NOTE

TRIPPING ON PATENT HURDLES: EXPLORING THE LEGAL AND POLICY IMPLICATIONS OF PSILOCYBIN PATENTS

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INTRODUCTION

Ask any hippie and they will tell you about the euphoric and therapeutic properties of psychedelic "magic" mushrooms (psilocybin). While the therapeutic effects of psilocybin have

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been long known among indigenous and underground practices, the medicalization of psilocybin therapy is a new phenomenon. Psilocybin poses a unique and promising solution for the growing mental illness public health crisis. Recent studies have shown positive results for psilocybin treatment, particularly for treatment-resistant depression and major depressive disorder.

In 2019, the United States Patent and Trademark Office (USPTO) issued the '175 Patent to Compass Pathways, a mental health care company that focuses on the research and development of psilocybin therapies. This patent claimed several processes for "treating drug resistant depression" by administering a synthetic, crystalline form of psilocybin, called Polymorph A.[1] In 2021, the USPTO subsequently granted two composition of matter patent continuations for several forms of Polymorph A and several forms of a different polymorph, Hydrate A: the '259 and '044 Patents, respectively.

In 2020, Compass Pathways filed several other patents with the World Intellectual Property Organization (WIPO) for psilocybin treatment of numerous disorders, including, anxiety disorders, headache disorders, eating disorders, neurocognitive disorders, chronic pain and inflammation, and depression. The patent applications included broad claims that describe fundamental components of psilocybin therapy, including the use of concurrent psychological support and the use of nonsterile treatment rooms.

I argue that the Compass Pathways process patent claims for psilocybin treatment with naturally occurring psilocybin should be rejected because the claims are obvious. Psilocybin has been used for centuries by indigenous groups and in underground settings. Additionally, many of the claims in the patent applications include settings and concurrent therapies already used in other psychedelic therapies.

In Part I, this Note discusses the background of the mental illness public health crisis and how psilocybin-assisted therapy can treat mental illness. In Part II, this Note discusses the requirements that must be met to gain a patent, in particular patentable subject matter and non-obviousness. Additionally, it describes the history of Compass Pathways' '175 Patent and the broad claims of its three WIPO psilocybin patent applications. In Part III, this Note analyzes the different permutations of process and composition of matter patents for natural psilo-

[1] U.S. Patent No. 10,519,175 (issued Dec. 31, 2019).

cybin and Polymorph A. In Part III, I argue that while United States courts will likely uphold the composition of matter patents, the process claims for treatment with naturally occurring psilocybin are obvious based on indigenous knowledge, treatments with other psychedelic therapies, and general knowledge among psychedelic users. In Part IV, this Note discusses the patent system's balance between innovation and access and the policy implications of allowing broad psilocybin treatment patents, such as biopiracy and exploitation. In Part V, this Note discusses the discrepancy between the goals of reducing biopiracy and promoting access to potentially life-saving psilocybin therapies and analyzes how potential solutions interact with these goals.

I
PSILOCYBIN BACKGROUND

A. Mental Illness: A Public Health Crisis

Mental illness is an increasing public health crisis in the United States.[2] Even before the COVID-19 pandemic, levels of depression and suicide were rising.[3] Since 2000, the national suicide rates have steadily increased from 10.4 to 14.2 age-adjusted deaths per 100,000 population, and suicide continues to be one of the top-ten leading causes of death in the United States.[4] 11.0 percent of physician office visit records in 2019 and 12.7 percent of emergency department visit records in 2020 indicated patients suffering from depression. In 2019, 4.7 percent of adults aged eighteen and over indicated that they had regular feelings of depression.[5]

The COVID-19 pandemic has only exacerbated the mental health crisis. For example, the prevalence of depressive disorder was approximately four times higher in the second quarter

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2 Mason Marks, *Psychedelic Medicine for Mental Illness and Substance Use Disorders: Overcoming Social and Legal Obstacles*, 21 N.Y.U. J. LEGIS. & PUB. POL'Y 69, 71 (2018) [hereinafter Marks, *Psychedelic Medicine*].

3 Mason Marks, *Controlled Substance Regulation for the COVID-19 Mental Health Crisis*, 72 ADMIN. L. REV. 649, 651 (2020).

4 CDC, *Table 5. Age-Adjusted Death Rates for Selected Causes of Death by Sex, Race, and Hispanic Origin: United States, Selected Years 1950-2018*, NAT'L CTR. FOR HEALTH STATS. (2009), https://www.cdc.gov/nchs/data/hus/2019/005-508.pdf [https://perma.cc/CSR7-PWCT].

5 Tainya C. Clarke, Jeannine S. Schiller & Peter Boersma, *Early Release of Selected Estimates Based on Data from the 2019 National Health Interview Survey*, NAT'L CTR. FOR HEALTH STATS. (Sept. 2020), https://www.cdc.gov/nchs/data/nhis/earlyrelease/EarlyRelease202009-508.pdf [https://perma.cc/BW3P-JQH7].

of 2020 than the second quarter of 2019,[6] and twice as many adults reported suicidal ideation in 2020 as compared to 2018.[7] Additionally, the impacts of this mental health crisis are felt disproportionately among populations, posing an issue of health inequity. During the COVID-19 pandemic, mental health conditions have been higher in young adults, essential workers, Black and Hispanic populations, and unpaid caregivers of adults.[8]

Today, antidepressants are one of the primary treatments for depression in the United States.[9] The number of Americans using antidepressants has risen in the past decade;[10] nevertheless, research demonstrates that existing psychiatric drugs are not effective for all individuals experiencing mental illness. Selective serotonin re-uptake inhibitors (SSRIs), a class of antidepressants, are ineffective to treat depression in 30-50 percent of users.[11] For treatment-resistant depression, electroconvulsive shock treatment (ECT) is still considered one of the safest and most effective therapies despite its significant risks, inconsistent results, and invasive nature.[12]

B. Psilocybin to Treat Mental Illness

However, new classes of drugs, such as psilocybin, promise to help address the growing mental health crisis. Psilocybin and other psychedelic drugs show promising results for individuals who do not respond to traditional psychiatric treat-

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6 The prevalence of depressive disorder in the second quarter of 2020 was 24.3 percent, compared to the 6.5 percent prevalence in the second quarter of 2019. Mark É. Czeisler et al., *Mental Health, Substance Use, and Suicidal Ideation During the COVID-19 Pandemic—United States, June 24-30, 2020*, 69 MORBIDITY AND MORTALITY WKLY. REP. 1049, 1053 (Aug. 14, 2020), https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7440121/pdf/mm6932a1.pdf [https://perma.cc/B86Z-AHGM].

7 *See id.* (comparing 4.3 percent of adults seriously considering suicide in the previous twelve months in 2018 to 10.7 percent of adults seriously considering suicide in the previous thirty days in 2020).

