

THE “CEREMONIAL USE” DEFENSE TO INFRINGEMENT OF PSYCHEDELIC PATENTS

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ABSTRACT

A psychedelic “renaissance” has led to renewed interest in the medical uses of psychedelics, particularly to assist in treatment of substance use disorders. This “renaissance” has included attempts to patent methods of using or synthesizing psychedelics. Long before this “renaissance,” however, indigenous peoples of the Americas used psychedelic plants in their religious rites, including using psychedelic plants to treat substance abuse disorders such as alcoholism. Therefore, indigenous peoples have raised concerns that the recent trend of patenting psychedelics will lead to the patenting of their traditional knowledge and impede their free exercise of religion. A current proposed solution to address such concerns is to create traditional knowledge repositories. Such repositories prevent the patenting of traditional knowledge that qualifies as “prior art” under the patent laws. However, due to the secret nature of religious ceremonies and oral transmission of religious instruction, prior indigenous uses of psychedelics may not qualify as “prior art.” Moreover, market forces may compel indigenous communities to substitute patented varieties of psychedelics for traditional varieties. Accordingly, a “ceremonial use” defense should also be recognized to provide a defense to patent infringement claims for indigenous communities and their members.

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I. INTRODUCTION

Psychedelic plants—cohoba, ayahuasca, psilocybin mushrooms, peyote—have long been used sacramentally by indigenous peoples of the Americas.¹ Initially targeted for suppression as part of colonial efforts to Christianize indigenous peoples, psychedelics enjoyed brief interest by the psychiatric community before being criminalized under the Controlled Substances Act in 1970.² Recently, shifting attitudes towards psychedelics have spurred renewed interest in their medical applications among researchers, particularly in using psychedelics to assist with psychotherapy for alcoholism and other substance use disorders.³ This, in turn, has led to the filing of several patent applications relating to such use of psychedelic plants, or the alkaloids within them.⁴

1. Chike Pilgrim, *Communicating with Spirits, Getting High: The Wooden Artefacts of the Caribbean Indigenous Cohoba Ceremony*, NAT'L TRUST OF TRINIDAD AND TOBAGO, <https://nationaltrust.tt/home/wooden-artefacts-cohoba-ceremony/?v=df1f3edb9115> (Apr. 28, 2021); Melanie J. Miller, Juan Albarracin-Jordan, Christine Moore & José M. Capriles, *Chemical Evidence for the Use of Multiple Psychotropic Plants in a 1,000-year-old Ritual Bundle from South America*, 116 PNAS 11207 (May 6, 2019), <https://www.pnas.org/doi/10.1073/pnas.1902174116>; Giorgio Samorini, *The Oldest Archeological Data Evidencing the Relationship of Homo Sapiens with Psychoactive Plants: A Worldwide Overview*, 3 J. OF PSYCHEDELIC STUDIES 63, 64 (2019); Dustin Marlan, *Beyond Cannabis: Psychedelic Decriminalization and Social Justice*, 23 LEWIS & CLARK L. REV. 851, 865 (2019).

2. Benjamin Breen, *The Failed Globalization of Psychedelic Drugs in the Early Modern World*, 65 HISTORICAL J. 12, 13–23 (2022); Arnaud Exbalin, *Discovering Hallucinogenic Mushrooms in Mexico*, CONVERSATION (Apr. 11, 2019), <https://theconversation.com/discovering-hallucinogenic-mushrooms-in-mexico-115033>; MIKE JAY, Mescaline: A GLOBAL HISTORY OF THE FIRST PSYCHEDELIC 40, 131, 193–198 (2019); Rick Strassman, DMT: THE SPIRIT MOLECULE A DOCTOR'S REVOLUTIONARY RESEARCH INTO THE BIOLOGY OF NEAR-DEATH AND MYSTICAL EXPERIENCES 25, 49 (2001); Controlled Substances Act, 21 U.S.C. § 812 (outlawing certain hallucinogenic substances, including dimethyltryptamine, mescaline, peyote, and psilocybin).

3. Mason Marks & I. Glenn Cohen, *Patents on Psychedelics: The Next Legal Battlefield of Drug Development*, 135 Harv. L. Rev. F. 212, 212–15 (2020) (noting growing research on psychedelics to treat “drug overdose epidemic” and stating “[i]n the past few decades, pioneering researchers rekindled interest in the therapeutic use of psychedelic substances.”); *Psychedelic Drug Therapy May Help Treat Alcohol Addiction*, NYU LANGONE HEALTH (Aug. 24, 2022) <https://nyulangone.org/news/psychedelic-drug-therapy-may-help-treat-alcohol-addiction>; Brendan Borrell, *The Next Big Addiction Treatment*, N.Y. TIMES (Mar. 31, 2022) <https://www.nytimes.com/2022/03/31/well/mind/psilocybin-mushrooms-addiction-therapy.html>.

4. See, e.g., Antidepressant-Psilocybin Co-treatment to Assist Psychotherapy, Application Pub. No. US 2022/0387456 (filed Mar. 10, 2022); Mescaline Derivatives with Modified Action, Application Pub. No. US 2022/0267252 (filed Feb. 20, 2022) (discussing use of mescaline derivatives for use in substance-assisted therapy); Effects of Mescaline and of Mescaline Analogs (Scalines) to Assist Psychotherapy, Application Pub. No. US 2022/0265582 (filed Feb. 18, 2022); Methods and Systems for Enhancing Clinical safety of Psychoactive Therapies, Application Pub. No. US 2023/0162851 (filed Mar. 9, 2021)

Indigenous religions, however, have long used psychedelics as sacraments in ceremonies that seek to address those same ills.⁵ Attempts to patent psychedelics, or methods of using psychedelics, have stoked fears among indigenous communities that patent laws will be the new tool of colonial suppression, preventing indigenous people's free exercise of religion.⁶

Currently, researchers have primarily proposed using traditional knowledge repositories to prevent the patenting of indigenous religious practices.⁷ While no traditional knowledge repository has been adopted in the United States,⁸ where such repositories do exist, researchers aim for repositories to improve patent examiners' access to traditional knowledge by translating and consolidating that knowledge into a searchable database.⁹ Improved access to traditional knowledge enables such knowledge to be found during "prior art" searching.¹⁰ Patent examiners use "prior art" searches to prevent patents from being erroneously granted on existing practices.¹¹ The content of the "prior art" is a question of patent validity—if a supposed

(discussing methods and systems for enhancing clinical safety of psychoactive therapies, including psilocybin therapy).

5. JAY, *supra* note 2, at 208; OMER C. STEWART, PEYOTE RELIGION: A HISTORY 157, 220–21 (1987).

6. Simon Spichak, *Psychedelics are Surging—at the Expense of Indigenous Communities*, DAILY BEAST, (Dec. 26, 2022), <https://www.thedailybeast.com/psychedelics-are-surging-at-the-expense-of-indigenous-communities> (expressing concerns that patents will make psychedelics used by indigenous people for ceremonial purposes inaccessible, and describing the patenting of psychedelics as "biopiracy" and part of a "colonial process").

7. Marks & Cohen, *supra* note 3, at 231–32.

8. *See Online Databases and Registries of Traditional Knowledge and Genetic Resources*, WIPO, https://www.wipo.int/export/sites/www/tk/en/resources/pdf/gr_table.pdf (listing WIPO members states with databases for traditional knowledge and genetic resources and showing United States has only adopted databases concerning genetic resources, not traditional knowledge) (last access Feb. 21, 2024).

9. Jay Erstling, *Using Patents to Protect Traditional Knowledge*, 15 TEX. WESLEYAN L. REV. 295, 319–20 (2009).

10. Murray Lee Eiland, *Patenting Traditional Medicine*, 89 J. PAT. & TRADEMARK OFF. SOC'Y 45, 64–65 (2007) ("A TM [traditional medicine] database would put information in the public domain. It would allow patent examiners to identify what is novel in reference to TK [traditional knowledge]. If a patent application were the same as what was recorded in the database, it would be denied.").

11. Patrick Nolan & Leonard Change, *Understanding the Patent Examination Process*, OFFICE OF PATENT TRAINING, U.S. Patent & Trademark Office at 7 (July 2020) https://www.uspto.gov/sites/default/files/documents/InventionCon2020_Understanding_the_Patent_Examination_Process.pdf (stating that patent examiner responsibilities include searching "existing technology for claimed invention").

invention was already publicly disclosed, it is not patentable.¹² In other words, examiners use “prior art” searches to ensure the novelty and nonobviousness of a patent application.¹³ Therefore, the focus of traditional knowledge repositories is patent validity—the content of existing public disclosures. Such repositories do not concern patent infringement, where claims compare an accused device or method to the patented invention.

The focus on patent validity has several drawbacks. Indigenous religious practices using sacramental psychedelics may not qualify as “prior art” under existing law. The definition of “prior art” focuses on whether the invention was previously disclosed to the public (either in writing or by its public use) or was on sale to the public.¹⁴ However, because indigenous religious practices are often secret, non-commercial, and transmitted through oral tradition, they may not qualify as “prior art.” Moreover, modern science has already created new (and often commercialized) varieties of non-psychedelic plants traditionally used by the indigenous peoples of the Americas, and some of these new varieties of plants have been patented.¹⁵ Economic forces favor these new varieties to their traditional counterparts, and the scarcity of the traditional varieties has already compelled indigenous people to substitute the more available nontraditional varieties in their religious and cultural practices.¹⁶ Similar forces could compel indigenous people to rely on patented versions of psychedelics for their religious rites if traditional psychedelic plants become scarce. Prior art repositories do not address these substitution concerns.

Accordingly, courts (or Congress) should recognize an affirmative defense to patent infringement for the religious practices of indigenous communities—a defense I will refer to herein as the “ceremonial use” defense. Similar to the “prior user rights” defense, the “ceremonial use” defense would permit continued use of patented technologies for an original (albeit secret) user. However, the “ceremonial use” defense is applied in a religious rather than a

12. *Prior Art Research*, LEXISNEXIS IP BLOG (Sept. 20, 2021) <https://www.lexisnexisip.com/resources/prior-art-research/> (“It is the job of patent examiners to comb through and evaluate an invention’s novelty and nonobviousness based on all prior art in the world (a tall order, we know).”).

13. *Id.*

14. 35 U.S.C. § 102(a).

15. See, e.g., Hugh Murphy, *Foods Indigenous to the Western Hemisphere*, AM. INDIAN HEALTH AND DIET PROJECT, <https://aihd.ku.edu/foods/corn.html> (last visited Aug. 4, 2023) (noting traditional Native American use of corn); Paul Harris, *Monsanto Sued Small Farmers to Protect Seed Patents-Report*, GUARDIAN (Feb. 2013), <https://www.theguardian.com/environment/2013/feb/12/monsanto-sues-farmers-seed-patents> (noting patent protection for corn varieties).

16. Carling Malouf, *Gosiute Peyotism*, 44 AM. ANTHROPOLOGIST 93, 97 (1942), <https://www.jstor.org/stable/662831?seq=1> at 99 n.12 (noting use of canned sweet corn in peyote ceremony).

commercial context. The “ceremonial use” defense goes further than the “prior user rights” defense in permitting substitution of new and novel variants of psychedelics that were inspired by prior ceremonial use of psychedelic plants. In this way, the “ceremonial use” defense would be similar to the “shop rights” doctrine, which allows an employer to use inventions developed by its employees when fairness and equity so require. The owners of the rights to the “ceremonial use” defense should be federally recognized Indian Tribes, pre-existing indigenous religious organizations, and others authorized to perform religious ceremonies under tribal custom.

II. BACKGROUND

A. RELIGIOUS PRACTICES OF INDIGENOUS PEOPLES OF THE AMERICAS INSPIRED SCIENTIFIC RESEARCH INTO PSYCHEDELICS

Psychiatric researcher Humphry Osmond coined the term “psychedelics” to the world at a 1956 conference and in a 1957 article.¹⁷ Osmond combined the Greek words *psyche* (“mind” or “soul”) and *delein* (“to make manifest”) to create a new word that meant “mind manifesting.”¹⁸ He needed new vocabulary to describe the effects he experienced from mescaline (an alkaloid found in peyote) and lysergic acid diethylamide (LSD).¹⁹ Certain chemicals are considered to be “classic” psychedelics due to a long history of use and research into them during the 1950s and 1960s, during the emergence of the field of molecular neuroscience.²⁰ These “classic” psychedelics are psilocybin, LSD, dimethyltryptamine (DMT), and mescaline.²¹ The “classic” psychedelics fall within one of two general chemical categories—tryptamines (LSD, psilocybin, and DMT) and phenethylamines (mescaline).²²

With the exception of LSD, the long history of use of “classic” psychedelics includes ancient use by indigenous peoples of the Americas.²³

17. Steven J. Novak, *LSD before Leary: Sidney Cohen's Critique of the 1950s Psychedelic Drug Research*, 88 *ISIS* 87, 95 (1997); Marlan, *supra* note 1, at 857 & n.1.

18. Marlan, *supra* note 1, at 857.

19. JAY, *supra* note 2, at 257 n.17; John Cloud, *When the Elite Loved LSD*, *TIME* (Apr. 23, 2007), <https://content.time.com/time/nation/article/0,8599,1613675,00.html>.

20. Matthew W. Johnson, Peter S. Hendricks, Frederick S. Barrett & Roland R. Griffiths, *Classic Psychedelics: An Integrative Review of Epidemiology, Therapeutics, Mystical Experience, and Brain Network Function*, 197 *PHARMACOLOGY & THERAPEUTICS* 83, 85 (2019).

21. James J.H. Rucker, Jonathan Iliff & David J. Nutt, *Psychiatry & the Psychedelic Drugs. Past, Present & Future*, 142 *NEUROPHARMACOLOGY* 200, 201 (2018).

22. Johnson, *supra* note 20, at 84.

23. See Marlan, *supra* note 1, at 861 regarding the use of ayahuasca, psilocybin mushroom, and peyote in the Americas dating back millennia. In contrast, LSD was not synthesized until 1938.

