IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of: Gabrielle Gobbi and Danilo De Gregorio Confirmation No:

Serial No.: 18/102,296 Group No.:

Filing or 371(c) Date: January 27th, 2023 Examiner:

Entitled: ADMINISTRATION OF MODULATORS OF 5-HT AND / OR AMPA RECEPTORS FOR

TREATING NEUROLOGICAL CONDITIONS

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. LEA (2020) "Perceived outcomes of psychedelic microdosing as self-managed therapies for mental and substance use disorders" Psychopharmacology. 237:1521-1532.
- 2. POLITO & STEVENSON (2019) "A systematic study of microdosing psychedelics" PLoS One. 14(2):1-26.
- 3. THESTONEDYOGAGIRL (2019) "30 Day Microdoing Experiment" Retrieved 20 September 2023. https://www.reddit.com/r/microdosing/comments/ctkz2k/30 day microdosing experiment/
- 4. FADIMAN & KORB (2019) "Might Microdosing Psychedelics Be Safe and Beneficial? An Initial Exploration" Journal of Psychoactive Drugs. 51(2):118-122.
- 5. HUTTEN (2019) "Motives and Side-Effects of Microdosing With Psychedelics Among Users" International Journal of Neuropsychopharmacology. 22(7):426-434.
- 6. JOHNSTAD (2018) "Powerful substances in tiny amounts: An interview study of psychedelic microdosing" Nordic Studies on Alcohol and Drugs. 35(1):39-51.
- 7. TETRISDROID (2018) "Microdosing for Anxiety and Depression" Retrieved 19 September 2023. https://erowid.org/experiences/exp.php?ID=108178
- 8. Intl. Pat. Doc. No. 2020/157569 (2020) "METHODS AND COMPOSITIONS COMPRISING A 5HT RECEPTOR AGONIST FOR THE TREATMENT OF PSYCHOLOGICAL, COGNITIVE, BEHAVIORAL, AND/OR MOOD DISORDERS" (Filed 29 January 2020)
- 9. RESIDENTPURPLE (2018) "IV LSD experience reports" Retrieved 4 October 2023. https://www.reddit.com/r/LSD/comments/a2yrk1/iv_lsd_experience_reports/
- 10. Pfizer Inc. (2018) "PATIENT HEALTH QUESTIONNAIRE (PHQ-9)" Retrieved from 19 June 2018. URL:

https://web.archive.org/web/20180619082559/https:/med.stanford.edu/fastlab/research/imapp/msrs/jcr_content/main/accordion/accordion_content3/download_256324296/file.res/PHQ9%20id%20date%2008.03.pdf

- 11. CDC (2018) "Mental Health Conditions: Depression and Anxiety" Retrieved from 31 December 2018. URL:
 - $\underline{\text{https://web.archive.org/web/20181231203416/https:/www.cdc.gov/tobacco/campaign/tips/diseases/depression-anxiety.html}$
- 12. SPITZER (2020) "GAD-7 Anxiety" Retrieved from 03 June 2020. URL: https://web.archive.org/web/20200603023323/https://adaa.org/sites/default/files/GAD-7_Anxiety-updated_0.pdf
- 13. MAYO CLINIC (2018) "Anxiety Disorders" Retrieved from 14 November 2018. URL: https://web.archive.org/web/20181114083639/https://www.mayoclinic.org/diseases-conditions/anxiety/symptoms-causes/syc-20350961
- 14. ANONYMOUS (2017) "The Freelance Writer Using LSD for Depression" Retrieved from 24 October 2017. URL: https://www.thecut.com/2017/10/microdosing-lsd-depression-coping-diaries.html

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. 18/102,296 Pending Claims	References
1-23. (Canceled)	
24. A method for	1. LEA (2020) "Perceived outcomes of psychedelic microdosing as self-
improving the symptoms	managed therapies for mental and substance use disorders"
of a neuropsychiatric condition, in an	Psychopharmacology. 237:1521-1532.
individual in need	From p. 1522 "Microdosing refers to the ingestion of low to very low
thereof, the method	doses of psychedelic drugs (typically between 5 and 10% of a standard
comprising: a. administering to the	dose) on a routine schedule (e.g., every third day) without the intention of experiencing effects typically experienced at higher psychedelic doses
individual a	(e.g., visual distortions, mystical experiences)"
therapeutically effective amount of lysergic acid	From p. 1524 "Thirty-nine percent of respondents reported that they
diethylamide (LSD), or a	primarily microdosed as mental health or substance use therapies,
pharmaceutically	including for depression (21.3%), anxiety (6.9%), other mental health
acceptable salt thereof, on a first day; and b .	conditions including PTSD and ADHD (8.9%), and cessation or reduction of alcohol and other drug use."
administering to the	
individual the therapeutically effective	From p. 1524 "Fourteen percent of respondents microdosed every day, 11.3% every second day, 26.6% every third day, 14.8% every fourth
amount of the lysergic	day, 18.2% once a week or less often and the remaining 15.5% had a
acid diethylamide (LSD), or a	different dosing schedule or no fixed schedule. The median LSD microdose reported by respondents was 11 micrograms (interquartile
pharmaceutically	range 10–20)."
acceptable salt thereof,	
on a second day, the second day being at least	

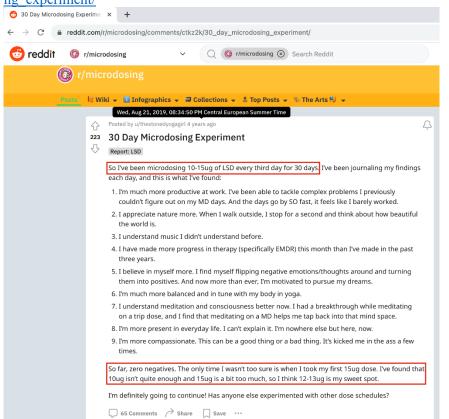
one day after the first day. wherein at least one of the therapeutically effective amount of lysergic acid diethylamide (LSD) is insufficient to provide a hallucinogenic experience. 2. POLITO & STEVENSON (2019). "A systematic study of microdosing psychedelics" PLoS One. 14(2):1-26.

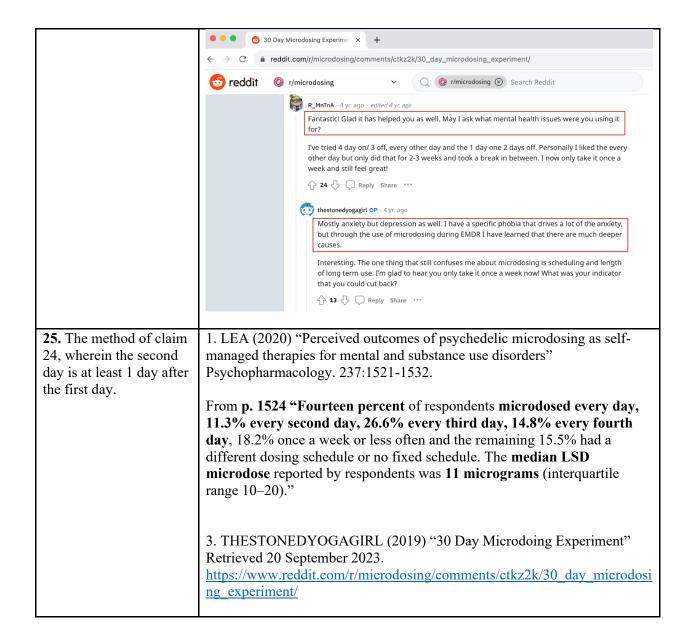
From p. 2 "So, for example, a microdose of lysergic acid diethylamide (LSD) might be 6–25 micrograms, or a microdose of psilocybin might be .1 to .5 grams of dried mushrooms [3]. People microdose using a wide range of different substances, although LSD and psilocybin are the most commonly discussed in online forums [4]."

