

**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE**

In re Application of: Terran Biosciences Confirmation No.: 8714  
Serial No.: 18/339,172 Group No.:  
Filing or 371(c) Date: June 21, 2023 Examiner:  
Entitled: Combination product for the treatment of neurological and/or psychiatric disorders

**THIRD-PARTY PRE-ISSUANCE SUBMISSION**

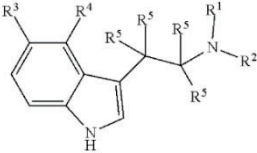
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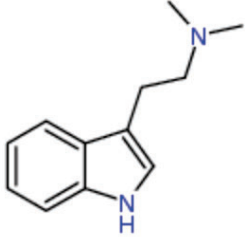
The following documents, which are also identified in the Form PTO/SB/429 filed herewith, are submitted for your consideration as being of potential relevance to the examination of the present application.

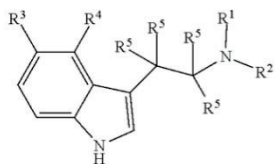
1. #6 DMT (2011) "N,N-Dimethyltryptamine" Isomer Design. Retrieved from March 7, 2016. URL [https://web.archive.org/web/\\*/http://isomerdesign.com/PIHKAL/read.php?id=6&domain=tk](https://web.archive.org/web/*/http://isomerdesign.com/PIHKAL/read.php?id=6&domain=tk)
2. Int'l Pat. App. No. WO/2015/127556 "Methods and uses for inducing or facilitating defecation in a patient in need thereof" (Published September 3, 2015)
3. BALSARA (2005) "Effects of the antidepressant trazodone, a 5-HT 2A/2C receptor antagonist, on dopamine-dependent behaviors in rats" Psychopharmacology. Vol. 179 (3): 597-605.
4. Intl' Pat. Doc. No. WO2018148605 "COMPOSITIONS AND METHODS COMPRISING A PSILOCYBIN DERIVATIVE" Published 16 August 2018.
5. Federal Register (2017) "Requirements on Content and Format of Labeling for Human Prescription Drug and Biological Products" Federal Register. Retrieved from May 1, 2017. URL <https://web.archive.org/web/20170501143753/https://www.federalregister.gov/documents/2006/01/24/06-545/requirements-on-content-and-format-of-labeling-for-human-prescription-drug-and-biological-products>
6. BONSON (1996) "Chronic administration of serotonergic antidepressants attenuates the subjective effects of LSD in humans" Neuropsychopharmacology. Vol. 14 (6): 425-436.
7. NICHOLS (2016) "Psychedelics" Pharmacological Reviews. Vol. 68 (2): 265-355.
8. CATLOW (2013) "Effects of psilocybin on hippocampal neurogenesis and extinction of trace fear conditioning" Experimental Brain Research. Vol. 228 (4), 481-491.

9. FLANAGAN (2018) "Psychedelics as anti-inflammatory agents" International Review of Psychiatry. Vol. 30 (4), 363-375.
10. BACHIS (2009) "Chronic Unpredictable Stress Promotes Neuronal Apoptosis in the Cerebral Cortex" Neuroscience Letters. Vol. 442 (2): 104-108.

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. 18/339,172 Pending Claims	References
<p>1. A pharmaceutical combination product comprising:</p> <p>(i) a compound described by the following formula (I):</p>  <p>R1 is selected from the group consisting of methyl, ethyl, n-propyl, allyl and isopropyl;</p> <p>R2 is selected from the group consisting of methyl, ethyl, n-propyl, allyl and isopropyl;</p> <p>R3 is selected from the group consisting of hydrogen, methoxy, methyl, hydroxy and a halogen; and</p> <p>R4 is selected from the group consisting of</p>	<p><b>From the application of interest 18/339,172 Claim 1</b></p> <p>(i) a compound described by the following formula (I):</p> <p>wherein,</p> <p>R1 is selected from the group consisting of <b>methyl</b>, ethyl, n-propyl, allyl and isopropyl;</p> <p>R2 is selected from the group consisting of <b>methyl</b>, ethyl, n-propyl, allyl and isopropyl;</p> <p>R3 is selected from the group consisting of <b>hydrogen</b>, methoxy, methyl, hydroxy and a halogen; and</p> <p>R4 is selected from the group consisting of <b>hydrogen</b>, hydroxy, phosphoryloxy and acetoxy;</p> <p>each R5 is independently selected from the group consisting of deuterium (2H) and <b>protium</b> (1H)</p> <p>1. #6 DMT (2011) "N,N-Dimethyltryptamine" Isomer Design. Retrieved from March 7, 2016. URL <a href="https://web.archive.org/web/*/http://isomerdesign.com/PiHKAL/read.php?id=6&amp;domain=tk">https://web.archive.org/web/*/http://isomerdesign.com/PiHKAL/read.php?id=6&amp;domain=tk</a></p> <p>From <b>structure</b>:</p>

<p>hydrogen, hydroxy, phosphoryloxy and acetoxy;</p> <p>each R5 is independently selected from the group consisting of deuterium (2H) and protium (H); and</p> <p>(ii) a 5-HT2A receptor antagonist; for use as a medicament.</p>	<div style="text-align: center;">  </div> <p>2. Int'l Pat. App. No. WO/2015/127556 "Methods and uses for inducing or facilitating defecation in a patient in need thereof" (Published September 3, 2015)</p> <p>From <b>Claim 1</b>: A composition comprising:</p> <ul style="list-style-type: none"> <li>(a) a cholinesterase inhibitor;</li> <li>(b) a <b>5-HT1A receptor agonist</b>;</li> <li>(c) a 5-HT1A/7 receptor agonist;</li> <li>(d) a <b>5-HT2/3 receptor agonist</b>;</li> <li>(e) a beta-2 adrenergic receptor agonist; or</li> <li>(f) <b>any combination of (a) to (e)</b>,</li> </ul> <p>From <b>Claim 6</b>: <b>The composition of any one of claims 1 to 5, wherein said 5-HT1A receptor agonist is:</b> (1) buspirone; (2) tandospirone; (3) cannabidiol; (4) f-15,599; (5) flesinoxan; (6) gepirone; (7) ipsapirone; (8) quetiapine; (9) <b>trazodone</b>; (10) yohimbine; (11) indole alkaloid; (12) asenapine; (13) vortioxetine; (14) ziprasidone; (15) a pharmaceutically acceptable derivative of any one of (1)-(14); or (16) any combination of (1)-(15).</p> <p>From <b>Claim 12</b>: <b>The composition of any one of claims 1 to 11 , wherein said 5-HT2/3 receptor agonist is:</b> (1) quipazine; (2) SR57227A; (3) LSD; (4) mescaline; (5) psilocin; (6) <b>DMT</b>; (7) 2C-B; (8) lorcaserin; (9) 2-methyl-5-HT; (10) BZP; (11) RS- 56812; (12) a pharmaceutically acceptable derivative of any one of (1)-(11); or (13) any combination of (1)-(12).</p> <p>3. BALSARA (2005) "Effects of the antidepressant trazodone, a 5-HT 2A/2C receptor antagonist, on dopamine-dependent behaviors in rats" Psychopharmacology. Vol. 179 (3): 597-605.</p> <p>From <b>Rationale</b>: <b>The antidepressant trazodone is a 5-HT 2A/2C receptor antagonist.</b></p>
<p>2. A pharmaceutical combination product comprising:</p> <p>(i) a compound described by the following formula (I):</p>	<p><b>From the application of interest 18/339,172 Claim 1</b></p> <p>(i) a compound described by the following formula (I):</p> <p>wherein,</p>



wherein,

R1 is selected from the group consisting of methyl, ethyl, n-propyl, allyl and isopropyl;

R2 is selected from the group consisting of methyl, ethyl, n-propyl, allyl and isopropyl;

R3 is selected from the group consisting of hydrogen, methoxy, methyl, hydroxy and a halogen; and

R4 is selected from the group consisting of hydrogen, hydroxy, phosphoryloxy and acetoxy;

each R5 is independently selected from the group consisting of deuterium (2H) and protium (H); and

(ii) a 5-HT<sub>2A</sub> receptor antagonist; for use in the treatment and/or prevention of psychiatric and/or neurological disorders.

