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# America Is Tripping

## PSYCHEDELIC PHARMACEUTICAL PATENT REFORMS FOSTERING ACCESS, INNOVATION, AND EQUITY

*Quentin Barbosa*<sup>†</sup>

### INTRODUCTION

After the death of his mother from cancer and a friend's suicide, Michael was at his lowest point.<sup>1</sup> Michael had struggled with treatment-resistant depression for nearly thirty years before stumbling upon an Imperial College London clinical trial that was studying psilocybin as a treatment option.<sup>2</sup> There, Michael took his first capsule of psilocybin—the psychedelic compound in “magic mushrooms”—while sitting in a hospital bed in a clinical room decorated with “candles and flowers,” and nervously waited for what was to come.<sup>3</sup> In under an hour, Michael was seeing lights and began a five-hour experience in which he confronted—and sought to heal—his deepest traumas.<sup>4</sup> After his journey, Michael described himself as “a different person,” and for three months his depression subsided.<sup>5</sup> He was more positive, open-minded, and less apathetic towards his

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<sup>1</sup> Josh Jacobs, *‘They Broke My Mental Shackles’: Could Magic Mushrooms Be the Answer to Depression?*, GUARDIAN (June 10, 2019), <https://www.theguardian.com/science/2019/jun/10/magic-mushrooms-treatment-depression-aztecs-psilocybin-mental-health-medicine> [<https://perma.cc/GD8E-2LRN>].

<sup>2</sup> *Id.*

<sup>3</sup> *Id.*

<sup>4</sup> *Id.*

<sup>5</sup> *See id.* (“I couldn’t wait to get dressed, get into the outside world, see people. I was supremely confident—more like I was when I was younger, before the depression started and got to its worst.”).

hobbies.<sup>6</sup> Another patient lauded the experience, claiming it broke her “mental shackles.”<sup>7</sup>

Psychedelics are a class of hallucinogenic drugs that primarily trigger substantially altered states of consciousness, including psychological, visual, and auditory changes.<sup>8</sup> In addition to psilocybin, these substances include lysergic acid diethylamide (LSD), peyote (mescaline), ketamine, and 3,4-methylenedioxymethamphetamine (MDMA), among others.<sup>9</sup> Imperial College London is not the only place conducting studies on psychedelics; in the United States, Johns Hopkins University has been studying psychedelics for twenty years, and other institutions like New York University and University of California, Los Angeles also have similar research programs.<sup>10</sup> These programs have seen success comparable to the studies at Imperial College: for example, a 2020 Johns Hopkins study of adults with major depression found that only two doses of psilocybin resulted in substantial reductions in symptoms when paired with talk therapy.<sup>11</sup> Four weeks after the two doses were administered, remission was achieved in half of the patients.<sup>12</sup>

The Johns Hopkins study and studies like it are revealing potential impacts on mental illnesses that are significantly more effective for a broader range of people, take less time to work, and have fewer undesirable side effects than traditional antidepressants.<sup>13</sup> MRI scans of brains of participants in

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<sup>6</sup> *See id.*

<sup>7</sup> *Id.* (“For so long, I felt my depression was part of me, there was nothing I could do to change it. The antidepressants only made me feel drowsy and stopped me caring about things. This made me completely break my mental shackles. I returned to work [after being unemployed] and I was euphoric. I felt: I can do this, I can change my situation.”).

<sup>8</sup> Raphaël Millière et al, *Psychedelics, Meditation, and Self-Consciousness*, 9 FRONTIERS IN PSYCH. 1, 3 (2018).

<sup>9</sup> Mason Marks, *Controlled Substance Regulation for the COVID-19 Mental Health Crisis*, 72 ADMIN. L. REV. 649, 654 (2020).

<sup>10</sup> Chris Hrapsky, *Shroom Boom: Studies Show ‘Magic Mushrooms’ Can Relieve Severe Depression*, KARE (Mar. 2, 2022), <https://www.kare11.com/article/news/local/kare11-extras/could-psychedelic-mushrooms-be-answer-to-severe-depression/89-9d7c79c0-6d4c-45c8-b13b-880b3863cdfa> [https://perma.cc/E3YC-4RHB]; Julie Sabatier, *Oregon’s Psilocybin Program Starts to Take Shape*, OR. PUB. BROAD. (June 17, 2021), <https://www.opb.org/article/2021/06/17/oregon-measure-109-psilocybin-program-start/> [https://perma.cc/G2KH-R9ZX].

<sup>11</sup> *Psychedelic Treatment with Psilocybin Relieves Major Depression, Study Shows*, JOHNS HOPKINS UNIV. (Nov. 4, 2020), <https://www.hopkinsmedicine.org/news/newsroom/news-releases/psychedelic-treatment-with-psilocybin-relieves-major-depression-study-shows> [https://perma.cc/K734-D63G].

<sup>12</sup> *Id.*

<sup>13</sup> *See id.* (quoting a Johns Hopkins professor, who stated “[t]he magnitude of the effect we saw was about four times larger than what clinical trials have shown for traditional antidepressants on the market . . . Because most other depression treatments take weeks or months to work and may have undesirable effects, this could

psychedelic studies reveal changes to the amygdala, the overactivity of which is associated with depression and anxiety.<sup>14</sup> These scans also show that neural connections are initially looser before reintegrating or “resetting” during treatment.<sup>15</sup> “The hypothesis is that [psychedelics] . . . put[] the brain in[] . . . an adaptable state [known as] ‘neuroplasticity’ . . . [which allows] the brain . . . to change.”<sup>16</sup> Neuroplasticity may be the reason some patients transcend their prior negative beliefs, thought patterns, and behaviors, especially when paired with talk therapy after treatment.<sup>17</sup> Psychedelics represent a marked shift from current treatments that help patients cope by dulling emotions rather than heightening emotions and encouraging paradigm shifts.<sup>18</sup> With these game-changing benefits, some researchers believe psychedelics could become approved medicines in just a few years.<sup>19</sup>

As a result of these findings, numerous start-ups, research labs, and other companies have started conducting their own research to capitalize on the emerging psychedelic medicine industry.<sup>20</sup> These companies are patenting the fruits of their research to protect their investments in drug research and development.<sup>21</sup> There are several common criticisms of allowing patents in the psychedelics industry. One criticism is that these patents monopolize natural products or long existing synthetic variants that should remain affordable and widely available.<sup>22</sup> Another issue is that patents can exploit Indigenous knowledge without compensation, as many of these substances have been used medicinally or religiously by Indigenous communities for

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be a game changer if these findings hold up in future ‘gold-standard’ placebo-controlled clinical trials.”).

<sup>14</sup> Jacobs, *supra* note 1.

<sup>15</sup> *Id.*

<sup>16</sup> Hrapsky, *supra* note 10.

<sup>17</sup> See Jacobs, *supra* note 1.

<sup>18</sup> *Id.*

<sup>19</sup> See *id.* (“By about that point . . . it would be like an irresistible force, and indefensible to ignore the weight of the evidence.”).

<sup>20</sup> *Psychedelic Treatment with Psilocybin Relieves Major Depression, Study Shows*, *supra* note 11.

<sup>21</sup> Mason Marks & I. Glenn Cohen, *Patents on Psychedelics: The Next Legal Battlefield of Drug Development*, 135 HARV. L. REV. F. 212, 216 (2022); see, e.g., Shayla Love, *Is It Possible to Create an Ethical Psychedelics Company?*, VICE (Apr. 6, 2021), <https://www.vice.com/en/article/m7amw4/is-it-possible-to-create-an-ethical-psychedelics-company> (reporting there has been an “explosion of for-profit psychedelic companies and patent applications,” some of which are “controversial”).

<sup>22</sup> Carolyn Gregoire, *Inside the Movement to Decolonize Psychedelic Pharma*, NEO.LIFE (Jan. 11, 2021), <https://neo.life/2020/10/inside-the-movement-to-decolonize-psychedelicpharma> [<https://perma.cc/FA2F-5C89>].

thousands of years.<sup>23</sup> These concerns also raise the issue that the patent system is meant to only incentivize new innovations, and thus many psychedelics should not be patented because they have long been used in traditional Indigenous practices.<sup>24</sup> Other critics worry about monopoly; the patent system can be abused such that only a few companies gatekeep psychedelic medicine, discouraging competitors, impeding research, restraining innovation, and limiting access to psychedelic therapy.<sup>25</sup> The war on drugs lingers over this debate too. Psychedelic prohibition denies people effective mental health treatments and thus some critics argue that the government should prioritize making psychedelic medicine affordable and accessible.<sup>26</sup>

A final concern is that some of these patents should not have been issued in the first place because they are not novel or are obvious to those skilled in the field.<sup>27</sup> But these patents have been issued, so now the question is how they can be challenged and prevented with reforms.<sup>28</sup> There is value in permitting psychedelic patents. Patents incentivize research and development of marketable products, and it is important to encourage research in the psychedelics space given how beneficial these substances likely will be in mental health care. Implementing patent reforms while the psychedelics industry is in its nascent stage can address the above concerns, prevent

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<sup>23</sup> *Id.*; see, e.g., Louis Metzger IV, *Mental Health Startup Journey Colab Aims to Develop Mescaline as an FDA-Approved Treatment for Alcohol Use Disorder*, FORBES (Apr. 26, 2022), <https://www.forbes.com/sites/louismetzgeriv/2022/04/26/mental-health-startup-journey-colab-aims-to-develop-mescaline-as-an-fda-approved-treatment-for-alcohol-use-disorder/?sh=18ede17f3f3a> [<https://perma.cc/DJC6-5PW2>] (noting that “[a]mong the sources of these psychoactive substances is peyote, which has been used by Native Americans for thousands of years. Apache, Huichol, Utes, Comanche, and Navajo peoples are among the current heirs of peyote’s ancient discoverers and stewards of its spiritual and medicinal uses.”); see also Jacobs, *supra* note 1 (“Psilocybin mushrooms have been part of religious rituals for thousands of years. The Aztecs of Mexico referred to the mushroom as *teonanacatl*, or ‘God’s flesh’, in homage to its believed sacred power.”).

<sup>24</sup> Gregoire, *supra* note 22.

<sup>25</sup> See, e.g., Marcelo Leite, *Capitalism Goes Rogue with Patent Claims on Psychedelics*, CHACRUNA (Mar. 17, 2021), <https://chacruna.net/psychedelic-patents-capitalism> [<https://perma.cc/RV5C-L7GP>]; KEVIN T. RICHARDS ET AL., CONG. RSCH. SERV., R46221, DRUG PRICING AND PHARMACEUTICAL PATENTING PRACTICES 2, 24 (2020), <https://crsreports.congress.gov/product/pdf/R/R46679>.

<sup>26</sup> See Mason Marks, *Why D.C. and Oregon Should Vote Yes on Psychedelics*, SLATE (Oct. 19, 2020), <https://slate.com/technology/2020/10/psychedelics-ballot-initiative-washington-dc-oregon-psilocybin.html> [<https://perma.cc/HFX5-CLQY>] (arguing that psychedelic prohibition prevented advances in psychiatry); Brian Barnett et al., *NIH: It’s Time to Make Your Mark on the Renaissance of Medicinal Psychedelics*, STAT (June 2, 2021), <https://www.statnews.com/2021/06/02/nih-make-mark-renaissance-psychedelic-medicine/> [<https://perma.cc/5RMH-DDUX>].

<sup>27</sup> *Infra* Part IV.

<sup>28</sup> *Infra* Part III, V.

abuse of the patent system, promote innovation, increase access, and facilitate equity.

## I. THE HISTORY OF DRUG POLICY AND PSYCHEDELIC MEDICINE IN THE UNITED STATES

It is important to begin the discussion of patent issues in the psychedelic space by first explaining the history of drug policy in the United States. Section A of this Part discusses the federal government's approach to the threat of psychedelics, culminating in the Controlled Substances Act (CSA).<sup>29</sup> Next, Section B explains the recent emergence of psychedelic-assisted therapies and the value of such treatments.<sup>30</sup> Finally, Section C describes the federal pharmaceutical development model and explores changes to state and local law on psychedelics that bypass federal restrictions and largely ignore the federal patent system for psychedelic substances altogether.<sup>31</sup> Ultimately, the history of psychedelics in the United States has been one steeped in stigma and misunderstandings that were codified under federal law, but as psychedelics go mainstream the law is catching up.

### A. *The Psychedelic Threat and the Controlled Substances Act*

In 1967, Timothy Leary—a former Harvard University psychologist who studied psychedelics and publicly advocated for their use—coined the legendary phrase: “Turn on, tune in, drop out.”<sup>32</sup> Leary was a featured speaker at the rally portion of the budding counterculture's Human Be-In event in San Francisco, proselytizing the infamous words before some twenty to thirty thousand hippies and radicals in Golden Gate Park.<sup>33</sup> In advising that people “turn on,” Leary meant expanding one's consciousness with drugs as an effective method of doing so; “tune in” meant engaging with the world and express new-found perspectives; “drop out” meant detaching from involuntary societal strictures that prevent individual choice and change.<sup>34</sup> It is not difficult to see how the prevailing post-World War II

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<sup>29</sup> *Infra* Section II.A.

<sup>30</sup> *Infra* Section II.B.

<sup>31</sup> *Infra* Section II.C.

<sup>32</sup> Peter Hartlaub & Sam Whiting, *Reliving the Human Be-In 50 Years Later*, S.F. CHRON. (Jan. 13, 2017), <https://www.sfchronicle.com/music/article/Reliving-the-Human-Be-In-50-years-later-10854785.php>.

<sup>33</sup> *Id.*

<sup>34</sup> TIMOTHY LEARY, FLASHBACKS: A PERSONAL AND CULTURAL HISTORY OF AN ERA 253 (1983).

culture could see this as a threat: Leary himself noted that his words had been misinterpreted to mean: “Get stoned and abandon all constructive activity.”<sup>35</sup>

The Be-In was born out of an earlier 1966 hippie protest in the countercultural hotbed of Haight-Ashbury against a new California law banning LSD.<sup>36</sup> The organizers viewed the Be-In as signifying the unification of two disparate counterculture groups: the militant antiwar and free speech Berkeley radicals with the peaceful, mostly apolitical San Francisco hippies.<sup>37</sup> The event inspired the Summer of Love—spawning a countercultural renaissance with lasting cultural impacts on American society.<sup>38</sup>

Widespread news of Leary’s speech at the Be-In was just one of many moments in the media driven moral panic leading to the federal government’s persecution of the psychedelic threat.<sup>39</sup> Surely startled by the counterculture movement and its

<sup>35</sup> *Id.*

<sup>36</sup> Steve Meacham, *The Day San Francisco Change the World*, FIN. TIMES (Jan. 13, 2017, 9:00 PM), <https://www.afr.com/life-and-luxury/arts-and-culture/the-day-san-francisco-changed-the-world-20170109-gtoa7g> [<https://perma.cc/CT27-HVL2>].

<sup>37</sup> *Id.*; Allen Cohen, *About the Human Be-In*, <http://www.allencohen.us/> [<https://perma.cc/N7VD-6JHV>] (“The anti-war and free speech movement in Berkeley thought the Hippies were too disengaged and spaced out. Their influence might draw the young away from resistance to the war. The Hippies thought the anti-war movement was doomed to endless confrontations with the establishment which would recoil with violence and fascism. We decided that to strengthen the youth culture, we had to bring the two poles together.”).

<sup>38</sup> Hartlaub & Whiting, *supra* note 32; Cohen, *supra* note 37 (“We had realized that the change in consciousness and culture we were experiencing had to be communicated throughout the world. We felt that the ideals of Peace, Love and Community based on the transcendental vision [i.e., psychedelics and spiritual awakening] could transform the world and end the war in Vietnam. In short, we wanted to turn the world on [referring to political consciousness] and to do it we would need to attract the spotlight from center stage Washington and Vietnam to center stage Haight-Ashbury.”); GREGORY L. WEISS, GRASSROOTS MEDICINE: THE STORY OF AMERICA’S FREE HEALTH CLINICS 29 (2006) (“As the news spread around the country at the speed of a millions of television tubes, a trickle of young people with smiles, flowers, and backpacks became a stream, and then a torrent, complete with reporters, television crews, and sociologists. . . . By March 1967, various groups within the community were reporting that Haight-Ashbury had filled beyond everyone’s expectations. They predicted that at least a hundred thousand young people would flock to the district when school was out.”); *Summer of Love: The Utopian Beginnings of Peace and Love Prevailed, and Ended in Chaos*, PBS: AM. EXPERIENCE, <https://www.pbs.org/wgbh/americanexperience/films/summer-of-love/#transcript> [<https://perma.cc/3CZT-7VSC>].

<sup>39</sup> WEISS, *supra* note 38 (discussing how the Be-In “stunned national media”); see also Miranda DiPaolo, *LSD and The Hippies: A Focused Analysis of Criminalization and Persecution in the Sixties*, 9 PEOPLE, IDEAS, & THINGS J. (2018), <https://pitjournal.unc.edu/2023/01/05/lsd-and-the-hippies-a-focused-analysis-of-criminalization-and-persecution-in-the-sixties/> [<https://perma.cc/X8NT-G28R>] (as Leary advocated for the use of LSD, “negative attitudes about hippies surfaced . . . . In an LA Times article from 1966 [titled] ‘U.S. Plans Intensive Campaign Against LSD,’ reporter Rudy Abramson writes that the FDA considered LSD ‘almost as dangerous as narcotics’ and considered LSD to be ‘all too available on college campuses.’”) (quoting Rudy

association with psychedelics—not to mention the counterculture’s pacifist, free speech, and sexually liberal elements—the federal government followed in California’s footsteps by banning consumption of LSD in 1968.<sup>40</sup> With this context in mind, it should come as no surprise that when reactionaries in the Nixon Administration and Congress worked out the details of the CSA, nearly all psychedelics were listed as strictly prohibited Schedule I substances with no accepted medical use and a high potential for abuse.<sup>41</sup> It is no secret that the scheduling was politically motivated to target communities of color and the counterculture movement.<sup>42</sup> Psychedelics and cannabis in particular were tied to hippies and the political counterculture and thus were a convenient device to scapegoat and alienate individuals in these groups.<sup>43</sup> Their inclusion in

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Abramson, *US Plans Intensive Campaign Against LSD: US Slates Intensive Drive Against LSD*, L.A. TIMES, Apr. 10, 1966); Erich Goode, *Moral Panics and Disproportionality: The Case of LSD Use in the Sixties*, 6 DEVIANT BEHAVIOR 533, 536, 539 (2008) (emphasis omitted) (noting that some claimed LSD was “the greatest threat facing the country.” and that the media “stereotyp[ed], exaggerat[ed], distort[ed], and sensitize[d]” LSD use to create “moral panic” towards the drug’s purported “deviant potential”).

