PATENTS ON PSYCHEDELICS: THE NEXT LEGAL BATTLEFRONT OF DRUG DEVELOPMENT

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ABSTRACT

In the past two decades, pioneering research has rekindled interest in the therapeutic use of psychedelic substances such as psilocybin, ibogaine, and dimethyltryptamine (DMT). Indigenous communities have used them for centuries, and researchers studied them in the 1950s and 60s. However, most psychedelics were banned in the 70s, when President Nixon launched the U.S. war on drugs. Fifty years later, rising rates of mental illness, substance use, and suicide are prompting researchers to revisit psychedelics, and some have gained permission to study them in limited quantities. Clinical trials are producing promising results, creating enthusiasm for commercializing and patenting psychedelics.

This Essay analyzes the ethical, legal, and social implications of patenting these controversial substances. Patents on psychedelics raise unique concerns associated with their unusual qualities, history, and regulation. Because they were criminalized for decades, the Patent Office lacks personnel with expertise in the field, increasing the likelihood of granting meritless psychedelic patents. Moreover, because Indigenous communities pioneered many aspects of modern psychedelic therapies, their patenting by Western corporations may promote biopiracy, the exploitation of Indigenous knowledge without compensation. Importantly, control of psychedelics by a small number of companies may stifle innovation and reduce access to these therapies. The Essay presents proposals to reduce the risk of biopiracy and the issuance of meritless psychedelic patents. Potential solutions include the implementation of psychedelic patent pledges, the creation of psychedelic prior art repositories, and the tightening of patentability requirements for novel drug therapies. The Essay concludes that ultimately, due to their importance to the advancement of science and public health, psychedelics are appropriately viewed as research tools, eligible only for limited patent protection.

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INTRODUCTION

In the past few decades, pioneering researchers rekindled interest in the therapeutic use of psychedelic substances. This controversial class of compounds includes psilocybin, dimethyltryptamine (DMT), ibogaine, ketamine, and 3,4-Methylenedioxymethamphetamine (MDMA).

Known for their potential to promote feelings of wellbeing and connectedness, many psychedelics have been used for centuries by Indigenous communities around the world.[1] Mental health professionals experimented with them as therapeutic aids during the 1950s and 60s.[2] However, most psychedelics were banned in the 70s when Congress passed the Controlled Substances Act and President Nixon launched the U.S. war on drugs.[3]

Except for ketamine, an essential medicine used in anesthesia, and MDMA, which was not banned until 1985, psychedelics were classified as Schedule I controlled substances. According to the Drug Enforcement Administration (DEA), they have "no currently accepted medical use in the United States, a lack of accepted safety for use under medical supervision, and a high potential for abuse."[4] However, a

[1] *See* David B. Yaden & Roland R. Griffiths, *The Subjective Effects of Psychedelics are Necessary for Their Enduring Therapeutic Effects*, 4 ACS PHARMACOLOGY TRANSLATIONAL SCI. 586, 587 (2021) (describing the historical use of psychedelics and their subjective effects as measured by recent clinical trials. Validated psychological instruments can measure these effects, which include feelings of unity or connectedness, feelings of reverence, alterations perception of space and time, and feelings of love or peace).

[2] *See* Mason Marks, *Controlled Substance Regulation for the COVID-19 Mental Health Crisis*, 72 ADMIN. L. REV. 649, 666-67 (2020) (describing clinical experiments with psychedelics of the 1950s and 60s, which were often reported as safe and useful to the therapeutic process).

[3] *See Id.* at 667-78 (explaining how in the 1960s, psychedelics became associated with the countercultural movement and opposition to the Vietnam War, which led to passage of the Controlled Substances Act and the prohibition of most psychedelics in the 1970s).

[4] *Controlled Substance Schedules*, U.S. DRUG ENFORCEMENT ADMIN., https://www.deadiversion.usdoj.gov/schedules/index.html (last visited July 23, 2021) (defining DEA criteria for categorization in Schedule I and listing psychedelic examples such as lysergic acid diethylamide (LSD), peyote, and MDMA).

growing body of clinical research casts doubt on this categorization, and psychedelics show promise for mitigating several public health crises, including the drug overdose epidemic, post-traumatic stress disorder (PTSD) in veterans, and rising rates of suicide.[5]

The therapeutic potential of psychedelics has triggered an explosion of popular media from prominent authors and publishers including Michael Pollan, the New York Times, 60 Minutes, and Scientific American.[6] Popular coverage of psychedelics research has reinforced public interest in their medical and non-medical use.

In the medical context, two psychedelics are making their way through the Food and Drug Administration (FDA) approval pipeline. In 2017, the FDA designated MDMA a breakthrough therapy for PTSD.[7] In 2018 and 2019, the agency identified psilocybin as a breakthrough therapy for treatment-depression and major depressive disorder.[8] These designations indicate that psychedelics may represent significant advancements over existing treatments for mental illness, such as selective serotonin reuptake inhibitors (SSRIs) like fluoxetine and paroxetine.[9] Accordingly, investment in psychedelics research and commercialization is

[5] *See, e.g.*, Jennifer M. Mitchell et al., 27 NATURE MED. 1025, 1026 (2021) (reporting significant improvement of PTSD symptoms following treatment with MDMA); *See also*, Matthew W. Johnson & Roland R. Griffiths, *Potential Therapeutic Effects of Psilocybin*, 14 NEUROTHERAPEUTICS 734, 735 (describing the therapeutic benefits of psilocybin therapy for cancer-related anxiety and depression); *See also*, Alec J. Divito & Robert F. Leger, *Psychedelics as an emerging novel intervention in the treatment of substance use disorder: a review*, 47 MOLECULAR BIOLOGY REP. 9791, 9796 (2020) (describing the use of psychedelics for treating problematic substance, alcohol, and tobacco use).

[6] *See, e.g.*, MICHAEL POLLAN, HOW TO CHANGE YOUR MIND: WHAT THE NEW SCIENCE OF PSYCHEDELICS TEACHES US ABOUT CONSCIOUSNESS, DYING, ADDICTION, DEPRESSION, AND TRANSCENDENCE (2018); *See also* Andrew Jacobs, *The Psychedelic Revolution Is Coming. Psychiatry May Never Be the Same*, NY TIMES (Jan. 27, 2021), https://www.nytimes.com/2021/05/09/health/psychedelics-mdma-psilocybin-molly-mental-health.html; *See also* 60 Minutes, *Cancer patient overcomes anxiety about death with psychedelics*, YouTube (Oct. 10, 2019), https://www.youtube.com/watch?v=lqnPVZUzDPc; *See also* Daniell Schlosser & Thomas R. Insel, *A Renaissance for Psychedelics Could Fill a Long-Standing Treatment Gap for Psychiatric Disorders*, SCI. AMER. (Sept. 14, 2021), https://www.scientificamerican.com/article/a-renaissance-for-psychedelics-could-fill-a-long-standing-treatment-gap-for-psychiatric-disorders/.