R1 is selected from the group consisting of **methyl**, ethyl, n-propyl, allyl and isopropyl;

R2 is selected from the group consisting of **methyl**, ethyl, n-propyl, allyl and isopropyl;

R3 is selected from the group consisting of **hydrogen**, methoxy, methyl, hydroxy and a halogen; and

R4 is selected from the group consisting of **hydrogen**, hydroxy, phosphoryloxy and acetoxy;

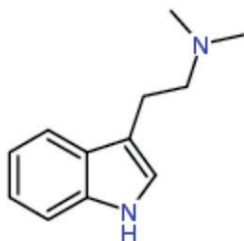
each R5 is independently selected from the group consisting of deuterium (2H) and **protium** (H)

From the application of interest 18/339,172 paragraph [0051]: "**Preferably, the compound described by formula (I) is N,N-dimethyltryptamine, N,N-diethyltryptamine, N,N-dipropyltryptamine, N,N-diisopropyltryptamine, 5-methoxy-N,N-dimethyltryptamine, 5-methoxy-N,N-diisopropyltryptamine, 5-hydroxy-N,N-dimethyltryptamine (bufotenin), 4-phosphoryloxy-N,N-dimethyltryptamine (psilocybin), 4-hydroxy-N,N-dimethyltryptamine (psilocin), N,N-diallyltryptamine, 5-Fluoro-N,N-diallyltryptamine, 5-Chloro-N,N-diallyltryptamine, 5-Bromo-N,N-diallyltryptamine, 5-Methyl-N,N-diallyltryptamine, 5-Methoxy-N,N-diallyltryptamine,  $\alpha,\alpha,\beta,\beta$ -tetradeutero-5-Methoxy-dimethyltryptamine,  $\alpha,\alpha,\beta,\beta$ -tetradeutero-dimethyltryptamine and/or O-acetylpsilocin"**

1. #6 DMT (2011) "N,N-Dimethyltryptamine" Isomer Design. Retrieved from March 7, 2016. URL

[https://web.archive.org/web/\\*/http://isomerdesign.com/PiHKAL/read.php?id=6&domain=tk](https://web.archive.org/web/*/http://isomerdesign.com/PiHKAL/read.php?id=6&domain=tk)

From **structure**:



2. Int'l Pat. App. No. WO/2015/127556 "Methods and uses for inducing or facilitating defecation in a patient in need thereof" (Published September 3, 2015)

From **Claim 1**: A composition comprising:

- (a) a cholinesterase inhibitor;
- (b) a **5-HT1A receptor agonist**;
- (c) a 5-HT1A/7 receptor agonist;
- (d) a **5-HT2/3 receptor agonist**;
- (e) a beta-2 adrenergic receptor agonist; or
- (f) **any combination of (a) to (e)**,

From **Claim 6: The composition of any one of claims 1 to 5, wherein said 5-HT1A receptor agonist is:** (1) buspirone; (2) tandospirone; (3) cannabidiol; (4) f-15,599; (5) flesinoxan; (6) gepirone; (7) ipsapirone; (8) quetiapine; (9) **trazodone**; (10) yohimbine; (11) indole alkaloid; (12) asenapine; (13) vortioxetine; (14) ziprasidone; (15) a pharmaceutically acceptable derivative of any one of (1)-(14); or (16) any combination of (1)-(15).

From **Claim 12: The composition of any one of claims 1 to 11, wherein said 5-HT2/3 receptor agonist is:** (1) quipazine; (2) SR57227A; (3) LSD; (4) mescaline; (5) psilocin; (6) **DMT**; (7) 2C-B; (8) lorcaserin; (9) 2-methyl-5-HT; (10) BZP; (11) RS- 56812; (12) a pharmaceutically acceptable derivative of any one of (1)-(11); or (13) any combination of (1)-(12).

3. BALSARA (2005) "Effects of the antidepressant trazodone, a 5-HT 2A/2C receptor antagonist, on dopamine-dependent behaviors in rats" Psychopharmacology. Vol. 179 (3): 597-605.

From **Rationale: The antidepressant trazodone is a 5-HT 2A/2C receptor antagonist.**

4. Intl' Pat. Doc. No. WO2018148605 "COMPOSITIONS AND METHODS COMPRISING A PSILOCYBIN DERIVATIVE" Published 16 August 2018.

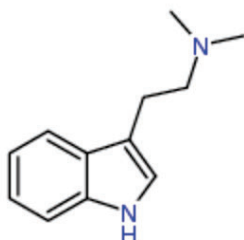
From **Claim 1: "A composition, comprising: a first purified psilocybin derivative**; wherein the first purified psilocybin derivative is chosen from **[3-(2-Dimethylaminoethyl)-1 H-indol-4-yl] dihydrogen phosphate**, 4-hydroxy-N, N-dimethyltryptamine, [3-(2-methylaminoethyl)-1 H-indol-4-yl] dihydrogen phosphate, 4-hydroxy-N-methyltryptamine, [3-(aminoethyl)-1 H-indol-4-yl] dihydrogen phosphate, 4-hydroxytryptamine, [3-(2-trimethylaminoethyl)-1 H-indol-4-yl] dihydrogen phosphate, and 4-hydroxy-N, N,N-trimethyltryptamine; and

From **Claim 82: A method of modulating activity at a neurotransmitter receptor comprising administering a neurotransmitter activity modulator, and administering a first dosage formulation comprising a first purified psilocybin derivative to the person in need of treatment,**

	<p><b>wherein the first dosage formulation modulates activity at a neurotransmitter receptor.</b></p> <p>From <b>Claim 86</b>: The method of claim 82, wherein the neurotransmitter receptor is chosen from a serotonin receptor, a cannabinoid receptor, <b>an adrenergic receptor</b>, a dopamine receptor, a GABAergic receptor, a glutaminergic receptor, a histaminergic receptor, a cholinergic receptor, an opioid receptor, or a glycinergic receptor.</p> <p>From <b>Claim 90</b>: <b>The method of claim 86, wherein the neurotransmitter receptor is an adrenergic receptor.</b></p> <p>From <b>Claim 91</b>: <b>The method of claim 90, wherein the neurotransmitter activity modulator is an adrenergic drug.</b></p> <p>From <b>Claim 92</b>: <b>The method of claim 91 , wherein the adrenergic drug is</b> chosen from adrenaline, agmatine, amoxapine, aptazapine, atomoxetine, bupropion, clonidine, doxepin, duloxetine, esmirtazpine, mianserin, mirabegron, mirtazapine, norepinephrine, phentolamine, phenylephrine, piperoxan, reserpine, ritodrine, setiptiline, tesofensine, timolol, <b>trazodone</b>, trimipramine, or xylazine.</p> <p>From <b>Description</b>: <b>The compositions disclosed herein are useful for the treatment of compulsive disorders in humans, a variety of intractable psychiatric disorders, chronic depression</b>, post-traumatic stress disorder, and drug or alcohol dependency. The compositions disclosed herein are also useful within the context of meditative, spiritual, and religious practices within a variety of contexts.</p>
<p>3. The combination product for use according to anyone of claims 1-2 wherein the compound described by formula (I) is selected from the group consisting of N,N-dimethyltryptamine, 5-methoxy-N,N-dimethyltryptamine, N,N-diethyltryptamine, N,N-dipropyltryptamine and N,N-diisopropyltryptamine.</p>	<p><b><i>From the application of interest 18/339,172 Claim 1</i></b></p> <p><i>(i) a compound described by the following formula (I):</i></p> <p><i>wherein,</i></p> <p><i>R1 is selected from the group consisting of <b>methyl</b>, ethyl, n-propyl, allyl and isopropyl;</i></p> <p><i>R2 is selected from the group consisting of <b>methyl</b>, ethyl, n-propyl, allyl and isopropyl;</i></p> <p><i>R3 is selected from the group consisting of <b>hydrogen</b>, methoxy, methyl, hydroxy and a halogen; and</i></p> <p><i>R4 is selected from the group consisting of <b>hydrogen</b>, hydroxy, phosphoryloxy and acetoxy;</i></p> <p><i>each R5 is independently selected from the group consisting of deuterium (2H) and <b>protium</b> (1H)</i></p>

1. #6 DMT (2011) "N,N-Dimethyltryptamine" Isomer Design. Retrieved from March 7, 2016. URL [https://web.archive.org/web/\\*/http://isomerdesign.com/PiHKAL/read.php?id=6&domain=tk](https://web.archive.org/web/*/http://isomerdesign.com/PiHKAL/read.php?id=6&domain=tk)

From **structure**:



2. Int'l Pat. App. No. WO/2015/127556 "Methods and uses for inducing or facilitating defecation in a patient in need thereof" (Published September 3, 2015)

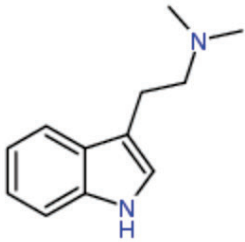
From **Claim 1**: A composition comprising:

- (a) a cholinesterase inhibitor;
- (b) a **5-HT1A receptor agonist**;
- (c) a 5-HT1A/7 receptor agonist;
- (d) a **5-HT2/3 receptor agonist**;
- (e) a beta-2 adrenergic receptor agonist; or
- (f) **any combination of (a) to (e)**,

From **Claim 6**: **The composition of any one of claims 1 to 5, wherein said 5-HT1A receptor agonist is:** (1) buspirone; (2) tandospirone; (3) cannabidiol; (4) f-15,599; (5) flesinoxan; (6) gepirone; (7) ipsapirone; (8) quetiapine; (9) **trazodone**; (10) yohimbine; (11) indole alkaloid; (12) asenapine; (13) vortioxetine; (14) ziprasidone; (15) a pharmaceutically acceptable derivative of any one of (1)-(14); or (16) any combination of (1)-(15).

From **Claim 12**: **The composition of any one of claims 1 to 11, wherein said 5-HT2/3 receptor agonist is:** (1) quipazine; (2) SR57227A; (3) LSD; (4) mescaline; (5) psilocin; (6) **DMT**; (7) 2C-B; (8) lorcaserin; (9) 2-methyl-5-HT; (10) BZP; (11) RS- 56812; (12) a pharmaceutically acceptable derivative of any one of (1)-(11); or (13) any combination of (1)-(12).

3. BALSARA (2005) "Effects of the antidepressant trazodone, a 5-HT 2A/2C receptor antagonist, on dopamine-dependent behaviors in rats" Psychopharmacology. Vol. 179 (3): 597-605.

