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That is Northern Lights Cannabis Indica . . . No, It's Marijuana: Navigating Through the Haze of Cannabis and Patents

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THAT IS NORTHERN LIGHTS CANNABIS INDICA . . . NO, IT’S MARIJUANA:
NAVIGATING THROUGH THE HAZE OF CANNABIS AND PATENTS

*Dawson Hahn**

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INTRODUCTION

Starting in 1942, the United States Patent & Trademark Office (USPTO) has allowed patents to be issued for cannabis-related innovations.¹

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¹ Eric Furman & Ari Feinstein, *Patent Protection for Cannabis?*, PHARMACEUTICAL EXECUTIVE (Nov. 13, 2018), <http://www.pharmexec.com/patent-protection-cannabis>.

Yet, the possession, cultivation, and distribution of marijuana has been outlawed since 1970 under the Controlled Substances Act (CSA).² How can this be? This juxtaposition of cannabis and patents has led to many questions in the cannabis and intellectual property fields. Since there remains no legality requirement to secure a patent, the USPTO has been able to issue seemingly valid patents for cannabis and cannabis-related innovations. However, in bringing an infringement case for a cannabis-related patent, the patent owner is likely to detail activities that are currently illegal under federal law. How will that play out? Are these patents really valid? Will the federal courts enforce a cannabis-related patent? What kind of patent protections are available for a cannabis-related invention? These questions have gone unanswered so far because the courts have not heard a patent infringement case involving a cannabis-related patent. Until now.

On July 30th, 2018, United Cannabis Corporation filed a complaint for patent infringement against Pure Hemp Collective, Inc. in the US District Court for the District of Colorado.³ Recreational cannabis use has been legalized in the state of Colorado,⁴ but patent infringement cases are a matter of federal law, where cannabis is still illegal.⁵ United Cannabis Corporation only asserted one patent in its complaint: U.S. Patent No. 9,730,911 (the ‘911 Patent).⁶ The ‘911 Patent claims various liquid formulations of highly enriched extracts of plant cannabinoids and has seven independent claims.⁷ As the CSA currently bans any “material, compound, mixture, or preparation” which contains any quantity of tetrahydrocannabinols or cannabimimetic agents, each of these claims describe a liquid formulation that would be illegal under federal law.⁸ In addition to United Cannabis Corporation’s suit, the Department of Justice and the Drug Enforcement Administration recently announced that Epidiolex, “the first FDA-approved drug made from the cannabis plant,” was reclassified as a Schedule V drug

² See Controlled Substances Act, 21 U.S.C. § 812 (1970).

³ Complaint for Patent Infringement and Demand for Jury Trial, *United Cannabis Corp. v. Pure Hemp Collective, Inc.*, No. 1:18-cv-01922-NYW (D. Colo. 2017).

⁴ COLO. REV. STAT. ANN. CONST. art. XVIII, § 16.

⁵ 21 U.S.C. § 812 Schedule I(c) (2012).

⁶ Complaint for Patent Infringement and Demand for Jury Trial, *United Cannabis* (No. 1:18-cv-01922-NYW).

⁷ See U.S. Patent No. 9,730,911 (filed Oct. 21, 2015) (patenting the extraction of pharmaceutically active components from plant materials).

⁸ Controlled Substances Act, § 812 Schedule I(c).

under the CSA.⁹ Does that mean that cannabis itself will soon be reclassified? That remains unclear. Since federal law still prohibits marijuana, any state laws that legalize marijuana seem to be at odds with federal law. While the 10th Amendment protects a state’s ability to govern itself, the Supremacy Clause prevents state law from contradicting federal law.¹⁰ Thus, it seems like marijuana laws at the state level conflict with federal law unless marijuana is reclassified under federal law, which seems unlikely under the current administration.¹¹ But maybe there’s another option.

This Comment will examine the interactions of patent laws and cannabis laws in the United States. Section I sets forth a brief history of patent laws, while also detailing the requirements in obtaining a patent, and how one may infringe on a patent. Section II discusses the present status of cannabis-related patents, introduces *United Cannabis Corp. v. Pure Hemp Collective, Inc.*, and debates possible outcomes of the case. Section III debates the legality of cannabis in America and the impact of Federalism and the Supremacy Clause to state cannabis laws and proposes a solution to the dichotomy between state and federal cannabis laws.

I. PATENT LAW OVERVIEW

A. *The U.S. Patent System*

Intellectual property can be thought of as “any product of the human intellect that the law protects from unauthorized use by others.”¹² Intellectual property covers a large area of law, including patents, trademarks, copyrights, and trade secrets. Under Article I of the U.S. Constitution, Congress is given the power “[t]o promote the Progress of Science and useful Arts, by securing for limited Times to Authors and Inventors the exclusive Right to their respective Writings and Discoveries.”¹³ State and federal lawmakers have parlayed this enumeration into the federal Patent Act and federal Copyright Act, as well as other state and federal laws, which make up our basic

⁹ Schedules of Controlled Substances: Placement in Schedule V of Certain FDA-Approved Drugs Containing Cannabidiol, 83 Fed. Reg. 48,950 (Sept. 28, 2018).

¹⁰ U.S. CONST. art. VI, cl. 2.

¹¹ See generally Memorandum from Attorney Gen. Jefferson B. Sessions, III to all United States Attorneys (Jan. 4, 2018) [hereinafter Sessions Memo] (*available at* <https://www.justice.gov/opa/press-release/file/1022196/download>).

¹² *Intellectual Property*, CORNELL LAW SCHOOL,

https://www.law.cornell.edu/wex/intellectual_property (last visited Mar. 29, 2019).

¹³ U.S. CONST. art. I.

intellectual property laws.¹⁴ Businesses, entities, and individuals all rely on intellectual property to further their economic goals. While each intellectual property right is significant in its own way, especially in the growing cannabis industry, this Comment focuses specifically on patents.