[7] Allison A. Feduccia et al., *Breakthrough for Trauma Treatment: Safety and Efficacy of MDMA-Assisted Psychotherapy Compared to Paroxetine and* Sertraline, 10 FRONTIERS PSYCHIATRY 650, 651 (2019)

[8] Rachel Feltman, *The FDA is fast-tracking a second psilocybin drug to treat depression*, POPULAR SCI. (Nov. 26, 2019), https://www.popsci.com/story/health/psilocybin-magic-mushroom-fda-breakthrough-depression/.

[9] *See* Mason M. Marks, *Controlled Substance Regulation for the COVID-19 Mental Health Crisis*, 72 ADMIN. L. REV. 649, 694 (2020).

rising.[10] Some predict the value of the U.S. market to reach $10.75 Billion by 2027.[11]

This Essay analyzes the ethical, legal, and social concerns raised by the growing trend of patenting psychedelic therapies, which has become a topic of considerable debate in recent months.[12] Though patents can incentivize innovation, their application to psychedelics threatens competition, scientific progress, and public health.[13] These concerns remain unexplored in the legal academic literature, and this Essay provides the first comprehensive analysis with recommendations for meaningful reform. It contains five parts.

Part I explains the risks associated with patents on psychedelics and how they relate to ongoing debates regarding pharmaceutical development. Part II analyzes how U.S. patent law facilitates the issuance of psychedelic patents that would likely be found invalid if scrutinized. Part III analyzes a case study involving the anesthetic drug ketamine to explain how patents can be abused to monopolize facets of the emerging psychedelics market. Part IV explains the role of bioprospecting in the commercialization of psychedelics and how it can exploit Indigenous communities through biopiracy. Part V provides solutions to reduce the likelihood of unwarranted patents on psychedelics.

I. Psychedelics in Debates Over Patents and Drug Development

Patents are a form of government granted monopoly. They entitle their holders to exclude others from making, using, or selling patented inventions for approximately 20 years from the date they filed a patent application.[14] The public policy justification for patents rest on the theory that the right to exclude

[10] *See, e.g.*, Andrew Jacobs, *The Psychedelic Revolution Is Coming. Psychiatry May Never Be the Same*, NY TIMES (May 9, 2021), https://www.nytimes.com/2021/05/09/health/psychedelics-mdma-psilocybin-molly-mental-health.html (describing the rush to invest in research on psychedelics and the companies raising hundreds of millions to commercialize them).

[11] *Psychedelic Drugs Market Size is Predicted to Reach $10.75 Billion by 2027*, PR NEWSWIRE (April 21, 2021), https://www.prnewswire.com/news-releases/psychedelic-drugs-market-size-is-projected-to-reach-10-75-billion-by-2027--301273405.html.

[12] *See, e.g.*, Psych, *PSYCH Investor Summit: Research & Development – Christian Angermeyer + Rick* Doblin, YOUTUBE (July 8, 2021), https://www.youtube.com/watch?v=yXJ0N3kmNjY (debating the risks and benefits of patents on psychedelic therapies and for-profit versus non-profit approaches to their development); *See also*, *Piper* McDaniel, *Is This Peter Thiel-Backed Startup Trying to Monopolize the Astral Plane?*, MOTHER JONES (July 6, 2021), https://www.motherjones.com/politics/2021/07/compass-pathways-peter-thiel-psilocybin-psychedics-monopoly-market-mushrooms-mental-health-depression-therapy-shrooms/.

[13] *See* Mason Marks & I. Glenn Cohen, *Psychedelic therapy: A roadmap for wide acceptance and utilization*, 27 NATURE MED. 1669, 1670-71 (2021) (arguing that patents on psychedelics may limit research, innovation, and public access).

[14] *See, e.g.*, *General Information Concerning Patents*, U.S. PATENT AND TRADEMARK OFFICE, https://www.uspto.gov/patents/basics/general-information-patents (last visited Aug. 2, 2021).

competitors incentivizes innovation and encourages inventors to disclosure their inventions to the public, instead of maintaining them as trade secrets.

Companies like the British pharmaceutical firm Compass Pathways (Compass) have sought and obtained patents to protect formulations of psychedelic compounds and methods of producing and administering them.[15] Such companies argue that patents are necessary to protect their investments not only in drug discovery, but the process of commercialization, which may involve expensive clinical trials and other requirements to obtain FDA approval and buy-in from the medical community thereafter.[16]

The sudden influx of psychedelic patents has prompted criticism from stakeholders including patient advocates, scientists, journalists, lawyers, and members of Indigenous communities.[17] Some claim patenting psychedelics monopolizes products of nature that should remain affordable and widely available. They contend that patents can exploit the traditional knowledge of Indigenous communities without permission or adequate acknowledgement and compensation.[18] Others argue psychedelic patents are making a small number of companies gatekeepers for the emerging psychedelics industry, which could inhibit research, stifle innovation, and restrict access to needed therapies.[19]

Some frame the medical product patent landscape as a thicket, a dense web of interlocking patent rights that restricts the entry of competitors. Formed when patent holders pepper the field with numerous patents on the same product, or closely related products, patent thickets discourage researchers and manufacturers

[15] *See, e.g.*, U.S. Patent No. 10,947,257 (filed Oct. 9, 2018) (claiming an oral formulation of psilocybin and methods of treating major depressive disorder) [hereinafter Compass 2018]; *See also*, WIPO Patent Application No. 212952 (Filed April 17, 2020) (claiming methods of administering psilocybin to treat major depressive disorder, bipolar disorder, anxiety disorders, obsessive compulsive disorder, alcoholism, personality disorder, cardiovascular disease, neurological disease, cancer, and dementia).

[16] *See, e.g.*, Christian Angermayer, *An open letter to Tim Ferriss about the value of patents in the psychedelic world*, LINKEDIN (March 9, 2021), https://www.linkedin.com/pulse/open-letter-tim-ferriss-value-patents-psychedelic-angermayer/.

[17] *See* Shayla Love, *Investors Are Debating Who Should Own the Future of Psychedelics*, VICE (March 10, 2021, 7:15 AM), https://www.vice.com/en/article/3an9eb/investors-are-debating-who-should-own-the-future-of-psychedelics (quoting philanthropist Tim Ferriss and psychedelics researcher and advocate Rick Doblin criticizing the widespread patenting of psychedelics); *See also*, Carolyn Gregoire, *Inside the Movement to Decolonize Psychedelic Pharma*, NEO.LIFE (Oct. 29, 2020), https://neo.life/2020/10/inside-the-movement-to-decolonize-psychedelic-pharma/.

