### IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of: BARROW, Robert Confirmation No.:

Serial No.: 17/734,102 Group No.:

Filing or 371(c) Date: May 1, 2022 Examiner:

**Entitled: MOVEMENT DISORDERS** 

## 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:

- Int'l Pat. App. Pub. No. WO/2019/246532 "METHOD OF INDUCING DENDRITIC AND SYNAPTIC GENESIS IN NEURODEGENERATIVE CHRONIC DISEASES" (Published 26 December 2019).
- 2. "Ecstasy May Relieve Parkinson's Symptoms," Web page <<u>http://www.erowid.org/chemicals/mdma/mdma\_research3.shtml</u>>, 1 page, 2 April 2008, retrieved from Internet Archive Wayback Machine <<u>https://web.archive.org/web/20080402083142/http://www.erowid.org/chemicals/mdma/mdma\_research3.shtml</u>> on 19 December 2022.
- 3. MORTON (2004) Ecstasy: pharmacology and neurotoxicity. Current Opinion in Pharmacology. 5(1):79-86. Published 13 December 2004.
- 4. "Ecstasy 'Relieves Parkinson's Disease" Web page

  <a href="http://news.bbc.co.uk/2/hi/health/1169980.stm">http://news.bbc.co.uk/2/hi/health/1169980.stm</a>> 3 pages, 18 July 2009, retrieved from Internet Archive Wayback Machine

  <a href="https://web.archive.org/web/20090718174357/http://news.bbc.co.uk/2/hi/health/1169980.stm">https://web.archive.org/web/20090718174357/http://news.bbc.co.uk/2/hi/health/1169980.stm</a>
  on 4 December 2022.
- 5. Int'l Pat. App. Pub. No. WO/2020/212948 "METHODS OF TREATING NEUROCOGNITIVE DISORDERS, CHRONIC PAIN AND REDUCING INFLAMMATION" (Published 22 October 2020).

- 6. RUTTEN (2014) Anxiety in Parkinson's disease: Symptom dimensions and overlap with depression and autonomic failure. Parkinsonism & Related Disorders. 21(3);189-193. Published 9 December 2014.
- 7. Int'l Pat. App. Pub. No. WO/2020/212951 "METHODS FOR TREATING ANXIETY DISORDERS, HEADACHE DISORDERS, AND EATING DISORDERS WITH PSILOCYBIN" (Published 22 October 2020).

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. 17/734,102	References
Pending Claims	
<b>1.</b> A method of treating	1. Int'l Pat. App. No. WO/2019/246532 "METHOD OF INDUCING
movement disorders,	DENDRITIC AND SYNAPTIC GENESIS IN NEURODEGENERATIVE
including the steps of:	CHRONIC DISEASES" (Published 26 December 2019).
administering an	
effective amount of a	From <b>claim 1</b> "A method of inducing neuron dendritic and synaptic genesis
psychedelic to an	in neurodegenerative diseases by administering one or more tryptamine
individual having a	molecules or pharmaceutically acceptable salts thereof, to a patient in
movement disorder; and	suffering from a neurodegenerative disease."
treating the movement	
disorder.	From <b>claim 2</b> "The method according to claim 1, wherein said <b>one or more</b>
	<b>tryptamine molecules</b> is selected from the group consisting of <b>lysergic</b>
	acid diethylamide, N, N-dimethyltryptamine, 5-methoxy-N, N-
	dimethyltryptamine, mescaline, psilocin, 3,4-
	methylenedioxymethamphetamine, and psilocybin, pharmaceutically
	acceptable salts thereof and combinations thereof."
	From <b>claim 4</b> "The method according to claim 1, wherein said
	neurodegenerative disease is a chronic condition."
	From <b>claim 5</b> "The method according to claim 4, wherein said chronic
	neurodegenerative disease is selected from the group consisting of dementia,
	Alzheimer's disease, <b>Parkinson's disease</b> , frontal temporal dementia,
	Huntington's disease and multiple Sclerosis."
	From <b>claim 27</b> "A formulation containing <b>one or more tryptamine</b>
	<b>molecules</b> or pharmaceutically acceptable salts and a pharmaceutically
	acceptable carrier thereof useful in treating a patient in suffering from a
	neurodegenerative disease."
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From claim 28 "The formulation according to claim 27, wherein said one or more tryptamine molecules is selected from the group consisting of lysergic acid diethylamide, N, N-dimethyltryptamine, 5-methoxy-N, N-dimethyltryptamine, mescaline, psilocin, 3,4-methylenedioxymethamphetamine, and psilocybin, pharmaceutically acceptable salts thereof and combinations thereof."