While ancient cultures in other parts of the world used psychoactive plants that contained “classic” psychedelics (particularly psilocybin), the context in which these plants were used has been lost to history; the only record of their use that remains is the archeological evidence.²⁴ In contrast, the religious use of psychedelics by Native Americans began in ancient times, but it has persisted to the present day.²⁵ With the exception of LSD, “classic” psychedelics come from plants that were used in a religious context by Native Americans. Mescaline, for instance, is found in cacti species native only to the Americas—the peyote cactus and San Pedro cactus.²⁶ “Evidence suggests that Native Americans have been using peyote as long ago as 5,700 years.”²⁷ Indigenous South Americans have been using San Pedro for religious purposes since 1500 BCE.²⁸ Similarly, psilocybin is found in a genus of mushroom (psilocybe).²⁹ Psilocybin mushrooms were used in the religious practices of indigenous peoples in the Americas as far back as 1000 BCE,³⁰ and their use continued until the Spanish conquest.³¹

DMT is a molecule that naturally occurs throughout the plant and animal kingdom: it is found in mammals (including humans), toads and frogs, as well as in grasses, molds, barks, roots, and other plants and animals.³² Importantly, DMT is found in the seeds of the cohoba tree.³³ Indigenous peoples of the

24. The archeological record indicates the use of psilocybin mushrooms by humans in the Sahara Desert between 6,000 and 4,500 B.C., and in Spain around 4,000 B.C. Samorini, *supra* note 1, at 70. Rock art also suggests potential psilocybin mushroom use in Australia and Tanzania. David E. Nichols, *Psychedelics*, 68 PHARMACOLOGICAL REVIEWS 264, 268 (2016). However, it was not until F. Gordon Wasson published an article in *LIFE* magazine about the existence of *velada* ceremonies making use of mushrooms in Mexico was the existence of continued use of mushrooms publicized to Western society. Nicky Kvitsinski, *Fungus Among Us: A Juxtaposition of the Psychological Benefits of Psilocybin Use and Its Federal Classification as a Schedule I Drug*, 50 W. ST. L. REV. 65, 67–68 (2023).

25. JAY, *supra* note 2, at 41; Strassman, *supra* note 2, at 22; Konstantin Gerber, Inti García Flores, Angela Christina Ruiz, Ismail Ali, Natalie Lyla Ginsberg & Eduardo E. Schenberg, *Ethical Considerations about Psilocybin Intellectual Property*, 4 ACS PHARMACOL. & TRANSL. SCI. 573 (2021), <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC8033603/> (discussing resilience of Mazatec mushroom ceremonies in face of centuries of persecution).

26. JAY, *supra* note 2, at 8, 15, 18.

27. Marlan, *supra* note 1, at 865.

28. F.J. Carod-Artal & C.B. Vázquez-Cabrera, *Mescaline and the San Pedro Cactus Ritual: Archeological and Ethnographic Evidence in Northern Peru*, 42 REVISTA DE NEUROLOGIA (2006), <https://pubmed.ncbi.nlm.nih.gov/16625512/>.

29. Marlan, *supra* note 1, at 860.

30. Samorini, *supra* note 1, at 64.

31. Gastón Guzmán, *Hallucinogenic Mushrooms in Mexico: An Overview*, 32 ECONOMIC BOTANY 404, 405–10 (2008).

32. Strassman, *supra* note 2, at 42.

33. Pilgrim, *supra* note 1.

Caribbean have used cohoba powder as snuff for hundreds of years.³⁴ In fact, the very first European work describing the ethnology of the New World by Ramone Pane (who accompanied Christopher Columbus on his second voyage) noted the use of cohoba by indigenous peoples in 1496.³⁵

Initial scientific research into psychedelics focused on schizophrenia, and researchers investigated any possible links between psychedelic compounds and the disease.³⁶ Mescaline was the first psychedelic chemically isolated³⁷ by German chemist Arthur Heffter in 1897.³⁸ The chemist Ernst Späath then synthesized Mescaline in a laboratory in 1919.³⁹ This led to the use of mescaline for psychiatric research, and mescaline experiments became widespread in the field of psychiatry by 1940.⁴⁰

The effects of mescaline inspired further scientific research into other psychedelics, such as LSD. For instance, when Albert Hoffman famously administered LSD on himself on April 19, 1943 (the first-ever human experience with LSD), he recognized that its effects were “not new to science,” but were similar to mescaline.⁴¹ LSD then went on to be used in psychiatry, often by researchers who had been experimenting with mescaline, and it eventually surpassed mescaline in popularity with researchers.⁴²

In 1954, psychiatrists Humphry Osmond and Abram Hoffer began experimenting with giving alcoholics LSD.⁴³ This research was inspired by their experience attending a ceremony of the Native American Church (the name given to the peyote religions of indigenous North Americans in 1918) in Canada, where they learned of the success of the Church in combating alcoholism.⁴⁴ Over the next half-decade, the research into LSD as a treatment for alcoholism led it to be known as “a miracle cure.”⁴⁵ The research into psychedelic drug therapy proliferated, with a thousand clinical papers, dozens

34. *Id.*

35. William Edwin Safford, *Identity of Cohoba, the Narcotic Snuff of Ancient Haiti*, 6 J. OF THE WASH. ACAD. OF SCIS. 547, 549–50 (1916).

36. *See, e.g.*, JAY, *supra* note 2, at 193–195; Strassman, *supra* note 2, at 25, 49.

37. *See* Rucker, et al, *supra* note 21, at 201.

38. *Id.*; JAY, *supra* note 2, at 257 n.17.

39. JAY, *supra* note 2, at 131.

40. *Id.* at 103–05, 132–46, 178.

41. *Id.* at 189.

42. *Id.* at 189–98.

43. Novak, *supra* note 17, at 97.

44. JAY, *supra* note 2, at 208.

45. Novak, *supra* note 17, at 98.

of books, and six international conferences on the topic between 1950 and the mid-1960s.⁴⁶

As another example, biochemist Alexander Shulgin's use of mescaline inspired him to look for other psychoactive phenethylamines, eventually leading to his synthesis of 3,4-Methylenedioxymethamphetamine (MDMA), which had been previously synthesized but never made available for research.⁴⁷ Shulgin took MDMA and, noting its effects, introduced it to a psychotherapist for use with clients.⁴⁸ MDMA then "spread rapidly through California's psychotherapeutic community."⁴⁹ Today, MDMA is on the verge of FDA approval for use in treatment of post-traumatic stress disorder.⁵⁰

Mescaline also indirectly inspired scientific interest in DMT. In 1953, Hungarian physician and chemist Stephen Szara was hoping to use LSD in his research regarding schizophrenia.⁵¹ However, Sandoz Laboratories refused to provide him with LSD because the drug company did not want to risk such a powerful drug being used in a communist country.⁵² In search of an alternative, Szara began experimenting with mescaline.⁵³ Encouraged by his experience with mescaline, Szara looked to other indigenous medicines and, after learning of cohoba, began exploring DMT.⁵⁴

Similarly, although psilocybin mushrooms are found throughout the world and were used in antiquity,⁵⁵ it was the use of these mushrooms by Mazatec Indians in Mexico that famously caught the attention of R. Gordon Wasson, who published a 1957 article in *Life* magazine⁵⁶ regarding the indigenous use of mushrooms.⁵⁷ Wasson, a bank executive and an amateur mushroom

46. Marlan, *supra* note 1, at 866 (quoting LESTER GRINSPOON & JAMES B. BAKLAR, PSYCHEDELIC DRUGS RECONSIDERED 192 (1997)).

47. JAY, *supra* note 2, at 243–44.

48. *Id.* at 244–45.

49. *Id.* at 245.

50. Katie Brown, *Legalizing MDMA for PTSD Treatment: Phase 3 Clinical Trial Results*, PSYCHIATRIST.COM (May 23, 2023), <https://www.psychiatrist.com/news/legalizing-mdma-for-ptsd-treatment-phase-3-clinical-trial-results/>.

51. Andrew R. Gallimore & David P. Luke, *DMT Research from 1956 to the Edge of Time*, REALITY SANDWICH (Oct. 15, 2015), <https://realitysandwich.com/dmt-research-from-1956-to-the-edge-of-time/>; *see also* Stephen Szara, PSYCHEDELIC SCI. REV., <https://psychedelicreview.com/person/stephen-szara/> (last visited July 24, 2023).

52. Stephen Szara, *supra* note 51; Strassman, *supra* note 2, at 44–45.

53. Strassman, *supra* note 2, at 44–45.

54. *Id.*

55. Samorini, *supra* note 1, at 64, 70.

56. R. Gordon Wasson, *Seeking the Magic Mushroom*, LIFE (May 13, 1957), at 102–09.

57. *See* Kathryn L. Tucker, *Psychedelic Medicine: Galvanizing Changes in Law and Policy to Allow Access for Patients Suffering Anxiety Associated with Terminal Illness*, 21 QUINNIPIAC HEALTH L.J. 239, 241 (2018).

enthusiast, and his wife Valentina, a pediatrician and scientist, gained admission to a Mazatec mushroom ceremony (called a *velada*) based on Wasson's lie that he was seeking help for his son.⁵⁸ Wasson's participation in the *velada* was conditioned on secrecy, although he would later breach his secrecy obligations by writing about the ceremony.⁵⁹ After participating in the Mazatec ceremony in Mexico, Wasson returned with samples of mushrooms from Mexico that he sent to Albert Hofmann (the same Swiss chemist that invented LSD).⁶⁰ In 1958, Hoffman used the samples to synthesize psilocybin, leading to its use in psychiatric studies.⁶¹ Wasson also influenced Timothy Leary, a psychology professor who read Wasson's *Life* article and "became highly interested in the experiences" described.⁶² In 1959, Leary joined the faculty at Harvard and, in 1960, inspired by Wasson, Leary traveled to Mexico to partake in psilocybin mushrooms.⁶³ Afterward he and another professor, Richard Alpert, started the Harvard Psilocybin Project, "which aimed to document psilocybin's effects on human consciousness."⁶⁴

B. LEGAL HISTORY OF THE SUPPRESSION OF PSYCHEDELICS

Scientific research into the "classic" psychedelics came to a screeching halt in the 1960s, as psychedelics became outlawed, as part of a growing "moral panic" that culminated in the "War on Drugs."⁶⁵ The use of psychedelics, however, had long been controversial and was subject to legal efforts to suppress their use even before the 1960s. Due to their use as a religious

58. James Stephen, R. Gordon Wasson & Maria Sabina: First Contact with Magic Mushrooms: The Troubled Rediscovery of Psilocybin Mushrooms, TRUFFLE REP. (Nov. 10, 2020) <https://truffle.report/maria-sabina-and-r-gordon-wasson-psychedelic-first-contact-warning/>; Amy Bartlett and Monnica T. Williams, *The Cost of Omission: Dr. Valentina Wasson and Getting Our Stories Right*, CHACRUNA (Nov. 11, 2020) <https://chacrana.net/dr-valentina-wasson-and-getting-our-stories-right/>.

59. Gerber et al., *supra* note 25, at 573.

60. Zachary LeCompte, *Not Groovy Man: Psilocybin's Long and Complicated History with the Law, and Its Potential to Treat the Growing Mental Health Crisis in America*, 90 U. CIN. L. REV. 1113, 1138 (2022).

61. Tucker, *supra* note 57, at 241; LeCompte, *supra* note 60, at 1138–39.

62. Scott Houghton, *From Medicine to Poison: The Magic Mushroom in 1960s America*, COLLECTOR (Dec. 5, 2021) <https://www.thecollector.com/magic-mushrooms-1960s-america/>; see also Carolyn Gregoire, *Inside the Movement to Decolonize Psychedelic Pharma*, PROTO.LIFE (Oct. 29, 2020), <https://proto.life/2020/10/inside-the-movement-to-decolonize-psychedelic-pharma/>.

63. LeCompte, *supra* note 60, at 1140; Houghton, *supra* note 62; Leary v. United States, 383 F.2d 851, 857 (5th Cir. 1967), 395 U.S. 6 (1969) (noting Leary testified that he ingested psychedelic mushrooms by travelling to Mexico in 1960).

64. LeCompte, *supra* note 60, at 1140; Houghton, *supra* note 62.

65. LeCompte, *supra* note 60, at 1142.

sacrament, these efforts have often been countered by arguments regarding free exercise of religion.

The religious use of psychedelics by indigenous peoples was the subject of colonial suppression. The first Europeans to encounter the indigenous use of these “classic” psychedelics were the Spanish—who had colonies in South America, Central America, and Mexico (which at that time included Texas, where the peyote cactus grows).⁶⁶ The Spanish condemned and prohibited the use of psychedelic plants as a form of witchcraft or necromancy.⁶⁷ In 1620, an Inquisitorial edict officially banned “peyote and other herbs . . . [that] cause images, fantasies, and representations . . . on which divinations are based.”⁶⁸ The Spanish referred to peyote as the “devilish root” (*raíz diabólica*) and between 1620 and 1779, the Inquisition heard seventy-four peyote cases.⁶⁹ Despite its suppression, near the northern borders of Mexico, where the Spanish presence was limited to “main roads,” “mining towns,” and “scattered and poorly supported missions,” “peyote traditions clung on.”⁷⁰ Likewise, although suppressed, the psilocybin mushroom traditions in Mexico were able to continue.⁷¹

In 1845, Texas became a state,⁷² and the United States had to confront the use of psychedelics (peyote in particular) amongst indigenous people in the new state. The initial policy of the U.S. federal government was suppression.⁷³ In 1888, the Bureau of Indian Affairs forbade the use of peyote, later classifying peyote as “liquor” in 1890.⁷⁴ The rationale for this classification was entirely paternalistic—the Bureau of Indian Affairs Special Agent forbidding

66. *New Spain and Spanish Colonization*, ENCYCLOPEDIA.COM <https://www.encyclopedia.com/history/encyclopedias-almanacs-transcripts-and-maps/new-spain-and-spanish-colonization> (last accessed Feb. 23, 2024); *ELSI Research Report, State Regulation of Psilocybin: Recommendations for the Oregon Health Authority*, 1 <https://www.oregon.gov/oha/PH/PREVENTIONWELLNESS/Documents/ELSI%20Report%20Draft-%20Historical%20and%20Indigenous%20Use.pdf> (“the modern history of psilocybin usually begins with the Spanish discovery of Aztec ceremonies in the New World.”).

67. Breen, *supra* note 2, at 13–23; Arnaud Exbalin, *Discovering Hallucinogenic Mushrooms in Mexico*, CONVERSATION (Apr. 11, 2019), <https://theconversation.com/discovering-hallucinogenic-mushrooms-in-mexico-115033>.