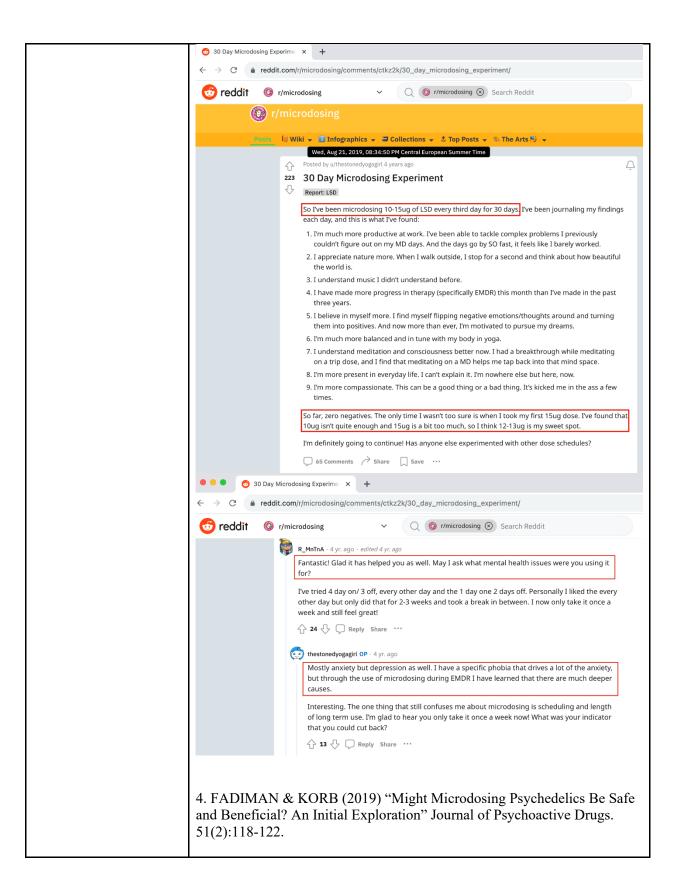
From p. 2 "People follow a variety of different schedules when microdosing, sometimes taking a dose each day..."

3. THESTONEDYOGAGIRL (2019) "30 Day Microdoing Experiment" Retrieved 20 September 2023.

<u>https://www.reddit.com/r/microdosing/comments/ctkz2k/30_day_microdosing</u>
ng experiment/







From **p. 118** "... **using a** psychedelic in the **microdose** range (10 micrograms) **every three days** was determined to be safe across a wide variety of individuals and conditions."

From p. 120 "When they filled out their enrollment form, most people said they had suffered from depressed mood in the last month. Both people who reported that they were diagnosed with major depressive disorder, bipolar disorder, and other mood disorders, and those who did not report this diagnosis reported negative affect scores that improved with microdosing for longer than 14 days."

From p. 118 "Participant reports suggested that spaced but repeated microdoses were followed by improvements in negative moods, especially depression, and increases in positive moods. Increased energy, improved work effectiveness, and improved health habits were observed in clinical and non-clinical populations. Smaller samples described alleviation of symptoms in migraine headaches, pre-menstrual syndromes, traumatic brain injury, shingles, and other conditions not previously associated with psychedelic use."

26. The method of claim 24, wherein the second day is at least 7 days after the first day.

From application of interest 18/102,296 paragraph [0037] "In some embodiments, the modulator of the AMPA receptor and/or the 5-HT2A receptor is an ergoline, or a pharmaceutically acceptable salt, solvate, metabolite, derivative, or prodrug thereof. In some embodiments, the modulator of the AMPA receptor and/or the 5-HT2A receptor is LSD, or a pharmaceutically acceptable salt, solvate, metabolite, derivative, or prodrug thereof."

From application of interest 18/102,296 paragraph [0039] "In some instances, the modulator of the AMPA receptor and/or the 5-HT2A receptor, or the pharmaceutically acceptable salt, solvate, metabolite, derivative, or prodrug thereof, is administered to the individual at an amount of at most 200 micrograms (mcg)."

4. FADIMAN & KORB (2019) "Might Microdosing Psychedelics Be Safe and Beneficial? An Initial Exploration" Journal of Psychoactive Drugs. 51(2):118-122.

From p. 120 "Most people who continued to microdose after their research month chose to do so less frequently—most commonly once a week or once a month."

From **p. 118** "... **using a** psychedelic in the **microdose** range (10 micrograms) every three days was determined to be safe across a wide variety of individuals and conditions."

5. WILLIAM (2018) "Tramatic Brain Injury Cured With Time and This Substance" Retrieved 2 October 2023.

27. The method of claim 24, wherein the method further comprises administering to the individual the therapeutically effective amount of the LSD, or a pharmaceutically acceptable salt thereof on a third day, wherein the third day is between the first and second day.

1. LEA (2020) "Perceived outcomes of psychedelic microdosing as self-managed therapies for mental and substance use disorders" Psychopharmacology. 237:1521-1532.

From **p. 1524** "Fourteen percent of respondents microdosed every day, 11.3% every second day, **26.6% every third day**, 14.8% every fourth day, 18.2% once a week or less often and the remaining 15.5% had a different dosing schedule or no fixed schedule."

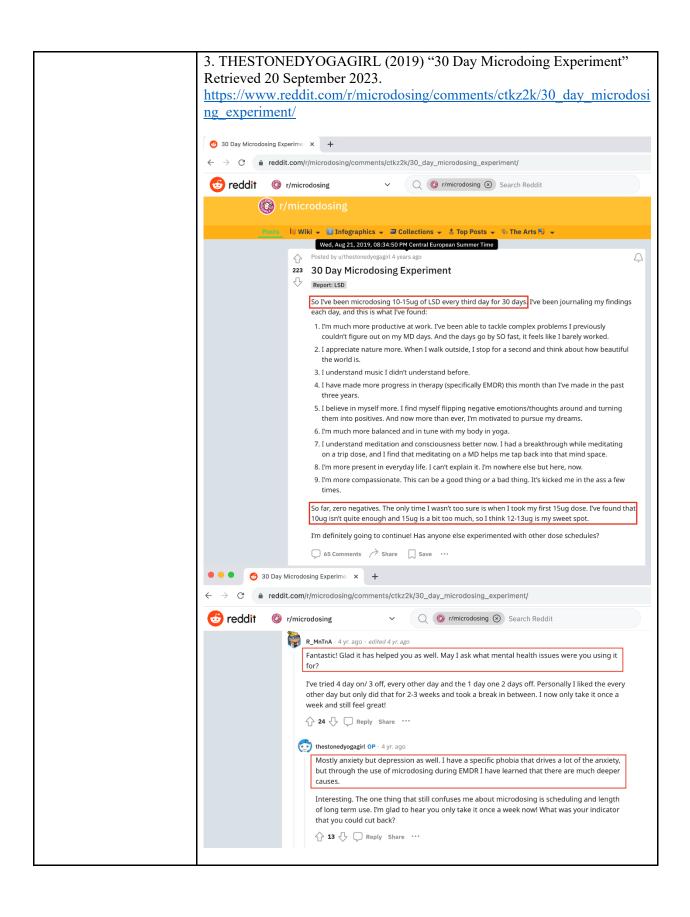
From **p. 1524** "The mean age at commencement of microdosing was 29 years (SD = 12.1), **most respondents (78.5%) had microdosed for up to 6 months in total**, and primarily microdosed psilocybin (46.4%) or LSD/1P-LSD (45.0%) (Table 1)."