<sup>40</sup> Act of Oct. 24, 1968, Pub. L. 90-639, 82 Stat. 1361 (1968) (codified in scattered sections of 21 U.S.C. and 42 U.S.C. § 289); DiPaolo, *supra* note 39 (explaining that the media evinced LSD’s deviant potential by pointing to hippie culture and views such as “unconventionality, sexual liberation, and constructive dissent.”); Michael E. Brown, *The Condemnation and Persecution of Hippies*, 6 TRANS-ACTION 33, 41 (1969) (arguing that the media-driven moral panic resulted in the persecution of hippies because the “emphasis on drugs” as the essential aspect of the counterculture and drugs’ negative impacts on society’s morals formed a “national character’ approach reminiscent of the World War II anti-Japanese propaganda.”).

<sup>41</sup> Controlled Substances Act, 21 U.S.C. §§ 801–904; *see* 21 U.S.C. §§ 812, 844. The CSA categorizes controlled substances into five distinct schedules based on their potential for abuse and whether there is an accepted medical use. JOANNA R. LAMPE, CONG. RSCH. SERV., R45948, THE CONTROLLED SUBSTANCES ACT (CSA): A LEGAL OVERVIEW FOR THE 118TH CONGRESS 1, 5–7 (2023), <https://crsreports.congress.gov/product/pdf/R/R45948/4>. Schedule I is the most strictly regulated category while Schedule V is the least regulated category. *Id.* at 8. Changes to these Schedules can be made by the federal Drug Enforcement Administration with insight from the Food and Drug Administration. *Id.* at 6.

<sup>42</sup> *See* Tom LoBianco, *Report: Aide Says Nixon’s War on Drugs Targeted Blacks, Hippies*, CNN (Mar. 24, 2016, 3:14 PM), <https://www.cnn.com/2016/03/23/politics/john-ehrllichman-richard-nixon-drug-war-blacks-hippie/index.html> [<https://perma.cc/8T6T-R5EY>] (“We knew we couldn’t make it illegal to be either against the war or black, but by getting the public to associate the hippies with marijuana and blacks with heroin. And then criminalizing both heavily, we could disrupt those communities. . . . We could arrest their leaders. [sic] raid their homes, break up their meetings, and vilify them night after night on the evening news. Did we know we were lying about the drugs? Of course we did.”).

<sup>43</sup> *Id.* For an inciteful discussion of the impacts of the War on Drugs and the Controlled Substances Act on groups like Peyotists and the Native American Church, *see* Joshua Rager, *Peyote and the Psychedelics: 20th Century Perceptions of the Religious Use of Psychoactive Substances*, 12 DENISON J. OF RELIGION 20, 28–29 (2013) (highlighting how the American government and conservatives fearfully perceive psychedelic use “by Native Americans and counterculturalists . . . as a ‘slippery slope.’ . . . manifest[ing] into



Schedule I was to silence the counterculture in an attempt to save the diminishing post-World War II cultural ideal of America and protect the political prospects of those in power.<sup>44</sup>

As a result of the war on drugs, the scheduling of psychedelics, and the moral panic in the media—all reinforcing the idea that psychedelics threatened society—the medical potential for these substances was overlooked.<sup>45</sup> Psychedelics were researched in the 1950s and 1960s; LSD, for example, showed promising results as a treatment method for alcoholism, which contradicts the determination that it had no medical use.<sup>46</sup> Furthermore, as to their high potential for abuse, psychedelics are likely not addictive and may even have an inverse relationship to lifetime use.<sup>47</sup> These nonaddictive properties are supported by data regarding the use of psychedelics as treatment options for substance abuse and addiction.<sup>48</sup> But despite this evidence, the reactionary effort to tie the counterculture to psychedelics was successful. This history sets the modern stage: a decades-long prohibition on psychedelics that has stymied medical research on these substances and denied the American public of effective psychedelic medicines and treatments.<sup>49</sup>

### B. *The Rise of Psychedelic Therapy*

The CSA permits institutional research of controlled substances under certain circumstances.<sup>50</sup> In the last twenty years, the Psychedelic Renaissance—marked by a resurgence in

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hedonistic immorality, dropping out of institutionalized mainline religion, and anarchy where individual conscience trumps a greater good.”).

<sup>44</sup> See LoBianco, *supra* note 42.

<sup>45</sup> DiPaolo, *supra* note 39.

<sup>46</sup> See Mo Costandi, *A Brief History of Psychedelic Psychiatry*, GUARDIAN (Sept. 2, 2014, 3:55 PM), <https://www.theguardian.com/science/neurophilosophy/2014/sep/02/psychedelic-psychiatry> [<https://perma.cc/BYV4-C9WX>] (noting that psychologist Humphrey Osmond employed LSD psychotherapy to treat patients with alcoholism in the early 1950s); Thomas Salazar, Note, *Trip or Treat: Psychedelic Drug Reform in California*, 53 U. PAC. L. REV. 421, 426–27 (2022). For a deeper dive on the history of psychedelics, see MICHAEL POLLAN, *HOW TO CHANGE YOUR MIND: WHAT THE NEW SCIENCE OF PSYCHEDELICS TEACHES US ABOUT CONSCIOUSNESS, DYING, ADDICTION, DEPRESSION, AND TRANSCENDENCE* (2018).

<sup>47</sup> See Matthew W. Johnson et al., *The Abuse Potential of Medical Psilocybin According to the 8 Factors of the Controlled Substances Act*, 142 NEUROPHARMACOLOGY 143, 147, 152 (2018); Evan J. Kyzar et al., *Psychedelic Drugs in Biomedicine*, 38 TRENDS PHARMACOLOGICAL SCI. 992, 995 (2017).

<sup>48</sup> See Costandi, *supra* note 46; Kyzar et al., *supra* note 47, at 995; see also Steven J. Novak, *LSD Before Leary: Sidney Cohen's Critique of 1950s Psychedelic Drug Research*, 88 ISIS 87, 96–99 (1997).

<sup>49</sup> Marks, *supra* note 26.

<sup>50</sup> Controlled Substances Act, 21 U.S.C. § 823(g).

federally approved psychedelic research pursuing better mental-health treatments—has exposed the farce of psychedelics’ Schedule I categorization.<sup>51</sup> In these studies, psychedelics have shown promise as treatment options for addiction, post-traumatic stress disorder (PTSD), depression, and other mental illnesses.<sup>52</sup>

In the last few years alone, two psychedelics have been moving through the Food and Drug Administration (FDA) approval process. The FDA designated MDMA as a “breakthrough therapy” for PTSD in 2017, and in 2018 and 2019 the agency similarly designated psilocybin for treatment-resistant depression and major depressive disorder.<sup>53</sup> The FDA has also approved ketamine nasal spray to treat depression.<sup>54</sup> In 2021, two Phase 2 clinical trials indicated that psilocybin treats symptoms of moderate-to-severe and treatment-resistant depression as effectively as daily use of selective serotonin reuptake inhibitors (SSRIs) after just two doses and talk therapy.<sup>55</sup> This evidence suggests that psychedelics may be

<sup>51</sup> Sabatier, *supra* note 10; Elaine McArdle, *Reassessing Psychedelics*, HARV. L. BULL. (Jan. 31, 2022), <https://today.law.harvard.edu/reassessing-psychedelics/>; *see, e.g.*, Jennifer M. Mitchell et al., *MDMA-Assisted Therapy for Severe PTSD: A Randomized, Double-Blind, Placebo-Controlled Phase 3 Study*, 27 NATURE MED. 1025, 1026 (June 2021) (describing successes in the use of MDMA as a treatment for PTSD symptoms in clinical trials); *see also* Alec J. Divito & Robert F. Leger, *Psychedelics as an Emerging Novel Intervention in the Treatment of Substance Use Disorder: A Review*, 47 MOLECULAR BIOLOGY REP. 9791, 9796–97 (Nov. 24, 2020) (explaining how to use psychedelics to treat substance abuse); Matthew W. Johnson & Roland R. Griffiths, *Potential Therapeutic Effects of Psilocybin*, 14 NEUROTHEAPEUTICS 734, 735–36 (June 5, 2017) (reporting on psilocybin therapy for cancer-related anxiety and depression).

<sup>52</sup> Mitchell et al., *supra* note 51, at 1026; Divito & Leger, *supra* note 51, at 9796–97; Johnson & Griffiths, *supra* note 51, at 735–36.

<sup>53</sup> Allison A. Feduccia et al., *Breakthrough for Trauma Treatment: Safety and Efficacy of MDMA-Assisted Psychotherapy Compared to Paroxetine and Sertraline*, 10 FRONTIERS PSYCHIATRY 1, 1–2 (Sept. 12, 2019); Rachel Feltman, *The FDA Is Fast-Tracking a Second Psilocybin Drug to Treat Depression*, POPULAR SCI. (Nov. 26, 2019), <https://www.popsoci.com/story/health/psilocybin-magic-mushroom-fda-breakthrough-depression/> [<https://perma.cc/PXZ2-VDFF>] (explaining that treatment-resistant depression “is defined by depressive symptoms that don’t improve with the use of two or more standard therapies”).

<sup>54</sup> *See* Kat Eschner, *The First New FDA-Approved Antidepressant in Decades Goes Up Your Nose*, POPULAR SCI. (Mar. 7, 2019), <https://www.popsoci.com/ketamine-depression-fda-spravato/> [<https://perma.cc/26NQ-5JWW>].

<sup>55</sup> *See* Robin Carhart-Harris et al., *Trial of Psilocybin Versus Escitalopram for Depression*, 384 NEW ENG. J. MED. 1402, 1402, 1408 (2021) (detailing that just two doses of psilocybin over six weeks was just as effective at treating depression as a daily SSRI taken over six weeks); *see also* Olivia Goldhill, *Largest Psilocybin Trial Finds the Psychedelic Is Effective in Treating Serious Depression*, STAT (Nov. 9, 2021), <https://www.statnews.com/2021/11/09/largest-psilocybin-trial-finds-psychedelic-effective-treating-serious-depression/> [<https://perma.cc/WBP9-8D2B>]; The FDA’s drug approval process requires clinical research of the drug in humans in three progressive phases over several years. *Step 3: Clinical Research*, U.S. FOOD & DRUG ADMIN., <https://www.fda.gov/patients/drug-development-process/step-3-clinical-research> [<https://perma.cc/H2EF-M2V5>]; *FDA’s Drug Review Process: Continued*, U.S. FOOD & DRUG ADMIN., <https://www.fda.gov/drugs/information-consumers-and-patients->

better alternatives to SSRIs and other existing treatments.<sup>56</sup> Psilocybin also may have positive impacts in treating anxiety, obsessive-compulsive disorder, and smoking addiction.<sup>57</sup> Studies on LSD have indicated substantial and long-term improvements in reversing alcoholism.<sup>58</sup> Similarly, some companies are studying the effects of mescaline on treating addiction and substance abuse.<sup>59</sup> MDMA appears to be a promising treatment option for veterans with PTSD: 83 percent of participants in one study had improvement in symptoms.<sup>60</sup> Because of these successful, groundbreaking psychedelic studies, there has been an increase in investments in research and commercialization.<sup>61</sup>

### C. *Changes in State Law and the Ownership of Medicine*

Despite a fifty-year federal prohibition, the Psychedelic Renaissance has invited a policy debate on the use of psychedelics.<sup>62</sup> Local jurisdictions and two states have recently adopted laws decriminalizing psychedelics—especially psilocybin mushrooms—and there appears to be a nationwide trend towards decriminalization.<sup>63</sup> But the trend may not stop at

drugs/fdas-drug-review-process-continued [https://perma.cc/MFH6-VBGD] (last visited Feb. 13, 2023).

<sup>56</sup> Marks, *supra* note 9, at 694; compare Alison Little, *Treatment-Resistant Depression*, 80 AM. FAM. PHYSICIANS 167, 167 (July 15, 2009) (“[B]etween one and two thirds of patients will not respond to the first antidepressant prescribed, and 15 to 33 percent will not respond to multiple interventions.”) with Nicola Davis, *Ease Rules on Research into Psychedelic Drugs, Urges David Nutt*, GUARDIAN (Apr. 2, 2020), <https://www.theguardian.com/politics/2020/apr/02/ease-rules-on-use-of-psychedelic-drugs-in-research-urges-david-nutt> [https://perma.cc/7CEG-S45X] (“Both the depression and tobacco smoking trials have shown that in some people psilocybin can produce clinical remission, in some cases persisting for years.”).

<sup>57</sup> Tingying Chi, *A Review of Emerging Therapeutic Potential of Psychedelic Drugs in the Treatment of Psychiatric Illnesses*, 411 J. NEUROLOGICAL SCI. 1, 3 (Apr. 15, 2020).

<sup>58</sup> See *id.* at 5 (noting that LSD was just as effective at treating alcoholism as a medication frequently used to treat substance abuse).

<sup>59</sup> See Metzger IV, *supra* note 23.

<sup>60</sup> See Chi, *supra* note 57, at 6 (contrasting the up to seventy-four month long therapeutic effects of MDMA with current treatments for PTSD that are frequently ineffective).

<sup>61</sup> See Andrew Jacobs, *The Psychedelic Revolution Is Coming. Psychiatry May Never Be the Same*, N.Y. TIMES (Nov. 11, 2021), <https://www.nytimes.com/2021/05/09/health/psychedelics-mdma-psilocybin-molly-mental-health.html> [https://perma.cc/5VKN-L6BP] (reporting on the hundreds of millions of dollars in investments for psychedelics research and commercialization).

<sup>62</sup> McArdle, *supra* note 51; Section I.B.

<sup>63</sup> See, e.g., Elizabeth Hernandez, *Denver May Ease Magic Mushrooms Laws Further Two Years After Decriminalization*, DENVER POST (Oct. 8, 2021), <https://www.denverpost.com/2021/10/08/magic-mushroom-denver-decriminalization-psilocybin-report/> [https://perma.cc/2NDZ-8M93]; Drug Addiction Treatment and Recovery Act, OR. REV. STAT. §§ 430.383-395 (2021) (decriminalizing all drugs and diverting funds that would be spent on law enforcement and incarceration on substance abuse programs); Psilocybin Services Act, OR. REV. STAT. § 475A (2021) (legalizing psilocybin for medical use in licensed service centers administered by licensed

decriminalization. In November 2020, Oregon voters adopted Measure 109, making Oregon the first state to legalize psilocybin products for medical use.<sup>64</sup> The medical use Measure 109 discusses is distinct from the current pharmaceutical development model that initially spawned the Psychedelic Renaissance; the below sections explore the differences between the two, with an emphasis on how Measure 109 sidesteps the issues with patenting psychedelics.<sup>65</sup>

### 1. The Pharmaceutical Development Model

The implementing regulations of the CSA require a person or entity that wants to research a controlled substance to first seek a license from the Drug Enforcement Administration (DEA).<sup>66</sup> In the psychedelic context, there are no guarantees that the license will be granted. The DEA restricts the number of scientists permitted to research psychedelics and the total amount of psychedelics that may be produced in a year, resulting in an artificial restraint on research and commercialization of psychedelics.<sup>67</sup> After receiving approval, there are additional regulations to ensure the researcher only uses substances for legitimate medical or scientific purposes and provides substances to patients who have a legitimate need.<sup>68</sup>

As a result of psychedelics being Schedule I substances, the required process to apply for a license and compliance with federal procedures makes legal domestic research on psychedelics burdensome and expensive.<sup>69</sup> Thus, often “only well-capitalized private companies can fund [this] research” in

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facilitators to people of at least twenty-one years of age); Natural Medicine Health Act of 2022, COLO. REV. STAT. §§ 12-170-101–115; 18-18-403.5, -404, -405, -410, -411, -412.7, -430.5; 16-13-303–304.

<sup>64</sup> Psilocybin Services Act, OR. REV. STAT. § 475A (2021).

<sup>65</sup> Vice News, *The Battle over Psychedelic Therapy's Future*, YOUTUBE (Jan. 11, 2022), <https://www.youtube.com/watch?v=w5iB0AQ24r4> [<https://perma.cc/XBG3-5AU2>].

<sup>66</sup> 21 C.F.R. § 1301.13 (2022); Press Release, DRUG ENF. ADMIN., *DEA Speeds Up Application Process for Research on Schedule I Drugs* (Jan. 18, 2018), <https://www.dea.gov/press-releases/2018/01/18/dea-speeds-application-process-research-schedule-i-drugs> [<https://perma.cc/V6ES-SF5G>]. Though the CSA grants rule-making authority on scheduling to the Attorney General, this authority was subdelegated to the head of the DEA in 1973. 21 U.S.C. § 821; Alex Kreit, *Controlled Substances, Uncontrolled Law*, 6 ALBANY GOV'T L. REV. 332, 335 (2013).

<sup>67</sup> Marks & Cohen, *supra* note 21, at 223–24; *see* Marks, *supra* note 9, at 685; *see* McArdle, *supra* note 51.

<sup>68</sup> *See* 21 C.F.R. §§ 1301.32, 1306.04 (2022).

