 2020. URL: https://web.archive.org/web/20200806102318/https://www.iceers.org/ayahuasca-basic-info/</p> <p>From Beta-carbolines section, paragraph 3 “Analysis of ayahuasca brews have found harmine at quantities of about 158mg per dose, which would be equivalent to a dose of about 2mg/kg for a person weighing around 70kg. This amount is sufficient to cause the inhibitory effects of monoamine oxidase, which allows the DMT to be orally effective. In their bioassays, Jonathan Ott and other authors found that the minimum amount</p>

<p>about 1 ng to about 50 mg, or about 1 ng to about 100 mg of the one or more tryptamines, salts thereof, or combinations thereof.</p>	<p>of harmine needed to induce the oral activity of DMT was about 70mg to 150mg, or around 1mg/kg to 2mg/kg.”</p> <p>10. GOULART DA SILVA (2021) “Anti-inflammatory activity of ayahuasca: therapeutical implications in neurological and psychiatric diseases” Behavioural Brain Research. Vol.400:1-8.</p> <p>From page 1 “Thus, the current scientific evidence, mainly in humans, make the ayahuasca a pioneer between classic psychedelics, because it has pointed its anti-inflammatory activity.”</p> <p>3. SZABO (2014) “Psychedelic N,N-Dimethyltryptamine and 5-Methoxy-N,N-Dimethyltryptamine Modulate Innate and Adaptive Inflammatory Responses through the Sigma-1 Receptor of Human Monocyte-Derived Dendritic Cells” PLOS One. Vol 9(8):1-12.</p> <p>From page 11 “We conclude that the function of dimethyltryptamines may extend the central nervous system activity and may play a more universal role in immune regulation. Here we demonstrate for the first time that NN-DMT and 5-MeO-DMT have potent immunomodulatory effects on the functional activities of human dendritic cells operating through the sigma-1 receptor. We also show that DMT-mediated sigma-1 activation can interfere with both innate and adaptive immune responses. On the one hand, it strongly decreases the levels of pro-inflammatory cytokines and chemokines such as IL-1β, IL-6, TNFα and IL8, while upregulates the production of the anti-inflammatory cytokine IL-10.”</p>
<p>32. The method of claim 30, wherein the one or more tryptamines are psilocybin, psilocin, norpsilocin, baeocystin, norbaeocystin, N,N-dimethyltryptamine (DMT), or combinations thereof.</p>	<p>9. ICEERS (2020) “Ayahuasca: Basic Info” Retrieved 6 August 2020. URL: https://web.archive.org/web/20200806102318/https://www.iceers.org/ayahuasca-basic-info/</p> <p>From Beta-carbolines section, paragraph 3 “Analysis of ayahuasca brews have found harmine at quantities of about 158mg per dose, which would be equivalent to a dose of about 2mg/kg for a person weighing around 70kg. This amount is sufficient to cause the inhibitory effects of monoamine oxidase, which allows the DMT to be orally effective. In their bioassays, Jonathan Ott and other authors found that the minimum amount of harmine needed to induce the oral activity of DMT was about 70mg to 150mg, or around 1mg/kg to 2mg/kg.”</p> <p>10. GOULART DA SILVA (2021) “Anti-inflammatory activity of ayahuasca: therapeutical implications in neurological and psychiatric diseases” Behavioural Brain Research. Vol.400:1-8.</p>

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<p>33. The method of claim 30, wherein the composition comprises about 1 ng to about 2000 mg of the extracts or isolates from <i>Hericium erinaceus</i> mushroom species, erinacines, hericenones, or combinations thereof.</p>	<p>5. DILING (2017) “Extracts from <i>Hericium erinaceus</i> relieve inflammatory bowel disease by regulating immunity and gut microbiota” Oncotarget. Vol 8:85838-85857.</p> <p>From page 85838 “The proportion of Foxp3- and IL-10-positive cells in rats in the model group was significantly lower than that in the normal group (P < 0.05), while the levels of TNF-α and NF-κB p65 were significantly higher (P < 0.05). After treatment with <i>H. erinaceus</i> extracts, the proportion of Foxp3- and IL-10-positive cells significantly increased, especially in the alcoholic extracts (AE) (P < 0.05), compared with the model group. Nevertheless, the proportion of TNF-α- and NF-κB p65- positive cells was significantly reduced compared with the model group (P < 0.05). Cumulatively, these results suggested that <i>H. erinaceus</i> extracts had effective anti-inflammatory effects in IBD.”</p> <p>4. SHEU (2013) “Immunomodulatory effects of polysaccharides isolated from <i>Hericium erinaceus</i> on dendritic cells” Process Biochemistry. Vol 48(9):1402-1408.</p> <p>From page 1402 “<i>Hericium erinaceus</i> (<i>H. erinaceus</i>; HE) polysaccharides (HE-PS) have been shown to have immunomodulatory activity. We found that the bioactive components of β-glucan derivatives consisted of 20% in HE-PS. We used an analytic platform for investigating the effects of HE-PS on the maturation of rat dendritic cells (DCs), which are derived from rat bone marrow hematopoietic cells (BMHCs). The results</p>

