COMMENTS

High Risk, High Reward: Patent Law’s Effects on the Medical Marijuana Industry

Hailey A. Barnett*

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I. INTRODUCTION

At the corner of profitability and illegality lies a hotly debated plant known by many names—cannabis, marijuana, Mary Jane, weed, grass, and pot, to name a few. Today, it resides at the four-way intersection of controversy, medicine, money, and the law. As of 2020, medical marijuana is legal in thirty-three states, while ten states permit recreational marijuana use by adults over the age of twenty-one.1 Yet, despite its apparent ubiquity, marijuana still remains illegal at the federal level, classified as a Schedule I drug since the passage of the Controlled Substances Act (CSA) in 1970.2

Although marijuana has historically been seen as a recreational drug, many Americans today recognize the growing number of medical benefits that can be derived from the plant’s properties.3 Several studies show marijuana treats an array of medical conditions and can alleviate conditions like chronic pain, post-traumatic stress disorder, epilepsy, and nausea associated with chemotherapy treatment for cancer, among others.4 According to a recent Gallup poll, 64% of Americans favor marijuana legalization, up from 44% in 2009.5 Of these supporters, 86% favor medical marijuana legalization.6

Aside from the medicinal implications, marijuana legalization has impacted nearly every sector of the law, from criminal cases to business organization to employment discrimination.7 Similarly, Intellectual

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3. Id. at 172.
6. Id.
Property (IP) law has not been left out of the legal marijuana debate. Lawyers who represent cannabis-based and -related clients must help navigate them through the current scheme of state regulations in order to protect their proprietary rights of a federally illegal substance.8 Most of the controversy that surrounds marijuana IP rights involves trademarks of various cannabis-related products and entities.9 However, this Comment will focus on another sphere of IP law—patents.

In 2018, the United States Patent and Trademark Office (USPTO) issued thirty-nine patents containing the words “cannabis” or “marijuana,” up from twenty-nine issued in 2017 and fourteen issued in 2016.10 This upward trend is likely to continue as cannabis companies compete with one another, as well as with companies from well-established industries, like pharmaceuticals and agriculture, for a seat at the patent protection table.11

This Comment specifically explores the impact of medical marijuana on patent rights at the national and international levels. First, I discuss general medical marijuana laws in the United States and their effects on cannabis strain patent rights. Second, I discuss medical marijuana laws and their impact on patent rights in a global context. Specifically, I use Thailand to highlight how pharmaceutical companies have obtained foreign marijuana patents at an increasing rate. Thailand is an interesting case study because their Department of Intellectual Property (DIP) revoked all foreign cannabis patent applications shortly after the country legalized medical marijuana.12 Moreover, I discuss how foreign countries and mega-corporations asserting their patent rights impact marijuana biodiversity. Lastly, I articulate a possible solution to cannabis strain patent problems, including the use of open source cannabis cultivation and growing, and discuss issues with drug reclassification of marijuana in the United States and international patent systems.

Each of the above points are rooted in the fact that the United States, as well as many other countries, classify marijuana as a drug with “particularly dangerous properties” with “little to no medicinal value.”

As our world becomes increasingly interconnected and old marijuana laws begin to fall away, it is necessary that the patent system fosters good marijuana market growth and practices, with more than just business in mind.

II. LAWS AND REGULATIONS OF MEDICAL MARIJUANA

A. A History of Marijuana Regulation in the United States

Historically, marijuana was held in high regard by those inside and outside of the medical field. Cannabis was listed in the 1850 United States Pharmacopoeia for its medicinal values, where smoking the flower for medicinal, recreational, and spiritual purposes was recognized for providing a multitude of benefits.

Fifty years later, marijuana regulation as we know it today started to take shape.

1. The Beginnings of Drug Regulation and Legislation

In the early 1900s, Congress passed the Food and Drug Act of 1906 in response to a nationwide spike in morphine addiction. The Food and Drug Act created the Food and Drug Administration (FDA) to regulate, research, and approve substances for safe and effective consumption. Congress subsequently passed the Harrison Narcotics Tax Act in 1914, which taxed and regulated opiates, and laid the groundwork for future drug regulation legislation. The intended purpose of the Harrison Act was to regulate prescription drugs and help curb cocaine and opioid use across

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16. Id.

17. Katner, supra note 2, at 175.

18. Id.

the country.\textsuperscript{20} However, the Harrison Act held physicians liable for illegal distribution if they wrote opiate-based prescriptions.\textsuperscript{21} Thus, the law was amended in 1922 to prohibit importation and use of certain narcotics for any non-medical purpose.\textsuperscript{22}

2. The Marihuana Tax Act and Its Regulatory Effects

The passage of the Marihuana Tax Act of 1937 (the Act) marked the first time “marijuana” was mentioned and identified in federal legislation.\textsuperscript{23} The Act allowed physicians to sell and prescribe marijuana for medical use on the condition that a tax stamp was purchased, denoting the right to legally possess it.\textsuperscript{24} However, the cost of the stamp was so high that the effects of the Act were essentially legally prohibitive.\textsuperscript{25}

Furthermore, the Act permitted the Secretary of the Treasury to grant the Tax Commissioner and agents of the Treasury Department’s Bureau of Narcotics absolute administrative, regulatory, and police powers in the Act’s enforcement.\textsuperscript{26} As a result, by the end of 1937, forty-six of forty-eight states classified marijuana as a narcotic, similar to cocaine, morphine, and heroin.\textsuperscript{27} The risk of prosecution under the Act led to the decline of open marijuana use and created a stigma around the drug, as well as a black market that still exists today.\textsuperscript{28}

3. From Further Regulation to Eventual Prohibition

Since the passage of the Marihuana Tax Act, federal legislation has continued to augment punishment and criminalization for marijuana use and possession.\textsuperscript{29} In 1951, Congress passed the Boggs Act, which harshly punished marijuana possessors and distributors with severe prison sentences.\textsuperscript{30} In 1970, the CSA was adopted as part of the larger Comprehensive Drug Abuse Prevention and Control Act of 1970, which

\begin{itemize}
\item \textsuperscript{20} See War on Drugs, HISTORY (Dec. 17, 2019), http://www.history.com/topics/crime/the-war-on-drugs.
\item \textsuperscript{21} Katner, supra note 2, at 175.
\item \textsuperscript{22} See Shima Baradaran, Drugs and Violence, 88 S. CAL. L. REV. 227, 242 (2015).
\item \textsuperscript{23} See David F. Musto, The Marijuana Tax Act of 1937, 26 ARCHIVES GEN. PSYCHIATRY (1972).
\item \textsuperscript{24} Katner, supra note 2, at 175, 177.
\item \textsuperscript{25} Id. at 177.
\item \textsuperscript{26} Helia Garrido Hull, Lost in the Weeds of Pot Law: The Role of Legal Ethics in the Movement to Legalize Marijuana, 119 PENN ST. L. REV. 333, 337 (2014).
\item \textsuperscript{27} Id. at 337-38.
\item \textsuperscript{28} Id. at 338.
\item \textsuperscript{29} Lesser, supra note 19.
\item \textsuperscript{30} Katner, supra note 2, at 175.
\end{itemize}
rendered “illegal [the] importation, manufacture, distribution, and possession and improper use of controlled substances.”31 The CSA classified marijuana as a Schedule I substance, defined as a “drug, substance, or chemical with no accepted medical use and the highest potential for abuse.”32 Schedule I drugs carry the highest legal penalties and, under federal law, may not be prescribed, administered, or dispensed for medical use by a physician.33 Marijuana was placed under Schedule I partly because of its lack of medicinal purposes, as well as a sociocultural belief that marijuana posed unreasonable risks of harm.34

One year later, President Richard Nixon declared a nationwide War on Drugs in response to a dramatic increase in drug and alcohol fatalities.35 President Nixon continued to promote the fear of drugs, specifically marijuana, throughout his administration.36 As a result, numerous other laws and federally funded programs were enacted to curb illicit drug use.37 In the 1980s, the Reagan Administration passed additional anti-drug laws and created the Office of National Drug Control Policy to give the federal government even greater power over drug control efforts.38

### B. The Current Status of Medical Marijuana in the United States

The CSA remains the controlling policy on federal controlled substances regulation. The Drug Enforcement Administration (DEA) within the Department of Justice (DOJ) is the primary law enforcement agency responsible for CSA enforcement and compliance.39 The CSA classifies controlled substances on a sliding schedule from I to V, with Schedule I being the most heavily regulated, having the highest potential

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31. 21 U.S.C. § 801(2) (2018); see also id. § 802(6) (“[C]ontrolled substance’ means a drug or other substance, or immediate precursor, included in schedule I, II, III, IV, or V.”).