[18] *Id.*

[19] *See, e.g.*, Marcelo Leite, *Capitalism Goes Rogue with Patents on Psychedelics*, CHACRUNA (March 17, 2021), https://chacruna.net/psychedelic-patents-capitalism/.

from entering out of fear of being sued for infringement or having to pay high license fees to patent holders.[20]

To be sure, these concerns are not unique to psychedelics. Patents on genetic technologies and cancer therapies, along with many other treatments, have engendered similar debates.[21] However, several unique features of psychedelics, including their long and complicated history, raise unique concerns that could exacerbate pre-existing problems with intellectual property protection related to commercializing medical products.

The U.S. war on drugs that banned psychedelics disproportionately impacted communities of color, and prohibition likely deprived those communities, and people with mental health conditions, of more effective therapies for decades.[22] Accordingly, many argue that the government should prioritize funding psychedelics research to make psychedelic therapies affordable and accessible.[23] Moreover, because psychedelics are often derived from natural products that have been used in traditional practices for centuries, some argue they should be off limits to the patent system, which is intended to incentivize only new and useful innovation.

II. The Potential for Granting Unwarranted Psychedelic Patents

To obtain a patent on a psychedelic compound, as with any other invention, applicants must convince examiners at the Patent and Trademark Office (PTO) that their technologies are novel, non-obvious, useful, and within the scope of patent eligible subject matter, the range of inventions for which patents can be granted.[24]

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[20] *See, e.g.*, Kevin T. Richards, Kevin J. Hickey & Erin H. Ward, *Drug Pricing and Pharmaceutical Patenting Practices* 2 (Congressional Research Service Report No. R46221, 2020), https://fas.org/sgp/crs/misc/R46221.pdf.

[21] *See, e.g.*, Lyrissa Lidsky, *Patent reform is needed to protect patients' access to lifesaving drugs*, STAT FIRST OPINION (July 23, 2019), https://www.statnews.com/2019/07/23/patent-reform-protect-access-lifesaving-drugs/.
Jon F. Merz & Mildred K. Cho, *What Are Gene Patents and Why Are People Worried About Them?*, 8 COMMUNITY GENETICS 203, 205 (2005).

[22] *See* Doris Marie Provine, *Race and Inequality in the War on Drugs*, 7 ANN. REV. L. SOC. SCI. 41, 54-55 (2011) (describing how the U.S. war on drugs disproportionately impacts racial minorities); *See also*, Mason Marks, *Why D.C. and Oregon Should Vote Yes on Psychedelics*, SLATE (Oct. 19, 2020, 11:55 AM), https://slate.com/technology/2020/10/psychedelics-ballot-initiative-washington-dc-oregon-psilocybin.html (arguing that the Nixon era prohibition on psychedelics limited progress in the field of psychiatry, which has not advanced as rapidly as other fields, in part because research on psychedelics was banned).

[23] *See* Brian Barnett, Rick Doblin, and Julie Holland, *NIH: It's time to make your mark on the renaissance of medicinal psychedelics*, STAT FIRST OPINION (June 2, 2021), https://www.statnews.com/2021/06/02/nih-make-mark-renaissance-psychedelic-medicine/.

[24] *See, e.g.*, Kevin J. Hickey, *Patent Law: A Handbook for Congress* 14-16 (Congressional Research Service Report No. R46525, 2020), https://crsreports.congress.gov/product/pdf/R/R46525/3.

Applicants must also describe their inventions adequately and establish that people skilled in the relevant field could make and use them based on these disclosures. Some of these requirements, such as novelty, can be difficult to meet in crowded technological fields. Others, such as utility, play a minor role in modern patent practice.

To be eligible for patent protection, an invention must be a "process, machine, manufacture, or composition of matter."[25] Moreover, it must not fall into one of three categories of excluded subject matter, the so-called judicial exceptions to patent eligibility, which include products of nature, abstract ideas, and natural phenomena.[26] Historically, the Supreme Court viewed the content of these exceptions as ensuring that fundamental tools of science and technology are free to all.[27] This animating principle excludes *naturally occurring* psychedelics, or the plants and fungi that produce them from patent eligibility -- inventors cannot patent them because they are products of nature. However, patent applicants can overcome this hurdle by modifying the structure of psychedelic compounds, producing them through new methods, or creating novel formulations.

There are several techniques applicants have used to game the system, securing patent rights on inventions that lack novelty or that would have been obvious to someone skilled in the relevant field.[28] One example is product hopping, where applicants patent existing technology by making subtle modifications and claiming the result as a novel invention.[29] Though technically different from the original, the updated version often provides little or no improved function. Product hopping can be achieved by filing *secondary patents* that claim modified versions of a base compound. For instance, they may claim the mirror image of a compound, which is called its enantiomer, different pharmaceutical formulations, or variations on its crystalline structure, which are called polymorphs.[30]

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[25] 35 U.S.C § 101 (1952).

[26] *2106 Patent Subject Matter Eligibility*, U.S. PATENT AND TRADEMARK OFFICE, https://www.uspto.gov/web/offices/pac/mpep/s2106.html (last visited July 23, 2021).

[27] *See, e,g,*, Funk Bros. Seed Co. v. Kalo Inoculant Co., 333 U.S. 127, 130 (1948) (stating that natural phenomena are "manifestations of laws of nature, free to all men and reserved exclusively to none").

[28] *See, e.g.*, Editorial Board, *How Big Pharma plays games with drug patents and how to combat it*, USA TODAY (July 18, 2019), https://www.usatoday.com/story/opinion/2019/07/18/big-pharma-plays-games-drug-patents-you-pay-editorials-debates/1769746001/.

[29] *See, e.g.*, Jennifer D. Claytor & Rita F. Redberg, *Product Hopping—An Expensive and Wasteful Practice*, 180 JAMA INTERNAL MED. 1154, 1154 (2021) (describing cases in which drug manufacturers swapped subtly modified versions for existing treatments to extend their product monopolies).

[30] *See* Amy Kapczynski, Chan Park & Bhaven Sampat, *Polymorphs and Prodrugs and Salts (Oh My!): An Empirical Analysis of "Secondary" Pharmaceutical Patents*, 7 PLOS ONE 1, 1 (2012).

Product hopping and the patenting of "me-too drugs" have been criticized for wasting scarce resources, increasing rents for dominant firms, and deterring meaningful innovation.[31] With aggressive marketing, copycat therapies can permeate a market despite being inferior to the more advanced therapies that could be developed if product hopping and other abuses of the patent system were disincentivized.[32] In Part III, we analyze a recent example of product hopping involving ketamine, a psychedelic anesthetic used to treat major depression.