Up until Congress passed the first federal Patent Act, patent protections were offered by state legislatures.¹⁵ Enacted in 1790, the first federal Patent Act was America's first attempt at codifying the federal patent laws we have today.¹⁶ Since then, Congress has made significant changes to our federal patent laws, including a major overhaul of the Patent Act in 1952¹⁷ and the America Invents Act of 2011.¹⁸ While the original Patent Act has been modified and updated, many key terms and concepts from the 1790 Act have survived to the present day.¹⁹ Today's federal Patent Act grants a patentee the right to exclude all others from making, using, offering for sale, and selling the patented invention within the United States, just as the 1790 Act did.²⁰

Patent law helps promote progress in the sciences and the useful arts by giving inventors a limited right to exclude others from using their new inventions or methods without permission.²¹ Additionally, patent law helps accomplish two other important goals. First, the patent system helps to publicize inventions. Inventors must provide a written disclosure of their innovation which allows those skilled in the field to make and use the invention.²² This makes a public record of progress in the field of innovation and allows the general public to receive meaningful disclosure of new innovations.²³ Second, patent laws help to reduce the risks of inadvertent disclosure and unprovable theft.²⁴ As patent law does not require proof that an infringer directly copied or even knew of the patent in question, one who

¹⁴ LYDIA PALLAS LOREN & JOSEPH SCOTT MILLER, *INTELLECTUAL PROPERTY LAW: CASES & MATERIALS* 4–6 (6th ed. 2018).

¹⁵ Herbert Hovenkamp, *The Emergence of Classical American Patent Law*, 58 ARIZ. L. REV. 263, 267 (2016).

¹⁶ Patent Act of 1790, Ch. 7, 1 Stat. 109–12 (amended 1793).

¹⁷ Patent Act of 1952, Pub. L. No. 82-593, 66 Stat. 792 (1952).

¹⁸ Leahy-Smith America Invents Act, Pub. L. No. 112-29, 125 Stat. 284 (2011).

¹⁹ 35 U.S.C. § 271 (2015).

²⁰ *Id.*; see also Patent Act of 1790 § 4.

²¹ See LOREN & MILLER, *supra* note 14, at 125.

²² 35 U.S.C. § 111 (2015).

²³ See LOREN & MILLER, *supra* note 14, at 125.

²⁴ Colleen V. Chien, *Opening the Patent System: Diffusionary Levers in Patent Law*, 89 S. CAL. L. REV. 793, 818 (2016).

is using the invention disclosed in the patent without permission is liable for infringement.²⁵ As a result, innovators that leverage the protections of patent law need not maintain secrecy from competitors or the public. This helps to strike a bargain between the public and the field of inventors to keep the nation abreast of new technologies, as well as granting protections to the inventors themselves; i.e., “fair notice for fair protection.”²⁶

B. *Obtaining a U.S. Patent*

As patent prosecution is solely a matter of federal law, U.S. patents can only be granted by the U.S. Patent & Trademark Office (USPTO). There are a series of formal administrative processes that must be completed at the USPTO in order to obtain patent protection.²⁷ Generally, the patent prosecution process begins when an inventor files an application for a patent.²⁸ This application will describe the invention and enable a hypothetical “person skilled in the art” to make and use the invention.²⁹ While the description is certainly an important aspect of the application, the most important part of the application are the claims specified. These claims state the subject matter that the inventor regards as her invention.³⁰ More notably, these claims “state the legal boundaries of the products (or processes) that the patent owner can exclude others from making, using, selling, offering to sell, or importing into the U.S.”³¹

Filing an application is not the only obstacle a party needs to overcome in order to be granted a patent. A patent claim must be supported by the written disclosures in the application,³² in addition to meeting the substantive requirements of patent law. As codified in the United States Code, Section 101 of Title 35 details the functional requirements of a patent: “Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement

²⁵ 35 U.S.C. § 271(a) (2015).

²⁶ See LOREN & MILLER, *supra* note 14, at 126.

²⁷ 35 U.S.C §§ 111–123 (2015).

²⁸ *Id.* § 111.

²⁹ *Id.* § 112(a); see also LOREN & MILLER, *supra* note 14, at 126–27 (“The application, if properly prepared, describes the invention and, through that description, enables the hypothetical *person having ordinary skill in the art*—often called *the phosita*—to make and use the invention.”).

³⁰ *Id.* § 112(b).

³¹ See LOREN & MILLER, *supra* note 14, at 127.

³² *Id.*

thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.”³³ These substantive requirements are broken down into four areas: patentable subject matter, utility, novelty, and nonobviousness.

In regards to patentable subject matter, the federal law seems clear that human intervention is key to three of the groups: machines, manufactures, and the composition of matters that do not occur naturally.³⁴ On the other hand, the Supreme Court has held that “[l]aws of nature, natural phenomena, and abstract ideas are not patentable.”³⁵ However, at some level, all inventions use or apply laws of nature and abstract ideas, so the Court has pointed out that “a process is not unpatentable simply because it contains a law of nature or a mathematical algorithm.”³⁶ Thus, the patentability of an invention or process falls upon whether the invention transforms the abstract idea into a “new and useful end.”³⁷ The utility bar of Section 101 is not hard to meet—to be considered useful, an invention or process must be capable of providing some identifiable benefit.³⁸

The novelty bar, which is codified in Section 102, can be more difficult to get past.³⁹ Generally speaking, the novelty requirement allows for only new inventions to be patentable: “Congress may not authorize the issuance of patents whose effects are to remove existent knowledge from the public domain, or to restrict free access to materials already available.”⁴⁰ While out of the scope of this Comment, the framework for novelty currently exists in two different forms because of the changes made by the America Invents Act of 2011.⁴¹ The new Section 102 governs all patents whose applications were filed on or after March 16, 2013, and focuses on the filing data of the application, whereas the previous version of Section 102 focused

³³ 35 U.S.C. § 101 (2015).

³⁴ See LOREN & MILLER, *supra* note 14, at 165 (“[M]achines’ and ‘manufactures’ are not found in nature, and naturally occurring materials are not ‘compos[ed]’”).