8 *Id.*

9 Debra J. Brody & Qiuping Gu, *Antidepressant Use Among Adults: United States, 2015-2018*, NAT'L CTR. FOR HEALTH STATS. 1 (Sept. 2020), https://www.cdc.gov/nchs/data/databriefs/db377-H.pdf [https://perma.cc/JJ8G-XQQA].

10 *See id.* at 4 (describing the increase from 10.6 percent of adults aged eighteen and over using antidepressants in the past thirty days in 2009-2010 to 13.8 percent in 2017-2018).

11 Marks, *Psychedelic Medicine*, *supra* note 2, at 652–53.

12 *Id.* at 653*; see also* Khalid Saad Al-Harbi, *Treatment-Resistant Depression: Therapeutic Trends, Challenges, and Future Directions*, 6 PATIENT PREFERENCE & ADHERENCE 369, 379 (2012) (indicating the 50-70 percent response rate to ECT for treatment-resistant depression and describing the significant risk of relapse after a successful course of ECT).

ment. In recent studies, psilocybin-assisted therapy has shown improved outcomes for patients suffering from mental illnesses such as major depressive disorder (MDD),[13] treatment-resistant depression (TRD),[14] and obsessive-compulsive disorder (OCD).[15] Furthermore, psilocybin likely has more therapeutic advantages than other psychedelics, such as ketamine, because of its "low potential for addiction" and "minimal adverse event profile."[16]

Despite psilocybin's potential to improve mental health treatment, it is still classified as a Schedule I drug under the Controlled Substance Act (CSA).[17] Although researchers may now study psilocybin, the amount of written research is limited, and only recently have clinical research studies been ramping up.[18] As research has shown increasingly promising results, there is a race in the pharmaceutical space to patent psilocybin and use of it for treatment. Companies have submitted at least 224 psilocybin-related patent applications that have become public, dating from 1958 to the present.[19]

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13 *See, e.g.*, Alan K. Davis et al., *Effects of Psilocybin-Assisted Therapy on Major Depressive Disorder: A Randomized Clinical Trial*, 78 JAMA PSYCHIATRY 481, 486 (2021) (discussing a randomized clinical trial of psilocybin-assisted therapy for MDD finding significantly lower depression scores in the immediate-treatment group at one-week and four-weeks post-treatment).

14 *See, e.g.*, R.L. Carhart-Harris et al., *Psilocybin with Psychological Support for Treatment Resistant Depression: Six-month Follow-up*, 235 PSYCHOPHARMACOLOGY 399, 403 (2018) (discussing a cohort study of psilocybin treatment for TRD with psychological support that found a statistically significant reduction in depression symptoms at one-week, three-months, and six-months post-treatment).

15 *See, e.g.*, Franz X. Vollenweider & Michael Kometer, *The Neurobiology of Psychedelic Drugs: Implications for the Treatment of Mood Disorders*, 11 NATURE REVS. 642, 643 (2010) (reporting a 23-100 percent decrease in OCD symptoms in psilocybin studies).

16 Davis et al., *supra* note13, at 486.

17 21 U.S.C. § 812(c); *see also* Marks, *supra* note 2, at 667-68 (describing how the United States' "war on drugs," CSA, and Psychotropics Act of 1978 caused stagnation in psychedelics research).

18 Marks, *supra* note 2, at 668. The lack of written research should not, however, be confused with a lack of understanding that psilocybin and other psychedelics can have therapeutic qualities. In fact, many indigenous communities around the world have been using psychedelics to promote feelings of unity, connectedness, and reverence. Mason Marks & I. Glenn Cohen, *Patents on Psychedelics: The Next Legal Battlefront of Drug Development*, 135 HARV. L. REV. F. 212, 213 (2022). This concept will be discussed further in Part IV of this paper.

19 *Psilocybin Patent Tracker*, PSYCHEDELIC ALPHA, https://psilocybinalpha.com/data/psilocybin-patent-tracker [https://perma.cc/5FTV-XWK2] (last visited Dec. 8, 2021).

II
PATENT BACKGROUND

A. Basic Patent Requirements

The United States Constitution grants Congress the power to "promote the [p]rogress of [s]cience and useful [a]rts, by securing for limited [t]imes to [a]uthors and [i]nventors the exclusive [r]ight to their respective [w]ritings and [d]iscoveries."[20] An inventor may obtain a patent for a "new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof" that meets certain requirements set forth by Congress.[21] To be patentable, an invention must be novel,[22] useful,[23] and non-obvious.[24]

In *Graham v. John Deere Co. of Kansas City*, the Supreme Court explained that while non-obviousness is a legal determination, it is nevertheless based on factual inquiries.[25] In particular, the Supreme Court focused on the "scope and content of the prior art"; the "differences between the prior art and the claims at issue"; the "level of ordinary skill in the pertinent art"; and secondary considerations such as "commercial success, long felt but unsolved needs, failure of others, etc."[26] The USPTO subsequently issued a guide on the non-obviousness requirement that includes exemplary rationales that would likely support a conclusion of obviousness.[27]

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20 U.S. CONST. art I, § 8, cl. 8.

21 35 U.S.C. § 101. This Note focuses on process patents (e.g., claims for the process of creating certain compounds or for the process of treating certain diseases) and composition-of-matter patents (e.g., claims for certain compounds themselves).

22 Novelty generally requires that the claimed invention was not "patented, described in printed publication, or in public use, on sale, or otherwise available to the public before the effective filing date." 35 U.S.C. § 102(a)(1).

23 35 U.S.C. § 101. The threshold for utility is quite low; however, one scholar has argued that "legal utility" may be a means by which the USPTO may deny certain patent claims. Manuela Cabal Carmona, *Dude, Where's My Patent?: Illegality, Morality, and the Patentability of Marijuana*, 51 VAL. U. L. REV. 651, 684-85 (2017).

24 An invention is obvious if "the differences between the claimed invention and the prior art are such that the claimed invention as a whole would have been obvious before the effective filing date of the claimed invention to a person having ordinary skill in the art to which the claimed invention pertains." 35 U.S.C. § 103.

25 383 U.S. 1, 17 (1966).

26 *Id.*

27 *2143 Examples of Basic Requirements of a* Prima Facie *Case of Obviousness [R-10.2019]*, U.S. PAT. & TRADEMARK OFF., https://www.uspto.gov/web/offices/pac/mpep/s2143.html [https://perma.cc/DS8A-TKVX] (last visited Dec. 8, 2021).