5. Int'l Pat. App. Pub. No. WO/2020/212948 "METHODS OF TREATING NEUROCOGNITIVE DISORDERS, CHRONIC PAIN AND REDUCING INFLAMMATION" (Published 22 October 2020).

From claim 7 "A method for treating a Parkinsonian syndrome or symptom thereof in a subject in need thereof, the method comprising administering to the subject a therapeutically effective amount of psilocybin or an active metabolite thereof."

From **claim 8** "The method of claim 7, wherein the Parkinsonian syndrome is **Parkinson's disease**"

2. The method of claim 1. wherein the movement disorder is chosen from the group consisting of ataxia, cervical dystonia, chorea, dystonia, functional movement disorder, Huntington's disease, multiple system atrophy, myoclonus, Parkinson's disease, Parkinsonism, progressive supranuclear palsy, restless legs syndrome, tardive dyskinesia, Tourette syndrome, tremor, and Wilson's disease.

1. Int'l Pat. App. No. WO/2019/246532 "METHOD OF INDUCING DENDRITIC AND SYNAPTIC GENESIS IN NEURODEGENERATIVE CHRONIC DISEASES" (Published 26 December 2019).

From **claim 1** "A method of inducing neuron dendritic and synaptic genesis in neurodegenerative diseases by administering one or more tryptamine molecules or pharmaceutically acceptable salts thereof, to a patient in suffering from a neurodegenerative disease."

From **claim 2** "The method according to claim 1, wherein said **one or more tryptamine molecules** is selected from the group consisting of lysergic acid diethylamide, N, N-dimethyltryptamine, 5-methoxy-N, N-dimethyltryptamine, mescaline, psilocin, 3,4-methylenedioxymethamphetamine, and psilocybin, pharmaceutically acceptable salts thereof and combinations thereof."

From **claim 4** "The method according to claim 1, wherein said neurodegenerative disease is a chronic condition."

From **claim 5** "The method according to claim 4, wherein said chronic neurodegenerative disease is selected from the group consisting of dementia, Alzheimer's disease, **Parkinson's disease**, frontal temporal dementia, **Huntington's disease** and multiple Sclerosis."

From **claim 27** "A formulation containing **one or more tryptamine molecules** or pharmaceutically acceptable salts and a pharmaceutically

acceptable carrier thereof useful in **treating a patient in suffering from a neurodegenerative disease**."

From **claim 28** "The formulation according to claim 27, wherein said one or more tryptamine molecules is selected from the group consisting of **lysergic acid diethylamide**, N, N-dimethyltryptamine, **5-methoxy-N**, N-dimethyltryptamine, mescaline, psilocin, 3,4-methylenedioxymethamphetamine, and psilocybin, pharmaceutically acceptable salts thereof and combinations thereof."

5. Int'l Pat. App. Pub. No. WO/2020/212948 "METHODS OF TREATING NEUROCOGNITIVE DISORDERS, CHRONIC PAIN AND REDUCING INFLAMMATION" (Published 22 October 2020).

From claim 7 "A method for treating a Parkinsonian syndrome or symptom thereof in a subject in need thereof, the method comprising administering to the subject a therapeutically effective amount of psilocybin or an active metabolite thereof."

From **claim 8** "The method of claim 7, wherein the Parkinsonian syndrome is **Parkinson's disease**"

3. The method of claim 1, wherein the psychedelic is chosen from the group consisting of lysergic acid diethylamide (LSD), psilocybin, psilocin, mescaline, 3,4-methylenedioxymetham phetamine (MDMA), 5-methoxy-N N-

psilocin, mescaline, 3,4methylenedioxymetham
phetamine (MDMA), 5methoxy-N,Ndimethyltryptamine (5MeO-DMT),
dimethyltryptamine
(DMT), 2,5-dimethoxy4-iodoamphetamine
(DOI), 2,5-dimethoxy4-bromoamphetamie
(DOB), salts thereof,
tartrates thereof,
solvates thereof.

isomers thereof, analogs thereof,

1. Int'l Pat. App. No. WO/2019/246532 "METHOD OF INDUCING DENDRITIC AND SYNAPTIC GENESIS IN NEURODEGENERATIVE CHRONIC DISEASES" (Published 26 December 2019).