34. Hull, supra note 26, at 338.


37. See Katner, supra note 2, at 175-76.

38. Id. at 176.

for abuse, and lacking any accepted medical use.\textsuperscript{40} Table 1 below illustrates the CSA classifications.\textsuperscript{41}

<table>
<thead>
<tr>
<th>Drug Schedule</th>
<th>Definition</th>
<th>Examples</th>
</tr>
</thead>
<tbody>
<tr>
<td>Schedule I</td>
<td>Drugs, substances, or chemicals with no currently accepted medical use and a high potential for abuse</td>
<td>Heroin, LSD, marijuana (cannabis), ecstasy, methaqualone, and peyote</td>
</tr>
<tr>
<td>Schedule II</td>
<td>Drugs, substances, or chemicals with a high potential for abuse, with use potentially leading to severe psychological or physical dependence</td>
<td>Cocaine, methamphetamine, Adderall\textsuperscript{®}, Vyvanse\textsuperscript{®}, methadone, oxycodone, and fentanyl</td>
</tr>
<tr>
<td>Schedule III</td>
<td>Drugs, substances, or chemicals with a moderate to low potential for physical and psychological dependence</td>
<td>Tylenol\textsuperscript{®} with codeine, ketamine, anabolic steroids, testosterone, and Vicodin\textsuperscript{®}</td>
</tr>
<tr>
<td>Schedule IV</td>
<td>Drugs, substances, or chemicals with a low potential for abuse and low risk of dependence</td>
<td>Xanax\textsuperscript{®}, Valium\textsuperscript{®}, Ativan\textsuperscript{®}, Ambien\textsuperscript{®}, and Tramadol</td>
</tr>
<tr>
<td>Schedule V</td>
<td>Drugs, substances, or chemicals with the lowest potential for abuse and consist of preparations containing limited quantities of certain narcotics</td>
<td>Drugs generally used for antidiarrheal, antitussive, and analgesic purposes, such as Robitussin Ac\textsuperscript{®} and Lyrica\textsuperscript{®}</td>
</tr>
</tbody>
</table>

\textsuperscript{40} 21 U.S.C. §§ 812(a), 812(b) (2012).
\textsuperscript{41} See Understanding Drug Schedules, supra note 33.
It is important to note that the CSA does not prohibit states from enacting laws to regulate marijuana, so long as they do not conflict with federal law.42 For example, California enacted the Compassionate Use Act in 1996 and became the first state to legalize marijuana for medicinal use under the supervision of a licensed physician.43 Nine years later, the Supreme Court in Gonzales v. Raich upheld the federal government’s authority to prohibit the use and cultivation of medical marijuana, despite local law to the contrary, as part of Congress’s Commerce Clause power.44 The Commerce Clause grants Congress the power to regulate commerce between the States, including the ability to restrict the intrastate possession, manufacturing, and distribution of marijuana.45

Although Raich affirmed the illegality of marijuana at the federal level, the Court did not limit individual states from enacting purely intrastate statutory schemes to govern marijuana use.46 Justice Thomas noted that the respondents’ use of medical marijuana under physician supervision to treat their medical ailments was “purely intrastate and noncommercial” conduct, and the CSA exceeded Congress’s Commerce Clause power as applied to this type of conduct.47

In 2009, the federal government published the Ogden Memorandum (the Memorandum) in response to an increase in state legalization of marijuana.48 The Memorandum “provide[d] clarification and guidance to federal prosecutors in States that . . . enacted laws authorizing the medical use of marijuana.”49 The Memorandum did not prohibit states from enacting medical marijuana legislation, so many believed the federal government implicitly sanctioned states’ authority to regulate intrastate cannabis use within their borders.50 Since then, thirty-two states have

42. Hull, supra note 26, at 339.
44. Gonzales v. Raich, 545 U.S. 1, 1 (2005).
45. See U.S. CONST. art. I, § 8, cl. 3.
47. Gonzales, 545 U.S. at 59 (O’Connor, J., dissenting); see also Grant-Keane, supra note 46.
49. Id.
followed California’s lead and legalized medical marijuana within their borders.  

To date, every state medical marijuana law allows qualified patients to possess and use small quantities of marijuana for medicinal purposes without being subject to criminal penalties. Most laws require that a patient have a debilitating medical condition such as HIV, cancer, or glaucoma, and be under the supervision of a licensed physician. The physician must provide written documentation that the patient could benefit from medical marijuana, or that the “potential benefits of medical use of marijuana would likely outweigh the health risks.” Eligible patient caregivers may also possess, but not use, marijuana. However, many laws do not regulate the potency or quality of marijuana, nor do they address ways to obtain marijuana, whether caregivers can buy and sell, and the status of dispensaries.

C. The Tension Between Science and the Law

*Cannabis sativa* L. (*C. sativa*) and *Cannabis indica* L. (*C. indica*) are the two primary marijuana species. Each cannabis plant byproduct, known colloquially as a “strain,” is different “based on its physical structure, aroma, and psychotropic effect and potency,” largely due to the growing conditions and harvesting methods used. Like other plants, cannabis exists in the form of pure breed strains and as hybrid mixes of numerous different strains. Consumers have long thought that *C. indica* strains primarily promote sedating effects, *C. sativa* strains primarily promote energy, and hybrid strains, cultivated from both *C. sativa* and *C. indica*, have effects falling somewhere in between. However, thanks to modern breeding and cultivation, most strains on the market today are

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55. *Id.*
56. *Id.*
hybrid mixes and have varying effects depending on the particular strain’s tetrahydrocannabinol (THC) and cannabidiol (CBD) makeup, as further discussed.61

Substances with botanical classifications are atypical for Schedule I drug classification.62 In fact, the American Medical Association (AMA) promulgated a resolution in 2016 to reschedule marijuana. The AMA supported rescheduling to facilitate greater research and development of cannabinoid-based medicine.63 The resolution represents a shift in thought and policymaking within the AMA, the nation’s largest association of physicians, regarding marijuana.64

Schedule I status of a drug does not automatically prevent research into its potential medicinal uses. However, researchers of a Schedule I drug must go through many administrative hurdles that can delay efforts significantly.65 Research into marijuana’s various effects and medicinal properties must first overcome a labyrinth of barriers that “enforce restrictive policies and regulations on research into the health harms or benefits of cannabis products that are available to consumers.”66 The CSA created these barriers to restrict procurement of marijuana, even by those seeking to use it for research purposes.67 One such research barrier includes review processes by the National Institute on Drug Abuse (NIDA), FDA, DEA, institutional review boards, state government offices, state boards of medical examiners, and other potential funders.68 Moreover, the federal government currently only allows marijuana grown at the University of Mississippi (Ole Miss) to be used for approved research.69 This marijuana is grown and produced by Ole Miss pursuant to

61. Id.
62. Katner, supra note 2, at 170.
68. NAT’L ACADS. OF SCI., ENG’G, & MED., supra note 66, at 378-79.
an exclusive contract with the NIDA in place since 1968.\textsuperscript{70} Not only is this marijuana the sole source of cannabis used in research, but it is much less potent and not representative of the marijuana available in the real world.\textsuperscript{71} However, in August 2019, the DEA announced it would process new cannabis grower applications, a move that aims to expand the number of federally authorized marijuana manufacturers for research purposes beyond Ole Miss.\textsuperscript{72} Approval of new marijuana manufacturers will make additional marijuana strains available to researchers, signaling a new step forward for the DEA, medical marijuana research, and the cannabis community at large.\textsuperscript{73}

Another research barrier is that Schedule I research registrations must be renewed every year, whereas research registrations for Schedules II-V controlled substances are valid for three years.\textsuperscript{74} A Schedule I substance researcher must obtain two separate registrations from the FDA and the DEA, and the registrations are protocol- and substance-specific.\textsuperscript{75} By contrast, if a physician possesses a valid registration to possess, prescribe, and administer products containing controlled Schedule II substances, they may conduct research (subject to FDA and ethics committee regulations) on the substance as an adjacent activity to those registrations and do not need a separate DEA registration.\textsuperscript{76} It is easy to see why current Schedule I policies may deter some from conducting marijuana research.

