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Mason Marks
Florida State University

I. Glenn Cohen
Harvard

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PATENTS ON PSYCHEDELICS: THE NEXT LEGAL BATTLEFRONT OF DRUG DEVELOPMENT

Mason Marks* & I. Glenn Cohen**

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 U.S. Patent and Trademark Office (PTO) lacks personnel with expertise in the field, rendering more questionable the quality of its evaluation of 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 unwarranted 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, it may be appropriate to view psychedelics as tools of scientific discovery, eligible only for limited patent protection.

INTRODUCTION

In the past few decades, pioneering researchers rekindled interest in the therapeutic use of psychedelic substances. This controversial class

* Assistant Professor, University of New Hampshire Franklin Pierce School of Law; Senior Fellow and Project Lead, Project on Psychedelics Law and Regulation (POPLAR) at the Petrie-Flom Center for Health Law Policy, Biotechnology, and Bioethics at Harvard Law School; Doctoral Researcher, Center for Law and Digital Technologies at Leiden Law School; Affiliated Fellow, Information Society Project at Yale Law School.

** James A. Attwood and Leslie Williams Professor of Law and Deputy Dean, Harvard Law School; Faculty Director and Investigator, Project on Psychedelics Law and Regulation (POPLAR) at the Petrie-Flom Center for Health Law Policy, Biotechnology, and Bioethics at Harvard Law School. Both Marks and Cohen receive research support from POPLAR, which is itself supported by a research grant from the Saisei Foundation. Marks has served as a governor-appointed volunteer member of the Oregon Psilocybin Advisory Board. He also serves on several nonprofit boards in the drug policy sector and advises clients on state and federal controlled substance regulation.

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of compounds includes psilocybin, dimethyltryptamine (DMT), ibogaine, ketamine, and 3,4-methylenedioxymethamphetamine (MDMA).¹

Known for their potential to promote feelings of well-being and connectedness, many psychedelics have been used for centuries by Indigenous communities around the world.² Mental health professionals experimented with them as therapeutic aids during the 1950s and '60s.³ However, most common psychedelics were banned in the '70s when Congress passed the Controlled Substances Act⁴ and President Nixon launched the U.S. war on drugs.⁵

Except for ketamine, an essential medicine used in anesthesia,⁶ and MDMA, which was not banned until 1985,⁷ the psychedelics were classified as Schedule I controlled substances.⁸ According to the Drug Enforcement Administration (DEA), Schedule I drugs 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.”⁹ However, a 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,

¹ Mason Marks, *Controlled Substance Regulation for the COVID-19 Mental Health Crisis*, 72 ADMIN. L. REV. 649, 654 (2020).

² See David B. Yaden & Roland R. Griffiths, *The Subjective Effects of Psychedelics Are Necessary for Their Enduring Therapeutic Effects*, 4 ACS PHARMACOLOGY & TRANSLATIONAL SCI. 568, 569 (2021) (describing the historical use of psychedelics and the use of validated psychological instruments to measure their subjective effects, which include feelings of unity or connectedness, feelings of reverence, altered perception of space and time, and feelings of love or peace). Ketamine, and a closely related compound called esketamine, are not considered classic psychedelics and some experts put them in another class, the dissociative anesthetics. See Rachel Quibell et al., *Ketamine*, 41 J. PAIN & SYMPTOM MGMT. 640, 640 (2011). However, we consider them psychedelics because they have the hallmarks of this class, including the ability to induce mystical experiences, treat depression, and, according to accumulating evidence, induce neuroplasticity. Simon Makin, *Behind the Buzz: How Ketamine Changes the Depressed Patient's Brain*, SCI. AM. (Apr. 12, 2019), <https://www.scientificamerican.com/article/behind-the-buzz-how-ketamine-changes-the-depressed-patients-brain> [<https://perma.cc/D2RT-23RX>].

³ See Marks, *supra* note 1, at 666–67 (describing clinical experiments with psychedelics during the 1950s and '60s, which were often reported as safe and useful to the therapeutic process).

⁴ 21 U.S.C. §§ 801–904.

⁵ See Marks, *supra* note 1, at 667–68 (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).

⁶ Quibell et al., *supra* note 2, at 640.

⁷ See *U.S. Will Ban “Ecstasy,” A Hallucinogenic Drug*, N.Y. TIMES, June 1, 1985, at 6.

⁸ See Controlled Substances Act, 21 U.S.C. § 812(c) (classifying twenty-eight “hallucinogenic substances” under Schedule I, including DMT, psilocybin, and ibogaine).

⁹ *Controlled Substance Schedules*, DRUG ENF'T ADMIN., <https://www.deadiversion.usdoj.gov/schedules/index.html> [<https://perma.cc/CZD3-K2Y3>] (defining DEA criteria for categorization in Schedule I and listing psychedelic examples such as lysergic acid diethylamide (LSD), peyote, and MDMA).

post-traumatic stress disorder (PTSD) in veterans, and rising rates of suicide.¹⁰

The therapeutic potential of psychedelics has triggered an explosion of discussion on popular media, including outlets like the *New York Times*, *60 Minutes*, and *Scientific American*.¹¹ Popular coverage of psychedelics research has reinforced public interest in the medical and non-medical use of these substances.

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.¹² In 2018 and 2019, the agency identified psilocybin as a breakthrough therapy for treatment-resistant depression and major depressive disorder.¹³ In 2019, the FDA designated esketamine, a variation of anesthetic ketamine, a breakthrough therapy for treatment-resistant depression.¹⁴ These breakthrough therapy 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.¹⁵ In 2021, the results of two

¹⁰ See, e.g., Jennifer M. Mitchell et al., *MDMA-Assisted Therapy for Severe PTSD: A Randomized, Double-Blind, Placebo-Controlled Phase 3 Study*, 27 *NATURE MED.* 1025, 1026 (2021) (reporting significant improvement of PTSD symptoms following treatment with MDMA in clinical trial); 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, 9796–97 (2020) (describing the use of psychedelics for treating problematic substance, alcohol, and tobacco use); Matthew W. Johnson & Roland R. Griffiths, *Potential Therapeutic Effects of Psilocybin*, 14 *NEUROTHERAPEUTICS* 734, 735–36 (2017) (describing the therapeutic benefits of psilocybin therapy for cancer-related anxiety and depression).

¹¹ 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); Andrew Jacobs, *The Psychedelic Revolution Is Coming. Psychiatry May Never Be the Same*, *N.Y. TIMES* (Nov. 11, 2021), <https://www.nytimes.com/2021/05/09/health/psychedelics-mdma-psilocybin-molly-mental-health.html> [<https://perma.cc/LGV5-5SWV>]; Danielle Schlosser & Thomas R. Insel, *A Renaissance for Psychedelics Could Fill a Long-Standing Treatment Gap for Psychiatric Disorders*, *SCI. AM.* (Sept. 14, 2021), <https://www.scientificamerican.com/article/a-renaissance-for-psychedelics-could-fill-a-long-standing-treatment-gap-for-psychiatric-disorders> [<https://perma.cc/33RW-YTV6>]; *60 Minutes*, *Cancer Patient Overcomes Anxiety About Death with Psychedelics*, *YOUTUBE* (Oct. 10, 2019), <https://www.youtube.com/watch?v=lqnPVZUzDPc> [<https://perma.cc/AVA7-DF8>].

