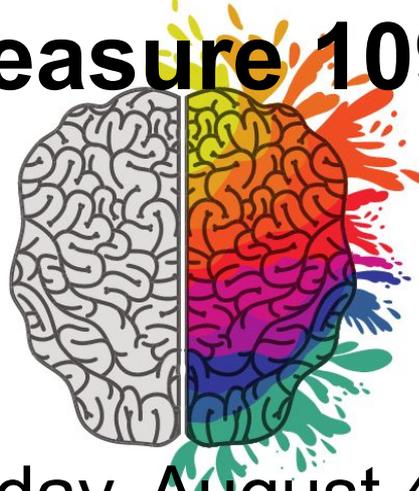


Intellectual Property in Psychedelics & Oregon's Psilocybin Services Act ("Measure 109")



Wednesday, August 4, 2021

Sean Clancy, Emerge Law Group

Graham Pechenik, Calyx Law

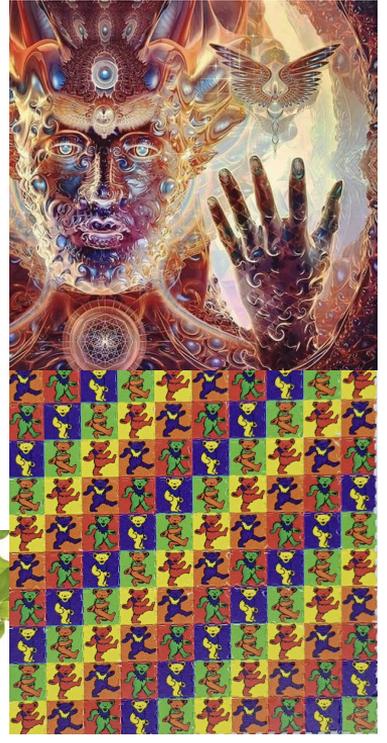
Outline for Today

- ❖ The Psychedelic “Renaissance”
- ❖ Measure 109
- ❖ Trademark Issues
- ❖ Copyright Issues
- ❖ Patent Issues
- ❖ Ethics Issues



What Are Psychedelics

- ❖ *Psyche* + *delos* = “mind manifesting”
- ❖ “**Classic**” psychedelics or “hallucinogens”:
e.g., LSD, psilocybin (*magic mushrooms*),
DMT (*ayahuasca*), mescaline (*peyote*)
- ❖ MDMA: “**entactogen**” or “empathogen”
- ❖ Ketamine: **dissociative** anesthetic
- ❖ Many, many others...



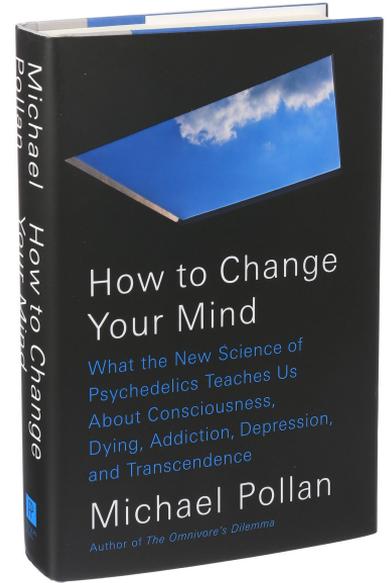
Most Psychedelics are Schedule I Drugs

- ❖ **“Classic” psychedelics** on Schedule I of CSA in 1970
 - e.g., LSD, psilocybin, DMT, mescaline
 - *“hallucinogenic substances”*
- ❖ **MDMA** added to Schedule I in 1985
- ❖ **Federal Analogue Act** added to CSA in 1986
 - drugs with *“substantially similar”* structure and effect

Federally Illegal—But Some Notable Exceptions

- ❖ Ketamine - **Schedule III** of the CSA
 - **“Off label” prescription**
 - Subject to professional standards of care for medical providers
 - May not qualify for insurance reimbursement
 - **Esketamine** (Spravato, Janssen/J&J) approved for TRD in 2019
- ❖ MDMA, psilocybin, & many others being legally researched now
 - Clinical trials with DEA approval
- ❖ **“Right to Try”** legislation

“The Psychedelic Revolution is Coming”



The New York Times

The Psychedelic Revolution Is Coming. Psychiatry May Never Be the Same.

Psilocybin and MDMA are poised to be the hottest new therapeutics since Prozac. Universities want in, and so does Wall Street. Some worry a push to loosen access could bring unintended consequences.



NY Times, May 9, 2021

The New York Times

A Psychedelic Drug Passes a Big Test for PTSD Treatment

A new study shows that MDMA, known as Ecstasy or Molly, can bring relief when paired with talk therapy to those with severe post-traumatic stress disorder.



NY Times, May 3, 2021

nature

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nature > news feature > article

NEWS FEATURE | 27 January 2021

How ecstasy and psilocybin are shaking up psychiatry

Regulators will soon grapple with how to safely administer powerful psychedelics for treating depression and post-traumatic stress disorder.

Paul Tullis



Nature, Jan 27, 2021

VOGUE

MAGAZINE

Could the Embrace of Psychedelics Lead to a Mental-Health Revolution?



BY MAYA SINGER
February 12, 2021



Vogue,
Feb. 12, 2021

The New York Times

OPINION
GUEST ESSAY

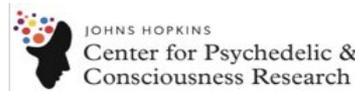
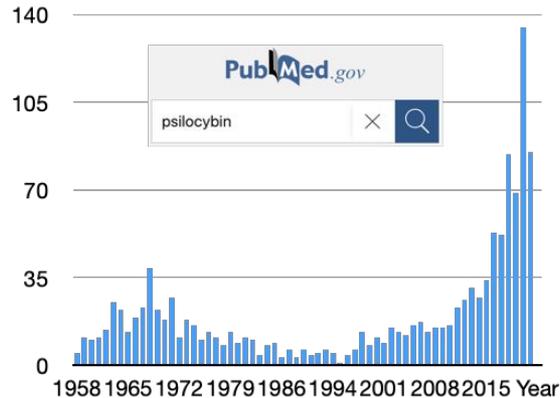
How Should We Do Drugs Now?