The exemplary rationales include:

> (A) [c]ombining prior art elements according to known methods to yield predictable results; (B) [s]imple substitution of one known element for another to obtain predictable results; (C) [u]se of known technique to improve similar devices (methods, or products) in the same way; (D) [a]pplying a known technique to a known device (method, or product) ready for improvement to yield predictable results; (E) '[o]bvious to try' — choosing from a finite number of identified, predictable solutions, with a reasonable expectation of success; (F) [k]nown work in one field of endeavor may prompt variations of it for use in either the same field or a different one based on design incentives or other market forces if the variations are predictable to one of ordinary skill in the art; and (G) [s]ome teaching, suggestion, or motivation in the prior art that would have led one of ordinary skill to modify the prior art reference or to combine prior art reference teachings to arrive at the claimed invention.[28]

In addition to meeting the novelty, utility, and non-obviousness requirements, an inventor may only obtain a patent if the claimed invention is a patentable subject matter. Courts have carved out three specific exceptions for non-patentable subject matter: laws of nature, natural phenomena, and abstract ideas.[29] Natural phenomena include products of nature, such as a naturally occurring DNA segments;[30] however, "any distinct and new variety of plant" that meets the requirements of novelty, utility, and non-obviousness may be patented by someone who "invents or discovers and asexually reproduces" the plant.[31]

B. Recent Synthetic Psilocybin Patents

At the end of 2019, Compass Pathways was granted the '175 Patent for "large-scale production of psilocybin for use in medicine" using synthetic, crystalline psilocybin in the "Polymorph A" form.[32] The claims of this process patent specifically refer to the "method of treating drug resistant depression" by orally administering Polymorph A.[33] In response, Kohn & Associates PLLC filed a petition requesting a post-grant review of

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28 *Id.*
29 Alice Corp. v. CLS Bank Int'l, 573 U.S. 208, 216 (2014).
30 Ass'n for Molecular Pathology v. Myriad Genetics, Inc., 569 U.S. 576, 580 (2013).
31 35 U.S.C. § 161.
32 U.S. Patent No. 10,519,175 (issued Dec. 31, 2019).
33 *Id.*

the patent.[34] Kohn & Associates asserted that the claims in the '175 Patent were obvious based on four scientific-literature pieces of prior art: Folen, Nichols, Carhart-Harris, and Guo. Folen includes X-ray powder diffraction data and relative-intensity peak data for psilocybin; Nichols describes several "double-blind placebo-controlled . . . studies" of psilocybin treatment for cancer-related anxiety and depression; Carhart-Harris describes a feasibility trial of psilocybin treatment for TRD; and Guo describes the advantages of using silicified microcrystalline cellulose in hard gelatin capsules due to its physio-mechanical properties.[35]

The Patent Trial and Appeals Board (PTAB) denied the post-grant review, holding that it was not "more likely than not that any of the challenged claims [of the '175 Patent] are unpatentable."[36] The PTAB reasoned that the X-ray powder diffraction (XRPD) peaks found in Folen did not teach or suggest the peaks described in the '175 Patent because they deviated from the prior art by more than the "acceptable instrument tolerances" and would thus not be considered to be equivalent by a "person of ordinary skill in the art."[37] See Figure 1 for the XPRD diffractogram of Polymorph A, noting the characteristic peaks in controversy.

By contrast, the United Kingdom Intellectual Property Office examiner, in a non-binding decision, came to the opposite conclusion for several claims, stating, "I consider that claims 1, 3 and 10-20 are not inventive, based on Folen and Nichols."[38] The UK examiner reasoned that three of four characteristic XRPD peaks in the '175 Patent were within the experimental error of the patent and that the fourth peak was within the experimental error of the Folen methods.[39] Thus, the examiner concluded that the recrystallization process escribed in the '175 Patent would have been obvious to a person skilled in the art given the prior art.[40]

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34 A post-grant review may only be instituted when the petition demonstrates that "it is more likely than not that at least 1 of the claims challenged in the [p]etition is unpatentable." Kohn & Assocs. PLLC v. Compass Pathways Ltd., No. PGR2020-00030, 2020 WL 4906344, at *1 (P.T.A.B. Aug. 20, 2020).

35 *Id.* at *4.

36 *Id.* at *6.

37 *Id.* at *5.

38 *Final Opinion 07/21: Opinion on Patent GB 2572023 B*, PATENTS ACT 1977 OPINION UNDER SECTION 74A (July 28, 2021) at 15 [hereinafter *UK Intellectual Property Opinion*].

39 *Id.* at 11.

40 *Id.* at 12–13.

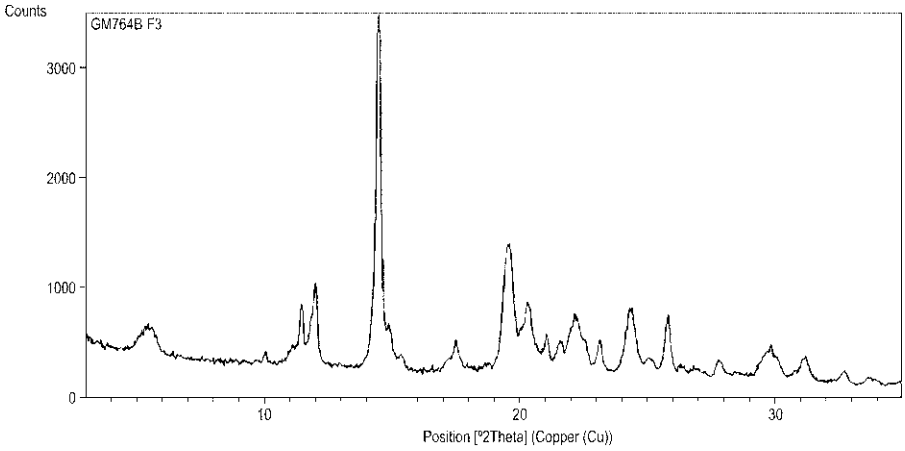

FIGURE 1. An XPRD diffractogram of Polymorph A, characterized by peaks at 11.5, 12.0, 14.5, 17.5 and 19.7°2?.[41]

Since the issuance of the '175 Patent for the treatment process, the USPTO has granted Compass Pathways two continuations, including the '259 Patent—which is a composition of matter patent for several different forms of Polymorph A including capsules and tablets[42]—and the '044 Patent—which is a composition of matter patent for several forms of a different polymorph, "Hydrate A."[43] See Figure 2 for the XPRD diffractogram of Hydrate A, noting its characteristic peaks that are unique from those of Polymorph A.