68. Breen, *supra* note 2, at 69.

69. JAY, *supra* note 2, at 40.

70. JAY, *supra* note 2, at 41.

71. See Strassman, *supra* note 2, at 22.

72. H.R.J. Res. 46, 9 Stat. 108 (Mar. 1, 1845).

73. Stewart, *supra* note 5, at 128 (“When the use of peyote became apparent to missionaries and Indian agents of the federal government, they immediately sought to suppress it.”).

74. Varun Soni, *Freedom from Subordination: Race, Religion, and the Struggle for Sacrament*, 15 TEMP. POL. & CIV. RTS. L. REV. 33, 39–40 (2005).

its use remarked, it “is for the good of the Indians—many of whom are being destroyed by the use of this bean.”⁷⁵ However, in 1916, a U.S. District Court Judge in South Dakota held that peyote “is neither an intoxicating liquor nor a drug.”⁷⁶ In response and in order to continue to prohibit the use of peyote by Native Americans, a bill was introduced that same year in Congress to prohibit the interstate “traffic” of peyote.⁷⁷ The bill failed, as did bills introduced in 1917, 1918, 1919, 1921, 1922, 1924, 1926, and 1937.⁷⁸ On October 10, 1918,⁷⁹ peyotists from several Tribes in Oklahoma incorporated the “Native American Church” under state law in order to bolster the legitimacy of their use of peyote as a religion.⁸⁰ Peyote practitioners in other states—e.g., Nebraska, Montana, South Dakota, Wisconsin—soon incorporated similar organizations.⁸¹ In 1944, these various chapters confederated into a single national organization: the Native American Church of the United States (later renamed the Native American Church of North America).⁸²

Despite this early religious opposition to laws forbidding peyote, the federal government eventually prohibited peyote and all other psychedelics, after questions were raised regarding the validity of the scientific (not indigenous) community’s use of psychedelics.⁸³ Infamously, LSD researchers started using LSD for recreational parties rather than legitimate research.⁸⁴ Leary and Alpert, the founders of the Harvard Psilocybin Project, were dismissed after complaints surfaced that the two were using psilocybin along with their research subjects and promoting recreational use of psilocybin.⁸⁵ The pair became countercultural icons, with President Nixon declaring Leary to be the “most dangerous man in America” in 1971.⁸⁶ Concern about the diversion of LSD led Congress to pass the 1962 Kefauver-Harris Amendments

75. *Id.* (citing Stewart, *supra* note 5, at 128-129).

76. *Id.* at 41.

77. *Id.* at 42; see also WESTON LA BARRE, *THE PEYOTE CULT* 223–24 (5th ed. 1989)

78. LA BARRE, *supra* note 77, at 224.

79. Soni, *supra* note 73, at 45.

80. Stewart, *supra* note 5, at 222.

81. LA BARRE, *supra* note 77, at 171.

82. Stewart, *supra* note 5, at 239–40.

83. See Marlan, *supra* note 1, at 867–68 (describing early 1960s criticism of Harvard Research Project using psychedelics, 1962 Amendments to 1938 Food, Drug, and Cosmetics Act that tightened FDA scrutiny of psychedelics, and Drug Abuse Control Amendments of 1965 that prohibited drugs with “hallucinogenic effect”).

84. Novak, *supra* note 17, at 99.

85. LeCompte, *supra* note 60, at 1140–41.

86. *Id.* at 1141.

to the Federal Food, Drug, and Cosmetics Act of 1938 to tighten control on research.⁸⁷

Increasing bad publicity led Congress to enact the Drug Abuse Control Amendments of 1965, prohibiting drugs found by the Secretary of Health, Education and Welfare to have a “hallucinogenic effect.”⁸⁸ By January 1966, LSD, DMT, mescaline, and psilocybin were all subject to such findings.⁸⁹ The legislation initially prohibited peyote as well, but the federal government quickly provided a regulatory exemption after several courts found that members of the Native American Church had a First Amendment right to use peyote—a regulatory exemption that persists to the present day.⁹⁰ In 1969, Congress enacted the Comprehensive Drug Abuse Prevention and Control Act of 1970.⁹¹ Title II of the Act is the “Controlled Substances Act,” under which the Attorney General has the authority to classify drugs into different “schedules.”⁹² All the “classic” psychedelics (LSD, DMT, psilocybin, mescaline) are listed as Schedule I,⁹³ with an exemption for peyote used in “bona fide ceremonies” of the Native American Church.⁹⁴ This legal prohibition largely led to the cessation of medical research into psychedelics. The Food and Drug Administration began shutting down research projects relating to LSD and mescaline.⁹⁵ Pharmaceutical companies also stopped distributing LSD.⁹⁶ However, the Native American Church’s ceremonial use of peyote was not curtailed under federal law due to the specific exemption for its own “bona fide ceremonies.”⁹⁷ Nevertheless, peyote was still illegal under some state laws, an issue that eventually made its way to the Supreme Court in 1990.⁹⁸

87. Marlan, *supra* note 1, at 867.

88. *Id.* at 868.

89. *Hallucinogens*, 68 COLUM. L. REV. 521, 544 (1968).

90. Memorandum Opinion for the Chief Counsel, Drug Enforcement Administration on the Peyote Exemption for Native American Church (Dec. 22, 1981) (on file with U.S. Dep’t of Just.) at 405, available at <https://www.justice.gov/file/22846/download>; *see also* 21 C.F.R. § 1307.31 (2023).

91. Comprehensive Drug Abuse Prevention and Control Act of 1970, Pub. L. No. 91-513, 84 Stat. 1236.

92. Controlled Substances Act, 84 Stat. 1242, 1245. The law remains the same today. 21 U.S.C. § 811 (2023).

93. 21 C.F.R. §§ 1308.11(d)(19), (22), (24), (29) (2023).

94. 21 C.F.R. § 1307.31 (2023).

95. Marlan, *supra* note 1, at 868–69.

96. Marlan, *supra* note 1, at 869.

97. 21 C.F.R. § 1307.31 (2023).

98. *Employment Div., Dept. of Human Resources of Or. v. Smith*, 494 U.S. 872, 877–90 (1990).

C. THE PSYCHEDELIC “RENAISSANCE”

The 1990s saw a renewed interest in psychedelics—particularly plant medicines used by indigenous peoples of the Americas, after their religious use came to the forefront of policy discussions in the courts and Congress. Many states adopted an exemption for the religious use of peyote by the Native American Church (often modeled on the federal regulatory exemption).⁹⁹ Oregon failed to adopt such an exemption—a failure that reached the Supreme Court in 1990.¹⁰⁰ In *Employment Division v. Smith*, the Supreme Court considered whether Oregon’s prohibition on the use of peyote was invalid under the Free Exercise Clause.¹⁰¹ The Court held that the Free Exercise Clause of the First Amendment does not exempt an individual from compliance with criminal laws of general applicability.¹⁰² This decision challenged prior understandings of the First Amendment,¹⁰³ and Congress responded swiftly by enacting not one, but two, legislative fixes: the Religious Freedom Restoration Act of 1993 (RFRA)¹⁰⁴ and the American Indian Religious Freedom Act Amendments of 1994 (“AIRFA Amendments”).¹⁰⁵ RFRA reinstated the “compelling interest” test used prior to *Smith* to evaluate the validity of a law (even of general applicability) that substantially burdens religious practices. The AIRFA Amendments preempt any state laws that prohibit the use, possession, or transportation of peyote by members of federally recognized Indian Tribes for “bona fide traditional ceremonial purposes.”¹⁰⁶

99. LA BARRE, *supra* note 77, at 265. Compare 21 C.F.R. § 1307.31 (providing exemption for “nondrug use of peyote in bona fide religious ceremonies of the Native American Church”) with, e.g., Kansas Stat. § 65-4116(c)(9) (providing exemption for members of Native American Church in “bona fide religious ceremonies of the Native American Church”); Minn. Stat. § 152.02 subd. 2(e) (providing exemption for “the nondrug use of peyote in bona fide religious ceremonies of the American Indian Church”); Wis. Stat. § 961.115 (providing exemption for “nondrug use of peyote and mescaline in the bona fide religious ceremonies of the Native American Church”).

100. *Employment Div., Dept. of Human Res. of Or. v. Smith*, 494 U.S. 872 (1990).

101. *Id.* at 874–76.

102. *Id.* at 877–90.

103. See, e.g., *Fraternal Order of Police Newark Lodge No. 12 v. City of Newark*, 170 F.3d 359, 362 (3d Cir. 1999) (“In 1990, however, the legal landscape changed dramatically when the Supreme Court handed down its decision in [*Smith*]” (full citation omitted)); *Black v. Snyder*, 471 N.W.2d 715, 719 (Ct. App. Minn. 1991) (“The Supreme Court’s most recent free exercise decision, [*Smith*], effected a significant change in first amendment law” (full citation omitted)); see generally Kenneth Marin, Note, *Employment Division v. Smith: The Supreme Court Alters the State of Free Exercise Doctrine*, 40 AM. U. L. REV. 1431 (1991).

104. 42 U.S.C. § 2000bb(a)(4).

105. 42 U.S.C. § 1996a(a)(4).

106. 42 U.S.C. § 1996a(b)(1).

Peyote was not the only psychedelic that garnered attention. From 1990 to 1995, Dr. Rick Strassman led research into the effects of DMT,¹⁰⁷ which was the first government-funded psychedelics research in over two decades.¹⁰⁸ Strassman was inspired in part by Terrence McKenna,¹⁰⁹ an advocate of psychedelics who famously theorized that consumption by human primate ancestors of psilocybin mushrooms was a step in human evolution.¹¹⁰ McKenna also brought tales of ayahuasca to the masses in the 1980s.¹¹¹

Indigenous people in South America use a combination of plants called ayahuasca in religious ceremonies.¹¹² Archeological evidence shows that the religious use of ayahuasca in the Amazon dates back to at least 1,000 BCE.¹¹³ The law concerning religious use of psychedelics came full circle when ayahuasca laws were challenged under RFRA. An ayahuasca-using church, O Centro Espirita Beneficiente Uniao do Vegetal (UDV), challenged the government's ban on importation of the plants used to make ayahuasca.¹¹⁴ The case, *Gonzalez v. O Centro Espirita Beneficiente Uniao do Vegetal*, eventually reached the Supreme Court, where the Court invalidated the importation prohibition under the RFRA.¹¹⁵

The renewed interest in psychedelics has spurred additional research and legislative reforms. In 2006, a study on the psychological effects of psilocybin reported that volunteers' experiences with psilocybin had "substantial personal meaning and spiritual significance" and that they "attributed to the experience

107. Strassman, *supra* note 2, at xv-xvi.

108. Strassman, *supra* note 2, at xv.

109. *Id.* at 349 n.11; *see also id.* at 187, 358 n. 2.

110. Douglas Martin, *Terrence McKenna, 53, Dies; Patron of Psychedelic Drugs*, N.Y. TIMES (Apr. 9, 2000).

111. Strassman, *supra* note 2, at 349 n.11; *see also* Ariel Levy, *The Drug of Choice in the Age of Kale*, NEW YORKER (Sept. 5, 2016), <https://www.newyorker.com/magazine/2016/09/12/the-ayahuasca-boom-in-the-u-s> (describing McKenna's influence on use of ayahuasca in United States).

112. Ayahuasca is typically prepared by combining the vine *Banisteriopsis caapi* with *Psychotria viridis* leaves. *Psychotria viridis* contains DMT, while the *B. caapi* allows the DMT to become orally active. Marlan, *supra* note 1, at 864.

113. Miller, et al., *supra* note 1.

114. The church referred to its sacrament as "hoasca," as does the Court in its opinion. "Hoasca" is the Portuguese transliteration of ayahuasca. *See* O Centro Espirita Beneficiente Uniao Do Vegetal v. Ashcroft, 342 F.3d 1170, 1174 (10th Cir. 2003). For the sake of consistency, ayahuasca is used herein. 115. *Gonzalez v. O Centro Espirita Beneficiente Uniao do Vegetal*, 546 U.S. 418, 428–39 (2006).

115. *Gonzalez v. O Centro Espirita Beneficiente Uniao do Vegetal*, 546 U.S. 418, 428–39 (2006).

sustained positive changes in attitudes and behavior.”¹¹⁶ In 2019, Denver, Colorado became the first city in the United States to decriminalize psilocybin.¹¹⁷ Several cities (including Washington, D.C., Oakland (CA), Santa Cruz (CA), Ann Arbor (MI), Detroit (MI), Somerville (MA), Cambridge (MA), Seattle (WA), and San Francisco (CA)), alongside Oregon and Colorado, have since followed suit.¹¹⁸ Patents concerning the use of “classic” psychedelics—such as mescaline and psilocybin—in psychotherapy have been filed with the U.S. Patent and Trademark Office (USPTO) and World Intellectual Property Organization (WIPO).¹¹⁹

Some of these patent applications are drafted broadly enough to cover religious practices. For example, one application sought to patent treatment of substance use disorder by using mescaline to induce a psychedelic state in an individual.¹²⁰ As originally drafted, this patent would have been infringed by the existing practice of convening a Native American Church ceremony to cure alcoholism.¹²¹ The claims in the application were later amended and would now require that the treated individual previously have had an adverse effect from psilocybin or LSD.¹²² Accordingly, a Native American Church ceremony

116. R.R. Griffiths, W. A. Richards, U. McCann & R. Jesse, *Psilocybin Can Occasion Mystical-type Experiences Having Substantial and Sustained Personal Meaning and Spiritual Significance*, 187 *PSYCHOPHARMACOLOGY* 268–83 (2006).

117. Marlan, *supra* note 1, at 872.

118. *Where Are Psychedelics Legal in the U.S. (or Decriminalized)?*, MICRODOSE (June 18, 2023), <https://microdose.buzz/news/where-are-psychedelics-legal-in-the-u-s-or-decriminalized/>.