NY Times, July 11, 2021

The “Psychedelic Renaissance” is Here

- ❖ **1950s-1960s** (pre-CSA): >1,000 articles published, >40,000 patients received treatment
- ❖ **1970s-1990s**: use and research halted; no major psychedelic research programs
- ❖ **1990s-2010s**: research returns with neuroimaging and safety and tolerability studies
- ❖ **2010s-present**: flourishing of clinical trials and growing number of research programs



Psychedelics Currently in Numerous Clinical Trials

	Post-traumatic stress disorder (PTSD)	MDMA	III		Treatment-resistant depression (TRD)	GB001	I / II
	Treatment-resistant depression (TRD)	COMP360	II		Major depressive disorder (MDD)	SPL006	I / II
	Major depressive disorder (MDD)	Psilocybin	II		Opioid use disorder	DMX-1000	I
	Eating disorders (anorexia nervosa and binge-eating disorder)	MDMA	II		Alzheimer's Disease	ELJ-LSD	I
	Anxiety associated with a life-threatening illness	MDMA	II		Opioid use disorder	18-MC	I
	Social anxiety in autistic adults	MDMA	II		Endiclosed	DMT	I
	Anxiety	LSD	II		Endiclosed	MDMA-LSD	I
	Cluster headaches	LSD	II		Endiclosed	Mescaline	I
	Acute suicidal ideation and behaviour (ASIB) in major depressive disorder	SLS-000	II		Endiclosed	Ketamine	I
	Alcohol use disorder	MDMA	II		Endiclosed	PCN-001	I
	Major depressive disorder	CY001	II		Ischemic stroke and post-stroke rehabilitation	AP-188	I
	Opioid use disorder	DMX-NB1	II		Endiclosed	5-MeO-DMT	I
	Major depressive disorder (adjunctive treatment)	ELJ-Ket+	II		Short-lasting unilateral neuralgiform headache attacks (SUNHA)	Psilocybin	I
	CRCT for PTSD	MDMA	II		Anxiety	Psilocybin	I
	Attention deficit hyperactivity disorder (ADHD)	LSD	II		(Unspecified) Substance use disorder	DMT	I
	Endiclosed severe pain indication	LSD	II		Alcohol use disorder	Mescaline	I
	Post-traumatic stress disorder (PTSD)	Psilocybin	II		Endiclosed	Apibasca	I
	Levodopa-induced dyskinesia in patients with Parkinson's disease	Ketamine	II				

- ❖ **MDMA** for PTSD—Phase 3
- ❖ **Psilocybin** for TRD—Ph. 2b
- ❖ **Psilocybin** for MDD—Ph. 2
- ❖ **MDMA, psilocybin** for AUD...
- ❖ **LSD** for anxiety, ADHD, cluster headaches, pain...
- ❖ **DMT, 5-MeO-DMT, ketamine, mescaline, ibogaine...**

Indications Targeted by Current Research

- ❖ PTSD
- ❖ TRD, MDD
- ❖ Suicidal ideation
- ❖ End-of-life anxiety
- ❖ Social anxiety
- ❖ Eating disorders
- ❖ Alcohol use disorder
- ❖ Opioid use disorder
- ❖ Substance use disorders
- ❖ ADHD
- ❖ OCD
- ❖ Severe pain, phantom limb pain
- ❖ Migraine, cluster headaches
- ❖ Neuralgiform headaches
- ❖ Parkinson's disease
- ❖ Alzheimer's disease
- ❖ Stroke rehabilitation
- ❖ Fibromyalgia

Legal Now: **Right To Try** (21 U.S.C. § 360bbb-0)

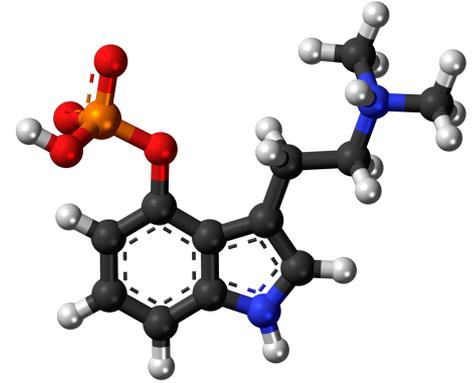
- ❖ “Eligible Patients”
 - life threatening disease or condition
 - exhausted approved treatment and unable to participate in clinical trial for the drug
 - certified by physician
 - informed written consent
- ❖ “Eligible Investigational Drug”
 - completed FDA-approved Phase I clinical trial
 - not approved/licensed for any use
 - remain under investigation



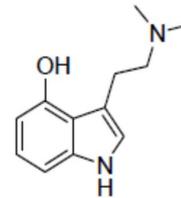
Photo courtesy of Matthew W. Johnson, Wikimedia Commons, & Johns Hopkins University

Psilocybin

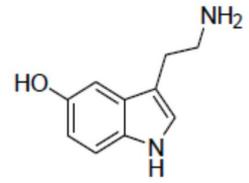
- ❖ Naturally occurring tryptamine in over 200 species of mushrooms including from the genus *Psilocybe*
- ❖ A “prodrug” of **psilocin**, the active metabolite
- ❖ Activity at serotonin receptors
- ❖ High affinity for 5-HT_{2A} receptor



Psilocybin



Psilocin



Serotonin

AIMS v. DEA, No. 21-70544 (9th Cir. March 8, 2021)

A coalition of 8 state attorneys general + DC, ACLU, end-of-life groups, researchers, and physicians have filed amicus briefs in support, arguing among other things that (1) the DEA's statutory and regulatory interpretations were improper; (2) the DEA's final agency action would improperly restrict states' rights or otherwise upset the balance of federalism; and (3) the DEA's final action is counter to the Right to Try Act's underlying purpose and legislative intent.



Photo courtesy of [SeattleTimes.com](https://www.seattletimes.com)

Oregon Psilocybin Services Act

- ❖ Allows manufacture, delivery, administration of psilocybin at supervised, licensed facilities by licensed facilitator
- ❖ Two-year development period
Psilocybin Advisory Board will issue recommendations