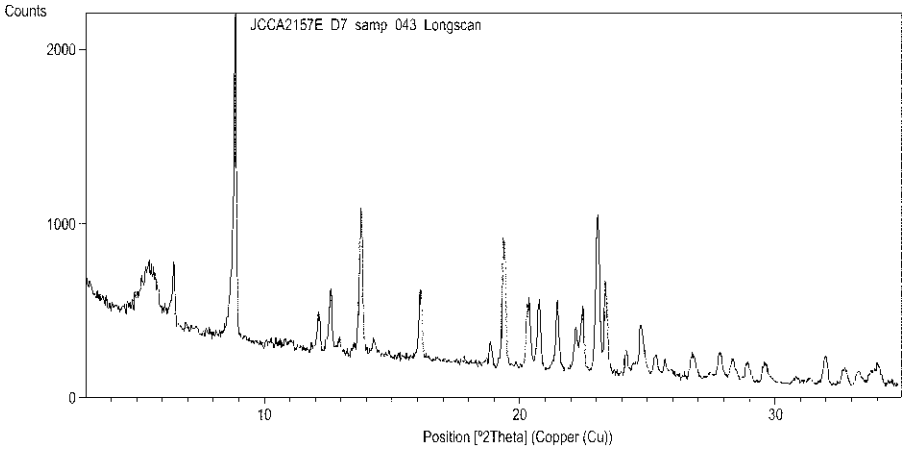

FIGURE 2. An XPRD diffractogram of Hydrate A, characterized by peaks 8.9, 13.8, 19.4, 23.1, and 23.5°2?.[44]

41 U.S. Patent No. 10,519,175, *supra* note 32.
42 U.S. Patent No. 10,954,259 (issued Mar. 23, 2021).
43 U.S. Patent No. 11,149,044 (issued Oct. 19, 2021).
44 *Id.*

C. Broad Psilocybin Patent Applications

Recently, Compass Pathways has filed several other patent applications that have caused quite a stir in the psychedelic community. Compass Pathways has filed at least three patents with WIPO for the use of psilocybin in treating "depression and other various disorders";[45] treating "neurocognitive disorders, chronic pain and reducing inflammation";[46] and treating "anxiety disorders, headache disorders, and eating disorders."[47] Some of these WIPO patent-application claims specify that they apply to use related to treatment with synthetic Polymorph A, but others simply refer to treatment with "an effective amount of psilocybin or an active metabolite thereof."[48]

Compass Pathways' applications seek to patent some of the basic components of psychedelic therapy treatment. For example, one application includes claims to psilocybin treatment in rooms with "soft furniture," decorated with "muted colors," including a "high-resolution sound system," and with a "bed or couch."[49] Furthermore, the patent applications include claims related to treatment methods, including the use of concurrent psychological support by a therapist, and one application specifies treatment where the therapist "provides reassuring physical contact" or holds the patient's "hand, arm, or shoulder."[50]

III
LEGAL ANALYSIS

A. Patentable Subject Matter

While the '175 Patent is for the process of treating depressions with Polymorph A, the '259 and '044 Patents are for the composition of matter of Polymorph A and Hydrate A and thus must demonstrate that they are not products of nature in order to be patentable subject matter. Under the United States patent system, composition of matter patents for Polymorph A and Hydrate A are likely patentable subject matter because they are

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45 WIPO Patent No. WO 2020/212952 (filed Apr. 17, 2020).

46 WIPO Patent No. WO 2020/212948 (filed Apr. 17, 2020).

47 WIPO Patent No. WO 2020/212951 (filed Apr. 17, 2020).

48 WIPO Patent No. WO 2020/212952 (filed Apr. 17, 2020); WIPO Patent No. WO 2020/212948 (filed Apr. 17, 2020); WIPO Patent No. WO 2020/212951 (filed Apr. 17, 2020).

49 WIPO Patent No. WO 2020/212952 (filed Apr. 17, 2020).

50 *Id.*; *see* Graham Pechenik (@calyxlaw), TWITTER (Feb. 3, 2021, 12:22 PM), https://twitter.com/calyxlaw/status/1357016683051847681 [https://perma.cc/TXJ4-FYHD] (asking if the claims in the Compass Pathways application could be used against therapists).

synthetic and sufficiently different from naturally occurring psilocybin to fall outside of the products of nature exception.

In *Association for Molecular Pathology v. Myriad Genetics, Inc.*, the Supreme Court held that Myriad's composition of matter claims for an isolated strand of DNA were patent-ineligible as products of nature because the DNA did not have "markedly different characteristics from any found in nature."[51] By contrast, the Supreme Court found that Myriad's composition claims for the cDNA—an exon-only molecule of which Myriad had spliced out the introns—were patent-eligible because the cDNA was not naturally occurring and was "distinct from the DNA from which it was derived."[52] *Myriad* did not however address the case of synthetic DNA that was identical to the naturally occurring DNA.[53]

In the case of the '259 and '044 Patents, the claimed molecules were synthesized through a series of reactions rather than isolated from their existing place in nature like the genes in *Myriad*. Whether the claimed molecule is identical to naturally occurring psilocybin, however, is likely a similar factual question to the question of obviousness based on Folen on which the US PTAB and UK Intellectual Property Office have come to seemingly conflicting opinions.[54] Nevertheless, given the synthetic nature of Polymorph A and Hydrate A and their differences to naturally occurring psilocybin, the '259 and '044 Patent claims would likely be upheld in the United States. Other countries are not as welcoming to polymorph patents as the United States. For example, India does not grant patents for polymorphs, and the United Nations 2015 recommendation states that polymorph and enantiomer applications should be presumed unpatentable.[55]

While there have been no composition-of-matter patent applications for naturally occurring psilocybin, if an individual were to cultivate a new strain of psilocybin mushroom, they could theoretically apply for a plant patent for the strain. This patent, however, would be subject to the same requirements of

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51 569 U.S. 576, 577 (2013).

52 *Id.* at 595.

53 *See, e.g.*, *id.* at 596 (Scalia J., concurring) ("It suffices for me to affirm . . . that the portion of DNA isolated from its natural state sought to be patented is identical to that portion of the DNA in its natural state; and that complementary DNA (cDNA) is a synthetic creation not normally present in nature.").

54 Kohn & Assocs. PLLC v. Compass Pathways Ltd., No. PGR2020-00030, 2020 WL 4906344, at *5 (P.T.A.B. Aug. 20, 2020); *UK Intellectual Property Opinion*, *supra* note 38, at 11.

55 Marks & Cohen, *supra* note 18, at 227.

novelty, non-obviousness, and utility. Because psilocybin is illegal at a federal level, it is unclear whether a plant patent for a psilocybin mushroom strain would meet the test of legal utility.[56]

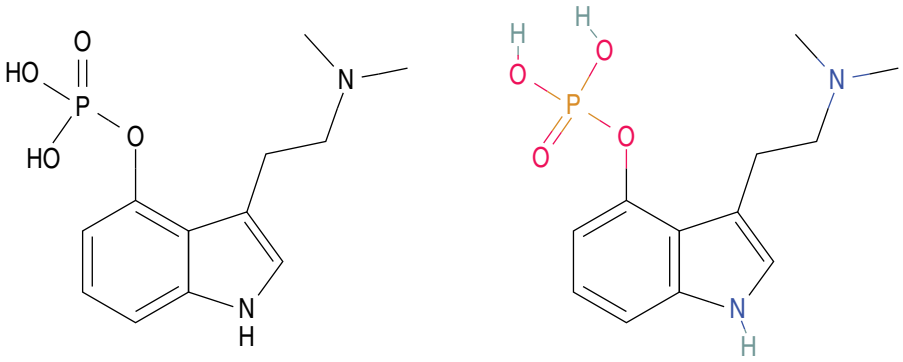

FIGURE 3. A side-by-side comparison of the chemical structure of naturally occurring psilocybin (right) and Polymorph A (left).[57] While the structures of the molecules are identical, the differences in characteristic XPRD-diffractogram peaks are likely different enough to show that Polymorph A and Hydrate A are not the same as naturally occurring psilocybin.