	<p>From <b>Rationale: The antidepressant trazodone is a 5-HT 2A/2C receptor antagonist.</b></p>
<p>4. The combination product for use according to any one of claims 1-3 wherein the 5-HT<sub>2A</sub> receptor antagonist is selected from the group consisting of Methiothepin, Ritanserin, Ketanserin, Flibanserin, Methysergide, Trazodone, Nefazodone, Cinitapride, Cyproheptadine, Brexpiprazole, Cariprazine, Agomelatine, Pimavanserin, Eplivanserin, Volinanserin, Altanserin, Setoperone, LY-367,265, 1-(1-Naphthyl)piperazine, SB 206553, Pirenperone, SB-215505, Metergoline, Deramciclane, Amperozide, Glemanserin, 5-MeO-NBpBrT, Adatanserin, AMDA, Cinanserin, Fananserin, Iferanserin, AC-90179, LY86057, GSK-215083, Cyamemazine, Mesulergine, BF-1, LY215840, Sergolexole, Spiramide, LY53857, Amesergide, LY108742, Pipamperone,</p>	<p><b>From the application of interest 18/339,172 Claim 1</b></p> <p>(i) a compound described by the following formula (I):</p> <p>wherein,</p> <p>R<sub>1</sub> is selected from the group consisting of <b>methyl</b>, ethyl, n-propyl, allyl and isopropyl;</p> <p>R<sub>2</sub> is selected from the group consisting of <b>methyl</b>, ethyl, n-propyl, allyl and isopropyl;</p> <p>R<sub>3</sub> is selected from the group consisting of <b>hydrogen</b>, methoxy, methyl, hydroxy and a halogen; and</p> <p>R<sub>4</sub> is selected from the group consisting of <b>hydrogen</b>, hydroxy, phosphoryloxy and acetoxy;</p> <p>each R<sub>5</sub> is independently selected from the group consisting of deuterium (2H) and <b>protium</b> (1H)</p> <p>1. #6 DMT (2011) "N,N-Dimethyltryptamine" Isomer Design. Retrieved from March 7, 2016. URL <a href="https://web.archive.org/web/*/http://isomerdesign.com/PiHKAL/read.php?id=6&amp;domain=tk">https://web.archive.org/web/*/http://isomerdesign.com/PiHKAL/read.php?id=6&amp;domain=tk</a></p> <p>From <b>structure:</b></p>  <p>2. Int'l Pat. App. No. WO/2015/127556 "Methods and uses for inducing or facilitating defecation in a patient in need thereof" (Published September 3, 2015)</p> <p>From <b>Claim 1:</b> A composition comprising:</p> <p>(a) a cholinesterase inhibitor;</p> <p>(b) a <b>5-HT<sub>1A</sub> receptor agonist</b>;</p> <p>(c) a 5-HT<sub>1A/7</sub> receptor agonist;</p> <p>(d) a <b>5-HT<sub>2/3</sub> receptor agonist</b>;</p> <p>(e) a beta-2 adrenergic receptor agonist; or</p> <p>(f) <b>any combination of (a) to (e),</b></p>

<p>LY314228 and 5-I-R91150.</p>	<p>From <b>Claim 6: The composition of any one of claims 1 to 5, wherein said 5-HT<sub>1A</sub> receptor agonist is:</b> (1) buspirone; (2) tandospirone; (3) cannabidiol; (4) f-15,599; (5) flesinoxan; (6) gepirone; (7) ipsapirone; (8) quetiapine; (9) <b>trazodone</b>; (10) yohimbine; (11) indole alkaloid; (12) asenapine; (13) vortioxetine; (14) ziprasidone; (15) a pharmaceutically acceptable derivative of any one of (1)-(14); or (16) any combination of (1)-(15).</p> <p>From <b>Claim 12: The composition of any one of claims 1 to 11, wherein said 5-HT<sub>2/3</sub> receptor agonist is:</b> (1) quipazine; (2) SR57227A; (3) LSD; (4) mescaline; (5) psilocin; (6) <b>DMT</b>; (7) 2C-B; (8) lorcaserin; (9) 2-methyl-5-HT; (10) BZP; (11) RS- 56812; (12) a pharmaceutically acceptable derivative of any one of (1)-(11); or (13) any combination of (1)-(12).</p> <p>3. BALSARA (2005) "Effects of the antidepressant trazodone, a 5-HT 2A/2C receptor antagonist, on dopamine-dependent behaviors in rats" Psychopharmacology. Vol. 179 (3): 597-605.</p> <p>From <b>Rationale: The antidepressant trazodone is a 5-HT 2A/2C receptor antagonist.</b></p>
<p>5. The combination product for use according to any one of claims 1-4 which further comprises a monoamine oxidase inhibitor.</p>	<p><i>From the application of interest 18/339,172 paragraph [0051]: "Preferably, the compound described by formula (I) is N,N-dimethyltryptamine, N,N-diethyltryptamine, N,N-dipropyltryptamine, N,N-diisopropyltryptamine, 5-methoxy-N,N-dimethyltryptamine, 5-methoxy-N,N-diisopropyltryptamine, 5-hydroxy-N,N-dimethyltryptamine (bufotenin), 4-phosphoryloxy-N,N-dimethyltryptamine (psilocybin), 4-hydroxy-N,N-dimethyltryptamine (psilocin), N,N-diallyltryptamine, 5-Fluoro-N,N-diallyltryptamine, 5-Chloro-N,N-diallyltryptamine, 5-Bromo-N,N-diallyltryptamine, 5-Methyl-N,N-diallyltryptamine, 5-Methoxy-N,N-diallyltryptamine, α,α,β,β-tetradeutero-5-Methoxy-dimethyltryptamine, α,α,β,β-tetradeutero-dimethyltryptamine and/or O-acetylpsilocin"</i></p> <p>4. Intl' Pat. Doc. No. WO2018148605 "COMPOSITIONS AND METHODS COMPRISING A PSILOCYBIN DERIVATIVE" Published 16 August 2018.</p> <p>From <b>Claim 1: "A composition, comprising: a first purified psilocybin derivative;</b> wherein the first purified psilocybin derivative is chosen from [3-(2-Dimethylaminoethyl)-1 H-indol-4-yl] dihydrogen phosphate, <b>4-hydroxy-N, N-dimethyltryptamine</b>, [3-(2-methylaminoethyl)-1 H-indol-4-yl] dihydrogen phosphate, 4-hydroxy-N-methyltryptamine, [3-(aminoethyl)-1 H-indol-4-yl] dihydrogen phosphate, 4-hydroxytryptamine, [3-(2-trimethylaminoethyl)-1 H-indol-4-yl] dihydrogen phosphate, and 4-hydroxy-N, N,N-trimethyltryptamine;..."</p>

	<p>From <b>Claim 82</b>: <b>A method of modulating activity at a neurotransmitter receptor comprising administering a neurotransmitter activity modulator, and administering a first dosage formulation comprising a first purified psilocybin derivative to the person in need of treatment, wherein the first dosage formulation modulates activity at a neurotransmitter receptor.</b></p> <p>From <b>Claim 86</b>: The method of claim 82, wherein the neurotransmitter receptor is chosen from a serotonin receptor, a cannabinoid receptor, <b>an adrenergic receptor</b>, a dopamine receptor, a GABAergic receptor, a glutaminergic receptor, a histaminergic receptor, a cholinergic receptor, an opioid receptor, or a glycinergic receptor.</p> <p>From <b>Claim 90</b>: <b>The method of claim 86, wherein the neurotransmitter receptor is an adrenergic receptor.</b></p> <p>From <b>Claim 91</b>: <b>The method of claim 90, wherein the neurotransmitter activity modulator is an adrenergic drug.</b></p> <p>From <b>Claim 92</b>: <b>The method of claim 91 , wherein the adrenergic drug is chosen from adrenaline, agmatine, amoxapine, aptazapine, atomoxetine, bupropion, clonidine, doxepin, duloxetine, esmirtazpine, mianserin, mirabegron, mirtazapine, norepinephrine, phentolamine, phenylephrine, piperoxan, reserpine, ritodrine, setiptiline, tesofensine, timolol, trazodone, trimipramine, or xylazine.</b></p> <p>From <b>Claim 85</b>: The method of claim 82, comprising <b>administering a monoamine oxidase inhibitor.</b></p> <p>3. BALSARA (2005) “Effects of the antidepressant trazodone, a 5-HT 2A/2C receptor antagonist, on dopamine-dependent behaviors in rats” Psychopharmacology. Vol. 179 (3): 597-605.</p> <p>From <b>Rationale</b>: <b>The antidepressant trazodone is a 5-HT 2A/2C receptor antagonist.</b></p>
<p>6. The combination product for use according to any one of claims 1-5 wherein the combination product is a composition, or the compound described by formula (I) and the 5-HT2A receptor</p>	<p><i>From the application of interest 18/339,172 paragraph [0051]: "<b>Preferably, the compound described by formula (I) is N,N-dimethyltryptamine, N,N-diethyltryptamine, N,N-dipropyltryptamine, N,N-diisopropyltryptamine, 5-methoxy-N,N-dimethyltryptamine, 5-methoxy-N,N-diisopropyltryptamine, 5-hydroxy-N,N-dimethyltryptamine (bufotenin), 4-phosphoryloxy-N,N-dimethyltryptamine (psilocybin), 4-hydroxy-N,N-dimethyltryptamine (psilocin), N,N-diallyltryptamine, 5-Fluoro-N,N-diallyltryptamine, 5-Chloro-N,N-diallyltryptamine, 5-Bromo-N,N-diallyltryptamine, 5-Methyl-N,N-diallyltryptamine, 5-Methoxy-N,N-diallyltryptamine, α,α,β,β-</b></i></p>

