THE EVOLVING ROLE OF HISTORY IN THE PAST, PRESENT, AND FUTURE OF PSYCHEDELIC PATENTING

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Abstract: The resurgence of mainstream psychedelic research has spurred a capitalist interest in patenting to exclude competitors from producing, using, or selling psychedelic technology. Some exploit the patenting process to monopolize well-established psychedelic knowledge with overly broad claims. If patent examiners find evidence, known as "prior art," showing that what is claimed is known, patent rights are not granted. Historical psychedelic prior art therefore plays a critical role in shaping the future of patent law in the context of psychedelic capitalism. Given that some psychedelic prior art exists in nontraditional forms, patent examiners may not be able to identify relevant prior art to nullify overly broad claims. Consequently, several psychedelic patents have erroneously been granted. Organizations and intellectual property activists leverage direct methods of introducing historical psychedelic prior art to fight these overly broad patents and applications on a claim-by-claim basis with the U.S. Patent and Trademark Office. Valuable historical archival psychedelic prior art is likewise curated and made available to patent examiners and innovators through the work of the online psychedelic prior art library Porta Sophia and its broad interdisciplinary network of experts. The psychedelic field is at a critical developmental juncture, and it is essential that all involved work to ensure that its landscape remains equitable, research can flourish, and vulnerable communities with strong cultural connections to psychedelics are protected.

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Color version of this article is available online at: https://hopp.uwpress.org

HISTORY OF PHARMACY AND PHARMACEUTICALS | 65:1
ISSN 2694-3034 | E-ISSN 2694-3042 | doi:10.3368/hopp.65.1.117

Keywords: intellectual property, patents, prior art, public domain, psychedelics, hallucinogens

An Introduction to the State of the Psychedelic Field

Indigenous cultures have used psychedelic plants and animals in spiritual and medicinal applications for millennia.[1] A wave of twentieth-century Western research provided further evidence of psychedelics' utility as medicaments.[2] This momentum was hampered by 1960s and 1970s legislation outlawing psychedelic possession, sale, and use across multiple continents—implying that psychedelics have no therapeutic value. In 1971, the UN Convention on Psychotropic Substances promulgated an international treaty to control psychoactive substances, including psychedelics, globally.[3] To date, 182 of 193 UN member states remain parties to this convention, and many countries have legislation that label psychedelics and many other hallucinogens, such as empathogens and dissociatives, as illegal substances.[4]

A resurgence of psychedelic research continues to support the medicinal value of psychedelic compounds.[5] This research boom has spurred a concurrent interest in sequestering and monopolizing psychedelic technologies for profit.[6] There are currently more than fifty publicly traded companies specializing in psychedelic medicines,[7] and the top five companies in this space grossed more

1. Riccardo Miceli McMillan, "Global Bioethical Challenges of Medicalising Psychedelics," *Journal of Psychedelic Studies* 5, no. 2 (2021): 57–64, https://doi.org/10.1556/2054.2021.00188; F. J. Carod-Artal, "Hallucinogenic Drugs in Pre-Columbian Mesoamerican Cultures," *Neurología* (English Edition) 30, no. 1 (2015): 42–49, https://doi.org/10.1016/j.nrleng.2011.07.010.
2. Robin L. Carhart-Harris and Guy M. Goodwin, "The Therapeutic Potential of Psychedelic Drugs: Past, Present, and Future," *Neuropsychopharmacology* 42, no. 11 (2017): 2105–13, https://doi.org/10.1038/npp.2017.84; Mason Marks and I. Glenn Cohen, "Psychedelic Therapy: A Roadmap for Wider Acceptance and Utilization," *Nature Medicine* 27, no. 10 (2021): 1669–71, https://doi.org/10.1038/s41591-021-01530-3.
3. "Convention on Psychotropic Substances, 1971," United Nations Office on Drugs and Crime, 1971, http://www.unodc.org/unodc/en/treaties/psychotropics.html.
4. "Narcotic Drugs and Psychotropic Substances," United Nations Treaty Collection, https://treaties.un.org/Pages/ViewDetails.aspx?src=TREATY&mtdsg_no=VI-16&chapter=6&clang=_en (accessed August 17, 2022).
5. Collin M. Reiff et al., "Psychedelics and Psychedelic-Assisted Psychotherapy," *American Journal of Psychiatry* 177, no. 5 (2020): 391–410, https://doi.org/10.1176/appi.ajp.2019.19010035.
6. Microdose, "Special Report: IP & Patents for the Psychedelic Industry," Microdose, 2021, https://microdose.buzz/industry-reports/ip-patents-report/.
7. Joshua Phelps, Ravi N. Shah, and Jeffrey A. Lieberman, "The Rapid Rise in Investment in Psychedelics—Cart Before the Horse," *JAMA Psychiatry* 79, no. 3 (2022): 189–90, https://doi.org/10.1001/jamapsychiatry.2021.3972.