119. *See, e.g.*, N,N-Dimethyltryptamine and Related Psychedelics and Uses Thereof, Application Pub. No. US 2023/0212119 (filed Feb. 23, 2023) (relating to derivatives of DMT); Psilocybin and O-Acetylpsilocin, Salts and Solid State Forms Thereof, Application Pub. No. US 2023/0151036 (filed Dec. 28, 2022) (claiming crystalline forms of psilocybin); Mescaline for the Treatment of Substance Use Disorders, Application No. PCT/US2022/031423 (filed May 27, 2022); N,N-Dimethyltryptamine Compositions and Methods, Application Pub. No. US2022/0339139 (filed Apr. 26, 2022) (discussing method of treating neurological diseases using DMT); Antidepressant-Psilocybin Co-treatment to Assist Psychotherapy, Application Pub. No. US 2022/0387456 (filed Mar. 10, 2022); Mescaline Derivatives with Modified Action, Application Pub. No. US 2022/0267252 (filed Feb. 20, 2022) (discussing use of mescaline derivatives for use in substance-assisted therapy); Effects of Mescaline and of Mescaline Analogs (Scalines) to Assist Psychotherapy, Application Pub. No. US 2022/0265582 (filed Feb. 18, 2022); Methods and Systems for Enhancing Clinical Safety of Psychoactive Therapies, Application Pub. No. US 2023/0162851 (filed Mar. 9, 2021) (discussing methods and systems for enhancing clinical safety of psychoactive therapies, including psilocybin therapy).

120. Effects of Mescaline and of Mescaline Analogs (Scalines) to Assist Psychotherapy, Application Pub. No. US 2022/0265582 (filed Feb. 18, 2022).

121. JAY, *supra* note 2, at 208; Stewart, *supra* note 5, at 157, 220–21.

122. Attorney Docket No 0614.00100 (Feb. 23, 2024), Effects of Mescaline and of Mescaline Analogs (Scalines) to Assist Psychotherapy, Application Pub. No. US 2022/0265582 (filed Feb. 18, 2022).

convened to pray for someone struggling with addiction would still infringe upon the applied-for claims if that person previously used psilocybin or LSD with an adverse effect (which is not improbable for someone dealing with addiction).¹²³ Similarly, another patent application that has been granted covers crystalline psilocybin with certain characteristics.¹²⁴ If natural psilocybin becomes scarce or indigenous communities are priced out of obtaining it, substitution of this crystalline psilocybin into a *velada* ceremony will constitute infringement.

The shifting attitudes towards psychedelics has been dubbed the “psychedelic renaissance.”¹²⁵ Many scholars have criticized this “renaissance” for exploiting the indigenous communities that inspired the use of psychedelics in the first place. Indeed, for some scholars the term “renaissance” rings too *apropos*. As one critic noted, “[t]he European Renaissance did not simply coincide with the imperial expansionism . . . the riches plundered from the so-called Third World and what are now the contemporary settler states of Canada, the United States, Mexico, New Zealand, and Australia fueled the creativity, learning, and economic growth associated with the European Renaissance.”¹²⁶ These critics note that psychedelics have become a billion-dollar industry, with the potential to be magnitudes larger if legalized, and yet little to no benefits have been shared with indigenous peoples.¹²⁷ In the words of one journalist: “It’s a tale as old as colonialism itself: European settlers and explorers come into [i]ndigenous lands, pillage their natural resources, and patent new medicinal compounds based on those resources, furthering modern medicine while bringing destruction to Indigenous habitats and ways of life.”¹²⁸

123. See Brittany Killion, Audrey Hang Hai, Abdulaziz Alsolami, Michael G. Vaughn, P. Sehun Oh & Christopher P. Salas-Wright, *LSD Use in the United States: Trends, Correlates, and a Typology of US*, 223 DRUG & ALCOHOL DEPENDENCE 108715, 2 (June 2021) (noting that lifetime hallucinogen use is highly comorbid with other substance use); Bheatrix Bienemann, Nina Stamato Ruschel, Maria Luiza Campos, Marco Aurélio Negreiros & Daniel C. Mograbi, *Self-Reported Negative Outcomes of Psilocybin Users: A Quantitative Textual Analysis*, 15 PLoS ONE 1, 10 (Feb. 21, 2020) (noting that use of psilocybin with other substances may increase negative outcomes).

124. Psilocybin and O-Acetylpsilocin, Salts and Solid State Forms Thereof, Application Pub. No. US 2023/0151036 (filed Dec. 28, 2022) issued as U.S. Patent No. 11,851,452.

125. See, e.g., Emily Witt, *The Science of the Psychedelic Renaissance*, NEW YORKER (May 29, 2018), <https://www.newyorker.com/books/under-review/the-science-of-the-psychedelic-renaissance>.

126. Keith Williams, Osiris Sinuhé González Romero, Michelle Braunstein & Suzanne Brant, *Indigenous Philosophies and the “Psychedelic Renaissance,”* 33 ANTHROPOLOGY OF CONSCIOUSNESS 506, 508 (2022).

127. *Id.*

128. Gregoire, *supra* note 62.

In particular, critics of the psychedelic renaissance have voiced concern about potential disruption to indigenous communities by increased commercialization of psychedelics. This includes a scarce supply of psychedelics for indigenous communities, caused by increased prices, over-harvesting, or use of habitat.¹²⁹ Due to these concerns about habitat for peyote, several members of the Native American Church advocate that peyote should not be included in psychedelic decriminalization initiatives,¹³⁰ and the National Congress of American Indians accordingly passed a resolution opposing the legalization or decriminalization of peyote.¹³¹ More broadly, patenting of psychedelics poses a threat to the practice of all indigenous religions that use psychedelic sacraments. Critics argue that commercial interests may exclude indigenous communities and that patent examiners may not accurately evaluate whether psychedelic patents are entitled to patent protection.¹³²

III. THE CONFLICT BETWEEN PSYCHEDELIC PATENTS AND RELIGIOUS FREEDOM

The law of psychedelics presently finds itself at the intersection of intellectual property and religious freedom. This intersection raises two concerns: (1) whether indigenous communities should have a property right to their religious practices that is infringed when others use their sacramental psychedelics, and (2) whether the intellectual property rights recognized by the dominant society will impede the free exercise of religion of indigenous peoples using sacramental psychedelics. This Article concerns the latter, dwelling on the rights that indigenous peoples possess when others obtain patent protection for purported inventions involving psychedelics that have been used in indigenous religious rites.

Patents are property that provide an *exclusive* right to make, use, sell, offer for sale, or import patent technology for a limited duration of time.¹³³ Accordingly, the purpose of patenting psychedelic-related technology is to obtain a limited term monopoly on a particular psychedelic or use of

129. *Id.*; Spichak, *supra* note 6.

130. Louis Sahagún, *Why are Some Native Americans Fighting Efforts to Decriminalize Peyote?*, L.A. TIMES (Mar. 29, 2020), <https://latimes.com/environment/story/2020-03-29/native-americans-want-mind-bending-peyote-cactus-removed-from-efforts-to-decriminalize-psychedelic-plants>.

131. *The National Congress of American Indians Resolution ECWS-22-009*, NAT'L CONG. OF AM. INDIANS, <https://ncai.assetbank-server.com/assetbank-ncai/assetfile/913.pdf>.

132. Spichak, *supra* note 6; Marks & Cohen, *supra* note 3, at 231–32.

133. 35 U.S.C. § 271(a); 35 U.S.C. § 154; *see also* *Horne v. Dept. of Agric.*, 576 U.S. 350, 359 (2015) (“[A patent] confers upon the patentee an exclusive property in the patented invention . . .”) (alterations in original).

psychedelics. Where an invention relates to medicinal plants (or their naturally occurring chemical components) used by indigenous communities for hundreds or thousands of years, a possibility exists that a patent grant could cover an ancient practice *or* prohibit modern adaptation of ancient rites. Therefore, an acute fear exists that issuance of patents pertaining to medicinal plants used by indigenous communities—such as psilocybin mushrooms, peyote, ayahuasca—or patents pertaining to use of the molecular compounds, such as psilocybin, mescaline, or DMT, will impose a barrier to the free exercise of religion of indigenous peoples.

This fear is significant because American law places immense value on both religious freedom and intellectual property. Each is given particular treatment in the Constitution.¹³⁴ Yet, the interplay between the two has seldom been considered—each is conceived as operating within a separate and distinct sphere of society. Religious freedom concerns private worship practices, typically ones that have a long history and are noncommercial; while intellectual property concerns the latest technological advancements, frequently for use in a commercial setting. This is particularly true of patent law, which by its nature requires a novel invention.¹³⁵ Today, as the psychedelic industry draws inspiration from the religious practices of indigenous peoples, these two spheres overlap in ways seldom previously considered.

Consequently, there is no guidance on what, if any, religious rights a person has to justify patent infringement. The First Amendment to the Constitution, of course, provides that “Congress shall make no law respecting an establishment of religion, or prohibiting the free exercise thereof . . .”¹³⁶ Due to the historic suppression of indigenous peoples’ religions, specific laws have been enacted to address religious freedom for indigenous peoples. This includes laws that specifically address the right of indigenous peoples to use psychedelics as a religious sacrament. In particular, the AIRFA Amendments forbid state and federal governments from prohibiting the use, possession, or transportation of peyote by members of federally-recognized Indian Tribes in connection with the practice of a “traditional Indian religion.”¹³⁷ The RFRA provides that the federal government “shall not substantially burden a person’s exercise of religion even if the burden results from a rule of general applicability,” except if the government demonstrates that application of the burden to the person “(1) is in furtherance of a compelling governmental

134. U.S. CONST., art. I, § 8; U.S. CONST. amend. I.

135. 35 U.S.C. § 102.

136. U.S. CONST. amend. I.

137. 42 U.S.C. § 1996a(b).

interest; and (2) is the least restrictive means of furthering that compelling governmental interest.”¹³⁸

This law has been applied to prevent the federal government from banning the importation of ayahuasca.¹³⁹ All of these laws are drawn in terms of providing a negative right—the government has a duty to avoid action that prohibits the free exercise of religion, prohibits use, possession, or transportation of peyote, or that substantially burdens religion. The United States has not recognized that indigenous people have a positive right that requires the government to ensure the survival of their religious practices.

When religious practices come into conflict with property rights, property rights have often prevailed. For instance, in *Lying v. Northwest Indian Cemetery Protective Association*, a Native American organization, individual Native Americans, and others, challenged the decision of the U.S. Forest Service to build a paved road and allow timber harvesting near a sacred site.¹⁴⁰ The Supreme Court held that the First Amendment’s promise of free exercise was not even implicated because the land at issue was federal land, and therefore the government’s decisions regarding its use was an “internal affair[]” and not action that “penalize[d] religious activity by denying any person an equal share of the rights, benefits, and privileges enjoyed by other citizens.”¹⁴¹

Likewise, it could be held that the decision to grant a patent concerning psychedelics is not a decision designed to “penalize religious activity” at all but is simply a secular recognition of property rights. Indeed, in the analogous context of trademark law, courts have recognized that they may properly adjudicate the right to use a religious mark so long as they rely on “secular principles of property.”¹⁴²

IV. CURRENT PROPOSALS TO RESOLVE TENSION BETWEEN INTELLECTUAL PROPERTY LAWS AND RELIGIOUS FREEDOM FOCUS ON ENHANCING ACCURACY OF PATENT OFFICE DECISIONS

The concern that an outsider would co-opt existing inventions of indigenous people and then monopolize them through intellectual property laws is not new. International discussions on the rights of indigenous peoples

138. 42 U.S.C. § 2000bb-1.

139. *Gonzalez v. O Centro Espirita Beneficente Uniao do Vegetal*, 546 U.S. 418, 428–39 (2006).

140. 485 U.S. 439, 442–43 (1988).

141. *Id.* at 449.

142. *Maktab Tarighe Oveyssi Shah Maghsoudi, Inc. v. Kianfar*, 179 F.3d 1244, 1249 (9th Cir. 1999).

have long recognized the existence of “traditional knowledge.”¹⁴³ No single definition of “traditional knowledge” exists but it is defined by the WIPO Intergovernmental Committee on Intellectual Property and Genetic Resources, Traditional Knowledge and Folklore (IGC) as

the content or substance of knowledge that is the result of intellectual activity and insight in a traditional context, and includes the know-how, skills, innovations, practices and learning that form part of traditional knowledge systems, and knowledge that is embodied in the traditional lifestyle of a community or people, or is contained in codified knowledge systems passed between generations. It is not limited to any technical field, and may include agricultural, environmental and medicinal knowledge, and knowledge associated with genetic resources.¹⁴⁴

The discussions concerning “traditional knowledge” have also recognized the need to protect such knowledge from so-called “biopiracy.” Biopiracy is the exploitation of traditional knowledge, such as through patenting inventions based on traditional knowledge without the consent of knowledge holders or payment of compensation.¹⁴⁵

The patent system theoretically has built-in guardrails to protect against direct biopiracy: patents are required by statute to be novel (that is, a new invention, not a pre-existing invention of others) and nonobvious.¹⁴⁶ Indeed, in an error-free world, a patent should never cover pre-existing traditional knowledge, especially a religious practice that dates back millennia, because that patent would not be novel. However, there are several infamous examples where errors in patent examination led to the patenting of traditional knowledge. One such example is a 1995 patent that was granted on the use of turmeric for wound healing.¹⁴⁷ That use of turmeric, however, was not novel in 1995. People in India have been using turmeric to heal wounds for centuries, and such use constitutes traditional knowledge in India.¹⁴⁸ India’s Council of Scientific and Industrial Research challenged the patent, and submitted prior art references in languages such as Sanskrit, Urdu, and Hindi concerning the

143. See Erstling, *supra* note 9, 296 (2009).

144. *Id.* at 295, 296.

145. *Id.* at 300.

146. 35 U.S.C. §§ 102,103.

147. U.S. Patent No. 5,401,504 (filed Mar. 28, 1995); K.S. Jayaraman, *US Patent Office Withdraws Patent on Indian Herb*, 389 NATURE 6 (1997).