OHA Licenses

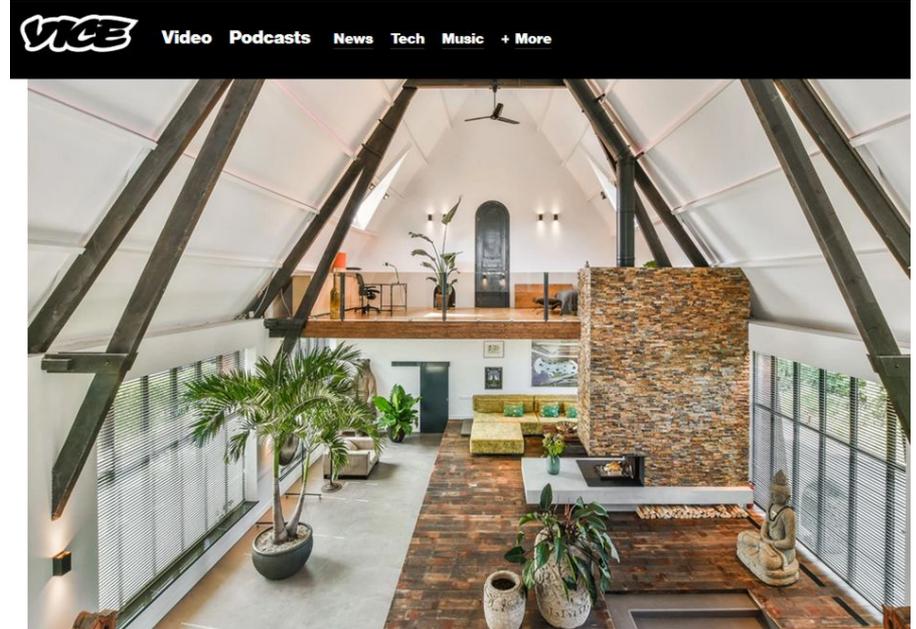
- ❖ Manufacturer
- ❖ Service center operator
- ❖ Facilitator (individual)
- ❖ Laboratory



Preparation, administration, integration session



Courtesy of Johns Hopkins University via MAPS.org



THE LIGHTHOUSE INTERIOR. COURTESY OF SYNTHESIS.

Federal Trademarks require Lawful Goods & Services

- ❖ Compare cannabis TM strategy
 - smoking accessories
 - online sites & services
 - consulting
 - Farm Bill compliant hemp with less than 0.3% THC
 - apparel? etc...
 - “circle the wagons” or “spaghetti”



Psychedelics in commerce

- ❖ What will people be buying?
 - Goods? Services?
 - Experience
 - “Set and setting”
 - Service Center
 - Facilitator
- ❖ Measure 109 enables OHA:
 - “rules prohibiting advertising psilocybin products to the public”
 - to regulate advertising psilocybin services similar to alcohol



Trademark Territory

❖ “zone of expansion”

- Health & medical services
- Travel & hospitality
- Education & entertainment
- Wellness
- Functional mushroom products
- Dietary supplements
- Information & education services
- Religion & spirituality
- Other ???



Use in lawful commerce

Alfacell Corporation v. Anticancer, Inc. (TTAB 2002)

- shipments of pharmaceuticals within the United States and overseas for use in *pre-clinical testing* in US and clinical testing abroad
- placed labels bearing the mark ONCASE on bottles containing the goods
- Issue: “use in commerce?”

15 U.S.C. § 1127.

“use in commerce” means

the bona fide use of a mark in the ordinary course of trade, and not made merely to reserve a right in a mark. For purposes of this chapter, a mark shall be deemed to be used in commerce--

(1) on goods when--

(A) it is placed in any manner on the goods or their containers or the displays associated therewith or on the tags or labels affixed thereto, or if the nature of the goods makes such a placement impracticable, then on documents associated with the goods or their sale, and

(B) the goods are sold or transported in commerce....

Use in lawful commerce

Alfacell Corporation v. Anticancer, Inc. (TTAB 2002)

“as a matter of law, Congress intended the term “use in commerce” to encompass shipments of pharmaceuticals for clinical studies prior to receiving FDA approval as a reflection of common industry practice. See *G.D. Searle & Co. v. Nutrapharm, Inc.*, 199 U.S. Dist. LEXIS 168622 (S.D.N.Y. 1999) (citing the legislative history of the 1989 Amendment to the Lanham Act, the court denied defendant's motion for summary judgment and found that shipments of plaintiff's pharmaceuticals for clinical testing constitutes “use in commerce”). See also, J. Thomas McCarthy, *McCarthy on Trademarks and Unfair Competition*, § 19:118, at 19-271, (4th ed. 2001).”

Use in lawful commerce

In re Eli Lilly and Co.
(TTAB 2015)

Serial No. 85183667

Specimen refusal overturned:
label applied to the goods when
distributed to clinical trial sites

H9X-MC-GBDG

Lot: CT588529

Package Number: s / 73302



Confirmation Number: XXXXXX

Patient number: _____

Investigator: _____

Carton contains 5 syringes. Syringe contains a 0.5 mL solution for injection of Trulicity™ (dulaglutide) or placebo.

For subcutaneous use only. Use as directed by investigator.

Ready to use syringe. Do not expel air from syringe.

Store refrigerated (2 °C - 8 °C; 36 °F - 46 °F). Do not freeze.

Do not destroy. Return packaging and unused medication to the investigator. Keep out of reach of children.

CAUTION: New drug -Limited by Federal (or United States) law to investigational use.

Eli Lilly and Company, Indianapolis, IN 46285 USA

MINDMED

(Serial No. 88676093 - 1(b) filing basis - published for opposition)



Goods and Services

IC 016. US 002 005 022 023 029 037 038 050. G & S: Notepads; Pencils; Pens

IC 018. US 001 002 003 022 041. G & S: Back packs; Beach bags; Purses; Overnight bags; Weekend bags

IC 021. US 002 013 023 029 030 033 040 050. G & S: Coffee mugs; Shot glasses

IC 024. US 042 050. G & S: Towels; Beach towels

IC 025. US 022 039. G & S: Bandanas; Capris; Flip flops; Hoodies; Jackets; Pants; Sandals; Shirts; Shoes; Shorts; Socks; Sweat pants; Sweat shirts; Sweaters; Swimsuits; Baseball caps; T-shirts

COMPASS PATHWAYS

(Serial No. 79302207 - 66A filing basis - office action pending: 2(d) for software and consulting & goods/services ID)



Goods and Services

IC 005. US 005 006 018 044 046 051 052. G & S: Pharmaceuticals for the treatment of mental health conditions; pharmaceuticals for the treatment of depression; psychoactive medicines; psychedelic medicines

IC 009. US 021 023 026 036 038. G & S: Wearable computers in the nature of smartphones, smartglasses and activity trackers, all for monitoring and managing mental health and communicating mental health information; computer software for monitoring and managing mental health and communicating mental health information; software applications for mobile devices for monitoring and managing mental health and communicating mental health information; wearable computers in the nature of smartphones, smartglasses and activity trackers, all for monitoring and managing depression and communicating information on depression; computer software for monitoring and managing depression and communicating information on depression; software applications for mobile devices for monitoring and managing depression and communicating information on depression