2. POLITO & STEVENSON (2019) "A systematic study of microdosing psychedelics" PLoS One. 14(2):1-26.

From **p. 2** "People follow a variety of different schedules when microdosing, sometimes **taking a dose each day** but much more frequently interspersing dosing days with rest days. One common schedule is to **microdose every three days** [7]. The idea behind this regimen is that there may be a residual effect from each microdose that lasts one to two days afterwards. Most popular press stories on microdosing have mentioned this three day cycle [8,9]."

From p. 2 "The current popularity of microdosing can be traced back to a book, The Psychedelic Explorers Guide by James Fadiman [1]. This was the first publication to describe microdosing in detail. Fadiman outlined the purported benefits of regular microdosing, with a

	recommendation to follow a three-day cycle, and guidelines for appropriate doses."
28. The method of claim 24, wherein the method further comprises administering to the	1. LEA (2020) "Perceived outcomes of psychedelic microdosing as self-managed therapies for mental and substance use disorders" Psychopharmacology. 237:1521-1532.
individual the therapeutically effective amount of the LSD, or a pharmaceutically acceptable salt thereof	From p. 1522 "Microdosing refers to the ingestion of low to very low doses of psychedelic drugs (typically between 5 and 10% of a standard dose) on a routine schedule (e.g., every third day) without the intention of experiencing effects typically experienced at higher psychedelic doses (e.g., visual distortions, mystical experiences)"
on a third day, wherein the third day is after the second day.	From p. 1524 "Thirty-nine percent of respondents reported that they primarily microdosed as mental health or substance use therapies, including for depression (21.3%), anxiety (6.9%), other mental health conditions including PTSD and ADHD (8.9%), and cessation or reduction of alcohol and other drug use."
	From p. 1524 "Fourteen percent of respondents microdosed every day, 11.3% every second day, 26.6% every third day, 14.8% every fourth day , 18.2% once a week or less often and the remaining 15.5% had a different dosing schedule or no fixed schedule."
29. The method of claim 24, wherein the first day is no less than one day apart from the second	4. FADIMAN & KORB (2019) "Might Microdosing Psychedelics Be Safe and Beneficial? An Initial Exploration" Journal of Psychoactive Drugs. 51(2):118-122.
day and the second day is no less than one day apart from the third day.	From p. 118 " using a psychedelic in the microdose range (10 micrograms) every three days was determined to be safe across a wide variety of individuals and conditions."
	From p. 120 "When they filled out their enrollment form, most people said they had suffered from depressed mood in the last month. Both people who reported that they were diagnosed with major depressive disorder, bipolar disorder, and other mood disorders, and those who did not report this diagnosis reported negative affect scores that improved with microdosing for longer than 14 days."
	From p. 118 "Participant reports suggested that spaced but repeated microdoses were followed by improvements in negative moods, especially depression, and increases in positive moods. Increased energy, improved work effectiveness, and improved health habits were observed in clinical and non-clinical populations. Smaller samples described alleviation of symptoms in migraine headaches, pre-menstrual syndromes, traumatic brain injury, shingles, and other conditions not previously associated with psychedelic use."



- 30. The method of claim 24, wherein the therapeutically effective amount of the LSD is administered at least once daily for at least two days.
- 1. LEA (2020) "Perceived outcomes of psychedelic microdosing as self-managed therapies for mental and substance use disorders" Psychopharmacology. 237:1521-1532.
- From **p. 1524 "Fourteen percent** of respondents **microdosed every day**, 11.3% every second day, 26.6% every third day, 14.8% **every** fourth day, 18.2% once a week or less often and the remaining 15.5% had a different dosing schedule or no fixed schedule. The **median LSD microdose** reported by respondents was **11 micrograms** (interquartile range 10–20)."
- 31. The method of claim 24, wherein the therapeutically effective amount of the LSD, or the pharmaceutically acceptable salt thereof, is less than or equal to 200 mcg.
- 1. LEA (2020) "Perceived outcomes of psychedelic microdosing as self-managed therapies for mental and substance use disorders" Psychopharmacology. 237:1521-1532.

From p. 1522 "Microdosing refers to the ingestion of low to very low doses of psychedelic drugs (typically between 5 and 10% of a standard dose) on a routine schedule (e.g., every third day) without the intention of experiencing effects typically experienced at higher psychedelic doses (e.g., visual distortions, mystical experiences)..."

From p. 1524 "Thirty-nine percent of respondents reported that they primarily microdosed as mental health or substance use therapies, including for depression (21.3%), anxiety (6.9%), other mental health conditions including PTSD and ADHD (8.9%), and cessation or reduction of alcohol and other drug use."

From p. 1524 "Fourteen percent of respondents microdosed every day, 11.3% every second day, 26.6% every third day, 14.8% every fourth day, 18.2% once a week or less often and the remaining 15.5% had a different dosing schedule or no fixed schedule. The median LSD microdose reported by respondents was 11 micrograms (interquartile range 10–20)."

5. HUTTEN (2019) "Motives and Side-Effects of Microdosing With Psychedelics Among Users" International Journal of Neuropsychopharmacology. 22(7):426-434.

From **p. 427** "Another commonly reported motivation and subsequent outcome is the **alleviation of psychological symptoms including depressive mood and anxiety** and/or physiological symptoms such as pain..."

From **p. 430**

Table 3. Number (percentage) of respondents who indicated use of one of the listed substances as a microdose, with the self-reported dose in mode and the percentage of respondents who did not know the dose or failed to complete this item

	Psychedelic users per substance	Microdose det	ails	Users who do not know the dose or did not fill out this question		
Substance	n (%)	Amount, mg	Dose range, mg (min-max)	Do not know, n (%)	Missing, n (%)	
1P-LSD	129 (11.6)	0.01	0.0005–75	9 (7.0)	9 (7.0)	
2Cs	22 (2.0)	3-4	0.75-25	3 (13.6)	3 (13.6)	
5-MeO-DMT	5 (0.4)	0.005	0.005-7		2 (40.0)	
ALD-52/1A-LSD	41 (3.7)	0.01	0.0005-75	3 (7.3)	6 (14.6)	
Ayahuasca	15 (1.3)	14	14-500	10 (66.7)	2 (13.3)	
DMT	64 (5.7)	10	00.5-25	19 (29.7)	15 (23.4)	
LSD	666 (59.7)	0.01	0.00001-500	113 (17.0)	60 (9.0)	
MDMA/ecstasy	71 (6.4)	50	0.02-100	18 (25.4)	21 (29.6)	
Mescaline	26 (2.3)	50	0.3-1000	14 (53.8)	4 (15.4)	
NBOMes	9 (0.8)	0.5-50	0.5-50	3 (33.3)	4 (44.4)	
Other	60 (5.4)	5	0.01-1000	15 (25.0)	24 (40.0)	
Psilocybin	645 (57.8)	500	0.025-8000	146 (22.6)	93 (14.4)	
Salvinorin A	31 (2.8)	0.2	0.2-200	16 (51.6)	10 (32.3)	

Abbreviations: 1P-LSD, 1-propionyl-lysergic acid diethylamide; 2C, 2-ethylamine; 5-MeO-DMT, 5-methoxy-N,N-dimethyltryptamine; ALD-52/1A-LSD, 1-Acetyl-N,N-diethyltysergamide; DMT, N,N-dimethyltryptamine; LSD, lysergic acid diethylamide; MDMA, 3,4,-methylenedioxymethamphetamine; NBOMe, N-benzyl Methoxy.