than U.S. $2 billion in the first quarter of 2022.[8] This industry is expected to expand rapidly and has been projected to reach $10.75 billion by 2027.[9]

Patents: Capitalizing on Psychedelics

As with mainstream pharmaceutical companies, psychedelic drug developers rely on their intellectual property portfolios to gain a market advantage, which stimulates interest and continued investment.[10]

Patents are a form of intellectual property that provide an incentive for innovation through government-sanctioned monopolies that exclude others from producing, using, or selling patented technology during the patent's lifetime. This right to exclude is extremely lucrative and effectively forestalls the development of generic competitors. Without alternatives on the market, drug prices can be steeply increased by patent owners, and concerns of patent infringement can stifle academic research with patented products or processes.[11] In addition, prescription drug spending has increased 60 percent over the past ten years.[12] Therefore, patents are eagerly pursued by pharmaceutical innovators. For top drugs, on average, an individual drug is the subject of 140 patent application filings, of which an average of 74 are granted.[13]

Aggressive patent filing is an effective intellectual property strategy that allows patent holders to monopolize a pharmaceutical compound for significantly longer than the lifetime of a single patent. Although the enforceable term of a patent in the United States is twenty years, companies wield strategies that extend protection for much longer. For instance, Roche/Genentech has filed patents on the cancer drug Herceptin (trastuzumab) since 1985 and still has active applications that, if granted, would give the pharma-technology giants a monopoly on the compound that spans 48 years.[14] Although criticism of such strategies has grown, drug companies persist in using these methods to recoup investment costs and capitalize on their products.

8. Keith Speights, "Investing in Psychedelic Stocks," *Motley Fool*, https://web.archive.org/web/20220819001139/https://www.fool.com/investing/stock-market/market-sectors/healthcare/psychedelic-stocks/ (accessed August 19, 2022).
9. Phelps, Shah, and Lieberman, "The Rapid Rise in Investment in Psychedelics."
10. Phelps, Shah, and Lieberman, "The Rapid Rise in Investment in Psychedelics."
11. Alicia A. Russo and Jason Johnson, "Research Use Exemptions to Patent Infringement for Drug Discovery and Development in the United States," *Cold Spring Harbor Perspectives in Medicine* 5, no. 2 (2015): a020933, https://doi.org/10.1101/cshperspect.a020933.
12. I-MAK 2022, "Overpatented, Overpriced," I-MAK, 2022, https://www.i-mak.org/overpatented-overpriced-excessive-pharmaceutical-patenting-extending-monopolies-driving-drug-prices/.
13. I-MAK 2022, "Overpatented, Overpriced."
14. I-MAK 2018, "Overpatented, Overpriced," I-MAK, 2018, http://www.i-mak.org/wp-content/uploads/2018/08/I-MAK-Overpatented-Overpriced-Report.pdf.

The development of the psychedelic industry has followed the rise of the pharmaceutical sector, and many corporate actors are trying to apply mainstream pharmaceutical patenting strategies to build their psychedelic intellectual property foundations.[15] As a result, the number of psychedelic patent applications and issued patents have soared over the past twenty years,[16] which could significantly alter psychedelic availability.

Prior Art, Its Connection to History, and How It Affects Market Sequestration of Psychedelics

The patent laws of the country or region in which patent rights are being sought partly determine the patentability of a technology. While these laws vary, two consistent standards are that a claimed technology must be both novel and sufficiently inventive, as is the case in the United States where inventiveness is interpreted as "nonobviousness."[17] Patent applications are examined by the U.S. Patent and Trademark Office (USPTO) to determine the patentability of its claims. In this process, the application is assigned to a specialized patent examiner with a technical background in science or engineering relevant to the claimed technology. The patent examiner is charged with analyzing each claim to determine whether it meets the standards of novelty and nonobviousness.