¹² Allison A. Feduccia et al., *Breakthrough for Trauma Treatment: Safety and Efficacy of MDMA-Assisted Psychotherapy Compared to Paroxetine and Sertraline*, 10 *FRONTIERS PSYCHIATRY* 1, 2 (2019).

¹³ Rachel Feltman, *The FDA Is Fast-Tracking a Second Psilocybin Drug to Treat Depression*, *POPULAR SCI.* (Nov. 26, 2019, 4:07 PM), <https://www.popsci.com/story/health/psilocybin-magic-mushroom-fda-breakthrough-depression> [<https://perma.cc/KEP9-DF6U>].

¹⁴ Press Release, FDA, *FDA Approves New Nasal Spray Medication for Treatment-Resistant Depression; Available Only at a Certified Doctor's Office or Clinic* (Mar. 5, 2019), <https://www.fda.gov/news-events/press-announcements/fda-approves-new-nasal-spray-medication-treatment-resistant-depression-available-only-certified> [<https://perma.cc/FS4Z-T5ZK>].

¹⁵ See Marks, *supra* note 1, at 694.

landmark Phase 2 clinical trials indicated that psilocybin can effectively reduce symptoms of moderate-to-severe and treatment-resistant depression.¹⁶ Due to these studies and other impressive results, investment in psychedelics research and commercialization is rising.¹⁷ Indeed, some predict the value of the U.S. psychedelics market will reach \$10.75 billion by 2027.¹⁸

This Essay analyzes the ethical, legal, and social concerns raised by the growing trend of patenting psychedelic therapies, which has recently become a topic of considerable debate.¹⁹ Though patents can incentivize innovation, their application to psychedelics threatens competition, scientific progress, and public health.²⁰ 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 these patents 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 properly 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.

¹⁶ See Robin Carhart-Harris et al., *Trial of Psilocybin Versus Escitalopram for Depression*, 384 NEW ENG. J. MED. 1402, 1402, 1408 (2021) (reporting that two doses of psilocybin spaced three weeks apart treated depression as effectively as six weeks of daily escitalopram, an SSRI); see also Olivia Goldhill, *Largest Psilocybin Trial Finds the Psychedelic Is Effective in Treating Serious Depression*, STAT (Nov. 9, 2021), <https://www.statnews.com/2021/11/09/largest-psilocybin-trial-finds-psychedelic-effective-treating-serious-depression> [<https://perma.cc/74JV-SB5Q>].

¹⁷ See, e.g., Jacobs, *supra* note 11 (describing the rush to invest in research on psychedelics and the companies raising hundreds of millions of dollars to commercialize them).

¹⁸ *Psychedelic Drugs Market Size Is Predicted to Reach \$10.75 Billion by 2027*, PR NEWSWIRE (Apr. 21, 2021, 9:00 AM), <https://www.prnewswire.com/news-releases/psychedelic-drugs-market-size-is-projected-to-reach-10-75-billion-by-2027--301273405.html> [<https://perma.cc/R4PP-ST29>].

¹⁹ See, e.g., PSYCH, *PSYCH Investor Summit: Research & Development — For-Profit or Non-Profit? That Is the \$100b Question*, YOUTUBE (July 8, 2021), <https://www.youtube.com/watch?v=yXJoN3kmNjY> [<https://perma.cc/TYE6-8BHS>] (debating the risks and benefits of patents on psychedelic therapies and for-profit versus nonprofit 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-psychedelics-monopoly-market-mushrooms-mental-health-depression-therapy-shrooms> [<https://perma.cc/W8A8-N2G8>].

²⁰ See Mason Marks & I. Glenn Cohen, *Psychedelic Therapy: A Roadmap for Wider Acceptance and Utilization*, 27 NATURE MED. 1669, 1670 (2021) (arguing that patents on psychedelics may limit research, innovation, and public access).

I. PSYCHEDELICS IN DEBATES ON 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 twenty years from the date each patent application was filed.²¹ The public policy justification for patents rests on the theory that the right to exclude competitors incentivizes innovation and encourages inventors to disclose their inventions to the public, instead of maintaining them as trade secrets.

Companies like the British pharmaceutical firm Compass Pathfinder Limited (Compass) have sought and obtained patents to protect formulations of psychedelic compounds and methods of producing and administering them.²² Such companies argue that patents are necessary to protect their investments not only in drug discovery, but also because of the costs of commercialization, which may involve expensive clinical trials and other requirements to obtain FDA approval and buy-in from the medical community thereafter.²³

The sudden influx of psychedelic patents has prompted criticism from stakeholders including patient advocates, scientists, journalists, lawyers, and members of Indigenous communities.²⁴ Some claim patents on psychedelics monopolize products of nature that should remain affordable and widely available.²⁵ They contend that patents can exploit the traditional knowledge of Indigenous communities without permission or adequate acknowledgement and compensation.²⁶ Others argue psychedelic patents are making a small number of companies

²¹ See *General Information Concerning Patents*, U.S. PAT. & TRADEMARK OFF., <https://www.uspto.gov/patents/basics/general-information-patents> [<https://perma.cc/T65H-LEYZ>].

²² See U.S. Patent No. 10,947,257 (filed July 2, 2020) (claiming an oral formulation of psilocybin and methods of treating major depressive disorder); WIPO Patent Application No. WO 2020/212952 A1 (Compass Pathways Ltd.) Apr. 17, 2020 (claiming methods of administering psilocybin to treat depression and a variety of other conditions).

²³ See, e.g., Christian Angermayer, *An Open Letter to Tim Ferriss About the Value of Patents in the Psychedelic World*, LINKEDIN (Mar. 9, 2021), <https://www.linkedin.com/pulse/open-letter-tim-ferriss-value-patents-psychedelic-angermayer> [<https://perma.cc/6ZS4-8JVX>].

²⁴ See Shayla Love, *Investors Are Debating Who Should Own the Future of Psychedelics*, VICE (Mar. 10, 2021, 10:15 AM), <https://www.vice.com/en/article/3angeb/investors-are-debating-who-should-own-the-future-of-psychedelics> [<https://perma.cc/TV3U-KS4D>] (quoting philanthropist Tim Ferriss and psychedelics researcher and advocate Rick Doblin criticizing the widespread patenting of psychedelics); Carolyn Gregoire, *Inside the Movement to Decolonize Psychedelic Pharma*, NEO.LIFE (Jan. 11, 2021), <https://neo.life/2020/10/inside-the-movement-to-decolonize-psychedelic-pharma> [<https://perma.cc/J52U-ND32>].

²⁵ Gregoire, *supra* note 24.