	<p>showed that treatment with 50 µg/mL HE-PS changed the morphology of the DCs to an active form in parallel with a significant two fold increase in MHC class II and CD80/86 surface antigens compared to the control. Furthermore, endocytosis by the DCs was significantly reduced at the same dosage. IL-12, IFN-γ and IL-10 cytokine secretion was significantly increased by 2.7, 1.5 and 1.6-fold, respectively, compared to the control after treatment with 50 µg/mL of HE-PS.”</p>
<p>34. (canceled)</p>	
<p>35. The method of claim 30, wherein the composition comprises about 70 mg to about 200 mg of the one or more monoamine oxidase inhibitors.</p>	<p>9. ICEERS (2020) “Ayahuasca: Basic Info” Retrieved 6 August 2020. URL: https://web.archive.org/web/20200806102318/https://www.iceers.org/ayahuasca-basic-info/</p> <p>From Beta-carbolines section, paragraph 3 “Analysis of ayahuasca brews have found harmine at quantities of about 158mg per dose, which would be equivalent to a dose of about 2mg/kg for a person weighing around 70kg. This amount is sufficient to cause the inhibitory effects of monoamine oxidase, which allows the DMT to be orally effective. In their bioassays, Jonathan Ott and other authors found that the minimum amount of harmine needed to induce the oral activity of DMT was about 70mg to 150mg, or around 1mg/kg to 2mg/kg.”</p> <p>10. GOULART DA SILVA (2021) “Anti-inflammatory activity of ayahuasca: therapeutical implications in neurological and psychiatric diseases” Behavioural Brain Research. Vol.400:1-8.</p> <p>From page 1 “Thus, the current scientific evidence, mainly in humans, make the ayahuasca a pioneer between classic psychedelics, because it has pointed its anti-inflammatory activity.”</p> <p>3. SZABO (2014) “Psychedelic N,N-Dimethyltryptamine and 5-Methoxy-N,N-Dimethyltryptamine Modulate Innate and Adaptive Inflammatory Responses through the Sigma-1 Receptor of Human Monocyte-Derived Dendritic Cells” PLOS One. Vol 9(8):1-12.</p> <p>From page 11 “We conclude that the function of dimethyltryptamines may extend the central nervous system activity and may play a more universal role in immune regulation. Here we demonstrate for the first time that NN-DMT and 5-MeO-DMT have potent immunomodulatory effects on the functional activities of human dendritic cells operating through the sigma-1 receptor. We also show that DMT-mediated sigmar-1 activation can interfere with both innate and adaptive immune responses. On the one hand, it strongly decreases the levels of pro-inflammatory cytokines and chemokines such as IL-1β, IL-6, TNFα and IL8, while upregulates the production of the anti-inflammatory cytokine IL-10.”</p>