IC 010. US 026 039 044. G & S: Medical devices and wearable medical devices for monitoring and managing mental health and communicating mental health information; medical devices and wearable medical devices for monitoring and managing depression and communicating information on depression; drug delivery systems

IC 035. US 100 101 102. G & S: Compilation and processing of data relating to mental health; compilation and processing of patient data relating to depression; promoting public awareness of mental health conditions; promoting public awareness of depression

IC 041. US 100 101 107. G & S: Provision of education and training in the field of mental health conditions; provision of education and training in the treatment of mental health conditions; provision of education and training in the field of depression; provision of education and training in the treatment of depression; provision of education and training in the field of psychoactive medicines and psychedelic medicines

IC 044. US 100 101. G & S: Therapy for the treatment of mental health conditions; therapy for the treatment of depression; provision of information relating to mental health and mental healthcare; provision of information relating to depression

COMPASS PATHWAYS

(Serial No. 79302207 - 66A filing basis - office action pending: 2(d) for software and consulting & goods/services ID)



Applicant may adopt the following Class 5 wording, if accurate:

Pharmaceuticals for the treatment of mental health conditions, **namely, pharmaceutical preparations for the treatment of depression; psychoactive and psychedelic medicinal preparations for treatment of depression**

ELEV8 MD WELLNESS CENTER (Registration No. 5957325)



Goods and Services

IC 044. US 100 101. G & S: Behavioral health services in the nature of treatment of depression, mood disorders, pain disorders, chronic pain, post-traumatic stress disorder (PTSD), and overall physical and psychological wellbeing through **Ketamine** infusions, IV Hydration, and nutritional therapy services; Medical services. FIRST USE: 20190101. FIRST USE IN COMMERCE: 20190101

ZENDO PROJECT (Registration No. 6172520)

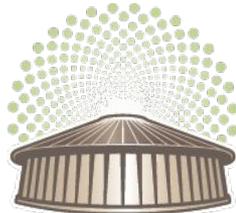
The English translation of "Zendo" in the mark is "A hall at a Zen buddhist monastery where formal seated meditation (zazen) is practiced".

Goods and Services

IC 009. US 021 023 026 036 038. G & S: Downloadable electronic publications, namely, instructional manuals, pamphlets, newsletters, and information sheets in the field of psychoactive substances, **psychedelics**, non-ordinary states of consciousness, and reduction of harm associated with psychoactive substance use. FIRST USE: 20120714. FIRST USE IN COMMERCE: 20120826

IC 016. US 002 005 022 023 029 037 038 050. G & S: Printed publications, namely, instructional manuals, pamphlets, newsletters, and information sheets in the field of psychoactive substances, **psychedelics**, non-ordinary states of consciousness, and reduction of harm associated with psychoactive substance use. FIRST USE: 20120714. FIRST USE IN COMMERCE: 20120826

IC 041. US 100 101 107. G & S: Educational services, namely, conducting classes, seminars, workshops, conferences, and courses of instruction in the field of psychoactive substances, **psychedelics**, non-ordinary states of consciousness, reduction of harm associated with psychoactive substance use, and counseling and emotional support for psychoactive substance users; providing personal, group, and peer to peer coaching services in the field of personal development and self-improvement; non-downloadable electronic publications, namely, instructional manuals, pamphlets, newsletters, and information sheets in the field of psychoactive substances, **psychedelics**, non-ordinary states of consciousness, and reduction of harm associated with psychoactive substance use. FIRST USE: 20120714. FIRST USE IN COMMERCE: 20120828



ZENDO
PROJECT



ZENDO PROJECT (Registration No. 6172520)

IC 045. US 100 101. G & S: Providing emotional counseling and emotional support services for users of psychoactive substances; organizing and conducting support groups in the field of **psychedelic** experiences, non-ordinary states of consciousness, personal development, and self-improvement; providing information regarding support groups for **psychedelic** experiences, non-ordinary states of consciousness, personal development, and self-improvement. FIRST USE: 20120714. FIRST USE IN COMMERCE: 20120828

Copyrights

- No lawful commerce requirement
 - Virtual Reality + biofeedback for psychedelic therapies
 - Facilitator/Guide session script
 - Creative commons and public domain materials are available
 - Music rights
 - Probably not a public performance
 - Training and educational materials
 - Logo designs
 - Architecture
 - Interactive Art
 - Typical website, social media, and marketing assets



Psychedelics and Patents

- ❖ What's a Patent?
- ❖ What's Patentable?
- ❖ What's Being Patented?
- ❖ What's So Controversial?

Federally Illegal—But Still Patentable?

- ❖ Yes: federal illegality under CSA is **irrelevant** to patentability
- ❖ Must fall within one of four “statutory categories of invention”
 - *Process, machine, manufacture, or composition of matter*
- ❖ Limited judicial and legislative exceptions to patentable subject matter
 - abstract ideas, laws of nature, natural phenomena (**products of nature**)
 - “encompassing a **human organism**” (“human embryos and fetuses”)
 - “special nuclear material or atomic energy in **atomic weapons**”
- ❖ Some question **enforceability** under “illegality doctrine”
- ❖ Unlike federal trademark requirement of “**lawful use in commerce**”

What is a Patent?

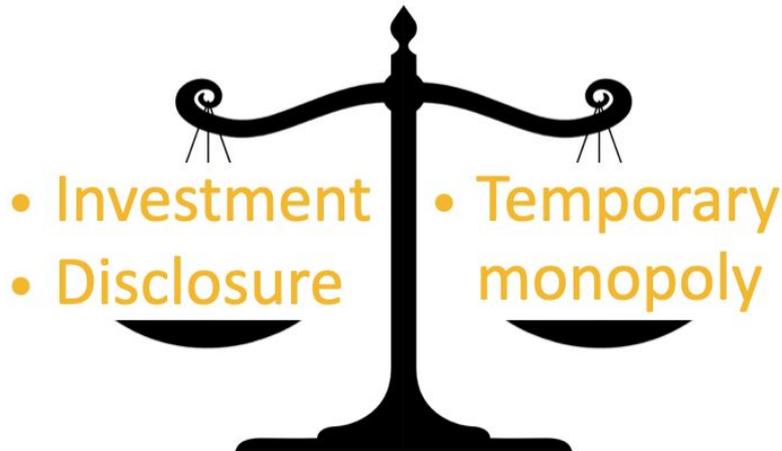
“Whoever invents or discovers any **new and useful** process, machine, manufacture, or composition of matter . . . may obtain a patent therefor”