<sup>69</sup> *See* David E. Nichols, *Hallucinogens*, 101 PHARMACOLOGY & THERAPEUTICS 131, 133 (2004).

the United States,<sup>70</sup> and it is not uncommon for start-up companies that can afford it to research in other countries that are more lenient on psychedelics research. Researching overseas is viable because it is possible to get FDA drug approval and an approved patent based on overseas research and clinical trials.<sup>71</sup>

The FDA drug approval process generally takes anywhere from “seven to ten years” altogether.<sup>72</sup> First, a drug sponsor engages in preclinical animal testing and a review of findings to decide if the drug should be tested in humans.<sup>73</sup> Next, an investigational new drug (IND) application is submitted to the FDA, describing the proposal for human testing in clinical trials.<sup>74</sup> Then clinical studies are done in three Phases: Phase 1 “typically involve[s] 20 to 80 people” and lasts several months, Phase 2 “typically involve[s] a few dozen to . . . 300 people” and lasts up to two years, and Phase 3 “typically involve[s] several hundred to . . . 3,000 people” and lasts up to four years.<sup>75</sup> Before a new drug application (NDA) is submitted, the FDA and sponsors will meet.<sup>76</sup> The sponsors then formally ask the FDA to consider the new drug for approval by submitting the NDA, the FDA has sixty days to decide whether to file it for review.<sup>77</sup> If filed, an FDA review team is assigned to evaluate the evidence from clinical trials for the safety and efficacy of the drug.<sup>78</sup> The FDA also reviews drug labeling information and inspects the manufacturing facilities.<sup>79</sup> Finally, the FDA approves the application or issues a complete response letter (denying the

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<sup>70</sup> See Mason Marks, Opinion, *A Strategy for Rescheduling Psilocybin*, SCI. AM. (Oct. 11, 2021), <https://www.scientificamerican.com/article/a-strategy-for-rescheduling-psilocybin> [<https://perma.cc/A7ES-MC42>]; McArdle, *supra* note 51.

<sup>71</sup> Marks & Cohen, *supra* note 21, at 224; see DEPT’ HEALTH & HUM. SERVS., GUIDANCE FOR INDUSTRY AND FDA STAFF: FDA ACCEPTANCE OF FOREIGN CLINICAL STUDIES NOT CONDUCTED UNDER AN IND, FREQUENTLY ASKED QUESTIONS 1, 1–2 (2012), <https://www.fda.gov/files/about%20fda/published/FDA-Acceptance-of-Foreign-Clinical-Studies-Not-Conducted-Under-an-IND—Frequently-Asked-Questions.pdf> [<https://perma.cc/TQ6S-6WDS>].

<sup>72</sup> See MASSIVEBIO, *How Long Do Clinical Trial Phases Take?*, <https://massivebio.com/how-long-do-clinical-trial-phases-take/> [<https://perma.cc/Q4C8-4R96>].

<sup>73</sup> *Step 2: Preclinical Research*, U.S. FOOD & DRUG ADMIN., <https://www.fda.gov/patients/drug-development-process/step-2-preclinical-research> [<https://perma.cc/GXC6-66V7>]; *FDA’s Drug Review Process: Continued*, *supra* note 55.

<sup>74</sup> *FDA’s Drug Review Process: Continued*, *supra* note 55.

<sup>75</sup> *Id.*; *Step 3: Clinical Research*, *supra* note 55.

<sup>76</sup> *FDA’s Drug Review Process: Continued*, *supra* note 55.

<sup>77</sup> *Id.*; *New Drug Application (NDA)*, U.S. FOOD & DRUG ADMIN., <https://www.fda.gov/drugs/types-applications/new-drug-application-nda> [<https://perma.cc/C5MG-MRMU>].

<sup>78</sup> Applications for FDA Approval to Market a New Drug, 21 C.F.R. §§ 314.2, 314.50 (2022); *FDA’s Drug Review Process: Continued*, *supra* note 55; *New Drug Application (NDA)*, *supra* note 77.

<sup>79</sup> *FDA’s Drug Review Process: Continued*, *supra* note 55.

application or requiring additional studies) within six to ten months of submission.<sup>80</sup>

To this point, only the ketamine nasal spray has completely made it through this FDA process, and ketamine is the only non-Schedule I psychedelic.<sup>81</sup> Still, MDMA and psilocybin have completed Phase 3 and Phase 2 clinical trials, respectively, with promising findings that may lead to FDA approval.<sup>82</sup> For better or worse, absent changes to state or local law, the only way to move forward on psychedelic medicine is via this pharmaceutical development model.<sup>83</sup>

## 2. Psychedelic Decriminalization Efforts in States, Cities, and Counties

In May 2019, Denver, Colorado became the first city in the United States to decriminalize psilocybin mushrooms.<sup>84</sup> Denver voters approved a ballot measure that declared psychedelic mushrooms to be the “lowest law-enforcement priority.”<sup>85</sup> The measure won with just 50.6 percent of the vote.<sup>86</sup> Oakland, California’s city council soon followed in June 2019, decriminalizing peyote in addition to psilocybin mushrooms after dozens of individuals testified about their experience with these psychedelics.<sup>87</sup> Many of these individuals discussed how plant medicines helped them address their depression, addiction, and anxiety, explaining that they suffered for years prior to using psychedelics.<sup>88</sup> Another speaker was director Susana Eager Valadez of the Huichol Center for Cultural

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<sup>80</sup> *Id.*; *Development & Approval Process | Drugs*, U.S. FOOD & DRUG ADMIN., <https://www.fda.gov/drugs/development-approval-process-drugs> [<https://perma.cc/7FN8-U65V>].

<sup>81</sup> Eschner, *supra* note 54; Marks & Cohen, *supra* note 21, at 213, 225–26; *but see* Mattha Busby, *Biden Administration Plans for Legal Psychedelic Therapies Within Two Years*, INTERCEPT (July 26, 2022), <https://theintercept.com/2022/07/26/mdma-psilocybin-fda-ptsd/> [<https://perma.cc/QPH6-YUGW>] (reporting on a letter from the Department of Health and Human Services Department disclosing that officials within the department anticipate FDA approval of “breakthrough therap[y]” MDMA and psilocybin treatments for PTSD and depression within two years).

<sup>82</sup> *See, e.g.*, Mitchell et al., *supra* note 51; Feduccia et al., *supra* note 53; Feltman, *supra* note 53; Carhart-Harris et al., *supra* note 55; Goldhill, *supra* note 55.

<sup>83</sup> Vice News, *supra* note 65.

<sup>84</sup> Hernandez, *supra* note 63.

<sup>85</sup> *Id.*

<sup>86</sup> Esther Hoing, *In Close Vote, Denver Becomes 1st U.S. City to Decriminalize Psychedelic Mushrooms*, NAT’L PUB. RADIO (May 9, 2019), <https://www.npr.org/sections/health-shots/2019/05/09/721660053/in-close-vote-denver-becomes-first-u-s-city-to-decriminalize-psychedelic-mushroom> [<https://perma.cc/F38C-6JEW>].

<sup>87</sup> Elizabeth Weise & Marco della Cava, *Oakland in California Decriminalizes Magic Mushrooms and Peyote*, USA TODAY (June 5, 2019), <https://www.usatoday.com/story/news/2019/06/05/oakland-california-legalizes-magic-mushrooms-and-peyote/1347888001/> [<https://perma.cc/H9NB-8A68>].

<sup>88</sup> *Id.*

Survival and Traditional Arts, who explained the indigenous ritual uses for hallucinogenic plants.<sup>89</sup> Valadez noted that Americans “can learn from” these traditions to “create their own rituals.”<sup>90</sup> Despite some concerns, the Oakland city council voted in favor of the law.<sup>91</sup>

Psychedelic decriminalization is still a controversial topic. Some people fear such steps may impact safety, noting that the medical literature is still in its early stages and that indigenous groups use psychedelics in “controlled situations” rather than in a recreational context.<sup>92</sup> But there is a clear trend in the last couple years toward decriminalization across the country. The cities of Santa Cruz and Arcata in California; the City of Ann Arbor and Washtenaw County in Michigan; the cities of Somerville, Cambridge, Northampton, and Easthampton in Massachusetts; the cities of Seattle and Port Townsend in Washington state; and the District of Columbia all decriminalized various psychedelics between 2020 and 2021.<sup>93</sup> The state of

<sup>89</sup> *Id.*

<sup>90</sup> *Id.*

<sup>91</sup> *Id.*; Marco della Cava, *Oakland City Council Looks to Decriminalize ‘Magic Mushrooms’ After Denver Vote*, USA TODAY (Jun. 2, 2019, 9:51 AM), <https://www.usatoday.com/story/news/nation/2019/06/02/magic-mushrooms-could-soon-become-legal-oakland-california/1298939001/> [<https://perma.cc/CY5E-DK6M>].

<sup>92</sup> Weise & della Cava, *supra* note 87.

<sup>93</sup> Kelly McCarthy, *Santa Cruz Decriminalizes Psychedelic Mushrooms*, ABC NEWS (Jan. 29, 2020, 1:52 PM), <https://abcnews.go.com/US/santa-cruz-decriminalizes-psychedelic-mushrooms/story?id=68611065> [<https://perma.cc/X33S-BC4R>] (“The City Council of Santa Cruz voted unanimously on Tuesday to . . . make investigation and arrest for ‘the adult possession, use or cultivation of psychoactive plants and fungi’ a low-priority infraction.”); Ryan Stanton, *Ann Arbor OKs Move to Decriminalize Psychedelic Mushrooms, Plants*, MLIVE (Sept. 21, 2020, 9:44 PM), <https://www.mlive.com/news/ann-arbor/2020/09/ann-arbor-oks-move-to-decriminalize-psychedelic-mushrooms-plants.html> [<https://perma.cc/5V87-TPUZ>]; Matt Pusatory, *Magic Mushrooms Officially Decriminalized in DC*, WUSA9 (last updated Mar. 16, 2021, 11:26 AM), <https://www.wusa9.com/article/news/local/dc/dc-magic-mushroom-decriminalized-as-of-march-16/65-d7d47bd-c-60f4-497d-81e9-e9db4d109406> [<https://perma.cc/G7BC-U4SP>] (describing how voters passed Initiative 81 by 76 percent of the vote, making “policing and prosecut[ing]” entheogenic plants and fungi “a low priority”); Jerilyn Jordan, *Washtenaw County Says Cases Involving Natural Psychedelics Will No Longer Be Charged*, DETROIT METRO TIMES (Jan. 12, 2021, 12:39 PM), <https://www.metrotimes.com/detroit/washtenaw-county-prosecutor-announces-cases-involving-marijuana-magic-mushrooms-and-psychedelic-plants-will-no-longer-be-charged/Content?oid=26218702> [<https://perma.cc/2A8U-RUDU>] (“You’re not tripping—newly appointed Washtenaw County prosecutor Eli Savit introduced two new policy directives Tuesday that detail why he’s no longer charging criminal cases involving marijuana, ‘magic’ mushrooms, or other entheogenic plants.”); Kyle Jaeger, *Local Massachusetts Lawmakers Unanimously Approve Psychedelics Decriminalization Measure*, MARIJUANA MOMENT (Jan. 15, 2021), <https://www.marijuanamoment.net/local-massachusetts-lawmakers-unanimously-approve-psychedelics-decriminalization-measure/> [<https://perma.cc/FC7M-P2L8>]; Marc Levy, *War on Use of Mushrooms, Cacti and Ayahuasca Has Been Called Off in Cambridge by Council Order*, CAMBRIDGE DAY (Feb. 4, 2021), <https://www.cambridgeday.com/2021/02/04/war-on-use-of-mushrooms-cacti-and-ayahuasca-has-been-called-off-in-cambridge-by-council-order/> [<https://perma.cc/4MMJ-5RNE>]; Kyle Jaeger, *Third Massachusetts City Approves*

Oregon adopted Measure 110 in November 2020, effectively decriminalizing all drugs; Oregon also adopted Measure 109, allowing supervised use of psilocybin under certain circumstances.<sup>94</sup> There is currently a bill in California to similarly decriminalize psychedelics.<sup>95</sup> And in 2021, Denver’s Psilocybin Mushroom Policy Review Panel—which included its District Attorney—expressed its intention to further explore psychedelics regulation. This plan includes potential therapeutic uses and law enforcement deprioritization of gifting psilocybin without purchase, after a study from the District Attorney’s office revealed there have not been significant impacts to crime, health, and safety since the city’s 2019 decriminalization.<sup>96</sup>

The decriminalization trend is indicative of a recognition of the therapeutic value of psychedelics.<sup>97</sup> Part of the rationale for some decriminalization regimes is to increase and facilitate

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*Psychedelics Decriminalization Measure*, MARIJUANA MOMENT (Apr. 2, 2021), <https://www.marijuanamoment.net/third-massachusetts-city-approves-psychedelics-decriminalization-measure/> [<https://perma.cc/9BWT-9DY5>]; Tiffany Kary, *Seattle Votes to Decriminalize Psilocybin and Similar Substances*, BLOOMBERG (Oct. 4, 2021), <https://www.bloomberg.com/news/articles/2021-10-04/seattle-votes-to-decriminalize-psylocybin-and-similar-substances>; Kyle Jaeger, *Third California City Moves to Decriminalize Psychedelics as Reform Movement Expands*, MARIJUANA MOMENT (Oct. 7, 2021), <https://www.marijuanamoment.net/third-california-city-moves-to-decriminalize-psychedelics-as-reform-movement-expands/> [<https://perma.cc/9SU7-UW9C>]; James Stephen, *Easthampton, Massachusetts Votes to Decriminalize, End Arrests for Growing Psychedelics*, TRUFFLE REP. (Oct. 21, 2021), <https://truffle.report/easthampton-massachusetts-votes-to-decriminalize-end-arrests-for-growing-psychedelics/> [<https://perma.cc/7QQ4-3DDX>]; Gus Burns, *Detroit Mushroom Vote Adds Momentum to Michigan Efforts to Decriminalize Psychedelics*, MLIVE (Nov. 3, 2021), <https://www.mlive.com/public-interest/2021/11/detroit-mushroom-vote-adds-momentum-to-michigan-efforts-to-decriminalize-psychedelics.html> [<https://perma.cc/48S2-NLK6>]; Diane Urbani de la Paz, *Port Townsend Council Makes Entheogens Low Police Priority*, PENINSULA DAILY NEWS (Dec. 24, 2021), <https://www.peninsuladailynews.com/news/port-townsend-council-makes-entheogens-low-police-priority> [<https://perma.cc/M863-DNCG>].

<sup>94</sup> Drug Addiction Treatment and Recovery Act, OR. REV. STAT. §§ 430.383-395 (2021); Psilocybin Services Act, OR. REV. STAT. § 475A (2021). In 2022, Colorado voters passed Measure 122, which prohibited criminalization of certain entheogenic plants and fungi while also permitting supervised medical use of psilocybin at healing centers, similar to Oregon Measures 109 and 110. See Natural Medicine Health Act, COLO. REV. STAT. § 12.170 (2022).

<sup>95</sup> S.B. 58, 2023-2024 Leg., Reg. Sess. (Cal. 2023); Press Release, Sen. Scott Wiener, Senator Wiener Reintroduces Legislation to Decriminalize Psychedelics (Dec. 19, 2022), <https://sd11.senate.ca.gov/news/20221219-senator-wiener-reintroduces-legislation-decriminalize-psychedelics> [<https://perma.cc/4TET-QFAS>].

<sup>96</sup> See Hernandez, *supra* note 63 (“According to data from the Denver District Attorney’s office, there have been only 47 cases related to psilocybin in Denver since decriminalization was adopted in May 2019 (compared to 44 cases in 2018 alone) . . . Of the five arrests involving psilocybin or psilocin only [rather than additional illicit substances], 60% were arrests for amounts greater than for personal use.”).

<sup>97</sup> See, e.g., Weise & della Cava, *supra* note 87 (discussing how the Oakland City Council heard comments from the public about the therapeutic benefits of entheogenic plants before voting to decriminalize those substances).



psychedelic research.<sup>98</sup> State and local laws that offer alternatives to the strictures of the CSA's psychedelic prohibition and exclusive research approval process present a unique opportunity for researchers to safely engage in their work domestically.<sup>99</sup> Decriminalization may prove an effective avenue promoting further research on psychedelics as it allows more cost-effective research that sidesteps federal restrictions.<sup>100</sup> Though the trends is observable, the decriminalization movement is still in its early stages and not yet widespread.<sup>101</sup>

### 3. Oregon Measure 109

In November 2020, Oregon voters approved Measure 109 by 55.74 percent.<sup>102</sup> Oregon Measure 109 allows the use of psilocybin in supervised facilities for persons twenty-one years or older.<sup>103</sup> The ballot measure required the Oregon Health Authority (Authority) to create an advisory board to draft rules and recommendations for a comprehensive regulatory framework on “psilocybin services.”<sup>104</sup> The state had until January 1, 2023 to create the framework and start accepting licenses to permit service providers to administer psilocybin.<sup>105</sup> The advisory board engaged stakeholders like underground practitioners, prospective licensees, and Indigenous communities, and invited input from the scientific and medical

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<sup>98</sup> See, e.g., Kyle Jaeger, *Colorado Governor Backs Psychedelics Reform And Says Prohibition Inhibits Research Into Medical Benefits*, MARIJUANA MOMENT (May 5, 2022), <https://www.marijuanamoment.net/colorado-governor-backs-psychedelics-reform-and-says-prohibition-inhibits-research-into-medical-benefits/> [https://perma.cc/799U-PB3G] (“Psychedelics ‘might have some therapeutic uses around people that are trying to get off of opioids or people [with] major issues with depression or anxiety,’ Polis said. ‘There are some clinical studies that have been done—and frankly, the clinical studies are inhibited by the illegality of some of the substances. So it’s very frustrating.’”).

<sup>99</sup> See Dustin Marlan, *Beyond Cannabis: Psychedelic Decriminalization and Social Justice*, 23 LEWIS & CLARK L. REV. 851, 872–73 (2019); Marks & Cohen, *supra* note 21, at 223–24; McArdle, *supra* note 51.