From **claim 1** "A method of inducing neuron dendritic and synaptic genesis in neurodegenerative diseases by administering one or more tryptamine molecules or pharmaceutically acceptable salts thereof, to a patient in suffering from a neurodegenerative disease."

From claim 2 "The method according to claim 1, wherein said one or more tryptamine molecules is selected from the group consisting of lysergic acid diethylamide, N, N-dimethyltryptamine, 5-methoxy-N, N-dimethyltryptamine, mescaline, psilocin, 3,4-methylenedioxymethamphetamine, and psilocybin, pharmaceutically acceptable salts thereof and combinations thereof."

From **claim 4** "The method according to claim 1, wherein said neurodegenerative disease is a chronic condition."

From **claim 5** "The method according to claim 4, wherein said chronic neurodegenerative disease is selected from the group consisting of dementia, Alzheimer's disease, **Parkinson's disease**, frontal temporal dementia, **Huntington's disease** and multiple Sclerosis."

homologues thereof, or deuterated forms thereof.

From claim 27 "A formulation containing one or more tryptamine molecules or pharmaceutically acceptable salts and a pharmaceutically acceptable carrier thereof useful in treating a patient in suffering from a neurodegenerative disease."

From claim 28 "The formulation according to claim 27, wherein said one or more tryptamine molecules is selected from the group consisting of lysergic acid diethylamide, N, N-dimethyltryptamine, 5-methoxy-N, N-dimethyltryptamine, mescaline, psilocin, 3,4-methylenedioxymethamphetamine, and psilocybin, pharmaceutically acceptable salts thereof and combinations thereof."

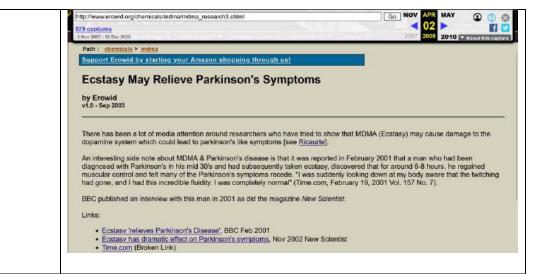
5. Int'l Pat. App. Pub. No. WO/2020/212948 "METHODS OF TREATING NEUROCOGNITIVE DISORDERS, CHRONIC PAIN AND REDUCING INFLAMMATION" (Published 22 October 2020).

From claim 7 "A method for treating a Parkinsonian syndrome or symptom thereof in a subject in need thereof, the method comprising administering to the subject a therapeutically effective amount of psilocybin or an active metabolite thereof."

From **claim 8** "The method of claim 7, wherein the Parkinsonian syndrome is **Parkinson's disease**"

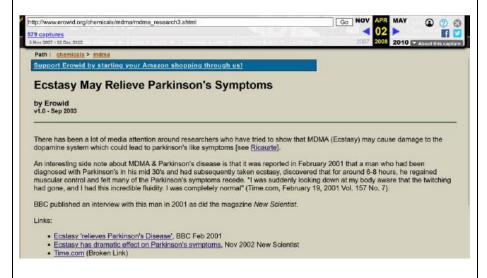
- **4.** The method of claim 1, wherein said treating step further includes the step of reducing and/or eliminating undesired movement or tremors.
- 2. "Ecstasy May Relieve Parkinson's Symptoms," Web page <a href="http://www.erowid.org/chemicals/mdma/mdma\_research3.shtml">http://www.erowid.org/chemicals/mdma/mdma\_research3.shtml</a>, 1 page, 2 April 2008, retrieved from Internet Archive Wayback Machine <a href="https://web.archive.org/web/20080402083142/http://www.erowid.org/chemicals/mdma/mdma\_research3.shtml">https://web.archive.org/web/20080402083142/http://www.erowid.org/chemicals/mdma/mdma\_research3.shtml</a> on 19 December 2022.