³⁵ Ass’n for Molecular Pathology v. Myriad Genetics, Inc., 569 U.S. 576, 589 (2013) (quoting Mayo Collaborative Services v. Prometheus Laboratories, Inc., 566 U.S. 66, 66 (2012)).

³⁶ Parker v. Flook, 437 U.S. 584, 590 (1978).

³⁷ *Id.* at 591.

³⁸ Brenner v. Manson, 383 U.S. 519, 534 (1966).

³⁹ 35 U.S.C. § 102 (2015).

⁴⁰ Graham v. John Deere Co. of Kan. City, 383 U.S. 1,6 (1966).

⁴¹ Leahy-Smith America Invents Act, Pub. L. No. 112-29, 125 Stat. 284, 285–86 (2011).

on the actual invention date.⁴² Finally, an invention must be nonobvious in order to obtain patent protections. Under Section 103, a claimed invention may be considered obvious “if the differences between the claimed invention and the prior art are such that the claimed invention as a whole would have been obvious before the effective filing date of the claimed invention to a person having ordinary skill in the art to which the claimed invention pertains.”⁴³ If a claimed invention meets all of these substantive requirements—patentable subject matter, utility, novelty, and nonobviousness—it is then available for federal patent protections.

C. *Patent Infringement*

In most cases, a patent, and the subsequent rights awarded by it, are in force from the date the patent was issued until 20 years from its original filing date.⁴⁴ These rights given to the patentee protect the patent from being either directly or indirectly infringed upon. The Patent Act helps to define these rights by listing some activities that constitute infringement: “whoever without authority makes, uses, offers to sell, or sells any patented invention, within the United States or imports into the United States any patented invention during the term of the patent therefor, infringes the patent.”⁴⁵ These five activities all have one thing in common—they are carried out by the accused infringer and they encompass every limitation (or element) described in the specified patent claim. This Comment focuses on direct infringement, which can be accomplished through literal infringement or nonliteral infringement.⁴⁶

Literal infringement occurs when each and every limitation of the claimed invention is present in another’s product or process.⁴⁷ “One proves direct infringement by a mapping process of sorts, demonstrating that the defendant’s accused product or process meets every limitation of the claim considered individually.”⁴⁸ In other words, the accused infringer’s product or

⁴² 35 U.S.C. § 102. For a more detailed discussion of how the America Invents Act changes our patent system from first-to-invent to first-to-file, see Robert A. Armitage, *Understanding the America Invents Act and its Implications for Patenting*, 40 AIPLA Q. J. 1 (2012).

⁴³ 35 U.S.C. § 103 (2015).

⁴⁴ 35 U.S.C. § 154(a)(2) (2015).

⁴⁵ 35 U.S.C. § 271(a) (2015).

⁴⁶ See LOREN & MILLER, *supra* note 14, at 262.

⁴⁷ *Cybor Corp. v. FAS Technologies, Inc.*, 138 F.3d 1448, 1467 (Fed. Cir. 1998).

⁴⁸ See LOREN & MILLER, *supra* note 14, at 262.

process must contain or use every element defined in the patent claim to be considered direct infringement. For example, if a patent claim is for a widget X comprising sections A, B, and C, an inventor would directly infringe on the claim if she made widget Y comprised of sections A, B, and C. Additionally, if the inventor made a widget Z comprised of sections A, B, C, and D, this would also infringe upon the patent claim of widget X.⁴⁹ In order to determine if there has been literal infringement, the court will use a two-step test: “First, the claims are properly construed and then those construed terms are compared to the accused product.”⁵⁰ That is to say, the court will first examine the claims to determine what is actually being claimed and then compare those claims to the unauthorized product or process. If the construed claims match the accused product, then there is literal infringement.

Conversely, nonliteral infringement can occur when an unauthorized party’s product or process does not literally meet every limitation in a patent claim.⁵¹ This ideology is known as the doctrine of equivalents. As the Federal Circuit has noted, “[a] claim of infringement under the doctrine of equivalents modifies [the infringement analysis] . . . by requiring that the fact finder determine whether differences between particular elements of the accused device and the asserted claims are insubstantial.”⁵² For example, if a patent claimed the use of a laser pointer to be used for cat exercise, would an unauthorized party be infringing on that patent if they used a laser pointer to exercise their dog? The patent does not literally claim a dog, but a dog may be considered the equivalent of a cat. In order to determine whether an alleged equivalent is an insubstantial change, courts use the function/way/result test.⁵³ This test looks at “whether the alleged equivalent performs substantially the same function, in substantially the same way, to achieve substantially the same result.”⁵⁴ Using this test, courts can determine whether or not a product or process may nonliterally infringe upon a patent. Through these protections, patent holders are protected from the unauthorized use of

⁴⁹ *Cybor*, 138 F.3d at 1467.

⁵⁰ *University of Pittsburgh of Commonwealth System of Higher Educ. v. Varian Medical Sys.*, 561 Fed. Appx. 934, 942 (Fed. Cir. 2014).

⁵¹ *Cybor*, 138 F.3d at 1467

⁵² *Id.*

⁵³ *See* LOREN & MILLER, *supra* note 14, at 272.

⁵⁴ *Id.*

their invention, as well as the unauthorized use of an equivalent to the patented invention.⁵⁵

II. PATENT LAW AND CANNABIS

As discussed above, an invention or process must be new, useful, and nonobvious in order to be patentable.⁵⁶ Additionally, the invention or process must be a patentable subject matter.⁵⁷ But what if the subject matter is illegal or prohibited? What if the subject matter is seen as “immoral” by some people? While the Constitution and federal law do not specify a legality or “moral” requirement for patents, the courts have had some thoughts on the matter.⁵⁸

A. *Cannabis Patents*

In his opinion in *Lowell v. Lewis* in 1817, Justice Story created the doctrine of “moral utility.”⁵⁹ In *Lowell*, Justice Story heard a dispute regarding patent infringement on a water pump design, which seemed pretty standard on its face.⁶⁰ However, Justice Story decided to use this clash to add a new condition to the patent utility requirement—an inventor must establish his invention as “new and useful,” not merely superior to current or previously existing iterations of a product.⁶¹ Additionally, Justice Story expanded that idea in an infamous passage:

All that the law requires is, that the invention should not be frivolous or injurious to the well-being, good policy, or sound morals of society. The word ‘useful,’ therefore, is incorporated into the act in contradistinction to mischievous or immoral. For instance, a new invention to poison people, or to promote debauchery, or to facilitate private assassination, is not a patentable invention.⁶²

⁵⁵ *Cybor*, 138 F.3d at 1467.