148. Jayaraman, *supra* note 147.

traditional medicinal uses of turmeric.¹⁴⁹ After re-examination of the patent, the USPTO rejected all its claims as obvious and anticipated by that prior art.¹⁵⁰ As another example concerning traditional knowledge from India, it has been known for millennia in India that the neem tree is a source of medicine that can be used as insect repellent.¹⁵¹ A company filed patent applications covering an oil extract of the neem tree for use as an insecticide and fungicide.¹⁵² The patent was rejected in the European Union but upheld in the United States and New Zealand.¹⁵³

In response to these well-publicized failures of Western patent systems to prevent the patenting of traditional knowledge, scholars and the WIPO have advocated for the adoption of “traditional knowledge repositories.”¹⁵⁴ Patent examiners often lack access to traditional knowledge. This lack of access may be due to language barriers,¹⁵⁵ or because traditional knowledge is often described in sources unfamiliar to a patent examiner, such as historical texts or anthropological works, as opposed to prior patent applications and the general scientific literature routinely searched by patent offices.¹⁵⁶ Another obstacle to access is that traditional knowledge may not be described in writing at all, but may instead exist in an unrecorded oral tradition.¹⁵⁷ A potential solution to prevent patenting of traditional knowledge is to create prior art repositories that contain translations and transcriptions of works describing traditional knowledge.¹⁵⁸ This proposal has been implemented in India, where an online repository—known as the Traditional Knowledge Digital Library—was created to translate traditional knowledge into international languages familiar

149. Anusree Bhowmick, Smaranika Deb Roy & Mitu De, A Brief Review on the Turmeric Patents Case with its Implication on the Documentation of Traditional Knowledge, 1 NDC E-BIOS 83, 86 (2021), <https://www.ndcebios.in/v1n1/2021010110.pdf>.

150. *Id.*

151. Eiland, *supra* note 10, at 62.

152. *Id.*

153. *Id.* at 62–64.

154. *Id.* at 65; see generally Erstling, *supra* note 9; *Recognition of Traditional Knowledge Within the Patent System*, WIPO, Intergovernmental Committee on Intellectual Property and Genetic Resources, Traditional Knowledge and Folklore, Thirteenth Session, WIPO/GRTKF/IC/13/7 (Oct. 13–17, 2008).

155. See Erstling, *supra* note 9, at 320 (noting that Indian Traditional Knowledge Digital Library includes translations of references into languages understood by patent examiners and also contemporary names of medicinal plants, diseases, and processes).

156. *Recognition of Traditional Knowledge Within the Patent System*, *supra* note 154, at 20.

157. Javier Garcia, *Fighting Biopiracy: The Legislative Protection of Traditional Knowledge*, 18 BERKELEY LA RAZA L.J. 5, 6, n.8 (2007).

158. See generally Erstling, *supra* note 9; *Recognition of Traditional Knowledge Within the Patent System*, *supra* note 154; Eiland, *supra* note 10, at 65.

to patent examiners.¹⁵⁹ Several other countries (such as Finland, New Zealand, Peru, the Philippines, South Korea, South Africa, and Venezuela) have adopted traditional knowledge repositories of some kind.¹⁶⁰

Indigenous religious rites using sacramental psychedelics are a subspecies of traditional knowledge: these religious rites include knowledge on how to harness the power of potent plant medicines. Therefore, one proposed solution to strike a balance between intellectual property rights, such as patents, and religious freedom is to create repositories of traditional uses of psychedelics.¹⁶¹ Repositories may alleviate some concerns about direct attempts to copy indigenous religious ceremonies known in the literature. This is particularly true for existing descriptions of indigenous religious practices that are not in scientific literature generally searched by patent examiners. However, for practitioners of religious ceremonies—which may involve an element of secrecy and have survived despite a long history of attempted suppression—the proposal to deposit details of the use of psychedelic plants in a searchable, and potentially public,¹⁶² database is not inviting.

Indeed, repositories have several limitations. One previously discussed limitation is that repositories burden indigenous communities with the obligation (and associated costs) of cataloging their traditional knowledge.¹⁶³ Another limitation of repositories is that they are intended for “traditional knowledge” generally, and not religious practices specifically. As discussed below, religious freedom includes additional considerations for which addressing patent validity alone is insufficient. Repositories do not address the problem of how to weigh conflicting rights where a properly granted patent prevents religious free exercise. Proper weighing of that conflict requires providing a defense to infringement for indigenous religions, in addition to increasing accuracy of patenting decisions.

V. FOCUS ON PATENT VALIDITY ALONE IS INSUFFICIENT—A DEFENSE TO INFRINGEMENT FOR

159. *About the Traditional Knowledge Digital Library*, WIPO, https://www.wipo.int/meetings/en/2011/wipo_tkdl_del_11/about_tkdl.html (last visited Aug. 4, 2023).

160. *Online Databases and Registries of Traditional Knowledge and Genetic Resources*, *supra* note 8, (listing WIPO members states with databases for traditional knowledge and genetic resources and showing United States has only adopted databases concerning genetic resources, not traditional knowledge).

161. Marks & Cohen, *supra* note 3, at 231–32.

162. Erstling, *supra* note 9, at 318.

163. *Id.*

TRADITIONAL SACRAMENT USE OF PSYCHEDELICS SHOULD BE RECOGNIZED

A claim for patent infringement requires both that a patent be valid and that a patent be infringed.¹⁶⁴ While repositories are valuable in addressing validity, repositories do not address the issue of infringement. Other proposals such as tightening of patentability requirements also address validity alone.¹⁶⁵ One proposal that does address infringement is for patent owners to make voluntary “pledges” not to assert patents against certain people or communities.¹⁶⁶ Whether these “pledges” are binding is untested, and these “pledges” are voluntary in any event. Therefore, a more robust defense to infringement for indigenous communities making religious use of psychedelics is needed.

The lack of proposals concerning the infringement half of the analysis may be because at first blush it seems contradictory that a newly granted patent could be used to prevent practice of age-old religions, such as those of indigenous peoples of the Americas. However, there is an appreciable risk that existing indigenous religious practices could be found to infringe valid psychedelic patents for at least three reasons: (1) the belief systems of indigenous peoples may prevent their religious rites from qualifying as “prior art” for patents, (2) evidentiary requirements for “prior art” may make it difficult to prove indigenous religious rites are “prior art” even if they are, and (3) market forces may force substitution of patented technology for non-patented technology in religious rites.

A. INDIGENOUS RELIGIOUS PRACTICES MAY NOT QUALIFY AS “PRIOR ART” DUE TO RELIGIOUS BELIEFS CONCERNING THOSE PRACTICES

The religious requirements of indigenous religions themselves create a risk that patents could be granted covering those rites. Patent law generally does not permit a secret inventor to obtain patent protection.¹⁶⁷ Part of the policy rationale for patent laws is a *quid pro quo*—an inventor discloses his or her invention to the world and in exchange, receives a limited duration

164. *See, e.g.,* Five Star Mfg., Inc. v. Ramp Lite Mfg., Inc., 14 F. Supp. 2d 1228, 1231 (D. Kan. 1998) (“The two necessary elements to the patent infringement claim are (1) the validity of the patent, and (2) the infringement of the patent.”).

165. Marks & Cohen, *supra* note 3, at 232.

166. *Id.* at 232–33.

167. Instead, industrial secrets obtain intellectual property protection through trade secrets law. Trade secrets law, however, does not protect religious rites, as its protection is limited to information with “economic value.” UNIF. TRADE SECRETS ACT § 1(4)(i) (UNIF. L. COMM’N 2000).

monopoly.¹⁶⁸ Whether a patent should be issued or not turns on the content of the “prior art”—that is, whether the invention was previously disclosed to the public, or is obvious in light of what was previously disclosed to the public.¹⁶⁹ The Patent Act (as amended by the America Invents Act of 2011 (AIA)), currently provides that

A person shall be entitled to a patent unless—(1) the claimed invention was patented, described in a printed publication, or in public use, on sale, or otherwise available to the public before the effective filing date of the claimed invention.¹⁷⁰

None of these categories of prior art cleanly apply to indigenous religious practices.

The first category of prior art—other patents—is frequently the type of art cited by patent examiners.¹⁷¹ It is also inapplicable to indigenous religions—indigenous communities have not sought patent protection on their practices, and likely would not want to make a public disclosure of their religious practices due to the confidentiality considerations discussed above with respect to traditional knowledge repositories.

The next category of prior art—described in a printed publication—is unlikely to apply to many indigenous religious practices due to cultural norms around secrecy. The requirement of secrecy of indigenous religious practices is well-documented.¹⁷² These established secrecy requirements have led to several administrative accommodations, such as permitting Native Americans to omit information about religious practices when applying for eagle feathers

168. “Patent monopolies are granted in order to stimulate invention of useful devices, protect investments required to produce invention, and encourage the disclosure of trade secrets.” 1 DONALD S. CHISUM, 1A CHISUM ON PATENTS § 3.01 (2023); *see also* W.L. Gore & Assocs. v. Garlock, Inc., 721 F.3d 1540, 1550 (Fed. Cir. 1983) (“Early public disclosure is a linchpin of the patent system.”).

169. 35 U.S.C. §§ 102,103.

170. 35 U.S.C. § 102(a).

171. James Yang, *What is Prior Art?*, OC Patent Lawyer (June 25, 2022), <https://ocpatentlawyer.com/what-is-prior-art/> (“Patents and pre-grant publications are the most common types of prior art.”).

172. *See* Jody Neal-Post, *Sacred Sites and Federal Land Management: An Analysis of the Proposed Native American Free Exercise of Religion Act of 1993*, 34 NAT. RESOURCES J. 443, 461 (1994) (“Certain Native American religious traditions prohibit disclosure of information relating to their beliefs and practices.”); *see also* Glen Stoht, *The Repercussions of Orality in Federal Indian Law*, 31 ARIZ. ST. L.J. 679, 680 (1999) (“[T]he use of Native American or anthropological experts is fraught with difficulties, including the common situation in which sacred knowledge is secret and may not be shared with non-tribal members.”); Connie Rogers, *Native American Consultation in Resource Development on Federal Lands*, 31 COLO. L. (Jan. 2002), at 113 (“for both protective and religious reasons, Native Americans usually have a profound need for secrecy about their beliefs and sacred sites.”).

for religious use or to withhold information concerning religious and cultural properties during tribal-federal consultations under the National Historic Preservation Act.¹⁷³ Moreover, even where the ceremonial procedures of indigenous religions are well-documented by social scientists—as is the case for the Native American Church¹⁷⁴—the level of generality of the description may be insufficient to invalidate new psychedelic patents.

The threshold for being “described in a printed publication” is high: “each and every element of the claimed invention’ must be disclosed either explicitly or inherently, and the elements must be ‘arranged or combined in the same way as in the claim.’”¹⁷⁵ Therefore, the law is intrinsically biased in favor of prior patents and applications, rather than social science sources, because patents are required to include a written description of the invention,¹⁷⁶ and are therefore more likely to meet the bar of disclosing each element of a claimed invention. In contrast, social science sources are likely to focus on elements of cultural interest (song, language, etc.), and may gloss over the elements of a ceremony that produce a result notable to medical science, such as the exact mechanism used to cure alcoholism or substance abuse.

The third category of prior art—public use—also may not apply to indigenous religious practices. Previously, “public use” was required to be “in this country,” but that language was eliminated by the AIA.¹⁷⁷ Other than the elimination of the territorial limitation, prior case law will likely inform the meaning of “public use” in the current statute.¹⁷⁸ Under such case law, the test for whether an invention was in “public use” prior to the patent application was “whether the purported use: (1) was accessible to the public; or (2) was commercially exploited.”¹⁷⁹ The Federal Circuit has further clarified that “[c]onsideration of public use includes analysis of, inter alia, the nature of and

173. U.S. Fish and Wildlife Service, *Eagle Parts for Native American Religious Purposes Permit Application*, <https://www.reginfo.gov/public/do/DownloadDocument?objectID=3384501> (permitting name of ceremony, required by regulation 50 C.F.R. § 22.22, to be omitted if providing name would violate religious beliefs); 36 C.F.R. § 800.4(a)(4); U.S. Department of Transportation, *Federal Highway Administration, Tribal Transportation*, <https://www.fhwa.dot.gov/tribal/topics/historic/tcqa.htm#:~:text=The%201992%20Amendments%20to%20the,on%20or%20off%20Tribal%20lands> (last visited Aug. 4, 2023).

174. See generally Stewart, *supra* note 5; LA BARRE, *supra* note 77.

175. MPEP (9th Edition Rev. July 2022) § 2152 (citing *In re Gleave*, 560 F.3d 1331, 1334 (Fed. Cir. 2009); *Eli Lilly & Co. v. Zenith Goldline Pharms., Inc.*, 471 F.3d 1369, 1375 (Fed. Cir. 2006); *Net MoneyIN, Inc. v. VeriSign, Inc.*, 545 F.3d 1359, 1371 (Fed. Cir. 2008); *In re Bond*, 910 F.2d 831, 832–33 (Fed. Cir. 1990)).

176. 35 U.S.C. § 112(a).

177. MPEP (9th ed. Rev. July 2022) § 2152.

178. *Id.*

179. *Am. Seating Co. v. USSC Grp., Inc.*, 514 F.3d 1262, 1267 (Fed. Cir. 2008).

public access to activities involving the invention; confidentiality obligations imposed upon observers; commercial exploitation; and the circumstances surrounding testing and experimentation.”¹⁸⁰

Under this standard, psychedelic patents that cover indigenous religious practices may be invalid as the religious practices were in “public use.” Indeed, the general public’s participation in ceremonies, especially South American ayahuasca ceremonies, has generated criticism for its commercialism and has been dubbed “psychedelic tourism.”¹⁸¹ Such ceremonies would likely be considered as “public use”—however, these ceremonies have also been criticized for their lack of authenticity as indigenous religious expression.¹⁸² More authentic religious ceremonies may be subject to stricter limitations on participation. For instance, ceremonies of the Native American Church are not open to the public but rather accessible only to members of federally-recognized Indian Tribes.¹⁸³ Similarly, Mazatec mushroom ceremonies—despite being the subject of Wasson’s well-known *Life* magazine article—are subject to confidentiality obligations (which Wasson breached).¹⁸⁴

The WIPO has expressed concern that such limitations may prevent traditional knowledge from being deemed in “public use.”¹⁸⁵ An important factor in the “public use” use analysis is the existence of confidentiality obligations.¹⁸⁶ Accordingly, to the extent that religious obligation requires confidentiality, the use is likely not “public.” Moreover, indigenous

180. *Id.*

181. Inti García Flores, Rosalía Acosta López & Sarai Piña Alcántara, *Niños Santos, Psilocybin Mushrooms and the Psychedelic Renaissance*, CHACRUNA (Nov. 12, 2020), https://chacruna.net/mazatec_mushroom_ceremony Psychedelic_tourism/ (discussing commercialization of Mazatec ceremony by inauthentic “neoshamans”).

