

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

In re Application of: Anand; Nitin Confirmation No.: 4176  
Serial No.: 18/045,843 Group No.:  
Filing or 371(c) Date: October 12, 2022 Examiner:  
Entitled: Methods of Treatment with Combinations of Cannabidiol and Psilocybin

**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. Int'l Pat. App. No. WO/2022/115796 (Compositions and Methods for Treating Neurological Conditions) (Published June 2, 2022)
2. Int'l Pat. App. No. WO/2021/072530 (Controlled Release Formulations of Psilocybe-Derived Agents and Method for their Use, and Methods and Compositions for Treating Mild Traumatic Brain Injury with Post Traumatic Stress Disorder) (Published April 22, 2021)

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. 18/045,843  
Pending Claims

References

1. A method for treating brain injuries comprising:  
administering to a patient a first dosage of about 100 mg to about 300 mg of cannabidiol (CBD); and  
administering to the patient, concomitantly with the first dosage, a second dosage of about 1 mg to about 5 mg of Psilocybin.

1. Int'l Pat. App. No. WO/2022/115796 (Compositions and Methods for Treating Neurological Conditions) (Published June 2, 2022)

From **Summary** "As described below, the present disclosure features compositions comprising a **psilocybin and/or cannabidiol (CBD)** and/or psilocin, optionally in combination with a mushroom blend. Other embodiments include compositions comprising psilocybin or a derivative thereof, in combination with a neurotransmitter activity modulator (e.g., serotonin, norepinephrine, histaminergic, muscarinic, and dopaminergic). The present disclosure also features **methods for treating traumatic brain injury (TBI)** using compositions described herein."

From **Cannabinoids and Derivatives** "The compositions may include from about **1 mg to about 1000 mg of a cannabinoid**. The cannabinoid in various embodiments is **cannabidiol (CBD)**."

From **Summary** "Presented herein are methods for reducing a symptom of **traumatic brain injury** or postconcussion syndrome in a subject, the method comprising administering to the subject one or more loading dose(s) of **at least about 1 mg psilocybin**"

2. Int'l Pat. App. No. WO/2021/072530 (Controlled Release Formulations of Psilocybe-Derived Agents and Method for their Use, and Methods and Compositions for Treating Mild Traumatic Brain Injury with Post Traumatic Stress Disorder) (Published April 22, 2021)

From **Claim 14** "A method for alleviating one or more symptoms of **mTBI** with PTSD, said method comprising administering to a subject suffering from **mTBI** with PTSD a **psilocybe-derived agent in combination with a cannabis-derived agent**."

From **Claim 16** "The method of claim 14, wherein the psilocybe-derived agent and cannabis-derived agent are administered **simultaneously**."

From **Claim 19** "The method of claim 14, wherein the **psilocybe-derived agent is administered before the cannabis-derived agent**."