⁵⁶ 35 U.S.C. § 101 (2015).

⁵⁷ *Id.*

⁵⁸ See generally *Lowell v. Lewis*, 15 F. Cas. 1018 (Story, Circuit Justice, C.C.D. Mass. 1817) (creating the requirement of moral utility for patents); *Juicy Whip, Inc. v. Orange Bang, Inc.*, 185 F.3d 1364 (Fed. Cir. 1999) (dismissing Justice Story’s “moral utility” requirement).

⁵⁹ *Lowell*, 15 F. Cas. at 1019.

⁶⁰ *Id.*

⁶¹ *Id.*

⁶² *Id.*

This moral utility requirement influenced patent cases for the next century and half, protecting society from the moral evils of gambling gadgets⁶³ and rakes,⁶⁴ until the Federal Circuit dismissed Justice Story's antiquated views in the 1999 case *Juicy Whip, Inc. v. Orange Bang, Inc.*⁶⁵

The patent at issue in *Juicy Whip* was a "post-mix" beverage dispenser that kept beverage syrup concentrate and water in separate containers until the drink was ready to be dispensed.⁶⁶ Conversely, a "pre-mix" beverage dispenser stores syrup concentrate and water (that have already been mixed together) in a display reservoir bowl until it's ready to be dispersed.⁶⁷ The main point of contention in *Juicy Whip* was a fake display bowl used with the "post-mix" dispenser that created the illusion of the "pre-mix" dispenser and led customers to believe that the "fluid contained in the bowl is the actual beverage that they are receiving."⁶⁸ While the "post-mix" beverage dispenser may deceive some customers, the Federal Circuit held that the patent was valid and that patents would no longer be denied based on the grounds of morality.⁶⁹ The court reasoned that it was the place of the states to decide "by which the health, good order, peace and general welfare of the community are promoted," and that patent laws were not intended to displace those state powers.⁷⁰ Thus, the moral utility requirement in patent law was undone. While there may be some debate throughout the country on whether or not marijuana is "moral," the outcome of that debate has no standing (anymore) on whether or not marijuana is patentable.

Further confirming the fact that the moral utility requirement is dead is the existence of the '507 patent, which is held by the U.S. Department of

⁶³ See, e.g., *Nat'l Automatic Device Corp. v. Lloyd*, 40 F. 89 (C.C.N.D. Ill. 1889) (automatic toy racehorse used in gambling establishments); *Reliance Novelty Co. v. Dworzek*, 80 F. 902 (C.C.N.D. Cal. 1897) (card-playing slot machine); *Schultze v. Holtz*, 82 F. 448 (C.C.N.D. Cal. 1897) (coin return device for slot machine); *Meyer v. Buckley Mfg. Co.*, 15 F. Supp. 640 (N.D. Ill. 1936) (lottery ticket dispenser).

⁶⁴ See *Fowler v. Swift*, 3 Ind. 188 (1851) (finding the patent invalid because consumer was told rake was more efficient than other rakes).

⁶⁵ *Juicy Whip, Inc. v. Orange Bang, Inc.*, 185 F.3d 1364 (Fed. Cir. 1999).

⁶⁶ *Id.* at 1365.

⁶⁷ *Id.*

⁶⁸ *Id.* at 1366.

⁶⁹ *Id.* at 1367 ("[Y]ears ago courts invalidated patents ... on the ground that they were immoral ... but that is no longer the law.").

⁷⁰ *Id.* at 1368–69 (quoting *Webber v. Virginia*, 103 U.S. 344, 347–48 (1880)).

Health, and Human Services.⁷¹ That patent is currently being utilized by KannaLife Sciences, a late-stage biotechnology development firm, to develop new therapeutic agents with neuroprotectant and neuromodulation benefits through the use of medicinal cannabinoids.⁷² The company is currently working on research and development of a drug to treat Hepatic Encephalopathy (HE) and Chronic Traumatic Encephalopathy (CTE), both of which are oxidative stress related diseases that affect the cognitive and behavioral functions of the brain, as well as the brain's overall wellness.⁷³ While it is certainly ironic that the federal government denies any "accepted medical utility" for marijuana⁷⁴ while simultaneously holding a patent for that same utility, the existence of the '507 patent highlights the value of marijuana patents and the need for medical research. The U.S. Patent and Trademark Office has issued over 500 cannabis-related patents since 2000, relating to strains of marijuana-related plants, chemical formulations, medical treatments, and devices used to make and/or consume marijuana products.⁷⁵ However, the true validity of these patents may be unknown.⁷⁶ Due to the limited information available regarding prior inventions and questions as to what information is known in the cannabis industry, the patent office may be granting patents that are actually invalid.⁷⁷ Additionally, the patent office may be allowing overly broad cannabis patents, which could result in patents that cover many strains and could stifle competition.⁷⁸ Thanks to an upcoming case in the District of Colorado, we may get some answers to these validity questions.

B. *United Cannabis Corp. v. Pure Hemp Collective, Inc.*

On July 30th, 2018, United Cannabis Corporation (UCANN) filed a Complaint for Patent Infringement against Pure Hemp Collective, Inc. (Pure

⁷¹ U.S. Patent No. 6,630,507 (filed Feb. 2, 2001) (patenting cannabinoids as antioxidants and neuroprotectants as treatment for Alzheimer's, Parkinson's, HIV, dementia, and other progressive brain diseases).

⁷² See generally *The Company*, KANNALIFE, <https://www.kannalife.com/company> (last visited Mar. 29, 2019).