Funding ineligibility is another barrier to marijuana research. Federal funding sponsors and underwrites a majority of scientific research in the United States.\textsuperscript{77} However, most marijuana research is ineligible for federal funding because of its Schedule I status.\textsuperscript{78} Since the federal government is


\textsuperscript{72}. DEA Announces It Will Finally Take Action on Marijuana Grower Applications, BOS. GLOBE (Aug. 26, 2019), http://www.bostonglobe.com/news/marijuana/2019/08/26/dea-announces-will-finally-take-action-marijuana-grower-applications/koMlUYsbrsAAZOz1prTsgI/story.html (“In the three years since DEA first said it would be accepting applications for cannabis manufacturers, the agency has received 33 submissions.”).

\textsuperscript{73}. \textit{See id.}

\textsuperscript{74}. Sabet, supra note 65, at 97.

\textsuperscript{75}. \textit{Id.}

\textsuperscript{76}. \textit{Id.}


\textsuperscript{78}. In September 2019, nine research grants totaling $3 million were awarded by the National Institutes of Health to study the potential pain-relieving properties of CBD. Press Release,
a substantial source of funding for research projects, research into medical marijuana is stunted because there are fewer groups researching the plant. Thus, it is of little surprise that there is misinformation in the scientific and legal communities concerning the benefits and drawbacks of marijuana.79

D. The Medicinal Benefits of Marijuana

Despite the difficulties researching marijuana for its medicinal benefits, studies have shown it is therapeutic to some patients.80 The cannabis plant contains over one hundred active compounds called cannabinoids—and the two most effective, well-studied, and popular cannabinoids are THC and CBD.81 THC and CBD each confer their own effects and health benefits.82 THC is responsible for the psychoactive “high” one feels after smoking marijuana.83 Much of the stigma surrounding the legalization and use of medical marijuana stems from the intoxicating and impairing effects associated with THC.84 In contrast, CBD lacks this psychoactive quality but provides similar medicinal benefits as THC.85

Marijuana’s physiological effects are due to the human body’s complex endocannabinoid system (ECS).86 The ECS regulates vital organ function through a network of receptors that bind endogenous cannabinoids (endocannabinoids) or exogenous cannabinoids, like THC or CBD.87 CB1 and CB2 receptors are the two main cannabinoid receptors found in the human body.88 CB1 receptors are found in regions of the brain

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80. See generally NAT’L ACADS. OF SCI., ENG’G, & MED., supra note 66.


82. See id.

83. Katner, supra note 2, at 170.


85. Peki, supra note 81.


88. See Piomelli, supra note 86.
responsible for physiological processes such as memory, emotion, and motor coordination, while CB2 receptors are found throughout the immune and central nervous systems and regulate immune responses. THC and CBD interaction between the CB1 and CB2 receptors underlies the perceived health benefits of marijuana, but the two cannabinoids do not interact with CB1 and CB2 receptors in the same way. This is why CBD does not impact mental or physical functions in most consumers, even in very high doses, in the same way THC does.

Promising published scientific and clinical research shows that marijuana can treat and improve the quality of life for those suffering from debilitating diseases. The largest anthology of research is a 2017 report published by the National Academies of Sciences, Engineering, and Medicine entitled The Health Effects of Cannabis and Cannabinoids: The Current State of Evidence and Recommendations for Research. Scientific researchers reviewed over 10,000 available studies and concluded that cannabis provides medical benefits for adults, including alleviation of chronic Multiple Sclerosis-induced muscle spasms, nausea and vomiting associated with chemotherapy, chronic pain, depression, addiction, and schizophrenia and other psychoses.

Promisingly, in June 2018, the FDA made history and approved its first-ever drug derived from marijuana, Epidiolex®. Epidiolex is manufactured by British biopharmaceutical company GW Pharmaceuticals (GW) as an oral solution that contains CBD and is used to treat seizures in patients over the age of two. Epidiolex’s classification as a Schedule V substance instead of a Schedule I will promote additional

89. Cadena, supra note 87.
90. Id.
93. See NAT’L ACADS. OF SCL., ENG’G, & MED., supra note 66.
94. Id. (review box S-2 for more therapeutic effects of marijuana use).
95. Epidiolex was approved to treat two forms of severe epilepsy: Lennox-Gastaut Syndrome and Dravet Syndrome. Press Release, FDA, FDA Approves First Drug Comprised of an Active Ingredient Derived from Marijuana to Treat Rare, Severe Forms of Epilepsy (June 25, 2018), http://www.fda.gov/newsevents/newsroom/pressannouncements/ucm611046.htm.
96. Id.
drug discovery and help bring the drug to the market more quickly.\textsuperscript{97} Although marijuana remains illegal as a Schedule I drug, Epidiolex serves as an encouraging point for the future of medical marijuana.\textsuperscript{98} 

Despite this progress, there are significant research drawbacks and confounds associated with current medical marijuana studies. As mentioned previously, researchers contend Ole Miss marijuana is less potent than the marijuana available at dispensaries.\textsuperscript{99} This makes it difficult to compare the effects of commercially available marijuana products, compounds, and strains to those used in research.\textsuperscript{100} This ultimately impacts the ability to understand marijuana’s therapeutic properties and medical providers’ ability to prescribe accurate doses.

Like any other tried, true, and tested medicinal product, many medical marijuana users are after a “consistent [drug] to reliably target either a particular medical ailment or to bring about a specific, desired effect.”\textsuperscript{101} However, much of the evidence surrounding relief associated with marijuana products is anecdotal and has not been confirmed scientifically or clinically.\textsuperscript{102} Medical marijuana has been legal in California for over twenty years and has produced a massive amount of anecdotal evidence that should not be ignored.\textsuperscript{103} Thousands of people have described how medical marijuana has helped reduce or discontinue their prescription opiate use and alleviate other medical conditions.\textsuperscript{104} For example, a New Mexico father whose teenage son uses medical marijuana


\textsuperscript{98} Id.; \textit{FDA Approves First Drug Comprised of an Active Ingredient Derived from Marijuana to Treat Rare, Severe Forms of Epilepsy}, supra note 95 (“This [Epidiolex] approval serves as a reminder that advancing sound development programs that properly evaluate active ingredients contained in marijuana can lead to important medical therapies. And, the FDA is committed to this kind of careful scientific research and drug development . . . .”).


\textsuperscript{102} See Katner, supra note 2, at 200-01.


\textsuperscript{104} Id.
suppositories to treat his epileptic seizures says it is the only drug that has truly worked to keep his son from having upwards of eighty seizures per day. Scientific research is needed to corroborate this anecdotal evidence, but unless and until the aforementioned research barriers are removed, marijuana’s true medicinal potential could remain unfulfilled. After all, marijuana is still a drug, and like other drugs, it is safer to create a legal, regulatory framework for people to know what products they are consuming, rather than have them take their chances buying it off the street. The shift away from anecdotal evidence towards tangible research data will inform future medical marijuana policies and give rise to a new era of consumer education and experiences.

Additionally, there are concerns that physicians will not accurately dose marijuana because most individuals experiment independently and experience varied effects at different doses. As a result, clinicians will not have guidance on how to effectively treat patients with medical marijuana like they do with other prescription drugs.

Currently, medical marijuana’s Schedule I status and patchwork of state legalizations leaves it in a vulnerable position with many unknowns. There is a need for expanded research, enhanced data collection to aid in that research, and the elimination of research barriers in order for medical marijuana to truly be taken seriously as a way to treat debilitating diseases in the United States.

107. Id.
109. Taylor & Bailey, supra note 100.
110. See Lewis, supra note 106.
111. Kovacevich, supra note 77.
III. CANNABIS AND PATENT LAW

Marijuana plants undergo asexual or sexual reproduction to create new offspring that are naturally occurring or selectively bred. “Asexual reproduction is the propagation of a plant without the use of fertilized seeds to assure an exact genetic copy of the plant being reproduced.”112 During asexual reproduction, a single plant cell contains the requisite genetic information to produce a complete plant and allows the plant to undergo repeated rounds of reproduction.113 Common techniques used to asexually reproduce marijuana include cutting, layering, and root division.114 For example, during the cloning process, a grower takes a cutting from a cannabis plant and roots it in a contained body of water.115 These clones will be genetically identical to the mother plant if the growing conditions are identical too.116

Sexual reproduction of marijuana plants occurs when a male and female plant are fused to create a seed.117 The offspring are genetically different than their parents and give rise to new cannabis varieties.118 As indoor growing practices become widespread, growers are increasingly likely to exchange cuttings of proven clones instead of carefully bred seeds from a different plant. Consequently, the genetic diversity of cannabis is likely to decrease.119


114. Id. at 461. “Cutting” is the practice or method of propagating cannabis plants by means of cuttings, “layering” is where the plant’s stem is buried with the stem still attached when it goes into the ground so that the stem forms roots and grows a new plant, and “root division” entails dividing and planting cannabis plants in clumps, with each section having some roots, and the sections are then planted as separate plants. See also Plant Propagation Methods, GARDENTIA, http://gardentia.net/plant-propagation-methods/ (last visited Feb. 22, 2020).