2. POLITO & STEVENSON (2019) "A systematic study of microdosing psychedelics" PLoS One. 14(2):1-26.

From **p. 9** "Some reports of **LSD doses** were in a format such as "1/10th dose", in such cases **we estimated typical doses as 100ug**."

- **32.** The method of claim 24, wherein the therapeutically effective amount of the LSD, or the pharmaceutically acceptable salt thereof, is less than or equal to 100 mcg.
- 1. LEA (2020) "Perceived outcomes of psychedelic microdosing as self-managed therapies for mental and substance use disorders" Psychopharmacology. 237:1521-1532.

From p. 1522 "Microdosing refers to the ingestion of low to very low doses of psychedelic drugs (typically between 5 and 10% of a standard dose) on a routine schedule (e.g., every third day) without the intention of experiencing effects typically experienced at higher psychedelic doses (e.g., visual distortions, mystical experiences)..."

From p. 1524 "Thirty-nine percent of respondents reported that they primarily microdosed as mental health or substance use therapies, including for depression (21.3%), anxiety (6.9%), other mental health conditions including PTSD and ADHD (8.9%), and cessation or reduction of alcohol and other drug use."

From p. 1524 "Fourteen percent of respondents microdosed every day, 11.3% every second day, 26.6% every third day, 14.8% every fourth day, 18.2% once a week or less often and the remaining 15.5% had a different dosing schedule or no fixed schedule. The median LSD microdose reported by respondents was 11 micrograms (interquartile range 10–20)."

5. HUTTEN (2019) "Motives and Side-Effects of Microdosing With Psychedelics Among Users" International Journal of Neuropsychopharmacology. 22(7):426-434.

Table 3. Number (percentage) of respondents who indicated use of one of the listed substances as a microdose, with the self-reported dose in mode and the percentage of respondents who did not know the dose or failed to complete this item

	Psychedelic users per substance	Microdose deta	ails	Users who do not know the dose or did not fill out this question		
Substance	n (%)	Amount, mg	Dose range, mg (min-max)	Do not know, n (%)	Missing, n (%)	
1P-LSD	129 (11.6)	0.01	0.0005–75	9 (7.0)	9 (7.0)	
2Cs	22 (2.0)	3-4	0.75-25	3 (13.6)	3 (13.6)	
5-MeO-DMT	5 (0.4)	0.005	0.005-7	-	2 (40.0)	
ALD-52/1A-LSD	41 (3.7)	0.01	0.0005-75	3 (7.3)	6 (14.6)	
Ayahuasca	15 (1.3)	14	14-500	10 (66.7)	2 (13.3)	
DMT	64 (5.7)	10	00.5-25	19 (29.7)	15 (23.4)	
LSD	666 (59.7)	0.01	0.00001-500	113 (17.0)	60 (9.0)	
MDMA/ecstasy	71 (6.4)	50	0.02-100	18 (25.4)	21 (29.6)	
Mescaline	26 (2.3)	50	0.3-1000	14 (53.8)	4 (15.4)	
NBOMes	9 (0.8)	0.5-50	0.5-50	3 (33.3)	4 (44.4)	
Other	60 (5.4)	5	0.01-1000	15 (25.0)	24 (40.0)	
Psilocybin	645 (57.8)	500	0.025-8000	146 (22.6)	93 (14.4)	
Salvinorin A	31 (2.8)	0.2	0.2-200	16 (51.6)	10 (32.3)	

Abbreviations: 1P-LSD, 1-propionyl-lysergic acid diethylamide; 2C, 2-ethylamine; 5-MeO-DMT, 5-methoxy-N,N-dimethyltryptamine; ALD-52/1A-LSD, 1-Acetyl-N,N-diethyltysergamide; DMT, N,N-dimethyltryptamine; LSD, lysergic acid diethylamide; MDMA, 3,4,-methylenedioxymethamphetamine; NBOMe, N-benzyl Methoxy.

2. POLITO & STEVENSON (2019) "A systematic study of microdosing psychedelics" PLoS One. 14(2):1-26.

From **p. 9** "Some reports of **LSD doses** were in a format such as "1/10th dose", in such cases **we estimated typical doses as 100ug**."

- 33. The method of claim 24, wherein the therapeutically effective amount of the LSD, or the pharmaceutically acceptable salt thereof, is less than or equal to 60 mcg.
- 1. LEA (2020) "Perceived outcomes of psychedelic microdosing as self-managed therapies for mental and substance use disorders" Psychopharmacology. 237:1521-1532.

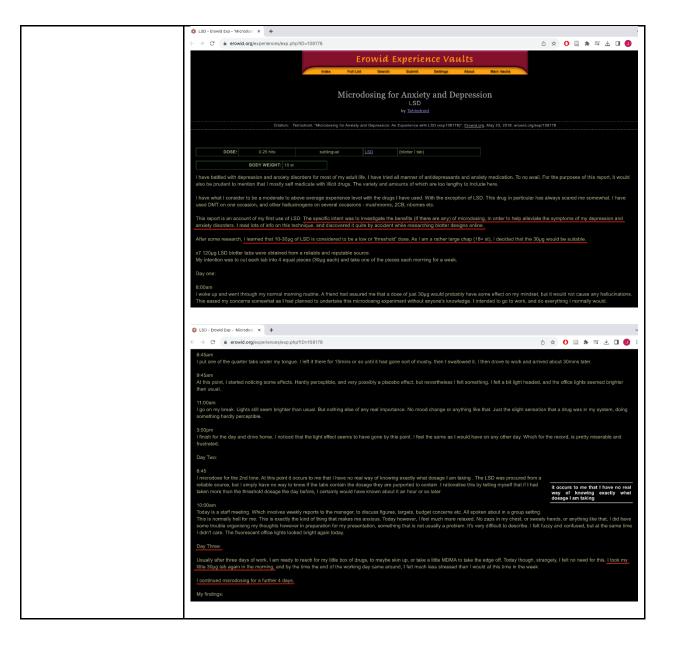
From p. 1522 "Microdosing refers to the ingestion of low to very low doses of psychedelic drugs (typically between 5 and 10% of a standard dose) on a routine schedule (e.g., every third day) without the intention of experiencing effects typically experienced at higher psychedelic doses (e.g., visual distortions, mystical experiences)..."