The USPTO is required to provide evidence and reasoning if a claim is deemed not allowable. This evidence is provided in the form of "prior art." In the United States, prior art includes patents, patent applications, printed publications (e.g., journal articles), anything that is in public use or on sale, and anything that is "otherwise available to the public."[18] The phrase "otherwise available to the public" in the America Invents Act (AIA) expanded the definition of prior art to include everything from foreign and domestic published patent applications and granted patents to magazine articles, newspaper articles, electronic publications, online databases, websites, and internet publications. Importantly, the wording of this definition may encompass knowledge of historical Indigenous remedies, which has significant implications for the examination of psychedelic patent applications.[19]

The complex cultural and legal histories of psychedelics have dramatically affected the type of prior art that exists and its accessibility to patent examiners.

15. Microdose, "IP & Patents Report."
16. Microdose, "IP & Patents Report."
17. 35 U.S.C. §102 and §103.
18. 35 U.S.C. §102.
19. "Summary of the America Invents Act," *National Law Review*, April 12, 2012, https://www.natlawreview.com/article/summary-america-invents-act.

Important troves of prior art include Indigenous knowledge, archival documents, old documents and articles from historical psychedelic research, and anecdotal and documentary evidence in online forums.

Indigenous practices related to psychedelics have been well documented throughout history, and as a result of the AIA, this historical evidence can now be used when examining modern patent applications.[20] However, much of this information exists in archives that are not digitized or commonly considered, making it inaccessible to patent examiners and thus not easily used in an examination.

Even under restrictive legal conditions, research focusing on the utility of psychoactive compounds as medicinal therapies continued underground through the prohibitionary period.[21] Research in this era took place in many contexts—from individuals experimentally self-medicating to psychiatrists illicitly administering these substances in conjunction with psychotherapeutic regimens.[22] Some results have been published in well-established prior art mediums, such as peer-reviewed social science and medical research papers and news articles.[23] However, much of this prior art exists in self-published public online forums (e.g., Erowid, https://www.erowid.org/). It is not common or expected practice for patent examiners to sift through decades of online blogging forums given that these examiners spend an average of nineteen hours evaluating each patent application.[24] So while this prior art is publicly available, the time required to analyze online entries complicates targeted searches for this critical source of prior art.

As a result of inaccessibility and time-consuming screening, valuable historical psychedelic prior art is often missed, and patents have been granted on technically unpatentable innovations. There have been a variety of efforts to improve the availability of relevant prior art and otherwise increase the quality of patents in the psychedelic space.

One such effort is the creation of Porta Sophia, a nonprofit online psychedelic prior art library that identifies prior art in common and uncommon spaces and makes it searchable with a simple online tool. To build the Porta Sophia library, an interdisciplinary team of scholars finds and curates prior art relevant to the current psychedelic patent landscape to ensure that core concepts are accurately

20. McMillan, "Global Bioethical Challenges."
21. Reiff et al., "Psychedelics and Psychedelic-Assisted Psychotherapy."
22. Ben Sessa and Friederike Meckel Fischer, "Underground MDMA-, LSD- and 2-CB-Assisted Individual and Group Psychotherapy in Zurich: Outcomes, Implications and Commentary," *Drug Science, Policy and Law* 2 (2016): 2050324515578080, https://doi.org/10.1177/2050324515578080.
23. Sessa and Fischer, "Underground MDMA."
24. Michael D. Frakes and Melissa F. Wasserman, "The Failed Promise of User Fees: Empirical Evidence from the U.S. Patent and Trademark Office," *Journal of Empirical Legal Studies* 11, no. 4 (2014): 602–36, https://doi.org/10.1111/jels.12051.

represented and easily accessible. By crowdsourcing prior art from a global network of archivists and historians through their Archival Researcher Network (ARN), Porta Sophia works to make their library inclusive of key archival sources in the history of psychedelics.[25]

Psychedelic Patenting Then and Now: Increasing Threats to the Public Domain

Patent applications can claim many aspects of psychedelic synthesis and use, including methods of production, methods of treatment, administration and formulation, set and setting in which the drug is administered, drug combinations, and derivative compounds. The early days of psychedelic patenting date back to the 1940s with the first patent describing the process of generating LSD, first granted in the United Kingdom to Sandoz LTD in 1946. At the time, LSD had not been identified or disclosed publicly; therefore, the patent that gave Sandoz rights to production met the threshold of being both novel and sufficiently inventive.