²⁶ *Id.*

gatekeepers for the emerging psychedelics industry, which could inhibit research, stifle innovation, and restrict access to needed therapies.²⁷

In addition, some commentators 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 from entering the field out of fear of being sued for infringement or having to pay high license fees to patent holders.²⁸

To be sure, these patent thicket concerns are not unique to psychedelics. Patents on genetic technologies and cancer therapies, along with many other treatments, have engendered similar debates.²⁹ However, several distinctive 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 this prohibition likely deprived those communities, and people with mental health conditions, of more effective therapies for decades.³⁰ Accordingly, many argue that the government should prioritize funding psychedelics research to make psychedelic therapies more affordable and accessible.³¹ 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.³²

²⁷ See, e.g., Marcelo Leite, *Capitalism Goes Rogue with Patent Claims on Psychedelics*, CHACRUNA (Mar. 17, 2021), <https://chacruna.net/psychedelic-patents-capitalism> [<https://perma.cc/335S-E7GD>].

²⁸ See, e.g., KEVIN T. RICHARDS ET AL., CONG. RSCH. SERV., R46221, DRUG PRICING AND PHARMACEUTICAL PATENTING PRACTICES 2, 24 (2020).

²⁹ See, e.g., Jon F. Merz & Mildred K. Cho, *What Are Gene Patents and Why Are People Worried About Them?*, 8 CMTY. GENETICS 203, 205 (2005); Lyriisa Lidsky, *Patent Reform Is Needed to Protect Patients' Access to Lifesaving Drugs*, STAT (July 23, 2019), <https://www.statnews.com/2019/07/23/patent-reform-protect-access-lifesaving-drugs> [<https://perma.cc/M5PU-ZVZN>].

³⁰ 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 has impacted racial minorities in the criminal justice system); 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> [<https://perma.cc/D5AD-GMB3>] (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).

³¹ See Brian Barnett, Rick Doblin & Julie Holland, *NIH: It's Time to Make Your Mark on the Renaissance of Medicinal Psychedelics*, STAT (June 2, 2021), <https://www.statnews.com/2021/06/02/nih-make-mark-renaissance-psychedelic-medicine> [<https://perma.cc/3AKW-4YCF>].

³² See Gregoire, *supra* note 24.

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 U.S. Patent and Trademark Office (PTO) that their technologies are novel, nonobvious, useful, and within the scope of patent-eligible subject matter, which is the range of inventions for which patents can be granted.³³ 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.³⁴ Some of these requirements, such as novelty, can be difficult to meet in crowded technological fields. Others, such as utility, play a relatively minor role in modern patent practice.

To be eligible for patent protection, an invention must be a “process, machine, manufacture, or composition of matter.”³⁵ Moreover, it must not fall into one of three categories of excluded subject matter, the so-called judicial exceptions to patent eligibility, which include laws of nature, abstract ideas, and natural phenomena.³⁶ Historically, the Supreme Court viewed the content of these exceptions as ensuring that fundamental tools of science and technology are free to all.³⁷ This animating principle excludes *naturally occurring* psychedelics, and 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.³⁸ One example is product hopping, where applicants patent existing technology by

³³ See, e.g., KEVIN J. HICKEY, CONG. RSCH. SERV., R46525, PATENT LAW: A HANDBOOK FOR CONGRESS 14–16 (2020).

³⁴ *Id.* at 13.

³⁵ 35 U.S.C. § 101.

³⁶ 2106 Patent Subject Matter Eligibility [R-10.2019], U.S. PAT. & TRADEMARK OFF., <https://www.uspto.gov/web/offices/pac/mpep/s2106.html> [https://perma.cc/5FMJ-URA3].

³⁷ 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”).

³⁸ See, e.g., The Editorial Board, Opinion, *How Big Pharma Plays Games with Drug Patents and How to Combat It*, USA TODAY (July 18, 2019, 6:29 PM), <https://www.usatoday.com/story/opinion/2019/07/18/big-pharma-plays-games-drug-patents-you-pay-editorials-debates/1769746001> [https://perma.cc/CF2G-S8EK].

making subtle modifications and claiming the result as a novel invention.³⁹ Though technically different from the original, the updated version often provides little or no improved function. Product hopping, as we use the term here, can be achieved by filing *secondary patents* that claim modified versions of a base compound. For instance, a patent may claim a molecule that was previously available as a mixture of the right- and left-handed versions of the molecule (enantiomers) different pharmaceutical formulations of the compound, or variations on its crystalline structure.⁴⁰

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.⁴¹ 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.⁴² In Part III, we analyze a recent example of secondary patenting involving ketamine, a psychedelic anesthetic used to treat major depression, as a cautionary tale for what may happen to other psychedelics if secondary patenting is allowed to proceed unchecked.

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, together with 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,

³⁹ 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).

⁴⁰ See Michael A. Carrier & Steve D. Shadowen, *Product Hopping: A New Framework*, 92 NOTRE DAME L. REV. 167, 172 (2016) (describing the process of product hopping by patenting a left- or right-handed molecule that has been isolated from a mixture of enantiomers); see also Amy Kapczynski et al., *Polymorphs and Prodrugs and Salts (Oh My!): An Empirical Analysis of “Secondary” Pharmaceutical Patents*, 7 PLOS ONE 1, 1 (2012).

⁴¹ See Joseph E. Stiglitz & Arjun Jayadev, *Medicine for Tomorrow: Some Alternative Proposals to Promote Socially Beneficial Research and Development in Pharmaceuticals*, 7 J. GENERIC MEDS. 217, 218–19 (2010). Me-too drugs are substances that pharmaceutical companies claim are novel and nonobvious inventions to obtain a new patent despite there being little or no structural or functional differences between existing drugs and the subject matter claimed in the new patent. See *id.* at 218.

⁴² *Id.* at 219.

few people have developed deep expertise in the field.⁴³ 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.⁴⁴ 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.⁴⁵ 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.⁴⁶ In addition, stewards of traditional psychedelic knowledge may transmit that information orally instead of in writing. Even 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.⁴⁷ When combined with the presumption of validity that is characteristic of U.S. patent law,⁴⁸ 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.⁴⁹ 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.⁵⁰

⁴³ See Marks, *supra* note 1, at 667–68.

⁴⁴ See Jay P. Kesan, *Carrots and Sticks to Create a Better Patent System*, 17 BERKELEY TECH. L.J. 763, 765 (2002).

⁴⁵ See, e.g., *id.* at 765–66 (describing constraints on PTO prior art searches, including limited resources and a lack of examiner familiarity with the relevant technology).

⁴⁶ See Marks, *supra* note 1, at 657–58.

⁴⁷ See Kesan, *supra* note 44, at 767.

⁴⁸ 35 U.S.C. § 282(a) (“A patent shall be presumed valid.”).

⁴⁹ See Arti K. Rai, *Machine Learning at the Patent Office: Lessons for Patents and Administrative Law*, 104 IOWA L. REV. 2617, 2621 (2019).

⁵⁰ *Id.*

We are arguably starting to see a similar trend emerge in the psychedelics space. Compass has a pending patent application that claims methods of administering psilocybin in a room with muted colors and soft furniture, a bed, a couch, a high-resolution sound system, or a therapist holding the patient's hand.⁵¹ 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.⁵² However, because examiners are unfamiliar with this history, they may issue patents on this and similar inventions that lack novelty.