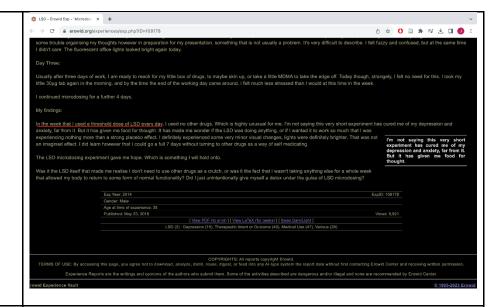
From p. 1524 "Thirty-nine percent of respondents reported that they primarily microdosed as mental health or substance use therapies, including for depression (21.3%), anxiety (6.9%), other mental health conditions including PTSD and ADHD (8.9%), and cessation or reduction of alcohol and other drug use."

From p. 1524 "Fourteen percent of respondents microdosed every day, 11.3% every second day, 26.6% every third day, 14.8% every fourth day, 18.2% once a week or less often and the remaining 15.5% had a different dosing schedule or no fixed schedule. The median LSD microdose reported by respondents was 11 micrograms (interquartile range 10–20)."

5. HUTTEN (2019) "Motives and Side-Effects of Microdosing With Psychedelics Among Users" International Journal of Neuropsychopharmacology. 22(7):426-434.

		(percentage) of respondents who independent of respondents who did not			icrodose, with the self-	reported dose in
	mode and the per	Psychedelic users per substance	Microdose deta		Users who do not kn	
	Substance	n (%)	Amount, mg	Dose range, mg (min-max)	Do not know, n (%)	Missing, n (%)
	1P-LSD 2Cs	129 (11.6) 22 (2.0)	0.01	0.0005–75 0.75–25	9 (7.0) 3 (13.6)	9 (7.0) 3 (13.6)
	5-MeO-DMT ALD-52/1A-LSD	5 (0.4) 41 (3.7)	0.005 0.01	0.005–7 0.0005–75	3 (7.3)	2 (40.0) 6 (14.6)
	Ayahuasca DMT	15 (1.3) 64 (5.7)	14 10	14–500 00.5–25	10 (66.7) 19 (29.7)	2 (13.3) 15 (23.4)
	LSD MDMA/ecstasy	666 (59.7) 71 (6.4)	0.01 50	0.00001–500 0.02–100	113 (17.0) 18 (25.4)	60 (9.0) 21 (29.6)
	Mescaline NBOMes Other	26 (2.3) 9 (0.8)	50 0.5–50 5	0.3–1000 0.5–50	14 (53.8) 3 (33.3)	4 (15.4) 4 (44.4)
	Psilocybin Salvinorin A	60 (5.4) 645 (57.8) 31 (2.8)	5 500 0.2	0.01-1000 0.025-8000 0.2-200	15 (25.0) 146 (22.6) 16 (51.6)	24 (40.0) 93 (14.4) 10 (32.3)
34. The method of claim	diethyllysergamide; l	SD, 1-propionyl-lysergic acid diethylamide DMT, N,N-dimethyltryptamine; LSD, lyserg STAD (2018) "Powe	ic acid diethylamide	; MDMA, 3,4,-methylenedioxymetha	mphetamine; NBOMe, N-be	nzyl Methoxy.
32, wherein the		sychedelic microdo				
therapeutically effective	35(1):39-5	•	ising inc	raic studies on A	Aiconoi and	Drugs.
amount of the LSD, or	55(1).57 5					
the pharmaceutically	_	4 "Doses were usua	•			
acceptable salt thereof, is	For LSD ,	this amounted to	somewhe	re between 10 ar	nd 25 mcg ²	•
about 20 mcg to about 50 mcg.	From n 4	4 "The most comm	only dec	eribed affects we	ra haalth ral	ntad
50 meg.	_	nign influence noted	•			
	and for a 1	5 "Therapeutic eff range of conditions ost-traumatic stre s."	including	g obsessive-com	pulsive diso	rder
35. The method of claim 34, wherein the therapeutically effective amount of the LSD, or	Retrieved	SDROID (2018) "N 19 September 2023 wid.org/experience	3.		nd Depression	on''
amount of the LSD, or the pharmaceutically acceptable salt thereof, is about 25 mcg to about						





36. The method of claim 24, wherein the therapeutically effective amount of the LSD, or a pharmaceutically acceptable salt thereof, is administered to the individual in need thereof as a controlled release formulation to the individual in need thereof.

8. Intl. Pat. Doc. No. 2020/157569 (2020) "METHODS AND COMPOSITIONS COMPRISING A 5HT RECEPTOR AGONIST FOR THE TREATMENT OF PSYCHOLOGICAL, COGNITIVE, BEHAVIORAL, AND/OR MOOD DISORDERS" (Filed 29 January 2020)

From Claim 1: "A method of managing a neurological condition or one or more symptoms thereof in a subject in need thereof, comprising administering to the subject a pharmaceutical composition comprising:

- a) a therapeutically effective amount of one or more 5HT receptor agonist or a pharmaceutically acceptable salt, solvate, metabolite, derivative, or prodrug thereof; and
- b) a pharmaceutically acceptable excipient wherein the therapeutically effective amount of the 5HT receptor agonist or a pharmaceutically acceptable salt, solvate, metabolite, derivative, or prodrug thereof is provided to the subject in need thereof in an amount insufficient to provide an adverse side effect, such as hallucinogenic experience."

From Claim 2: "A method of treating the symptoms of a neurological condition in a subject suffering from or susceptible to the neurological condition, comprising administering to the subject a pharmaceutical composition comprising:

- a) a therapeutically effective amount of one or more 5HT receptor agonist or a pharmaceutically acceptable salt, solvate, metabolite, derivative, or prodrug thereof; and
- b) a pharmaceutically acceptable excipient; wherein the therapeutically effective amount of the 5HT receptor agonist or a pharmaceutically acceptable salt, solvate, metabolite, derivative, or prodrug thereof is provided to the subject in need thereof

in an amount insufficient to provide an adverse side effect, such as hallucinogenic experience."

From Claim 3: "The method of any one of the preceding claims, wherein the 5HT receptor agonist or a pharmaceutically acceptable salt, solvate, metabolite, derivative, or prodrug thereof is present in an amount of from about 0.1 mg to about 50 mg (e.g. about 0.1 mg to about 10 mg, about 0.2 mg to about 5 mg, about 10 mg to about 50 mg, or the like)."

From Claim 7: "The method of any one of the preceding claims, wherein the pharmaceutical composition comprises a controlled release component."

From Claim 18: "The method of any one of the preceding claims, wherein the pharmaceutical composition further comprises an effective amount of a second agent."

From Claim 21: "The method of claim 18, wherein the second agent is a stimulant, an antihistamine, an antiemetic, an antidepressant, an anti-inflammatory, a growth factor, a lithium compound, resveratrol, phosphatidylcholine, curcumin, magnesium, melatonin, pregnenolone, ginseng, lysergic acid diethylamide, or combinations thereof."

37. The method of claim 24, wherein the neuropsychiatric condition is an anxiety or depression disorder.

1. LEA (2020) "Perceived outcomes of psychedelic microdosing as self-managed therapies for mental and substance use disorders" Psychopharmacology. 237:1521-1532.

From p. 1524 "Thirty-nine percent of respondents reported that they primarily microdosed as mental health or substance use therapies, including for depression (21.3%), anxiety (6.9%)..."

From p. 1524 "Fourteen percent of respondents microdosed every day, 11.3% every second day, 26.6% every third day, 14.8% every fourth day, 18.2% once a week or less often and the remaining 15.5% had a different dosing schedule or no fixed schedule. The median LSD microdose reported by respondents was 11 micrograms (interquartile range 10–20)."