	<p>From <b>Claim 20</b> “The method of claim 14, wherein the <b>psilocybe-derived agent is administered after the cannabis-derived agent.</b>”</p> <p>From <b>Claim 21</b> “The method of any of claims 14 through 20, wherein the <b>psilocybe-derived agent is psilocybin.</b>”</p> <p>From <b>Claim 22</b> “The method of any of claim 14 through 21 , wherein the <b>cannabis-derived agent is cannabidiol.</b>”</p>
<p>2. The method of <u>claim 1</u> wherein the treatment is for TBI.</p>	<p>1. Int’l Pat. App. No. WO/2022/115796 (Compositions and Methods for Treating Neurological Conditions) (Published June 2, 2022)</p> <p>From <b>Summary</b> “As described below, the present disclosure features compositions comprising a <b>psilocybin and/or cannabidiol (CBD)</b> and/or psilocin, optionally in combination with a mushroom blend. Other embodiments include compositions comprising psilocybin or a derivative thereof, in combination with a neurotransmitter activity modulator (e.g., serotonin, norepinephrine, histaminergic, muscarinic, and dopaminergic). The present disclosure also features <b>methods for treating traumatic brain injury (TBI)</b> using compositions described herein.”</p>
<p>3. The method of <u>claim 1</u> wherein the treatment is for mTBI.</p>	<p>1. Int’l Pat. App. No. WO/2022/115796 (Compositions and Methods for Treating Neurological Conditions) (Published June 2, 2022)</p> <p>From <b>Summary</b> “The present disclosure also features methods for treating <b>traumatic brain injury (TBI)</b> using compositions described herein. Other neurological conditions (e.g., anxiety, depression, stress, <b>post-concussion syndrome</b>, post-traumatic headache, and/or progressive headache) or symptoms thereof, are also treatable with the methods described herein.”</p> <p>From <b>Definitions</b> “By “<b>post-concussion syndrome</b>” is meant symptoms associated with a concussion that persist beyond the expected recovery period after. In some embodiments, the traumatic brain injury is a <b>mild or acute traumatic brain injury (mTBI).</b> “</p> <p>2. Int’l Pat. App. No. WO/2021/072530 (Controlled Release Formulations of Psilocybe-Derived Agents and Method for their Use, and Methods and Compositions for Treating Mild Traumatic Brain Injury with Post Traumatic Stress Disorder) (Published April 22, 2021)</p>

	<p>From <b>Claim 14</b> “A method for alleviating one or more symptoms of <b>mTBI</b> with PTSD, said method comprising administering to a subject suffering from <b>mTBI</b> with PTSD a <b>psilocybe-derived agent in combination with a cannabis-derived agent.</b>”</p>
<p>4. The method of <u>claim 1</u>, wherein the first dosage is about 250 mg to about 300 mg CBD and the second dosage is about 1.25 mg to about 2.5 mg Psilocybin.</p>	<p>1. Int’l Pat. App. No. WO/2022/115796 (Compositions and Methods for Treating Neurological Conditions) (Published June 2, 2022)</p> <p>From <b>Cannabinoids and Derivatives</b> “The compositions may include from about <b>1 mg to about 1000 mg of a cannabinoid.</b> The cannabinoid in various embodiments is <b>cannabidiol (CBD).</b>”</p> <p>From <b>Summary</b> “Presented herein are methods for reducing a symptom of <b>traumatic brain injury</b> or postconcussion syndrome in a subject, the method comprising administering to the subject one or more loading dose(s) of <b>at least about 1 mg psilocybin</b>”</p> <p>From <b>Cannabinoids and Derivatives</b> “In some embodiments, the loading dose comprises about <b>1 mg to about 50 mg of purified and/or synthetic psilocybin.</b>”</p>
<p>5. The method of <u>claim 1</u>, wherein a ratio between the first dosage and the second dosage is about 100:1 to about 250:1.</p>	<p>1. Int’l Pat. App. No. WO/2022/115796 (Compositions and Methods for Treating Neurological Conditions) (Published June 2, 2022)</p> <p>From <b>Cannabinoids and Derivatives</b> “The compositions may include from about <b>1 mg to about 1000 mg of a cannabinoid.</b> The cannabinoid in various embodiments is <b>cannabidiol (CBD).</b>”</p> <p>From <b>Cannabinoids and Derivatives</b> “Presented herein are methods for reducing a symptom of <b>traumatic brain injury</b> or postconcussion syndrome in a subject, the method comprising administering to the subject one or more loading dose(s) of <b>at least about 1 mg psilocybin</b>”</p> <p>From <b>Cannabinoids and Derivatives</b> “In some embodiments, the loading dose comprises about <b>1 mg to about 50 mg of purified and/or synthetic psilocybin.</b>”</p>
<p>6. The method of <u>claim 1</u>, wherein a ratio between the first dosage and the second dosage is about 145:1 to about 155:1.</p>	<p>1. Int’l Pat. App. No. WO/2022/115796 (Compositions and Methods for Treating Neurological Conditions) (Published June 2, 2022)</p> <p>From <b>Cannabinoids and Derivatives</b> “The compositions may include from about <b>1 mg to about 1000 mg of a cannabinoid.</b>”</p>