In many cases, only large, well-capitalized firms can navigate the murky regulatory waters surrounding psychedelics research and development. Granting patent exclusivity enhances existing disparities, and the unique characteristics of psychedelics, and the regulatory environment surrounding them, may increase the likelihood of issuing bad patents—patents granted on inventions that do not meet patentability requirements or that were patented in bad faith to block competition.

The possibility of issuing bad patents on psychedelics is likely increased because the PTO lacks examiners with sufficient knowledge of these substances and their history. Due to a longstanding prohibition, few people have developed deep expertise in the field. The associated stigma and criminalization could threaten one's professional reputation and employment prospects. A lack of examiners with detailed knowledge of psychedelic compounds, and their history of Indigenous and underground use, could allow bad patents to breeze through the PTO without opposition.

To illustrate, consider the prior art search, the stage of patent prosecution where PTO examiners canvas various databases for inventions that resemble the one being claimed. Previously documented uses of the claimed invention are referred to as relevant prior art, and if discovered by PTO examiners, they can serve as the basis for rejecting a patent. However, the PTO has limited resources and the time it spends searching for relevant prior art may often be inadequate.[33] Because psychedelics have been prohibited for decades, and relevant knowledge is often derived from non-U.S. sources, prior art on psychedelics may be more difficult to find than in other disciplines. For instance, nearly all psychedelics consumption occurs in the shadows, and underground practitioners are less likely to publish their methods due to fear of arrest and prosecution. In addition, stewards of traditional psychedelic knowledge may transmit that information orally instead of in writing.

[31] *See* Joseph E. Stiglitz & Arjun Jayadev, *Medicine for tomorrow: Some alternative proposals to promote socially beneficial research and development in pharmaceuticals*, 7 J. GENERIC MEDICINES 217, 218 (2010).

[32] *Id.* at 219.

[33] *See, e.g.*, Jay P. Kesan, *Carrots and Sticks to Create a Better Patent System*, BERKELEY TECH. L. J. 145, 147-48 (2002) (describing constraints on PTO prior art searches including limited resources and a lack of examiner familiarity with the relevant technology).

If recorded, it may not have been written in English or published in databases that are easily accessed by PTO examiners.

A lack of experience might cause examiners to miss relevant prior art, provide a lower standard of review, and issue bad psychedelic patents.[34] When combined with the presumption of validity that is characteristic of U.S. patent law, some stakeholders could exploit these blind spots to blanket the landscape with broad patent claims, using language and technology that is foreign to examiners. Similar events occurred when the U.S. Court of Appeals for the Federal Circuit curbed PTO attempts to reject software patents using the judicial exception regarding abstract ideas. The PTO was inundated with software patent applications containing unfamiliar vocabulary and ambitious claiming strategies, which led to a sudden influx of low-quality patents.[35] A similar trend has already emerged in the psychedelics space.

Compass has a pending patent application that claims features of the room in which psilocybin is administered, including muted colors and soft furniture, the presence of music, and a therapist holding the patient's hand.[36] Critics allege that these claims lack novelty because the inventions they describe have been used for decades in clinical trials, Indigenous ceremonies, and underground therapy sessions.[37] However, because examiners are unfamiliar with this history, they may issue patents on this and similar inventions that lack novelty.

Compass has acquired several compositions of matter patents that claim crystalline polymorphs of psilocybin. One patent, granted in 2021, claims several formulations of crystalline Polymorph A of psilocybin.[38] A second, also granted in 2021, claims several formulations of a second polymorph, crystalline Hydrate A.[39] Some countries are less welcoming to polymorph patents. The Indian Patent Act of 1970 distinguishes between polymorphic patents that represent true technological

[34] *See Id.*

[35] *See* Art K. Rai, *Machine Learning at the Patent Office: Lessons for Patents and Administrative Law*, 104 IOWA L. REV. 2617, 2621 (2019).

[36] WIPO Patent No. WO 2020/212952 (filed April 17, 2020).

[37] *See, e.g.*, Shayla Love, *Psychedelics Patent Claim Raises Questions From Researchers Who Say They Did It First*, MOTHERBOARD (June 3, 2021, 10:00am), https://www.vice.com/en/article/qj8vmp/psychedelics-patent-claim-raises-questions-from-researchers-who-say-they-did-it-first (describing a patent on genetically modified yeast that produce psilocybin, which German scientists claim is invalid due to anticipation by their technology) [hereinafter Love Psychedelic Research]; *See also* Shayla Love, Can a Company Patent the Basic Components of Psychedelic Therapy?, MOTHERBOARD (Feb. 9, 2021), https://www.vice.com/en/article/93wmxv/can-a-company-patent-the-basic-components-of-psychedelic-therapy (describing patent claims that are likely anticipated due to prior use by academic researchers, psychedelic retreats, and underground practitioners) [hereinafter Love Psychedelic Therapy].

[38] U.S. Patent No. 10,954,259 (filed Dec. 9, 2020).

[39] U.S. Patent No. 11,149,044 (filed Feb. 10, 2021).

advancements, and those that merely bolster a patentee's intellectual property portfolio.[40] In 2015, the United Nations recommended that patent examiners presume that polymorphs and enantiomers are unpatentable.[41]

Importantly, to receive a patent, and applicant need not prove that the claimed invention will work. In 2021, the PTO granted a patent to Palo Alto Investors, claiming methods of using psychedelics to treat food allergies.[42] However, there is no proof (at least not yet) that psychedelics can treat food allergies. Regarding evidence of safety and efficacy, the bar is far lower for obtaining a patent compared to gaining FDA approval, which required evidence of safety and efficacy derived from clinical trials. Patent applicants need only establish that after reading the patent document, someone having knowledge in the relevant technological field could potentially make and use the invention. There is no requirement that the method be fully fleshed out, or that its safety and efficacy be established. In fact, patent doctrine considers data from fictional, purely imagined scenarios called *prophetic examples* to be equivalent to data derived from real experiments.[43]
In addition to being unproven, the invention claimed in the food allergy patent may lack novelty. Critics commented that related methods had been publicly disclosed as early as the 1960s.[44] These disclosures constitute prior art that casts doubt on the novelty of the invention. But nonetheless, the PTO granted the patent.

Fortunately, patent rights are not ironclad. They are often challenged and invalidated in court for lack of novelty, non-obviousness, patent eligibility, or failure to satisfy other requirements. Inventions lack novelty when similar inventions predate their patent filing date, which is called anticipation.[45] Patents can be invalidated for lack of non-obviousness, when the difference between the claimed invention and pre-existing inventions would have been obvious to a person having ordinary skill in the relevant field of science or technology.[46] Patents can

[40] *See* Runjhun Tandon, Nitin Tandon & Rajesh Kumar Thapar, *Patenting of polymorphs*, 7 FUTURE SCI. 59, 59 (2018) (interpreting Section 3d of the Indian Patent Act of 1970).