38. The method of claim 37, wherein the anxiety disorder is social anxiety.

1. LEA (2020) "Perceived outcomes of psychedelic microdosing as self-managed therapies for mental and substance use disorders" Psychopharmacology. 237:1521-1532.

From p. 1524 "Over half of respondents (56.7%) had ever been diagnosed with a mental disorder (excluding substance use disorders), including...social anxiety disorder, 14.5%..."

From p. 1524 "Fourteen percent of respondents microdosed every day, 11.3% every second day, 26.6% every third day, 14.8% every fourth day, 18.2% once a week or less often and the remaining 15.5% had a different dosing schedule or no fixed schedule. The median LSD

	microdose reported by respondents was 11 micrograms (interquartile range 10–20)."
39. The method of claim 37, wherein the anxiety disorder is generalized anxiety disorder.	1. LEA (2020) "Perceived outcomes of psychedelic microdosing as self-managed therapies for mental and substance use disorders" Psychopharmacology. 237:1521-1532.
	From p. 1524 "Over half of respondents (56.7%) had ever been diagnosed with a mental disorder (excluding substance use disorders), includinggeneralised anxiety disorder, 25.4%"
	From p. 1524 "Fourteen percent of respondents microdosed every day, 11.3% every second day, 26.6% every third day, 14.8% every fourth day, 18.2% once a week or less often and the remaining 15.5% had a different dosing schedule or no fixed schedule. The median LSD microdose reported by respondents was 11 micrograms (interquartile range 10–20)."
40. The method of claim 24, wherein the symptoms of the	1. LEA (2020) "Perceived outcomes of psychedelic microdosing as self-managed therapies for mental and substance use disorders" Psychopharmacology. 237:1521-1532.
neuropsychiatric condition are physical, behavioral, emotional, mental, or a combination thereof.	From p. 1524 "Over half of respondents (56.7%) had ever been diagnosed with a mental disorder (excluding substance use disorders), including depression (41.2%), anxiety disorders (32.0%; generalised anxiety disorder, 25.4%; social anxiety disorder, 14.5%; panic disorder/panic attacks, 12.5%), ADHD (19.5%), PTSD (15.6%), bipolar disorder (7.4%), personality disorder (5.1%), eating disorder (4.8%), obsessive compulsive disorder (4.7%) and schizophrenia (1.0%). The median number of diagnosed mental disorders was 1 (interquartile range 0–3). Forty-four percent of all respondents had been prescribed psychiatric medications and 8.1% were prescribed these at the time of the survey. Sixty-five percent of respondents had ever seen a counsellor or psychotherapist for their mental health. At the time of the survey, 17.5% of respondents showed at least moderate levels of depression on the PHQ-9, and 12.6% showed at least moderate levels of anxiety on the GAD-7 (Table 1)." From p. 1524 "Fourteen percent of respondents microdosed every day, 11.3% every second day, 26.6% every third day, 14.8% every fourth day, 18.2% once a week or less often and the remaining 15.5% had a different dosing schedule or no fixed schedule. The median LSD microdose reported by respondents was 11 micrograms (interquartile
	range 10–20)." 10. Pfizer Inc. (2018) "PATIENT HEALTH QUESTIONNAIRE (PHQ-9)" Retrieved from 19 June 2018. URL:
	https://web.archive.org/web/20180619082559/https:/med.stanford.edu/fastl

ab/research/imapp/msrs/ jcr_content/main/accordion/accordion_content3/d ownload 256324296/file.res/PHQ9%20id%20date%2008.03.pdf

From **p. 1**

PATIENT HEALTH QUESTIONNAIRE (PHQ-9)

ID #:		DATE:		
Over the last 2 weeks, how often have you been				
bothered by any of the following problems? (use "<" to indicate your answer)	Not at all	Several days	More than half the days	Nearly every day
Little interest or pleasure in doing things	0	1	2	3
2. Feeling down, depressed, or hopeless	0	1	2	3
3. Trouble falling or staying asleep, or sleeping too much	0	1	2	3
4. Feeling tired or having little energy	0	1	2	3
5. Poor appetite or overeating	0	1	2	3
6. Feeling bad about yourself—or that you are a failure or have let yourself or your family down	0	1	2	3
7. Trouble concentrating on things, such as reading the newspaper or watching television	0	1	2	3
8. Moving or speaking so slowly that other people could have noticed. Or the opposite —being so figety or restless that you have been moving around a lot more than usual	0	1	2	3
9. Thoughts that you would be better off dead, or of hurting yourself	0	1	2	3
	add columns		+	+
(Healthcare professional: For interpretation of TOTA please refer to accompanying scoring card).	AL, TOTAL:			
10. If you checked off any problems, how difficult have these problems made it for you to do your work, take care of things at home, or get along with other people?		Somew Very dif	cult at all hat difficult ficult ely difficult	

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From **p. 2** "For initial diagnosis:

- 1. Patient completes PHQ-9 Quick Depression Assessment.
- 2. If there are at least 4 3s in the shaded section (including Questions #1 and #2), consider a depressive disorder. Add score to determine severity.

Consider Major Depressive Disorder

- if there are at least 5 3s in the shaded section (one of which corresponds to Question #1 or #2)

Consider Other Depressive Disorder

- if there are 2-4 3s in the shaded section (one of which corresponds to Question #1 or #2)

Note: Since the questionnaire relies on patient self-report, all responses should be verified by the clinician, and a definitive diagnosis is made on clinical grounds taking into account how well the patient understood the questionnaire, as well as other relevant information from the patient.

Diagnoses of Major Depressive Disorder or Other Depressive Disorder also require impairment of social, occupational, or other important areas of functioning (Question #10) and ruling out normal bereavement, a history of a Manic Episode (Bipolar Disorder), and a physical disorder, medication, or other drug as the biological cause of the depressive symptoms"

11. CDC (2018) "Mental Health Conditions: Depression and Anxiety" Retrieved from 31 December 2018. URL:

https://web.archive.org/web/20181231203416/https:/www.cdc.gov/tobacco/campaign/tips/diseases/depression-anxiety.html

From webpage "What Is Depression?

Depression is more than just feeling down or having a bad day. When a sad mood lasts for a long time and interferes with normal, everyday functioning, you may be depressed.