<p>36. The method of claim 30, wherein the one or more monoamine oxidase inhibitors is Norharman, Harmine, 1,2,3,4-tetrahydro-β-carboline-3-carboxylic acid, 1-methyl-1,2,3,4-tetrahydro-β-carboline-3-carboxylic acid, 1-methyl-2,3,4,9-tetrahydro-1H-β-carboline-1,3-dicarboxylic acid, Harmaline, N-methoxy-1-vinyl-β-carboline, ethyl 9H-β-arboline-3-carboxylate, 1-furyl-β-carboline-3-carboxylic acid, 1-[5-(methoxymethyl)-2-furyl]-9H-β-carboline-3-carboxylic acid, 6-hydroxy-3-(6-hydroxy-1H-indol-3-yl)-9H-β-carboline-4-carboxylic acid, Strictosidine, (1S)-1-[(2S,3R,4S)-2-(β-L-glucopyranosyloxy)-5-(methoxycarbonyl)-3-vinyl-3,4-dihydro-2H-pyran-4-yl]methyl}-2,3,4,9-tetrahydro-1H-β-carboline-1,3-dicarboxylic acid, or combinations thereof.</p>	<p>9. ICEERS (2020) “Ayahuasca: Basic Info” Retrieved 6 August 2020. URL: https://web.archive.org/web/20200806102318/https://www.iceers.org/ayahuasca-basic-info/</p> <p>From Beta-carbolines section, paragraph 3 “Analysis of ayahuasca brews have found harmine at quantities of about 158mg per dose, which would be equivalent to a dose of about 2mg/kg for a person weighing around 70kg. This amount is sufficient to cause the inhibitory effects of monoamine oxidase, which allows the DMT to be orally effective. In their bioassays, Jonathan Ott and other authors found that the minimum amount of harmine needed to induce the oral activity of DMT was about 70mg to 150mg, or around 1mg/kg to 2mg/kg.”</p> <p>10. GOULART DA SILVA (2021) “Anti-inflammatory activity of ayahuasca: therapeutical implications in neurological and psychiatric diseases” Behavioural Brain Research. Vol.400:1-8.</p> <p>From page 1 “Thus, the current scientific evidence, mainly in humans, make the ayahuasca a pioneer between classic psychedelics, because it has pointed its anti-inflammatory activity.”</p> <p>3. SZABO (2014) “Psychedelic N,N-Dimethyltryptamine and 5-Methoxy-N,N-Dimethyltryptamine Modulate Innate and Adaptive Inflammatory Responses through the Sigma-1 Receptor of Human Monocyte-Derived Dendritic Cells” PLOS One. Vol 9(8):1-12.</p> <p>From page 11 “We conclude that the function of dimethyltryptamines may extend the central nervous system activity and may play a more universal role in immune regulation. Here we demonstrate for the first time that NN-DMT and 5-MeO-DMT have potent immunomodulatory effects on the functional activities of human dendritic cells operating through the sigma-1 receptor. We also show that DMT-mediated sigmar-1 activation can interfere with both innate and adaptive immune responses. On the one hand, it strongly decreases the levels of pro-inflammatory cytokines and chemokines such as IL-1β, IL-6, TNFα and IL8, while upregulates the production of the anti-inflammatory cytokine IL-10.”</p>
<p>37. The method of claim 30, wherein the anti-inflammatory cytokine is IL-4, IL-10, IL-1RA, or a combination thereof.</p>	<p>9. ICEERS (2020) “Ayahuasca: Basic Info” Retrieved 6 August 2020. URL: https://web.archive.org/web/20200806102318/https://www.iceers.org/ayahuasca-basic-info/</p> <p>From Beta-carbolines section, paragraph 3 “Analysis of ayahuasca brews have found harmine at quantities of about 158mg per dose, which would be equivalent to a dose of about 2mg/kg for a person weighing</p>

around 70kg. This amount is sufficient to cause the inhibitory effects of monoamine oxidase, which allows the **DMT** to be orally effective. In their bioassays, Jonathan Ott and other authors found that the minimum amount of harmine needed to induce the oral activity of **DMT was about 70mg to 150mg**, or around 1mg/kg to 2mg/kg.”

10. GOULART DA SILVA (2021) “Anti-inflammatory activity of ayahuasca: therapeutical implications in neurological and psychiatric diseases” Behavioural Brain Research. Vol.400:1-8.

From **page 1** “Thus, the current scientific evidence, mainly in humans, make the **ayahuasca a pioneer between classic psychedelics, because it has pointed its anti-inflammatory activity.**”

3. SZABO (2014) “Psychedelic N,N-Dimethyltryptamine and 5-Methoxy-N,N-Dimethyltryptamine Modulate Innate and Adaptive Inflammatory Responses through the Sigma-1 Receptor of Human Monocyte-Derived Dendritic Cells” PLOS One. Vol 9(8):1-12.