	<p>The cannabinoid in various embodiments is <b>cannabidiol (CBD).</b>”</p> <p>From <b>Summary</b> “Presented herein are methods for reducing a symptom of <b>traumatic brain injury</b> or postconcussion syndrome in a subject, the method comprising administering to the subject one or more loading dose(s) of <b>at least about 1 mg psilocybin</b>”</p> <p>From <b>Cannabinoids and Derivatives</b> “In some embodiments, the loading dose comprises about <b>1 mg to about 50 mg of purified and/or synthetic psilocybin.</b>”</p>
<p>7. The method of <u>claim 1</u>, wherein the administration of the first dosage and the second dosage occurs twice a day, for about seven days to about 10 days.</p>	<p>1. Int’l Pat. App. No. WO/2022/115796 (Compositions and Methods for Treating Neurological Conditions) (Published June 2, 2022)</p> <p>From <b>Claim 24</b> “The method of any of claims 1-23, wherein the maintenance dose is administered according to a <b>predetermined schedule.</b>”</p>
<p>8. The method of <u>claim 1</u>, wherein the administration of the first dosage and the second dosage occurs once a day, for about seven days to about 10 days.</p>	<p>1. Int’l Pat. App. No. WO/2022/115796 (Compositions and Methods for Treating Neurological Conditions) (Published June 2, 2022)</p> <p>From <b>Claim 24</b> “The method of any of claims 1-23, wherein the maintenance dose is administered according to a <b>predetermined schedule.</b>”</p> <p>From <b>Summary</b> “In some embodiments, the maintenance dose is administered <b>about daily.</b>”</p>
<p>9. A method of activating both a CB2 receptor and a 5HT receptor of a patient, the method comprising: administering to the patient a first dosage of about 100 mg to about 300 mg of cannabidiol (CBD); and administering to the patient, concomitantly with the first dosage, a second dosage of about 1 mg to about 5 mg of Psilocybin.</p>	<p>2. Int’l Pat. App. No. WO/2021/072530 (Controlled Release Formulations of Psilocybe-Derived Agents and Method for their Use, and Methods and Compositions for Treating Mild Traumatic Brain Injury with Post Traumatic Stress Disorder) (Published April 22, 2021)</p> <p>From <b>[0024]</b> “<b>Psilocybin</b> is rapidly metabolized to <b>psilocin</b>, which then activates or partially activates <b>several serotonin receptors in the brain</b>. For example, psilocin has a high affinity for 5-HT2B and 5-HT2C receptors in the human brain, and a slightly lower affinity for the 5-HT2A receptor. Psilocin further binds with low affinity to 5-HT 1 receptors, including 5-HT1 A and 5-HT 1 D.”</p> <p>1. Int’l Pat. App. No. WO/2022/115796 (Compositions and Methods for Treating Neurological Conditions) (Published June 2, 2022)</p> <p>From <b>Definitions</b> “By “<b>cannabinoid</b>” is meant a group of chemicals known to activate <b>cannabinoid receptors</b> in cells”</p>