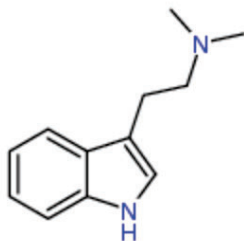
<p>antagonist are physically separated.</p>	<p><i>tetradetero-5-Methoxy-dimethyltryptamine, <math>\alpha,\alpha,\beta,\beta</math>-tetradetero-dimethyltryptamine and/or O-acetylpsilocin"</i></p> <p>4. Intl' Pat. Doc. No. WO2018148605 "COMPOSITIONS AND METHODS COMPRISING A PSILOCYBIN DERIVATIVE" Published 16 August 2018.</p> <p>From <b>Claim 1</b>: "A composition, comprising: a first purified psilocybin derivative; wherein the first purified psilocybin derivative is chosen from <b>[3-(2-Dimethylaminoethyl)-1 H-indol-4-yl] dihydrogen phosphate</b>, 4-hydroxy-N, N-dimethyltryptamine, [3-(2-methylaminoethyl)-1 H-indol-4-yl] dihydrogen phosphate, 4-hydroxy-N-methyltryptamine, [3-(aminoethyl)-1 H-indol-4-yl] dihydrogen phosphate, 4-hydroxytryptamine, [3-(2-trimethylaminoethyl)-1 H-indol-4-yl] dihydrogen phosphate, and 4-hydroxy-N, N,N-trimethyltryptamine; and</p> <p>From <b>Claim 82</b>: A method of modulating activity at a neurotransmitter receptor comprising administering a neurotransmitter activity modulator, and administering a first dosage formulation comprising a first purified psilocybin derivative to the person in need of treatment, wherein the first dosage formulation modulates activity at a neurotransmitter receptor.</p> <p>From <b>Claim 86</b>: The method of claim 82, wherein the neurotransmitter receptor is chosen from a serotonin receptor, a cannabinoid receptor, an <b>adrenergic receptor</b>, a dopamine receptor, a GABAergic receptor, a glutaminergic receptor, a histaminergic receptor, a cholinergic receptor, an opioid receptor, or a glycinergic receptor.</p> <p>From <b>Claim 90</b>: The method of claim 86, wherein the neurotransmitter receptor is an adrenergic receptor.</p> <p>From <b>Claim 91</b>: The method of claim 90, wherein the neurotransmitter activity modulator is an adrenergic drug.</p> <p>From <b>Claim 92</b>: The method of claim 91, wherein the adrenergic drug is chosen from adrenaline, agmatine, amoxapine, aptazapine, atomoxetine, bupropion, clonidine, doxepin, duloxetine, esmirtazpine, mianserin, mirabegron, mirtazapine, norepinephrine, phentolamine, phenylephrine, piperoxan, reserpine, ritodrine, setiptiline, tesofensine, timolol, <b>trazodone</b>, trimipramine, or xylazine.</p> <p>From <b>Description</b>: "In one embodiment, the methods disclosed herein comprise administering one or more active ingredients, e.g., psilocybin derivatives, cannabinoids, terpenes, neurotransmitter activity modulators,</p>
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	<p>etc., <b>in more than two doses, e.g., two or more tablets, two or more compositions, two or more formulations, etc.</b>”</p> <p>3. BALSARA (2005) “Effects of the antidepressant trazodone, a 5-HT 2A/2C receptor antagonist, on dopamine-dependent behaviors in rats” <i>Psychopharmacology</i>. Vol. 179 (3): 597-605.</p> <p>From <b>Rationale: The antidepressant trazodone is a 5-HT 2A/2C receptor antagonist.</b></p>
<p>7. The combination product for use according to any one of claims 1-5 wherein the combination product comprises:</p> <p>(a) a compound described by formula (I) and instructions on how to administer the compound described by formula (I) with a 5-HT<sub>2A</sub> receptor antagonist; or</p> <p>(b) a 5-HT<sub>2A</sub> receptor antagonist and instructions on how to administer the 5-HT<sub>2A</sub> receptor antagonist with a compound described by formula (I).</p>	<p>5. Federal Register (2017) “Requirements on Content and Format of Labeling for Human Prescription Drug and Biological Products” Federal Register. Retrieved from May 1, 2017. URL <a href="https://web.archive.org/web/20170501143753/https://www.federalregister.gov/documents/2006/01/24/06-545/requirements-on-content-and-format-of-labeling-for-human-prescription-drug-and-biological-products">https://web.archive.org/web/20170501143753/https://www.federalregister.gov/documents/2006/01/24/06-545/requirements-on-content-and-format-of-labeling-for-human-prescription-drug-and-biological-products</a></p> <p>From <b>Summary: For both new and recently approved products and older products, the final rule requires that all FDA-approved patient labeling be reprinted with or accompany the labeling.</b></p> <p>From <b>Comment 92: For example, some FDA-approved patient labeling contains risk information, and some contains only detailed instructions about how to administer a drug product.</b></p>
<p>8. The combination product for use according to any one of claims 1-7 wherein the combination product is prepared for oral, sublingual, buccal, intranasal, intravenous, intramuscular, subcutaneous, rectal, transdermal, topical and/or inhalation-mediated administration.</p>	<p><b><i>From the application of interest 18/339,172 Claim 1</i></b></p> <p><i>(i) a compound described by the following formula (I):</i></p> <p><i>wherein,</i></p> <p><i>R1 is selected from the group consisting of <b>methyl</b>, ethyl, n-propyl, allyl and isopropyl;</i></p> <p><i>R2 is selected from the group consisting of <b>methyl</b>, ethyl, n-propyl, allyl and isopropyl;</i></p> <p><i>R3 is selected from the group consisting of <b>hydrogen</b>, methoxy, methyl, hydroxy and a halogen; and</i></p> <p><i>R4 is selected from the group consisting of <b>hydrogen</b>, hydroxy, phosphoryloxy and acetoxy;</i></p>

each R5 is independently selected from the group consisting of deuterium (2H) and **protium** (H)

1. #6 DMT (2011) "N,N-Dimethyltryptamine" Isomer Design. Retrieved from March 7, 2016. URL [https://web.archive.org/web/\\*/http://isomerdesign.com/PiHKAL/read.php?id=6&domain=tk](https://web.archive.org/web/*/http://isomerdesign.com/PiHKAL/read.php?id=6&domain=tk)

From **structure**:



4. Int'l Pat. App. No. WO/2015/127556 "Methods and uses for inducing or facilitating defecation in a patient in need thereof" (Published September 3, 2015)

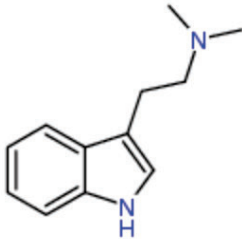
From **Claim 1**: A composition comprising:

- (a) a cholinesterase inhibitor;
- (b) a **5-HT1A receptor agonist**;
- (c) a 5-HT1A/7 receptor agonist;
- (d) a **5-HT2/3 receptor agonist**;
- (e) a beta-2 adrenergic receptor agonist; or
- (f) **any combination of (a) to (e)**,

From **Claim 6**: The composition of any one of claims 1 to 5, wherein said **5-HT1A receptor agonist** is: (1) buspirone; (2) tandospirone; (3) cannabidiol; (4) f-15,599; (5) flesinoxan; (6) gepirone; (7) ipsapirone; (8) quetiapine; (9) **trazodone**; (10) yohimbine; (11) indole alkaloid; (12) asenapine; (13) vortioxetine; (14) ziprasidone; (15) a pharmaceutically acceptable derivative of any one of (1)-(14); or (16) any combination of (1)-(15).

From **Claim 12**: The composition of any one of claims 1 to 11, wherein said **5-HT2/3 receptor agonist** is: (1) quipazine; (2) SR57227A; (3) LSD; (4) mescaline; (5) psilocin; (6) **DMT**; (7) 2C-B; (8) lorcaserin; (9) 2-methyl-5-HT; (10) BZP; (11) RS- 56812; (12) a pharmaceutically acceptable derivative of any one of (1)-(11); or (13) any combination of (1)-(12).