That patent and many other landmark psychedelic patents have long since expired, and the information disclosed therein now belongs in the public domain—defined as "the realm of publications, inventions, and processes that are not protected by copyright and patent things" that "can be appropriated by anyone without liability for infringement."[26] Essentially, technologies that have entered the public domain can be used without the threat of intellectual property litigation.

In recent years, there has been a surge of granted patents and patent applications containing claims that privatize or seek to privatize technology that currently exists in the public domain (Figure 1A) and that cover a broad cross section of psychedelic aspects (Figure 1B). Entities trying to gain patent rights over these compounds include for-profit companies, university systems, and private citizens (Figure 1C).

Several high-profile examples of applications containing claims attempting to sequester information from the public domain have sent shockwaves of outrage through the psychedelic field.[27] The UK-based psychedelic technology company COMPASS Pathways has been widely criticized for claiming mundane components of the set and setting in which patients are dosed with psilocybin in U.S. Patent Application no. 17/604,610, including rooms with "muted colors," music

25. "Porta Sophia | Archival Researcher Network," Porta Sophia, https://www.portasophia.org/archival-researcher-network (accessed February 13, 2023).
26. World Intellectual Property Organization, Identifying Inventions in the Public Domain: A Guide for Inventors and Entrepreneurs, 2020, https://www.wipo.int/publications/en/details.jsp?id=4501.
27. I. Glenn Cohen and Mason Marks, "Patents on Psychedelics: The Next Legal Battlefront of Drug Development," *Harvard Law Review Forum* 12 (2022), https://harvardlawreview.org/2022/02/patents-on-psychedelics-the-next-legal-battlefront-of-drug-development/.