Compass has acquired several composition-of-matter patents that claim crystalline polymorphs of psilocybin. When a substance exists as a solid, it can be present in amorphous or crystalline forms.⁵³ The former is characterized by a disordered arrangement of molecules, and the latter is characterized by a highly ordered spatial relationship of molecules.⁵⁴ Ice is the crystalline form of water in which molecules are present in a highly ordered lattice structure, and many different crystalline structures of ice have been characterized.⁵⁵ Similarly, psilocybin molecules can become arranged in a variety of crystalline structures.

One Compass patent, granted in 2021, claims several pharmaceutical formulations of crystalline Polymorph A of psilocybin.⁵⁶ A second, also granted in 2021, claims several formulations of a different psilocybin polymorph, crystalline Hydrate A.⁵⁷ As discussed further below, some countries and organizations are less tolerant of polymorph patents than the United States. They argue that in many cases, polymorphs of a substance should not be seen as novel chemical entities or inventions.

⁵¹ WIPO Patent Application No. WO 2020/212952 A1 (Compass Pathways Ltd.) Apr. 17, 2020, at 251.

⁵² See, e.g., Gregoire, *supra* note 24; Shayla Love, *Can a Company Patent the Basic Components of Psychedelic Therapy?*, VICE (Feb. 9, 2021, 1:41 PM), <https://www.vice.com/en/article/93wmxv/can-a-company-patent-the-basic-components-of-psychedelic-therapy> [<https://perma.cc/P4XT-XUGM>] [hereinafter Love, *Psychedelic Therapy*] (describing patent claims that are likely anticipated due to prior use by academic researchers, psychedelic retreats, and underground practitioners); Shayla Love, *Psychedelics Patent Claim Raises Questions from Researchers Who Say They Did It First*, VICE (June 3, 2021, 1:00 PM), <https://www.vice.com/en/article/cj8vmp/psychedelics-patent-claim-raises-questions-from-researchers-who-say-they-did-it-first> [<https://perma.cc/2RCU-TTJG>] [hereinafter Love, *Psychedelic Research*] (describing a patent on genetically modified yeast and bacteria that produce psilocybin, which German scientists claim is invalid due to anticipation by their technology).

⁵³ See Rolf Hilfiker, Fritz Blatter & Markus von Raumer, *Relevance of Solid-State Properties for Pharmaceutical Products*, in *POLYMORPHISM IN THE PHARMACEUTICAL INDUSTRY* 1, 1 (Rolf Hilfiker & Markus von Raumer eds., 2006).

⁵⁴ See *id.*

⁵⁵ Michelle Starr, *Scientists Just Confirmed the Existence of a New Crystalline Structure of Ice*, SCI. ALERT (Feb. 18, 2021), <https://www.sciencealert.com/scientists-have-discovered-a-new-crystalline-structure-of-ice> [<https://perma.cc/QLP7-GDE3>].

⁵⁶ U.S. Patent No. 10,954,259 (filed Dec. 9, 2020) (issued Mar. 23, 2021).

⁵⁷ U.S. Patent No. 11,149,044 (filed Feb. 10, 2021) (issued Oct. 19, 2021).

Importantly, to receive a patent, an applicant need not prove that the claimed invention will function as described. In 2021, the PTO granted a patent to Palo Alto Investors, which claimed methods of using psychedelics to treat food allergies.⁵⁸ However, there is no proof (at least not yet) that psychedelics can treat food allergies.⁵⁹

Regarding evidence of safety and efficacy, the bar is far lower for obtaining a patent compared to gaining FDA approval, which requires evidence of safety and efficacy derived from clinical trials.⁶⁰ 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.⁶¹ 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.⁶²

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.⁶³ These disclosures constitute prior art that casts doubt on the novelty of the invention. Nonetheless, the PTO granted the patent.

Fortunately, patent rights are not ironclad. They are often challenged and invalidated in court for lack of novelty, nonobviousness, patent eligibility, or failure to satisfy other requirements. Inventions lack novelty when similar inventions predate their patent filing date, which is called anticipation.⁶⁴ Patents can be invalidated for lack of nonobviousness, that is, when the difference between the claimed invention and preexisting inventions would have made the claimed invention obvious to a person having ordinary skill in the relevant field of science or technology.⁶⁵ Patents can also be invalidated if they claim subject matter that is ineligible for patent protection, such as mathematical formulas

⁵⁸ See Shayla Love, *Can LSD Treat Food Allergies? We Don't Know, But It's Already Been Patented*, VICE (July 1, 2021, 10:00 AM), <https://www.vice.com/en/article/g5gdzy/can-bsd-treat-food-allergies-we-dont-know-but-its-already-been-patented> [<https://perma.cc/828V-L6CC>].

⁵⁹ *Id.*

⁶⁰ Applications for FDA Approval to Market a New Drug, 21 C.F.R. §§ 314.2, 314.50(5)(iv) (2019).

⁶¹ See HICKEY, *supra* note 33, at 2 n.14.

⁶² 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).

⁶³ See Love, *supra* note 58; 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 RSCH. 257, 257 (1965).

⁶⁴ See 35 U.S.C. § 102(a) (describing the novelty requirement).

⁶⁵ See 35 U.S.C. § 103 (describing nonobvious subject matter).

or laws of nature.⁶⁶ 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.⁶⁷

Critics of psychedelic patents argue that many granted and recently filed patents would not stand up to scrutiny. While some could lack novelty,⁶⁸ others may lack nonobviousness because a person having ordinary skill in the field could have easily foreseen how to make them.⁶⁹ Others would be invalid if they claim naturally occurring psychedelic plants and fungi or phenomena exhibited by these organisms.

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).⁷⁰ To use an evocative phrase of Professor Bob Mnookin, business decisions are often made "in the shadow of law,"⁷¹ such that the threat of such litigation by a patent holder may deter investors from backing a rival.⁷²

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, except for ketamine, as Schedule I controlled substances, because it believes they have no currently accepted medical use and a high potential for abuse.⁷³ The Schedule I status of psychedelics increases market uncertainty, scaring away risk-averse investors. Prohibition may also reinforce patent monopolies.⁷⁴ DEA permission is required to conduct

⁶⁶ See 2106 Patent Subject Matter Eligibility [R-10.2019], *supra* note 36.

⁶⁷ See 35 U.S.C. § 112 (describing the written description and enablement requirements).

⁶⁸ See sources cited *supra* note 52.

⁶⁹ See Love, *Psychedelic Therapy*, *supra* note 52.

⁷⁰ See Malathi Nayak, *Costs Soar for Trade Secrets, Pharma Patent Suits, Survey Finds*, BLOOMBERG L. (Sept. 10, 2019, 8:01 AM), <https://news.bloomberglaw.com/ip-law/costs-soar-for-trade-secrets-pharma-patent-suits-survey-finds> [<https://perma.cc/HX7T-7TVY>] (estimating the median cost of pharmaceutical patent cases to be \$2.5 million in 2019, a sixty-seven percent increase compared to the cost in 2015).