⁷³ *Id.*

⁷⁴ 21 U.S.C. § 812(b)(1), (c)(10) (2015).

⁷⁵ See Malathi Nayak, *Cannabis Industry Seeks Clarity in Intellectual Property Haze (Corrected)*, BLOOMBERG BNA (July 27, 2018), <https://www.bna.com/cannabis-industry-seeks-n73014481143/>.

⁷⁶ *Id.*

⁷⁷ *Id.*

⁷⁸ *Id.*

Hemp) in the U.S. District Court for the District of Colorado.⁷⁹ Pure Hemp is a Colorado-based company that makes and sells plant-based remedies that combine hemp extract with natural blends of ingredients.⁸⁰ UCANN is a biotechnology company in Golden, Colorado that is “dedicated to the development of phyto-therapeutic based products.”⁸¹ UCANN is suing Pure Hemp for infringing on its ‘911 Patent, which claims “various liquid formulations of highly enriched extracts of plant cannabinoids.”⁸² The ‘911 Patent was issued to UCANN’s Chief Technologies Officer, Tony Verzura, and UCANN’s Chief Executive Officer, Earnie Blackmon, on August 15, 2017.⁸³ This patent is entitled “Cannabis extracts and methods of preparing and using same,” and it claims various liquid cannabinoid formulations, including those “wherein at least 95% of the total cannabinoids is cannabidiol (CBD).”⁸⁴ UCANN claims in its suit that it purchased one of Pure Hemp’s 5000mg products (Pure Hemp’s Vina Bell) and ran chemical composition tests on it to determine the cannabinoid formulations.⁸⁵ According to UCANN, these tests revealed that Pure Hemp’s product contained a cannabinoid formulation wherein at least 95% of the total cannabinoids were CBD, which directly infringed upon one or more claims of the ‘911 Patent, specifically claim 10: “A liquid cannabinoid formulation, wherein at least 95% of the total cannabinoids is cannabidiol (CBD).”⁸⁶ Following this discovery, UCANN sent Pure Hemp a letter to inform Pure Hemp of their infringement on the ‘911 Patent and to offer a licensing agreement.⁸⁷ UCANN claims that Pure Hemp has continued to actively advertise, promote, and sell its infringing product, despite knowledge of the infringement.⁸⁸

Pure Hemp has also filed an Answer to UCANN’s complaint (amended on November 5, 2018) in which Pure Hemp denies any

⁷⁹ Complaint for Patent Infringement and Demand for Jury Trial, *United Cannabis Corp. v. Pure Hemp Collective, Inc.*, No. 1:18-cv-01922-NYW (D. Colo. 2017).

⁸⁰ *Our Legacy*, PURE HEMP COLLECTIVE, <https://purehempcollective.com/our-story/> (last visited Mar. 29, 2019).

⁸¹ UCANN: UNITED CANNABIS, <https://www.unitedcannabis.us/> (last visited Mar. 29, 2019).

⁸² Complaint for Patent Infringement and Demand for Jury Trial at 1, *United Cannabis* (No. 1:18-cv-01922-NYW).

⁸³ *Id.* at 3.

⁸⁴ *Id.* at 4.

⁸⁵ *Id.* at 5.

⁸⁶ *Id.* at 6.

⁸⁷ *Id.*

⁸⁸ *Id.*

infringement on the ‘911 Patent.⁸⁹ Specifically on the Willful Infringement claim, Pure Hemp “denies that it infringes or has infringed any valid, enforceable patent claim.”⁹⁰ Pure Hemp’s answer claims that UCANN’s ‘911 Patent is not valid because naturally occurring compounds (such as CBD) do not qualify as patentable subject matter due to the Supreme Court’s decision in *Molecular Pathology v. Myriad Genetics*.⁹¹ Not only does claim 10 of UCANN’s ‘911 Patent apply to isolated products of nature, but UCANN’s complaint also admits that cannabinoids “occur naturally in the cannabis plant.”⁹² Moreover, Pure Hemp claims that UCANN’s ‘911 Patent should not be valid because the ideas covered in it are not new.⁹³ Citing studies and experiments from the 1940s,⁹⁴ a U.S. Patent granted in 1942,⁹⁵ and numerous pharmaceutical companies that have been selling CBD formulations that are at least 98% pure CBD since at least October 2011,⁹⁶ Pure Hemp claims that the nearly pure CBD liquid compositions that are claimed in the ‘911 Patent are not new due to the fact that they were on sale and in use for years before the earliest priority date of the ‘911 Patent.⁹⁷

In addition to the ‘911 Patent being invalid due to non-patentable subject matter and novelty, Pure Hemp claims that UCANN is attempting to monopolize the market for liquid CBD products, due to the extensive scope of the claims in the ‘911 Patent.⁹⁸ Pure Hemp claims that:

Claim 10 is so broad, in fact, that UCANN could likely attempt to assert it against (1) any farmer growing high-CBD chemovar cannabis who knows the cannabis will be used to make liquid formulations, (2) any midstream processor of high-CBD chemovar cannabis, (3) any producer of liquid

⁸⁹ Defendant’s First Amended Answer, Defenses, and Counterclaims, United Cannabis Corp. v. Pure Hemp Collective, Inc., No. 1:18-cv-01922-NYW (D. Colo. 2017).

⁹⁰ *Id.* at 4.

⁹¹ *Id.* at 9; *Ass’n for Molecular Pathology v. Myriad Genetics, Inc.*, 569 U.S. 576 (2013) (holding that claims directed to isolated, naturally occurring compounds do not qualify as patentable subject matter).

⁹² Defendant’s First Amended Answer, Defenses, and Counterclaims, *supra* note 89, at 9.

⁹³ *Id.*

⁹⁴ *Id.* (“Pharmacological experiments with single cannabinoids have been carried out since the 1940s.”).

⁹⁵ *Id.* (“[T]he United States Patent Office granted U.S. Patent No. 2,304,669, titled Isolation of Cannabidiol.”).