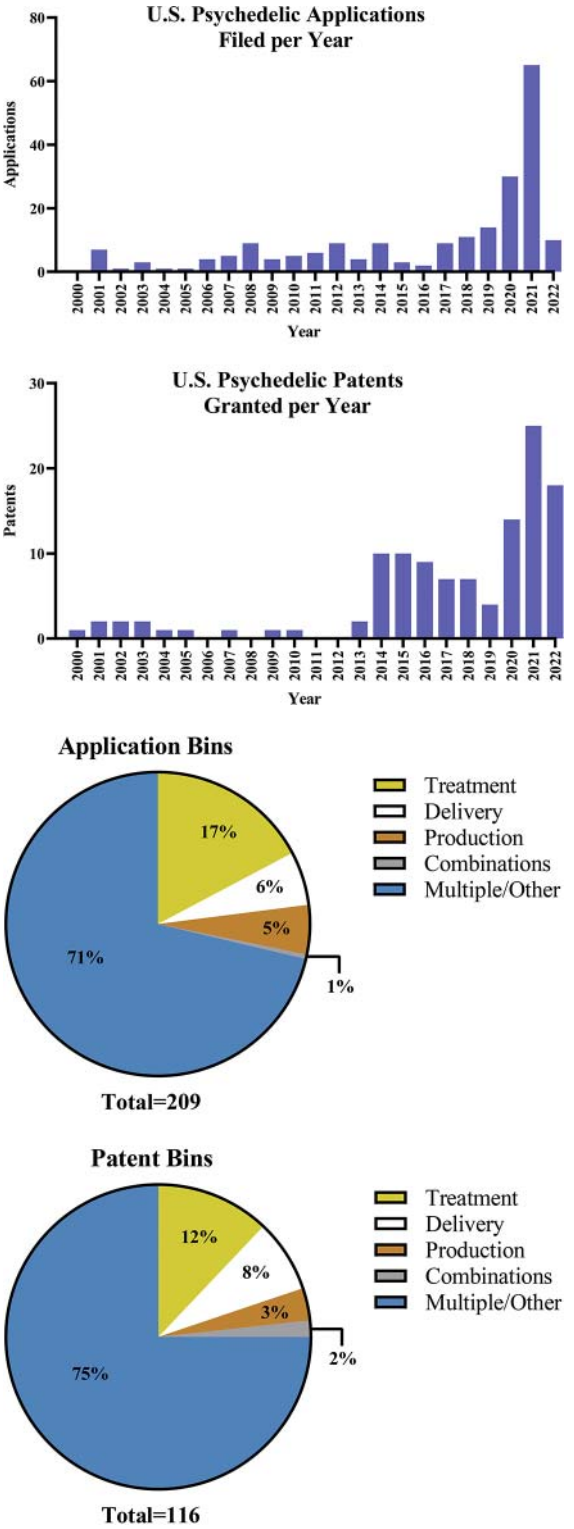

Figure 1. Overly broad psychedelic patent document trends. The number of filed patent documents and granted patents by year that contain claims describing information currently in the public domain on LSD, psilocybin, DMT, 5-MeO-DMT, and mescaline (A). The focus of the claims these documents contain, which falls into one or more (multiple) categories, or bins—including methods of using psychedelics for the treatment of a disease or disorder (treatment), how psychedelics are formulated or delivered (delivery), method of producing and isolating psychedelic compounds (production), and combinations of psychedelics with other conventional and unconventional drugs (combinations) (B). The owners (assignees) of these overly broad patent documents (C).

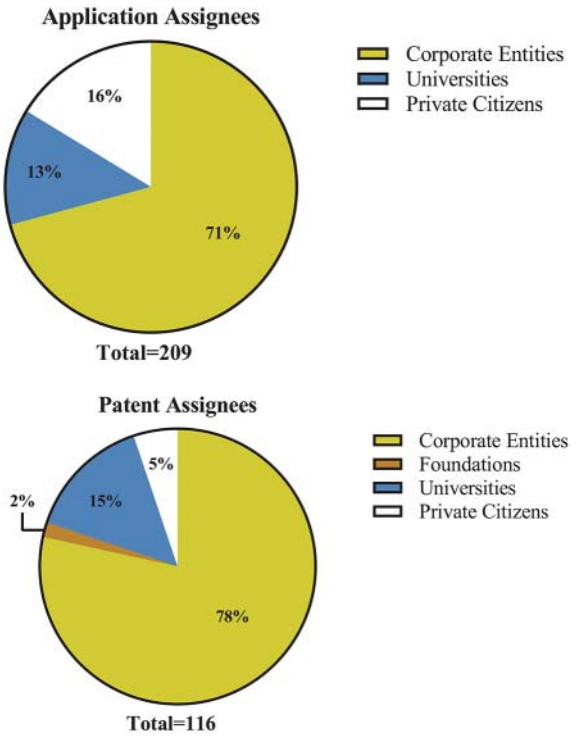

Figure 1. Continued

playing on in-room sound systems where the drug is administered, or patients wearing eye masks.[28] If patent rights are granted, COMPASS Pathways could theoretically bring a patent infringement lawsuit against parties that use extant best practices around set and setting. New York University came under fire for a 2020 patent application claiming the use of psilocybin to treat anxiety and depression in cancer patients as innovative—a central indication in psychedelic medicine since the early 1980s.[29] Beyond the threats from individual applications, granting just one overly broad patent opens the door for patent owners to file floods of follow-on "child applications" to extend their monopolies.

Every week, more psychedelic patent applications are published that pose significant threats to the public domain. Beyond the accessibility issues related

28. Andrew Jacobs, "With Promise of Legalization, Psychedelic Companies Joust over Future Profits," *New York Times*, October 25, 2022, https://www.nytimes.com/2022/10/25/health/psychedelic-drug-therapy-patents.html.

29. Jane C. Hu, "This Week in Psychedelics: Patenting Psilocybin for Cancer Patients, Crowdfunding for Psychedelic Brain Science, and Measuring Psychedelic Integration," *The Microdose* (blog), May 27, 2022, https://themicrodose.substack.com/p/this-week-in-psychedelics-patenting; William A. Richards et al., "DPT as an Adjunct in Brief Psychotherapy with Cancer Patients," *OMEGA Journal of Death and Dying* 10, no. 1 (1980): 9–26, https://doi.org/10.2190/NGUB-V4RM-T7DC-XTH3.

to psychedelic prior art already described, examiners are often unfamiliar with psychedelics and their complex history.[30] These challenges are increasingly exploited by psychedelic patent applicants to compromise the integrity of the public domain. Therefore, making prior art as accessible as possible is essential to ensure that it combats overly broad claims.