⁷¹ Robert H. Mnookin & Lewis Kornhauser, *Bargaining in the Shadow of the Law: The Case of Divorce*, 88 YALE L.J. 950, 950 (1979).

⁷² *Cf. id.* at 971–73 (describing how the threat and potential costs of litigation influence negotiations in divorce settlements).

⁷³ U.S. DRUG ENF'T ADMIN., DEP'T OF JUST., DRUGS OF ABUSE: A DEA RESOURCE GUIDE 9 (2020).

⁷⁴ See Mason Marks, *FDA's Kratom Ban Would Harm the Public and Damage the Agency's Credibility*, STAT (Aug. 23, 2021), <https://www.statnews.com/2021/08/23/fdas-kratom-ban-would-harm-the-public-and-damage-the-agencys-credibility> [<https://perma.cc/TB74-HAHW>] (arguing that companies with financial stakes in Schedule I substances can benefit from their prohibition).

psychedelics research in the United States,⁷⁵ 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 are more accepting of psychedelics research.⁷⁶ 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 these substances.⁷⁷ However, the fruits of overseas research can still be patented in the United States. Therefore, current federal policies on psychedelics create obstacles to domestic researchers and companies, which can be overcome by firms that can afford to take their research and development overseas.

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 some mental health treatments often promote abuses of the intellectual property system through tactics like biopiracy, patent trolling, evergreening, and product hopping.

It is important to contextualize the role patents have played in psychiatry. Patent protection has long been available for mental health treatments. However, in the past thirty years, there has been little meaningful innovation in psychopharmacology.⁷⁸ The gold standard for treating many psychiatric conditions — prescribing SSRIs — has changed little since the introduction of Prozac in 1987.⁷⁹ 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 a common practice in drug development.⁸⁰ Product hopping allows drug companies to prevent

⁷⁵ Press Release, U.S. Drug Enf't Admin., DEA Speeds Up Application Process for Research on Schedule I Drugs (Jan. 18, 2018), <https://www.dea.gov/press-releases/2018/01/18/dea-speeds-application-process-research-schedule-i-drugs> [<https://perma.cc/4VAH-AZVV>].

⁷⁶ Mason Marks, Opinion, *A Strategy for Rescheduling Psilocybin*, SCI. AM. (Oct. 11, 2021), <https://www.scientificamerican.com/article/a-strategy-for-rescheduling-psilocybin> [<https://perma.cc/H69N-PG4N>].

⁷⁷ See Marks, *supra* note 1, at 685.

⁷⁸ See, e.g., Richard A. Friedman, *A Dry Pipeline for Psychiatric Drugs*, N.Y. TIMES (Aug. 19, 2013), <https://www.nytimes.com/2013/08/20/health/a-dry-pipeline-for-psychiatric-drugs.html> [<https://perma.cc/S8L8-F8MW>].

⁷⁹ See David T. Wong et al., *The Discovery of Fluoxetine Hydrochloride (Prozac)*, 4 NATURE REV. DRUG DISCOVERY 764, 764 (2005).

⁸⁰ See Michael A. Carrier, *Product Hopping*, 23 J. COM. BIOTECH. 52, 52 (2017).

their products from becoming substitutable with generic drugs. By hopping from one formulation to the next, drug companies extend their patent monopolies. A related practice involves making subtle modifications to substances that are in the public domain, such as generic drug products or polymorphs of existing drugs, and patenting the results as new inventions.

The use of ketamine to treat depression illustrates why this practice can be problematic. Since the 1960s, ketamine has been used widely as an anesthetic and analgesic.⁸¹ 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 settings, from the pediatric clinic to the battlefield.⁸²

The discovery that ketamine could be prescribed off-label to manage treatment-resistant depression was an important breakthrough. To capitalize on it, Janssen Pharmaceuticals patented the intranasal use of esketamine (S-ketamine) to treat depression.⁸³ Esketamine is a molecule already present, in equal parts with arketamine (R-ketamine), in ketamine solutions used frequently in anesthesia and psychiatry.⁸⁴

Not all molecules have right- and left-handed versions — a property called chirality — but when they do, pharmaceutical companies can exploit this property by patenting one enantiomer of existing formulations containing a mixture of both enantiomers as a means of product hopping.⁸⁵ In this manner, Janssen patented treatments using a formulation of isolated S-ketamine,⁸⁶ despite longstanding off-label use of mixtures of S- and R-ketamine for treating depression, and received FDA approval to market the isolated product under the trade name Spravato.⁸⁷ It is also common practice to patent an enantiomer after its isolated counterpart has been in therapeutic use. Some common SSRIs were

⁸¹ Linda Li & Phillip E. Vlisides, *Ketamine: 50 Years of Modulating the Mind*, 10 FRONTIERS HUM. NEUROSCI. 1, 1 (2016).

⁸² 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, in psychiatry, in rural and battlefield medicine, and during natural disasters).

⁸³ U.S. Patent No. 2013/0236573 A1, at [1] (issued Sept. 12, 2013).

⁸⁴ Fernanda S. Correia-Melo et al., *Comparative Study of Esketamine and Racemic Ketamine in Treatment-Resistant Depression: Protocol for a Non-inferiority Clinical Trial*, 97 MEDICINE 1, 1 (2018).

⁸⁵ Carrier & Shadowen, *supra* note 40, at 172.

⁸⁶ U.S. Patent No. 10,860,844 (filed Dec. 26, 2019).

⁸⁷ Press Release, U.S. Food & Drug Admin., FDA Approves New Nasal Spray Medication for Treatment-Resistant Depression; Available Only at a Certified Doctor's Office or Clinic (Mar. 5, 2019), <https://www.fda.gov/news-events/press-announcements/fda-approves-new-nasal-spray-medication-treatment-resistant-depression-available-only-certified> [<https://perma.cc/C6EE-FV9W>].

isolated and patented this way, including escitalopram, which is the left-handed version of citalopram.⁸⁸

FDA approval of intranasally administered esketamine is a major step forward for people with depression because it is the first ketamine variant to earn this designation. But despite being patented and approved for marketing as a treatment for depression, Spravato has failed to show a meaningful benefit over generic ketamine.⁸⁹ One meta-analysis even concluded that intravenously administered racemic ketamine — a mixture of equal parts S- and R-ketamine — appears to be more effective than intranasal esketamine for addressing treatment-resistant depression.⁹⁰ This observation, and the fact that *generic* racemic mixtures of ketamine are relatively inexpensive, has created something of a quandary for patients and providers who favor the generic formulation. Because it is prescribed off-label, generic ketamine is less likely to be covered by insurance than Spravato, which is FDA approved for addressing treatment-resistant depression.⁹¹ The difficulty of being reimbursed for administering ketamine therapy compared to esketamine therapy may leave doctors with less incentive to prescribe or conduct research on ketamine.⁹² This safe, inexpensive, and widely used therapy could be displaced by a patented product for which Janssen and insurance companies serve as gatekeepers.