182. *See id.* (discussing commercialization of Mazatec ceremony by inauthentic “neoshamans”).

183. *Peyote Way Church of God, Inc. v. Thornburgh*, 922 F.2d 1210, 1215–16 (5th Cir. 1991) (“We hold that the record conclusively demonstrates that NAC membership is limited to Native American members of federally recognized tribes who have at least 25% Native American ancestry . . .”).

184. Gerber et al., *supra* note 25 (discussing Mazatec secrecy requirements surrounding velada ceremony, persecution during Inquisition, and that secrecy requirements that were disregarded by Gordon Wasson for his LIFE article); *see also* Flores, et al., *supra* note 183 (noting that mushroom ceremony is secret and if it is not kept secret, the “ceremony is useless”).

185. *See, e.g.*, WIPO, Intergovernmental Committee on Intellectual Property and Genetic Resources, Traditional Knowledge and Folklore, *supra* note 153, at 24 (“Generally, information which is held confidential is not considered prior art. In the case of [traditional knowledge] the term ‘the public’ has been particularly scrutinized with respect to the question whether a teaching has been disclosed to ‘the public’ when it has been used in a traditional community, but not outside.”).

186. *Dey, L.P. v. Sunovion Pharms., Inc.*, 715 F.3d 1351, 1355 (Fed. Cir. 2013).

communities may not wish to argue that their religious practices are “public.” Wasson’s *Life* article is illustrative as to why. The use of psilocybin mushrooms in Mexico was the subject of violent suppression by the Spanish, and survived only by remaining hidden to outsiders.¹⁸⁷ After Wasson breached his secrecy obligations, the rush of outsiders to the Sierra Mazateca was so overwhelming that it altered the community and prompted retaliation against the leader of the ceremony in which Wasson had participated.¹⁸⁸ Indigenous communities would likely wish to enforce the confidentiality obligations that their religions impose where possible, and may reject the label of “public” for their ceremonies out of concern that it would comprise enforcement of confidentiality obligations.

Similar considerations exist for the so-called “on sale” category of prior art. The “on sale” bar requires that a product is the subject of a commercial offer for sale.¹⁸⁹ Despite growing concerns of psychedelic tourism (which, as discussed above, are largely for inauthentic versions of indigenous religious ceremonies),¹⁹⁰ a tenet of many indigenous religions using psychedelics continues to be that the religious experience is not for sale—a commercial exchange of psychedelics may be prohibited.¹⁹¹ In other instances, the religious experience may have some commercial elements—such as a culture of gift exchange¹⁹²—but it would be repugnant to religious practitioners to refer to this as being “on sale.” The cultural values of indigenous religions prohibit the

187. Kaleb R. Smith, Modeling the Flesh of God: Semantic Hyperpriming and the Teonancátl Cults of Mexico, 14 NEUROQUANTOLOGY 297, 298 (2016); Gerber et al., *supra* note 25, at 573.

188. Smith, *supra* note 187, at 299-300 (2016); Flores, et al., *supra* note 181.

189. Pfaff v. Wells Elecs., 525 U.S. 55, 67 (1998) (construing pre-AIA statute); *see also* Helsinn Healthcare S.A. v. Teva Pharms. USA, Inc., 139 S. Ct. 628, 630 (2019) (holding that “on sale” has the same meaning pre- and post-AIA).

190. Flores, et al., *supra* note 181; Carlos Suarez Alvarez, *Why You Will Never Get a Traditional Ayahuasca Treatment*, CHACRUNA (Aug. 10, 2017), <https://chacruna.net/you-will-never-get-traditional-ayahuasca-treatment/>.

191. Anna Lutkajtis, *Lost Saints: Desacralization, Spiritual Abuse, and Magic Mushrooms*, 14 FIELDWORK IN RELIGION 118, 130 (2020) (“[S]ome older, more traditional healers will not charge a fee for their services as they believe that if they accept money the mushrooms will not have a curative effect.”).

192. *See* Osiris Sinuhe Gonzalez Romero, *Maria Sabina, Mushrooms, and Colonial Extractivism*, CHACRUNA (May 27, 2021), <https://chacruna.net/maria-sabina-mushrooms-and-colonial-extractivism/> (noting that Maria Sabina did not charge a fixed amount of money for ceremonies with sacred mushrooms); Alvarez, *supra* note 190 (noting that traditionally an ayahuasca healer would receive food, work, merchandize, or money); Stewart, *supra* note 5, at 69 (noting that for a peyote ceremony there “was not a set fee, and payment was always viewed as a gift”).

use of traditional knowledge for profit or self-gain.¹⁹³ To view a gift provided for a religious purpose as commercial sale would be blasphemy.¹⁹⁴ Therefore, even if religious use of psychedelics could theoretically be said to have been “on sale,” indigenous religious communities may again resist such a classification for cultural reasons and purposefully forgo such argument.

The AIA recently added a final category of prior art—a “catch-all” that reads “otherwise available to the public.”¹⁹⁵ Due to the relative newness of this provision, little case law exists to elucidate its meaning. In considering the phrase’s impact on interpretation of the on-sale bar, the Supreme Court noted that the phrase “otherwise available to the public,” like other catch-all phrases, “captures material that does not fit neatly into the statute’s enumerated categories but is nevertheless meant to be covered.”¹⁹⁶ Accordingly, the meaning of the word “public” would likely be interpreted in a similar manner for this phrase—meaning that secrecy, confidentiality obligations, disclosure to non-members would likely weigh against finding prior technology was “otherwise available to the public.” Therefore, for all the reasons discussed above, a risk exists that indigenous religious practices could be found to not be “otherwise available to the public,” despite their continuous practice for hundreds or thousands of years.

B. EVEN IF INDIGENOUS RELIGIOUS PRACTICES ARE “PRIOR ART,”
EVIDENTIARY HURDLES TO PROVING INVALIDITY ARE HIGH

Moreover, even if indigenous psychedelic religious practices could be prior art—such as if they could qualify as in “public use,” or “on sale,” or “otherwise available to the public” due to their sustained use since time immemorial—evidentiary hurdles may make proving the *content* of these religious rites practically difficult. First, the threshold for proving patent invalidity is higher

193. Testimony of Jon Brady, Arikara MHA Nation, President Native American Church of N. Am., U.S. House of Representatives Committee on Appropriations, Subcommittee on Interior, Environment, and related Agencies, 118th Cong. 3 (2023) (statement of Jon Brady, President of Native American Church North America), <https://docs.house.gov/meetings/AP/AP06/20230309/115414/HHRG-118-AP06-Wstate-BradyJ-20230309.pdf>.

194. For example, Mazatec curandera Maria Sabina accepted voluntary donations for her ceremonies. Maria Sabina, *A Most Fascinating Mexican Healer*, FAENA ALEPH, <https://www.faena.com/aleph/maria-sabina-a-most-fascinating-mexican-healer> (last accessed Feb. 22, 2024). However, local residents of the Sierra Mazateca (along with tourists and anthropologist) may consider obtaining profit from psilocybin mushrooms as a “desecration.” Marcos García de Teresa, *Seeking a True Shaman in the Sierra Mazateca*, CHACRUNA (Mar. 8, 2021), <https://chacrana.net/mazatec-shaman-authenticity/>.

195. 35 U.S.C. § 102(a)(1); MPEP (9th ed. Rev. July 2022) § 2152.

196. *Helsinn Healthcare S.A. v. Teva Pharms. USA, Inc.*, 139 S. Ct. 628, 634 (2019) (holding that the phrase “otherwise available to the public” had no impact on the interpretation of the on-sale bar).

than for infringement. In litigation, patent invalidity must be proven by clear and convincing evidence.¹⁹⁷ Second, indigenous cultures often rely on oral tradition. Therefore, when religious practices are fully disclosed, such as to a member of the community for the express purpose of transmitting knowledge of the ceremonial rites, such disclosures are generally made orally rather than in writing.

This presents an evidentiary problem. Oral testimony alone is insufficient to invalidate a patent under the clear and convincing evidence standard required in court.¹⁹⁸ Indeed, the Federal Circuit has specifically noted that “uncorroborated oral testimony, particularly that of interested persons recalling long-past events, does not, of itself, provide the clear and convincing evidence.”¹⁹⁹ Instead, “oral testimony must be corroborated by some other evidence,” under a “rule of reason” analysis.²⁰⁰ The “rule of reason test” examines “all pertinent evidence . . . in order to determine whether [the oral testimony] is credible.”²⁰¹ The test places greater weight on contemporaneous documentary evidence.²⁰² However, as discussed above, indigenous religious practices are often transmitted orally, with confidentiality obligations imposed, and do not fit within the type of framework generally seen by courts in evaluating “clear and convincing” evidence of patent invalidity.

Indigenous religious practices do not come with user manuals, unlike the industrial devices for which patent laws were designed. Accordingly, due to these biases in the law, it is possible that a psychedelic patent could be issued that reads on an ancient indigenous religious practice. This is particularly true given the emergent nature of the field in the context of the patent office. Few patents have been issued concerning psychedelics. Prior patents and patent applications are the form of prior art most likely to be cited by patent examiners.²⁰³ Therefore, with few prior patents or applications, from the perspective of an examiner engaging in prior art searching, the field of psychedelics appears to be relatively open; there is little prior art from which patentees must distinguish their technologies in order to demonstrate the novelty of their inventions.

However, in truth, the field is crowded with the ancient practices of indigenous peoples, where knowledge is transmitted orally from one

197. *Microsoft Cop. v. i4i P’ship*, 564 U.S. 91, 95 (2011).

198. 1 DONALD S. CHISUM, 1A CHISUM ON PATENTS § 3.05 (2023).

199. *Woodland Trust v. Flowertree Nursery Inc.*, 148 F.3d 1368, 1369 (Fed. Cir. 1998).

200. *Transweb, LLC v. 3M Innovative Props. Co.*, 812 F.3d 1295, 1301 (Fed. Cir. 2016).

201. *Mosaic Brands, Inc. v. Ridge Wallet LLC*, 55 F.4th 1354, 1363 (Fed. Cir. 2022).

202. *Transweb, LLC v. 3M Innovative Props. Co.*, 812 F.3d 1295, 1301 (Fed. Cir. 2016).

203. Yang, *supra* note 171 (“Patents and pre-grant publications are the most common types of prior art.”).

practitioner to the next. For instance, the decision to grant a patent that broadly covers the use of psychedelics to treat substance abuse disorders or to improve mental health may not be erroneous in a technical sense, since no clear and convincing evidence admissible in a court of law exists to prove prior disclosure of the invention in patents, printed publications, public use, offer for sale, or other availability to the public. Nonetheless, such a patent could tread on the religious rites of indigenous peoples that have been used for a long time in a clandestine manner (secrecy that may itself have been compelled due to colonial suppression efforts). Therefore, addressing validity alone is insufficient, and an infringement defense for indigenous communities is required.

C. RELIGIOUS FREEDOM REQUIRES SOME ABILITY TO SUBSTITUTE NEW TECHNOLOGIES, AS MARKET FORCES FREQUENTLY FORCE SUCH SUBSTITUTION

An infringement defense is needed because the commercialization of psychedelics may force indigenous peoples to substitute modern versions of psychedelics into their religious practices, creating infringement via this substitution of the new for the ancient. History has demonstrated a pattern of indigenous peoples forced to adopt new or westernized versions of their own innovations. Consider, for instance, non-psychedelic medicinal plants used by indigenous peoples of the Americas such as tobacco or corn. Historically, indigenous people used a variety of wild plants from the tobacco family.²⁰⁴ Indigenous people also historically cultivated domestic maize of several varieties.²⁰⁵ Indigenous peoples often had religious beliefs, customs, and rituals that went along with their usage of the varieties of maize or tobacco.²⁰⁶

Today, tobacco and maize are commercial crops whose dominant production has interfered with Native American religious practices. About 202,000 acres of land in the United States is used for the commercial cultivation of tobacco.²⁰⁷ “[A]lmost all commercial production of tobacco” is

204. Alan Boyle, *Molecular Analysis Turns Up Unexpected Twist in Smoking Habits of Ancient Tribes*, GEEK WIRE (Oct. 29, 2018), [https://www.geekwire.com/2018/tobacco-smoking-habits-ancient-tribes/#:~:text=quadrivalvis%20\(Indian%20tobacco\)%20and%20N,ornamental%20plant%20for%20Northwest%20gardens\);](https://www.geekwire.com/2018/tobacco-smoking-habits-ancient-tribes/#:~:text=quadrivalvis%20(Indian%20tobacco)%20and%20N,ornamental%20plant%20for%20Northwest%20gardens);) Sojourner Ahebee, *Sacred Tobacco and American Indians, Tradition and Conflict*, WHYY (May 14, 2021), <https://whyy.org/segments/keep-it-sacred-smoking-indigenous-people-tradition-and-conflict/>; see also Spichak, *supra* note 6.

205. American Indian Health and Diet Project, *supra* note 15.

206. *Id.*; Dina Fine Maron, *The Fight to Keep Tobacco Sacred*, SCI. AM. (Mar. 29, 2018), <https://www.scientificamerican.com/article/the-fight-to-keep-tobacco-sacred/>.

207. *Area of Tobacco Harvested in the U.S. from 2001 to 2022 (in acres)*, STATISTA, <https://www.statista.com/statistics/192012/area-of-tobacco-harvested-in-the-us-since-2000/>

The fear, of course, is that a similar substitution process will take place with respect to the sacraments of indigenous religions. Patents require novelty, so several patent applications have already been submitted on synthetic versions of compounds found within sacramental plants used by indigenous peoples.²¹⁴ However, patent protection has already been granted for some sacramental plants. In 1986, a patent was granted under the Plant Patent Act, for a specific variety of *Banisteriopsis caapi*—a vine used to make ayahuasca.²¹⁵ A request for reexamination of this patent, which noted the religious use of the vine, was filed in 1999.²¹⁶ Ultimately, the USPTO found that the species of vine was entitled to patent protection, avoiding any discussion of religious use, and focusing on the ability to asexually reproduce the vine and its differing leaf size and shape from other varieties of the vine.²¹⁷ If the same were to happen with other species of ayahuasca, or other sacramental plants, such as mescaline, peyote, psilocybin mushrooms (or the alkaloids within them), it is possible that the dominant society's appetite for such plants would force indigenous communities to turn to substitutes, as corn and tobacco.²¹⁸

214. *See, e.g.*, N,N-Dimethyltryptamine and Related Psychedelics and Uses Thereof, Application Pub. No. US 2023/0212119 (filed Feb. 23, 2023) (relating to derivatives of DMT); Psilocybin and O-Acetylpsilocin, Salts and Solid State Forms Thereof, Application Pub. No. US 2023/0151036 (filed Dec. 28, 2022) (claiming crystalline forms of psilocybin); Mescaline for the Treatment of Substance Use Disorders, Application No. PCT/US2022/031423 (filed May 27, 2022); Mescaline Derivatives with Modified Action, Application Pub. No. US 2022/0267252 (filed Feb. 20, 2022) (discussing use of mescaline derivatives for use in substance-assisted therapy).