The Public Domain, Equitable Access, and Protecting Vulnerable Communities

Historically, the examination of patent applications and the granting of patents was largely an internal process in the USPTO. However, the passing of the AIA introduced several mechanisms for third parties to intervene at key points in the process. These mechanisms are viable tools that the psychedelic field can use to ward off growing threats to the psychedelic public domain.[31]

Third-Party Pre-Issuance Submissions

Parties unaffiliated with a U.S. patent application can submit prior art relevant to the patentability of one or more claims of the application in a process known as a third-party pre-issuance submission (3PS).[32] The 3PS serves as an important mechanism for assisting patent examiners and preventing overly broad claims from being granted.

Any individual can submit a 3PS to the USPTO through a simple online portal at a marginal cost. Because of the ease of submission and low financial burden, 3PS represents an underutilized tool that can slow down the issuing of overly broad patents. Allowing those who have expertise on psychedelics and their history to transmit prior art to examiners affects the whole psychedelic field.[33]

Direct action through 3PS can have a rapid effect. Porta Sophia's team of scientific and legal experts have, at the time of this writing, filed 3PS against eighteen individual overly broad U.S. patent applications. Within a month of Porta Sophia's 3PS, CaaMTech Inc. canceled all original claims of U.S. Patent Application no. 17/095,430, which described serotonergic drug combinations to treat neuropsychiatric disorders. CaaMTech filed a new set of claims that were far narrower in scope in place of the originals. Five months after Porta Sophia's 3PS

30. Cohen and Marks, "Patents on Psychedelics."
31. Ryan Levy and Spencer Green, "Pharmaceuticals and Biopiracy: How the America Invents Act May Reduce the Misappropriation of Traditional Medicine," *University of Miami Business Law Review* 23, no. 3 (2015): 401–24; Cohen and Marks, "Patents on Psychedelics"; Levy and Green, "Pharmaceuticals and Biopiracy."
32. 35 U.S.C. §122(e).
33. Levy and Green, "Pharmaceuticals and Biopiracy."

against U.S. Patent Application no. 17/604,610, COMPASS Pathways canceled 137 of their original 162 claims—including all of the above-mentioned controversial set and setting claims.[34] The remaining claims were amended to focus solely on their previously patented psilocybin polymorph. This demonstrates how 3PS can motivate applicants to change their patent strategies to ensure that their applications remain viable.

Petition for Postgrant Review

When overly broad claims to innovation are granted, they can be challenged through several forms of postgrant opposition procedures.[35] Similar to a 3PS, these procedures can involve the submission of prior art demonstrating that one or more claims were granted in error because the subject matter is unpatentable. These postgrant opposition procedures are quasi-judicial trials that are heard by a panel of administrative law judges.

However, these opposition procedures are far more intensive than a 3PS, both legally and financially. Despite limitations, this new mechanism is being increasingly used in the biotechnology and pharmaceutical industries and has been attempted in the psychedelic field as well.[36]

The first overly broad psychedelic patents to be challenged through petition for postgrant review (PGR) were U.S. Patent nos. 10,947,257 and 10,954,259, both assigned to COMPASS Pathfinder, in late 2021.[37] The filing was made by Freedom to Operate Inc. (FTO), a nonprofit organization with a goal of protecting psychedelic science and medical development for public benefit. The petition focuses on COMPASS's Polymorph A—a form of psilocybin that FTO challenged as not novel, arguing that it has been known to exist for decades. FTO's filing included support via advanced analysis of historical and modern psilocybin samples by chemists and crystallographers. Upon review of the petition by the US Patent Trial and Appeal Board (PTAB), COMPASS's patents were allowed to stand. However, the PTAB interpretation of the claims of the patent was

34. "COMPASS Pathways Amends Claims of US Patent Application," Porta Sophia, August 25, 2022, https://www.portasophia.org/news/press-releases/compass-pathways-amends-claims.
35. 35 U.S.C. §321; 37 C.F.R. §§42.200–224.
36. Krista E. Bianco and Kristi McIntyre, "The Rise of Post-Grant Proceedings," *ACS Medicinal Chemistry Letters* 8, no. 1 (2016): 4–6, https://doi.org/10.1021/acsmedchemlett.6b00460; Shayla Love, "Judges Deny Challenge to Psilocybin Patent," *Motherboard* (blog), June 23, 2022, https://www.vice.com/en/article/93a5x3/judges-deny-challenge-to-psilocybin-patent.
37. Shayla Love, "New Filing Challenges Compass Pathways' Infamous Patent on Synthetic Psilocybin," *Motherboard* (blog), December 15, 2021, https://www.vice.com/en/article/pkpg7b/synthetic-psilocybin-patent-challenge-compass-pathways.

narrow and therefore likely allows generic psilocybin manufacturers a legal means of producing and commercializing their product with little risk of infringement litigation from COMPASS.[38]

In addition to applying submitted prior art to the applications or patents for which a 3PS or PGR is prepared, the USPTO also applies submitted prior art against other related applications under active examination filed by the applicant, greatly expanding the impact of the singular submission.