<sup>100</sup> See Marlan, *supra* note 99, at 872–73; Marks & Cohen, *supra* note 21, at 223–24; McArdle, *supra* note 51.

<sup>101</sup> *Supra* note 93 and accompanying text.

<sup>102</sup> OR. SEC’Y OF STATE, NOVEMBER 3, 2020, GENERAL ELECTION ABSTRACT OF VOTES MEASURE 109 (2020), <https://sos.oregon.gov/elections/Documents/results/november-general-2020.pdf> [https://perma.cc/B4EM-DHDL].

<sup>103</sup> Psilocybin Services Act, OR. REV. STAT. § 475A (2021).

<sup>104</sup> *Id.*; Sabatier, *supra* note 10; Lizzy Acker, *How Soon Will It Be Before Oregonians Can Access Legal Therapeutic Psilocybin?*, REG. GUARD (Jan. 22, 2022, 5:30 AM), <https://www.registerguard.com/story/news/2022/01/22/when-can-oregonians-access-legal-therapeutic-psilocybin-measure-109/6589291001/> [https://perma.cc/9B2Q-EU57].

<sup>105</sup> Psilocybin Services Act; Sabatier, *supra* note 10; Acker, *supra* note 104.

communities.<sup>106</sup> The board and the brand new Oregon Psilocybin Services Section of the Authority reviewed the research and literature and adopted rules and recommendations for a wide range of activities, including facilitator training, licensing and compliance, and product tracking.<sup>107</sup> The Authority adopted rules for training programs and products testing in May 2022.<sup>108</sup> The agency completed the rulemaking process in December 2022, began processing licenses in January 2023, expecting service centers to be fully in operation sometime within 2023.<sup>109</sup>

Measure 109's model operates in a way that circumvents patent and rescheduling issues, reduces Big Pharma power, and offers greater access. The product testing rules ensure the safety of the substances that will be consumed at licensed facilities through various testing and product safety requirements.<sup>110</sup> Most surprising is that the rules prohibit the manufacture and administration of synthetically derived psilocybin, as well as products not for oral consumption.<sup>111</sup> Synthetically derived psilocybin is easier to control in terms of dosage and consistently producing at scale.<sup>112</sup> Because the recommended products are not synthetic psilocybin and are only orally consumable, there is likely a reduced chance that Big Pharma can sweep in and

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<sup>106</sup> Sabatier, *supra* note 10; Acker, *supra* note 104.

<sup>107</sup> OR. ADMIN. R. 333-333 (2022); Amanda Arden, *Oregon's Final Rules for Adopting Psilocybin Services are Set*, KOIN (Dec. 29, 2022), <https://www.koin.com/news/oregon/oregons-final-rules-for-adopting-psilocybin-services-are-set/> [<https://perma.cc/KJ5B-G6Y9>]; Michaela Bourgeois & Ken Boddie, *Oregon Rolls Out Psilocybin, Anticipates Service Center Openings in 2023*, KOIN (Jan. 6, 2023), <https://www.koin.com/nwpolitics/oregon-rolls-out-psilocybin-anticipates-service-center-openings-in-2023/> [<https://perma.cc/AJ2X-WMPX>]; Acker, *supra* note 104.

<sup>108</sup> Letter from Oregon Health Authority to the Public (May 20, 2022), <https://www.oregon.gov/oha/PH/PREVENTIONWELLNESS/Documents/Letter-to-Public-5.20.2022.pdf> [<https://perma.cc/K4FP-YVU9>].

<sup>109</sup> Andrew Jacobs, *Legal Use of Hallucinogenic Mushrooms Begins in Oregon*, N.Y. TIMES (Jan. 3, 2023), <https://www.nytimes.com/2023/01/03/health/psychedelic-drugs-mushrooms-oregon.html>; Arden, *supra* note 107.

<sup>110</sup> OR. ADMIN. R. 333-333-70300, -7040, -7070 (2022) (requiring a 100 percent Psilocybe Cubensis speciation test, uniform batch potency tests, microbiological contaminant testing upon request, and destruction of an entire batch if a single lot fails any of these tests to prevent contamination).

<sup>111</sup> OR. ADMIN. R. 333-333-2120 (2022) (noting that patches, inhalers, nasal sprays, injections, and suppositories are not permitted under the rules).

<sup>112</sup> *Oregon Psilocybin Advisory Board Draft Testing Rules; To Discuss Tomorrow (2/24)*, GLEAM L. (Feb. 23, 2022), <https://www.gleamlaw.com/cannabis-law-blog/psychedelics/oregon-psilocybin-advisory-board-draft-testing-rules/> [<https://perma.cc/3VLE-G5JR>]; *Oregon Psilocybin Advisory Board Release Draft Rules; Rules Advisory Committee to Discuss Draft Psilocybin Training Rules Tomorrow (2/14) and Draft Psilocybin Products Rules Thursday (2/17)*, GLEAM L. (Feb. 13, 2022), <https://www.gleamlaw.com/cannabis-law-blog/psychedelics/oregon-psilocybin-advisory-board-release-draft-rules-rules-advisory-committee-to-discuss-draft-psilocybin-training-rules-tomorrow-2-14-and-draft-psilocybin-products-rules-thursday-2-17/> [<https://perma.cc/C64L-NQXP>].

corner the manufacture, sale, and administration of psilocybin products. Thus, access may increase by preventing a medical monopoly. Additionally, the requirement of only organic psilocybin avoids many federal patent issues because the permitted products and methods of producing them are not novel or are obvious. This state law nonpharmaceutical model also avoids the problems with rescheduling medicines derived from scheduled substances through a federal bureaucratic process.<sup>113</sup>

The training rules provide the qualifications for the curriculum and training of psilocybin service centers and facilitators. Prospective training program licensees must demonstrate their curriculum satisfies a specified number of hours for each module of the nine required modules.<sup>114</sup> Interestingly, a prescription will not be required, and the board is not calling the administration of psilocybin “therapy.”<sup>115</sup> Rather, the board is careful to call it “psilocybin services,” which is how the text of the measure actually refers to the administration of psilocybin.<sup>116</sup> Some members of the board have

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<sup>113</sup> See, e.g., Rescheduling of the Food and Drug Administration Approved Product Containing Synthetic Dronabinol From Schedule II to Schedule III, 64 Fed. Reg. 35,928 (July 2, 1999) (to be codified at 21 C.F.R. pts. 1308, 1312) (administratively rescheduling Marinol from Schedule II to Schedule III based on recommendations from the Secretary for the Department of Health and Human Services, after already having rescheduled from Schedule I to Schedule II once the FDA approved Marinol). The process of administrative rescheduling begins with either a petition by an interested party or a recommendation by the Secretary of Health that rescheduling at a particular Schedule is appropriate based on scientific and medical evaluations. See LAMPE, *supra* note 41. “The HHS Secretary has delegated the authority to prepare the scientific and medical evaluation to FDA.” *Id.* at 10. After the Secretary of Health (via the FDA) makes such recommendations, the DEA may reschedule the drug. *Id.* The United States recently saw this process start in real time, when President Joe Biden announced his intent to reschedule marijuana and asked Secretary Xavier Becerra and Attorney General Merrick Garland to begin “to review expeditiously how marijuana is scheduled under federal law.” *Statement from President Biden on Marijuana Reform*, WHITE HOUSE (Oct. 6, 2022), <https://www.whitehouse.gov/briefing-room/statements-releases/2022/10/06/statement-from-president-biden-on-marijuana-reform/> [<https://perma.cc/DAA9-G96V>]; Mona Zhang, *Pardons, Descheduling and the DEA: Making Sense of Biden’s Weed Actions*, POLITICO (Oct. 7, 2022), <https://www.politico.com/news/2022/10/07/biden-weed-executive-action-dea-00060978>. But see Robert Hendricks & Alan Rogalski, *The Complexity of Rescheduling or Descheduling Marijuana Under Federal Law*, JD SUPRA (Oct. 20, 2022), <https://www.jdsupra.com/legalnews/the-complexity-of-rescheduling-or-8303986/> [<https://perma.cc/BH2K-ZECT>] (explaining the necessity of medical evidence that marijuana does not meet any of the criteria of a Schedule I drug, and that such evidence likely will not exist any time soon). And administrative rescheduling may occur in 2024 for the breakthrough therapies of MDMA and psilocybin for treatment of PTSD and depression, respectively. Busby, *supra* note 81.

<sup>114</sup> OR. ADMIN. R. 333-333-3050 (2022) (specifying these nine modules as “(a) Historical, Traditional, and Contemporary Practices and Applications; (b) Cultural Equity in relation to Psilocybin Services; (c) Safety, Ethics and Responsibilities; (d) Psilocybin Pharmacology, Neuroscience, and Clinical Research; (e) Core Facilitation Skills; (f) Preparation and Orientation; (g) Administration; (h) Integration; and (i) Group Facilitation.”).

<sup>115</sup> Vice News, *supra* note 65.

<sup>116</sup> Psilocybin Services Act, OR. REV. STAT. § 475A (2021).

been explicit that this phrasing represents the understanding that though these services are therapeutic and medical, the Measure 109 regime rejects the traditional American medical model.<sup>117</sup> Rather than developing drugs through the federal government's research and approval process, Measure 109's regime allows the state to set its own standards for the licensed administration of psilocybin products.<sup>118</sup> Under Measure 109, the pharmaceutical industry and standard Western medicine is entirely out of the picture; no doctor's visit or prescription is necessary prior to requesting psilocybin services; facilitators do not need a medical or psychological degree; and nearly all products administered are outside of the pharmaceutical development process.<sup>119</sup>

Indeed, Measure 109's model appears to place the ownership of its medicine with historically underground and traditional practitioners in a safe, regulated, and clinical setting. In that sense, this model for medicalizing psychedelics resembles the movement to legalize medical cannabis by advocates like Dennis Peron, who coauthored California's Compassionate Use Act.<sup>120</sup> Measure 109's regime not only ensures safety, it also addresses some of the core concerns about the ethics of patenting psychedelic substances that this article contemplates.<sup>121</sup> For example, in prohibiting synthetic psilocybin and requiring state licensure for facilitators to provide therapeutic services, Oregon's regime directly responds to issues in patenting synthetic polymorphs and the basics of underground psychedelic therapy this article later highlights.<sup>122</sup>

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<sup>117</sup> Vice News, *supra* note 65.

<sup>118</sup> See McArdle, *supra* note 51.

<sup>119</sup> OR. ADMIN. R. 333-333 (2022); Vice News, *supra* note 65; Sabatier, *supra* note 10.

<sup>120</sup> See Lizzie Johnson, *Dennis Peron, Activist Who Helped Legalize Medical Marijuana, Dies*, SFGATE (Jan. 27, 2018), <https://www.sfgate.com/bayarea/article/Dennis-Peron-called-father-of-medical-12531260.php> [<https://perma.cc/E7BQ-N76L>] (noting that Peron, the "father of medical marijuana," opened the first dispensary in the United States in San Francisco in 1991); Isabella Vanderheiden, *25 Years Later: How Prop. 215 Changed the Cannabis Landscape for Humboldt County and California*, TIMES-STANDARD (Nov. 6, 2021) <https://www.times-standard.com/2021/11/06/25-years-later-how-prop-215-changed-the-cannabis-landscape-for-humboldt-county-and-california> [<https://perma.cc/B2WG-LJ6X>] (identifying Peron as a co-author of Proposition 215, also known as the Compassionate Use Act).

<sup>121</sup> See *infra* Parts IV–V (highlighting the issue of bad patents in the psychedelic space that results in a multitude of issues, including anticompetitive behaviors, biopiracy, reduced access, and less ambitious innovations).

<sup>122</sup> *Infra* Part IV. The downside of this model is that if there is a truly innovative product, process, or method created, patent protections are likely not available for the subject matter due to violations of federal law. See *infra* Part III.

Moreover, Measure 109's regime appears to focus on access to this life-changing medicine.<sup>123</sup> The federal government strictly guards the number of psychedelics that can be produced for research and social stigma makes federal funding difficult to receive, and as a result, "only well-capitalized private companies can fund this research," or companies need to conduct their research outside the United States.<sup>124</sup> Thus, it is difficult to enter the market under a traditional medical model and some of those costs may shift to the patients seeking treatment. In allowing Oregon to set its own standards, Measure 109 attempts to sidestep federal restrictions and the pharmaceutical process with the goal of making psilocybin medicines accessible.<sup>125</sup> This goal is clear in the rules' less clinical focus for what kinds of products are permitted (not synthetic and only orally consumable) and in the facilitator training and curriculum standards.<sup>126</sup>

On balance, Measure 109 represents a promising model for psychedelic medicine outside the traditional medical model that could spawn a new wave of legalization across the country.<sup>127</sup> Advocates have attempted to decriminalize psilocybin and legalize it for medical use via ballot initiative in California and other states.<sup>128</sup> As Measure 109's regime is implemented and

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<sup>123</sup> See McArdle, *supra* note 51.

<sup>124</sup> *Id.*; see also Marks & Cohen, *supra* note 21, at 219.

<sup>125</sup> Vice News, *supra* note 65. Of course, there are risks in allowing an unregulated treatment modality. See, e.g., NAT'L CANCER INST., *Laetrile/Amygdalin (PDQ®)—Health Professional Version*, <https://www.cancer.gov/about-cancer/treatment/cam/hp/laetrile-pdq> [<https://perma.cc/53PY-5TJF>]. However, the volume of science regarding the efficacy of psychedelics as a treatment for mental health issues both in recent decades and in the mid-twentieth century lends far more credence to their medical uses, even in unregulated environments. See, e.g., McArdle, *supra* note 51; HOW TO CHANGE YOUR MIND, EPISODE 1 (Netflix 2022) (discussing unregulated medicinal uses of LSD, including the practice of "micro-dosing," as researched and advocated by individuals such as Dr. James Fadiman).

<sup>126</sup> OR. ADMIN. R. 333-333-3050 (2022). Another unique way that Measure 109 promotes access is by permitting licensing throughout Oregon unless local jurisdictions prohibit manufacture or service centers via ballot measure. This form of local control avoids problems with access to medicine by requiring a vote among the people instead of local governments. *Oregon Measure 109, Psilocybin Services Act, Legalizes Psilocybin Therapy Across the State*, ROGOWAY L. GRP. (Nov. 17, 2020), <https://www.rogowaylaw.com/oregon-measure-109-psilocybin-services-act-legalizes-psilocybin-therapy-across-the-state/> [<https://perma.cc/58YC-QDA2>].

<sup>127</sup> See e.g., Kyle Jaeger, *California Activists Drop 2022 Psilocybin Legalization Ballot Initiative After Falling Short Of Signature Requirement*, MARIJUANA MOMENT (Mar. 17, 2022), <https://www.marijuanamoment.net/california-activists-drop-2022-psilocybin-legalization-ballot-initiative-after-falling-short-of-signature-requirement/> [<https://perma.cc/X4F3-N4SM>] (noting that California, Colorado, Connecticut, Georgia, Hawaii, Maryland, Michigan, Missouri, New Hampshire, Oklahoma, Rhode Island, Texas, Utah, Virginia, and Washington all have legislative or ballot initiative efforts underway to decriminalize, legalize for medical use, or study the efficacy of either policy).

<sup>128</sup> See, e.g., *id.* (discussing how activists in California failed to collect the required number of signatures to be on the 2022 ballot, but that activists want to try to get on the ballot for 2024); Kyle Jaeger, *Michigan Activists Begin Signature Gathering*

more medical research becomes available, state law legalizing medical psilocybin and other psychedelics may become a national trend.<sup>129</sup> However, absent changes in state law like Measure 109, the traditional pharmaceutical development model is the only way to legally approach psychedelic medicine.<sup>130</sup> Thus, this article will focus on the unique patent law issues emerging in psychedelic medicine in the context of the federal pharmaceutical development model.

## II. PATENT LAW

The Patent and Copyright Clause of the United States Constitution provides that Congress may “promote the Progress of Science and the useful Arts, by securing for limited Times to Authors and Inventors the exclusive Right to their respective Writings and Discoveries.”<sup>131</sup> Patents are rooted in this provision, and—as a government-sanctioned monopoly—permit patent holders to exclude others from misappropriating the

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*For Psychedelics Legalization Ballot Initiative Following State Certification*, MARIJUANA MOMENT (Mar. 28, 2022), <https://www.marijuanamoment.net/michigan-activists-begin-signature-gathering-for-psychedelics-legalization-ballot-initiative-following-state-certification/> [https://perma.cc/XK6N-KBGX] (noting that activists in Michigan were gathering signatures for a 2022 ballot measure on psychedelics); *see also Colorado Proposition 122 Election Results: Decriminalize and Regulate Certain Psychedelics*, N.Y. TIMES (last updated Dec. 13, 2022) <https://www.nytimes.com/interactive/2022/11/08/us/elections/results-colorado-proposition-122-decriminalize-and-regulate-certain-psychedelics.html> [https://perma.cc/ND97-P3RK] (showing that Colorado activists were successful in passing Measure 122, which decriminalized certain entheogenic plants and fungi and legalized the administration of them to people aged twenty-one and older for medical use).