While a company like Janssen may deserve the benefit of patent protection for inventing a new molecular entity or a nonobvious method of administering an existing substance, where it bore the expense and risk of discovery, the case for granting a patent right is less appealing when there is an existing synthetic variant or naturally occurring version of a substance. Accordingly, some jurisdictions restrict secondary patents,⁹³

⁸⁸ See, e.g., Monica Budău et al., *Chirality of Modern Antidepressants: An Overview*, 7 ADVANCED PHARM. BULL. 495, 496 (2017) (describing the chirality of SSRIs such as citalopram).

⁸⁹ Roger S. McIntyre et al., *Synthesizing the Evidence for Ketamine and Esketamine in Treatment-Resistant Depression: An International Expert Opinion on the Available Evidence and Implementation*, 178 AM. J. PSYCHIATRY 383, 386 (2021).

⁹⁰ Anees Bahji et al., *Comparative Efficacy of Racemic Ketamine and Esketamine for Depression: A Systematic Review and Meta-Analysis*, 278 J. AFFECTIVE DISORDERS 542, 542 (2021).

⁹¹ See David Dodge, *The Ketamine Cure*, N.Y. TIMES (Nov. 5, 2021), <https://www.nytimes.com/2021/11/04/well/ketamine-therapy-depression.html> [<https://perma.cc/5X2D-YHPA>]; Steve Levine, *Ketamine: A Cautionary Tale*, PSYCH. TODAY (Nov. 30, 2021), <https://www.psychologytoday.com/ca/blog/pathways-progress/202111/ketamine-cautionary-tale> [<https://perma.cc/YE96-5SEV>].

⁹² See Levine, *supra* note 91.

⁹³ See Runjhun Tandon et al., *Patenting of Polymorphs*, 7 PHARM. PAT. ANALYST 59, 60–61 (2018) (interpreting section 3(d) of the Indian Patent Act of 1970); see also Christopher M. Holman et al., *Patentability Standards for Follow-On Pharmaceutical Innovation*, 37 BIOTECH. L. REP. 131, 132–33 (2018) (describing the UN Development Programme's *Guidelines for Pharmaceutical Patent Examination* (2016)).

and the Supreme Court has interpreted U.S. patent law to exclude naturally occurring products from patent eligibility.⁹⁴ To be sure, esketamine is not identical to generic ketamine formulations, but characterizing it, or its intranasal administration, 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” eligible for data exclusivity, a type of monopoly right issued by drug regulatory agencies instead of patent offices.⁹⁵

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.⁹⁶ The Canadian Federal Court of Appeal based its Spravato decision on an earlier case, *Takeda Canada Inc. v. Canada (Minister of Health)*,⁹⁷ which held that a drug comprising a medicinal ingredient of a previously approved drug, such as an enantiomer, salt, or ester of the original, may constitute a mere “variation” on the original instead of an “innovative drug.”⁹⁸

Although the United States allows them, some countries and organizations are less tolerant of patents on enantiomers and polymorphs. The Indian Patent Act of 1970 distinguishes between polymorph patents that represent true technological advancements and those that merely bolster patentees’ intellectual property portfolios.⁹⁹ Similarly, in 2015, the United Nations recommended that patent examiners presume that enantiomers and polymorphs of existing inventions are unpatentable.¹⁰⁰ Nevertheless, U.S. law does not distinguish between patents on novel inventions and patents on polymorphs or enantiomers of existing inventions, and secondary patents are common, which allowed Janssen to patent intranasal delivery of esketamine and Compass to patent polymorphs of psilocybin.¹⁰¹

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

⁹⁴ See *Funk Bros. Seed Co. v. Kalo Inoculant Co.*, 333 U.S. 127, 130 (1948).

⁹⁵ *Janssen Inc. v. Att’y Gen. of Can. (Minister of Health)*, 2021 FCA 137, paras. 2, 17–19.

⁹⁶ *Frequently Asked Questions on Patents and Exclusivity*, U.S. FOOD & 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 [https://perma.cc/K4U3-MGU3].

⁹⁷ 2013 FCA 13.

⁹⁸ *Id.* at paras. 13–14.

⁹⁹ See Tandon et al., *supra* note 93, at 60–61.

¹⁰⁰ See Holman et al., *supra* note 93, at 132–33.

¹⁰¹ See Kapczynski et al., *supra* note 40, at 2.

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 to this move — giving a substance a fancy new chemical name may destigmatize it, which may also increase the likelihood of societal acceptance and insurance reimbursement. At the same time, 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,¹⁰² topics we discuss next.

IV. BIOPROSPECTING AND BIOPIRACY

Bioprospecting is the practice of identifying useful natural resources that can be commercialized.¹⁰³ 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 and commercialization of Indigenous technologies without adequate permission, acknowledgment, or compensation.¹⁰⁴

Many psychedelics have long been used by communities around the world.¹⁰⁵ Practitioners of the Bwiti religion in Gabon use a plant called iboga in their spiritual practices.¹⁰⁶ Iboga contains the psychedelic compound ibogaine, which shows promise for treating substance use conditions.¹⁰⁷ It is being commercialized by Western drug developers, and Mind Cure Health, a life sciences company, recently announced a provisional patent filing on methods of synthesizing it.¹⁰⁸

¹⁰² See, e.g., Lulu Garcia-Navarro, *Mexico's Peyote Endangered by "Drug Tourists,"* NPR (Sept. 3, 2007, 12:00 AM), <https://www.npr.org/templates/story/story.php?storyId=14064806> [<https://perma.cc/6VSV-FZW6>] (describing how increased demand and overharvesting of peyote endanger the limited supply of this psychedelic cactus, which is sacred to Indigenous communities of Mexico).

¹⁰³ See, e.g., Tim K. Mackey & Bryan A. Liang, *Integrating Biodiversity Management and Indigenous Biopiracy Protection to Promote Environmental Justice and Global Health*, 102 AM. J. PUB. HEALTH 1091, 1091 (2012).

¹⁰⁴ *Id.* (defining biopiracy).

¹⁰⁵ See, e.g., Yaden & Griffiths, *supra* note 2, at 569.

¹⁰⁶ Pierre Didier Nyongo Ndoua & Kaveh Vaghar, *Bwiti, Iboga, Trance and Healing in Gabon*, 21 MENTAL HEALTH, RELIGION & CULTURE 755, 755–56 (2018).

¹⁰⁷ See, e.g., Thomas Kingsley Brown & Kenneth Alper, *Treatment of Opioid Use Disorder with Ibogaine: Detoxification and Drug Use Outcomes*, 44 AM. J. DRUG & ALCOHOL ABUSE 24, 24 (2018).

¹⁰⁸ MINDCURE 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 AM), <https://www.newswire.ca/news-releases/mindcure-announces-filing-of-u-s->

Indigenous communities argue that companies patenting psychedelic substances are exploiting practices they have developed over centuries for use in healing and religious ceremonies.¹⁰⁹ These technologies have been taken and commercialized without consent, acknowledgement, or compensation. In one case, German drugmaker Schwabe Pharmaceuticals patented an extract of the plant *Pelargonium sidoides*.¹¹⁰ Critics argued that the patent was invalid for lack of novelty because Indigenous communities had used roots of the plant to treat respiratory infections.¹¹¹ The European Patent Office agreed and invalidated the patent.¹¹² 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,¹¹³ and some aspects of international treaties may facilitate it.