It should be noted that both mechanisms require systematic and time-intensive research efforts because third parties interested in intervening must monitor patent databases to identify relevant applications and patents on which to take action within specific timeframes. This may be a daunting task if undertaken independently, there are several entities that track patenting activity in the psychedelic space, such as the UC Berkeley Center for the Sciences of Psychedelics and Psychedelic Alpha.[39] Several applications or patents have been discovered that have been so egregious and threatening to the public domain that they have achieved a level of notoriety that catches the attention of mainstream media outlets, Therefore it is possible that parties in a position to challenge overly broad documents can learn of them beyond surveilling patent databases directly.[40] In addition, those who seek to intervene in overly broad patent application filings frequently reach out to the psychedelic community to ask for specific pieces of prior art critical for determining the patentability of a specific claim, such as Porta Sophia through the ARN. Although closely monitoring the patent document registers is a very thorough way of identifying every overly broad patent filing, there are other means of becoming involved in protecting the bounds of the psychedelic public domain.

It is important to note that even though the process of filing overly broad claims is common in pharmaceutical patenting strategies, the lack of readily available relevant prior art is a unique feature of the psychedelic patenting space. Entities whose claims even unknowingly overstep the bounds of the public

38. Freedom to Operate, "Freedom to Operate Issues Statement Regarding U.S. Patent Trial and Appeal Board's Response to Petition for Post Grant Review of Compass Psilocybin Patents," *PR Newswire*, June 24, 2022, https://www.prnewswire.com/news-releases/freedom-to-operate-issues-statement-regarding-us-patent-trial-and-appeal-boards-response-to-petition-for-post-grant-review-of-compass-psilocybin-patents-301575019.html.
39. "Patent Tracker," UC Berkeley Center for the Science of Psychedelics, https://psychedelics.berkeley.edu/patent-tracker/ (accessed February 10, 2023); "Psychedelic Sector Data Bank," Psychedelic Alpha, https://psychedelicalpha.com/data (accessed February 10, 2023).
40. Shayla Love, "Can a Company Patent the Basic Components of Psychedelic Therapy?," *Motherboard* (blog), February 9, 2021, https://www.vice.com/en/article/93wmxv/can-a-company-patent-the-basic-components-of-psychedelic-therapy.

domain can suffer greatly as a result of even a single filing, particularly in terms of public perception, which is essential for public and private entities. Therefore, it is critical that psychedelic prior art is made readily available to examiners and potential applicants so that all parties are well informed of the state of the field before critical decisions on intellectual property rights are determined.

Moves toward Mainstreaming and the Challenge for Equitable Access

As psychedelics move steadily toward mainstreaming via biomedicalization, decriminalization, legalization, and sacramental "imaginaries," it is important to take stock of who stands to benefit from the corollary rise in patenting and for whom this surge represents a disadvantage.[41] Some U.S. states and counties have already decriminalized recreational use of several psychedelics with more expected to follow, but until recently changes at the federal level were considered unlikely to occur.[42] Since 2017, the FDA has granted the coveted "breakthrough therapy" designation to two Schedule I compounds: the empathogen MDMA for the treatment of PTSD and the psychedelic psilocybin for the treatment of depression—sharply at odds with their continuing illicit status.[43] The heads of the FDA and NIH as well as several members of Congress have publicly voiced their support for easing psychedelic restrictions to assist research and decriminalization efforts—and have introduced legislation to do so.[44] Another pivotal federal move came in 2022 when the U.S. Drug Enforcement Agency announced it would not be pursuing Schedule I status for five psychedelic compounds (4-OH-DiPT, 5-MeO-AMT, 5-MeO-MiPT, 5-MeO-DET and DiPT)—a reversal on its previous stance.[45]

Although mainstreaming would likely correlate to a financial boom in the psychedelic industry, there is a need to ensure that equity is maintained so that