From **Description**: In some embodiments, the compositions described herein may be for administration by a route which is: oral; parenteral; or sublingual

	<p>3. BALSARA (2005) "Effects of the antidepressant trazodone, a 5-HT 2A/2C receptor antagonist, on dopamine-dependent behaviors in rats" Psychopharmacology. Vol. 179 (3): 597-605.</p> <p>From <b>Rationale: The antidepressant trazodone is a 5-HT 2A/2C receptor antagonist.</b></p>
<p>9. The combination product according to anyone of claims 2-8 for use in the treatment and/or prevention of a disorder selected from the group consisting of acquired brain injury, ataxia, brain tumor, dementia, dystonia, epilepsy, functional and dissociative neurological symptoms, meningitis, motor neuron disease, multiple sclerosis, muscular dystrophy, myalgic encephalomyelitis, Parkinson's disease, progressive supranuclear palsy, Huntington's disease, Alzheimer's disease, fronto-temporal dementia, vascular dementia, cognitive decline associated with aging, spina bifida, hydrocephalus, spinal injury, stroke, Tourette syndrome, transverse myelitis, panic disorder, agoraphobia, social anxiety disorder, phobias, post-traumatic stress disorder, obsessive compulsive disorder, generalized</p>	<p><b>From the application of interest 18/339,172 Claim 1</b></p> <p><i>(i) a compound described by the following formula (I):</i></p> <p><i>wherein,</i></p> <p><i>R1 is selected from the group consisting of <b>methyl</b>, ethyl, n-propyl, allyl and isopropyl;</i></p> <p><i>R2 is selected from the group consisting of <b>methyl</b>, ethyl, n-propyl, allyl and isopropyl;</i></p> <p><i>R3 is selected from the group consisting of <b>hydrogen</b>, methoxy, methyl, hydroxy and a halogen; and</i></p> <p><i>R4 is selected from the group consisting of <b>hydrogen</b>, hydroxy, phosphoryloxy and acetoxy;</i></p> <p><i>each R5 is independently selected from the group consisting of deuterium (2H) and <b>protium</b> (H)</i></p> <p>1. #6 DMT (2011) "N,N-Dimethyltryptamine" Isomer Design. Retrieved from March 7, 2016. URL <a href="https://web.archive.org/web/*/http://isomerdesign.com/PiHKAL/read.php?id=6&amp;domain=tk">https://web.archive.org/web/*/http://isomerdesign.com/PiHKAL/read.php?id=6&amp;domain=tk</a></p> <p>From <b>structure:</b></p>  <p>4. Int'l Pat. App. No. WO/2015/127556 "Methods and uses for inducing or facilitating defecation in a patient in need thereof" (Published September 3, 2015)</p> <p>From <b>Claim 1:</b> A composition comprising: (a) a cholinesterase inhibitor;</p>

<p>anxiety disorder, bipolar disorder, depression, anorexia nervosa, binge eating disorder, bulimia nervosa, psychosis, schizophrenia, substance addiction and personality disorders.</p>	<p>(b) a <b>5-HT1A receptor agonist</b>;  (c) a 5-HT1A/7 receptor agonist;  (d) a <b>5-HT2/3 receptor agonist</b>;  (e) a beta-2 adrenergic receptor agonist; or  (f) <b>any combination of (a) to (e)</b>,</p> <p>From <b>Claim 6: The composition of any one of claims 1 to 5, wherein said 5-HT1A receptor agonist is:</b> (1) buspirone; (2) tandospirone; (3) cannabidiol; (4) f-15,599; (5) flesinoxan; (6) gepirone; (7) ipsapirone; (8) quetiapine; (9) <b>trazodone</b>; (10) yohimbine; (11) indole alkaloid; (12) asenapine; (13) vortioxetine; (14) ziprasidone; (15) a pharmaceutically acceptable derivative of any one of (1)-(14); or (16) any combination of (1)-(15).</p> <p>From <b>Claim 12: The composition of any one of claims 1 to 11, wherein said 5-HT2/3 receptor agonist is:</b> (1) quipazine; (2) SR57227A; (3) LSD; (4) mescaline; (5) psilocin; (6) <b>DMT</b>; (7) 2C-B; (8) lorcaserin; (9) 2-methyl-5-HT; (10) BZP; (11) RS- 56812; (12) a pharmaceutically acceptable derivative of any one of (1)-(11); or (13) any combination of (1)-(12).</p> <p>From <b>Description: In some aspects, the present description relates to the use of a combination of one or more agent, wherein the agent is: a 5-HT1A receptor agonist, a 5-HT1A/7 receptor agonist, a 5HT2/3 receptor agonist, a beta-2 adrenergic receptor agonist, a cholinesterase inhibitor, or a NK2 receptor agonist, and a further therapeutic agent indicated for the treatment of spinal cord injuries of traumatic (car accident) or non-traumatic origin (e.g., multiple sclerosis or Parkinson’s disease) for inducing or facilitating defecation in a patient in need thereof.</b></p> <p>4. Intl’ Pat. Doc. No. WO2018148605 “COMPOSITIONS AND METHODS COMPRISING A PSILOCYBIN DERIVATIVE” Published 16 August 2018.</p> <p>From <b>Claim 1: “A composition, comprising: a first purified psilocybin derivative</b>; wherein the first purified psilocybin derivative is chosen from <b>[3-(2-Dimethylaminoethyl)-1 H-indol-4-yl] dihydrogen phosphate</b>, 4-hydroxy-N, N-dimethyltryptamine, [3-(2-methylaminoethyl)-1 H-indol-4-yl] dihydrogen phosphate, 4-hydroxy-N-methyltryptamine, [3-(aminoethyl)-1 H-indol-4-yl] dihydrogen phosphate, 4-hydroxytryptamine, [3-(2-trimethylaminoethyl)-1 H-indol-4-yl] dihydrogen phosphate, and 4-hydroxy-N, N,N-trimethyltryptamine; and</p> <p>From <b>Claim 82: A method of modulating activity at a neurotransmitter receptor comprising administering a neurotransmitter activity modulator, and administering a first dosage formulation comprising a first purified psilocybin derivative to the person in need of treatment,</b></p>
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	<p><b>wherein the first dosage formulation modulates activity at a neurotransmitter receptor.</b></p> <p>From <b>Claim 86</b>: The method of claim 82, wherein the neurotransmitter receptor is chosen from a serotonin receptor, a cannabinoid receptor, <b>an adrenergic receptor</b>, a dopamine receptor, a GABAergic receptor, a glutaminergic receptor, a histaminergic receptor, a cholinergic receptor, an opioid receptor, or a glycinergic receptor.</p> <p>From <b>Claim 90</b>: <b>The method of claim 86, wherein the neurotransmitter receptor is an adrenergic receptor.</b></p> <p>From <b>Claim 91</b>: <b>The method of claim 90, wherein the neurotransmitter activity modulator is an adrenergic drug.</b></p> <p>From <b>Claim 92</b>: <b>The method of claim 91 , wherein the adrenergic drug is</b> chosen from adrenaline, agmatine, amoxapine, aptazapine, atomoxetine, bupropion, clonidine, doxepin, duloxetine, esmirtazpine, mianserin, mirabegron, mirtazapine, norepinephrine, phentolamine, phenylephrine, piperoxan, reserpine, ritodrine, setiptiline, tesofensine, timolol, <b>trazodone</b>, trimipramine, or xylazine.</p> <p>From <b>Description</b>: <b>The compositions disclosed herein are useful for the treatment of compulsive disorders in humans, a variety of intractable psychiatric disorders, chronic depression</b>, post-traumatic stress disorder, and drug or alcohol dependency. The compositions disclosed herein are also useful within the context of meditative, spiritual, and religious practices within a variety of contexts.</p> <p>3. BALSARA (2005) “Effects of the antidepressant trazodone, a 5-HT 2A/2C receptor antagonist, on dopamine-dependent behaviors in rats” Psychopharmacology. Vol. 179 (3): 597-605.</p> <p>From <b>Rationale</b>: <b>The antidepressant trazodone is a 5-HT 2A/2C receptor antagonist.</b></p>
<p>10. The combination product for use according to claim 9, wherein the disorder is Parkinson's disease and/or Alzheimer's disease, preferably Parkinson's disease.</p>	<p><b><i>From the application of interest 18/339,172 Claim 1</i></b></p> <p><i>(i) a compound described by the following formula (I):</i></p> <p><i>wherein,</i></p> <p><i>R1 is selected from the group consisting of methyl, ethyl, n-propyl, allyl and isopropyl;</i></p> <p><i>R2 is selected from the group consisting of methyl, ethyl, n-propyl, allyl and isopropyl;</i></p>

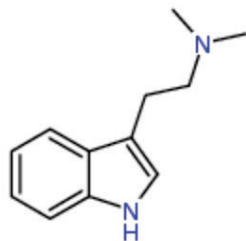
*R3 is selected from the group consisting of **hydrogen**, methoxy, methyl, hydroxy and a halogen; and*

*R4 is selected from the group consisting of **hydrogen**, hydroxy, phosphoryloxy and acetoxy;*

*each R5 is independently selected from the group consisting of deuterium (2H) and **protium** (H)*

1. #6 DMT (2011) "N,N-Dimethyltryptamine" Isomer Design. Retrieved from March 7, 2016. URL [https://web.archive.org/web/\\*/http://isomerdesign.com/PiHKAL/read.php?id=6&domain=tk](https://web.archive.org/web/*/http://isomerdesign.com/PiHKAL/read.php?id=6&domain=tk)

From **structure**:



4. Int'l Pat. App. No. WO/2015/127556 "Methods and uses for inducing or facilitating defecation in a patient in need thereof" (Published September 3, 2015)

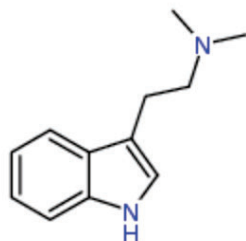
From **Claim 1**: A composition comprising:

- (a) a cholinesterase inhibitor;
- (b) a **5-HT1A receptor agonist**;
- (c) a 5-HT1A/7 receptor agonist;
- (d) a **5-HT2/3 receptor agonist**;
- (e) a beta-2 adrenergic receptor agonist; or
- (f) **any combination of (a) to (e)**,

From **Claim 6**: **The composition of any one of claims 1 to 5, wherein said 5-HT1A receptor agonist is:** (1) buspirone; (2) tandospirone; (3) cannabidiol; (4) f-15,599; (5) flesinoxan; (6) gepirone; (7) ipsapirone; (8) quetiapine; (9) **trazodone**; (10) yohimbine; (11) indole alkaloid; (12) asenapine; (13) vortioxetine; (14) ziprasidone; (15) a pharmaceutically acceptable derivative of any one of (1)-(14); or (16) any combination of (1)-(15).