<sup>129</sup> *See, e.g., Kyle Jaeger, Connecticut Lawmakers Send Psychedelic Treatment Program Proposal To Governor As Part Of Budget Bill*, MARIJUANA MOMENT (May 3, 2022), <https://www.marijuanamoment.net/connecticut-house-approves-psychedelic-treatment-program-as-part-of-budget-bill/> [https://perma.cc/R595-QJEK]; Ben Adlin, *Psilocybin Services Would Be Legalized In Washington State Under New Bill*, MARIJUANA MOMENT (Jan. 6, 2022), <https://www.marijuanamoment.net/psilocybin-services-would-be-legalized-in-washington-state-under-new-bill/> [https://perma.cc/H4CP-VVWC]; Kyle Jaeger, *Colorado Activists Pick One Of Several Psychedelics Reform Initiatives To Pursue For November Ballot*, MARIJUANA MOMENT (Mar. 15, 2022), <https://www.marijuanamoment.net/colorado-activists-pick-one-of-several-psychedelics-reform-initiatives-to-pursue-for-november-ballot/> [https://perma.cc/FX97-Q7GE]; Kyle Jaeger, *Michigan Activists Begin Signature Gathering For Psychedelics Legalization Ballot Initiative Following State Certification*, MARIJUANA MOMENT (Mar. 28, 2022), <https://www.marijuanamoment.net/michigan-activists-begin-signature-gathering-for-psychedelics-legalization-ballot-initiative-following-state-certification/> [https://perma.cc/JX63-W59G]; Kyle Jaeger, *Missouri Lawmakers Discuss GOP-Led Psychedelics Therapy And Decriminalization Bill In Committee*, MARIJUANA MOMENT (Mar. 21, 2022), <https://www.marijuanamoment.net/missouri-lawmakers-discuss-gop-led-psychedelics-therapy-and-decriminalization-bill-in-committee/> [https://perma.cc/WWY4-A5WR].

<sup>130</sup> VICE NEWS, *supra* note 65.

<sup>131</sup> U.S. CONST. art. I, § 8, cl. 8.

patented inventions for approximately twenty years.<sup>132</sup> The public policy justification for this approach is that granting exclusive rights to inventors rewards innovation and encourages public disclosure of inventions.<sup>133</sup> Without these rights, there may be little incentive to “invest the time, energy, and money necessary to create these works because they might be copied cheaply and easily by free riders, eliminating authors’ ability to profit from their works.”<sup>134</sup> This core principle of US patent law is reflected in the drug development model.<sup>135</sup>

#### A. *Patent Law Basics*

To receive a patent, an applicant must apply to the US Patent and Trademark Office (PTO) explaining how their inventions—defined as “process[es], machine[s], manufactur[es], or composition[s] of matter”—are novel, nonobvious, and useful.<sup>136</sup> Laws of nature, abstract ideas, and natural phenomena are not patentable subject matter because they are fundamental to scientific and technological progress.<sup>137</sup> Additionally, applicants must adequately describe and “enable” the invention such that people skilled in the field could reproduce and use the invention based on the description.<sup>138</sup>

The patent requirements of novelty and nonobviousness can be particularly challenging to meet in crowded fields—like drug development—while utility is often easy to satisfy.<sup>139</sup> An invention is not novel if it is not different from other inventions

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<sup>132</sup> *General Information Concerning Patents*, U.S. PAT. & TRADEMARK OFF., <https://www.uspto.gov/patents/basics/general-information-patents> [<https://perma.cc/H3XU-85QD>].

<sup>133</sup> See, e.g., Jeanne C. Fromer, *Expressive Incentives in Intellectual Property*, 98 VA. L. REV. 1745, 1746, 1751–52 (2012) (“According to the dominant American theory of intellectual property, copyright and patent laws are premised on providing creators with just enough incentive to create artistic, scientific, and technological works of value to society by preventing certain would-be copiers’ free-riding behavior.”).

<sup>134</sup> *Id.* at 1751.

<sup>135</sup> See *infra* Part III.

<sup>136</sup> 35 U.S.C. §§ 101, 102, 103; KEVIN J. HICKEY, CONG. RSCH. SERV., R46525, PATENT LAW: A HANDBOOK FOR CONGRESS 14–16 (2020), <https://crsreports.congress.gov/product/pdf/R/R46525/3>.

<sup>137</sup> See, e.g., *Funk Bros. Seed Co. v. Kalo Inoculant Co.*, 333 U.S. 127, 130 (1948) (defining natural phenomena as “manifestations of laws of nature, free to all men and reserved exclusively to none”); *2106 Patent Subject Matter Eligibility [R-10.2019]*, U.S. PAT. & TRADEMARK OFF., <https://www.uspto.gov/web/offices/pac/mpep/s2106.html> [<https://perma.cc/6RF2-48WR>].

<sup>138</sup> 35 U.S.C. § 112(a); HICKEY, *supra* note 136, at 13.

<sup>139</sup> See *Marks & Cohen*, *supra* note 21, at 218; *Panduit Corp. v. Stahlin Bros. Fibre Works, Inc.*, 298 F. Supp. 435, 442 (W.D. Mich. 1969) (“Utility, within the meaning of the patent statute, means that the object of the patent is capable of performing *some* beneficial function claimed for it.”) (emphasis in original), *aff’d*, 430 F.2d 221 (6th Cir. 1970).

that were previously patented, or disclosed to, used by, or available to the public.<sup>140</sup> The public works that predate the invention are known as “prior art.”<sup>141</sup> An invention is not nonobvious if it is so minimally different from the prior art that a person of ordinary skill in the relevant field would have found it obvious.<sup>142</sup>

Patents allow their holders to prevent others from making, using, or selling the invention—or even similar inventions—for twenty years unless the holder gives permission.<sup>143</sup> The defenses to patent infringement are limited; reverse engineering or even independently coming up with the same invention is not an excuse.<sup>144</sup> As such, patents offer the strongest form of intellectual property protections.<sup>145</sup> Returning to the reasoning behind patents, these protections are meant to reward innovation and encourage public disclosure of the invention.<sup>146</sup> Once a patent application is filed with the PTO, it becomes public after eighteen months.<sup>147</sup> Therefore, filing for a patent voids any trade secret protection an applicant could claim—even if the PTO ends up rejecting the application—allowing the public to learn from the claimed invention.<sup>148</sup>

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<sup>140</sup> See 35 U.S.C. § 102(a) (defining novelty); *What Makes an Invention “Novel”?*, BROOKS ACORDIA, <http://www.brooksacordia.com/faq/patent-faqs/what-makes-an-invention-novel/> [https://perma.cc/K6S3-4N83].

<sup>141</sup> *What Makes an Invention “Novel”?*, *supra* note 140.

<sup>142</sup> See 35 U.S.C. § 103 (defining nonobviousness).

<sup>143</sup> See *id.* § 154(a)(2) (explaining what happens after receiving a patent).

<sup>144</sup> See *id.* § 282(b) (excluding defenses for independent inventions or reverse engineering but providing defenses for “[n]oninfringement, absence of liability for infringement or unenforceability” and “[i]nvalidity of the patent or any claim”).

<sup>145</sup> See Viva R. Moffat, *The Copyrighted/Patent Boundary*, 48 U. RICH. L. REV. 611, 612 (2014) (comparing patent and copyright protections).

<sup>146</sup> See Fromer, *supra* note 133, at 1746, 1751.

<sup>147</sup> 35 U.S.C. § 122(b)(1)(a) (“[E]ach application for a patent shall be published . . . promptly after the expiration of a period of [eighteen] months from the earliest filing date.”); see STAN. U. OFF. TECH. LICENSING, INVENTORS GUIDE 1, 24 (2012) (observing that the PTO holds patent applications confidential until eighteen months have lapsed).

<sup>148</sup> See *Published Patent Application Access and Status Information Sheet for Members of the Public*, U.S. PAT. & TRADEMARK OFF., <http://www.uspto.gov/patents-application-process/patent-search/published-patent-application-access-and-status-information> [https://perma.cc/8JA5-ALYB] (“If the application is abandoned, the entire application (except in the situation where the publication was a redacted publication) is available to the public for inspection and for making copies through the File Information Unit (FIU).”); Brian J. Love & Christopher B. Seaman, *Best Mode Trade Secrets*, 15 YALE J.L. & TECH. 1, 3 (2012) (“Trade secrecy and patent rights traditionally have been considered mutually exclusive. Trade secret rights are premised on secrecy. Without it, they evaporate. Patent rights, on the other hand, require public disclosure. Absent a sufficiently detailed description of the invention, patents are invalid.”).



## B. *Patents Involving Schedule I Substances*

The PTO can grant patents on Schedule I substances and their medical uses despite their scheduling status.<sup>149</sup> However, holders of patents involving Schedule I substances have been reluctant to go to federal court out of fear of federal prosecution or concern that federal courts would not enforce them.<sup>150</sup> In just filing a patent application, one risks federal prosecution in that the application requires detailed description and enablement of the invention, which may present evidence that the applicant was violating federal law.<sup>151</sup> Furthermore, patents are only enforceable in federal court and a plaintiff seeking to enforce their patent will likely need to reveal to the judge how they are engaging in activities that may be illegal under federal law.<sup>152</sup> Thus, a court may decide not to grant equitable relief, “balk[ing]

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<sup>149</sup> See e.g., Ari Feinstein & Eric Furman, *Patent Protection for Cannabis?*, PHARMEXEC.COM (Nov. 13, 2018), <https://www.pharmexec.com/view/patent-protection-cannabis> [<https://perma.cc/2T53-EDQP>] (noting Epidiolex is “the first FDA-approved drug made from the cannabis plant” (internal citation omitted)); U.S. Patent No. 9,066,920 (filed June 29, 2010) (describing what was later marketed as Epidiolex; the PTO issued the patent in 2015); *Epidiolex (cannabidiol)*, MED. NEWS TODAY, <https://www.medicalnewstoday.com/articles/epidiolex#about> [<https://perma.cc/FXZ4-BTJJ>] (noting that Epidiolex received FDA approval in June 2018); Kari Oakes, *DEA Reclassifies Epidiolex as Schedule V*, MDEDGE (Nov. 26, 2018), <https://www.mdedge.com/neurology/epilepsyresourcecenter/article/175943/epilepsy-seizures/dea-reclassifies-epidiolex> [<https://perma.cc/B8PA-XY2C>] (explaining that the DEA rescheduled Epidiolex from Schedule I to V following FDA approval because there was an established medical use to treat seizures); Shayla Love, *Can LSD Treat Food Allergies? We Don't Know, But It's Already Been Patented*, VICE (July 1, 2021), <https://www.vice.com/en/article/g5gdzy/can-bsd-treatfood-allergies-we-dont-know-but-its-already-been-patented> (discussing a patent on using LSD to treat food allergies despite a lack of any experiments that suggest LSD is an effective treatment). Drugs derived from Schedule I substances, such as cannabinoids that are derived from the cannabis plant, are automatically Schedule I until proof of medical use and or low potential for abuse. See JANET E. JOY, STANLEY J. WATSON JR., & JOHN A. BENSON JR., INST. OF MED., MARIJUANA AND MEDICINE: ASSESSING THE SCIENCE BASE 199–201 (1999); Rescheduling of the Food and Drug Administration Approved Product Containing Synthetic Dronabinol From Schedule II to Schedule III, 64 Fed. Reg. 35,928 (July 2, 1999) (to be codified at 21 C.F.R. pts. 1308, 1312) (rescheduling Marinol from Schedule II to Schedule III based on recommendations from the Secretary for Health, after already having rescheduled from Schedule I to Schedule II once the FDA approved Marinol).

<sup>150</sup> See Sam Kamin & Viva Moffat, *Trademark Laundering, Useless Patents, and Other IP Challenges for the Marijuana Industry*, 73 WASH. & LEE L. REV. 217, 263–67 (2016) (noting how having a marijuana-related patent “may end up being an illusory benefit. Even though it theoretically creates an enforceable right, the continuing federal prohibition operates as a substantial impediment to the enforcement of that right and to the possibility of a remedy.”); Feinstein & Furman, *supra* note 149.

<sup>151</sup> Kamin & Moffat, *supra* note 150, at 244–45, 247.

<sup>152</sup> *Id.*; Feinstein & Furman, *supra* note 149.

at the prospect of awarding [a plaintiff] lost profits because those profits would be the fruit of a violation of federal law.”<sup>153</sup>

In the cannabis context, the first ever patent infringement case was not brought until 2018.<sup>154</sup> Another case followed shortly after, but unfortunately the first case is on hold due to the holder going through Chapter 11 Bankruptcy proceedings and the parties in the second case settled, agreeing there was no infringement.<sup>155</sup> As a result, there is still significant uncertainty as to how courts will treat these patents, both in the cannabis context and in the emerging psychedelics context. But even if these patents are possibly unenforceable, the strong protections they may offer make them valuable to pursue, especially if the federal government reschedules the substances involved in the patents.<sup>156</sup>

There is an easy way to avoid having an unenforceable patent: an applicant can better ensure the enforceability of their patent if they comply with DEA and FDA requirements to conduct the research that forms the basis of the application such that federal law is not violated. In the psychedelic context, the substances and uses for these patented substances have gone through or will likely soon go through the drug development model rather than a state law alternative.<sup>157</sup> This means that they either receive DEA approval to research in the United States or are researching overseas, and are seeking FDA approval for a new drug.<sup>158</sup> The basis of receiving the patent does not violate the CSA; as such, the problems of enforceability and potential federal prosecution disappear.<sup>159</sup>

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<sup>153</sup> See Kamin & Moffat, *supra* note 150, at 266 (“[A] federal court may be quite unwilling to give equitable relief to a party whose sole business consists of violating the Controlled Substances Act.”).

<sup>154</sup> Feinstein & Furman, *supra* note 149; Katie Rubino, *First Cannabis Patent Infringement Case Extinguished by Bankruptcy Proceeding*, JD SUPRA (May 14, 2021) <https://www.jdsupra.com/legalnews/first-cannabis-patent-infringement-case-5112267/> [<https://perma.cc/7BGX-CYDC>].

<sup>155</sup> Rubino, *supra* note 154; John Selwanes, *Texas Federal Judge Tosses Canopy Growth Lawsuit*, PAT. FORECAST (Mar. 3, 2022), <https://www.patentforecast.com/2022/03/03/texas-federal-judge-tosses-canopy-growth-lawsuit/> [<https://perma.cc/5TYQ-RVZR>]; Final Judgment, *Canopy Growth Corp. v. GW Pharma Ltd.*, No. 6:20-cv-01180-ADA (W.D. Tex. Feb. 25, 2022), ECF No. 56.

<sup>156</sup> See Kamin & Moffat, *supra* note 150, at 260; Feinstein & Furman, *supra* note 149.

<sup>157</sup> See, e.g., U.S. Patent No. 10,954,259 (filed Dec. 9, 2020); U.S. Patent No. 11,149,044 (filed Feb. 10, 2021); Jacobs, *supra* note 1 (“In October, [the FDA] gave Compass’s treatment breakthrough therapy status, a designation given to new medicines that might improve treatments for serious conditions, which means authorities will expedite their review of evidence.”).

<sup>158</sup> See *supra* Section I.C.1.

<sup>159</sup> See Kamin & Moffat, *supra* note 150, at 266 (explaining that “federal court[s] may be quite unwilling to give equitable relief to a party whose sole business consists of violating the Controlled Substances Act”).

The Schedule I status issue also goes away (after a bureaucratic process involving the DEA and Secretary of Health) if the FDA approves the drug—because of the clear medical use and low potential for abuse—which would likely result in a rescheduling.<sup>160</sup> Conversely, if a psilocybin-related business were operating in Oregon under the Measure 109 model and sought to patent its method of manufacturing psilocybin mushrooms, extracts, or edibles, it is likely that the business would be violating the CSA as Measure 109 intentionally sidesteps federal restrictions.<sup>161</sup> As a result, if the business were to receive a patent on its methods, it may prove an illusory benefit; the patent may be unenforceable and the business may be subject to federal prosecution as it likely admitted to violating the CSA in its patent application.<sup>162</sup>

### III. THE PTO'S BAD TRIP ON PSYCHEDELIC PATENTS

Plants and fungi that produce psychedelics are not patentable subject matter as they are natural phenomena; however, applicants can work around this limitation by creating new synthetic structures or developing a new process for producing them.<sup>163</sup> The purpose of seeking a patent is to provide these inventions with protections from other copycat companies.<sup>164</sup> If other companies can easily copy the inventions, this could cut into the inventor's profits, potentially hindering the development of the drug.<sup>165</sup> Not only do patents operate to protect early investment in drug or treatment development, they also hedge against the “costs of commercialization.”<sup>166</sup> Bringing new drugs to market is risky, with a high rate of failure.<sup>167</sup> Not

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<sup>160</sup> See, e.g., Rescheduling of the Food and Drug Administration Approved Product Containing Synthetic Dronabinol From Schedule II to Schedule III, 64 Fed. Reg. 35,928 (July 2, 1999) (to be codified at 21 C.F.R. pts. 1308, 1312) (rescheduling Marinol); Oakes, *supra* note 149 (discussing how the DEA rescheduled Epidiolex “from Schedule I to Schedule V”); see *supra* note 113 and accompanying text for an explanation of the rescheduling process. The prospect of administratively rescheduling psychedelics is at its most tangible state than it has ever been considering recent news that the Biden administration is anticipating FDA approval of MDMA and psilocybin for treating PTSD and depression within the next twenty-four months. Busby, *supra* note 81.

<sup>161</sup> *Supra* Section I.C.2–3.

<sup>162</sup> Kamin & Moffat, *supra* note 150, at 264–65.

<sup>163</sup> Marks & Cohen, *supra* note 21, at 218.

<sup>164</sup> See Joseph E. Stiglitz & Arjun Jayadev, *Medicine for Tomorrow: Some Alternative Proposals to Promote Socially Beneficial Research and Development in Pharmaceuticals*, 7 J. GENERIC MEDS. 217, 218–19 (2010).

<sup>165</sup> *Id.*

<sup>166</sup> Marks & Cohen, *supra* note 21, at 216.