- ❖ **Right to exclude** others from making, using, selling, offering for sale, and importing invention
- ❖ For **20 years** from the filing date of the application
- ❖ Invention is defined by the **claims**

35 U.S.C. § 101

“Bargain” Between Inventor and Public

“Congress shall have power . . . to ***promote the progress of science and useful arts***, by **securing for limited times** to authors and inventors **the exclusive right** to their respective writings and discoveries.” (“*Progress Clause*”)



U.S. Constitution, Art. I, § 8, cl. 8

Requirements for a Patent

- ❖ **Novelty**: cannot be previously disclosed in the “prior art”
- ❖ **Non-obviousness**: cannot be obvious to one of “ordinary skill” in view of the state of the art (“inventive step”)
- ❖ **Utility**: a specific, substantial, and credible use
- ❖ **Written description**: application must describe the invention in sufficient detail to demonstrate “possession” by the inventor
- ❖ **Enablement**: one must be able to make and use the claimed invention without “undue experimentation”

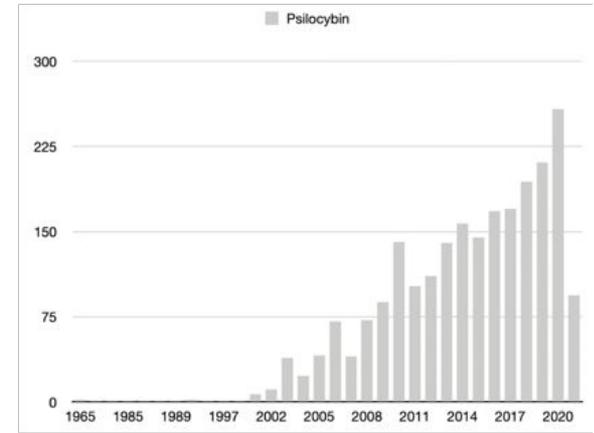
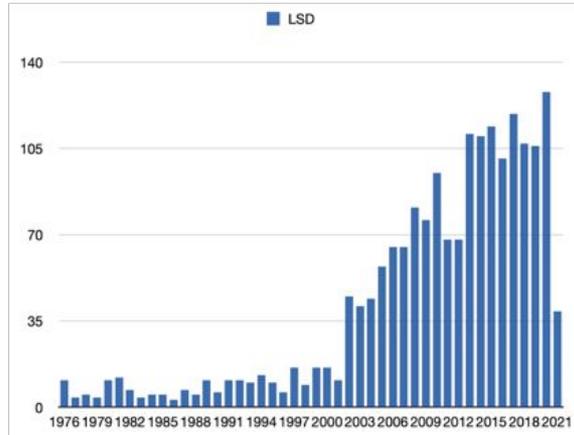
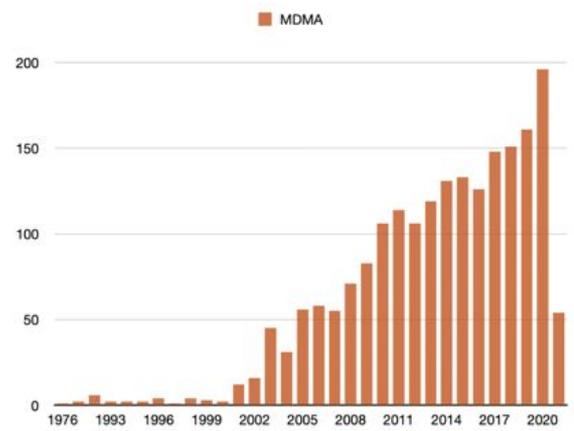
35 U.S.C. §§ 101 et seq.

Psychedelics—Novel and Non-Obvious?

- ❖ **Psilocybin**: isolated and synthesized by Albert Hofmann, patents filed in **1958** and **'59**; naturally occurs in mushrooms ingested for **millenia**
- ❖ **LSD**: synthesized by Hofmann in **1938**, patented by Sandoz
- ❖ **DMT**: synthesized by Richard Manske in **1931**; DMT-containing preparations such as ayahuasca used for **centuries**
- ❖ **MDMA**: synthesized by scientists at Merck, patents filed in **1912**
- ❖ **Mescaline**: isolated in **1897** by Arthur Heffter and synthesized in **1918** by Ernst Späth; naturally occurs in plants ingested for **millenia**

Psychedelics—Novel and Non-Obvious?

- ❖ Many dozens of patents filed, in ever-increasing numbers



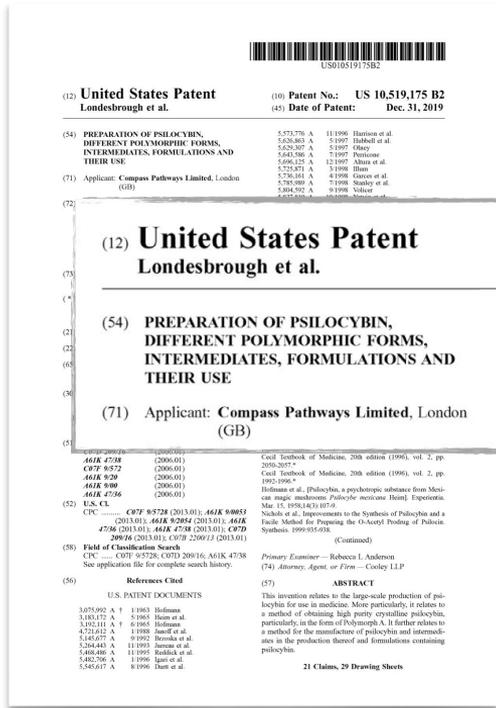
- ❖ *If already known and used, what's being patented now?*

Many Patent Strategies for Known Drugs

- ❖ Not possible to patent the known compound **itself**
- ❖ However, “**secondary**” patents may be available:
 - solid forms: salts, polymorphs, hydrates, solvates, co-crystals
 - single enantiomers, enantiomeric mixtures
 - prodrugs, metabolites, deuterated versions
 - formulations
 - dosage forms, dosing regimens
 - delivery methods, methods of administration
 - indications, patient populations, methods of treatment
 - manufacturing methods: chemical synthesis, biosynthesis

How to Patent a Known Psychedelic?