[41] Christopher M. Holman, Timo Minssen & Eric M. Solovy, *Patentability Standards for Follow-On Pharmaceutical Innovation*, 37 BIOTECH. L. REPORT 131, 132-33 (2018) (describing the UN Development Programme *Guidelines for Pharmaceutical Patent Examination: Examining Pharmaceutical Patents from a Public Health Perspective*).

[42] *See* Shayla Love, *Can LSD Treat Food Allergies? We Don't Know, But It's Already Been Patented*, VICE (July 1, 2021, 7:00 AM), https://www.vice.com/en/article/g5gdzy/can-lsd-treat-food-allergies-we-dont-know-but-its-already-been-patented

[43] Janet Freilich, *Prophetic Patents*, 53 U.C. DAVIS L. REV. 663, 666 (2019) (explaining how courts and the PTO allow patents to be granted based on imaginary experiments, which are treated as equivalent to data derived from real experiments).

[44] *See Id.*; *See* also, Harold A. Abramson, *Lysergic Acid Diethyl Amide (LSD-25): XXXVII. Antiserotonin Action of Lysergic Acid Derivatives in Allergy and Neuropsychiatry*, 2 J. ASTHMA RES. 257 (1965).

[45] *See* 35 U.S.C. § 102 (1952) (describing the novelty requirement).

[46] *See* 35 U.S.C. § 102 (1952) (describing non-obvious subject matter).

also be invalidated if they claim subject matter that is ineligible for patent protection, such as mathematical formulas or laws of nature.[47] Other grounds for invalidating patents include failure to adequately describe the claimed invention to establish it is in the inventor's possession or to enable a person having ordinary skill in the art to make and use it.[48]

Critics of psychedelic patents argue that many would not stand up to scrutiny. Some lack novelty because they claim methods already used by scientists, Indigenous groups, or underground psychedelics practitioners.[49] Some may lack non-obviousness because a person having ordinary skill in the field could have easily foreseen how to make them.[50] Others would be invalid if they claim naturally occurring psychedelic plants and fungi or phenomena exhibited by these organisms. But unfortunately, even patents that might ultimately be invalidated if challenged can be used offensively to cause significant harm. Patent holders can claim infringement by potential competitors, many of whom will be unable to mount an effective defense due to the prohibitively high cost of litigation (which can quickly reach millions).[51] To use an evocative phrase of Bob Mnookin, business decisions are often made "in the shadow of law," such that the threat of such litigation by a patent holder may deter investors from backing a rival.

Asymmetries of power resulting from abuses of the patent system are particularly relevant to the emerging psychedelics industry where barriers to entry are already high. The DEA classifies most psychedelics, exception for ketamine, as Schedule I controlled substances, because it believes they have no currently accepted medical use and a high potential for abuse.[52] The Schedule I status of psychedelics increases market uncertainty, scaring away risk averse investors. Prohibition may also reinforce patent monopolies.[53] DEA permission is required to conduct psychedelics research in the U.S., and obtaining the required license is not easy nor guaranteed. Consequently, patents and DEA licenses may act synergistically to deter competitors. Many startup companies are forced to work overseas where regulators

[47] *See* U.S. PATENT AND TRADEMARK OFFICE, *supra* note 26.

[48] *See* 35 U.S.C. § 112(a) (1952) (describing the written description and enablement requirements).

[49] *See* Love Psychedelic Research, *supra* note 37; *see also* Love Psychedelic Therapy, *supra* note 37.

[50] *See Id.*

[51] *See Costs Soar for Trade Secrets, Pharma Patent Suits, Survey Finds*, BLOOMBERG L. (Sept. 10, 2019, 5:01 AM), https://news.bloomberglaw.com/ip-law/costs-soar-for-trade-secrets-pharma-patent-suits-survey-finds (estimating the median cost of pharmaceutical patent cases to be $5 million in 2019, a 67 percent increase compared to the cost in 2015).

[52] *See Drug Scheduling*, U.S. DRUG ENFORCEMENT ADMINISTRATION, https://www.dea.gov/drug-information/drug-scheduling (last visited Aug. 3, 2021).

[53] *See* Mason Marks, *FDA's kratom ban would harm the public and damage the agency's credibility*, STAT FIRST OPINION (Aug. 23, 2021), https://www.statnews.com/2021/08/23/fdas-kratom-ban-would-harm-the-public-and-damage-the-agencys-credibility/ (arguing that companies with financial stakes in schedule I substances can benefit from prohibition).

are more accepting of psychedelics research. Domestically, the DEA limits the number of scientists who can participate in research, and the total mass of psychedelics produced each year, artificially restricting efforts to research and commercialize them.[54]

III. Ketamine: A Cautionary Tale of Chiral Chemistry

To better understand how these issues affect real therapies, consider the case of ketamine. It could be argued that instead of incentivizing new and useful innovation, patents on mental health treatments often promote abuses of the intellectual property system through tactics like biopiracy, patent trolling, evergreening, and product hopping.

Consider the role patents have played in psychiatry. Patent protection has long been available for mental health treatments. However, in the past fifty years, there has been little meaningful innovation in psychopharmacology.[55] The gold standard for treating many psychiatric conditions, prescribing SSRIs, has changed little since the introduction of Prozac in 1987. Newer SSRIs are typically subtle variations on older versions, offering only modestly improved side effect profiles, and little improvement in safety or efficacy.

The process of subtly modifying an existing product and patenting the result is called product hopping, which is common practice in drug development.[56] Product hopping allows drug companies to prevent their products from becoming substitutable with generic drugs. By hopping from one formulation to the next, they extend their patent monopolies. A related practice involves making subtle modifications to substances that are in the public domain, such as generic drug products, and patenting the results as new inventions. The use of ketamine to treat depression illustrates why this practice can be problematic. Ketamine has been used widely since the 1960s as an anesthetic and analgesic. The World Health Organization ranks it among the world's essential medicines, and its safety and versatility allow it to be used in a variety of setting from the pediatric clinic to the battlefield.[57]

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[54] *See* Marks, *supra* note 2, at 685.

[55] *See, e.g.*, Richard A. Friedman, *A Dry Pipeline for Psychiatric Drugs*, NY TIMES (Aug. 20, 2013), https://www.nytimes.com/2013/08/20/health/a-dry-pipeline-for-psychiatric-drugs.html.

[56] *See* Michael A. Carrier, *Product Hopping*, 23 J. COMMERCIAL BIOTECHNOLOGY 52, 52 (2017).