<sup>167</sup> Duxin Sun, *90% of Drugs Fail Clinical Trials—Here's One Way Researchers Can Select Better Drug Candidates*, CONVERSATION (Feb. 23, 2022),

only do new drug sponsors need to pay money to go through FDA trials to get federal approval, they also need to get the approval of the broader medical community as well.<sup>168</sup>

But in the emerging psychedelics industry, some of the patents being issued probably should not have been granted due to a lack of novelty or nonobviousness. One reason these bad patents are issued is that the federal prohibition of psychedelics caused a dearth of examiners at the PTO with an adequate understanding of “these substances and their history” in underground and Indigenous traditions.<sup>169</sup> As a result, inventions that are neither new nor nonobvious may be granted patents due to this lack of expertise at the PTO.<sup>170</sup> Moreover—despite the Psychedelic Renaissance—there may be gaps in the prior art available on psychedelics because of the federal prohibition. When the PTO reviews its databases for prior art that may serve as a basis for rejecting the patent, it may only conduct what is actually a cursory search since the PTO’s databases may lack a complete catalogue of the prior art and the PTO has limited resources to dig deep during the prior art review.<sup>171</sup> And despite underground psychedelic retreats and therapies existing for decades, underground practitioners avoid publishing their methods out of fear of legal consequences.<sup>172</sup> The PTO databases are also unlikely to include Indigenous traditions because psychedelic knowledge may not be transmitted in writing, let alone in English.<sup>173</sup>

Because of these gaps in PTO expertise and the prior art, the PTO is receiving applications featuring broad claims that exploit the examiners’ unfamiliarity with the substances, their uses, and their history, which results in bad patents.<sup>174</sup> This is especially true because of the first to file system, which encourages broad patent applications with the least amount of data to convince an examiner to grant the patent.<sup>175</sup> One example

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<https://theconversation.com/90-of-drugs-fail-clinical-trials-heres-one-way-researchers-can-select-better-drug-candidates-174152/> [<https://perma.cc/4DDB-JNEH>].

<sup>168</sup> See, e.g., Christian Angermayer, *An Open Letter to Tim Ferriss About the Value of Patents in the Psychedelic World*, LINKEDIN (Mar. 9, 2021), <https://www.linkedin.com/pulse/open-letter-tim-ferriss-value-patents-psychedelic-angermayer/> [<https://perma.cc/7KFQ-RLT6>].

<sup>169</sup> See Marks, *supra* note 9, at 656, 666–68; Marks & Cohen, *supra* note 21, at 219–20.

<sup>170</sup> Vice News, *supra* note 65.

<sup>171</sup> Jay P. Kesan, *Carrots and Sticks to Create a Better Patent System*, 17 BERKELEY TECH. L.J. 763, 765–66 (2002).

<sup>172</sup> Marks, *supra* note 9, at 657–58; Marks & Cohen, *supra* note 21, at 220.

<sup>173</sup> Marks & Cohen, *supra* note 21, at 220.

<sup>174</sup> *Id.*; see Kesan, *supra* note 171, at 767.

<sup>175</sup> Clinical Rsch. Ass’n of Can., *Intellectual Property Panel: Psychedelics and Cannabis Drug Development*, YOUTUBE (Oct. 24, 2021),

is an application from Compass Pathways (Compass), a British company seeking to patent synthetic psilocybin and methods of administering it to treat a wide range of mental health issues.<sup>176</sup> The application pertains to administering psilocybin with claims involving “set and setting,” which is the mindset and environment in which an individual consumes psychedelic substances.<sup>177</sup> The application claims to treat depression with “psilocybin . . . administered . . . in a room with a substantially non-clinical appearance,” including “soft furniture,” “muted colors,” “a high resolution sound system” and music, “a bed or couch,” and “reassuring physical contact” and conversation from the therapist.<sup>178</sup> All of these claims are features in psychedelic therapy in academic research, in underground settings, and traditional Indigenous practices.<sup>179</sup> Thus, there are serious questions as to the novelty and nonobviousness of these claims; but these are contexts entirely unknown to the PTO examiners.

An example of a bad patent, again involving Compass, is the company’s patents claiming certain crystalline compositions of synthetic psilocybin.<sup>180</sup> A substance can have a variety of

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[https://www.youtube.com/watch?v=MiiUPZne5ok&ab\\_channel=ClinicalResearchAssociationofCanada](https://www.youtube.com/watch?v=MiiUPZne5ok&ab_channel=ClinicalResearchAssociationofCanada) (“The first to file system, combined with this confidentiality periods and the general hyperactivity in the psychedelics space has resulted in very aggressive patent filing strategies for companies. . . . [I]t is not uncommon to see patent applications that appear to be light on the amount of data [typical in a pharmaceutical patent] . . . [T]here are significant pressures to file as early as possible in this space, . . . which raises the question of whether there’s enough support for the invention when the application is filed. Another challenge here is that patents may seem overly broad.”).

<sup>176</sup> See U.S. Patent No. 10,947,257 (filed July 2, 2020) [hereinafter ‘257 Patent] (claiming a synthesis of psilocybin administered orally to treat major depressive disorder); WIPO Patent Application No. WO 2020/212952 A1 (Apr. 17, 2020) (claiming the basics of psychedelic therapy to treat depression and other mental health disorders).

<sup>177</sup> WIPO Patent Application No. WO 2020/212952 A1, *supra* note 176, at 58 (explaining that “set and setting” refers to the subject’s mindset (“set”) and the physical and social environment (“setting”) in which the user has the psilocybin session”); Vice News, *supra* note 65 (explaining the content of Compass’s international patent application).

<sup>178</sup> WIPO Patent Application No. WO 2020/212952 A1, *supra* note 176, at 250–52.

<sup>179</sup> See, e.g., Gregoire, *supra* note 22; Shayla Love, *Can a Company Patent the Basic Components of Psychedelic Therapy?*, VICE (Feb. 10, 2021) [hereinafter Love, *Psychedelic Therapy*], <https://www.vice.com/en/article/93wmxv/can-a-company-patent-the-basic-components-of-psychedelic-therapy> (discussing patent claims that are likely invalid because they are identical to prior art in academic, indigenous, and underground settings); Shayla Love, *Psychedelics Patent Claim Raises Questions from Researchers Who Say They Did It First*, VICE (June 4, 2021), <https://www.vice.com/en/article/qj8vmp/psychedelics-patent-claim-raises-questions-from-researchers-who-say-they-did-it-first> (reporting on a patent on genetically modified yeast and bacteria as methods to make psilocybin and how it will likely be challenged because German scientists can credibly claim to have made the invention first).

<sup>180</sup> U.S. Patent No. 10,954,259 (filed Dec. 9, 2020) [hereinafter ‘259 Patent]; 57 U.S. Patent No. 11,149,044 (filed Feb. 10, 2021) [hereinafter ‘044 Patent]; see Rolf Hilfiker et al., *Relevance of Solid-State Properties for Pharmaceutical Products*, in POLYMORPHISM IN THE PHARM. INDUS. 1, 1 (Rolf Hilfiker & Markus von Raumer eds., 2006) (explaining how solid substances can exist in crystalline forms).

crystalline structures that are “new” or “different”—known as polymorphs—that have little improved function if any as a result of the variation in crystalline structure.<sup>181</sup> Compass received patents in 2021 that claim more than one formulation of Polymorph A of psilocybin.<sup>182</sup> A second patent, also granted to Compass in 2021, claims more than one formulation of psilocybin polymorph Hydrate A.<sup>183</sup> Some countries are more restrictive “of polymorph patents than the United States”, arguing that polymorphs are not novel since they are insignificant advances.<sup>184</sup>

Patenting a new polymorph like this is a form of product hopping: where an applicant effectively patents an existing technology by claiming a novel invention through slight modifications to the existing technology.<sup>185</sup> Though the two technologies are different, they are identical in their effectiveness; and in this case with the Compass polymorphs, the only true difference from the prior is the crystalline structure of the substance.<sup>186</sup> Thus, these polymorphs are already suspect in terms of patent eligibility because they are arguably not novel (the same compound is created but with a slightly different variation in its structure) or nonobvious (an expert may find it obvious to create based on prior art).<sup>187</sup>

These claims are especially distressing when considering challenges to these issued patents by a nonprofit organization known as Freedom to Operate (FTO), which is dedicated to preventing patent monopolies in the psychedelics space.<sup>188</sup> In its

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<sup>181</sup> See, e.g., Jennifer D. Claytor & Rita F. Redberg, *Product Hopping—An Expensive and Wasteful Practice*, 180 JAMA INTERNAL MED. 1154, 1154 (2021) (outlining how drug manufacturers slightly modify existing treatments to continue their patent monopolies); Michael A. Carrier & Steve D. Shadownen, *Product Hopping: A New Framework*, 92 NOTRE DAME L. REV. 167, 172, 220–21 (2016) (explaining how it is possible to product hop by patenting isolated molecules derived from a mixture of enantiomers); Amy Kapczynski et al., *Polymorphs and Prodrugs and Salts (Oh My!): An Empirical Analysis of “Secondary” Pharmaceutical Patents*, 7 PLOS ONE 1, 1 (2012).

<sup>182</sup> '259 Patent, *supra* note 180; see also U.S. Patent No. 10,947,257 (filed July 2, 2020) (issued March 16, 2021).

<sup>183</sup> '044 Patent, *supra* note 180.

<sup>184</sup> Marks & Cohen, *supra* note 21, at 221.

<sup>185</sup> Claytor & Redberg, *supra* note 181, at 1154.

<sup>186</sup> '259 Patent, *supra* note 180; '257 Patent, *supra* note 176; '044 Patent, *supra* note 180.

<sup>187</sup> See Vice News, *supra* note 65.

<sup>188</sup> *Letter from the Founder*, FREEDOM TO OPERATE [hereinafter *FTO Letter*], <https://freedomtooperate.org/home/letter-from-the-founder/#letterfromthefounder> [https://perma.cc/77EZ-82AS]; Freedom to Operate, Inc. v. Compass Pathways, Ltd., Petition for Post-Grant Review of U.S. Patent No. 10,947,257 (Dec. 2021) [hereinafter '257 Filing], <https://freedomtooperate.org/wp-content/uploads/2021/12/PGR-Petition-Filed-1221.pdf> [https://perma.cc/82LU-B8K3]; Freedom to Operate, Inc. v. Compass Pathways, Ltd., Petition for Post-Grant Review of U.S. Patent No. 10,954,259 (Dec. 2021)

challenges before the Patent Trial and Appeal Board (PTAB) initiated in December 2021, FTO has asserted that Compass's Polymorph A is not novel because it is actually a mixture of two previously existing polymorphs, and noted that a sample of prior art from 1975 actually had the same crystalline structures present.<sup>189</sup> Similarly, the subsequent filing by FTO contains testimony from several experts in the field that the claimed Polymorph A would be obvious to an ordinary person skilled in the art.<sup>190</sup> FTO was also quick to note that in assessing obviousness, the Board "considers whether a skilled artisan would have been motivated to combine the prior art to achieve the claimed invention and whether there would have been a reasonable expectation of success in doing so."<sup>191</sup> Thus in FTO's view, the patents for Polymorph A should not have been granted because they lack novelty and are obvious, and if the PTAB agrees could result in a radical precedent in the psilocybin space. FTO has not challenged the Hydrate A patent yet, but it wrote a letter to Compass in April 2022 explaining the patent is invalid since the "claimed Hydrate A was available as early as 1963 and was used in human clinical trials as early as 2017."<sup>192</sup> FTO requested that Compass renounce the patent or at least pledge to not enforce it because of the lack of novelty.<sup>193</sup> If these allegations are true, these are clear examples of bad patents resulting from a lack of a sufficient understanding of the prior art.

Another example of a bad patent is Palo Alto Investors' 2021 patent for LSD as a treatment for food allergies despite the filing including no real-world data that this would be an effective treatment.<sup>194</sup> The PTO's approval of the patent was technically allowed because "prophetic examples"—in which imaginary experiments are included in the application such that an expert in the field could potentially make use of them to create the claimed invention—are sufficient to receive a patent.<sup>195</sup> But even

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[hereinafter '259 Filing], <https://freedomtooperate.org/wp-content/uploads/2021/12/FTO-PGR-Second-Filing.pdf> [<https://perma.cc/P7MD-C84F>].

<sup>189</sup> See Vice News, *supra* note 65; '257 Filing, *supra* note 188; '259 Filing, *supra* note 188.

<sup>190</sup> '257 Filing, *supra* note 188; '259 Filing, *supra* note 188.

<sup>191</sup> '257 Filing, *supra* note 188; '259 Filing, *supra* note 188 (citing Fox Factory, Inc. v. SRAM, LLC, 944 F.3d 1366, 1372 (Fed. Cir. 2019)).

<sup>192</sup> Letter from Carey Turnbull, Director of FTO to George Goldsmith, Chief Executive Officer of Compass Pathways (Apr. 12, 2022), <https://freedomtooperate.org/wp-content/uploads/2022/04/Letter-FTO-to-Compass-re-044-Patent-Hydrate-A11061981.1.pdf> [<https://perma.cc/4L5E-HUU6>].

<sup>193</sup> *Id.*

<sup>194</sup> Love, *supra* note 149.

<sup>195</sup> Janet Freilich, *Prophetic Patents*, 53 U.C. DAVIS L. REV. 663, 666 (2019) (detailing how it is acceptable to patent an invention based on imaginary experiments).

if the application included real-world experiments, the patent should not have been issued due to a lack of novelty considering that the potential uses for the psychedelics to treat allergies were disclosed in the 1960s.<sup>196</sup> Again, the PTO missed the mark due to a lack of familiarity with psychedelics and the prior art in the field. Reform is required to ensure these mistakes—which reduce competition and chill research—do not continue to happen.

#### IV. ABUSING THE SYSTEM: GREED IS THWARTING ACCESS, INNOVATION, AND EQUITY

Mental health treatments have long been eligible for patent protection, yet there has not been much innovation in mental health treatments since the advent of SSRIs.<sup>197</sup> Psychedelics have the potential to be one of the biggest recent innovations in this field given their effectiveness compared to SSRIs.<sup>198</sup> As a result, research and competition in this space should be encouraged via the patent system, rather than rewarding mere technical differences with limited improvement or clear copies of prior art.

Limited access to more effective treatments, biopiracy and inequitable treatment of indigenous people, and reduced scientific progress all result from the PTO issuing so many bad psychedelics patents.<sup>199</sup> Some companies are attempting to take advantage of the system and the PTO's lack of knowledge of these substances to receive bad patents and shut out competition.<sup>200</sup> The current psychedelic patents are broad and the field is full of them, creating a thicket of patent rights that discourage competitors from entering the field.<sup>201</sup> Without competition in this industry—which already lacks investors and is difficult to research domestically given psychedelics' Schedule I status—there is a serious risk that an early patent ensures

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<sup>196</sup> Harold A. Abramson, *Lysergic Acid Diethyl Amide (LSD25): XXXVII. Antiserotonin Action of Lysergic Acid Derivatives in Allergy and Neuropsychiatry*, 2 J. ASTHMA RSCH. 257, 257 (1965); Love, *supra* note 149.

<sup>197</sup> See, e.g., Richard A. Friedman, *A Dry Pipeline for Psychiatric Drugs*, N.Y. TIMES (Aug. 19, 2013), <https://www.nytimes.com/2013/08/20/health/a-dry-pipeline-for-psychiatric-drugs.html> [<https://perma.cc/2PZV-YFMH>].

<sup>198</sup> See *supra* notes 55–56 and accompanying text; Steven A. Barker, *N, N-Dimethyltryptamine (DMT), an Endogenous Hallucinogen: Past, Present, and Future Research to Determine Its Role and Function*, 12 FRONTIERS OF NEUROSCIENCE. 1, 1, 12 (2018) (noting the potential psychedelics have not only for mental health treatment but also greater understanding of the mind).

<sup>199</sup> Gregoire, *supra* note 22; Leite, *supra* note 25; Barnett et al., *supra* note 26; see Marks, *supra* note 26.

<sup>200</sup> Letter from Carey Turnbull, *supra* note 192, at 2.

<sup>201</sup> Marks & Cohen, *supra* note 21, at 232; see also, e.g., RICHARDS ET AL., *supra* note 25, at 1.



perpetual monopoly.<sup>202</sup> While this is not unique to the psychedelics industry, these debates on monopolization and abuse of the system are important.<sup>203</sup>

Patents allow their holders to bring infringement actions against others that may be infringing on the holder's temporary monopoly without consent or compensation.<sup>204</sup> The type of patenting in the psychedelics space is offensive rather than defensive—designed to keep competition out—and when this tactic is employed, the patents are typically enforced liberally.<sup>205</sup> As a result, competitors may be disincentivized from researching out of fear of litigation, especially when costs are so high.<sup>206</sup> Even potentially invalid patents pose an issue because the risk of litigation does not disappear until the patent is held to be invalid.<sup>207</sup> Therefore, competitors are often cautious to enter a market when there is a patent thicket, and investors may similarly be discouraged.<sup>208</sup>

Via the applicant tactic of product hopping, there is a significant risk that—if a company like Compass is able to patent an already existing or obvious polymorph—it could continue to patent other polymorphs or slight modifications to extend the monopoly once its patent is about to lapse. If a company can continue its monopoly, it can continue to deter competitors. Additionally, these patents contribute to the thicket, disincentivizing competitors and investors of rival firms.

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<sup>202</sup> *Infra* Part III; See Michael A. Carrier & Steve Shadowen, *Product Hopping*, 92 NOTRE DAME L. REV. 167, 182 (2016); see also Mason Marks, *FDA's Kratom Ban Would Harm the Public and Damage the Agency's Credibility*, STAT (Aug. 23, 2021), <https://www.statnews.com/2021/08/23/fdas-kratom-ban-would-harm-the-public-and-damage-the-agencys-credibility/> [https://perma.cc/ZF7B-6MJF] (explaining how prohibition “strengthens government-granted [patent] monopolies”).

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

<sup>204</sup> 35 U.S.C. § 154 (2012).

<sup>205</sup> Letter from Carey Turnbull, *supra* note 192, at 3; Love, *supra* note 21. This tactic is not entirely unique to psychedelics. In the cannabis space, similar issues are emerging. For example, Canopy Growth Corporation sued GW Pharma Limited for infringement of its patent on a CO<sub>2</sub> extraction method of a THC and CBD extract. The lawsuit was filed the day Canopy received the patent, and the method is purportedly common in the industry. See Rubino, *supra* note 154; Selwanes, *supra* note 155; Canopy Growth Corp. v. GW Pharma Ltd., No. 6:20-cv-01180-ADA (W.D. Tex. Feb. 25, 2022), at \*1–2.