COMPASS Pathways '175 Patent on psilocybin "Polymorph A"



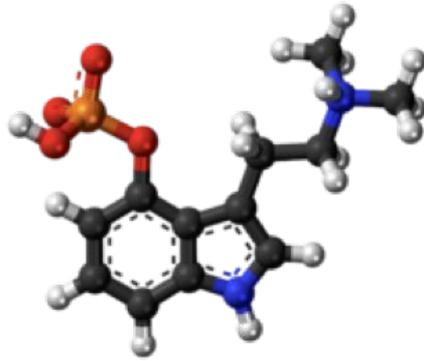
The invention claimed is:

1. A method of treating drug resistant depression comprising orally administering to a subject in need thereof a therapeutically effective amount of an oral dosage form, wherein, the oral dosage form comprises:

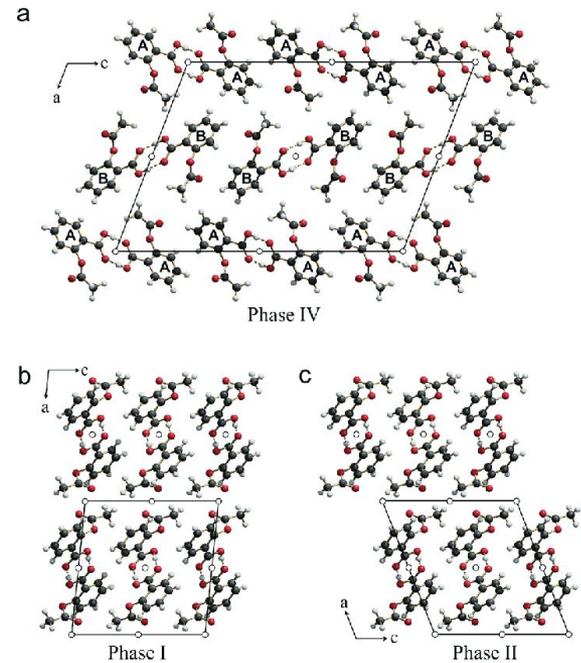
crystalline psilocybin in the form Polymorph A characterized by peaks in an XRPD diffractogram at 11.5, 12.0, 14.5, 17.5, and 19.7°2θ±0.1°2θ, wherein the crystalline psilocybin has a chemical purity of greater than 97% by HPLC, and no single impurity of greater than 1%; and silicified microcrystalline cellulose.

How to Patent a Known Psychedelic?

Psilocybin

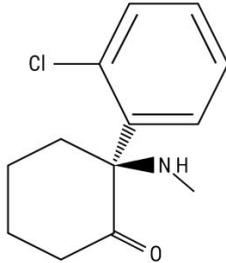
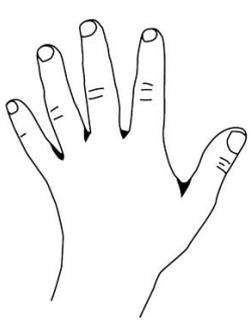


Solid materials often exist in multiple crystalline forms with different arrangements of individual molecules in 3D—known as **polymorphs**

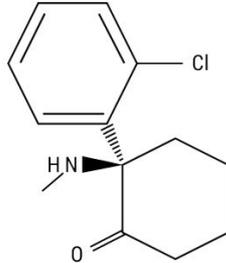


Aspirin polymorphs

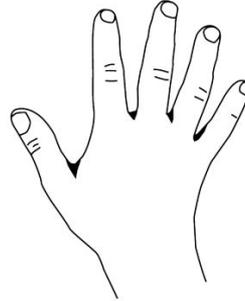
How to Patent a Known Psychedelic?



Left hand enantiomer
(S)-Ketamine



Right hand enantiomer
(R)-Ketamine



Generic ketamine = **racemic mixture**
(both enantiomers in equal amounts)



US10869844B2

(12) United States Patent
Ceres et al.

(16) Patent No.: US 10,869,844 B2
(45) Date of Patent: Dec. 22, 2020

(54) METHODS FOR THE TREATMENT OF DEPRESSION	6,323,942 B1	11/2001	Green et al.
	6,372,880 B2	6/2003	Shibata, Jr.
	6,372,881 B2	9/2003	Maruyama et al.
	6,467,098 B2	9/2004	Nakata
	7,086,430 B2	3/2004	Shimizu et al.
	7,074,282 B2	7/2004	Shimizu et al.
	8,758,530 B2	7/2014	Chen et al.
	9,380,232 B2	3/2017	Chen et al.
(71) Applicant: Janssen Pharmaceutics NV, Beerse (BE)	10,098,254 B2	10/2018	Devin et al.
(72) Inventor: Ludwilk, Ivo Gernot, Innsbruck (AT)	10,098,254 B2	10/2018	Devin et al.
Janssen Shiga, Shigeo, Japan, CA (JP)	10,098,254 B2	10/2018	Devin et al.
Peter Nicholas Zambkin, Doylestown, PA (US)	10,098,254 B2	10/2018	Devin et al.
Stuart Fe, C.A. (US); Elna Dabb, Doylestown, PA (US); Carla Marie Canino, Valley, PA (US); Margaret Frigolia, Collierville, TN (US); Frank Wiegand, Amundole, NJ (US)	10,098,254 B2	10/2018	Devin et al.
	2005/002727 A1	5/2005	Ortiz et al.
	2006/012793 A1	10/2006	Collins
	2006/012793 A1	10/2006	Collins
	2007/026608 A1	11/2007	Schmitt et al.

What is claimed is:

1. A method of treating major depressive disorder in a human patient in need thereof, comprising:
intranasally administering (S)-2-(2-(2-chlorophenyl)-2-(methylamino)cyclohexanone in an induction dosage to the patient in an amount in the range of from about 56 mg to about 84 mg in an induction phase, wherein the induction phase comprises a treatment period of about four weeks, and the induction dosage is administered at a frequency of twice per week during the induction phase.

38 Claims, 4 Drawing Sheets

Specification includes a Sequence Listing.

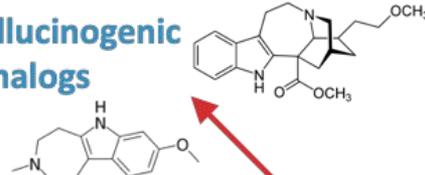
Spravato™
(esketamine) 
nasal spray



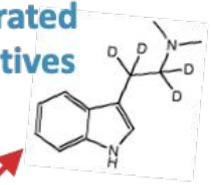
New Psychedelics in Discovery & Development

Various	Preclinical	Phase 1	Preclinical
Various	Preclinical	Phase 1	Preclinical
Various	Preclinical	Phase 1	Preclinical
Phase 1	Preclinical	Phase 1	Preclinical
Phase 1	Preclinical	Phase 1	Preclinical
Various	Preclinical	Phase 1	Preclinical
Discovery	Discovery	Discovery	

Non-hallucinogenic analogs



Deuterated derivatives



Known compounds



Better side effect profile

Faster onset, shorter half-life

Measure 109 Opens Door to Other Psilocybin Patents

❖ Manufacturer

- Cultivation methods and systems
- Processing and extraction
- Psilocybin-containing mushrooms themselves
- Bioreactor production, biosynthesis
- Formulation, including with other active ingredients

❖ Laboratory

- Testing equipment and procedures

❖ Service center/Facilitator

- Methods of treatment and therapeutic use
- Uses together with digital tools, telehealth and VR platforms

Can Psychedelic Therapy Be Patented?