B. Obviousness

While the obviousness of Polymorph A has been addressed in both *Kohn* and the UK Intellectual Property Opinion, the claims from the three WIPO patent applications are yet to be legally challenged. However, many of the psilocybin-treatment claims, in particular the ones that refer to treatment with naturally occurring psilocybin rather than Polymorph A or Hydrate A, are obvious based on historical indigenous psilocybin uses,[58] regular uses of psilocybin in the underground psychedelic communities, and previously published treatment protocols for other psychedelics.

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56 *See, e.g.*, Carmona, *supra* note 23, at 685) (arguing that the USPTO could potentially deny patent applications for marijuana strains based on legal utility because marijuana is illegal under federal law). Nevertheless, in December 2016, the USPTO started issuing plant patents for new marijuana strains and in August 2021, the USPTO had issued twenty-six cannabis plant patents. *Industry Snapshot: Cannabis Plant Patents*, NOLAN IP LAW (July 23, 2021), https://nolaniplaw.com/patent/plant-patents/industry-snapshot-cannabis-plant-patents [https://perma.cc/VV9L-HM9K].

57 *Compound Summary: Psilocybine*, PUBCHEM (2005), https://pubchem.ncbi.nlm.nih.gov/compound/Psilocybine [https://perma.cc/TUE6-F8JE] (last updated Mar. 25, 2023).

58 Indigenous psilocybin use is more thoroughly discussed in Part IV of this paper.

In the case of *In re Omeprazole Patent Litigation*, the Federal Circuit upheld AstraZeneca's patent for a two-layers-coating pill of omeprazole.[59] While the use of a subcoating to prevent degradation of the active ingredient in pharmaceutical preparations was generally known, the combination with the known element of omeprazole was not considered "[c]ombining prior art elements according to known methods to yield predictable results."[60] The Federal Circuit instead reasoned that even though the addition of the subcoating was technologically possible at the time, a person skilled in the art would not have incurred the additional time and expense of adding the subcoating because they did not know about the degradation.[61]

Similarly, in *Crocs, Inc. v. International Trade Commission*, the Federal Circuit held that the combination of a foam base with the foam strap in Crocs' patent, even if it was a combination of prior known elements, was nonobvious.[62] The Federal Circuit reasoned that the prior art actually counseled against adding a foam heel strap because it would likely "stretch and deform, in addition to causing discomfort for a wearer."[63]

By contrast, in *Wyers v. Master Lock Co.*, the Federal Circuit invalidated two claims for the removable sleeve and external covering of hitch pin locks.[64] The Federal Circuit found that there was adequate motivation to combine the prior art references because there was a well-known need in the art for different size hitch pins as well as a well-known need to protect locks from contaminants.[65] Because the prior art references were combined to form a predictable result, the court found that the claims were obvious.[66]

1. *Underground Use*

Evidence of underground use of psilocybin demonstrates that the claims related to the treatment rooms, such as a nonclinical presence of a couch or bed, as well as the presence of a guide to accompany a person using psilocybin, are obvious. These methods have long been standard in the psychedelic community because they are conducive to good psilocybin ex-

59 536 F.3d 1361, 1365 (Fed. Cir. 2008).
60 *2143 Examples of Basic Requirements of a Prima Facie Case of Obviousness [R-10.2019]*, *supra* note 27.
61 *In re Omeprazole Pat. Litig.*, 536 F.3d at 1381.
62 598 F.3d 1294, 1309 (Fed. Cir. 2010).
63 *Id.* at 1308.
64 616 F.3d 1231, 1234 (Fed. Cir. 2010).
65 *Id.* at 1241, 1245.
66 *Id.*

periences. In a Reddit thread from five years ago, one user recommended "[taking] the shrooms in a familiar environment like your home or a friend's home" and noted that "having a trip sitter can also make the trip much easier."[67] Another psilocybin enthusiast, in a thread from twelve years ago, wrote, "[a]t home, I make sure I've loads of cushions and duvets around to make the place as soft and cuddly as possible."[68]

Additionally, underground use of psilocybin, like many historical indigenous uses, has demonstrated that users feel a sense of connectedness to the universe and improvement in feelings of depression. For example, one Reddit user, who claims to have suffered from depression for years, describes the positive influence that psilocybin use had for their mental state in a thread from nine years ago.[69] In a 2019 Netflix documentary, *Fantastic Fungi*, a first-time psilocybin user describes his feelings of connectedness to the world.[70] He explains that after his first time using psilocybin, he overcame a stutter that had afflicted him throughout his life.[71]

Furthermore, not all users are taking doses large enough to cause hallucinations. Instead, members of the psychedelic community discuss "microdosing." Microdosing is the use of a much smaller dose, intending to "increase creativity, calm anxiety, decrease the need for caffeine, and reduce depression."[72] The underground psychedelic community has known for decades that the use of psilocybin may improve their depressive symptoms. Reddit threads such as r/shroomers[73] and r/shrooms[74] have been active for many years before the WIPO patent applications and continue to be active in the present.

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67 Alismo, REDDIT (June 16, 2017, 11:42 AM), https://www.reddit.com/r/shrooms/comments/6hlqai/first_time_taking_shrooms_advice/ [https://perma.cc/JZ4E-9FAB].

68 TheLeaderIsGood, REDDIT (Oct. 15, 2009, 5:59 PM), https://www.reddit.com/r/AskReddit/comments/9uhpk/reddit_going_on_my_first_shroom_trip_this_weekend/ [https://perma.cc/M4JJ-ZCKC].

69 Whoskii, REDDIT (June 12, 2013, 9:24 AM), https://www.reddit.com/r/psychology/comments/1g6qw7/could_magic_mushrooms_be_used_to_treat_anxiety/ [https://perma.cc/4QCW-644S] ("I literally felt completely undepressed.").

70 FANTASTIC FUNGI (Netflix 2019), at 28:55–32:10.

71 *Id.*

72 Sharon Begley, *'Microdosing' is Touted by 'Shroomers and Reddit Users. Science is Starting to Test Their Claims — and Finding Some Truth*, STAT NEWS (Aug. 23, 2018), https://www.statnews.com/2018/08/23/science-testing-claimed-benefits-of-psilocybin-microdosing/ [https://perma.cc/X5GR-HRAU].