⁹⁶ *Id.* at 8 (claiming that Echo Pharmaceuticals B.V., Tocris Bioscience, and Sigma-Aldrich have all been selling CBD formulations prior to the granting of UCANN’s ‘911 Patent).

⁹⁷ *Id.* at 9.

⁹⁸ *Id.* at 10.

CBD products, (4) any seller or reseller of liquid CBD products, (5) any purchaser of liquid CBD products, or (6) any user of liquid CBD products.⁹⁹

Thus, in addition to Pure Hemp's affirmative defenses that the '911 Patent is invalid, Pure Hemp filed a counterclaim under the Sherman Act claiming that the '911 Patent would grant UCANN monopoly power over the liquid CBD product market.¹⁰⁰

Not only has Pure Hemp filed its answer and counterclaim against UCANN, it also filed a motion for partial summary judgment on November 29, 2018.¹⁰¹ Pure Hemp is requesting early partial summary judgment that claims 10, 12, 14, 20-22, 25, 27, 28, and 33 of the '911 Patent are invalid because they are "directed to patent-ineligible natural phenomena."¹⁰² In Pure Hemp's statement of facts, it claims that: (1) cannabis plants naturally contain differing quantities of cannabinoids; (2) cannabidiol (CBD), tetrahydrocannabinol (THC), and cannabinol (CBN) are cannabinoids that are found naturally in cannabis plants; (3) CBD and THC are the cannabinoids that are usually produced in the greatest abundance; (4) standard principles of pharmaceutical formulation can be used to prepare liquid dosage forms; (5) methods of computing cannabinoid content are well known to those skilled in the art; and (6) the Fourth Decennial Revision of the Pharmacopoeia of the United States of America, which was published in 1864, provides directions for "preparing a liquid Tinctura Cannabis (or Tincture of Hemp) based on a Purified Extract of Hemp."¹⁰³

Using the framework set forth by the Supreme Court in *Alice v. CLS Bank*, Pure Hemp argues that the '911 Patent claims (specifically the claims that were mentioned earlier) are invalid because they fail to "contain an inventive concept sufficient to transform the claimed naturally occurring phenomena into a patent-eligible application."¹⁰⁴ The test from *Alice* is a two-step test: (1) courts must "determine whether the claims at issue are directed

⁹⁹ *Id.* at 10–11.

¹⁰⁰ *Id.* at 13.

¹⁰¹ Defendant's Early Motion for Partial Summary Judgment, *United Cannabis Corp. v. Pure Hemp Collective, Inc.*, No. 1:18-cv-01922-NYW (D. Colo. 2017).

¹⁰² *Id.* at 1.

¹⁰³ *Id.* at 2–3 (claims 1, 2, 3, 6, 7, and 9).

¹⁰⁴ *Id.* at 3 (quoting *Cleveland Clinic Found. V. True Health Diagnostics, LLC*, 859 F.3d 1352, 1361, (Fed. Cir. 2017), *cert. denied*, 138 S. Ct. 2621 (2018)).

to one of those patent-ineligible concepts;”¹⁰⁵ and (2) if the answer to step one is “yes,” then the courts must ask: “[w]hat else is there in the claims before us?”¹⁰⁶ Pure Hemp claims (and the ‘911 Patent agrees) that CBD, THC, and CBN are cannabinoids that are found naturally in the cannabis plant.¹⁰⁷ Additionally, Pure Hemp claims that neither the liquid formulation limitation nor the “percent of total cannabinoid” limitation found in the ‘911 Patent provide an inventive concept that would make the ‘911 Patent claims valid.¹⁰⁸ Both of these limitations are routine and well-known to those skilled in the art, which is admitted in the ‘911 Patent. Thus Pure Hemp argues that claims 10, 12, 14, 20-22, 25, 27, 28, and 33 should not be valid since these claims are “directed to patent-ineligible natural phenomena without anything more that would constitute an eligible inventive concept.”¹⁰⁹

C. *Outlook After UCANN v. Pure Hemp*

How this suit will play out is unknown at this time. What is known though, is that any outcome may have far-reaching consequences, due to the potential to set a precedent for how federal courts will handle marijuana-related patents in the future.¹¹⁰ This case between UCANN and Pure Hemp is the first case involving a patent for a cannabis-based extract to reach the federal court system.¹¹¹ Looking to Pure Hemp’s Answer and Motion for Partial Summary Judgment, it appears the court should invalidate the ‘911 Patent, or at least the claims at issue in Pure Hemp’s motion. Validating the claims in the ‘911 Patent would likely give UCANN a monopoly over the liquid CBD market, as well as impede innovation in the CBD arena.¹¹² While

¹⁰⁵ See *Alice Corp. Pty. v. CLS Bank Int’l*, 134 S. Ct. 2347, 2355 (2014). The test in *Alice* is used for “distinguishing patents that claim laws of nature, natural phenomena, and abstract ideas from those that claim patent-eligible applications of those concepts.” *Id.*

¹⁰⁶ *Id.*

¹⁰⁷ Defendant’s Early Motion for Partial Summary Judgment at 4, *United Cannabis* (No. 1:18-cv-01922-NYW).

¹⁰⁸ *Id.* at 7–10.

¹⁰⁹ *Id.* at 9–12 (highlighting Pure Hemp’s additional argument that claim 31 should be invalid because it does not contain a reference to previous claim and it is a multiple dependent claim that depends on other multiple dependent claims).

¹¹⁰ See Cheryl Miller, *Why Patent Lawyers Are Watching This Colorado Cannabis Case*, THE RECORDER (Aug. 8, 2018, 06:48 PM), <https://www.law.com/therecorder/2018/08/08/why-patent-lawyers-are-watching-this-colorado-cannabis-case/>.