- ❖ Claims filed on aspects of “**set and setting**”
- ❖ Claims filed on therapist and patient interactions
- ❖ **Scalability** stands in way of broad access, and different ways to address it may become patented:
 - digital phenotyping to select patients
 - integrated software platforms and apps
 - integration of biosensors and wearables
 - use of AI and machine learning across data
 - telemedicine visits and virtual reality therapy

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TECH BY VICE

Can a Company Patent the Basic Components of Psychedelic Therapy?

Compass Pathways, a Peter Thiel-backed psychedelic mental health company, has made patent application claims on aspects of psilocybin-assisted therapy as basic as using soft furniture and holding hands.

 By Shayla Love

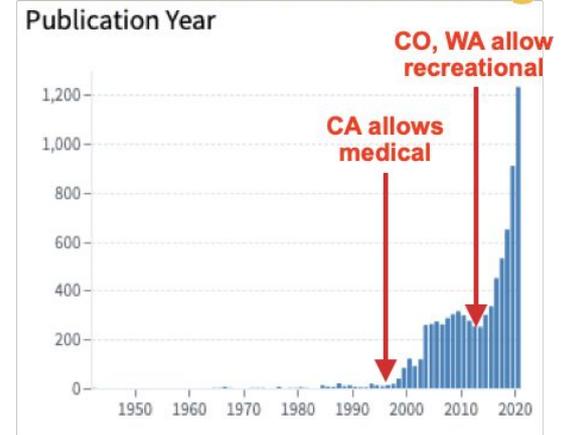


VICE, Feb. 9, 2021

A Coming Psychedelic Patent Explosion?

- ❖ Will legalization and decriminalization lead to an increase in patent activity?
- ❖ Numerous possibilities for patentable technology along entire value chain
- ❖ Will patent holders want to forestall legalization or decriminalization?

Cannabis Patenting



Upstream

Downstream

Drug Development

Generics

API/GMP Manufacturing

Naturals Cultivation

Digital Platforms

Consumer/CPG

Clinics/ Infrastructure

Psychedelic Tourism

Ethical Concerns About Patenting Abound

pubs.acs.org/jptsci Viewpoint

Ethical Concerns about Psilocybin Intellectual Property

Konstantin Gerber, Inti García Flores, Angela Christina Ruiz, Ismail Ali, Natalie Lyla Ginsberg, and Eduardo E. Schenberg*

Cite This: *ACS Pharmacol. Transl. Sci.* 2021, 4, 573–577

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ABSTRACT: Since a 1957 exposé in Life Magazine, chemical compounds derived from Psilocybe mushrooms have been the focus of dozens of attempted and successful patents, most recently to treat

ies who party to treaties age.

Some Thoughts on For-Profit Psychedelic Startups and Companies

MARCH 8, 2021 BY TIM FERRELLS
TOPIC: PSYCHEDELICS



There's a Land Grab for Psychedelic Patents: Here's What We Can Do About It

Psychedelic Times Staff • Apr 19, 2021

A fight over patents in the psychedelics industry is just getting started, and it stands to shape the future of a \$100 billion market

Psychedelics at a Crossroads: We Need Constructive Not Extractive Capital

David Bronner and Les Szabo • May 04, 2021

Microdose

PsyCap Special Report: The Role of Ethical IP in Psychedelic Drug Development

Capitalism Goes Rogue with Patent Claims on Psychedelics

March 17, 2021

Psychedelic Intellectual Property

Dr. James Cooke | May 13, 2021



BUSINESS

Researchers Examine Psilocybin Patent Claims

BY ANN HARRISON
APRIL 23, 2020

Psychedelic patent wars

Jeremy Berke and Yoji Jesse Lee Jun 4, 2021, 9:11 AM

As COMPASS Pathways continues its attempts to build a psychedelic monopoly, Usuna Institute keeps publishing open research



COMPASS Pathways Is Trying to Patent Psilocybin for More Mental Health Conditions Than You Can Name

March 16, 2021

FOUNDERS & FINANCE, LEGAL

Psychedelic Monopoly: A Discussion on the Patent Race

BY BETTA DUBBY
MAY 26, 2021



SOLIDARITY FRIDAYS: 54

with Kyle Buller, Joe Moore and Michelle Janikian

Theft, Patents, and Ethical Psychedelic Companies

MOTHERBOARD
TECHNOLOGY

Is it Possible to Create an Ethical Psychedelics Company?

The debate around psychedelic patents reflects a deeper question about how to create a business model that puts values before profits.

By Shadi Lora

Worthy Or Superfluous? Psychedelics Experts Discuss The Sector's Ongoing Patent Debate

Co-written by Andrew Ward and Natan Ponienan



Why Are Psychedelic Patents Controversial?

- ❖ Issues of **patent quality**
- ❖ Issues of **patent policy**
- ❖ Issues of **patent ethics**

Why Are Psychedelic Patents Controversial?

❖ Issues of patent quality

- Patent examination is imperfect
- Prior art was never published, or is difficult to find
- Overbroad patents may end up being granted
- Continued research and follow-on innovation may be stifled

❖ Responses?

- **Prior art repositories** for patent examiners (e.g., Porta Sophia)
- **Pre-issuance submissions** of prior art into pending application files
- **Post-grant challenges** (>50% of pharma patents invalidated at PTAB)

Why Are Psychedelic Patents Controversial?

❖ Issues of patent policy

- Do inventions satisfy the “bargain” with the public and deserve the reward of a temporary monopoly?
- Should insubstantial changes or minor improvements be sufficient to receive 20 years of patent exclusivity?

❖ Responses?

- Broader patent reform
- E.g., Indian Patents Act §3(d) requires “new uses” and “new forms” of known drugs to have “**significant enhancement in therapeutic efficacy**”

Why Are Psychedelic Patents Controversial?