73 *Shroomers*, REDDIT (Sept. 14, 2010), https://www.reddit.com/r/shroomers/ [https://perma.cc/V4LR-8KXZ].

74 *Shrooms and the Psychedelic Experience*, REDDIT (Feb. 11, 2009), https://www.reddit.com/r/shrooms/ [https://perma.cc/5HHU-QWCU].

Unlike the unknown need for double-coated omeprazole in *In re Omeprazole Patent Litigation*, here, psilocybin use to treat depression and other various disorders addresses a previously known issue. The lack of commercialization of psilocybin treatment was a result of criminalization rather than the lack of adequate motivation. Finally, unlike the foam strap in *Crocs*, underground practices teach towards treating depression and various other disorders with psilocybin-assisted therapy in non-sterile settings and accompanied by a guide for the process.

2. *Use in Other Psychedelic Therapies and Clinical Trials*

The use of concurrent psychological support and non-clinical administration setting are already well-documented for other psychedelic therapies and in clinical trials of psilocybin itself. The Multidisciplinary Association for Psychedelic Studies (MAPS) has already created a protocol for MDMA-assisted therapy with many of the setting and concurrent-therapy ideas listed in Compass Pathways' patent applications.[75] For example, the 2015 MAPS protocol includes a description of the recommended physical setting, including the presence of "a futon or similar furniture," aesthetic considerations such as "fresh flowers and artwork," and the presence of a stereo.[76] The protocol even goes so far as describing the type of music that should be used during MDMA-assisted therapy.[77]

The MAPS protocol further describes the use of concurrent psychotherapy during the MDMA treatment, including the therapist's role before, during, and after the session.[78] For example, the protocol specifies that, subject to cultural and personal acceptability, the therapist may provide guidance by "[h]olding the participant's hand or providing other nurturing touch."[79] Furthermore, the protocol gives sample dialogue to

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75 *See* Welsh Psychedelic Circle (@welshpsilocybin), TWITTER (Feb. 3, 2021, 3:50 PM), https://twitter.com/welshpsilocybin/status/1357069049587527681 [https://perma.cc/PM62-ZULV] (arguing that the MAPS protocols will be 90% similar to the Compass Pathway setting and concurrent therapy claims).

76 Michael C. Mithoefer, *A Manual for MDMA-Assisted Psychotherapy in the Treatment of Posttraumatic Stress Disorder*, MAPS 12 (Aug. 19, 2015), https://maps.org/research-archive/mdma/MDMA-Assisted-Psychotherapy-Treatment-Manual-Version7-19Aug15-FINAL.pdf [https://perma.cc/E3Z6-RMC4].

77 See *id.* at 14 (suggesting that the music choice should be culturally appropriate for the population participating in the study).

78 *Id.* at 26.

79 *Id.* at 37.

help therapists prepare to foster a therapeutic alliance with the participant during the MDMA-assisted treatment.[80]

Finally, clinical studies have already demonstrated the use of concurrent psychological support during the administration of psilocybin for treatment of various depressive disorders.[81] In fact, many of these studies predate the WIPO patent applications' filing dates, thus demonstrating that the claims for simultaneous psychological support are not even novel in the context of depression and are obvious in the context of other disorders. Furthermore, clinical research and existing MDMA-assisted therapy teach toward the use of concurrent psychological support and comfortable, non-clinical setting for psilocybin treatment. While the MAPS protocol is focused towards MDMA therapy and thus may not be analogous prior art, it is nevertheless relevant in the obviousness inquiry. Like the need for different sizes of hitch pins and the need to protect locks from contamination in *Wyers*, the need for psilocybin-assisted therapy protocol is well known in the prior art. Thus there is adequate motivation to apply the MAPS protocol to psilocybin treatment.

IV
POLICY CONSIDERATIONS

A. Balancing Innovation and Access

The patent system tries to balance access and innovation by allowing inventors to invest in new technologies with the security that their investment will pay off through a limited monopoly. Allowing private companies to patent psychedelics may improve access to psychedelic therapies by promoting investment despite heavy regulation of the pharmaceutical industry. In order to get coverage by health insurance carriers, medical treatments generally need FDA approval. For psilocybin therapy for TRD, Compass Pathways received FDA breakthrough therapy designation.[82]

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80 *Id.* at 19–22.

81 Davis et al., *supra* note 13, at 487; *see* Kelan Thomas, Benjamin Malcolm & Dan Lastra, *Psilocybin-Assisted Therapy: A Review of a Novel Treatment for Psychiatric Disorders*, 49 J. PSYCHOACTIVE DRUGS 446, 453 (2017).

82 Tracy Cheung & Chris Strutt, *COMPASS Pathways Receives FDA Breakthrough Therapy Designation for Psilocybin Therapy for Treatment-Resistant Depression*, PRNEWSWIRE (Oct. 23, 2018, 9:22 AM), https://www.prnewswire.com/news-releases/compass-pathways-receives-fda-breakthrough-therapy-designation-for-psilocybin-therapy-for-treatment-resistant-depression-834088100.html [https://perma.cc/74W6-X4WQ].

Simultaneously, the rationale of promoting innovation is only fruitful if the patented claims are innovative. To allow patents granted for techniques and ideas that have existed for centuries is at odds with the purpose of the patent system. If the ideas are obvious, however, the lack of competition will simply allow one company to monopolize the market, thus causing prices for consumers to skyrocket. Additionally, patenting of indigenous knowledge poses a grave issue of exploitation through biopiracy.

B. Indigenous Psilocybin Use

Psychedelic mushrooms have been used by indigenous peoples of many different regions to promote feelings of connectedness and religiosity. As early has 10,000 BCE, there is evidence of indigenous people of northern Australia creating cave paintings of mushrooms with psychedelic themes.[83] In Mexico and Central America, visual and written history demonstrates that pre-Mayan cultures used psychedelic mushrooms as early as 1500 BCE.[84] Furthermore, priests in Mesoamerica gathered and consumed psychedelic mushrooms for their visionary properties.[85]

Indigenous groups continue to use psychedelic mushrooms for religious purposes. For example, one member of a Native American church in New Mexico leads ayahuasca and mushroom ceremonies. She describes her work with the mushrooms as "healing," "beautiful," and "wonderful."[86] Sandor Iron Rope, the President of the Native American Church of South Dakota, describes the whitewashing of psychedelic use as similar to the "colonial mindset of manifest destiny."[87]

C. Biopiracy

"Biopiracy" in the context of intellectual property is the "exploitation of traditional knowledge by innovations registered

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83 *Plant Medicines in Indigenous Cultures*, THE PSYCHEDELIC SCIENTIST (Apr. 16, 2019), https://thepsychedelicscientist.com/2019/04/16/plant-medicines-in-indigenous-cultures [https://perma.cc/ZK5Q-XPLC].