¹¹¹ *Id.*

¹¹² Defendant’s First Amended Answer, Defenses, and Counterclaims, *supra* note 89, at 13.

judges have addressed that “[i]t goes without saying that patents have adverse effects on competition”¹¹³ and “the essence of a patent grant is the right to exclude others from profiting by the patented invention,”¹¹⁴ patents are also supposed to drive innovation.¹¹⁵

Patent law attempts to strike a balance between seemingly competing areas by rewarding innovation without disproportionately impeding competition.¹¹⁶ As discussed earlier, a patent grants certain rights to the patent-holder, which allows her to exclude others from “making, using, offering for sale, or selling the invention” while the patent is valid.¹¹⁷ “But just as exclusion has always been the means, the diffusion of innovation has always been the desired end.”¹¹⁸ Unfortunately, when an invalid patent has been granted, the patent grants the same exclusionary rights to impede competition, but doesn’t grant the same reward to innovation. “This presents a problem because while our patent system attempts to strike a balance between encouraging innovation and suppressing competition, that balance is thrown off when an invalid patent issues. The invalid patent suppresses competition without enhancing innovation.”¹¹⁹ As Judge Learned Hand so aptly put, an invalid patent can be compared to a scarecrow—detering competition and innovation even without doing anything.¹²⁰ Not only can an invalid patent deter competition in the market, it can also impact attempts to improve on products. Competitors who are fearful of infringement litigation may decide not to invest in research and development in an area that is covered by an invalid patent or patents.¹²¹ This uncertainty in the scope of one’s intellectual property rights can lead to a chilling effect by leaving innovators unclear whether or not they are infringing upon a “pioneer’s intellectual property right.”¹²² Stifling technological advancement, regardless

¹¹³ *In re Ciprofloxacin Hydrochloride Antitrust Litig.*, 363 F. Supp. 2d 514, 523 (E.D.N.Y. 2005).

¹¹⁴ *Dawson Chem. Co. v. Rohm & Haas Co.*, 448 U.S. 176, 215 (1980).

¹¹⁵ U.S. CONST. art. I (“To promote the Progress of Science and useful Arts . . .”).

¹¹⁶ Christopher R. Leslie, *The Anticompetitive Effects of Unenforced Invalid Patents*, 91 MINN. L. REV. 101, 114 (2006).

¹¹⁷ 35 U.S.C. § 154(a)(1)–(a)(2) (2015).

¹¹⁸ Chien, *supra* note 24, at 804.

¹¹⁹ Leslie, *supra* note 116, at 115.

¹²⁰ *Bresnick v. U.S. Vitamin Corp.*, 139 F.2d 239, 242 (2d Cir. 1943).

¹²¹ *See* Mark A. Lemley, *Property, Intellectual Property, and Free Riding*, 83 TEX. L. REV. 1031, 1060 (2005).

¹²² *Id.* at 1061.

of the field, harms consumers and harms society. Competitors who fear an infringement suit may attempt to innovate around a patent in order to create a non-infringing product or invention. Some judges view this process as a benefit of the patent system, but it's often not an effective use of a limited research budget.¹²³ “Other disputes arise because the set of potentially relevant patents is large, the scope of the claims is vague, and many of the claims might be invalid. Under these conditions, designing around patents is difficult and clearing the rights can be prohibitively expensive.”¹²⁴ In short, when an invalid patent, or a patent with invalid claims, such as the ‘911 Patent, is granted or upheld, innovation suffers.¹²⁵ However, even if the ‘911 Patent is invalidated, as long as cannabis is still illegal under federal law, innovation will naturally be hindered.

III. FUTURE OF CANNABIS AND CANNABIS-RELATED PATENTS

A. *Legality of Cannabis*

Cannabis, more commonly known as marijuana, has had a distinguished history in America. Early settlers to America used the cannabis stalk to produce hemp: a multifaceted material that can be used to make numerous products such as clothing, paper, and rope.¹²⁶ While the stalk of the cannabis plant was historically used as a material in manufacturing, the flower has had many medicinal, recreational, and spiritual uses through the years.¹²⁷ In fact, the medicinal use of cannabis was recognized as providing enough medical benefits that cannabis was added to the United States Pharmacopeia in 1850 due to its remedial value.¹²⁸ However, starting in the early 1900s, fear began to grow that the use of cannabis, as well as alcohol

¹²³ *State Indus., Inc. v. A.O. Smith Corp.*, 751 F.2d 1226, 1236 (Fed. Cir. 1985) (“One of the benefits of a patent system is its so-called ‘negative incentive’ to ‘design around’ a competitor's products, even when they are patented, thus bringing a steady flow of innovations to the marketplace.”); *see also* *WMS Gaming, Inc. v. Int'l Game Tech.*, 184 F.3d 1339, 1355 (Fed. Cir. 1999) (observing that “patent law encourages competitors to design or invent around existing patents”).

¹²⁴ Christopher R. Leslie, *Antitrust and Patent Law as Component Parts of Innovation Policy*, 34 J. CORP. LAW. 1259, 1272 n.79 (2009).

¹²⁵ *Id.* at 161.

¹²⁶ 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, 336 (2014).

¹²⁷ *Id.*

¹²⁸ Rosalie Liccardo Pacula et al., *State Medical Marijuana Laws: Understanding the Laws and Their Limitations*, 23 J. PUB. HEALTH POL'Y 413, 415 (2002).

and opium, would lead to addiction, violence, and overdoses.¹²⁹ By the time Congress passed the Marihuana Tax Act in 1937,¹³⁰ every state in America had already enacted laws that criminalized the possession and sale of marijuana.¹³¹ The Marihuana Tax Act didn't outlaw the possession or sale of marijuana, but it did require all buyers and sellers of marijuana to register with federal authorities and pay an annual tax.¹³² The extra work imposed by the Act, along with the aggressive fines and punishments,¹³³ effectively led to a prohibition on cannabis, as shown by the removal of cannabis from the United States Pharmacopeia and other medical reference texts by 1942.¹³⁴

After the Marihuana Tax Act was declared unconstitutional in 1969,¹³⁵ the Controlled Substances Act (“CSA”) was passed by Congress in 1970 as a pseudo replacement.¹³⁶ The CSA placed all controlled substances into five categories, or Schedules, based on the medicinal value, harmfulness, and potential for abuse.¹³⁷ Because cannabis was effectively no longer being used for medicinal purposes, it was placed in Schedule I, which made it illegal for doctors to medically prescribe it.¹³⁸ This means that cannabis is in the same category as heroin, ecstasy, and LSD because of a high potential for abuse, an absence of accepted medical utility, and a lack of accepted safety standards for cannabis use under medical supervision.¹³⁹ Remarkably, opium, cocaine, and methamphetamine are categorized into a less restrictive Schedule than cannabis.¹⁴⁰ There have been numerous petitions to the Drug Enforcement Agency (DEA) to reschedule marijuana.¹⁴¹ A 2002 petition requested that marijuana be removed from Schedule I because “cannabis has an accepted medical use in the United States, is safe for use under medical supervision, and has an abuse potential and a dependency liability that is

¹²⁹ *Id.*

¹³⁰ See Marihuana Tax Act of 1937, Pub. L. No. 75-238, 50 Stat. 551 (1937).