[57] *See* Mason Marks, *Psychedelic Medicine for Mental Illness and Substance Use Disorders: Overcoming Social and Legal Obstacles*, 21 N.Y.U. J. LEGIS. & PUB. POL'Y 69, 84-85 (2018) (describing the use of ketamine as an anesthetic in pediatrics, psychiatry, rural and battlefield medicine, and during natural disasters).

The discovery that ketamine could be prescribed off-label to manage treatment resistant depression was an important breakthrough. To capitalize on it, Janssen pharmaceuticals isolated esketamine (S-ketamine), a molecule present in all solutions of ketamine, which is composed of equal parts S-ketamine and R-ketamine. Called enantiomers, these left- and right-handed versions of ketamine are mirror images of each other. Such molecular "handedness" is referred to as chirality, and when left and right enantiomers are present in equal parts, the resulting solutions are called racemic mixtures.

Not all molecules exhibit chirality, but when they do, drug makers can exploit this property by patenting the enantiomer of an existing drug as a means of product hopping. Some SSRIs were isolated and patented this way including escitalopram, marketed as Lexapro, which is the left-handed version of citalopram, marketed as Celexa.[58] Similarly, despite longstanding use of ketamine to treat depression, Janssen patented treatments using esketamine and received FDA approval to market it under the trade name Sprovato.[59]

FDA approval of esketamine is a major step forward for people with depression. But it has also created something of a quandary for patients and providers who favor using *generic* ketamine. Because it is FDA approved unlike generic ketamine, Spravato is the ketamine variant for which some insurance companies will reimburse, which allowed it to gain market share. But despite being patented and approved for marketing as a treatment for depression, Spravato has failed to show a meaningful benefit over generic ketamine prescribed off label. Nevertheless, the result is that doctors have less incentive to prescribe or conduct research on ketamine. This safe, inexpensive, and widely used therapy has been displaced by a patented product for which Janssen and insurance companies serve as gatekeepers.

While a company like Janssen may deserve the benefit of this market for a new molecular entity where it bore the risk of discovery, the case for the patent benefit is less appealing when there is an existing synthetic variant or naturally occurring version – the exact reason why the Supreme Court has interpreted patent law to exclude naturally occurring products, and why other jurisdictions restrict secondary patents.[60] To be sure, esketamine is not identical to generic ketamine, but characterizing it as a novel invention is a stretch. Based on this logic, the Canadian Federal Court of Appeal recently held that Spravato is not an "innovative drug"

[58] *See, e.g.*, Monica Budău et al., *Chirality of Modern Antidepressants: An Overview*, 7 ADVANCED PHARMACEUTICAL BULLETIN 495, 496 (2017) (describing the chirality of SSRIs such as citalopram).

[59] U.S. Patent No. 10,869,844 (filed Dec. 6, 2019).

[60] *See* Runjhun, *supra* note 40; *See also* Holman, *supra* note 41.

eligible for data exclusivity, a type of monopoly right issued by drug regulatory agencies.[61]

While a patent conveys the right to exclude others from making, using, or selling an invention, data exclusivity prohibits drug regulators from approving competing versions of a recently approved drug, allowing the manufacturer with exclusivity to remain its sole provider.[62] The Canadian court based its Spravato decision on an earlier case, Takeda Canada v. Canadian Minister of Health, which held that a drug comprising a medicinal ingredient of a previously approved drugs, such an enantiomer, salt, or ester of the original, constitutes a mere "variation" on the original instead of an "innovative drug."[63] Nevertheless, U.S. patent law does not acknowledge these distinctions, which allowed drug companies to patent escitalopram and esketamine. One of Janssen's patents claims methods of producing esketamine salts.[64]

We fear that without action by policymakers, the ketamine story is a harbinger of things to come for psychedelics. Companies commercializing naturally-occurring psychedelic compounds may follow a similar playbook. Instead of patenting subtle variations on existing medications, they can patent subtle variations on widely used natural compounds, or methods of administering them, preventing competitors from entering the field. On the one hand, there are some advantages for this move – giving it a fancy new chemical name may destigmatize the drug and this may also enable insurance reimbursement. At the same time, though, there is a real risk of chilling research and competition in the psychedelics industry, which is at a particularly important embryonic moment. Moreover, it may represent the theft of traditional knowledge and promote the commercialization and destruction of natural resources.[65]

IV. Bioprospecting and Biopiracy

Bioprospecting is the practice of identifying useful natural resources that can be commercialized. It is not inherently bad. However, some claim it can serve as a façade for exploiting Indigenous communities. Without clear ethical and legal guardrails, bioprospecting can veer into the realm of biopiracy, the appropriation

[61] Janssen Inc. v. Attorney General of Canada (Minister of Health), 2021 FCA 137.

[62] *Frequently Asked Questions on Patents and Exclusivity*, U.S. FOOD AND DRUG ADMIN. (Feb. 5, 2020), https://www.fda.gov/drugs/development-approval-process-drugs/frequently-asked-questions-patents-and-exclusivity#What_is_the_difference_between_patents_a.

[63] Takeda Canada Inc v Canada (Minister of Health), 2013 FCA 13.

[64] U.S. Patent No. 10,815,196 (filed June 4, 2018).

[65] *See, e.g.*, Lulu Garcia Navarro, *Mexico's Peyote Endangered by 'Drug Tourists,'* NPR (Sept. 3, 2007), https://www.npr.org/templates/story/story.php?storyId=14064806 (describing how increased demand and overharvesting of peyote endanger the limited supply of this psychedelic cactus, which is sacred to Indigenous communities of Mexico).

and commercialization of technologies created by Indigenous groups, without adequate permission, acknowledgement, or compensation.[66]

Many psychedelics have long been used by communities around the world.[67] Practitioners of the Bwiti religion in Gabon use a plant called iboga in their spiritual practices. Iboga contains the psychedelic compound ibogaine, which shows promise for treating substance use conditions.[68] It is being commercialized by Western drug developers, and Mind Cure Health recently announced a provisional patent filing on methods of synthesizing it.[69]

Indigenous communities argue that companies patenting psychedelic substances are exploiting practices they have developed over centuries for use in healing and religious ceremonies.[70] These technologies have been taken and commercialized without consent, acknowledgement, or compensation. In one case, German drug maker Schwabe Pharmaceuticals patented an extract of the plant *Pelargonium sidoides.* Critics argued that the patent was invalid for lack of novelty because Indigenous communities had used roots of the plant to treat respiratory infections.[71] The European Patent Office agreed and invalidated the patent. Similarly, companies patenting psychedelics for therapeutic use are commercializing, medicalizing, and monopolizing practices that Indigenous cultures view as central to their identities. However, U.S. patent law lacks protections against biopiracy, and some aspects of international treaties may facilitate it.