84 Sandra Nomoto, *Indigenous Cultures that Used Psychedelic Plants*, TRUHAVN (Nov. 25, 2019), https://www.truhavn.com/news/indigenous-cultures-that-used-psychedelic-plants [https://perma.cc/4XYS-DYZM].

85 *Plant Medicines in Indigenous Cultures*, *supra* note 83.

86 Suzannah Weiss, *The Push to Legalize Psychedelics Has Ignored Indigenous Communities*, MIC (May 1, 2021), https://www.mic.com/life/the-push-to-legalize-psychedelics-has-ignored-indigenous-communities-75816090 [https://perma.cc/FW2E-DMZK].

87 *Id.*

through the patent system."[88] The term is a new way to describe a colonial practice of collecting plants and animals that has been occurring for centuries.[89] Psilocybin biopiracy is problematic because the pharmaceutical industry is pursuing intellectual property rights "with no plans for reciprocity with or compensation for the indigenous communities who have protected these traditional mushroom practices for millennia."[90]

One reason why biopiracy of indigenous knowledge is so prevalent in the patent system is a lack of written sources of prior art. Stewardship of traditional psychedelic knowledge often takes place in the form of oral communication, and if there is written material, it may be in languages other than English or in databases that are hard for PTO examiners to access.[91] Furthermore, because of the criminalization of psychedelics in America, much of the underground knowledge has remained unpublished for fear of arrest and prosecution.[92]

The USPTO has granted several plant patents for indigenous plants with religious significance. For example, in June of 1986, the USPTO issued a plant patent for ayahuasca (*Banisteriopsis caapi*).[93] However, long before the patent was issued, ayahuasca had been used by indigenous people in Peru for religious and healing ceremonies.[94] After a request for reexamination, the USPTO changed course and rejected the patent in November of 1999 based on prior art of an herbarium specimen sheet.[95] Without the existence of such prior art, however, it is unclear whether the patent would have been upheld. Part V will address some ways that the issue of biopiracy in psilocybin patents may be reduced, including creating prior art repositories of indigenous psychedelic knowledge and recognizing traditional knowledge rights.

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88 Daniel F. Robinson, *Biopiracy and the Innovations of Indigenous Peoples and Local Communities*, *in* INDIGENOUS PEOPLES' INNOVATION: INTELLECTUAL PROPERTY PATHWAYS TO DEVELOPMENT 77, 77 (Peter Drahos & Susy Frankel eds., 2012).

89 *Id.* at 78.

90 Konstantin Gerber et al., *Ethical Concerns about Psilocybin Intellectual Property*, 4 ACS PHARMACOLOGY & TRANSLATIONAL SCI. 573, 576 (2021).

91 Marks & Cohen, *supra* note 18, at 220.

92 *Id.*

93 Daniel S. Sem, *Co-Developing Drugs with Indigenous Communities: Lessons from Peruvian Law and the Ayahuasca Patent Dispute*, 23 RICH. J. L. & TECH. 1, 12 (2016).

94 *Id.* at 8.

95 *Id.* at 19.

V
PROPOSED SOLUTIONS

The goals of promoting access to psilocybin therapy and reducing biopiracy do not fully align. While the legislative solution of recognizing traditional knowledge rights would be the most likely to prevent biopiracy, it poses several legal issues and could in fact result in decreased access to psilocybin treatment. Other solutions such as patent pledge and open licensing would promote access to psilocybin therapy but would nevertheless rely on patent-holder cooperation and would do little to prevent biopiracy. Finally, one simple solution that can reduce biopiracy and promote access by reducing the number of psilocybin patents granted is to increase psychedelic repositories of prior art.

A. Traditional Knowledge Rights

Instead of working within the traditional framework of the patent system, Congress could combat biopiracy by creating traditional knowledge rights (TKRs) for the indigenous groups that have historically used traditional plant knowledge. Traditional knowledge is defined as "wisdom that is held communally by members of a particular culture[ ] and that evolves in reaction to the needs of that culture."[96] Under the current model, indigenous groups do not have an intellectual property remedy for misappropriation of traditional knowledge. Instead, stewards of traditional knowledge must rely on an unfair competition model and would thus only have a remedy for "wrongful" appropriation, like acquiring knowledge through "deceit or bribery" or breaching a promise not to use the knowledge.[97]

The creation of TKRs would give indigenous tribes intellectual property-like interests in their traditional knowledge.[98] While some conclude that strong TKRs are not justified by intellectual property theories because they do not promote innovation, others argue that TKRs find support in a "reward for creativity" theory, particularly in traditional knowledge held by non-mainstream cultures.[99]

However, TKRs are not a perfect solution and pose several issues in the context of psilocybin patents. First, general intel-

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96 John T. Cross, *Justifying Property Rights in Native American Traditional Knowledge*, 15 TEX. WESLEYAN L. REV. 257, 257 (2009).
97 *Id.* at 258–59.
98 *Id.*
99 *Id.* at 260.

lectual property theories require an author or inventor.[100] This is at odds with the theory of TKRs, which instead seek to reward and enrich a culture or tribe as a whole.[101] Because psilocybin use has historically spanned numerous indigenous groups, this poses an issue for a single group's inventorship designation. Additionally, intellectual property protections generally require one inventor's or set of inventors' rights to be exclusive and thus prevail over the claims of others.

TKRs would also likely be subject to the "limited times limitation."[102] While the time restriction could possibly extend to 500 years or even the "life of the tribe,"[103] this may not be workable in the context of a plant that has been used as early as 10,000 BCE and by many different indigenous groups on different continents.

If TKRs for psilocybin use are granted, this might decrease access to psilocybin-assisted therapy for patients that could seriously benefit from such therapy. For example, multiple groups use psilocybin for religious purposes, and it is unclear what uses they would support.[104] On the other hand, it is unclear whether private ownership of knowledge is even consistent with many indigenous groups' philosophies. Regardless of what solution is taken, one thing is clear: any proposals should be created in communication with indigenous groups that have been preserving this traditional knowledge for centuries.

B. Patent Pledges and Licensing

While less forceful than a legislative solution, patent pledges and open licensing provide a different approach to increasing accessibility of psilocybin therapy. Companies such as Compass Pathways can ensure that psilocybin treatment remains accessible for patients' benefit through patent pledges. Patent pledges are promises by individuals, companies, or pat-

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100 *Id.* at 267.

101 *Id.*

102 *Id.* at 281.

103 *Id.*; *see also* Eldred v. Ashcroft, 537 U.S. 186, 199–203 (2003) (requiring no absolute maximum term for copyright protections).