215. U.S. Patent No. Plant 5,751 (filed June 17, 1986); Marlan, *supra* note 1, at 864.

216. Detailed Statement in Support of Request for Reexamination of U.S. Plant Patent No. 5,751, <https://www.ciel.org/wp-content/uploads/2015/06/ReexaminationofUSPlantPatent5751.pdf>.

217. Notice of Intent to Issue Reexamination Certificate, https://www.ciel.org/wp-content/uploads/2015/06/PTO_Examiner_Transcript.pdf.

218. A countervailing substitution effect could also occur. The current prohibition of psychedelics may motivate some to falsely claim religious beliefs in order to consume psychedelics for which religious exemptions to the drug laws currently exist. *See* LA BARRE, *supra* note 78, at xiii (discussing “Neo-American Church” making use of mescaline under false guise of religion). If psychedelics were legalized, such users may abandon pretext and simply consume potent synthetic psychedelics, like LSD, outside of a religious context, leaving greater supply for religious users. However, the history of religious use by indigenous peoples is part of the allure of some psychedelics to the non-indigenous user. For instance, author Carlos Castañeda wrote several books falsely claiming to have been taught indigenous knowledge regarding peyote. LA BARRE, *supra* note 77, at 270-75, 307-08. This is part of a broader, and well-documented, phenomenon of “playing Indian.” *See, e.g.*, Arlene Hirschfelder and Paulette F. Molin, *I is for Ignoble: Stereotyping Native Americans*, JIM CROW MUSEUM OF RACIST IMAGERY (Feb. 22, 2018), <https://jimcrowmuseum.ferris.edu/native/homepage.htm>. It is thus my opinion that the magnitude of substitution away from sacramental psychedelic plants is likely to be small compared to those that would seek out psychedelic plants due to their history of

This concern is heightened by the current widespread interest in psychedelics by the dominant society. Oregon, Colorado, and many cities have decriminalized psychedelics. The potential use of psychedelics to treat mental health disorders has entered popular culture. For example, author Michael Pollan created a Netflix series based on his novel *How to Change Your Mind*, which details the use of psychedelics.²¹⁹ In June 2023, an estimated 12,000 people attended the Multidisciplinary Association for Psychedelic Studies (MAPS) conference in Denver, Colorado—the largest psychedelics conference ever.²²⁰ If, as it appears may be the case, psychedelics are legalized, the market demand for psychedelics could be astronomical. The obvious market incentive, therefore, will be to dedicate habitat for psychedelic plants, not to the pre-existing wild varieties of plants, but instead to patented products with high profit margins. The familiar result will be the dominance of newer varieties of plants to the detriment of the heirloom varieties used for religious practices. Shrinking habitat and waning availability will then necessitate (again) substitution towards commodified and potentially patented protected versions of sacramental plants in order to sustain the practice of indigenous religions.

This concern is particularly pronounced for peyote, for which habitat pressures have existed for years. In the United States, peyote grows only in a small area of South Texas.²²¹ The local economy in that region includes cattle and energy, both of which pose threats to peyote plants. Root plowing for cattle grazing is the largest threat to peyote plants currently.²²² Energy development from both oil exploration and wind energy necessitates road infrastructure and energy pads that further contribute to the loss of peyote habitat.²²³ The limited habitat for peyote raises substantial concern that commercialization of patented varieties of peyote will lead to dedication of this habitat to these patented varieties. This result would force the Native

religious use. Indeed, La Barre observed that Castañeda's books caused an increase of peyote poaching, to the detriment of supply to the Native American Church. LA BARRE, *supra* note 77, at 290.

219. *How to Change Your Mind* (Netflix 2022).

220. Alejandro A. Alonso Galva & Jenna McMurtry, "Psychedelics is About Healing": Thousands Gather in Denver for Largest Psychedelic Conference to Date, CPR NEWS (June 25, 2023), <https://www.cpr.org/2023/06/25/denver-psychedelic-mushrooms-conference-health-and-policy/>.

221. Stewart, *supra* note 5, at 10, map 2; *id.* at 15, map 3.

222. *Known Challenges to Lophophora*, CACTUS CONSERVATION INST., <https://www.cactusconservation.org/CCI/ch/hi.html> (June 17, 2018); Alexander Lekhtman, *National Indigenous Church Urges Congress to Protect Peyote Habitat*, FILTER (Sept. 20, 2022), <https://filtermag.org/indigenous-church-protect-peyote/>.

223. *Lophophora Williamsii*, NATURESERVE EXPLORER (Oct. 7, 2020), https://explorer.natureserve.org/Taxon/ELEMENT_GLOBAL.2.139920/Lophophora_williamsii.

American Church to substitute these newer varieties to continue practicing their religion.

Similar market dynamics could influence the decisions of practitioners of other indigenous religions. For instance, natural habitat for the ayahuasca vine or certain varieties of psilocybin mushrooms exist only outside the United States in Mexico, South, and Central America.²²⁴ Therefore, availability of these sacramental plants in the United States depends on domestic cultivation or importation. If these plants are commercialized, the preference in cultivation or importation for higher profit margin and patented varieties could limit the supply of traditional varieties domestically. Even in Mexico, the commercialization of the market for psilocybin mushrooms for tourists has contributed to shortages of mushroom sacrament.²²⁵ If traditional varieties of these religious sacraments are in short supply, the only means for indigenous people to continue to practice their religions will be to substitute patented varieties into their religious practices. However, using a patented invention is infringement—notwithstanding the prior use of a similar and unpatented plant variety. Accordingly, focus on patent validity alone is insufficient and must be augmented by infringement defenses for indigenous communities making use of psychedelic sacraments.

VI. THE PROPOSED “CEREMONIAL USE” DEFENSE

The religious freedom of indigenous communities is presently on a collision course with the attempts by the biotech industry to patent uses of psychedelics or patent varieties of psychedelics themselves. This is especially true as it concerns the use of psychedelics to combat alcoholism and other substance use disorders. It has been long observed that traditional indigenous religions had success in combating such disorders,²²⁶ and many of the pending psychedelic patents concerning the use of psychedelic-assisted psychotherapy also relate to treatment of such disorders.²²⁷ In resolving this collision of rights,

224. *See* O Centro Espirita Beneficiente Uniao Do Vegetal v. Ashcroft, 342 F.3d 1170, 1175 (10th Cir. 2003) (noting that plants in ayahuasca “do not grow in the United States” and therefore were “prepared in Brazil by Church officials and exported to the United States”); Anya Ermakova, *Psychoactive Mushrooms in Mexico: Overview of Ecology and Ethnomycology*, CHACRUNA (Nov. 12, 2021), <https://chacrana.net/psychoactive-mushrooms-in-mexico-overview-of-ecology-and-ethnomycology/> (noting that while some species of mushrooms are widespread, others are endemic only to Mexico with highly localized habitat).

225. Flores, et al., *supra* note 181.

226. JAY, *supra* note 2, at 208; Stewart, *supra* note 5, at 157, 220–21.

227. Mescaline for the Treatment of Substance Use Disorders, Application No. PCT/US2022/031423 (filed May 27, 2022); Novel N,N-Dimethyltryptamine Compositions and Methods, Application Pub. No. US2022/0339139 (filed Apr. 26, 2022) (discussing method of

courts (or Congress) should provide an infringement defense to indigenous communities making sacramental use of psychedelics. Indigenous communities need such a defense due to the shortcomings of focusing solely on patent validity for the reasons discussed above. This defense finds precedent in similar defenses for prior commercial users of patented inventions and the “shop rights” doctrine that allows employers to use inventions of their employees. Indeed, the social value placed on religious freedom is much weightier than either the interest in prior commercial users of an invention or the interests of an employer.

A. ELEMENTS OF DEFENSE

I have coined the “ceremonial use” defense to describe the defense to patent infringement based on prior religious use of psychedelics, acknowledging the ceremonial context in which psychedelics are used as a sacrament by indigenous peoples. The elements of such a defense are inspired by the “prior user rights” and “shop rights” defenses, discussed below, and are shaped to provide a narrow defense for authentic religious exercise of indigenous peoples. The elements of this defense should be:

1. Prior religious use of a plant;
2. Current use of a patented variety of that plant, patented method of cultivating that plant, patented variant of an alkaloid within that plant, or patented method of synthesizing an alkaloid within that plant; and
3. Other than substitution of patented plant varieties or alkaloids, substantial similarity between infringing use and prior religious practices.

The purpose of this defense is to ensure that patented uses of psychedelic plants, patented varieties of psychedelic plants or patented uses or versions of their alkaloids, do not prevent the free exercise of pre-existing religions.

Further contours of this defense are shaped by its inspirations—the “prior user rights” defense and “shop rights” doctrine. For example, the “prior user rights” defense for commercial uses is nontransferable, except with the

treating neurological diseases using DMTI); Antidepressant-Psilocybin Co-treatment to Assist Psychotherapy, Application Pub. No. US 2022/0387456 (filed Mar. 10, 2022); Mescaline Derivatives with Modified Action, Application Pub. No. US 2022/0267252 (filed Feb. 20, 2022) (discussing use of mescaline derivatives for use in substance-assisted therapy); Effects of Mescaline and of Mescaline Analogs (Scalines) to Assist Psychotherapy, Application Pub. No. US 2022/0265582 (filed Feb. 18, 2022); Methods and Systems for Enhancing Clinical Safety of Psychoactive Therapies, Application Pub. No. US 2023/0162851 (filed Mar. 9, 2021) (discussing methods and systems for enhancing clinical safety of psychoactive therapies, including psilocybin therapy).

transfer of an entire enterprise or line of business.²²⁸ Making the “ceremonial use” defense non-transferrable could reassure the biotech industry that their intellectual property will be protected. However, just as the “prior user rights defense” is transferrable in the case of an assignment of an entire line of business, the “ceremonial use” defense should be transferable in the case of a split of a church (or similar organization) or in the event that the ability to lead ceremonies is transferred from person to person in accordance with tribal customs, discussed further below.

B. PRECEDENTIAL JUSTIFICATION—PRIOR USER RIGHTS AND SHOP RIGHTS DOCTRINES

A “ceremonial use” defense is not currently recognized, but courts and Congress have both acted to recognize similar defenses in less compelling circumstances than religious free exercise—“prior user rights” and “shop rights.” One reason a “ceremonial use” defense is needed is to respect the confidentiality obligations attendant to indigenous religious practices. Congress has enacted a “prior user rights” defense for a similar reason—to provide a defense for businesses whose trade secrets are patented by others. A “ceremonial use” defense can also be justified to allow fairness and equity—scientific research into psychedelics was inspired by ceremonial uses in the first place, and it would be inequitable to allow patents to deprive society of the continued ceremonial use of psychedelics. Fairness is the base justification is for the judicially-created “shop rights” doctrine. And, just as the “shop rights” doctrine allows employers to use inventions created by their employees using the employer’s resources, the “ceremonial use” defense would allow indigenous communities to use the inventions created by psychedelic researchers drawing on traditional knowledge and use of psychedelics for inspiration.

The “prior user rights” doctrine owes its genesis in the United States to the Federal Circuit’s 1998 decision in *State Street Bank & Trust v. Signature Financial Group*.²²⁹ In that case, the Federal Circuit held that no “business method” exception exists for patentable subject matter.²³⁰ This holding raised a concern because many business methods are maintained as trade secrets: what if a competitor properly obtained a patent on a method previously used

228. 35 U.S.C. § 273(e)(1).

229. 149 F.3d 1368, 1375–77 (Fed. Cir. 1998).

230. *Id.*

in secret by another?²³¹ In response to such concerns, Congress created the “prior user rights” defense in 1999.²³²

Later, the AIA was passed into law and the United States moved from a first-to-invent system to a first-to-file system—again raising the specter of the unjust outcome of a person infringing a patent by merely continuing to use their own previously used but undisclosed invention.²³³ Accordingly, Congress again acted to expand the “prior user rights” defense beyond business methods. The current iteration of the “prior user rights” defense is as follows:

A person shall be entitled to a defense under section 282(b) with respect to subject matter consisting of a process, or consisting of a machine, manufacture, or composition of matter used in a manufacturing or other commercial process, that would otherwise infringe a claimed invention being asserted against the person if—

(1) such person, acting in good faith, commercially used the subject matter in the United States, either in connection with an internal commercial use or an actual arm’s length sale or other arm’s length commercial transfer of a useful end result of such commercial use; and

(2) such commercial use occurred at least 1 year before the earlier of either—

(A) the effective filing date of the claimed invention; or

(B) the date on which the claimed invention was disclosed to the public in a manner that qualified for the exception from prior art under section 102(b).²³⁴

The statute may not apply to indigenous religious practices due to its limitation to “commercial” uses. Nonetheless, it is an important confirmation that good policy, equity, and fairness require that continued secret uses are a defense to allegations of patent infringement. Therefore, to address concerns about the confidentiality requirements, as well as other reasons that indigenous religious practices may not qualify as “prior art” under the Patent Act, such as oral transmission and closure to the public, this defense should be extended from the commercial context to the religious context in the form of the “ceremonial use” defense.

231. Aleksey Khamin, *America Invents Act’s Prior User Defense: Lessons from Global Patent Regimes and Legislative History*, 15 U. PITT. J. TECH. L. POL’Y 132, 143 (2015).

232. *Id.*; Patrick M. Boucher & Daniel J. Sherwinter, *The America Invents Act*, 41 COLO. LAW.1,47, 54 (2012).

233. Khamin, *supra* note 231, at 146–47.

234. 35 U.S.C. § 273(a).