In 1995, the World Trade Organization Agreement on Trade-Related Aspects of Intellectual Property Rights¹¹⁴ (TRIPS Agreement) harmonized global intellectual property standards.¹¹⁵ The TRIPS framework requires participating countries to allow certain natural resources and processes to be patented if they meet the criteria for patentability.¹¹⁶ Proponents of strong intellectual property rights claim patents contribute to each country's growth by promoting international trade, licensing, and foreign investment.¹¹⁷

The Doha Declaration on the TRIPS Agreement and Public Health, signed in 2001, addressed the commercializing of Indigenous knowledge.¹¹⁸ However, the treaty has been criticized for providing inadequate compensation and acknowledgment to those who produce this

provisional-patent-applications-for-company-s-first-fully-synthetic-routes-to-create-an-ibogaine-psychedelic-compound-847516509.html [https://perma.cc/Q7TV-2AGU].

¹⁰⁹ See Gregoire, *supra* note 24.

¹¹⁰ 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, 83 (2020).

¹¹¹ See *id.*

¹¹² *Id.*

¹¹³ Daanyaal R. Kumar, *United States Patents, Biopiracy, and Cultural Imperialism: The Theft of India's Traditional Knowledge*, 11 INQUIRIES J., no. 10, 2019, <https://www.inquiriesjournal.com/articles/1769/united-states-patents-biopiracy-and-cultural-imperialism-the-theft-of-indias-traditional-knowledge> [https://perma.cc/BBA2-NTFT].

¹¹⁴ Apr. 15, 1994, Marrakesh Agreement Establishing the World Trade Organization, Annex 1C, 108 Stat. 4809, 1869 U.N.T.S. 299.

¹¹⁵ 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).

¹¹⁶ See Das, *supra* note 110, at 76–77.

¹¹⁷ *Id.* at 77.

¹¹⁸ See *id.*

knowledge.¹¹⁹ The prevailing international framework rewards innovation as conceived by Western nations, comprising advancements made by individual inventors in the context of universities and commercial laboratories instead of collective discoveries made by Indigenous societies.¹²⁰ Some scholars argue that Western discourse on psychedelics more generally has focused on the achievements of individuals instead of the needs, experience, and expertise of communities.¹²¹ Anthropologist Evgenia Fotiou argues that individualistic perspectives erase the traditions from which Western society has appropriated the use of psychedelics.¹²²

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.”¹²³ In the name of environmental conservation, Indigenous communities have been driven from their land, while pharmaceutical companies receive priority access.¹²⁴ According to Jamilah R. George and colleagues, 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.”¹²⁵

V. PROPOSED SOLUTIONS

We have tried to explain how current patent laws threaten to produce bad outcomes for the nascent psychedelics industry and for Indigenous communities. What should be done?

Third parties can challenge the validity of patents after they have issued through trial proceedings called “post-grant review” and “inter

¹¹⁹ *Id.* at 78.

¹²⁰ *Id.*

¹²¹ See Evgenia Fotiou, *The Role of Indigenous Knowledge in Psychedelic Science*, 4 J. PSYCHEDELIC STUD. 16, 16 (2020); cf. Multidisciplinary Ass’n Psychedelic Stud. (MAPS), *PANEL: Psychedelics, Injustice & Intersectionality of Trauma w/ Sevelius, Williams, Kahn & RedBear* at 14:45, YOUTUBE (Apr. 26, 2017), <https://www.youtube.com/watch?v=-O7tzFCnomc> [<https://perma.cc/4747-P7K6>] (describing differences between Western approaches to trauma as an individual problem and those of communities that experience collective trauma).

¹²² See Fotiou, *supra* note 121, at 16.

¹²³ Das, *supra* note 110, at 84.

¹²⁴ *Id.* at 87.

¹²⁵ Jamilah R. George et al., *The Psychedelic Renaissance and the Limitations of a White-Dominant Medical Framework: A Call for Indigenous and Ethnic Minority Inclusion*, 4 J. PSYCHEDELIC STUD. 4, 5 (2020); see also *id.* at 9–11 (highlighting inequities in the field of psychedelic research and treatment).

partes review.¹²⁶ Third parties must file petitions for post-grant review with the Patent Trial and Appeal Board (PTAB) at the PTO within nine months of the date on which a patent was granted or reissued.¹²⁷ In contrast, petitions for inter partes review cannot be filed until either nine months have lapsed or a petition for post-grant review is terminated, whichever is later.¹²⁸ For post-grant review, petitioners must show that more likely than not, at least one challenged claim is unpatentable.¹²⁹ For inter partes review, petitioners must demonstrate that there is a reasonable likelihood that they will prevail with respect to challenging at least one claim.¹³⁰ Unless a petition is dismissed, the PTAB issues rulings on both types of petition within one year.¹³¹

On December 15, 2021, a nonprofit organization called Freedom to Operate petitioned the PTAB for post-grant review of Compass's claims on Polymorph A.¹³² Aiming to prove that the claimed inventions lack novelty, Freedom to Operate collected samples of psilocybin that pre-date the patent and worked with chemists and x-ray crystallographers to analyze them.¹³³ One sample originated from 2008, and another was made in 1963.¹³⁴ Based on the analysis, Freedom to Operate's petition argued: "[I]t is more likely than not that at least one of the challenged claims is unpatentable, and a trial for post-grant review must therefore be initiated."¹³⁵ Watchdog organizations like Freedom to Operate can monitor patent filings and intervene quickly after psychedelic patents are granted. However, despite the option for post-grant review, this path to challenging psychedelic patents requires significant resources, and the nine-month time limit raises additional barriers.

A more preventative approach to improving the quality of psychedelic patents involves bolstering the prior art search by creating prior art repositories. Porta Sophia is a nonprofit library for psychedelic prior art intended to aid patent applicants and PTO examiners.¹³⁶ Resources like Porta Sophia could improve prior art searches and help prevent issuance of bad patents by ensuring that lesser-known references are not

¹²⁶ *Inter Partes Disputes*, U.S. PAT. & TRADEMARK OFF., <https://www.uspto.gov/patents/laws/america-invents-act/aia/inter-partes-disputes> [<https://perma.cc/4GWW-T64T>].

¹²⁷ *Id.*

¹²⁸ *Id.* (explaining other differences between post-grant and inter partes review related to the scope of review and other variables).

¹²⁹ *Id.*

¹³⁰ *Id.*

¹³¹ *Id.*

¹³² Shayla Love, *New Filing Challenges Compass Pathways' Infamous Patent on Synthetic Psilocybin*, VICE (Dec. 15, 2021, 6:05 PM), <https://www.vice.com/en/article/pkpg7b/synthetic-psilocybin-patent-challenge-compass-pathways> [<https://perma.cc/FA3Q-BP9T>].

¹³³ *Id.*

¹³⁴ *Id.*

¹³⁵ Petition for Post-grant Review of U.S. Patent No. 10,954,259 at 1, Freedom to Operate, Inc. v. Compass Pathways, No. PGR2022-00018 (P.T.A.B. 2021), 2021 WL 6109293.