115. This technique is known as hydroponics. See Summer, supra note 58, at 177.


118. Summer, supra note 58, at 177-78.

A. The Current State of Federal Cannabis Strain Patents

1. Patenting Marijuana and Marijuana Strains

The power of the federal government to grant and regulate patents has existed nearly as long as the United States itself.120 A patent is a property right that is granted to an inventor by the USPTO.121 Patent protection is granted to those who “invent or discover any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof.”122

The USPTO recognizes three different types of patents: utility patents, design patents, and plant patents.123 Cannabis products may be protected with plant or utility patents. For example, a plant patent is granted to an inventor “who has invented or discovered and asexually reproduced a distinct and new variety of plant, other than a tuber propagated plant or a plant found in an uncultivated state.”124 A plant patent gives a cannabis plant breeder the exclusive right to clonally propagate a specific strain or cultivar of cannabis.125 A cultivar is the collective name for a plant variety that has been produced in cultivation by selective breeding.126 Marijuana cultivars are definitively narrower, almost always originate from human cultivation, and often cannot be grown from seeds from the original plant.127 Moreover, the “grant of a plant patent precludes others from asexually reproducing, selling, offering for sale or using the patented plant or any of its parts in the United States or importing them into the United States.”128

120. See U.S. CONST. art. I, § 8, cl. 8.
123. A design patent would not be used to patent cannabis. General Information About 35 U.S.C. 161 Plant Patents, supra note 112.
124. Id.
127. Id.
While plant patents are an effective way to protect new cannabis strains, utility patents are broader in scope. Utility patents “can be granted for plants, seeds, plant varieties, plant parts (e.g., fruit and flowers), and processes of producing plants, plant genes, and hybrids.” Both sexually and asexually reproduced cannabis plant types enjoy utility patent protection, which enables growers, businesses, and other entities to seek patent protection for their unique strains.

To be patented, an invention must satisfy several statutory requirements relating to, among others, patentable subject matter, novelty, and obviousness. Patent eligible subject matter is codified in 35 U.S.C. § 101. Under the patent statutes, only particular subject matters are eligible for patenting and are limited to “any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof.” Thus, things like laws of nature, products of nature, natural phenomena, abstract ideas, and processes done with the human body, are not patentable subject matter. However, the patentability of living things was settled in a 1980 Supreme Court ruling. In *Diamond v. Chakrabarty*, the Court held that non-natural, human-made microorganisms are indeed patentable subject matter. The key question for patentability of living things is whether the inventor utilized the “product of human ingenuity” to alter nature’s handiwork so the resulting invention is a non-naturally occurring substance. Accordingly, no one can patent natural strains of wild cannabis if they did not genetically mutate or breed them, so as to render them distinct from their naturally occurring form.

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131. *Id.*


133. *Id.* §§ 102, 103.

134. *Id.* § 101.

135. *Id.*


138. *Id.* at 309-310.

Novelty and obviousness are two quasi-related principles that are codified in 35 U.S.C. § 102 and § 103, respectively. “A claimed invention may be rejected under 35 U.S.C. § 102 when the invention is anticipated (or is ‘not novel’) over a disclosure that is available as prior art.”140 In other words, the invention must be new when compared to inventions currently known in the world. Under 35 U.S.C. § 103, a claimed invention may be rejected “if the differences between the claimed invention and the prior art are such that the claimed invention as a whole would have been obvious . . . to a person of ordinary skill in the art.”141 In sum, a patent may only be obtained if it is new and contains obvious differences over prior art.

Novelty and obviousness rejections involve an analysis of prior art. Prior art constitutes all information that has been made available to the public in any form before a given date that might be relevant to a patent’s claims of originality.142 Examples of prior art include printed publications and inventions in public use, on sale, or otherwise available to the public.143 If an invention is described in prior art, or can be considered obvious in light of prior art, the novelty and nonobvious requirements for a patent have not been satisfied and the patent will not issue.144 For example, a cannabis strain patent application will not be approved if the strain is already available in prior art (e.g., for sale, described in books, found in previous patent applications, etc.) or has been in the public domain for more than one year prior to the patent application filing date.145 Similarly, a cannabis strain patent application will not mature into a patent if the modifications to the strain are obvious to a person of ordinary skill in the art.146

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141. Id. § 2141.
143. Id. § 102.
146. MPEP § 2141 (9th ed. Rev. 08.2017, Jan. 2018). (“The person of ordinary skill in the art is a hypothetical person who is presumed to have known the relevant art at the time of the invention.”).
The USPTO has already granted cannabis utility patents for strains with new chemical profiles. In fact, the USPTO has been criticized for being too lenient in its grant of cannabis utility patents. Ironically, the federal government owns a cannabis patent itself, a utility patent on the method of use of a non-psychoactive cannabinoid compound to treat some diseases. The Department of Health and Human Services (HHS) applied for a cannabinoid-based patent in 1998 and was issued U.S. Patent No. 6,630,507 in October 2003. The patent covers the potential use of non-psychoactive cannabinoids to protect the brain from damage or degeneration caused by particular diseases. The patent lists certain cannabinoids useful to treat diseases such as Parkinson’s, Alzheimer’s, and HIV-associated dementia. Despite owning this patent, the federal government has not rescheduled marijuana or loosened its grip on medical marijuana research and funding. Since 2003, additional patents have been granted to entities besides the federal government for other methods of use and for marijuana-associated or -based products, such as CBD oils. One such patent was granted in October 2018 to Axim Biotechnologies, Inc., an American-based pharmaceutical company, for a cannabis-based suppository to treat irritable bowel syndrome.

In 2015, a group of California marijuana breeders under the name of BioTech Institute, LLC (Biotech) received the first-ever utility patent (the ‘554 patent) for a specific marijuana strain. The patent claimed “a hybrid cannabis plant, or an asexual clone of said hybrid cannabis plant, or a plant part, tissue, or cell thereof, which produces a female inflorescence,” comprising, among other things, a unique genotype and terpene profile,

148. Landau & Wright, *supra* note 125.
152. Id.
and a CBD content greater than 3%. The patent also claimed methods for breeding the specific strain, cannabis extracts derived from the strain, and edible products derived from the strain and extract. Biotech is currently building a portfolio of plant and utility patents that cover multiple aspects of the cannabis plant itself, causing concern for many in the cannabis industry. For example, Biotech received two additional cannabis patents, which are continuations of the ‘554 patent. Although the new patents do not represent new methods, they are broader in scope. Currently, some reports estimate that BioTech’s patents could cover 50%-70% of all strains on the market today. BioTech has essentially created a quasi-monopoly on unique marijuana strain patents, “cement[ing] its footing in the industry and its likely ability to submit additional successful applications in the future.”

By aggressively pursuing cannabis patent protection in the United States and abroad, companies like BioTech are starting to corner the marijuana market and ensure that individuals and smaller growing entities must pay a licensing fee to use their products. However, even after a licensee pays the fees and royalties, they cannot use the seeds produced by their own plants—they must buy new, patented seeds. This monopolization of cannabis seeds and strains could lead to some interesting legal outcomes.

2. Legal Issues with Cannabis Strain Patents

In the United States, patent law is exclusively federal and involves many legal gray areas, so a cannabis patent holder must comport with the fact that their patent may be unenforceable against infringers. As previously mentioned, although several states have legalized medical and

157. Id.
158. Id.
162. Schuman et al., supra note 159.
165. See Nard, supra note 139.
recreational marijuana, marijuana still remains prohibited at the national level due to its Schedule I status. Generally, “federal illegality of marijuana also means the industry lacks clarity over how intellectual property rights would hold up if challenged in a US federal court.” Although marijuana’s Schedule I status is not a significant challenge to patentability, it is unclear whether federal courts are willing to enforce cannabis patent rights against alleged infringers.

Another key issue is whether the patent being sought is overly broad in the context of preexisting prior art. The lack of cohesive, documented scientific marijuana research has prevented many of its uses from being described in scientific articles typically presented as prior art in patent cases. This can have implications for cannabis patent holders trying to enforce their rights in courts, and experts say it could both hurt and help their chances. The lack of cannabis prior art has allowed applicants to file overly broad, obvious, or non-novel cannabis claims that have passed USPTO examination because many examiners are not well trained in the field. However, because the legal cannabis industry itself is still in its infancy, the lack of prior art is prompting the cannabis community to take action and establish libraries of cannabis strains for use as prior art.