<sup>206</sup> See Malathi Nayak, *Costs Soar for Trade Secrets, Pharma Patent Suits, Survey Finds*, BLOOMBERG L. (Sept. 10, 2019, 8:01 AM), <https://news.bloomberglaw.com/ip-law/costs-soar-for-trade-secrets-pharma-patent-suits-survey-finds> (estimating that the average pharmaceutical patent case costs \$2.5 million, a 67 percent increase from 2015 to 2019).

<sup>207</sup> See Marks & Cohen, *supra* note 21, at 223.

<sup>208</sup> *Id.*

As a result, research may be chilled and scientific progress may be delayed. Furthermore, such patents reward technical differences that are not the kind of scientific innovation the patent system intends to reward and protect. This tactic has also been criticized as an abuse of the system, not only for limiting true innovation, but also for being a waste of the PTO's resources.<sup>209</sup> Ultimately, by contributing to the thicket, access to these treatments may be reduced and the cost of the treatment may be inflated as a result of monopolization.<sup>210</sup>

Another abuse of the system stems from the lack of acknowledgement of Indigenous traditions that psychedelic companies may be drawing from in their patented inventions. In a practice called bioprospecting, useful natural resources are identified and assessed for their commercialization potential.<sup>211</sup> But this can teeter into the realm of biopiracy: where the knowledge of Indigenous communities is exploited for Western commercialization without real acknowledgement or compensation.<sup>212</sup> For example, ibogaine is a psychedelic compound in the plant iboga, and appears to be a promising treatment option for substance abuse; but the plant is used by members of the Bwiti religion in Gabon ceremonially.<sup>213</sup> Western drug developers are seeking to commercialize ibogaine, announcing a provisional patent on a synthesis of the compound, yet no mention is made of the Bwiti faith and its traditional healing rituals.<sup>214</sup> This is a clear equity issue, as Indigenous

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<sup>209</sup> See Stiglitz & Jayadev, *supra* note 164, at 218–19.

<sup>210</sup> See, e.g., *FTO Letter*, *supra* note 188 (criticizing a “patent troll” firm for guarding a patent they did not invent to prevent others from using it).

<sup>211</sup> Tim K. Mackey & Bryan A. Liang, *Integrating Biodiversity Management and Indigenous Biopiracy Protection to Promote Environmental Justice and Global Health*, 102 AM. J. PUB. HEALTH 1091, 1091 (2012).

<sup>212</sup> *Id.*

<sup>213</sup> Pierre Didier Nyongo Ndoua & Kaveh Vaghar, *Bwiti, Iboga, Trance and Healing in Gabon*, 21 MENTAL HEALTH, RELIGION & CULTURE 755, 755–56 (2018); see, e.g., Thomas Kingsley Brown & Kenneth Alper, *Treatment of Opioid Use Disorder with Ibogaine: Detoxification and Drug Use Outcomes*, 44 AM. J. DRUG & ALCOHOL ABUSE 24, 24 (2018).

<sup>214</sup> *MINDCURE Announces Filing U.S. Provisional Patent Applications for Company's First Fully Synthetic Routes to Create an Ibogaine Psychedelic Compound*, PR NEWSWIRE (July 13, 2021, 3:30 AM), <https://www.mindcure.com/news/mindcure-announces-filing-of-u-s-provisional-patent-applications-for-companys-first-fully-synthetic-routes-to-create-an-ibogaine-psychedelic-compound> [<https://perma.cc/G9P5-9LZY>]; GUIGNON YANN GUIGNON, *ECOLOGICAL REPORT ON TABERNANTHE IBOGA* (2014), (describing how early Pygmy practitioners of Bwiti used iboga to help community members overcome compulsive behaviors, including substance abuse of palm wine); MARCELIN MAHON TONYE, ET AL., U.S. AGENCY FOR INTERNATIONAL DEVELOPMENT, *STATE OF KNOWLEDGE STUDY ON TABERNANTHE IBOGA BAILLON: A REPORT FOR THE CENTRAL AFRICAN REGIONAL PROGRAM FOR THE ENVIRONMENT* 17 (2000), [http://pdf.usaid.gov/pdf\\_docs/Pnads957.pdf](http://pdf.usaid.gov/pdf_docs/Pnads957.pdf) [<https://perma.cc/NMQ5-TCRX>] (“Most of the

communities have pointed out that companies patenting psychedelics are merely commodifying healing and religious practices with rich histories that go back centuries.<sup>215</sup> And these companies are doing this without consent, permission, or compensating relevant Indigenous communities.

But it does not need to be this way. In a nonpsychedelic case, a German pharmaceutical company patented an extract of the *Pelargonium sidoides* plant to treat bronchitis.<sup>216</sup> The patent was challenged for a lack of novelty because Indigenous communities in South Africa used the roots of the plant to treat respiratory infection.<sup>217</sup> Convinced by this evidence, the European Patent Office invalidated the patent.<sup>218</sup> In the psychedelics space, patents for therapeutic use of psychedelic substances—derived from plant medicines that some Indigenous groups find essential to their cultural identity—are being granted to companies that seek to both commercialize and monopolize these substances and practices.<sup>219</sup> Without biopiracy protections, this exploitation—and alienation of these practices from Indigenous identity—will only continue.<sup>220</sup>

## V. MEANINGFUL PATENT REFORM IN AN EMERGING INDUSTRY

Bad patents are being issued because of a lack of knowledge of psychedelics and a lack of access to prior art at the PTO. As a result, there is less competition in the psychedelics industry and thus higher costs on patients for these treatments, less meaningful innovation, and exploitation through a failure to recognize that psychedelic medicines draw on Indigenous

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traditional healers named sicknesses like fever, stomachache, liver disorders, madness, and addiction (consumers of local drug called MBANGA and local alcohol called FOFO).”)

<sup>215</sup> See Gregoire, *supra* note 22, at 4.

<sup>216</sup> Kaushiki Das, *The Global Quest for Green Gold: Implications of Bioprospecting and Patenting for Indigenous Bioresources and Knowledge*, 6 SOC’Y & CULTURE S. ASIA 74, 83 (2020).

<sup>217</sup> *Id.*

<sup>218</sup> *Id.*

<sup>219</sup> Marks & Cohen, *supra* note 21, at 228–29.

<sup>220</sup> See Daanyaal R. Kumar, *United States Patents, Biopiracy, and Cultural Imperialism: The Theft of India’s Traditional Knowledge*, 11 INQUIRIES J. 1 (2019), <https://www.inquiriesjournal.com/articles/1769/united-states-patents-biopiracy-and-cultural-imperialism-the-theft-of-indias-traditional-knowledge> [<https://perma.cc/MDA3-BWZP>]; Jamilah R. George et al., *The Psychedelic Renaissance and the Limitations of a White-Dominant Medical Framework: A Call for Indigenous and Ethnic Minority Inclusion*, 2019 J. PSYCHEDELIC STUD. 1, 2, 6–8 (“[When] White-dominant culture borrows from the cultural practices and ceremonial expression of often marginalized and disenfranchised indigenous groups, members of these groups end up alienated from the practices informed by their own cultural traditions.”); see also *id.* at 6–8 (discussing a lack of minority inclusion in psychedelic research and treatment).

traditions. There are solutions to these problems, including expanding and encouraging third-party challenges; expanding, creating, and assisting libraries of psychedelic prior art; clarifying novelty and nonobviousness by statute; patent pledges; other forms of limited patent protection that promote innovation and foster equality; and entirely forgoing patents on psychedelics.<sup>221</sup> This article outlines a multipronged approach, incorporating many of the above solutions, to provide adequate outcomes for all stakeholders in psychedelic patents.<sup>222</sup>

A. *Potential Solutions to Limit Abuse of the System*

There are a number of solutions to the issues resulting from the abuses of the patent system in the medical psychedelics industry. Beginning with the short-term solutions, third parties are able to challenge the validity of issued patents through “postgrant” and “inter partes” proceedings before the PTAB.<sup>223</sup> This solution is what FTO attempted to do in challenging the validity of Compass’s Polymorph A patents.<sup>224</sup> In postgrant review, petitioners must file with the PTAB within nine months of the issue date of the patent and show that one or more claim in the patent is likely unpatentable.<sup>225</sup> In inter partes review, petitioners must file nine months after the issue date of the patent or upon termination of a petition for post-grant review, whichever is later.<sup>226</sup> Petitioners in inter partes review need to show that there is a reasonable likelihood of success in demonstrating at least one claim is invalid.<sup>227</sup> FTO sought postgrant review of the Compass patents, and presented analyses from chemists and the opinion of experts in the field to prove that samples predating the issuance of the Polymorph A patents are identical and therefore not novel.<sup>228</sup> In the alternative, FTO argued that the polymorphs are obvious and therefore at least one claim is likely unpatentable.<sup>229</sup> This

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<sup>221</sup> See *infra* Section V.A.

<sup>222</sup> See *infra* Section V.B.

<sup>223</sup> *Inter Partes Disputes*, U.S. PAT. & TRADEMARK OFF., <https://www.uspto.gov/patents/laws/america-invents-act-aia/inter-partes-disputes> [<https://perma.cc/TE5U-5KK4>].

<sup>224</sup> See *supra* Part III; Shayla Love, *New Filing Challenges Compass Pathways’ Infamous Patent on Synthetic Psilocybin*, VICE (Dec. 15, 2021), <https://www.vice.com/en/article/pkpg7b/syntheticpsilocybin-patent-challenge-compass-pathways>.

<sup>225</sup> *Inter Partes Disputes*, *supra* note 223.

<sup>226</sup> *Id.*

<sup>227</sup> *Id.*

<sup>228</sup> Love, *supra* note 224; ’257 Filing, *supra* note 188, at 12–25, 33; ’259 Filing, *supra* note 188, at 12–24, 32.

<sup>229</sup> ’257 Filing, *supra* note 188, at 4–5, 38; ’259 Filing, *supra* note 188, at 4–5, 38.

solution, though reactive, is a good avenue to shut down bad patents before they allow their holders to create perpetual monopolies; it also helps define what the PTO will deem novel and nonobvious.

A proactive short-term approach would be to expand, assist, and create psychedelic prior art libraries. A nonprofit library called Porta Sophia curates psychedelic prior art and makes it available to PTO examiners as well as to patent applicants.<sup>230</sup> Having more or better funded prior art libraries in this field could assist the PTO in conducting the prior art search as it will not have to strain its limited resources searching for more obscure prior art or references in patent applications that it would otherwise miss. “The knowledge exists, it just isn’t where examiners are looking.”<sup>231</sup> Wide availability of the information will reduce bad patents because applicants’ knowledge of the prior art may induce them to expand upon it in truly innovative ways rather than waste their time seeking a patent on something already known. But this short-term solution still does not address the root cause of bad patents, and often requires scientific, Indigenous, and underground communities to catalogue and submit their practices and findings to prior art libraries.<sup>232</sup>

To get at the core of the issue, legislation is required that clarifies the patent requirements of novelty and nonobviousness to address the abuses of things like product hopping and biopiracy. If Congress passed a law stating that compositions of polymorphs—and other slight variations like salts and enantiomers—lacking little if any improvement or innovation of existing inventions are not novel or are obvious, then the issue of product hopping in psychedelics and rewarding technical differences rather than major innovations with patent protection is resolved. Similarly, Congress should pass a law stating that

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<sup>230</sup> *Porta Sophia Psychedelic Prior Art Library*, PORTA SOPHIA, <https://www.portasophia.org> [<https://perma.cc/39H8-LGC7>].

<sup>231</sup> Paul Coble (@p\_coble), TWITTER (Apr. 27, 2022, 4:15 PM), [https://twitter.com/p\\_coble/status/1519410031170519040?ext=HHwWgICsgfHXg5YqAA](https://twitter.com/p_coble/status/1519410031170519040?ext=HHwWgICsgfHXg5YqAA) [<https://perma.cc/AA4L-VY78>] (“Bad” patents are a problem in every industry, but they are particularly prevalent in the cannabis and psychedelics industries due to the relative lack of traditional, published prior art.”); *see generally* Lauren Wilson, *A New Database Seeks to Prevent “Bad” Psychedelic Patents*, LUCID NEWS (Apr. 25, 2022), <https://www.lucid.news/a-new-database-seeks-to-prevent-bad-psychedelic-patents/> [<https://perma.cc/3B3W-D9BV>] (explaining the prevalence of bad patents in the psychedelic industry and noting the role that Porta Sophia can play in remedying the bad patent issue).

<sup>232</sup> *See* Marks & Cohen, *supra* note 21, at 232 (“[T]hough admirable, projects like Porta Sophia are more of a band-aid than a long-term solution because they burden local communities with cataloguing their practices and submitting them to prior art libraries.”).

preventing biopiracy will be prioritized in the patent process ensuring that psychedelics are truly novel and nonobvious rather than directly derived from underground or Indigenous practices. The only issue with drafting legislation that tightens up patent requirements is that it could be challenged by Big Pharma lobbyists. These lobbyists could persuasively argue that these product hopping and biopiracy protections also cover drug and treatment development broadly—not just in the psychedelics space.<sup>233</sup> This resistance is especially likely given Big Pharma’s legislative efforts to expand patent eligibility requirements.<sup>234</sup>

Thus, a better option might be “patent pledges” whereby companies pledge to not enforce their patent rights under certain conditions.<sup>235</sup> Such a pledge was recently made during the COVID-19 pandemic when companies took the Open COVID Pledge assuring those that used patented innovations to address COVID-19 would not be sued.<sup>236</sup> But these pledges are not unique to the pandemic; there have been similar pledges in the electric- and hybrid-vehicle industry and the space industry.<sup>237</sup> Returning to Compass’s pending patent application claiming core aspects of set and setting, the company’s president stated in 2021 that Compass would not enforce any patent claims it has related to set and setting.<sup>238</sup> But it is unclear just how

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<sup>233</sup> See, e.g., Emmarie Huetteman, *Senators Who Led Pharma-Friendly Patent Reform Also Prime Targets for Pharma Cash*, KAISER HEALTH NEWS (Mar. 24, 2020), <https://khn.org/news/senators-who-led-pharma-friendly-patent-reform-also-prime-targets-for-pharma-cash> [https://perma.cc/F2J9-LN6X].

<sup>234</sup> *Id.*

<sup>235</sup> PAT. COMMONS PROJECT, OPEN SOURCE DEV. LABS, INC., UNDERSTANDING PATENT PLEDGES: AN OVERVIEW OF LEGAL CONSIDERATIONS (2006), [https://patentcommons.org/publications/OSDL\\_Whitepaper\\_Final\\_final\\_4-12-06.pdf](https://patentcommons.org/publications/OSDL_Whitepaper_Final_final_4-12-06.pdf) [https://perma.cc/EG5N-DMMW].

<sup>236</sup> *Make the Pledge to Share Your Intellectual Property in the Fight Against COVID-19*, OPEN COVID PLEDGE, <https://opencovidpledge.org> [https://perma.cc/ZX9J-8EEA]. While the data is still limited, it is believed that the Open COVID Pledge has been successful in providing contextual information for development of devices for virus detection, despite a lack of “ongoing stewardship and active assessment of the rights being made available.” Ginevra Assia Antonelli et al., *Exploring the Open COVID Pledge in the Fight Against COVID-19: A Semantic Analysis of the Manifesto, the Pledgors and the Featured Patents*, R & D MGMT. 255, 258 (2021); see also Jorge L. Contreras, *The Open COVID Pledge: Design, Implementation and Preliminary Assessment of an Intellectual Property Commons*, 2021 UTAH L. REV. 833 (2021).

<sup>237</sup> Elon Musk, *All Our Patent Are Belong to You*, TESLA BLOG (June 12, 2014), <http://www.teslamotors.com/blog/all-our-patent-are-belong-you> [https://perma.cc/4BPU-BKVY]; Naomi Tajitsu, *Toyota to Give Royalty-Free Access to Hybrid-Vehicle Patents*, REUTERS (Apr. 2, 2019), <https://www.reuters.com/article/us-toyota-patents-idUSKCN1RE2KC> [https://perma.cc/HFD5-PTFX]; Michael Heller & James Salzman, *Elon Musk Doesn’t Care About Patents. Should You?*, HARV. BUS. REV. (Mar. 4, 2021), <https://hbr.org/2021/03/elon-musk-doesnt-care-about-patents-should-you> [https://perma.cc/RJ4Q-CWPA].

<sup>238</sup> WIPO Patent Application No. WO 2020/212952 A1 (Compass Pathways Ltd.) Apr. 17, 2020, at 49–54, 59–62; Oxford Psychedelic Soc’y, *Psychedelic Capitalism* (A

enforceable and legally binding these informal statements are.<sup>239</sup> And in any event, Compass's CEO stated that the company was not going to sign a patent pledge on these claims.<sup>240</sup>

As it stands, patent pledges are a weak avenue for fostering healthy competition, scientific progress, and equitable access to psychedelic medicine. This is especially true considering that the pledges allow companies that sign the pledge wide latitude as to the choice of when to enforce patent rights.<sup>241</sup> Furthermore, the conditions on patent pledges that are required for a reliant researcher or manufacturer to avoid enforcement are sometimes challenging for courts and the public to understand, which can result in unintentional infringement.<sup>242</sup> There may be a better way to handle patent pledges, including legislative reforms that more clearly define the obligations, standards, and enforceability of patent pledges and encourage making and relying on patent pledges.<sup>243</sup> Big Pharma may find such reforms more palatable, as the reforms may clarify when and how companies can make use of pledged patents, which could stimulate more follow-on innovation that could be patented.