In 1995, the World Trade Organization Trade-Related Aspects of Intellectual Property Rights (TRIPS) Agreement harmonized global intellectual property standards.[72] The TRIPS framework requires participating countries to allow certain natural resources and processes to be patented if they meet the criteria for

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[66] *See* Tim K. Mackey & Brian A. Liang, *Integrating Biodiversity Management and Indigenous Biopiracy Protection to Promote Environmental Justice and Global Health,* 102 AMER. J. PUBLIC HEALTH 1091, 1091 (2012) (defining biopiracy).

[67] *See, e.g.*, Yaden, *supra* note 1, at 587.

[68] *See, e.g.*, Thomas Kingsley Brown & Kenneth Alper, *Treatment of opioid use disorder with ibogaine: detoxification and drug use outcomes*, 44 AMER. J. DRUG ALCOHOL ABUSE 24, 24 (2016).

[69] *Mind Cure Announces Filing U.S. Provisional Patent Applications for Company's First Fully Synthetic Routes to Create an Ibogaine Psychedelic Compound*, PR NEWSWIRE (July 13, 2021, 3:30 PM), https://www.newswire.ca/news-releases/mindcure-announces-filing-of-u-s-provisional-patent-applications-for-company-s-first-fully-synthetic-routes-to-create-an-ibogaine-psychedelic-compound-847516509.html.

[70] *See* Gregoire, *supra* note 17.

[71] *See* Kaushiki Das, *The Global Quest for Green Gold: Implications of Bioprospecting and Patenting for Indigenous Bioresources and Knowledge*, 6 SOC'Y CULTURE S. ASIA 74, 76 (2019).

[72] *See* Frederick M. Abbott & Jerome H. Reichman, *The DOHA Round's Public Health Legacy: Strategies for the Production and Diffusion of Patented Medicines Under the Amended TRIPS Provisions*, 10 J. INT'L ECON. L. 921, 923 (2007).

patentability.[73] Proponents of strong intellectual property rights claim patents contribute to each country's growth by promoting international trade, licensing, and foreign investment.[74]

The Doha Declaration on the TRIPS Agreement and Public Health, signed in 2001, addressed the commercializing of Indigenous knowledge.[75] However, the treaty has been criticized for providing inadequate compensation and acknowledgment to those who produce it.[76] The prevailing international framework rewards innovation as conceived by Western nations, comprising advancements made in the context of universities and commercial laboratories instead of Indigenous communities.[77]

Some describe the bioprospecting agreements produced under TRIPS as paternalistic and exploitative. They often involve "creating an extensive database of the ethnobiological knowledge of the indigenous communities; identifying the plants with therapeutic potential; setting up biological parks to protect the plant from indiscriminate exploitation; extraction of active compounds from the plants and patenting the drug for commercial use."[78] In the name of environmental conservation, Indigenous communities have been driven from their land while pharmaceutical companies receive priority access.[79] Similarly, Jamilah R. George and colleagues argue that when "White-dominant culture borrows from the cultural practices and ceremonial expression of often marginalized groups, members of these groups end up alienated from the practices informed by their own cultural traditions . . . ."[80]

V. Proposed Solutions

We have tried to make the case for why current patent laws threaten to produce bad outcomes for development of the nascent psychedelics therapy industry. What should be done? One approach to improving the quality of psychedelic patents involves bolstering the prior art search by creating prior art repositories. Porta Sophia is a non-profit library for psychedelic prior art intended to aid patent applicants and PTO examiners.[81] Resources like Porta Sophia could improve prior

[73] *See* Kaushiki, *supra* note 71, at 76.
[74] *Id.*
[75] *Id.* at 77.
[76] *Id.*
[77] *Id.* at 78.
[78] *Id.* at 84.
[79] *Id.*
[80] *See* Jamilah R. George, Timothy I. Michaels, Jae Sevelius & Monnica T. Williams, *The psychedelic renaissance and the limitations of a White-dominant medical framework: A call for indigenous and ethnic minority inclusion*, 4 J. PSYCHEDELIC STUDIES 4, 5 (2020) (highlighting inequities in the field of psychedelic research and treatment).
[81] *Psychedelic Prior Art Library*, PORTA SOPHIA, https://www.portasophia.org/ (last visited Aug. 2, 2021).

art searches and help prevent issuance of bad patents by ensuring that lesser-known references are not easily overlooked. Nevertheless, though admirable, projects like Porta Sophia are more of a band-aid than a long-term solution because they burden local communities with cataloguing their practices and submitting them to prior art libraries.

Another approach involves tightening up U.S. requirements for novelty and non-obviousness. For instance, Congress, courts, and the PTO could follow the example set by the Canadian court by prohibiting patents claiming salts, enantiomers, and other variations on existing inventions because they lack inventiveness and do not merit patent protection. Granting patents on such variations contributes to the patent thicket, potentially impeding science and inhibiting useful innovation. However, attempts to constrict patent requirements are likely to be met with significant resistance from pharmaceutical industry lobbyists. There are ongoing efforts to expand the scope of patent eligibility led by industry-funded federal lawmakers.[82]

A better option may be to limit the enforcement of patents on psychedelics. Companies in many technological areas have pledged not to enforce their patent rights under certain conditions. "Patent pledges" can be made by individuals, companies, and groups of patent holders, and they often focus on specific industries or technologies. During the COVID-19 pandemic, a group of companies took the Open COVID Pledge, promising not to enforce their rights against competitors who use their patented technology to address the pandemic.[83]

Long before COVID, in 2014, CEO Elon Musk announced that Tesla Motors would no longer enforce its patent rights against competitors who use its technology in good faith.[84] Today Tesla is the most valuable automotive company, and it is arguably the most innovative.[85] Following its lead, Toyota made a similar pledge regarding over 24,000 patents on electric and hybrid vehicle technology.[86] Musk's other company SpaceX has also eschewed patents as a means of guarding its

[82] *See, e.g.*, Emmarie Huettman, *Senators Who Led Pharma-Friendly Patent Reform Also Prime Targets for Pharma Cash*, KAISER HEALTH NEWS (March 24, 2020), https://khn.org/news/senators-who-led-pharma-friendly-patent-reform-also-prime-targets-for-pharma-cash/.

[83] *Make the pledge to share your intellectual property in the fight against COVID-19*, Open COVID Pledge, https://opencovidpledge.org/ (last visited Aug. 2, 2021).

[84] Elon Musk, *All Our Patents Are Belong to You*, TESLA BLOG (June 12, 2014), http://www.teslamotors.com/blog/all-our-patent-are-belong-you; see also infra notes 161–166 and accompanying text.