In July 2018, United Cannabis Corporation (UCANN) filed the first cannabis patent infringement complaint in the United States. UCANN alleged Pure Hemp Collective, Inc. (Pure Hemp) infringed UCANN’s

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170. Using large-scale clinical trials is a typical way to prove to the federal government that a drug has beneficial medicinal value, and to date, there have been no such trials on marijuana. See Lopez, supra note 166.


patented formulation of highly concentrated liquid cannabinoids.\textsuperscript{175} Pure Hemp filed an early motion for partial summary judgment, arguing that all of UCANN’s asserted patent claims were invalid.\textsuperscript{176} The district court rejected Pure Hemp’s argument that UCANN’s patent was invalid.\textsuperscript{177} The court discussed how UCANN’s patent was not “directed to” unpatentable subject matter, because it was UCANN’s handiwork that led to the precise concentrations contained within the formulations of the liquid cannabinoids.\textsuperscript{178} The court found UCANN’s patent was “directed to” a “non-naturally occurring delivery method of naturally occurring chemicals in non-naturally occurring proportions and concentrations,” which is indeed patentable subject matter.\textsuperscript{179} Pure Hemp also counterclaimed that UCANN’s patent was already present in the prior art; however, the court has yet to address this claim.\textsuperscript{180} Of note, prior to the lawsuit, UCANN extended a licensing deal to Pure Hemp, foreshadowing how a patent holder could use their patent portfolio, and a successful lawsuit under their belt, to target other businesses or growers.\textsuperscript{181} The case is currently at the claim construction stage.\textsuperscript{182} In January 2020, the court issued a Claim Construction Order, “a critical step in any patent infringement case,” because the way the claims are construed can play a significant role in the outcome of the case.\textsuperscript{183} The case’s final outcome is still pending but will hopefully shed much-needed light on how federal courts will address infringement actions concerning cannabis patents, as well as answer other questions involving validity and enforceability of these patents.\textsuperscript{184}


\textsuperscript{177} United Cannabis Corp., 2019 WL 1651846, at *1.

\textsuperscript{178} See id. at *7.

\textsuperscript{179} See id.


\textsuperscript{181} Id.


\textsuperscript{183} Id.

As they say, the future is not near—it’s here. Thanks to earlier-discussed legalization, it is likely that patent turf wars over cannabis products, especially specifically engineered strains, will begin to ensue here in the United States, as they have in Canada. Currently, foreign pharmaceutical companies are sweeping Canadian patent holding. Switzerland-based Novartis International AG holds twenty-one cannabis-related patents, U.S.-based Pfizer Products, Inc. owns fourteen, and GW has thirteen. Canada’s recent surge in marijuana patent applications, largely for medical uses, is telling. Who will win these wars? It is too early to say, but major multinational pharmaceutical companies already have an early lead.

B. Cannabis Patents and Pharmaceutical Companies

Patent protection is a key component of the United States legal system. On principle, we should compensate and reward those who have rightfully invented something, as well as incentivize and stimulate further innovation. The marijuana industry has been historically composed of people who believe in the cause, the plant, and the health benefits it brings. Yet, many of the field’s “new players” are getting involved with a specific business purpose in mind. Cannabis patents are one way to normalize and bring the industry to the mainstream, but the winners in the patent system are often those who are first and have the most money.

It’s no secret why everyone wants a piece of the marijuana industry pie: according to an April 2018 report by Grand View Research, Inc., the global legal marijuana market is projected to be worth $146.4 billion by

The report additionally found that in 2016, medical marijuana emerged as the largest segment of the industry and is estimated to be valued at $100.03 billion by 2025.\footnote{Press Release, Grand View Research, Inc., Legal Marijuana Market Worth $146.4 Billion by 2025 | CAGR: 34.6\% (Apr. 2018), http://www.grandviewresearch.com/press-release/global-legal-marijuana-market.}

One way to obtain a monetary stake in the medical marijuana market is to use the patent process to acquire ownership over a particular strain and its seeds.\footnote{Id.} This limited monopoly ensures that the patent holder “is the only one who can make or sell the product, or license other people to do so.”\footnote{Margolin, supra note 101.} However, there are so many unanswered questions that surround IP protection of a federally illegal substance, it is unclear if the patents will be upheld.\footnote{Wolfe, supra note 10.} If cannabis patents are upheld in federal courts, it is possible that a handful of companies could be in a position to demand licensing fees from the rest of the industry.\footnote{Id.}

This incentive is particularly appealing to major multinational pharmaceutical companies (Big Pharma) and is already being capitalized on today. For example, pharmaceutical firms are already seven of the top ten cannabis patent holders in Canada.\footnote{Press Release, supra note 185.} These patents, filed prior to the country’s full legalization of marijuana, would have been difficult to enforce prior to legalization.\footnote{Id.} However, after Canada legalized marijuana on October 17, 2018, the patents became fully enforceable and gave the companies a key strategic advantage over non-patent holders in the ever-increasingly competitive market.\footnote{See id. The biggest concern is that Big Pharma companies will harness their powerful lobbies and seemingly bottomless payrolls to engage in patent blitzes. In other words, they will try to enlarge their patent portfolios and subsequent ownership of marijuana strains and their ancillary byproducts, such as oils, to marginalize competitors.\footnote{Is a Marijuana Patent War Coming to the U.S. in 2018?, COMPASSIONATE CERTIFICATION CTR. (Feb. 16, 2018), http://www.compassionatecertificationcenters.com/is-a-marijuana-patent-war-coming-to-the-u-s-in-2018/.}
In the United States, the FDA plays a crucial role in approving and regulating medications for public use.201 Big Pharma requires the FDA’s approval to bring their products to the public market, and it’s no secret that Big Pharma’s influence on the agency has accrued over many decades and billions of dollars spent.202 The current FDA Commissioner Scott Gottlieb recently slammed Big Pharma and accused drugmakers of using “gaming tactics” to stall the introduction of generic versions of biologic drugs, “a move that cost the U.S. healthcare system billions of dollars last year.”203 One of these tactics is to engage in patent blitzes, or evergreening, right before a drug’s patent protection (and subsequent market exclusivity period) expires.204 “In the pharmaceutical trade, when brand-name companies patent ‘new inventions’ that are really just slight modifications of old drugs, it’s called ‘evergreening.”205 Evergreening occurs because once a drugmaker’s patent on a particular drug expires, the door is open for other producers to bring generic versions of the drug to market.206 Patents in patent blitzes are often granted for even the most trivial improvements and innovations related to existing drugs.207 The purpose of evergreening is two-fold: first, to extend the commercial dominance of brand-name drugs, and second, to tie up producers of the generic drugs in costly, time-consuming litigation.208 Evergreening prevents a generic drug’s market entry and further extends Big Pharma’s monopolies.209

A prime example of recent evergreening is when Mylan hiked the price of its life-saving epinephrine injectable drug, EpiPen®, by more than 400%.210 After Teva Pharmaceuticals gained approval from the FDA for

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201. Id.
202. See id.
207. Id.
208. Id.
209. Id.; see also Edney, supra note 204.
210. Mylan’s profits increased to $1.1 billion a year after they raised the price of the EpiPen from $50 to more than $600 for a two-pack. Beth Mole, Years After Mylan’s Epic EpiPen Price Hikes, It Finally Gets a Generic Rival, ARS TECHNICA (Aug. 17, 2018, 9:05 AM), http://ars
the first generic version of EpiPen, Mylan sued them for patent infringement, although epinephrine alone was already a generic drug.\textsuperscript{211} Mylan settled and kept “Teva off the EpiPen market until 2015.”\textsuperscript{212} Much like AbbVie’s battle with AmGen over a generic version of the former’s costly biologic drug Humira®, Big Pharma’s inclination to place company profits over the needs and desires of patients could continue with cannabis strain patents.\textsuperscript{213} This will ultimately affect cost and access to medical marijuana products.