From paragraph 2 "I was suddenly looking down at my body aware that the **twitching had gone**, and I had this incredible fluidity. **I was completely normal**."



- **5.** The method of claim 1, wherein said treating step further includes the step of returning abnormal movement to a normal state.
- 2. "Ecstasy May Relieve Parkinson's Symptoms," Web page <a href="http://www.erowid.org/chemicals/mdma/mdma\_research3.shtml">http://www.erowid.org/chemicals/mdma/mdma\_research3.shtml</a>, 1 page, 2 April 2008, retrieved from Internet Archive Wayback Machine <a href="https://web.archive.org/web/20080402083142/http://www.erowid.org/chemicals/mdma/mdma\_research3.shtml">https://web.archive.org/web/20080402083142/http://www.erowid.org/chemicals/mdma/mdma\_research3.shtml</a> on 19 December 2022.

From **paragraph 2** "I was suddenly looking down at my body aware that the **twitching had gone**, and I had this incredible fluidity. **I was completely normal**."



- **6.** The method of claim 1, wherein said treating step further includes the step of reducing anxiety and reducing abnormal movement due to anxiety.
- 6. RUTTEN (2014) Anxiety in Parkinson's disease: Symptom dimensions and overlap with depression and autonomic failure. Parkinsonism & Related Disorders. 21(3);189-193. Published 9 December 2014.

From page 189 "Anxiety in PD patients is associated with increased subjective motor symptoms, more severe gait problems, dyskinesias, freezing, motor response fluctuations, and a decrease in health-related quality of life."

7. Int'l Pat. App. Pub. No. WO/2020/212951 "METHODS FOR TREATING ANXIETY DISORDERS, HEADACHE DISORDERS, AND EATING DISORDERS WITH PSILOCYBIN" (Published 22 October 2020).

From **claim 1** "A **method of treating an anxiety disorder** in a subject in need thereof, the method comprising administering to the subject a therapeutically effective amount of **psilocybin** or an active metabolite thereof."

From **claim 8** "The method of any one of claims 1 -7, wherein the subject has at least one comorbidity."

From **claim 9** "The method of claim 8, wherein the comorbidity is a mood disorder, major depressive disorder, bipolar disorder, schizophrenia, an eating disorder, attention deficit/hyperactivity disorder, epilepsy, cardiovascular disease, migraine, a headache disorder, irritable bowel syndrome, dementia, Alzheimer's disease, **Parkinson's disease**, or combinations thereof."

From page 64, paragraph 2 "As used herein, the term "anxiety disorder" refers to a state of apprehension, uncertainty, and/or fear resulting from the anticipation of an event and/or situation. Anxiety disorders cause physiological and psychological signs or symptoms. Non-limiting examples of physiological symptoms include muscle tension, heart palpitations, sweating, dizziness, shortness of breath, tachycardia, tremor, fatigue, worry, irritability, and disturbed sleep. Non-limiting examples of psychological symptoms include fear of dying, fear of embarrassment or humiliation, fear of an event occurring, etc. Anxiety disorders also impair a subject's cognition, information processing, stress levels, and immune response. In some embodiments, the methods disclosed herein treat chronic anxiety disorders. As used herein, a "chronic" anxiety disorder is recurring."

5. Int'l Pat. App. Pub. No. WO/2020/212948 "METHODS OF TREATING NEUROCOGNITIVE DISORDERS, CHRONIC PAIN AND REDUCING INFLAMMATION" (Published 22 October 2020)

From claim 7 "A method for treating a Parkinsonian syndrome or symptom thereof in a subject in need thereof, the method comprising administering to the subject a therapeutically effective amount of psilocybin or an active metabolite thereof."

From **claim 8** "The method of claim 7, wherein the Parkinsonian syndrome is **Parkinson's disease**"

From **claim 10** "The method of claim 7 or 8, wherein the subject has a neuropsychiatric disturbance, and wherein the neuropsychiatric disturbance is dementia, depression, psychosis, apathy, **anxiety**, or hallucinations, or combinations thereof."

3. MORTON (2004) Ecstasy: pharmacology and neurotoxicity. Current Opinion in Pharmacology. 5(1):79-86. Published 13 December 2004.