Symptoms of depression include:

- Feeling sad or anxious often or all the time
- Not wanting to do activities that used to be fun
- Feeling irritable, easily frustrated, or restless
- Having trouble falling asleep or staying asleep
- Waking up too early or sleeping too much
- Eating more or less than usual or having no appetite
- Experiencing aches, pains, headaches, or stomach problems that do not improve with treatment
- Having trouble concentrating, remembering details, or making decisions
- Feeling tired, even after sleeping well
- Feeling guilty, worthless, or helpless
- Thinking about suicide or hurting yourself"

12. SPITZER (2020) "GAD-7 Anxiety" Retrieved from 03 June 2020. URL:

https://web.archive.org/web/20200603023323/https:/adaa.org/sites/default/files/GAD-7_Anxiety-updated_0.pdf

From	PD	H
11101111	11,	1

GAD-7 Anxiety

Over the <u>last two weeks</u> , how often have you been bothered by the following problems?	Not at all	Several days	More than half the days	Nearly every day
Feeling nervous, anxious, or on edge	0	1	2	3
Not being able to stop or control worrying	0	1	2	3
Worrying too much about different things	0	1	2	3
Trouble relaxing	0	1	2	3
Being so restless that it is hard to sit still	0	1	2	3
Becoming easily annoyed or irritable	0	1	2	3
 Feeling afraid, as if something awful might happen 	0	1	2	3

			Total score
	blems, how difficult have the along with other people?	y made it for you to	do your work, take care of
Not difficult at all	Somewhat difficult	Very difficult	Extremely difficult

Column totals

Source: Primary Care Evaluation of Mental Disorders Patient Health Questionnaire (PRIME-MD-PHQ). The PHQ was developed by Drs. Robert L. Spitzer, Janet B.W. Williams, Kurt Kroenke, and colleagues. For research information, contact Dr. Spitzer at ris8@columbia.edu. PRIME-MD® is a trademark of Pfizer Inc. Copyright® 1999 Pfizer Inc. All rights reserved. Reproduced with permission

From PDF "Scoring GAD-7 Anxiety Severity

This is calculated by assigning scores of 0, 1, 2, and 3 to the response categories, respectively, of "not at all," "several days," "more than half the days," and "nearly every day."

GAD-7 total score for the seven items ranges from 0 to 21.

0-4: minimal anxiety 5-9: mild anxiety

10–14: moderate anxiety

15–21: severe anxiety"

13. MAYO CLINIC (2018) "Anxiety Disorders" Retrieved from 14 November 2018. URL:

https://web.archive.org/web/20181114083639/https:/www.mayoclinic.org/diseases-conditions/anxiety/symptoms-causes/syc-20350961

From webpage "Common anxiety signs and symptoms include:

- Feeling nervous, restless or tense
- Having a sense of impending danger, panic or doom
- Having an increased heart rate
- Breathing rapidly (hyperventilation)
- Sweating
- Trembling
- Feeling weak or tired

- Trouble concentrating or thinking about anything other than the present worry
- Having trouble sleeping
- Experiencing gastrointestinal (GI) problems
- Having difficulty controlling worry
- Having the urge to avoid things that trigger anxiety"

41. The method of claim 24, wherein the therapeutically effective amount of the LSD, or a pharmaceutically acceptable salt thereof, is administered as an oral formulation, intravenous formulation, or an intraparietal formulation to the individual in need thereof.

From application of interest 18/102,296 paragraph [0037] "In some embodiments, the modulator of the AMPA receptor and/or the 5-HT2A receptor is an ergoline, or a pharmaceutically acceptable salt, solvate, metabolite, derivative, or prodrug thereof. In some embodiments, the modulator of the AMPA receptor and/or the 5-HT2A receptor is LSD, or a pharmaceutically acceptable salt, solvate, metabolite, derivative, or prodrug thereof."

From application of interest 18/102,296 paragraph [0039] "In some instances, the modulator of the AMPA receptor and/or the 5-HT2A receptor, or the pharmaceutically acceptable salt, solvate, metabolite, derivative, or prodrug thereof, is administered to the individual at an amount of at most 200 micrograms (mcg)."

5. HUTTEN (2019) "Motives and Side-Effects of Microdosing With Psychedelics Among Users" International Journal of Neuropsychopharmacology. 22(7):426-434.

From **p. 427** "Another commonly reported motivation and subsequent outcome is the alleviation of psychological symptoms including depressive mood and anxiety and/or physiological symptoms such as pain..."

From **p. 428** "An overview of route of administration and frequency of use per psychedelic for microdosing is presented in Table 4..."

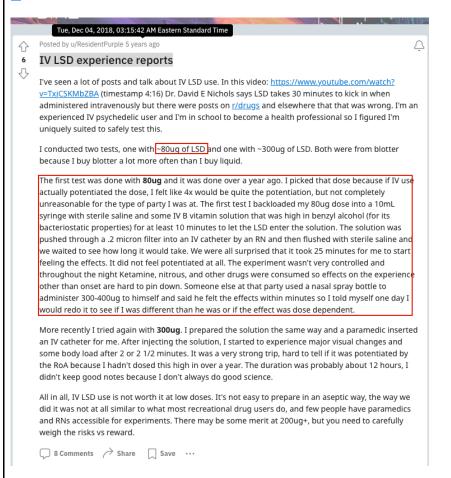
	Route of administra	ation, n (%)								Frequency of micro	dosing per week	
	Number of respondents who									Number of respondents who	Frequency of dosing per week	Range of dosing per week
Substance		Oral	Sublingual	Inspiration	Intranasal	Ocular	lar Cutaneous Rectal Othe	Other	answered N (%)	M (SD)	(min-max)	
1P-LSD	120 (77.5)	71 (55.0)	28 (21.7)	-	-	-	-	1 (0.8)	-	76 (58.9)	2.13 (2.23)	0.001-14
2Cs	13 (59.1)	11 (50.0)		-	1 (4.5)	-	-	1 (4.5)	-	10 (45.5)	2.89 (4.11)	0.2-14
5-MeO-DMT	2 (30.0)	1 (20.0)	-	-	-	-	-	1 (20.0)	-	2 (40.0)	7.5 (9.19)	1-14
ALD-52/ 1A-LSD	28 (68.3)	18 (43.9)	9 (22.0)	-	-	-	-	1 (2.4)	-	22 (53.7)	2.23 (2.82)	0.005-14
Ayahuasca	7 (46.7)	5 (33.3)	-	1 (6.7)	-	-	-	1 (6.7)	-	6 (40.0)	4.37 (5.16)	0.25-14
DMT	35 (54.7)	2 (3.1)	-	32 (50.0)	-	-	-	1 (1.6)	-	25 (39.1)	2.26 (3.17)	0.002-14
LSD	491 (73.7)	387 (58.1)	99 (14.9)	-	1 (0.2)	1 (0.2)	-	1 (0.2)	2 (0.3)	384 (57.7)	2.02 (1.89)	0.0001-15
MDMA/ ecstasy	34 (47.9)	24 (33.8)	2 (2.8)	-	7 (9.9)	-	-	1 (1.4)	-	19 (26.8)	2.08 (3.46)	0.005-14
Mescaline	12 (46.2)	11 (42.3)	-	-	-	-	-	1 (3.8)	-	6 (23.1)	3.46 (5.26)	0.25-14
NBOMes	3 (33.3)	-	2 (22.2)	-	-	-	-	1 (11.1)	-	3 (33.3)	5.67 (7.23)	1-14
Other	26 (43.3)	16 (26.7)	-	6 (10.0)	2 (3.3)	-	1 (1.7)	1 (1.7)	-	21 (35.0)	6.78 (6.98)	0.5-30
Psilocybin	416 (64.5)	415 (64.3)	-	-	-	-	-	1 (0.2)	-	325 (78.3)	3.74 (3.35)	0.001-30
Salvinorin A	15 (45.4)	3 (9.7)	2 (6.5)	8 (25.8)	_	-	_	1 (3.2)	1 (3.2)	8 (25.8)	2.63 (4.65)	0.01-14

From p. 428 "... the frequency of microdosing ranges between 2 and 7 times per week, depending on the substance. For instance, 57% up to

78% of the respondents that microdosed with LSD and psilocybin reported to use microdosing several times per week, ranging between 2 and 4 times per week."