Thanks to shifting public opinion and state legalization, a growing number of cannabis patent applications have been filed with the USPTO, and it is very likely they will be granted.\textsuperscript{214} Although marijuana remains illegal at the federal level, the premature filings signal hope that sometime in the near future, the federal government will reconsider its stance on cannabis, and make medical and recreational marijuana use legal from sea to shining sea.\textsuperscript{215}

Companies with a large number of cannabis strain patents, such as BioTech, could become an even bigger national player in the field of cannabis strain patents as they acquire more market share.\textsuperscript{216} Overall, if Big Pharma obtains exclusive rights to use, produce, and sell particular cannabis strains, together with their large influence over the FDA and other government regulatory bodies, they can control public access and maintain already robust profit margins.\textsuperscript{217}

Not surprisingly, Big Pharma is not the only industry chasing profits from marijuana IP rights. Smaller breeders, including scientists who alter the plant for medicinal purposes, worry that large bioagricultural companies like Monsanto and Syngenta will hoard cannabis-based patents and deploy their massive economic power to position themselves as another dominant force in the market.\textsuperscript{218} In short, an open and accessible

\textsuperscript{212} Mole, supra note 210.
\textsuperscript{213} Edney, supra note 204.
\textsuperscript{215} Nard, supra note 139.
\textsuperscript{216} De Corso, supra note 163.
\textsuperscript{217} Is a Marijuana Patent War Coming to the U.S. in 2018?, supra note 200.
\textsuperscript{218} Nard, supra note 139.
marketplace for cannabis products, especially for medicinal use, depends on tracking the patent activity of wealthy, powerful entities to ensure smaller entities are not marginalized.219

IV. THAILAND AS A CASE STUDY FOR THE FUTURE OF CANNABIS STRAIN PATENTS

Thailand’s legalization of medical marijuana in February 2019 presents an interesting case study for the future of legal marijuana use and cannabis strain patents.220 The legalization of marijuana in Thailand could negatively impact global biodiversity and has already spurred the Thai government to enforce new patent policies and marijuana growing laws.221

A. Biodiversity Implications for Cannabis Strain Patents

Biodiversity, or biological diversity, is an ongoing controversy in the marijuana patent industry. Like comprehensive research on the benefits and drawbacks of medical marijuana, “empirical analysis on biodiversity in the patent system is limited.”222 Biodiversity is a broad term but is generally defined as “biological diversity in an environment as indicated by numbers of different species of plants and animals.”223 Increasingly, however, countries and companies are asserting IP rights in native flora, impacting global biodiversity.224

“Historical documents from around the world, some dating as far back as 2900 B.C., tell us that cannabis has lived alongside humans for thousands of years, cultivated for food, fiber, and fodder, as well as for religious and medicinal purposes.”225 The fear is that without a wide variety of cannabis strains available for breeding and growing, production

and processing of the plant will inevitably consolidate into the hands of large conglomerates.226

The United States and Thailand are signatories to the Convention on Biological Diversity (Biodiversity Convention), a multilateral treaty committed to sustainable development.227 The Biodiversity Convention’s goals include “conserving biological diversity, promoting the sustainable use of its components, and the fair use and equitable sharing of benefits from biological resources.”228 The Biodiversity Convention requires signatories to enforce regulations on plant patent applications and mandates that new patent applications include the plant’s genetic resources and evidence of local use if they seek to patent the plant in a certain country.229 This is the chief reason behind the Biodiversity Sustainable Agriculture Food Sovereignty Action Thailand’s (Biothai) call for careful scrutiny of recently filed foreign cannabis patents in the country, as discussed in greater detail in the next Section.230

Since medical marijuana is now legal for use and manufacture in Thailand, the mere implication that fabled Thai marijuana strains, such as “Northern Lights,” could be available on the global market has generated much buzz.231 Like Cuban cigars or French champagne, Thai marijuana is known for its potency and quality.232 Thailand’s marijuana is a pure sativa landrace strain, meaning it is a local strain of cannabis that has adapted to Thailand’s native environment and conditions over time.233 Environment plays a key role in the THC, CBD, and terpene quality and quantity and is part of what makes landrace strains so unique.234 For example, the

229. Id.
230. Id.
234. Rahn, supra note 225.
marijuana plants and seeds that are indigenous to the tropical jungles of Thailand are bred to preserve their naturally occurring high THC levels.\textsuperscript{235}

As more cannabis strain patents are granted worldwide, it is possible that growers will be increasingly dependent on seed makers that hold patents on certain types of seeds and methods used to produce them. As a result, growers will be subject to agreements and royalties and will be charged licensing fees for use of the seeds.\textsuperscript{236} A healthy number and variety of available cultivars are vital for advancing cannabis legalization and the industry’s continued growth.\textsuperscript{237} From an agricultural perspective, the patent system encourages a consolidation and reduction of variety in order to enhance and maximize profits.\textsuperscript{238} This can be seen in today’s staple crops, such as corn, soy, and wheat, where fewer cultivars exist than they did decades ago.\textsuperscript{239} Other crops globally consumed today, such as fruits and vegetables, are likely grown from patented varieties or cultivars.\textsuperscript{240} As a result, agricultural biodiversity has diminished due to the introduction and consolidation of genetically modified, patented varieties, and it is highly likely the cannabis industry could see a similar fate.\textsuperscript{241}

Cannabis biodiversity will be threatened if there are fewer available cultivars and, thus, fewer strain options.\textsuperscript{242} Fewer available strains could also lead to limited consumer experiences and patient treatment options. This notion, coupled with already limited clinical and scientific research, could significantly throttle advances in medical marijuana availability and use.\textsuperscript{243} The corporatization of the industry, thanks to patent law, could see smaller growers and businesses merging into giant conglomerates, with the profits being held in the hands of a very few.\textsuperscript{244} In short, the “winners” of the cannabis patent wars will dominate the industry post-prohibition.\textsuperscript{245}

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\item \textsuperscript{235} Gray, \textit{supra} note 233.
\item \textsuperscript{236} Sty, \textit{supra} note 226.
\item \textsuperscript{238} Sty, \textit{supra} note 226.
\item \textsuperscript{239} Angela Baccar, \textit{Patent Zero: If Big Business Continues to Pursue Cannabis Patents, What Will Happen to Small-Scale Growers and Breeders?}, BIG BUDS MAG. (July 9, 2018), http://bigbudsmag.com/what-happens-if-corporations-patent-cannabis-genetics/.
\item \textsuperscript{240} See Crucial to Breeding Cannabis to Its Full Potential, \textit{GREEN CULTURED}, http://www.greencultured.co/open-source-cannabis-breeding/ (last visited Sept. 5, 2019).
\item \textsuperscript{241} Baccar, \textit{supra} note 239.
\item \textsuperscript{242} Sty, \textit{supra} note 226.
\item \textsuperscript{243} \textit{Id.}; see also Baccar, \textit{supra} note 239.
\item \textsuperscript{244} Sty, \textit{supra} note 226.
\item \textsuperscript{245} Zuber, \textit{supra} note 11.
\end{itemize}
Some argue that expanding strain patents could have the opposite effect and allow researchers and physicians to “correctly identify, dose, and perhaps even personalize prescriptions for particular strains in the future” to treat specific ailments. Patents are a hallmark of innovation, and with wide access to more and better cannabis strains, there could be innovation advances in the industry as a whole. However, the reality is that cannabis patents are likely to be held by large corporations, given what we have seen before with the United States government and the FDA’s involvement.

Both medical marijuana patients and recreational marijuana users are strain-driven. While the current cannabis landscape is rich with hundreds of different varieties, strain patents could lead to a “locked genetic landscape where innovation becomes rare and costly.” Further, a monopoly on the local strains of one country could have disastrous effects on that country’s biodiversity and its rights to that biodiversity.

B. Thailand’s Medical Marijuana Legalization and Rejection of Cannabis Patent Requests

Internationally, marijuana still remains generally illegal. Signatories to The Single Convention on Narcotic Drugs of 1961 (the Convention) restrict legal marijuana uses to medical and scientific purposes only. The Convention requires international cooperation and enforcement and considers marijuana a Schedule IV drug, akin to Schedule I classification in the United States. Despite the Convention, some countries have legalized marijuana use within their borders, in the same manner as some U.S. states. As of December 2019, Thailand is one

248. See Sty, supra note 237.
249. Sty, supra note 226.
250. See Biothai Wades into Patents Row, supra note 228.
253. Id.
of the latest countries to legalize medical marijuana, and the first in the Southeast Asia region to do so.\textsuperscript{254}