	<p>From <b>Definitions</b> “Non limiting examples of <b>cannabinoids</b> include the following molecules: ... <b>Cannabidiol (CBD)</b> ...”</p>
<p>10. The method of claim 9, wherein the first dosage is about 250 mg to about 300 mg CBD and the second dosage is about 1.25 mg to about 2.5 mg Psilocybin.</p>	<p>1. Int’l Pat. App. No. WO/2022/115796 (Compositions and Methods for Treating Neurological Conditions) (Published June 2, 2022)</p> <p>From <b>Cannabinoids and Derivatives</b> “The compositions may include from about <b>1 mg to about 1000 mg of a cannabinoid</b>. The cannabinoid in various embodiments is <b>cannabidiol (CBD)</b>.”</p> <p>From <b>Summary</b> “Presented herein are methods for reducing a symptom of <b>traumatic brain injury</b> or postconcussion syndrome in a subject, the method comprising administering to the subject one or more loading dose(s) of <b>at least about 1 mg psilocybin</b>”</p> <p>From <b>Summary</b> “In some embodiments, the loading dose comprises about <b>1 mg to about 50 mg of purified and/or synthetic psilocybin</b>.”</p>
<p>11. The method of claim 9, wherein a ratio between the first dosage and the second dosage is about 100:1 to about 250:1.</p>	<p>1. Int’l Pat. App. No. WO/2022/115796 (Compositions and Methods for Treating Neurological Conditions) (Published June 2, 2022)</p> <p>From <b>Cannabinoids and Derivatives</b> “The compositions may include from about <b>1 mg to about 1000 mg of a cannabinoid</b>. The cannabinoid in various embodiments is <b>cannabidiol (CBD)</b>.”</p> <p>From <b>Summary</b> “Presented herein are methods for reducing a symptom of <b>traumatic brain injury</b> or postconcussion syndrome in a subject, the method comprising administering to the subject one or more loading dose(s) of <b>at least about 1 mg psilocybin</b>”</p> <p>From <b>Summary</b> “In some embodiments, the loading dose comprises about <b>1 mg to about 50 mg of purified and/or synthetic psilocybin</b>.”</p>
<p>12. The method of claim 9, wherein a ratio between the first dosage and the second dosage is about 145:1 to about 155:1.</p>	<p>1. Int’l Pat. App. No. WO/2022/115796 (Compositions and Methods for Treating Neurological Conditions) (Published June 2, 2022)</p> <p>From <b>Cannabinoids and Derivatives</b> “The compositions may include from about <b>1 mg to about 1000 mg of a cannabinoid</b>. The cannabinoid in various embodiments is <b>cannabidiol (CBD)</b>.”</p>

	<p>From <b>Summary</b> “Presented herein are methods for reducing a symptom of <b>traumatic brain injury</b> or postconcussion syndrome in a subject, the method comprising administering to the subject one or more loading dose(s) of <b>at least about 1 mg psilocybin</b>”</p> <p>From <b>Summary</b> “In some embodiments, the loading dose comprises about <b>1 mg to about 50 mg of purified and/or synthetic psilocybin.</b>”</p>
<p>13. The method of claim 9, wherein the administration of the first dosage and the second dosage occurs twice a day, for about seven days to about 10 days.</p>	<p>1. Int’l Pat. App. No. WO/2022/115796 (Compositions and Methods for Treating Neurological Conditions) (Published June 2, 2022)</p> <p>From <b>Claim 24</b> “The method of any of claims 1-23, wherein the maintenance dose is administered according to a <b>predetermined schedule.</b>”</p>
<p>14. The method of claim 9, wherein the administration of the first dosage and the second dosage occurs once a day, for about seven days to about 10 days.</p>	<p>1. Int’l Pat. App. No. WO/2022/115796 (Compositions and Methods for Treating Neurological Conditions) (Published June 2, 2022)</p> <p>From <b>Claim 24</b> “The method of any of claims 1-23, wherein the maintenance dose is administered according to a <b>predetermined schedule.</b>”</p> <p>From <b>Summary</b> “In some embodiments, the maintenance dose is administered about daily.”</p>
<p>15. A method of reducing a contusion volume of a mammal, the method comprising: administering to the mammal a first dosage of about 100 mg to about 300 mg of cannabidiol (CBD); and administering to the mammal, concomitantly with the first dosage, a second dosage of about 1 mg to about 5 mg of Psilocybin.</p>	<p>1. Int’l Pat. App. No. WO/2022/115796 (Compositions and Methods for Treating Neurological Conditions) (Published June 2, 2022)</p> <p>From <b>Summary</b> “As described below, the present disclosure features compositions comprising a <b>psilocybin and/or cannabidiol (CBD)</b> and/or psilocin, optionally in combination with a mushroom blend. Other embodiments include compositions comprising psilocybin or a derivative thereof, in combination with a neurotransmitter activity modulator (e.g., serotonin, norepinephrine, histaminergic, muscarinic, and dopaminergic). The present disclosure also features <b>methods for treating traumatic brain injury (TBI)</b> using compositions described herein.”</p> <p>From <b>Cannabinoids and Derivatives</b> “The compositions may include from about <b>1 mg to about 1000 mg of a cannabinoid.</b> The cannabinoid in various embodiments is <b>cannabidiol (CBD).</b>”</p> <p>From <b>Summary</b> “Presented herein are methods for reducing a symptom of <b>traumatic brain injury</b> or postconcussion syndrome in a subject, the method comprising administering</p>