104 For example, some indigenous people see issues with the psychedelic decriminalization movement being led by non-indigenous people advocating for recreational use of psychedelics without "thinking about the network of interconnected relationships with plants and indigenous communities." Weiss, *supra* note 86. They argue that in the decriminalization context, politicians "will go through the same colonial tactics as to find their own 'Native American' and put them on their team and listen to a few 'Native voices' to say they heard the Native/Indigenous communities. Those are old tactics still being used today." *Id.*

ent-holder groups that they will not enforce the patent against patent infringers.[105] Patent pledges generally apply to uses of the patented material that are "fair, reasonable, and non-discriminatory."[106] During the COVID-19 pandemic, more companies are committing to patent pledges to allow market competitors to address the pandemic without fear of expensive infringement-litigation costs.[107]

Patent pledges do not necessarily result in decreased innovation. For example, industry leaders in the electric and hybrid vehicle space, such as Tesla and Toyota, continue to be highly profitable despite their patent pledges.[108] Additionally, SpaceX has not sought patents for its intellectual assets and continues to be an innovator in the space industry.[109]

Patent pledges have already been seen in the psychedelics space as well. MAPS, a non-profit that specializes in MDMA-assisted therapy, has committed to keeping the work it does available to the public.[110] In fact, MAPS previously hired a patent attorney to determine if there was enough written about MDMA's therapeutic potential to disallow anyone from obtaining new patents, and if there was not, to apply for such patents in order to prevent MDMA's potential therapeutic uses from being monopolized.[111] In order to promote more access to MDMA therapy, MAPS encouraged research by its market competitors, stating, "If any well-funded pharmaceutical company thinks they can profit from MDMA by sponsoring research and gaining FDA approval before MAPS does, I want them to feel free to step right in and do so."[112]

In the use of psilocybin-assisted treatment, specifically, USONA, a non-profit specializing in psilocybin-treatment research and manufacturing, has continued to be profitable without compiling a patent portfolio.[113] Additionally, in a lives-

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105 Marks & Cohen, *supra* note 18, at 232.

106 Jorge L. Contreras, *A Market Reliance Theory for FRAND Commitments and Other Patent Pledges*, 2015 UTAH L. REV. 479, 480 (2015).

107 Marks & Cohen, *supra* note 18, at 232.

108 *Id.*

109 *Id.* at 232–33.

110 Rick Doblin, *MDMA: Patentability and Orphan Drug Designation*, 3 MAPS 32, 32 (1992), https://maps.org/wp-content/uploads/1992/01/v03n4_32-33_mdmapatentabilityandorphandrugdesignation.pdf [https://perma.cc/ZKE2-RGD5].

111 *Id.*

112 *Id.*

113 Shayla Love, *Is it Possible to Create an Ethical Psychedelics Company?*, VICE: MOTHERBOARD (Apr. 6, 2021, 10:30 AM), https://www.vice.com/en/article/m7amw4/is-it-possible-to-create-an-ethical-psychedelics-company [https://perma.cc/E6N3-WPHA].

tream, Lars Wilde, the President, Chief Business Officer, and co-founder of Compass Pathways, stated, "I want to make that public on the record here: we're not going to enforce anything related to set and setting," in reference to the WIPO patent applications.[114] However, critics question whether this type of pledge is actually binding on the company.[115]

Current theories of contract law, property law, and antitrust law do not provide concrete answers for potential infringers on a pledged patent.[116] Nevertheless, one scholar argues that if competitors act in fair, reasonable, and non-discriminatory reliance on these pledges, a market reliance theory based on promissory estoppel can provide security for the potential infringer.[117] Other scholars, however, point to the informality of patent pledges and the stipulations attached that can lead to a potential legal minefield for competitors acting in good faith reliance on the pledges.[118]

Another way in which psychedelic patent holders may promote patient access to psychedelic therapies is through a broader open license of their patents. Like patent pledges, open licensing would allow others to use innovating technologies without uncertainty of infringement or fear of litigation. Open licenses would hopefully be done formally and without any stipulations. One scholar has argued that the COVID-19 pandemic, which exacerbated the mental health crisis, provided an even stronger rationale for psychedelic patent-holders to open-license their psychedelic therapy patents.[119]

While patent pledges and open licensing can promote broader access to potentially life-saving psilocybin therapies, they do little to prevent biopiracy and rely on the good-will of patent-holders.

C. Prior Art Repositories

One way to decrease the number of psilocybin patents granted is to increase the data in prior art repositories. While

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114 Shayla Love (@shayla_love), TWITTER (May 27, 2021, 3:27 PM), https://twitter.com/shayla__love/status/1397997996491554830 [https://perma.cc/BVR2-2HGP].

115 Graham Pechenik (@calyxlaw), TWITTER (May 27, 2021, 5:58 PM), https://twitter.com/calyxlaw/status/1398035968544808960 [https://perma.cc/GM78-ZMJQ-] (asking whether the president's statements constituted a "psychedelic patent pledge" and whether the statements were "binding commitments").

116 Contreras, *supra* note 106, at 479.

117 *Id.*

118 Marks & Cohen, *supra* note 18, at 233.

119 Marks, *supra* note 3, at 715.

there is a strong argument that certain psilocybin patent claims are obvious, there is a risk that the patent examiners will be unfamiliar with the subject matter and thus will not know about indigenous uses and underground uses.[120] Therefore, increasing the amount of written prior art and consolidating it in one location can help to ensure that only meritorious patent claims are granted.[121] Several scholars point to an existing database, the Porta Sophia Psychedelic Prior Art Library.[122] Prior art repositories pose a simple solution because unlike TKRs, patent pledges, or open licenses, adding data to a repository can be done without Congressional intervention and without relying on the good-will of patent-holders.

CONCLUSION

Psilocybin poses unique opportunities to address the growing mental health crisis. Because current classes of drugs are ineffective for conditions such as TRD, psilocybin treatment may be able to fill this gap, improving patient outcomes. While psilocybin patents for synthetic forms may promote innovation through encouraging investment, allowing a monopoly for a plant that has historic indigenous uses poses grave concerns of biopiracy and exploitation.

In order to strike the correct balance between innovation and access, broad process patent claims for treatment with naturally occurring psilocybin should be rejected based on obviousness. In addition to its long historical uses by indigenous peoples, psilocybin has been used for many years in underground settings and more recently in clinical research studies. Many of these prior uses included claimed components of the WIPO patent applications, such as non-clinical administration settings and concurrent psychological support.

Ultimately, the goals of reducing biopiracy and increasing access to potentially life-saving psilocybin treatment do not necessarily align. While legislative recognition of TKRs may reduce biopiracy, such recognition would not necessarily promote access to psilocybin therapies. Conversely, patent pledges and licensing do not reduce biopiracy but can greatly broaden access. Nevertheless, simple solutions, such as in-

120 Marks & Cohen, *supra* note 18, at 220.

121 *Id.*

122 *Porta Sophia Psychedelic Prior Art Library*, PORTA SOPHIA, https://www.portasophia.org/ [https://perma.cc/L7EP-FG6A] (last visited Dec. 13, 2021).

creasing repositories of psychedelic prior art, can address both goals.