From page 79 "Ecstasy is the colloquial name given by its users to 3,4-methylene-dioxymethamphetamine (MDMA). It is a ring-substituted amphetamine derivative that is also related to the hallucinogenic compound mescaline. Although it is classified as a hallucinogen, ecstasy does not produce the profound sensory disruptions or hallucinations associated with classical hallucinogens such as lysergic acid diethylamine (LSD), phencyclidine or mescaline. Rather, it increases emotional sensitivity and empathy, with users reporting a loss of inhibitions, reduced anxiety and an increased sense of closeness with other people."

From **page 83** "The program was a BBC documentary, in which the subject was a young man with early-onset PD. He was taking l-DOPA to control the symptoms of PD, but his disease had progressed to the stage at which his treatment caused dyskinesia (**uncontrollable arm and leg movements** that plague PD sufferers). He discovered that taking ecstasy markedly reduced his dykinesia to a level where **normal function was restored.**"

- 7. The method of claim 1, wherein said treating step further includes the step of reducing tremors due to side effects of drugs that the individual is taking.
- 4. "Ecstasy 'Relieves Parkinson's Disease" Web page < <a href="http://news.bbc.co.uk/2/hi/health/1169980.stm">http://news.bbc.co.uk/2/hi/health/1169980.stm</a> 3 pages, 18 July 2009, retrieved from Internet Archive Wayback Machine < <a href="https://web.archive.org/web/20090718174357/http://news.bbc.co.uk/2/hi/health/1169980.stm">https://web.archive.org/web/20090718174357/http://news.bbc.co.uk/2/hi/health/1169980.stm</a> on 4 December 2022.

From **paragraph 6** "Now he spends much of his day either unable to move at all, or **twitching uncontrollably**."

From paragraph 9 "Like many people who contract the illness early in life, Tim suffers just as badly from the drug he takes to combat the disease. The drug, L-DOPA helps to unlock his frozen limbs, but it also gives him wild, flailing movements called dyskinesias."

From **paragraph 14** "However, until now scientists have failed to come up with an effective alternative for L-DOPA, or any **treatment to moderate its effects.**"

From **paragraph 15** "Tim made the discovery about **Ecstasy** completely by chance. He had taken the drug while on a night-club visit with friends. He

said: "I was just suddenly aware that everything was completely smooth,
as though I never had the disease in the first place." The drug appears to
tame his body and give him back control over his limbs."

Electronic Acknowledgement Receipt			
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Application Number:	17734102		
International Application Number:			
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Title of Invention:	MOVEMENT DISORDERS		
First Named Inventor/Applicant Name:	Robert BARROW		
Customer Number:	48924		
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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	42994 595fd16725a25a216cfd397fb547d0128ec6 ed6f	no	6
Warnings:		•	-	-	

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2	Third-Party Submission Under 37 CFR 1.290	Third-party-preissuance- submission.pdf	66962	no	3
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Information:					
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3	Request for Notification of Non- compliant Third-Party Submission	Third-party-notification- request.pdf	3c4a94e2be822943359e03d367ffd9cb460 38e07	no	
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Information:					
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4	Evidence of Publication	1-WO2019246532A1Comp.pdf	399390d437e45c48ea8c8352d376dd2fddc c79c3	no	22
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			199715	no	1
5	Evidence of Publication	2-EROWID.pdf	b2f1d77215716e066bd94bd13bfc09003df b99b8		
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7	Evidence of Publication		4eb3664947aff71b10489f99e4856ce3270d 62e9		
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			5072492		
8	Evidence of Publication	5-WO2020212948A1Comp.pdf	c36c116155d24b843337d823cd5a0068a63 7f147	no	417
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9	Evidence of Publication	6-RUTTEN.pdf	80d0845641a8b52cb04cd90ee34a4433e22 8c116	no	5	
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10	10 Evidence of Publication	7-WO2020212951A1Comp.pdf	e0cb17fc95977f73c76b935ad576e0df24f8 1526	no	341	
Warnings:		1				
Information	1					
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11	Concise Description of Relevance	US20220354831ClaimsChartRe submissionComp.pdf	0fd1e37ebfdf7c46c53d7126282f050de91f0 737	no	9	
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Information	•					
		Total Files Size (in bytes)	108	343321		
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### **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.