41. Claudia Schwarz-Plaschg, "Socio-Psychedelic Imaginaries: Envisioning and Building Legal Psychedelic Worlds in the United States," *European Journal of Futures Research* 10, no. 1 (2022): 10, https://doi.org/10.1186/s40309-022-00199-2.
42. Jacob S. Aday, Emily K. Bloesch, and Christopher C. Davoli, "2019: A Year of Expansion in Psychedelic Research, Industry, and Deregulation," *Drug Science, Policy and Law* 6 (2020): 2050324520974484, https://doi.org/10.1177/2050324520974484.
43. Mason Marks, "A Strategy for Rescheduling Psilocybin," *Scientific American*, October 11, 2021, https://www.scientificamerican.com/article/a-strategy-for-rescheduling-psilocybin/; "FDA Grants Breakthrough Therapy Designation for MDMA-Assisted Therapy for PTSD, Agrees on Special Protocol Assessment for Phase 3 Trials," Multidisciplinary Association for Psychedelic Studies, August 26, 2017, https://maps.org/news/media/press-release-fda-grants-breakthrough-therapy-designation-for-mdma-assisted-psychotherapy-for-ptsd-agrees-on-special-protocol-assessment-for-phase-3-trials/.
44. Aday, Bloesch, and Davoli, "2019: A Year of Expansion."
45. Microdose NewsDesk, "Breaking News: DEA Reverses Decision to Ban 5 Psychedelics," Microdose, July 23, 2022, https://microdose.buzz/news/breaking-news-dea-reverses-decision-to-ban-5-psychedelics/.

historically vulnerable communities are not further exploited and continue to have access to psychedelic technologies long in the public domain. Beyond patentability, legal issues, and research accessibility, there remain ethical arguments that psychedelic patenting constitutes biopiracy that culturally and ecologically harms Indigenous communities.[46] In particular, a 1986 patent granted on a "novel" strain of ayahuasca illustrates how the patent system enables the erasure of Indigenous knowledge, biopiracy, and the commodification of a sacred compound.[47] The patent prompted Indigenous peoples of Ecuador to demand its revocation; it was subsequently revoked, and then reinstated after a successful appeal from the Western inventor.[48] The International Bioethics Committee of 2012 likewise raised the concern that traditional medicine commercialization could constitute biopiracy, may lead to the dispossession of Indigenous communities and their knowledge, and cause scarcity of medicinal plants for these communities.[49] It is thus essential that significant and concerted efforts are made to not further endanger ecosystems or appropriate and assist in the erasure of traditional knowledge in the continuing development of psychedelics.[50] A central component of maintaining an ethical orientation to psychedelic development is in ensuring that the history of psychedelics—in terms of ancestral Indigenous and Western research contexts—is accessible and understood for those making decisions about psychedelic intellectual property rights.

Conclusions

As psychedelic therapies are further developed and refined, efforts to monopolize and capitalize on their utility in the form of patent rights will continue. Leveraging historical knowledge as prior art and making it easily accessible to prevent overly broad patents doubly protects the public domain. First, it allows patent examiners to use the full spectrum of the complex history of psychedelics when evaluating patent claims. Second, making prior art available allows applicants seeking to patent psychedelic technologies to tailor their intellectual property strategies to ensure they do not encroach on the public domain, thus saving the applicant time and money in prosecution. Active means of combating overly broad patents and patent applications in the form of petitions for PGR and 3PS

46. Russo and Johnson, "Research Use Exemptions"; McMillan, "Global Bioethical Challenges"; Sara V. Press, "Ayahuasca on Trial: Biocolonialism, Biopiracy, and the Commodification of the Sacred," *History of Pharmacy and Pharmaceuticals* 63, no. 2 (2022): 328–53, https://doi.org/10.3368/hopp.63.2.328.
47. Press, "Ayahuasca on Trial."
48. Press, "Ayahuasca on Trial."
49. McMillan, "Global Bioethical Challenges."
50. McMillan, "Global Bioethical Challenges."

puts prior art directly in front of the USPTO and requires their representatives to consider it when determining patentability. Both passive and active means of participating as third parties in the patenting process hinges on critical historic, cultural, and scientific information presented in prior art. Given the growing threat of capitalist sequestration and monopolization of psychedelic compounds, there is a need for interdisciplinary experts in law, science, and history to collaborate to preserve the public domain and combat overly aggressive intellectual property strategies.