From **Claim 12**: **The composition of any one of claims 1 to 11, wherein said 5-HT2/3 receptor agonist is:** (1) quipazine; (2) SR57227A; (3) LSD; (4) mescaline; (5) psilocin; (6) **DMT**; (7) 2C-B; (8) lorcaserin; (9) 2-methyl-

	<p>5-HT; (10) BZP; (11) RS- 56812; (12) a pharmaceutically acceptable derivative of any one of (1)-(11); or (13) any combination of (1)-(12).</p> <p>From <b>Description</b>: In some aspects, the present description relates to the use of a combination of one or more agent, wherein the agent is: a 5-HT1A receptor agonist, a 5-HT1A/7 receptor agonist, a 5HT2/3 receptor agonist, a beta-2 adrenergic receptor agonist, a cholinesterase inhibitor, or a NK2 receptor agonist, and a further therapeutic agent indicated for the treatment of spinal cord injuries of traumatic (car accident) or non-traumatic origin (e.g., multiple sclerosis or Parkinson's disease) for inducing or facilitating defecation in a patient in need thereof.</p> <p>3. BALSARA (2005) "Effects of the antidepressant trazodone, a 5-HT 2A/2C receptor antagonist, on dopamine-dependent behaviors in rats" Psychopharmacology. Vol. 179 (3): 597-605.</p> <p>From <b>Rationale</b>: The antidepressant trazodone is a 5-HT 2A/2C receptor antagonist.</p>
<p>11. A kit for use in the treatment and/or prevention of psychiatric and/or neurological disorders comprising the combination product according to any one of claims 1-7.</p>	<p><b><i>From the application of interest 18/339,172 Claim 1</i></b></p> <p><i>(i) a compound described by the following formula (I):</i></p> <p><i>wherein,</i></p> <p><i>R1 is selected from the group consisting of methyl, ethyl, n-propyl, allyl and isopropyl;</i></p> <p><i>R2 is selected from the group consisting of methyl, ethyl, n-propyl, allyl and isopropyl;</i></p> <p><i>R3 is selected from the group consisting of hydrogen, methoxy, methyl, hydroxy and a halogen; and</i></p> <p><i>R4 is selected from the group consisting of hydrogen, hydroxy, phosphoryloxy and acetoxy;</i></p> <p><i>each R5 is independently selected from the group consisting of deuterium (2H) and protium (1H)</i></p> <p>1. #6 DMT (2011) "N,N-Dimethyltryptamine" Isomer Design. Retrieved from March 7, 2016. URL <a href="https://web.archive.org/web/*/http://isomerdesign.com/PiHKAL/read.php?id=6&amp;domain=tk">https://web.archive.org/web/*/http://isomerdesign.com/PiHKAL/read.php?id=6&amp;domain=tk</a></p> <p>From <b>structure</b>:</p>



4. Int'l Pat. App. No. WO/2015/127556 "Methods and uses for inducing or facilitating defecation in a patient in need thereof" (Published September 3, 2015)

From **Claim 1**: A composition comprising:

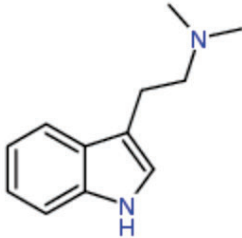
- (a) a cholinesterase inhibitor;
- (b) a **5-HT1A receptor agonist**;
- (c) a 5-HT1A/7 receptor agonist;
- (d) a **5-HT2/3 receptor agonist**;
- (e) a beta-2 adrenergic receptor agonist; or
- (f) **any combination of (a) to (e)**,

From **Claim 6**: **The composition of any one of claims 1 to 5, wherein said 5-HT1A receptor agonist is:** (1) buspirone; (2) tandospirone; (3) cannabidiol; (4) f-15,599; (5) flesinoxan; (6) gepirone; (7) ipsapirone; (8) quetiapine; (9) **trazodone**; (10) yohimbine; (11) indole alkaloid; (12) asenapine; (13) vortioxetine; (14) ziprasidone; (15) a pharmaceutically acceptable derivative of any one of (1)-(14); or (16) any combination of (1)-(15).

From **Claim 12**: **The composition of any one of claims 1 to 11, wherein said 5-HT2/3 receptor agonist is:** (1) quipazine; (2) SR57227A; (3) LSD; (4) mescaline; (5) psilocin; (6) **DMT**; (7) 2C-B; (8) lorcaserin; (9) 2-methyl-5-HT; (10) BZP; (11) RS- 56812; (12) a pharmaceutically acceptable derivative of any one of (1)-(11); or (13) any combination of (1)-(12).

From **Description**: **In some aspects, the present description relates to the use of a combination of one or more agent, wherein the agent is: a 5-HT1A receptor agonist, a 5-HT1A/7 receptor agonist, a 5HT2/3 receptor agonist, a beta-2 adrenergic receptor agonist, a cholinesterase inhibitor, or a NK2 receptor agonist, and a further therapeutic agent indicated for the treatment of spinal cord injuries of traumatic (car accident) or non-traumatic origin (e.g., multiple sclerosis or Parkinson's Disease) for inducing or facilitating defecation in a patient in need thereof.**

From **Description**: **In some aspects, the present description relates to a kit comprising the composition as defined herein; and a suitable container.**

	<p>3. BALSARA (2005) "Effects of the antidepressant trazodone, a 5-HT 2A/2C receptor antagonist, on dopamine-dependent behaviors in rats" <i>Psychopharmacology</i>. Vol. 179 (3): 597-605.</p> <p>From <b>Rationale: The antidepressant trazodone is a 5-HT 2A/2C receptor antagonist.</b></p>
<p>12. The combination product for use according to any one of claims 1-10, wherein the 5-HT<sub>2A</sub> receptor antagonist alleviates or eliminates the hallucinogenic and/or psychedelic side effects caused by the compound described by formula (I)</p>	<p><b><i>From the application of interest 18/339,172 Claim 1</i></b></p> <p><i>(i) a compound described by the following formula (I):</i></p> <p><i>wherein,</i></p> <p><i>R1 is selected from the group consisting of <b>methyl</b>, ethyl, n-propyl, allyl and isopropyl;</i></p> <p><i>R2 is selected from the group consisting of <b>methyl</b>, ethyl, n-propyl, allyl and isopropyl;</i></p> <p><i>R3 is selected from the group consisting of <b>hydrogen</b>, methoxy, methyl, hydroxy and a halogen;</i></p> <p><i>R4 is selected from the group consisting of <b>hydrogen</b>, hydroxy, phosphoryloxy and acetoxy;</i></p> <p><i>each R5 is independently selected from the group consisting of deuterium (2H) and <b>protium</b> (H)</i></p> <p>1. #6 DMT (2011) "N,N-Dimethyltryptamine" Isomer Design. Retrieved from March 7, 2016. URL <a href="https://web.archive.org/web/*/http://isomerdesign.com/PiHKAL/read.php?id=6&amp;domain=tk">https://web.archive.org/web/*/http://isomerdesign.com/PiHKAL/read.php?id=6&amp;domain=tk</a></p> <p>From <b>structure:</b></p>  <p>4. Int'l Pat. App. No. WO/2015/127556 "Methods and uses for inducing or facilitating defecation in a patient in need thereof" (Published September 3, 2015)</p> <p>From <b>Claim 1:</b> A composition comprising:</p> <p>(a) a cholinesterase inhibitor;</p> <p>(b) a <b>5-HT<sub>1A</sub> receptor agonist</b>;</p> <p>(c) a 5-HT<sub>1A/7</sub> receptor agonist;</p>