	<p>to the subject one or more loading dose(s) of <b>at least about 1 mg psilocybin</b>”</p> <p>2. Int’l Pat. App. No. WO/2021/072530 (Controlled Release Formulations of Psilocybe-Derived Agents and Method for their Use, and Methods and Compositions for Treating Mild Traumatic Brain Injury with Post Traumatic Stress Disorder) (Published April 22, 2021)</p> <p>From <b>Claim 14</b> “A method for alleviating one or more symptoms of <b>mTBI</b> with PTSD, said method comprising administering to a subject suffering from <b>mTBI</b> with PTSD a <b>psilocybe-derived agent in combination with a cannabis-derived agent.</b>”</p> <p>From <b>Claim 16</b> “The method of claim 14, wherein the psilocybe-derived agent and cannabis-derived agent are administered <b>simultaneously.</b>”</p> <p>From <b>Claim 19</b> “The method of claim 14, wherein the <b>psilocybe-derived agent is administered before the cannabis-derived agent.</b>”</p> <p>From <b>Claim 20</b> “The method of claim 14, wherein the <b>psilocybe-derived agent is administered after the cannabis-derived agent.</b>”</p> <p>From <b>Claim 21</b> “The method of any of claims 14 through 20, wherein the <b>psilocybe-derived agent is psilocybin.</b>”</p> <p>From <b>Claim 22</b> “The method of any of claim 14 through 21 , wherein the <b>cannabis-derived agent is cannabidiol.</b>”</p>
<p>16. The method of claim 15, wherein the first dosage is about 250 mg to about 300 mg CBD and the second dosage is about 1.25 mg to about 2.5 mg Psilocybin.</p>	<p>1. Int’l Pat. App. No. WO/2022/115796 (Compositions and Methods for Treating Neurological Conditions) (Published June 2, 2022)</p> <p>“The compositions may include from about <b>1 mg to about 1000 mg of a cannabinoid.</b> The cannabinoid in various embodiments is <b>cannabidiol (CBD).</b>”</p> <p>From <b>Summary</b> “Presented herein are methods for reducing a symptom of <b>traumatic brain injury</b> or postconcussion syndrome in a subject, the method comprising administering to the subject one or more loading dose(s) of <b>at least about 1 mg psilocybin</b>”</p> <p>From <b>Summary</b> “In some embodiments, the loading dose comprises about <b>1 mg to about 50 mg of purified and/or synthetic psilocybin.</b>”</p>