[85] *Tesla overtakes Toyota to become world's most valuable carmaker*, BBC NEWS (July 1, 2020), https://www.bbc.com/news/business-53257933.

[86] Naomi Tajitsu, *Toyota to give royalty-free access to hybrid-vehicle patents*, Reuters (April 2, 2019, 3:29 PM), https://www.reuters.com/article/us-toyota-patents-idUSKCN1RE2KC.

intellectual assets.[87] Despite a lack of patents to incentivize it to innovate, SpaceX has revitalized the U.S. space industry.[88]

Some call for patent pledges in the psychedelics industry. On May 27, 2021, Lars Christian Wilde, Co-Founder and President of Compass, stated that his company would not enforce patent claims related to "set and setting," the environment or mindset in which people receive psychedelics.[89] His statement presumably included the company's pending application for room colors, music, and physical touch.[90] Attorneys and psychedelics advocates questioned whether Wilde's statements constitute an enforceable patent pledge.[91] However, the law is unclear on whether informal promises not to enforce patents are legally binding.[92] Despite their potential benefits, patent pledges have other shortcomings. Those taking a pledge retain significant control over when and how they enforce their rights. They often attach stipulations to their promises, making them difficult for courts and the public to interpret, which can cause confusion and promote unintentional infringement.

Instead of creating exceptions to the enforceability of patents on psychedelics, a different more radical option would be to entirely forego granting patents on them in the first place. In addition to exploiting Indigenous communities and restricting access, some have questioned whether psychedelic patents are necessary to incentivize innovation. A non-profit organization called the Multidisciplinary Association for Psychedelic Studies (MAPS) has arguably done more to advance psychedelic science than any other entity. Without patenting the fruits of its research, MAPS has made MDMA a viable therapy for PTSD. It has even pursued an anti-patent strategy to prevent MDMA from being monopolized.[93] A newer non-profit called Usona conducts clinical trials with psilocybin and has a similar philosophy regarding intellectual property.[94]

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[87] Michael Heller & James Salzman, *Elon Musk Doesn't Care About Patents. Should You?*, HARV. BUS. REV. (March 4, 2021), https://hbr.org/2021/03/elon-musk-doesnt-care-about-patents-should-you.

[88] *See* Adam Mann, *SpaceX now dominates rocket flight, brining big benefits—and risks—to NASA*, SCI. MAG. (May 20, 2020), https://www.sciencemag.org/news/2020/05/spacex-now-dominates-rocket-flight-bringing-big-benefits-and-risks-nasa (reporting that SpaceX handles about two-thirds of NASA launches).

[89] Oxford Psychedelic Society, *Psychedelic Capitalism (Moderated Discussion with Alexander Beiner and Lars Wilde, 27/05/21)*, YOUTUBE (May 28, 2021), https://www.youtube.com/watch?v=C4ilk9OiyW4.

[90] *Supra* note 42.

[91] Graham Pechenik (@calyxlaw), Twitter (May 27, 2021, 2:58 PM), https://twitter.com/AlexanderBeiner/status/1398274308284338187.

[92] *See* Jorge L. Contreras, *Patent Pledges*, 47 ARIZ. ST. L.J. 543, 592-594 (2015) (describing the enforceability of different types of public statements regarding patents).

[93] Catherine Elton, *The Interview: MDMA-Therapy Expert Dr. Rick Doblin*, BOSTON MAG. (Sept. 10, 2019), https://www.bostonmagazine.com/health/2019/09/10/rick-doblin/.

[94] *See* Love Psychedelic Therapy, *supra* note 37 (describing Usona's "open science" approach to psychedelic innovation that foregoes patents).

Strong arguments can be made for prohibiting patents on psychedelics. Patent protection has long been available on psychiatric drugs such as the SSRIs. But it has failed to incentivize significant innovation or reverse the worsening mental health crisis. Because psychedelics represent the most innovative approach to mental healthcare in decades, and the most promising potential solution to the mental health crisis, they are too important to be monopolized. Similar arguments have been made for other biomedical innovations such as vaccines and genetic technologies.[95]

In addition to treating mental health conditions, some researchers believe psychedelics could lead to a better understanding of the human mind and brain, which have puzzled scientists and philosophers throughout history. For this reason, keeping psychedelics in the public domain, off limits to the patent system, may be akin to prohibiting patents on abstract ideas, products of nature, and natural phenomena, because they are fundamental tools of scientific inquiry.

According to psychiatrist and psychedelics pioneer Stanislav Grof, "Psychedelics, used responsibly and with proper caution, would be for psychiatry what the microscope is for biology and medicine or the telescope for astronomy."[96] Instead of framing psychedelics as therapies to be commercialized, one can view them as instruments permitting unprecedented study of the psyche, which could expand humanity's limited understanding of itself. In other words, psychedelics are of such importance to science and public health that no individual, company, or group of entities should monopolize their production and use.

To be sure, prohibiting patents in this area would be a very radical step. If we expect significant costs in commercialization, crossing the so-called “valley of death” between drug discovery and satisfying FDA approval, it may be a step too far. But our purpose in this essay has been to put it on the table as something policymakers should be taking seriously.

CONCLUSION

The issuance of low-quality patents on psychedelics reflects unique characteristics of these substances, their complex history and regulation, and systemic problems with the patent system. Though prior art repositories and patent pledges can be helpful, meaningful patent reform is necessary to prevent the granting of meritless psychedelic patents.

[95] *See, e.g.*, Amy Kapczynski, *Order Without Intellectual Property: Open Science Influenza*, 102 CORNELL L. REV. 1539, 1594 (2017).

[96] Mason Schreck, *Stanislav and Christina Grof: Cartographers of the Psyche* 27, MAPS Bulletin Volume xxi Number 3), https://maps.org/news-letters/v21n3/v21n3-26_29.pdf.

The existing patent framework often rewards those who patent "me-too drugs" that are insignificant advancements over existing therapies, reducing the public benefit received per research dollar spent. Copycat therapeutics not only lack novelty, but they have also failed to produce significant improvements in mental healthcare as evidenced by rising rates of suicide and skyrocketing overdose deaths. Drug companies have recently applied this me-too approach to psychedelic experiences pioneered and revered by Indigenous communities.

Psychedelics may represent a paradigm shift for mental healthcare, and the most promising solution to the mental health crisis. However, if a small number of companies secure wide swaths of intellectual property early on, then the beneficial impact of that shift may be blunted.

In this Essay we have set out a series of possible ways to curb the downsides of patents in the psychedelics field, some radical, some less so. It is essential to have these conversations now, while the industry remains in its nascent stage. The political economy is such that once new players become large enough, they will have an outsized influence over potential changes to the law, especially those that threaten their dominant positions.