From **page 11** “We conclude that the function of dimethyltryptamines may extend the central nervous system activity and may play a more universal role in immune regulation. Here we demonstrate for the first time that **NN-DMT and 5-MeO-DMT have potent immunomodulatory effects** on the functional activities of human dendritic cells operating through the sigma-1 receptor. We also show that DMT-mediated sigma-1 activation can interfere with both innate and adaptive immune responses. On the one hand, **it strongly decreases the levels of pro-inflammatory cytokines and chemokines such as IL-1 β , IL-6, TNF α and IL8, while upregulates the production of the anti-inflammatory cytokine IL-10.**”

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From **page 85838** “The proportion of Foxp3- and IL-10-positive cells in rats in the model group was significantly lower than that in the normal group ($P < 0.05$), while the levels of TNF- α and NF- κ B p65 were significantly higher ($P < 0.05$). **After treatment with *H. erinaceus* extracts, the proportion of Foxp3- and IL-10-positive cells significantly increased**, especially in the alcoholic extracts (AE) ($P < 0.05$), compared with the model group. Nevertheless, the proportion of TNF- α - and NF- κ B p65- positive cells was significantly reduced compared with the model group ($P < 0.05$). Cumulatively, these results suggested that ***H. erinaceus* extracts had effective anti-inflammatory effects in IBD.**”

	<p>4. SHEU (2013) “Immunomodulatory effects of polysaccharides isolated from <i>Hericium erinaceus</i> on dendritic cells” <i>Process Biochemistry</i>. Vol 48(9):1402-1408.</p> <p>From page 1402 “<i>Hericium erinaceus</i> (<i>H. erinaceus</i>; HE) polysaccharides (HE-PS) have been shown to have immunomodulatory activity. We found that the bioactive components of β-glucan derivatives consisted of 20% in HE-PS. We used an analytic platform for investigating the effects of HE-PS on the maturation of rat dendritic cells (DCs), which are derived from rat bone marrow hematopoietic cells (BMHCs). The results showed that treatment with 50 μg/mL HE-PS changed the morphology of the DCs to an active form in parallel with a significant two fold increase in MHC class II and CD80/86 surface antigens compared to the control. Furthermore, endocytosis by the DCs was significantly reduced at the same dosage. IL-12, IFN-γ and IL-10 cytokine secretion was significantly increased by 2.7, 1.5 and 1.6-fold, respectively, compared to the control after treatment with 50 μg/mL of HE-PS.”</p>
<p>38. The method of claim 30, wherein inflammation is reduced and neuroregeneration is induced in the subject.</p>	<p>1. Priority Document of Int’l Pat. App. Pub. No. WO/2021/101926 “TRYPTAMINE COMPOSITIONS FOR ENHANCING NEURITE OUTGROWTH” (Priority date 9 April 2020)</p> <p>From page 26</p>

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Component	Example	Dosage
Tryptamine neurotrophics, tryptamine derivatives, esters, or salts thereof, or extracts from fungi or plants; In addition to or alternatively, phenethylamines, amphetamines; derivatives thereof, extracts from fungi or plants	Psilocybin, baeocystin, norbaeocystin, psilocin norpsilocin, 4-hydroxytryptamine, <i>N,N</i> -dimethyltryptamine, <i>N</i> -methyltryptamine, inter alia; In addition or alternatively, 3,4,5-trimethoxyphenethylamine (Mescaline), 2,4-dimethoxy-amphetamine (2,4-DMA), 3,4-dimethoxy-amphetamine (3,4-DMA), 3,4-methylenedioxy-amphetamine (MDA), 3-methoxy-4,5-methylenedioxy-amphetamine (MMDA), inter alia	10 ng to 10 mg
Optional secondary neurotrophic fungal or plant extracts, or purified compounds thereof	Erinacines, hericenones, cannabidiol, cannabichromene, cannabigerol, Δ 8-tetrahydrocannabinol, Δ 9-tetrahydrocannabinol, cannabinol, tetrahydrocannabivarin, cannabidiol-2',6'-dimethyl ether, inter alia <i>Antrodia, Beauveria, Copelandia, Cordyceps, Fomitopsis, Ganoderma, Grifola, Hericium, Hypsizygos, Inonotus, Isaria, Panaeolus, Phellinus, Phellinus, Piptoporus, Pleurotus, Polyporus</i> or <i>Trametes</i> species or combinations thereof; <i>Bacopa monnien, Centella asiatica, Gingko biloba, Zingiber officinale, Ocimum sanctum, Polygonum cuspidatum, Origanum vulgare, Origanum onites, Rosmarinus officinalis, Rosmarinus eriocalyx, Curcuma longa, Camellia sinensis, Psychotria viridis</i> , inter alia	10 ng to 500 mg
Optional neurotropic or nootropic fungal or plant extracts, or other natural products, or purified compounds thereof	β -carbolines (e.g., harmane, harmine, norharmine, perlolyrine, harmol, cordysin, inter alia)	10 μ g to 500 mg
Optional MAO inhibitor compounds	Niacin, capsaicin, ipecac, apomorphine, bittering agents (e.g., denatonium benzoate) inter alia	10 ng to 10 mg
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Title “TRYPTAMINE COMPOSITIONS FOR ENHANCING NEURITE OUTGROWTH”