	<p>(d) a <b>5-HT<sub>2/3</sub> receptor agonist</b>;  (e) a beta-2 adrenergic receptor agonist; or  (f) <b>any combination of (a) to (e)</b>,</p> <p>From <b>Claim 6: The composition of any one of claims 1 to 5, wherein said 5-HT<sub>1A</sub> receptor agonist is:</b> (1) buspirone; (2) tandospirone; (3) cannabidiol; (4) f-15,599; (5) flesinoxan; (6) gepirone; (7) ipsapirone; (8) quetiapine; (9) <b>trazodone</b>; (10) yohimbine; (11) indole alkaloid; (12) asenapine; (13) vortioxetine; (14) ziprasidone; (15) a pharmaceutically acceptable derivative of any one of (1)-(14); or (16) any combination of (1)-(15).</p> <p>From <b>Claim 12: The composition of any one of claims 1 to 11 , wherein said 5-HT<sub>2/3</sub> receptor agonist is:</b> (1) quipazine; (2) SR57227A; (3) LSD; (4) mescaline; (5) psilocin; (6) <b>DMT</b>; (7) 2C-B; (8) lorcaserin; (9) 2-methyl-5-HT; (10) BZP; (11) RS- 56812; (12) a pharmaceutically acceptable derivative of any one of (1)-(11); or (13) any combination of (1)-(12).</p> <p>3. BALSARA (2005) “Effects of the antidepressant trazodone, a 5-HT 2A/2C receptor antagonist, on dopamine-dependent behaviors in rats” <i>Psychopharmacology</i>. Vol. 179 (3): 597-605.</p> <p>From <b>Rationale: The antidepressant trazodone is a 5-HT 2A/2C receptor antagonist.</b></p> <p>6. BONSON (1996) “Chronic administration of serotonergic antidepressants attenuates the subjective effects of LSD in humans” <i>Neuropsychopharmacology</i>. Vol. 14 (6): 425-436.</p> <p>From <b>Abstract: Twenty-eight out of 32 subjects (88%) who had taken an antidepressant with inhibitory effects on serotonin (5-HT) reuptake (fluoxetine, paroxetine, sertraline, trazodone) for over 3 weeks had a subjective decrease or virtual elimination of their responses to LSD.</b></p> <p>7. NICHOLS (2016) “Psychedelics” <i>Pharmacological Reviews</i>. Vol. 68 (2): 265-355.</p> <p>From <b>Abstract:</b> After the virtually contemporaneous discovery of (5R,8R)-(+)-lysergic acid-N,N-diethylamide (LSD)-25 and the identification of serotonin in the brain, early research focused intensively on the possibility that <b>LSD and other psychedelics</b> had a serotonergic basis for their action.</p>
13. The combination product for use	<p><i>From the application of interest 18/339,172 paragraph [0051]: "Preferably, the compound described by formula (I) is N,N-dimethyltryptamine, N,N-</i></p>

according to any one of claims 1-10 and 12, wherein the compound described by formula (I) stimulates the proliferation, migration and/or differentiation of neural stem cells.

*diethyltryptamine, N,N-dipropyltryptamine, N,N-diisopropyltryptamine, 5-methoxy-N,N-dimethyltryptamine, 5-methoxy-N,N-diisopropyltryptamine, 5-hydroxy-N,N-dimethyltryptamine (bufotenin), 4-phosphoryloxy-N,N-dimethyltryptamine (psilocybin), 4-hydroxy-N,N-dimethyltryptamine (psilocin), N,N-diallyltryptamine, 5-Fluoro-N,N-diallyltryptamine, 5-Chloro-N,N-diallyltryptamine, 5-Bromo-N,N-diallyltryptamine, 5-Methyl-N,N-diallyltryptamine, 5-Methoxy-N,N-diallyltryptamine,  $\alpha,\alpha,\beta,\beta$ -tetra deutero-5-Methoxy-dimethyltryptamine,  $\alpha,\alpha,\beta,\beta$ -tetra deutero-dimethyltryptamine and/or O-acetylpsilocin"*

4. Intl' Pat. Doc. No. WO2018148605 "COMPOSITIONS AND METHODS COMPRISING A PSILOCYBIN DERIVATIVE" Published 16 August 2018.

From **Claim 1**: "A composition, comprising: a first purified psilocybin derivative; wherein the first purified psilocybin derivative is chosen from **[3-(2-Dimethylaminoethyl)-1 H-indol-4-yl] dihydrogen phosphate, 4-hydroxy-N, N-dimethyltryptamine, [3-(2-methylaminoethyl)-1 H-indol-4-yl] dihydrogen phosphate, 4-hydroxy-N-methyltryptamine, [3-(aminoethyl)-1 H-indol-4-yl] dihydrogen phosphate, 4-hydroxytryptamine, [3-(2-trimethylaminoethyl)-1 H-indol-4-yl] dihydrogen phosphate, and 4-hydroxy-N, N,N-trimethyltryptamine; and**

From **Claim 82**: **A method of modulating activity at a neurotransmitter receptor comprising administering a neurotransmitter activity modulator, and administering a first dosage formulation comprising a first purified psilocybin derivative to the person in need of treatment, wherein the first dosage formulation modulates activity at a neurotransmitter receptor.**

From **Claim 86**: The method of claim 82, wherein the neurotransmitter receptor is chosen from a serotonin receptor, a cannabinoid receptor, **an adrenergic receptor**, a dopamine receptor, a GABAergic receptor, a glutaminergic receptor, a histaminergic receptor, a cholinergic receptor, an opioid receptor, or a glycinergic receptor.

From **Claim 90**: **The method of claim 86, wherein the neurotransmitter receptor is an adrenergic receptor.**

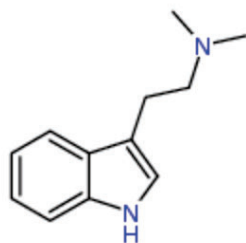
From **Claim 91**: **The method of claim 90, wherein the neurotransmitter activity modulator is an adrenergic drug.**

From **Claim 92**: **The method of claim 91 , wherein the adrenergic drug is chosen from adrenaline, agmatine, amoxapine, aptazapine, atomoxetine, bupropion, clonidine, doxepin, duloxetine, esmirtazpine, mianserin, mirabegron, mirtazapine, norepinephrine, phentolamine, phenylephrine,**

	<p>piperoxan, reserpine, ritodrine, setiptiline, tesofensine, timolol, <b>trazodone</b>, trimipramine, or xylazine.</p> <p>3. BALSARA (2005) "Effects of the antidepressant trazodone, a 5-HT 2A/2C receptor antagonist, on dopamine-dependent behaviors in rats" <i>Psychopharmacology</i>. Vol. 179 (3): 597-605.</p> <p><b>From Rationale: The antidepressant trazodone is a 5-HT 2A/2C receptor antagonist.</b></p> <p>8. CATLOW (2013) "Effects of psilocybin on hippocampal neurogenesis and extinction of trace fear conditioning" <i>Experimental Brain Research</i>. Vol. 228 (4), 481-491.</p> <p><b>From Abstract: "The primary objective is to determine the extent to which psilocybin (PSOP) modulates neurogenesis and thereby affects acquisition and extinction of HPC-dependent trace fear conditioning."</b></p> <p><b>From Discussion: "The data reported demonstrate that the administration of PSOP produced a biphasic response in hippocampal neurogenesis; a low dose (0.1 mg/kg) resulted in a trend toward increased neurogenesis..."</b></p>
<p>14. The combination product for use according to any one of claims 1-10 and 12-13, wherein the combination product is administered at least two times, preferably more than two times.</p>	<p><b><i>From the application of interest 18/339,172 Claim 1</i></b></p> <p><i>(i) a compound described by the following formula (I):</i></p> <p><i>wherein,</i></p> <p><i>R1 is selected from the group consisting of <b>methyl</b>, ethyl, n-propyl, allyl and isopropyl;</i></p> <p><i>R2 is selected from the group consisting of <b>methyl</b>, ethyl, n-propyl, allyl and isopropyl;</i></p> <p><i>R3 is selected from the group consisting of <b>hydrogen</b>, methoxy, methyl, hydroxy and a halogen; and</i></p> <p><i>R4 is selected from the group consisting of <b>hydrogen</b>, hydroxy, phosphoryloxy and acetoxy;</i></p> <p><i>each R5 is independently selected from the group consisting of deuterium (2H) and <b>protium</b> (1H)</i></p> <p>1. #6 DMT (2011) "N,N-Dimethyltryptamine" Isomer Design. Retrieved from March 7, 2016. URL</p>

[https://web.archive.org/web/\\*/http://isomerdesign.com/PiHKAL/read.php?id=6&domain=tk](https://web.archive.org/web/*/http://isomerdesign.com/PiHKAL/read.php?id=6&domain=tk)

From **structure**:



4. Int'l Pat. App. No. WO/2015/127556 "Methods and uses for inducing or facilitating defecation in a patient in need thereof" (Published September 3, 2015)

From **Claim 1**: A composition comprising:

- (a) a cholinesterase inhibitor;
- (b) a **5-HT1A receptor agonist**;
- (c) a 5-HT1A/7 receptor agonist;
- (d) a **5-HT2/3 receptor agonist**;
- (e) a beta-2 adrenergic receptor agonist; or
- (f) **any combination of (a) to (e)**,

From **Claim 6**: **The composition of any one of claims 1 to 5, wherein said 5-HT1A receptor agonist is:** (1) buspirone; (2) tandospirone; (3) cannabidiol; (4) f-15,599; (5) flesinoxan; (6) gepirone; (7) ipsapirone; (8) quetiapine; (9) **trazodone**; (10) yohimbine; (11) indole alkaloid; (12) asenapine; (13) vortioxetine; (14) ziprasidone; (15) a pharmaceutically acceptable derivative of any one of (1)-(14); or (16) any combination of (1)-(15).

From **Claim 12**: **The composition of any one of claims 1 to 11, wherein said 5-HT2/3 receptor agonist is:** (1) quipazine; (2) SR57227A; (3) LSD; (4) mescaline; (5) psilocin; (6) **DMT**; (7) 2C-B; (8) lorcaserin; (9) 2-methyl-5-HT; (10) BZP; (11) RS- 56812; (12) a pharmaceutically acceptable derivative of any one of (1)-(11); or (13) any combination of (1)-(12).

From **Description**: **The desired dose may conveniently be presented in a single dose or as divided dose administered at appropriate intervals, for example as two, three, four or more doses per day (e.g., one or more unitary doses).**

3. BALSARA (2005) "Effects of the antidepressant trazodone, a 5-HT 2A/2C receptor antagonist, on dopamine-dependent behaviors in rats" *Psychopharmacology*. Vol. 179 (3): 597-605.