Marijuana was used as a traditional medicine in Thailand for centuries before being banned in 1930.\textsuperscript{255} The country is notorious for its hardline approach to illegal drugs and strict penalties for drug-related crimes; thus, medical marijuana legalization represents a giant leap forward.\textsuperscript{256} In December 2018, Thailand’s junta-appointed parliament voted to amend the country’s Narcotic Act of 1979 to legalize medical marijuana.\textsuperscript{257} The chairman of the drafting committee said the amended legislation “could be considered as a New Year’s [2019] gift to [the] Thai [people].”\textsuperscript{258} Two months after parliament’s approval, King Maha Vajiralongkorn signed a royal decree that officially permitted physicians, patients, schools, farmers, entrepreneurs, and exporters to cultivate, possess, and dispense marijuana for medicinal purposes under physician supervision.\textsuperscript{259} Current Thai Prime Minister Prayut Chan-o-cha supports legalization but notes how important it is for medical marijuana users to be supervised by medical professionals.\textsuperscript{260} In a historic first for a public official, at a December 2019 event, Chan-o-cha inhaled and applied some cannabis oil to the back of his ear, saying he “was going to buy the oil and try it later.”\textsuperscript{261}

As the world becomes increasingly interconnected and companies continue to do business globally, there has been an increase in foreign pharmaceutical companies applying for and being granted cannabis patents in different countries.\textsuperscript{262} The main controversy with marijuana legalization in Thailand “involve[s] patent requests by foreign firms that could allow them to dominate the market, making it harder for Thai patients to access medicines and for Thai researchers to access marijuana extracts.”\textsuperscript{263} This controversy emerged after Japan-based Otsuka

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  \item[\textsuperscript{255}] Id.
  \item[\textsuperscript{256}] Id.
  \item[\textsuperscript{257}] Id.
  \item[\textsuperscript{258}] Id.
  \item[\textsuperscript{259}] Ehrlich, \textit{supra} note 232.
  \item[\textsuperscript{261}] Id.
  \item[\textsuperscript{262}] See Wolfe, \textit{supra} note 10.
\end{itemize}
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Pharmaceutical and GW filed a combined seven foreign cannabis patent applications prior to medical marijuana’s official legalization.\textsuperscript{264} Thailand’s Department of Intellectual Property (DIP) rushed the review of the controversial foreign applications, including one that sought to patent a phytocannabinoid, one of many raw active ingredients found naturally in marijuana.\textsuperscript{265} Less than a month after the patents’ initial approval, the Thai parliament issued a special executive order on January 28, 2019, that allowed the DIP to “revoke all pending patents that involve cannabis, or remove marijuana from those patents, within 90 days.”\textsuperscript{266} The executive order effectively revoked every marijuana patent request, including some that dated back to 2008.\textsuperscript{267}

The primary reason for the executive order and request revocation was to block foreign corporate monopolization of the country’s budding medical marijuana industry.\textsuperscript{268} Opponents of the phytocannabinoid patent claimed that the patent was an attempt to patent a raw extract of cannabis and argued the compound should not be considered an “invention” for patentability purposes.\textsuperscript{269} Like the United States, Thailand does not allow natural substances to be patented.\textsuperscript{270} Specifically, article 9(1) of the Thai Intellectual Property Act states that “inventions not protected under the Act include microorganisms and/or any part of the microorganisms found in nature, animals, plants and plant extracts.”\textsuperscript{271} Conversely, supporters of the patents argued that the level of funding for research and development from Big Pharma was needed in Thailand.\textsuperscript{272} They contended that the country’s previous cannabis prohibition left the country at a disadvantage, and that the government could be inhibiting the initial growth of the industry by not allowing Big Pharma’s patents to move forward.\textsuperscript{273}


\textsuperscript{265} The phytocannabinoid is used to treat muscle spasms. \textit{Id.}


\textsuperscript{267} \textit{Id.}

\textsuperscript{268} Boyle, \textit{supra} note 264.

\textsuperscript{269} \textit{Id.}

\textsuperscript{270} See Kaewindja, \textit{supra} note 12.


\textsuperscript{273} \textit{Id.}
While the request revocation seems like an outright rejection, the move is not so.\textsuperscript{274} Although the patent application requests have not been approved, they have also not been rejected or abandoned. This allows for amendments to the applications and potential future patentable cannabis.\textsuperscript{275} Additionally, the decree was to remain in effect until the legislation on medical marijuana was signed by King Vajiralongkorn, which happened one month after the revocation of the patent requests (though the decree extends ninety days from the date it was entered).\textsuperscript{276} Further, applicants affected by the revocation can appeal to the Thai Board of Patents within sixty days of receiving the cancellation of their requests.\textsuperscript{277}

It remains to be seen if Thailand will eventually grant the stalled cannabis patents.\textsuperscript{278} Regardless, the rejection of the cannabis patent requests shows promise that the traditional patent system could give way to a new model: open source cannabis. On the other hand, if marijuana is reclassified as a less-dangerous drug, the risk of biodiversity loss and Big Pharma’s monopoly of the legal marijuana market still persists.

V. \textsc{Looking Forward to Solutions and Further Problems}

\textbf{A. Open Source Cannabis and Prior Art}

“Open source” refers to data and information that is available to the general public.\textsuperscript{279} Information may be open source if it is published or broadcast for a public audience, available to the public by request, available to the public by subscription or purchase, or is seen or heard by a casual observer.\textsuperscript{280} Open source approaches to cannabis have become popular in recent years in an effort to share information with breeders and

\textsuperscript{274}. See Thepgumpanat & Wongcha-um, \textit{supra} note 266.
\textsuperscript{275}. Kaewindja, \textit{supra} note 12.
\textsuperscript{276}. Ehrlich, \textit{supra} note 232.
\textsuperscript{278}. New medical marijuana regulations are on the horizon in Thailand. However, in November 2019, Thailand’s Health Minister Anutin Charnvirakul announced that all Thais will soon be able to cultivate six cannabis plants in their homes and sell their home-grown harvest to the government, which will turn it into medical marijuana. Sara Brittany Somerset, \textit{Thailand Will Soon Allow Its Citizens to Grow Cannabis at Home to Sell to the Government}, FORBES (Nov. 17, 2019), http://www.forbes.com/sites/sarabrittanysomerset/2019/11/17/thailand-will-allow-its-citizens-to-grow-cannabis-at-home-to-sell-to-the-government/#495a4303591e.
\textsuperscript{280}. \textit{Id.}
other members of the cannabis industry.\textsuperscript{281} The hope is that individuals “could use their access to this great source of genetic diversity in developing new cultivars as well as simply to preserve biodiversity and improve the overall gene pool of cannabis cultivars developed by plant breeders.”\textsuperscript{282} However, in the United States, open source cannabis could also serve as a barrier to patent monopolies by keeping cannabis strain data in the prior art and the public domain.\textsuperscript{283} Open source cannabis repositories may include genetic and chemotypic data of a variety of strains, which are both considered prior art.\textsuperscript{284} Thus, if the genetic makeup of a cannabis strain is in the prior art, the strain will lack patentability based on statutory requirements of novelty and nonobviousness.\textsuperscript{285}

To date, the lack of a “deep reservoir of prior art” has been advantageous to cannabis strain patent applicants and patent holders, such as BioTech, and has allowed them to take advantage of broad protections.\textsuperscript{286} In order to patent a cannabis strain, it is essential to know exactly what is being patented, and having knowledge of the strain’s genetic makeup accomplishes this; conversely, if the genetic makeup is in the prior art, the strain will lack patentability.\textsuperscript{287} Thus, there is a need for organizations that promote and promulgate open source cannabis.\textsuperscript{288} An open source cannabis system is a less-commercial approach to breeding, and open source supporters do not want the “community value” of marijuana to be siphoned off to parties with different values and different goals, such as Big Pharma.\textsuperscript{289} The Open Cannabis Project (OCP), an Oregon-based nonprofit organization, sought to create an open source cannabis system in a variety of ways.\textsuperscript{290} For example, they published partial DNA sequences of cannabis plant varieties in an online database to ensure they remained in the public domain.\textsuperscript{291} The goal of OCP was to provide a comprehensive set of genetic data based on their open-source

\begin{footnotesize}
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\item \textsuperscript{282} Id.
\item \textsuperscript{283} Open Cannabis Project: The Fight to Get Marijuana Patents Right, HARRIS BRICKEN CANNA L. BLOG (Feb. 23, 2018), http://www.cannalawblog.com/open-cannabis-project-and-the/.
\item \textsuperscript{284} Id.
\item \textsuperscript{285} Roberts, supra note 193.
\item \textsuperscript{286} Schuman & Hardman, supra note 145.
\item \textsuperscript{287} Roberts, supra note 193.
\item \textsuperscript{288} Schuman & Hardman, supra note 145.
\item \textsuperscript{289} Hunt, supra note 281.
\item \textsuperscript{290} See generally About, OPEN CANNABIS PROJECT, http://opencannabisproject.org/about/ (last visited Mar. 25, 2019).
\item \textsuperscript{291} Schuman & Hardman, supra note 145.
\end{itemize}
\end{footnotesize}
repository for all cannabis varieties, to keep them from coming under the patent monopoly of a giant corporate entity, like a pharmaceutical company.\textsuperscript{292} Though the OCP dissolved on May 6, 2019, the data collected by the organization will continue to be publically accessible online and serve as prior art for future cannabis strain patent applications.\textsuperscript{293} The work of the OCP is important and is a great model for other pro-open source cannabis organizations to follow in the future.\textsuperscript{294} Additional open source organizations could make it possible for more cannabis strain patent applications to be rejected for lack of novelty and obviousness, making it harder for large corporations to dominate the emerging market.\textsuperscript{295}