From **claim 18** “The composition of claim 1, wherein **the composition is effective to treat, alleviate, prevent or ameliorate...neuronal injuries or physical neurodegeneration** (e.g....**neurotoxic viruses...**)”

From **claim 33** “A method of **inducing neuronal growth** and neuronal lengthening comprising administering an effective amount of one or more norpsilocin, norbaeocystin, baeocystin, or psilocybin combined with one or more erinacines or hericenones in pure form, extracts, or isolates from *Hericium* mushroom species, or combinations thereof and one or more pharmaceutically acceptable excipients to the subject.”

From **page 12** “In an embodiment, to ameliorating the disease or disorder (I.e., slowing or arresting or **reducing the development of the disease or at least one of the clinical symptoms thereof**).”

2. NUZZO (2021) “Post-Acute COVID-19 Neurological Syndrome: A New Medical Challenge” Journal of Clinical Medicine. Vol 10(9):1947.

From **abstract** “**Neurological complications after severe COVID-19 infection** might include delirium, **brain inflammation**, stroke, and nerve damage.”

From **page 4** “Furthermore, **high levels of inflammation (cytokine storm) and BBB lesions in the brain are very likely to have long-term consequences on neurodegeneration.**”

9. ICEERS (2020) “Ayahuasca: Basic Info” Retrieved 6 August 2020. URL: <https://web.archive.org/web/20200806102318/https://www.iceers.org/ayahuasca-basic-info/>

From **Beta-carbolines section, paragraph 3** “**Analysis of ayahuasca brews have found harmine at quantities of about 158mg per dose**, which would be equivalent to a dose of about 2mg/kg for a person weighing around 70kg. This amount is sufficient to cause the inhibitory effects of monoamine oxidase, which allows the **DMT** to be orally effective. In their bioassays, Jonathan Ott and other authors found that the minimum amount of harmine needed to induce the oral activity of **DMT was about 70mg to 150mg**, or around 1mg/kg to 2mg/kg.”

10. GOULART DA SILVA (2021) “Anti-inflammatory activity of ayahuasca: therapeutical implications in neurological and psychiatric diseases” Behavioural Brain Research. Vol.400:1-8.

From **page 1** “Thus, the current scientific evidence, mainly in humans, make the **ayahuasca a pioneer between classic psychedelics, because it has pointed its anti-inflammatory activity.**”

3. SZABO (2014) “Psychedelic N,N-Dimethyltryptamine and 5-Methoxy-N,N-Dimethyltryptamine Modulate Innate and Adaptive Inflammatory Responses through the Sigma-1 Receptor of Human Monocyte-Derived Dendritic Cells” PLOS One. Vol 9(8):1-12.

From **page 11** “We conclude that the function of dimethyltryptamines may extend the central nervous system activity and may play a more universal role in immune regulation. Here we demonstrate for the first time that **NN-DMT and 5-MeO-DMT have potent immunomodulatory effects** on the functional activities of human dendritic cells operating through the sigma-1 receptor. We also show that DMT-mediated sigmar-1 activation can interfere with both innate and adaptive immune responses. On the one hand, **it strongly decreases the levels of pro-inflammatory cytokines and**

chemokines such as IL-1 β , IL-6, TNF α and IL8, while upregulates the production of the anti-inflammatory cytokine IL-10.”