	<p>From <b>Rationale: The antidepressant trazodone is a 5-HT 2A/2C receptor antagonist.</b></p>
<p>15. The combination product for use according to any one of claims 1-10 and 12-14, wherein the compound described by formula (I) exerts a neuroprotective and anti-inflammatory effect thereby preventing neural cell degeneration, neural cell death and/or inflammatory responses associated with neural cell degeneration and/or death.</p>	<p><i>From the application of interest 18/339,172 paragraph [0051]: "Preferably, the compound described by formula (I) is N,N-dimethyltryptamine, N,N-diethyltryptamine, N,N-dipropyltryptamine, N,N-diisopropyltryptamine, 5-methoxy-N,N-dimethyltryptamine, 5-methoxy-N,N-diisopropyltryptamine, 5-hydroxy-N,N-dimethyltryptamine (bufotenin), 4-phosphoryloxy-N,N-dimethyltryptamine (psilocybin), 4-hydroxy-N,N-dimethyltryptamine (psilocin), N,N-diallyltryptamine, 5-Fluoro-N,N-diallyltryptamine, 5-Chloro-N,N-diallyltryptamine, 5-Bromo-N,N-diallyltryptamine, 5-Methyl-N,N-diallyltryptamine, 5-Methoxy-N,N-diallyltryptamine, <math>\alpha,\alpha,\beta,\beta</math>-tetradeutero-5-Methoxy-dimethyltryptamine, <math>\alpha,\alpha,\beta,\beta</math>-tetradeutero-dimethyltryptamine and/or O-acetylpsilocin"</i></p> <p>4. Intl' Pat. Doc. No. WO2018148605 "COMPOSITIONS AND METHODS COMPRISING A PSILOCYBIN DERIVATIVE" Published 16 August 2018.</p> <p>From <b>Claim 1</b>: "A composition, comprising: a first purified psilocybin derivative; wherein the first purified psilocybin derivative is chosen from [3-(2-Dimethylaminoethyl)-1 H-indol-4-yl] dihydrogen phosphate, 4-hydroxy-N, N-dimethyltryptamine, [3-(2-methylaminoethyl)-1 H-indol-4-yl] dihydrogen phosphate, 4-hydroxy-N-methyltryptamine, [3-(aminoethyl)-1 H-indol-4-yl] dihydrogen phosphate, 4-hydroxytryptamine, [3-(2-trimethylaminoethyl)-1 H-indol-4-yl] dihydrogen phosphate, and 4-hydroxy-N, N,N-trimethyltryptamine; and</p> <p>From <b>Claim 82</b>: A method of modulating activity at a neurotransmitter receptor comprising administering a neurotransmitter activity modulator, and administering a first dosage formulation comprising a first purified psilocybin derivative to the person in need of treatment, wherein the first dosage formulation modulates activity at a neurotransmitter receptor.</p> <p>From <b>Claim 86</b>: The method of claim 82, wherein the neurotransmitter receptor is chosen from a serotonin receptor, a cannabinoid receptor, an adrenergic receptor, a dopamine receptor, a GABAergic receptor, a glutaminergic receptor, a histaminergic receptor, a cholinergic receptor, an opioid receptor, or a glycinergic receptor.</p> <p>From <b>Claim 90</b>: The method of claim 86, wherein the neurotransmitter receptor is an adrenergic receptor.</p>

From **Claim 91**: **The method of claim 90, wherein the neurotransmitter activity modulator is an adrenergic drug.**

From **Claim 92**: **The method of claim 91 , wherein the adrenergic drug is chosen from adrenaline, agmatine, amoxapine, aptazapine, atomoxetine, bupropion, clonidine, doxepin, duloxetine, esmirtazpine, mianserin, mirabegron, mirtazapine, norepinephrine, phentolamine, phenylephrine, piperoxan, reserpine, ritodrine, setiptiline, tesofensine, timolol, trazodone, trimipramine, or xylazine.**

3. BALSARA (2005) “Effects of the antidepressant trazodone, a 5-HT 2A/2C receptor antagonist, on dopamine-dependent behaviors in rats” *Psychopharmacology*. Vol. 179 (3): 597-605.

From **Rationale**: **The antidepressant trazodone is a 5-HT 2A/2C receptor antagonist.**

9. FLANAGAN (2018) “Psychedelics as anti-inflammatory agents” *International Review of Psychiatry*. Volume 30, Issue 4, pages 363-375. Published 13 August 2018.

From **Introduction**: “It is now recognized that **inflammation plays a significant role in the pathophysiology underlying psychiatric disorders like depression and addiction** (Furtado & Katzman, Citation2015; Hong, Kim, & Im, Citation2016; Radtke, Chapman, Hall, & Syed, Citation2017).”

From **Abstract**: “Serotonin (5-hydroxytryptamine, 5-HT)2A receptor agonists have recently emerged as promising new treatment options for a variety of disorders. **The recent success of these agonists, also known as psychedelics, like psilocybin for the treatment of anxiety, depression, obsessive-compulsive disorder (OCD), and addiction**, has ushered in a renaissance in the way these compounds are perceived in the medical community and populace at large.”

From **Introduction**: “We have previously speculated that **the anti-inflammatory effects of psychedelics mediated through serotonin 5-HT2A receptor activation are a key component of not only the antidepressant effects of psilocybin**, but also contribute to its long-lasting effects after only a single treatment (Kyzar, Nichols, Gainetdinov, Nichols, & Kalueff, Citation2017).”

10. BACHIS (2009) “Chronic Unpredictable Stress Promotes Neuronal Apoptosis in the Cerebral Cortex” *Neuroscience Letters*. Vol. 442 (2): 104-108.

	<p>From Abstract: <b>Thus, cortical neuronal apoptosis should be added to a list of events that have been proposed to explain loss of neuronal function and viability seen in depressive disorders.</b> DMI reduced significantly the effect of CMS, supporting <b>the hypothesis that antidepressants could oppose the stress-induced loss of neuronal network by increasing neuronal survival.</b></p>
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## ELECTRONIC ACKNOWLEDGEMENT RECEIPT

APPLICATION #	RECEIPT DATE / TIME	ATTORNEY DOCKET #
<b>18/339,172</b>	<b>03/19/2024 10:37:29 AM Z ET</b>	

### Title of Invention

### Application Information

APPLICATION TYPE	PATENT #
CONFIRMATION #	FILED BY Jeremy Rolquin
PATENT CENTER # 64738575	FILING DATE 06/21/2023
CUSTOMER # -	FIRST NAMED INVENTOR
CORRESPONDENCE ADDRESS -	AUTHORIZED BY -

### Documents

**TOTAL DOCUMENTS: 23**

DOCUMENT	PAGES	DESCRIPTION	SIZE (KB)
Third-party-notification-request.pdf	1	Request for Notification of Non-compliant Third-Party Submission	13 KB
third-party-preissuance-submission.pdf	1	Third-Party Submission Under 37 CFR 1.290	2 KB
Concise-description-generated.pdf	1	Concise Description of Relevance	2 KB
Terran 3PS Embedded.pdf	27	-	405 KB
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5_Federal Register.pdf		98	-	645 KB
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## Digest

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7_Nichols.pdf	1DC89CE97120FD1DED90088603ECF59C00F983F943981AF38 BAF94A27C2F39A8BD6CCC409435922F4DC6E21D59FD80487 6648EA4BD7DA630BCB69E418DBBEFE5
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If a new application is being filed and the application includes the necessary components for filing date (see 37 CFR 1.53(b)-(d) and MPEP 506), a Filing Receipt (37 CFR 1.54) will be issued in due course and the date shown on this Acknowledgement Receipt will establish the filing date of the application

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

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

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If a new international application is being filed and the international application includes the necessary components for an international filing date (see PCT Article 11 and MPEP 1810), a Notification of the International Application Number and of the International Filing Date (Form PCT/RO/105) will be issued in due course, subject to prescriptions concerning national security, and the date shown on this Acknowledgement Receipt will establish the international filing date of the application.



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## ELECTRONIC PAYMENT RECEIPT

APPLICATION #	RECEIPT DATE / TIME	ATTORNEY DOCKET #
<b>18/339,172</b>	<b>03/19/2024 10:37:29 AM Z ET</b>	

### Title of Invention

### Application Information

APPLICATION TYPE	PATENT #
CONFIRMATION #	FILED BY Jeremy Rolquin
PATENT CENTER # 64738575	AUTHORIZED BY -
CUSTOMER # -	FILING DATE 06/21/2023
CORRESPONDENCE ADDRESS -	FIRST NAMED INVENTOR

### Payment Information

PAYMENT METHOD	PAYMENT TRANSACTION ID	PAYMENT AUTHORIZED BY
<b>CARD / 6701</b>	<b>E20243IA38267303</b>	<b>Jeremy Rolquin</b>

FEE CODE	DESCRIPTION	ITEM PRICE(\$)	QUANTITY	ITEM TOTAL(\$)
2818	DOCUMENT FEE FOR THIRD-PARTY SUBMISSIONS (SEE 37 CFR 1.290(F))	72.00	1	72.00
			<b>TOTAL AMOUNT:</b>	<b>\$72.00</b>

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