In addition to biopiracy protections by statute, companies can acknowledge and compensate the Indigenous communities they draw from directly. A simple way is to pledge to donate future profits, which is not uncommon in the industry.<sup>244</sup> Donating to charitable causes that benefit these communities or donating directly to the communities themselves could help remedy the wrongs of biopiracy and lead to a more equitable society. But like patent pledges, these are not clearly enforceable or legally binding, but often informal statements. And there is no guarantee that those profits ever materialize, especially in the context of drug development which is an industry with a high

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*Moderated Discussion with Alexander Beiner and Lars Wilde, 27/05/21*, YOUTUBE (May 28, 2021), <https://www.youtube.com/watch?v=C4ilk9OiyW4> [<https://perma.cc/F6U4-6WPV>].

<sup>239</sup> See Jorge L. Contreras, *Patent Pledges*, 47 ARIZ. ST. L.J. 543, 592–94 (2015) (describing how enforceable public statements on patents are in different contexts).

<sup>240</sup> Vice News, *supra* note 65 (“We don’t need to reassure people [with a patent pledge] right now. What we need to do is do the evidence of is it safe and effective and for whom.”).

<sup>241</sup> Marks & Cohen, *supra* note 21, at 233.

<sup>242</sup> *Id.*

<sup>243</sup> See *infra* Section VI.B; Nils Tracy, Duke U. Graduate Liberal Stud., *Patent Pledges: Private Tool For Public Good* 39–50 (Apr. 2016) (unpublished Master’s thesis, Duke Univ. Graduate Sch.), <https://dukespace.lib.duke.edu/dspace/bitstream/handle/10161/11965/Nils%20Tracy%20Masters%20Project.pdf> [<https://perma.cc/8USL-MHCL>].

<sup>244</sup> Jane C. Hu, *5 Questions for Jeeshan Choudhury*, MICRODOSE (Dec. 27, 2021), <https://themicrodose.substack.com/p/5-questions-for-jeeshan-chowdhury?s=r> [<https://perma.cc/L3K9-7LX4>] (“We see a lot of pledges to donate future profits. There’s always a space and need for charitable actions.”).

rate of failure.<sup>245</sup> Thus, these promises to donate may not actually do all that much to address past and present inequities and Indigenous exploitation.

A novel approach that gives back to Indigenous communities has come from Journey Collab, a start-up company that researches mescaline as a treatment for addiction.<sup>246</sup> Journey Collab has what it calls a “reciprocity trust,” where ten percent of the founding equity was set in an irrevocable trust to support mental health care for Indigenous peoples and facilitate “the conservation of Indigenous plant medicines.”<sup>247</sup> The trust also is a vehicle to consult with stakeholders: Indigenous communities are given a seat at the table in the form of ownership and opportunity to provide input on how “to steward these medicines responsibly” and benefit Indigenous communities.<sup>248</sup> Importantly, the trustees decide how the equity will be used independent of the rest of the company.<sup>249</sup> The idea is to avoid the traditional “extractive” biopiracy approach of the pharmaceutical industry by instead giving back to Indigenous communities and having a consent-based approach.<sup>250</sup>

Finally, the most radical solution would be to completely bar patents on psychedelics. Patents in the psychedelic space are less likely to incentivize innovation and may reward anticompetitive behaviors and protracted monopolies.<sup>251</sup> The Multidisciplinary Association for Psychedelic Studies (MAPS), a nonprofit studying MDMA as a treatment for PTSD, has advanced MDMA through Phase 3 clinical trials all without patenting its research.<sup>252</sup> In fact, MAPS makes use of an antipatent strategy to prevent monopolization of the use of MDMA as a mental health treatment.<sup>253</sup> Another nonprofit, Usona, has a similar “open science” approach to psilocybin, publishing all of its material for others to expand on to stimulate

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<sup>245</sup> Sun, *supra* note 167.

<sup>246</sup> Metzger IV, *supra* note 23.

<sup>247</sup> Hu, *supra* note 244 (“We wanted to wait to raise money until we put that founding equity within the trust, so it could never be taken back even if investors wanted us to.”); *The Reciprocity Trust*, JOURNEY COLLAB, <https://www.journeycolab.com/reciprocity> (last visited Mar. 24, 2023).

<sup>248</sup> *The Reciprocity Trust*, *supra* note 247; *see also* Hu, *supra* note 244 (“[R]eal structural change comes through ownership. . . for us, it was not a radical thing to say that the land, the people, and the cultures where this medicine comes from are an equal stakeholder—not only in the success of the business, but in the value that’s being created.”).

<sup>249</sup> Hu, *supra* note 244.

<sup>250</sup> *Id.*

<sup>251</sup> Marks & Cohen, *supra* note 21, at 233–34.

<sup>252</sup> *Id.* at 233.

<sup>253</sup> Catherine Elton, *The Interview: MDMA-Therapy Expert Dr. Rick Doblin*, BOS. MAG. (Sept. 10, 2019, 2:56 PM), <https://www.bostonmagazine.com/health/2019/09/10/rick-doblin> [<https://perma.cc/6HSH-8Y6Q>].



innovation.<sup>254</sup> Some commentators have argued that while SSRIs received patent protection the mental health industry did not progress but instead became monopolized and stagnated; with psychedelics representing the biggest advance in mental health treatment in decades, perhaps psychedelics should not suffer the fate of SSRIs.<sup>255</sup> The lack of monopolization resulting from barring psychedelics patents also avoids biopiracy issues. Some scholars have even compared psychedelics to unpatentable subject matter—“abstract ideas, products of nature, and natural phenomena”—“because they are fundamental tools of scientific inquiry.”<sup>256</sup> As such, the theory goes that they should not be permitted to be patentable and monopolized.

### B. *A Multipronged Approach*

While forgoing patents in their entirety has compelling arguments, it may not be the best approach. There are still benefits to having patents in the psychedelic space as with a bit of reform to the system, patents can continue to spur innovation, create healthy competition in the industry, and drive down price. Synthesizing psychedelic compounds, producing them, and administering them—so long as they are novel—all are valid patentable things that are “useful to ensure quality commensurate of a pharmaceutical product.”<sup>257</sup> The administration of psychedelic compounds in assisted therapy programs introduces these powerful tools to a Western medical context that can seriously benefit patients suffering from mental illnesses.<sup>258</sup> But because of the medical model, there need to be standardized protocols for production and administration of psychedelics and associated therapies. Historically, the best way to ensure investment goes towards novel methods of production and administration is through the enticing reward of a limited patent monopoly.<sup>259</sup> Medical and scientific stakeholders widely recognize this exclusivity as an important aspect of new medicine being developed, as funding stems from documented advances and a likelihood of a return on the investment, especially in such a competitive field as drug development.<sup>260</sup>

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<sup>254</sup> Love, *Psychedelic Therapy*, *supra* note 179 (internal quotation marks omitted); Vice News, *supra* note 65.

<sup>255</sup> Marks & Cohen, *supra* note 21, at 234.

<sup>256</sup> *Id.*

<sup>257</sup> Angermayer, *supra* note 168.

<sup>258</sup> *Id.*

<sup>259</sup> *See, e.g., id.*

<sup>260</sup> *Id.*; *see also* Sun, *supra* note 167.

Thus, patents stand to be a key component in the medicalization of psychedelics.

What drives some commentators away from the idea of patents in the psychedelics space is that it invites Big Pharma—which has a significantly negative image after the opioid crisis—to sink its teeth into an emerging industry that has its roots in Indigenous practices, spirituality, and counterculture.<sup>261</sup> But Big Pharma could be an asset in the psychedelics industry, which it likely will enter if it becomes evident that SSRIs are not the most effective treatment option for most people. For example, Big Pharma invested billions of dollars for a highly effective COVID-19 vaccine and is now selling it; nothing is inherently wrong with that and the public benefited immensely from it.<sup>262</sup>

The pharmaceutical industry has three levels.<sup>263</sup> First, there are pools of capital that invest heavily in trying to find new treatments for illnesses; the patent system encourages this search by granting exclusive rights on the inventions associated with the treatments of those illnesses.<sup>264</sup> Many start-up companies doing most of the research and manufacturing right now fit in this level. Once the monopoly expires, the second level starts, where generic companies “compete to be the high-quality low-cost provider.”<sup>265</sup> Big Pharma generally fits in at level two, capitalizing on its immense resources and infrastructure to make psychedelics more readily available sooner and more broadly.<sup>266</sup> So long as Big Pharma does not abuse the patent system by repackaging technologies to receive a monopoly or engage in offensive patent troll behaviors (including frivolous or vexatious litigation), there is no harm in their entry into the psychedelics market. And in any event, a harmful monopoly

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<sup>261</sup> Vice News, *supra* note 65; *see, e.g., Poll Shows Americans Are Fed Up with Pharmaceutical Industry*, HARV. SCH. PUB. HEALTH (2019), <https://www.hsph.harvard.edu/news/hsph-in-the-news/poll-shows-americans-are-fed-up-with-pharmaceutical-industry/> [<https://perma.cc/P3D7-FHFL>] (“58 [percent] of Americans held negative views of the pharmaceutical industry . . . . Gallup noted that high drug prices, the opioid epidemic, and Big Pharma’s big lobbying efforts are all factors that likely played into respondents’ frustration with the industry.”).

<sup>262</sup> *See, e.g., Sydney Lupkin, COVID Vaccines Are Set to Be Among the Most Lucrative Pharmaceutical Products Ever*, NAT’L PUB. RADIO (Nov. 24, 2021), <https://www.npr.org/2021/11/24/1059041725/covid-vaccines-are-set-to-be-among-the-most-lucrative-pharmaceutical-products-ev> [<https://perma.cc/6VJG-4YGE>].

<sup>263</sup> *FTO Letter*, *supra* note 188.

<sup>264</sup> *Id.*

<sup>265</sup> *Id.*

<sup>266</sup> *See id.* (noting that “[a] generic supplier would require supply chains, manufacturing facilities, [and] established distribution channels” to be successful in such “a competitive environment”).

would be difficult to achieve in a robust psychedelics industry.<sup>267</sup> At the third level are companies that seek to eradicate illnesses by giving out treatments for free, like the Gates Foundation with the polio vaccine in parts of the world where polio still exists.<sup>268</sup> Companies like MAPS and Usona are already doing this in the psychedelics space.<sup>269</sup>

Though patents have a place in psychedelic medicine, they should not be abused as a tool to reward technology that is repackaged and therefore not novel and obvious. This means that companies should not be able to claim some of the technologies in recent bad patents, with patents on psilocybin being no exception.<sup>270</sup> Therefore, legal reforms need to happen while the industry is still emerging to ensure the patent system is not being abused and prevent artificial monopolies that reduce access, technological advancement, and equity from being established.

In the short-term watchdogs like FTO need to continue monitoring patent filings and quickly intervene when feasible to invalidate bad patents.<sup>271</sup> However, this is a reactive approach that does not get to the core issue and requires significant resources, and the nine month time limit on post-grant review can be difficult to navigate.<sup>272</sup> To better address gaps in the PTO's knowledge of psychedelics and the prior art, there should be federal funding for prior art libraries in important biomedical fields like psychedelic medicine so these libraries can expand their services for and catalogues of lesser known prior art that the PTO might miss.<sup>273</sup>

Statutes that further clarify the novelty and nonobvious requirements for a patent would be significant and should be a primary focus of reform as they get at the heart of the problem.<sup>274</sup> The most salient things these statutes could do is provide biopiracy protections, recognize underground methods as prior art, and address subtle product hopping changes—like

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<sup>267</sup> See, e.g., *id.* (“If someone decided to patent insulin, its current distributors would immediately file to invalidate the patent.”). In a robust psychedelics industry, there would be similar challenges to invalidate bad patents on psychedelic technology that was not new or was obvious.

<sup>268</sup> *Id.*

<sup>269</sup> See *supra* Section V.A.

<sup>270</sup> See *FTO Letter*, *supra* note 188 (“[T]here can be no patent on psilocybin as a substance, nor on the known methods for making it or using it medically. There is an almost infinite number of novel contributions to be made to the future of psychedelic science. That there is a molecule named psilocybin and that it can be useful in treating depression is not one of them. It is already well documented.”).

<sup>271</sup> Marks & Cohen, *supra* note 21, at 231.

<sup>272</sup> *Id.*

<sup>273</sup> *Id.* at 231–32.

<sup>274</sup> *Supra* Section V.A.

polymorphs, salts, and enantiomers—that do not make novel or nonobvious improvements on prior art.<sup>275</sup> This aspect of the reforms may prove most difficult as it could impact the pharmaceutical industry more broadly and so may face legislative hurdles and prove politically unfeasible.<sup>276</sup> Therefore, legislative efforts should also include provisions that more clearly define and encourage the use of patent pledges.<sup>277</sup>

At minimum, the patent pledge portions of the legislation should explain that patent pledges are enforceable and more clearly define what needs to be in a patent pledge, when a patent pledge is legally binding, and what obligations the patent pledge imposes on both the pledging party and the reliant party.<sup>278</sup> Better yet, the legislation could establish a patent pledge registry in the PTO that houses all pledges and make registered pledges binding when another party relies on that pledge.<sup>279</sup> The legislation could require mandatory registration of all patent pledges, or it could encourage registration through tax or regulatory incentives.<sup>280</sup> For example, a pledging party could claim a tax credit or deduction upon registration, since its registration offers a significant benefit to scientific progress in highly important emerging industries.<sup>281</sup> Perhaps similar credits or deductions could even be granted to reliant parties, as doing so fosters an ecosystem of continuing innovation and their reliance on the pledge deserves to be affirmed and rewarded.<sup>282</sup> Another idea is to grant a voucher that expedites the process for patent approval on subsequent innovations that relied on patent pledged technology.<sup>283</sup> This voucher could apply to the pledging party and the reliant party, again fostering an ecosystem of innovation.

Finally, in addition to—or as a start on working towards—biopiracy protections, ways of involving or giving back to Indigenous communities should be incentivized.<sup>284</sup> A legal mandate to give back to Indigenous communities in order to receive a patent seems politically and administratively infeasible, especially when considering that these communities are spread

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<sup>275</sup> *Id.*

<sup>276</sup> *Supra* notes 233–234 and accompanying text.

<sup>277</sup> *Supra* note 244 and accompanying text.

<sup>278</sup> *Supra* notes 243–244 and accompanying text.

<sup>279</sup> *See Tracy, supra* note 243, at 41.

<sup>280</sup> *Id.*

<sup>281</sup> *Id.* at 42.

<sup>282</sup> *Id.*

<sup>283</sup> *See id.* at 44 (“One such lever employed by the FDA in promoting the production of generics in rare diseases is to offer a registration voucher. If a company produces a critical generic drug, that company will receive a voucher to speed up the process of FDA drug approval and the same program could be used by the USPTO.”).

<sup>284</sup> *Supra* notes 244–250 and accompanying text.

out across the globe. But again, tax and regulatory incentives may prove useful here. Perhaps the legislation could specify that granting ownership to these Indigenous communities, advocates, and other stakeholders, through a trust similar to Journey Collab's reciprocity trust, could receive tax credits; and if profits are donated, perhaps a tax deduction is proper.<sup>285</sup>

## CONCLUSION

The resurgence in psychedelics research and therapies is revealing how beneficial these substances can be as treatments for depression, anxiety, addiction, and other mental illnesses. While psychedelics are not the panacea to the mental health crisis, they represent a rapid and significant advancement on current technologies. Psychedelics also are a gamechanger for patients as they appear to induce neurological changes in the brain that allow patients to have the openness and motivation to begin working on themselves and overcome entrenched beliefs and compulsive thoughts and behaviors. These medicines are incredibly valuable to society, and innovation in this space should be encouraged through patents.

But as it stands now, the patent system is being abused by aggressive players in the psychedelics industry, like Compass Pathways. Far too many "bad patents" have been issued in the psychedelic pharmaceutical space. It is imperative to address these meritless patents now so that these more effective and life-changing treatments can get in the hands of patients that need them as soon as possible and at a more affordable price. The current patent system also incentivizes minor innovations that hardly represent the ambitious strides the system was initially designed to reward. These inventions are neither new nor are they nonobvious. Instead, these types of patents reward insignificant "advances" on current technologies that do not benefit the public. Rather, those research dollars are effectively wasted; these "advancements" should not be rewarded, nor protected so that bad actors can extend their patent monopoly and further entrench themselves in the industry.

Patent reforms are required now while the industry is beginning to emerge. If we wait too long, companies that are abusing the system so they can control most intellectual property in the industry will become too entrenched, making their monopolistic and anticompetitive behaviors more likely to become

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<sup>285</sup> See Tracy, *supra* note 243, at 42–44 (advocating for applying this incentive strategy to patent pledges).

the industry standard. The result being that psychedelic medicine will likely become less accessible and affordable, the knowledge of Indigenous communities will continue to be exploited, and competitors will be less likely to enter the field out of fear of infringement—reducing research and stifling innovation even more. The benefits that psychedelics could have on the mental health crisis would then be substantially impaired.

Therefore, the time is now to pursue all options to prevent this from happening. This Article encourages third-party challenges like those done by FTO and suggests pursuing comprehensive patent reform legislation.

This legislation should grant funding to prior art libraries to prevent bad patents from being issued as more niche information will be digitized and widely available for review by the PTO. Additionally, it should tighten up the novelty and nonobvious requirements to receive a patent, and biopiracy protections should also be implemented to limit Indigenous exploitation. Furthermore, to facilitate an ecosystem of innovation, the legislation should clarify the obligations of patent pledges and establish a registry for patent pledges. Those that register their patent pledges and those that rely on those pledges should receive a tax or regulatory benefit as an incentive to continue to innovate. Similar incentives could be implemented to encourage companies to compensate and acknowledge the Indigenous groups and traditions their work may draw from. There is still time to implement patent reform. But if we stall, there is a risk that mental health care will continue to stagnate due to issues involving anticompetitive behaviors and lack of innovation and access. Psychedelic research has come so far, and people have suffered too long for the status quo to remain undisrupted.