39. The method of claim 38, wherein neuroregeneration comprises neurite outgrowth.

1. Priority Document of Int’l Pat. App. Pub. No. WO/2021/101926 “TRYPTAMINE COMPOSITIONS FOR ENHANCING NEURITE OUTGROWTH” (Priority date 9 April 2020)

From page 26

Table 1. Exemplary neurotropic or nootropic compositions

Component	Example	Dosage
Tryptamine neurotrophics, tryptamine derivatives, esters, or salts thereof, or extracts from fungi or plants; In addition to or alternatively, phenethylamines, amphetamines; derivatives thereof, extracts from fungi or plants	Psilocybin, baeocystin, norbaeocystin, psilocin norpsilocin, 4-hydroxytryptamine, <i>N,N</i> -dimethyltryptamine, <i>N</i> -methyltryptamine, inter alia; In addition or alternatively, 3,4,5-trimethoxyphenethylamine (Mescaline), 2,4-dimethoxy-amphetamine (2,4-DMA), 3,4-dimethoxy-amphetamine (3,4-DMA), 3,4-methylenedioxy-amphetamine (MDA), 3-methoxy-4,5-methylenedioxy-amphetamine (MMDA), inter alia	10 ng to 10 mg
Optional secondary neurotrophic fungal or plant extracts, or purified compounds thereof	Erinacines, hericenones, cannabidiol, cannabichromene, cannabigerol, Δ 8-tetrahydrocannabinol, Δ 9-tetrahydrocannabinol, cannabinol, tetrahydrocannabivarin, cannabidiol-2',6'-dimethyl ether, inter alia <i>Antrodia, Beauveria, Copelandia, Cordyceps, Fomitopsis, Ganoderma, Grifola, Hericium, Hypsizygos, Inonotus, Isaria, Panaeolus, Phellinus, Phellinus, Piptoporus, Pleurotus, Polyporus</i> or <i>Trametes</i> species or combinations thereof; <i>Bacopa monnien, Centella asiatica, Ginkgo biloba, Zingiber officinale, Ocimum sanctum, Polygonum cuspidatum, Origanum vulgare, Origanum onites, Rosmarinus officinalis, Rosmarinus eriocalyx, Curcuma longa, Camellia sinensis, Psychotria viridis</i> , inter alia	10 ng to 500 mg
Optional neurotropic or nootropic fungal or plant extracts, or other natural products, or purified compounds thereof	<i>Bacopa monnien, Centella asiatica, Ginkgo biloba, Zingiber officinale, Ocimum sanctum, Polygonum cuspidatum, Origanum vulgare, Origanum onites, Rosmarinus officinalis, Rosmarinus eriocalyx, Curcuma longa, Camellia sinensis, Psychotria viridis</i> , inter alia	10 μ g to 500 mg
Optional MAO inhibitor compounds	β -carbolines (e.g., harmaline, harmine, norharmine, perlolyrine, harmol, cordysin, inter alia)	10 ng to 10 mg
Optional adersive	Niacin, capsaicin, ipecac, apomorphine, bittering agents (e.g., denatonium benzoate) inter alia	10 μ g to 200 mg
Optional pharmaceutical excipients	Fillers, binders, diluents, vehicles, lubricants, preservatives, flavors, colors, etc.	quantum sufficit

Title “TRYPTAMINE COMPOSITIONS FOR ENHANCING NEURITE OUTGROWTH”

From claim 18 “The composition of claim 1, wherein the composition is effective to treat, alleviate, prevent or ameliorate...neuronal injuries or physical neurodegeneration (e.g....neurotoxic viruses...)”

From claim 33 “A method of inducing neuronal growth and neuronal lengthening comprising administering an effective amount of one or more norpsilocin, norbaeocystin, baeocystin, or psilocybin combined with one or more erinacines or hericenones in pure form, extracts, or isolates from *Hericium* mushroom species, or combinations thereof and one or more pharmaceutically acceptable excipients to the subject.”

	<p>From page 12 “In an embodiment, to ameliorating the disease or disorder (I.e., slowing or arresting or reducing the development of the disease or at least one of the clinical symptoms thereof).”</p> <p>2. NUZZO (2021) “Post-Acute COVID-19 Neurological Syndrome: A New Medical Challenge” Journal of Clinical Medicine. Vol 10(9):1947.</p> <p>From abstract “Neurological complications after severe COVID-19 infection might include delirium, brain inflammation, stroke, and nerve damage.”</p> <p>From page 4 “Furthermore, high levels of inflammation (cytokine storm) and BBB lesions in the brain are very likely to have long-term consequences on neurodegeneration.”</p>
40. (canceled)	
41. (canceled)	
42. (canceled)	
43. (canceled)	
44. (canceled)	
45. (canceled)	
46. (canceled)	
47. (canceled)	
48. (canceled)	
49. (canceled)	
50. (canceled)	
<p>51. The method of claim 15, wherein the infectious disease or condition causes neurological damage in the subject and the method results in treatment of the neurological damage.</p>	<p>1. Priority Document of Int’l Pat. App. Pub. No. WO/2021/101926 “TRYPTAMINE COMPOSITIONS FOR ENHANCING NEURITE OUTGROWTH” (Priority date 9 April 2020)</p> <p>From page 26</p>