9. RESIDENTPURPLE (2018) "IV LSD experience reports" Retrieved 4 October 2023.

https://www.reddit.com/r/LSD/comments/a2yrk1/iv_lsd_experience_reports/



42. The method of claim 41, wherein the oral formulation is in a solid form or a liquid form.

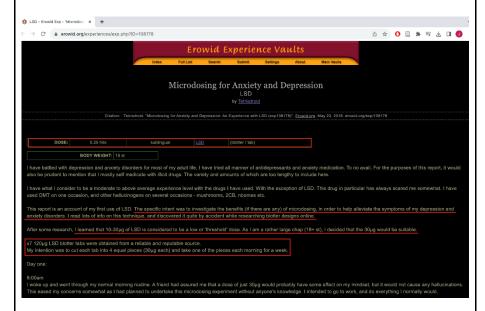
6. JOHNSTAD (2018) "Powerful substances in tiny amounts: An interview study of psychedelic microdosing" Nordic Studies on Alcohol and Drugs. 35(1):39-51.

From **p. 44** "Some indicated that their **microdose regimen** was informed by extant literature on psychedelic microdosing. These were some typical statements about dosage:

'I normally cut up a single blotter of 100 or 150 mcg into 8 pieces, giving microdoses in the range of 12.5 to 18.75 mcg. (ID38)"

7. TETRISDROID (2018) "Microdosing for Anxiety and Depression" Retrieved 19 September 2023.

https://erowid.org/experiences/exp.php?ID=108178



14. ANONYMOUS (2017) "The Freelance Writer Using LSD for Depression" Retrieved from 24 October 2017. URL: https://www.thecut.com/2017/10/microdosing-lsd-depression-coping-diaries.html

From webpage "Some people cut up their tabs but I do something called "volumetric dosing" — you take a quantity of liquid to correspond to the dosage of the tab. I take one 100 microgram tab of LSD and dissolve it in 50 ml of distilled water — and 50 ml of vodka so the water doesn't get moldy. Then I squirt 4.5 micrograms into my mouth...

... 7 a.m.: When I wake up, I can feel that LSD-like energy again, like my brain is charged. I'm more upbeat and silly around my mom. The more I microdose, the more likely I am to feel an afterglow.

Overall, I really feel like my depression is subsiding and I may even increase my dose slightly..."

Electronic Acl	knowledgement Receipt
EFS ID:	48778853
Application Number:	18102296
International Application Number:	
Confirmation Number:	9615
Title of Invention:	ADMINISTRATION OF MODULATORS OF 5-HT AND / OR AMPA RECEPTORS FOR TREATING NEUROLOGICAL CONDITIONS
First Named Inventor/Applicant Name:	Gabriella GOBBI
Customer Number:	21971
Filer:	Sisi Li
Filer Authorized By:	
Attorney Docket Number:	55554-705.301
Receipt Date:	30-OCT-2023
Filing Date:	27-JAN-2023
Time Stamp:	16:34:00
Application Type:	
Payment information:	1

Payment information:

Submitted with Payment	yes
Payment Type	CARD
Payment was successfully received in RAM	\$72
RAM confirmation Number	E20230TG33585400
Deposit Account	
Authorized User	

The Director of the USPTO is hereby authorized to charge indicated fees and credit any overpayment as follows:

File Listing	n•				
Document Number	Document Description	File Name	File Size(Bytes)/ Message Digest	Multi Part /.zip	Pages (if appl.)
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1	Concise Description of Relevance	Concise-description-generated. pdf	0364d61d6db5146d36b69db437d6516975 67f8dc	no	10
Warnings:					
Information:					
	Third-Party Submission Under 37 CFR	Third-party-preissuance-	74931		
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Warnings:			'		
Information:					
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3	Request for Notification of Non- compliant Third-Party Submission	Third-party-notification- request.pdf	97511919c6741f3e21ca212ba60644c03b3 bd5cc	no	
Warnings:			'		
Information:					
			2094431		23
4	Concise Description of Relevance	Claims_Chart.pdf	c6ed3ae22a85968fa33b17c7707594b3ab3 7402d	no	
Warnings:					
Information:					
			410611	no	12
5	Evidence of Publication	1_Lea2020.pdf	108f1a74328e06f08e8bca1475e59ed27339 cd7a		
Warnings:					
Information:					
		2_Polito2019.pdf 1181902 dce9cdea3f5a2f7a05022a54ba87efdb2ce8 3bfe n	1181902		
6	Evidence of Publication		no	26	
Warnings:		1			
Information:					

			795155	no	6
7	Evidence of Publication	4_Fadiman2019.pdf	9a1fd7465bfaf61419696c33aa540f6718e0 27da		
Warnings:		1	-		
Information:					
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Information:					
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Warnings:		-			
Information:					
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Warnings:		·	-		
Information:					
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Information:					
	Total Files Size (in bytes)		16.	218805	

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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.

Electronic Acknowledgement Receipt			
EFS ID:	48779022		
Application Number:	18102296		
International Application Number:			
Confirmation Number:	9615		
Title of Invention:	ADMINISTRATION OF MODULATORS OF 5-HT AND / OR AMPA RECEPTORS FOR TREATING NEUROLOGICAL CONDITIONS		
First Named Inventor/Applicant Name:	Gabriella GOBBI		
Customer Number:	21971		
Filer:	Sisi Li		
Filer Authorized By:			
Attorney Docket Number:	55554-705.301		
Receipt Date:	30-OCT-2023		
Filing Date:	27-JAN-2023		
Time Stamp:	16:41:02		
Application Type:			
Payment information:	1		

Payment information:

Submitted with Payment	yes
Payment Type	CARD
Payment was successfully received in RAM	\$72
RAM confirmation Number	E20230TG40586302
Deposit Account	
Authorized User	

The Director of the USPTO is hereby authorized to charge indicated fees and credit any overpayment as follows:

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File Listing Document Number	Document Description	File Name	File Size(Bytes)/ Message Digest	Multi Part /.zip	Pages (if appl.)
rumser			39505	i ui t /i.z.ip	(ii uppii)
1	Concise Description of Relevance	Concise-description-generated. pdf		no	5
Warnings:					
Information:					
	Third-Party Submission Under 37 CFR	Third-party-preissuance-	60689		
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Information:					
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3	Request for Notification of Non- compliant Third-Party Submission	Third-party-notification- request.pdf	Third-party-notification- request.pdf eb16b70e81f43318d96b1a61b3e98fec997 e640f	no	1
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Information:					
			2094431		23
4	Concise Description of Relevance	Claims_Chart.pdf	c6ed3ae22a85968fa33b17c7707594b3ab3 7402d	no	
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Information:					
		963340 11_CDC.pdf no 0a362fdae254862bffd3ac7f19ba89f9d823c f16	963340		
5	Evidence of Publication		no	4	
Warnings:		<u> </u>			
Information:					
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Warnings:					
Information:					

Total Files Size (in bytes): 5744082			57		
Information:					
Warnings:	,				•
9	Fee Worksheet (SB06)	fee-info.pdf	8d3848c6d0c7d5ae39f5edf46bd8437eab4 35d45	no	2
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			98718		
Information:					
Warnings:					
7	Evidence of Publication	14_THECUT.pdf	ae2a5591b88e70a347c5576a8ec4bdd7961 ac189	no	3
			1793668		

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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.