❖ Issues of patent ethics

- Patent system inherently valorizes individual effort, and the lone “inventive genius”
- Patent system is blind to the collective and cumulative effort and wisdom behind many technologies, especially relating to traditional knowledge
- Patent system has design features optimized for profit-maximizing capitalism

❖ Responses?

- Broader shifts in business culture (**PBCs**, “**North Star Ethics Pledge**”)
- Adoption of norms encouraging reciprocity and discouraging biopiracy (**Nagoya Protocol, Free Prior and Informed Consent**)
- Reimagining interactions with patent system (**patent pledges, IP commons**)

Is Patenting the Only Viable Strategy?

- ❖ **COMPASS Pathways** (psilocybin for TRD): four granted patents in U.S., one granted in U.K., additional pending patents in U.S. and in numerous countries worldwide
- ❖ **Usona** (psilocybin for MDD): “dedicated to working for the public good”; signatory of “***Statement on Open Science and Open Praxis***” under which it “will strive to place our discoveries into the public domain, for the benefit of all”
- ❖ **MAPS** (MDMA for PTSD): holds an “***anti-patent strategy***”

The First Psychedelic Patent Controversy?

- ❖ In 1981, an American filed a plant patent on a cultivar of *Banisteriopsis caapi* (**ayahuasca vine**)
- ❖ Described as “**an offense against indigenous peoples**”:
“Commercializing an ingredient of the religious ceremonies and of healing for our people is a real affront for the over 400 cultures that populate the Amazon basin.”
- ❖ Diplomatic fallout: Ecuadorian government refused to sign a bilateral IP agreement with U.S. in 1996, and Washington countered by threatening Ecuador with economic sanctions



I claim:

1. The new and unique *Banisteriopsis caapi* plant substantially as described and illustrated.

* * * * *

U.S. PP5,751 (“Da Vine”)

Are Patent Controversies Insoluble?

- ❖ Will fundamental concerns over **commercialization** and **commodification** of psychedelics always remain?

“I wonder though, how **authentically transformative** ayahuasca would be, grown *en masse* in industrial green houses across the globe, locked-in with patents, advertised on billboards and listed on the stock market, unceremoniously administered to individuals in clinics.”

- ❖ See *also* “We Will Call it Pala” and “In the Light of Dying Stars”

Psychedelic Patents: Blessing or Curse?

- ❖ “Psychedelics are tools”—“**They’re not good or bad in and of themselves. It’s how they are used.** It’s the relationship you have with them.” (*R. Doblin*)
- ❖ “The ancient Greeks grasped the ambiguous, **double-edged nature** of drugs much better than we do. Their word for them, ‘pharmakon,’ means both ‘medicine’ and ‘poison’. . . . **Blessing or curse, which will it be?**” (*M. Pollan*)
- ❖ “[N]ew psychedelic biotech companies should be innovative and exemplary as ethical trend setters, going above and beyond adherence to UN protocols and demonstrate radical and generous inclusion and reciprocity → **going from extractive to blessing.**” (*J. Barsuglia*)

Doblin, R. (April 8, 2020). Reason Podcast: ‘People Should Have the Fundamental Human Right To Change Their Consciousness’. MAPS

Pollan, M. (July 9, 2021). How Should We Do Drugs Now? N.Y. Times. [michaelpollan.com/articles-archive/how-should-we-do-drugs-now](https://www.michaelpollan.com/articles-archive/how-should-we-do-drugs-now)

Barsuglia, J.P. (2021). “From extractive to blessing,” Los Angeles Medicinal Plant Society Symposium 2021. www.josephbarsuglia.com

Legal Ethics slide (0.0 credit hours)

- ❖ Oregon Rules of Professional Conduct 1.2
 - [...] (c) A lawyer shall not counsel a client to engage, or assist a client, in conduct that the lawyer knows is illegal or fraudulent, but a lawyer may discuss the legal consequences of any proposed course of conduct with a client and may counsel or assist a client to make a good faith effort to determine the validity, scope, meaning or application of the law.
 - (d) Notwithstanding paragraph (c), a lawyer may counsel and assist a client regarding Oregon's marijuana-related laws. In the event Oregon law conflicts with federal or tribal law, the lawyer shall also advise the client regarding related federal and tribal law and policy

Human Ethics

- ❖ Role & costs of physical and mental health care
- ❖ Addiction
- ❖ Personal autonomy and freedom of choice
- ❖ (M109) Oregon Health Authority shall:
 - “Formulate a code of professional conduct for psilocybin service facilitators, giving particular consideration to a code of ethics”
 - Power dynamics under therapists (and facilitators) are magnified with vulnerable tripping patients/clients

North Star Ethics Pledge

*“Created over six months with input from one hundred stakeholders, the Pledge is a beginning: a **baseline commitment to put integrity at the heart of our work in the field.**”*

<https://northstar.guide/ethicspledge>

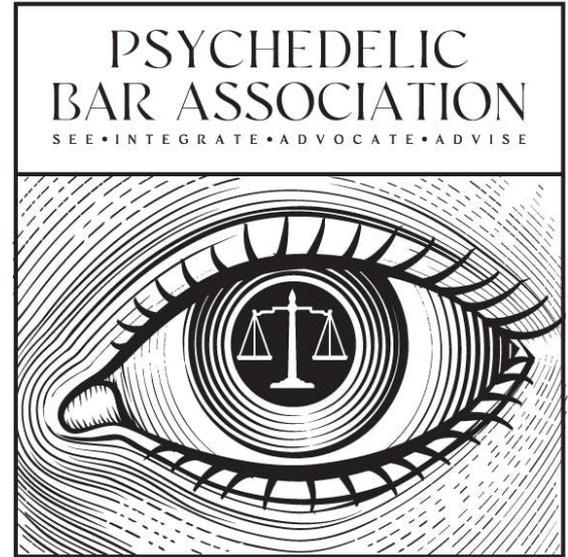


- ❖ Start Within
- ❖ Study the Traditions
- ❖ Build Trust
- ❖ Consider the Gravity
- ❖ Focus on Process
- ❖ Create Equality & Justice
- ❖ Pay it Forward

Psychedelic Bar Association

- ❖ Work “grounded in a **collective practice and embodiment of**” the North Star principles

<https://thepsychedelicbar.org/>



“We envision a world where psychedelic organizations, businesses, healers, and leaders have access to a network of lawyers operating from the highest standards of excellence and ethical considerations. We see the Psychedelic Bar Association contributing to the creation of a world where safe, legal access to psychedelics brings healing, equity and justice for all.”

Questions?

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