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Optional neurotropic or nootropic fungal or plant extracts, or other natural products, or purified compounds thereof	<i>Niacin, capsaicin, ipecac, apomorphine,</i> bittering agents (e.g., denatonium benzoate) inter alia	10 μ g to 500 mg
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Electronic Acknowledgement Receipt

EFS ID:	47634071
Application Number:	17738925
International Application Number:	
Confirmation Number:	3736
Title of Invention:	FUNGAL COMPOUND COMPOSITIONS AND METHODS FOR MODULATING INFLAMMATION
First Named Inventor/Applicant Name:	Paul E. STAMETS
Customer Number:	23409
Filer:	Shahin Shams
Filer Authorized By:	
Attorney Docket Number:	215261-9011-US02
Receipt Date:	06-MAR-2023
Filing Date:	06-MAY-2022
Time Stamp:	14:07:33
Application Type:	

Payment information:

Submitted with Payment	yes
Payment Type	CARD
Payment was successfully received in RAM	\$72
RAM confirmation Number	E202336E07265530
Deposit Account	
Authorized User	

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File Listing:

Document Number	Document Description	File Name	File Size(Bytes)/ Message Digest	Multi Part /.zip	Pages (if appl.)
1	Concise Description of Relevance	Concise-description-generated.pdf	49385	no	10
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Warnings:

Information:

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Warnings:

Information:

3	Request for Notification of Non-compliant Third-Party Submission	Third-party-notification-request.pdf	23720	no	1
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Warnings:

Information:

4	Concise Description of Relevance	US20220370483ClaimsChartComp.pdf	296202	no	37
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Information:

5	Evidence of Publication	1-PriorityDocWO2021101926.pdf	5412080	no	112
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Warnings:

Information:

6	Evidence of Publication	2-NUZZO.pdf	957302	no	10
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7	Evidence of Publication	3-SZABO.pdf	2335953	no	12
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Information:					
8	Evidence of Publication	4-SHEU.pdf	1744872	no	7
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Warnings:					
Information:					
9	Evidence of Publication	5-DILING.pdf	14302585	no	20
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Warnings:					
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10	Evidence of Publication	6-WO2020212948A1Comp.pdf	26105113	no	423
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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.

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New International Application Filed with the USPTO as a Receiving Office

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Electronic Acknowledgement Receipt

EFS ID:	47634443
Application Number:	17738925
International Application Number:	
Confirmation Number:	3736
Title of Invention:	FUNGAL COMPOUND COMPOSITIONS AND METHODS FOR MODULATING INFLAMMATION
First Named Inventor/Applicant Name:	Paul E. STAMETS
Customer Number:	23409
Filer:	Shahin Shams
Filer Authorized By:	
Attorney Docket Number:	215261-9011-US02
Receipt Date:	06-MAR-2023
Filing Date:	06-MAY-2022
Time Stamp:	14:14:07
Application Type:	

Payment information:

Submitted with Payment	yes
Payment Type	CARD
Payment was successfully received in RAM	\$72
RAM confirmation Number	E202336E14045819
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File Listing:

Document Number	Document Description	File Name	File Size(Bytes)/ Message Digest	Multi Part /.zip	Pages (if appl.)
1	Concise Description of Relevance	Concise-description-generated.pdf	32953	no	2
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Warnings:

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2	Third-Party Submission Under 37 CFR 1.290	Third-party-preissuance-submission.pdf	52928	no	2
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3	Request for Notification of Non-compliant Third-Party Submission	Third-party-notification-request.pdf	23721	no	1
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4	Concise Description of Relevance	US20220370483ClaimsChartCompany.pdf	296202	no	37
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Warnings:

Information:

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Warnings:

Information:

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