¹³⁶ *Porta Sophia Psychedelic Prior Art Library*, PORTA SOPHIA, <https://www.portasophia.org> [<https://perma.cc/J7SR-5SYG>].

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 potential approach entails tightening up U.S. patent law requirements for novelty and nonobviousness. For instance, Congress, courts, and the PTO could follow the example set by the Canadian court and declare that salts, enantiomers, and other subtle variations on existing inventions are not innovative drugs because they lack inventiveness. Though the Canadian court's decision dealt with data exclusivity, the same logic can be applied to patents. Granting patents on such variations contributes to the patent thicket and decreases the incentive to innovate, potentially impeding scientific and technological progress. 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.¹³⁷ 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.¹³⁸

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.¹³⁹ Today, Tesla is the world's most valuable automotive company, and it is arguably the most innovative.¹⁴⁰ Following its lead, Toyota made a similar pledge regarding nearly 24,000 patents on electric- and hybrid-vehicle technology.¹⁴¹ Musk's other company, SpaceX, has also eschewed patents as a means of guarding its

¹³⁷ See, e.g., Emmarie Huettelman, *Senators Who Led Pharma-Friendly Patent Reform Also Prime Targets for Pharma Cash*, KAISER HEALTH NEWS (Mar. 24, 2020), <https://khn.org/news/senators-who-led-pharma-friendly-patent-reform-also-prime-targets-for-pharma-cash> [https://perma.cc/2BXE-8DH5].

¹³⁸ *Make the Pledge to Share Your Intellectual Property in the Fight Against COVID-19*, OPEN COVID PLEDGE, <https://opencovidpledge.org> [https://perma.cc/YN4V-JX43].

¹³⁹ Elon Musk, *All Our Patent Are Belong to You*, TESLA BLOG (June 12, 2014), <http://www.teslamotors.com/blog/all-our-patent-are-belong-to-you> [https://perma.cc/6ERU-VU29].

¹⁴⁰ See *Tesla Overtakes Toyota to Become World's Most Valuable Carmaker*, BBC NEWS (July 1, 2020), <https://www.bbc.com/news/business-53257933> [https://perma.cc/TM2S-GU9C].

¹⁴¹ Naomi Tajitsu, *Toyota to Give Royalty-Free Access to Hybrid-Vehicle Patents*, REUTERS (Apr. 2, 2019, 6:29 PM), <https://www.reuters.com/article/us-toyota-patents-idUSKCN1RE2KC> [https://perma.cc/8U9E-S7TL].

intellectual assets.¹⁴² Despite a lack of patents to incentivize it to innovate, SpaceX has revitalized the U.S. space industry.¹⁴³

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.¹⁴⁴ His statement presumably included the company’s pending application that claims room colors, music, and physical touch.¹⁴⁵ Attorneys and psychedelics advocates questioned whether Wilde’s statements constitute an enforceable patent pledge.¹⁴⁶ However, the law is unclear on whether informal promises not to enforce patents are legally binding.¹⁴⁷ In a subsequent interview, CEO George Goldsmith indicated that Compass did not intend to sign a patent pledge.¹⁴⁸

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 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 nonprofit 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 potentially viable therapy for PTSD. It has

¹⁴² Michael Heller & James Salzman, *Elon Musk Doesn’t Care About Patents. Should You?*, HARV. BUS. REV. (Mar. 4, 2021), <https://hbr.org/2021/03/elon-musk-doesnt-care-about-patents-should-you> [<https://perma.cc/RW9K-UBZP>].

¹⁴³ See Adam Mann, *SpaceX Now Dominates Rocket Flight, Bringing 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> [<https://perma.cc/N9KV-FBHC>] (reporting that SpaceX handles about two-thirds of NASA launches).

¹⁴⁴ Oxford Psychedelic Soc’y, *Psychedelic Capitalism (A Moderated Discussion with Alexander Beiner and Lars Wilde, 27/05/21)* at 31:41, YOUTUBE (May 28, 2021), <https://www.youtube.com/watch?v=C4ilk9OiyW4> [<https://perma.cc/5HVT-MJNM>].

¹⁴⁵ WIPO Patent Application No. WO 2020/212952 A1 (Compass Pathways Ltd.) Apr. 17, 2020, at 51, 59.

¹⁴⁶ Graham Pechnik (@calyxlaw), TWITTER (May 27, 2021, 5:58 PM), <https://twitter.com/calyxlaw/status/1398035968544808960> [<https://perma.cc/6D8B-M3UH>].

¹⁴⁷ See Jorge L. Contreras, *Patent Pledges*, 47 ARIZ. ST. L.J. 543, 592–94 (2015) (describing the enforceability of different types of public statements regarding patents).

¹⁴⁸ VICE News, *The Battle over Psychedelic Therapy’s Future* at 27:44, YOUTUBE (Jan. 11, 2022), <https://www.youtube.com/watch?v=w51BoAQ24r4> [<https://perma.cc/M6CP-SGN7>] (“We don’t need to reassure people [with a patent pledge] right now. What we need to do is do the evidence of is it safe and effective and for whom.”).

even pursued an antipatent strategy to prevent MDMA from being monopolized.¹⁴⁹ A newer nonprofit called Usona conducts clinical trials with psilocybin and has a similar philosophy regarding open science and intellectual property.¹⁵⁰

Strong arguments can be made for prohibiting patents on psychedelics. Patent protection has long been available for psychiatric drugs such as SSRIs, but many would argue 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.¹⁵¹ However, the connection of psychedelics to Indigenous knowledge and the risk of biopiracy make the case against monopolization by large pharmaceutical companies even stronger.

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.¹⁵² 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 to the study of biology and medicine or the telescope for astronomy.”¹⁵³ 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 FDA approval,

¹⁴⁹ Catherine Elton, *The Interview: MDMA-Therapy Expert Dr. Rick Doblin*, BOS. MAG. (Sept. 10, 2019, 2:56 PM), <https://www.bostonmagazine.com/health/2019/09/10/rick-doblin> [<https://perma.cc/SNB2-7EE8>].

¹⁵⁰ See Love, *Psychedelic Therapy*, *supra* note 52 (describing Usona’s “open science” approach to psychedelic innovation that foregoes patents).

¹⁵¹ See, e.g., Amy Kapczynski, *Order Without Intellectual Property: Open Science in Influenza*, 102 CORNELL L. REV. 1539, 1594, 1624–25 (2017).

¹⁵² Steven A. Barker, *N, N-Dimethyltryptamine (DMT), An Endogenous Hallucinogen: Past, Present, and Future Research to Determine Its Role and Function*, 12 FRONTIERS NEUROSCI. 1, 1 (2018).

¹⁵³ Mason Schreck, *Stanislav and Christina Grof: Cartographers of the Psyche*, MAPS BULL., Winter 2011, at 26, 27.

it may be a step too far. Our purpose in this Essay has simply been to put it on the table for serious consideration by policymakers.

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.

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 proposals for discouraging unwarranted 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.