Similarly, Phylos Bioscience (Phylos), an Oregon-based agricultural genomics company, created their Galaxy tool from more than 3000 cannabis stem samples contributed by hundreds of local growers.\textsuperscript{296} The initial goal of the Galaxy tool was to sequence the DNA of the provided cultivars to create a genomic map of different strains.\textsuperscript{297} The Galaxy tool provided a three-dimensional visualization of strains and gave the public the ability to search over one thousand strains and locate close genetic relatives.\textsuperscript{298} Once Phylos made the genetic sequences available online, like the OCP, the strains entered the prior art and are ineligible for patent protection.\textsuperscript{299}

Interestingly, Phylos positioned themselves as an advocacy agriculture company from its inception in 2014, “mistrust[ing] Monsanto and champion[ing] small-scale growers and breeders.”\textsuperscript{300} Growers provided Phylos strain samples with the understanding that the samples would not be used to enhance a breeding program, after Phylos assured

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\item \textsuperscript{292} Open Cannabis Project: The Fight to Get Marijuana Patents Right, supra note 283.
\item \textsuperscript{293} Katie Shepherd, Open Cannabis Project Dissolves in Response to Controversy Over Ag-Science Company Phylos Bioscience’s Breeding Program, WILLAMETTE WK. (May 6, 2019), http://www.wweek.com/news/business/2019/05/06/open-cannabis-project-dissolves-in-response-to-controversy-over-ag-science-company-phylos-biosciences-breeding-program/.
\item \textsuperscript{294} Id.
\item \textsuperscript{295} See Zuber, supra note 11.
\item \textsuperscript{298} See Melissa Schiller, Phylos Bioscience Brings Transparency to Cannabis Industry Through Genetic Testing, CANNABIS BUS. TIMES (Jan. 28, 2018), http://www.cannabisbusinesstimes.com/article/phylos-bioscience-brings-transparency-to-cannabis-industry/.
\item \textsuperscript{299} Schuman & Hardman, supra note 145.
\item \textsuperscript{300} See Wallace, supra note 297.
\end{itemize}
them their intent was never to start such a program. However, on April 16, 2019, Phylos announced their plans for a breeding program to create new strain varieties, including mildew-resistant strains and high-THC, high-terpene flowers. Local growers and cannabis activists were outraged, feeling Phylos had misled them to gain a competitive advantage in the industry. Mowgli Holmes, a Phylos cofounder, was caught on video telling a room of potential investors that their four-year collection of data and IP was a “really huge barrier to entry protecting [Phylos]” from other competitors. Following the backlash, Holmes informed the Willamette Week that the data collection is “too small and lacks important context”; however, Phylos’ actions paint a picture of a troubling future. As a result of Phylos’ breeding program announcement and backlash, Beth Schechter, the executive director of OCP, decided to close down the organization. OCP initially began as a spin-off of Phylos, and Schechter said the deception inflicted upon it by its former business partners could never be undone.

It is hoped that other organizations will pick up where OCP left off, with a similar or new initiative to combat patent monopolies, because the effect is already apparent. For example, cannabis strain patent applications have already been denied, although the application claimed extrinsic genetic materials not present in wild cannabis plants. If more cannabis prior art is published, it is possible cannabis strain patents will continue to be rejected for lack of novelty or obviousness. Ultimately, a large corporation’s incentive to pursue marijuana patents and establish a monopoly in the industry will be eliminated since the strains cannot be patented.

However, in light of the Phylos developments and the fact that profits have taken over the cannabis industry alongside consolidation and conglomerate, it appears that time may be running out for smaller
growers and breeders. The potential adoption of the patent tactics of oft-despised Big Pharma and Agriculture by the cannabis industry could impact medical marijuana negatively, as research and general prohibition of the plant struggle to evolve at the same pace as technological advances.

Ultimately, medical marijuana patients and general long-time consumers are strain-aware, and it is important to the overall community that the variety and availability of use of cannabis strains be preserved, and not hindered, by the patent system.

B. The Problem with Reclassification of Marijuana in National and International Drug Schedules

Domestically, another potential solution is to reschedule cannabis from Schedule I to a less-strict classification, due to “the ever-widening split between federal and state legal systems.” As additional states legalize marijuana, old norms and opinions about marijuana use will fall away, especially those regarding its potential medicinal value. By rescheduling marijuana to Schedule II, more research opportunities and grants could emerge once the layers of bureaucracy are peeled away. With more opportunities available, medical marijuana research and information could make leaps and bounds. Those in the medical field can use the new research information to dispel myths and discern the truth about marijuana’s positive and negative effects, which will lead to better overall patient outcomes, which in turn will benefit society as a whole.

However, there is another side to the coin of cannabis rescheduling. It is possible that once federal prohibition of marijuana is lifted, patent protection will be necessary to further scientific research and get FDA approval for marijuana-related treatments and studies. The reality is that Big Pharma is in the business of making a profit and without the protection that the patent system provides, Big Pharma may be less inclined to

311. See Wallace, supra note 297.
312. Id.
313. See Crucial to Breeding Cannabis to Its Full Potential, supra note 240.
314. Katner, supra note 2, at 191.
316. See Katner, supra note 2, at 192-93.
317. Id. at 183-84.
318. Id.
provide the necessary funding for medical marijuana research and development.\footnote{Id. (“Cannabis has huge potential for pharmaceutical research, but actually getting cannabis-based treatments approved costs tens of millions of dollars . . . . And without the ability to protect relevant findings, the funding will never be there.”).} Even if marijuana is reclassified, smaller growers may still be at a disadvantage because they do not have the patent strategy or massive, quick filing abilities that pharmaceutical companies possess.\footnote{Id.} As mentioned previously, it will become extremely difficult for smaller, longtime breeders and growers to compete with larger agricultural and pharmaceutical corporations.\footnote{See Wallace, supra note 297.} The ability of large corporations and conglomerates to invest enormous sums of money into improving cannabis could ultimately disenfranchise those in the cannabis community who believe in the marijuana plant’s greater mission.\footnote{Id.}

Reclassification of cannabis could happen on the international stage as well. In February 2019, the World Health Organization called for whole-plant marijuana to be removed from Schedule IV on the advice of global health experts from the United Nations.\footnote{Tom Angell, \textit{World Health Organization Recommends Reclassifying Marijuana Under International Treaties}, FORBES (Feb. 1, 2019, 6:35 AM), \url{http://www.forbes.com/sites/tomangell/2019/02/01/world-health-organization-recommends-rescheduling-marijuana-under-international-treaties/#a5157666bcc0}.} However, along the line of reasoning previously mentioned, international reclassification could see a flood of new cannabis patent applications by foreign conglomerates in countries with recent legalization, as was the case in Thailand and Canada.\footnote{See Boyle, supra note 264.}

Countries can push back, as seen by the rejection of cannabis patent application requests by Thailand’s DIP.\footnote{Kaewindja, supra note 12.} In order to protect their local cannabis resources and prevent large pharmaceutical corporations from coming in and effectively stripping them of their biodiversity rights, it will be critical for nations worldwide to not let their interests be steamrolled by way of the patent system.
VI. CONCLUSION

Our planet is rich with natural resources, species, and animals, and it seems as though they should be treated as a collective good, owned by everyone and no one at the same time.327 Public perception on marijuana use, both for recreational and medicinal purposes, continues to shift in favor of full legalization, but as a planet, we are not there yet. It remains to be seen what the future of cannabis strain patents holds, but more research must be conducted, both for the medical community and the community at-large, so that there is a uniform consensus on the potential benefits and harms of marijuana. However, this research must be done within the framework of knowledge that marijuana is still a naturally occurring plant, so companies and businesses must take care that they do not put profits over people and the natural world as they pursue and protect their IP rights. We cannot afford the cultural loss of those smaller growers and activists who have carried the marijuana industry this far.328

328. Guercio, supra note 319.