A “ceremonial use” defense that permits continued religious use of psychedelics (which are still patentable because prior religious use was in secret) is important. However, the “ceremonial use” defense should go further to permit ceremonial use of patented psychedelics that are novel. Permitting use of novel versions of psychedelics is important to account for the potential coerced substitution of these psychedelics due to market forces. As discussed above, history has already shown that profit-incentives cause land-use to shift toward commercial varieties of plants with ceremonial uses. Particularly given the limited (as in the case of peyote) or remote (as in the case of ayahuasca) habitat for psychedelics, a real threat exists that the burgeoning psychedelics industry will shift production to patented psychedelics at the expense of access of indigenous communities.

Allowing royalty-free religious production and use of patented psychedelics has existing analogies in the law. Under the judicially-created “shop rights” doctrine, an employer has a defense to an infringement action brought by an employee in certain circumstances.²³⁵ The exact rationale behind the “shop rights” doctrine is a bit elusive, but courts have reiterated that the doctrine is motivated by equity and fairness.²³⁶ Courts recognize that it is inequitable for an employee to use the resources of their employer to test and develop an invention without providing rights to the employer to use that same invention.²³⁷

The same rationale can be extended to indigenous peoples’ religious use of psychedelics. Their religious use of psychedelics has inspired an entire “renaissance.” It was the use of peyote by indigenous peoples that led to the first ever scientific study of a psychedelic—mescaline.²³⁸ Mescaline further inspired scientific exploration of LSD once the similarity of psychoactive

235. *Exela Pharma Scis., LLC v. Lee*, 781 F.3d 1349, 1356 (Fed. Cir. 2015) (noting judicially created); *McElmurry v. Ark. Power & Light Co.*, 995 F.2d 1576, 1580–82 (explaining doctrine).

236. *McElmurry*, 995 F.2d at 1580–82; *see also* 1 DONALD S. CHISUM, 1A CHISUM ON PATENTS § 22.03 (2023) (“the equity basis is probably a more accurate description of what the courts actually do, to wit, make a case by case determination of whether it is fair for the employee to have all rights, given the parties’ respective contributions to the conception, reduction to practice, and commercial development of the idea.”).

237. *See United States v. Dubilier Condenser Corp.*, 289 U.S. 178 (1933) (“[Under the shop rights doctrine] where a servant, during his hours of employment, working with his master’s materials and appliances, conceives and perfects an invention for which he obtains a patent, he must accord his master a nonexclusive right to practice the invention. . . . This is an application of equitable principles. Since the servant uses his master’s time, facilities, and materials to attain a concrete result, the latter is in equity entitled to use that which embodies his own property and to duplicate it as often as he may find occasion to employ similar appliances in his business.”).

238. *JAY*, *supra* note 2, at 74–88, 98–100.

effects between the two was discovered.²³⁹ The Native American Church's use of peyote to cure alcoholism further inspired the current research into psychedelics for substance abuse disorders.²⁴⁰ Mescaline further inspired experimentation with other psychedelics such as MDMA, which the FDA could soon approve as a treatment for post-traumatic stress disorder.²⁴¹ Use of cohoba and ayahuasca further inspired the scientific community's interest in DMT.²⁴² Strassman, who revived government-funded research into psychedelics after two decades of inactivity, acknowledges the impact of sacramental use by indigenous peoples: "New World aboriginal people used, and continue to use, a wide range of mind-altering plants and mushrooms. Most of what we know about psychedelics comes from investigating chemicals first found in Western Hemisphere materials: DMT, psilocybin, mescaline, and several LSD-like compounds."²⁴³ And, many of the patent applications recently filed regarding also acknowledge the contributions of indigenous peoples.²⁴⁴

In such circumstances, fairness and equity demand that indigenous peoples be able to share in the benefits of the scientific advancements they themselves inspired. Indeed, non-indigenous usage of psychedelics has already impacted indigenous religious practices. For example, since the 1960s, tourists have flocked to the Sierra Mazateca, disrupting the Mazatec community and altering religious practices.²⁴⁵ In South America, ayahuasca tourism led to an increasing mestizo impact on indigenous traditions.²⁴⁶ Similarly, after peyote reached mainstream popularity (due in part to writers such as Carlos Castañeda touting its use), psychedelic tourists flocked to Texas looking for peyote.²⁴⁷ The resulting trespass by these tourists led to stricter laws concerning peyote that were enforced against Native American Church members, largely ending their

239. *Id.* at 189.

240. *Id.* at 208.

241. *Id.* at 243–45; Brown, *supra* note 25.

242. Strassman, *supra* note 2, at 44–45, 349 n.11; Levy, *supra* note 111.

243. Strassman, *supra* note 2, at 22.

244. *See, e.g.*, Novel N,N-Dimethyltryptamine Compositions and Methods, Application Pub. No. US2022/0339139 (filed Apr. 26, 2022) at [0004] (noting that naturally occurring psychedelics "have been used for centuries by indigenous cultures in ritualistic or sociocultural context, and in the context of religious sacraments"); Effects of Mescaline and of Mescaline Analogs (Scalines) to Assist Psychotherapy, Application Pub. No. US 2022/0265582 (filed Feb. 18, 2022) at [0080] ("Indigenous tribes across northern and southern parts of America have used mescaline for centuries for ethnomedical purposes."). Troublingly, not all patents on psychedelics acknowledge the contributions of indigenous peoples to the art.

245. Flores, et al., *supra* note 181.

246. Xavier Francuski, *The "Traditional" Ayahuasca Ceremony is Probably a Recent Invention*, KAHPI (Mar. 22, 2019), <https://kahpi.net/traditional-ayahuasca-ceremony-recent-invention/>.

247. LA BARRE, *supra* note 77, at 290.

ability to find peyote in the wild and forcing them to purchase from DEA-licensed dealers.²⁴⁸

Notably, the proposal for a “ceremonial use” defense is modest compared to other alternatives, such as providing a property right for indigenous communities in their traditional knowledge.²⁴⁹ Some scholars have advocated for a property right in traditional knowledge, which would enable indigenous communities to prevent use of their traditional knowledge and potentially eliminating the ability of others to innovate based on indigenous knowledge altogether.²⁵⁰ In this case, such innovations would include novel synthesis of mescaline, DMT, or psilocybin. Indeed, the Native American Church of North America has taken the position that mescaline is a “heritage molecule” that is being appropriated by the pharmaceutical industry.²⁵¹ However, the “ceremonial use defense,” like the “shop rights” doctrine, is not a property right entitling the owner to exclude others, but rather an affirmative defense to infringement. Just as the employer whose materials, tools, and workspace formed the building blocks of an inventor’s innovation receives an affirmative defense to infringement of a resulting patent,²⁵² so too should indigenous communities—whose traditional knowledge have formed the building blocks for later innovation in the science of psychedelics—receive an affirmative defense to infringement of resulting psychedelic patents.

Patenting of psychedelics will certainly impact indigenous communities in unforeseen ways. At a minimum, it will likely cause a shift of production to patented psychedelics for commercial purposes. To ensure that the religious practices of indigenous communities are not prohibited by patents, an

248. *Id.*

249. This is not to be construed as opposition to such alternatives, on which I take no position.

250. See, e.g., J. Janewa OseiTutu, *A Sui Generis Regime for Traditional Knowledge: The Cultural Divide in Intellectual Property Law*, 15 MARQ. INTELL. PROP. L. REV. 147, 154-55 (2011) (discussing proposal for sui generis regime to protect traditional knowledge that would include others from making use of intergenerational knowledge without consent); Gregory Younging, *Traditional Knowledge Exists; Intellectual Property Is Invented or Created*, 36 U. PA. J. INT’L L. 1077, 1083-85 (2015) (criticizing Western intellectual property system’s placement of traditional knowledge in public domain where it can be used in violation of indigenous customary law); Eliana Torelly de Carvalho, *Protection of Traditional Biodiversity-Related Knowledge: Analysis of Proposals for the Adoption of a Sui Generis System*, 11 MO. ENVTL. L. & POL’Y REV. 38, 63 (2003) (noting proposals for perpetual property right on innovations derived from traditional knowledge and arguing such proposals are overly broad).

251. Annette McGivney, *Peyote is the Darling of the Psychedelics Renaissance. Indigenous Users Say it Co-opts a “Sacred Way of Life,”* GUARDIAN (Dec. 19, 2023), <https://www.theguardian.com/us-news/2023/dec/19/indigenous-communities-protecting-psychedelics-peyote-corporations>.

252. *McElmurry v. Arkansas Power & Light Co.*, 995 F.2d 1576, 1582 (Fed. Cir. 1993).

infringement defense must be recognized. Indeed, given that religious freedom is at issue, the rationale for such a defense is much higher than for the “shop rights” doctrine. The interests of an employer in the inventions of an employee are nowhere near as compelling as the needs of indigenous communities to continue their religious practices. This is particularly true given that these religions have already been subject historically to suppression efforts. For this reason, international conversations are already underway regarding the rights of indigenous peoples to “benefit sharing” for the use by the dominant society of their traditional knowledge.²⁵³ At minimum, a “benefit” that indigenous peoples should enjoy is to be able to continue their religious practices without threat of patent infringement.

C. OWNERSHIP OF “CEREMONIAL USE DEFENSE”

One potential criticism of recognizing a “ceremonial use” defense for indigenous communities is that “indigenous communities” is itself a nebulous concept and that identifying the proper community to own the right to this defense may be difficult. In some contexts, it may be correct that identifying the owner of such a right may prove to be difficult (although it is doubtful it will be any more difficult than many of the factual issues that the judiciary is called upon to resolve every day). However, several pre-existing organizational structures exist that can be used to determine ownership of such a defense. Federally-recognized Indian Tribes are one such organizational structure that can be used. Another pre-existing organizational structure that can be used to determine ownership of the defense are the church organizations that formed to resist the historical suppression of sacramental psychedelic use. These organizations formed to assert First Amendment and religious free exercise claims—and accordingly already have developed sufficient structure to be reliably identified as the owner of a “ceremonial use” defense that requires prior religious use of psychedelic sacraments. Other owners may be determined to be owners of such a defense on a case-by-case basis in reference to tribal law and custom.

In the context of religious use of peyote by indigenous communities in the United States, identification of the proper “indigenous” community should be straightforward given their pre-existing organizational structure. First and foremost, the United States already recognizes the existence of certain tribal governments, and tribal governments are already recognized as the holders of

253. See, e.g., *Nagoya Protocol on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits Arising From their Utilization to the Convention on Biological Diversity*, SECRETARIAT OF THE CONVENTION ON BIOLOGICAL DIVERSITY MONTREAL (Oct. 29, 2010), <https://www.cbd.int/abs/doc/protocol/nagoya-protocol-en.pdf> (last visited Aug. 4, 2023).

many rights guaranteed by treaties as well as federal statutes. Plants and traditional medicines used by federally-recognized Indian Tribes, such as peyote, should be considered community property of those Tribes, and Tribes should be recognized as one class of owners of the “ceremonial use” defense for peyote.

Second, the history of indigenous resistance to the suppression of the religious use of peyote led to the formation of the Native American Church in 1918. Like many churches, the Native American Church has spawned several more churches—organizations such as the Native American Church of North America and the Azee Bee Nahaga of Dine Nation (ABNDN).²⁵⁴ However, just like with other churches, the ecclesiastical lineage of these churches can be traced to the original 1918 Native American Church, and thus entitlement to a “ceremonial use” defense can be verified.

The same is true for churches making use of ayahuasca as a sacrament, although such churches generally have a more recent vintage. Several ayahuasca using churches, the UDV, Church of the Holy Light of the Queen, and Ceu da Divina Rosa, brought successful religious free exercise challenges under RFRA in the early 2000s regarding their importation of ayahuasca tea.²⁵⁵

Now, as psychedelics are becoming mainstream and the subject of intellectual property, those pre-existing structures may be used to determine ownership of the proposed “ceremonial use” defense. In particular, courts may reference ecclesiastical customs to determine when the rights to perform ceremonies using psychedelic sacraments have been validly transferred to new churches or congregations. While such determinations may be complicated by the secrecy obligations, discussed above, unlike patented “prior art,” which is public, most courts have mechanisms for sealing records in cases where confidentiality is required.²⁵⁶ And, transfer of the right to perform indigenous ceremonies should not be held to the “clear and convincing” standard that

254. Stewart, *supra* note 5, at 240, 311–12 (discussing formation of Native of American Church of North America and Native American Church of Navajoland); Rima Krisst, “*Our Way of Healing*”: *Azee’ Bee Nahagha Working to Protect Peyote from State Decriminalization*, NAVAJO TIMES (Aug. 11, 2023), <https://navajotimes.com/reznews/our-way-of-healing-azee-bee-nahagha-working-to-protect-peyote-from-state-decriminalization/> (noting that Azee Bee Nahaga of Dine Nation formerly known as Native American Church of Navajoland).

255. *Gonzalez v. O Centro Espirita Beneficente Uniao do Vegetal*, 546 U.S. 418, 429–39 (2006); *Church of the Holy Light of the Queen v. Mukasey*, 615 F. Supp. 2d 1210, 1212, 1219–21 (D. Or. 2009), *rev’d for narrower injunction*, 443 F. App’x 302 (9th Cir., 2011).

256. *See, e.g., United States v. Pickard*, 733 F.3d 1297, 1300 (10th Cir. 2013) (“A court has authority to seal documents before it, based upon the court’s inherent supervisory authority over its own files and records.”); *see also* FED. R. CIV. P. 26(c) (permitting protective orders for discovery in federal litigation).

creates evidentiary issues in assessing “prior art” in the context of patent validity, as discussed above.

For other indigenous communities without a history of litigation nor federal recognition, such as Mexican indigenous communities making use of psilocybin mushrooms, no domestic structures exist. Nonetheless, courts often are required to make determinations of foreign law, and their determination of ownership of the “ceremonial use” defense may be made with reference to tribal law and custom.

VII. CONCLUSION

The “psychedelic renaissance” in the scientific community has been inspired by the religious practices of the indigenous peoples of the Americas. The patenting of psychedelics will create conflict between intellectual property laws and religious freedom laws in ways never previously considered. Prior proposals to address the issuance of invalid patents, such as traditional knowledge repositories, should be adopted. An infringement-based solution is also needed in light of the limitations of patent validity arguments. Therefore, at a minimum, a “ceremonial use” defense to infringement should be recognized in order to give proper weight to religious freedom in the context of the patent laws.