<p>17. The method of claim 15, wherein a ratio between the first dosage and the second dosage is about 100:1 to about 250:1.</p>	<p>1. Int'l Pat. App. No. WO/2022/115796 (Compositions and Methods for Treating Neurological Conditions) (Published June 2, 2022)</p> <p>From <b>Cannabinoids and Derivatives</b> “The compositions may include from about <b>1 mg to about 1000 mg of a cannabinoid</b>. The cannabinoid in various embodiments is <b>cannabidiol (CBD)</b>.”</p> <p>From <b>Summary</b> “Presented herein are methods for reducing a symptom of <b>traumatic brain injury</b> or postconcussion syndrome in a subject, the method comprising administering to the subject one or more loading dose(s) of <b>at least about 1 mg psilocybin</b>”</p> <p>From <b>Summary</b> “In some embodiments, the loading dose comprises about <b>1 mg to about 50 mg of purified and/or synthetic psilocybin</b>.”</p>
<p>18. The method of claim 15, wherein the administration of the first dosage and the second dosage occurs twice a day, for about seven days to about 10 days.</p>	<p>1. Int'l Pat. App. No. WO/2022/115796 (Compositions and Methods for Treating Neurological Conditions) (Published June 2, 2022)</p> <p>From <b>Claim 24</b> “The method of any of claims 1-23, wherein the maintenance dose is administered according to a <b>predetermined schedule</b>.”</p>
<p>19. The method of claim 15, wherein the administration of the first dosage and the second dosage occurs once a day, for about seven days to about 10 days.</p>	<p>1. Int'l Pat. App. No. WO/2022/115796 (Compositions and Methods for Treating Neurological Conditions) (Published June 2, 2022)</p> <p>From <b>Claim 24</b> “The method of any of claims 1-23, wherein the maintenance dose is administered according to a <b>predetermined schedule</b>.”</p>

## Electronic Acknowledgement Receipt

<b>EFS ID:</b>	48153580
<b>Application Number:</b>	18045843
<b>International Application Number:</b>	
<b>Confirmation Number:</b>	4176
<b>Title of Invention:</b>	METHODS OF TREATMENT WITH COMBINATIONS OF CANNABIDIOL AND PSILOCYBIN
<b>First Named Inventor/Applicant Name:</b>	Nitin ANAND
<b>Customer Number:</b>	20694
<b>Filer:</b>	Taylor Kurtzweil
<b>Filer Authorized By:</b>	
<b>Attorney Docket Number:</b>	29966.0002
<b>Receipt Date:</b>	14-JUN-2023
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<b>Time Stamp:</b>	16:31:30
<b>Application Type:</b>	

### Payment information:

Submitted with Payment	no
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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	33575 ae4162ba6ea8ecfb061845ea97f00c8dd8011617	no	3

### Warnings:

<b>Information:</b>					
2	Third-Party Submission Under 37 CFR 1.290	Third-party-preissuance-submission.pdf	55703 dbc30b1a315f611e34ac945bd46983c9e911f95a	no	2
<b>Warnings:</b>					
<b>Information:</b>					
3	Request for Notification of Non-compliant Third-Party Submission	Third-party-notification-request.pdf	23740 15c47fa02289cbee37a013bfc29fa3a8712a2360	no	1
<b>Warnings:</b>					
<b>Information:</b>					
4	Concise Description of Relevance	20230112459_Claims_Chart.pdf	146623 c7950f66852f2394b0593f3d1f8e3d90beb1193b	no	9
<b>Warnings:</b>					
<b>Information:</b>					
5	Evidence of Publication	WO2021072530.pdf	1413323 b58f05ce839dcd3d40bb94f547c9f637d0633832	no	34
<b>Warnings:</b>					
<b>Information:</b>					
6	Evidence of Publication	WO2022115796.pdf	9423382 e4f52834b6de56d10f0f5c4cc07116a809fd e2ee	no	152
<b>Warnings:</b>					
<b>Information:</b>					
<b>Total Files Size (in bytes):</b>				11096346	

**This Acknowledgement Receipt evidences receipt on the noted date by the USPTO of the indicated documents, characterized by the applicant, and including page counts, where applicable. It serves as evidence of receipt similar to a Post Card, as described in MPEP 503.**

**New Applications Under 35 U.S.C. 111**

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

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

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

**New International Application Filed with the USPTO as a Receiving Office**

**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.**