¹³¹ See Pacula, *supra* note 128, at 415.

¹³² Marihuana Tax Act § 2.

¹³³ Marihuana Tax Act § 12.

¹³⁴ See Pacula, *supra* note 128, at 416.

¹³⁵ *Leary v. United States*, 395 U.S. 6, 16 (1969).

¹³⁶ Controlled Substances Act, 21 U.S.C. §§ 801-904 (1970).

¹³⁷ 21 U.S.C. § 812 (2012).

¹³⁸ 21 U.S.C. § 812(b)(1)(A)-(B) (2012).

¹³⁹ 21 U.S.C. § 812(b)(1), (c)(10) (2012).

¹⁴⁰ 21 U.S.C. § 812(c) Schedule II(a) (2012).

¹⁴¹ Denial of Petition to Initiate Proceedings to Reschedule Marijuana, 76 Fed. Reg. 40,552, 40,552 (Dep't of Justice July 8, 2011).

lower than Schedule I or II drugs.”¹⁴² As per CSA rescheduling provisions, the DEA requested a scientific and medical evaluation of marijuana from the Department of Health and Human Services (DHHS) after it received the petition.¹⁴³ After completing the evaluation, the DHHS came to the determination that “marijuana has a high potential for abuse, has no accepted medical use in the United States, and lacks an acceptable level of safety for use even under medical supervision” and recommended that it remain in Schedule I.¹⁴⁴ Thus, the DEA denied the petition and kept marijuana as a Schedule I drug, where it remains today.¹⁴⁵

While cultivation, distribution, and possession of marijuana remains illegal under federal law, that hasn’t stopped a growing number of states from enacting marijuana-related laws of their own. In 2012, Colorado and Washington became the first two states to legalize recreational marijuana use.¹⁴⁶ Since then, eight other states (as well as Washington, D.C.) have legalized the use of recreational marijuana for adults over the age of 21: Alaska, California, Maine, Massachusetts, Nevada, Oregon, Michigan, and Vermont.¹⁴⁷ Additionally, 33 states have legalized marijuana for medical use.¹⁴⁸ Even though these states are allowing marijuana use in their respective states, that doesn’t mean that it’s legal under federal law.

B. *Federalism and the Supremacy Clause*

There have been a few instances showcasing the ability of the federal government to regulate marijuana use in a state where marijuana has been legalized—notably in the 2005 Supreme Court case *Gonzales v. Raich*.¹⁴⁹ In this case, the respondents included Monson, who was cultivating and consuming her own marijuana, and two California residents, who were using medical marijuana to treat serious medical conditions, as authorized under California’s medical marijuana statute.¹⁵⁰ Despite concluding that Monson’s

¹⁴² *Id.* at 40,553.

¹⁴³ *Id.* at 40,566.

¹⁴⁴ *Id.* at 40,552.

¹⁴⁵ *Id.*

¹⁴⁶ See Jeremy Berke, *Here's where you can legally consume marijuana in the US in 2018*, BUSINESS INSIDER (Nov. 7, 2018, 12:29 PM), <https://www.businessinsider.com/where-can-you-can-legally-smoke-weed-2018-1>.

¹⁴⁷ *Id.*

¹⁴⁸ *Id.*

¹⁴⁹ See *Gonzales v Raich*, 545 U.S. 1 (2005).

¹⁵⁰ *Id.* at 6–7.

use of marijuana was legal under California law, DEA agents and county deputy sheriffs raided Monson's house and destroyed her marijuana plants under the authority of the CSA.¹⁵¹ Respondents sued the U.S. Attorney General and the head of the DEA, arguing that enforcement of the CSA prevented "them from possessing, obtaining, or manufacturing cannabis for their personal medical use" and violated "the Commerce Clause, the Due Process Clause of the Fifth Amendment, the Ninth and Tenth Amendments of the Constitution, and the doctrine of medical necessity."¹⁵² The Supreme Court ultimately upheld the federal government's authority to prohibit the use of marijuana, despite compliance with California law, since the CSA classifies cannabis as "contraband for *any* purpose."¹⁵³ The Court concluded that Congress has a "rational basis" for believing that the intrastate possession and manufacture of cannabis would "substantially affect interstate commerce," and therefore was authorized in regulating its use under the Commerce Clause.¹⁵⁴ The Court's decision in *Gonzales* affirmed the federal government's authority to regulate marijuana, but it did not restrict the ability of state governments to create their own marijuana laws, nor did the Court address whether Congress intended the CSA to preempt state medical marijuana statutes.¹⁵⁵

While the U.S. Supreme Court has recognized Congress's constitutional authority to pass the existing federal restrictions on marijuana, principles of federalism prevent the federal government from requiring that states actively support, or participate in, applying the federal law.¹⁵⁶ The Tenth Amendment has been interpreted as protecting state sovereignty when the federal government's Article I powers are limited.¹⁵⁷ The Tenth Amendment prohibits the federal government from "commandeering" state government for federal purposes,¹⁵⁸ or from "commandeering" state officers for purposes of carrying out federal law.¹⁵⁹ Given these restrictions, Congress may not statutorily direct states to enact prohibitions on marijuana or repeal

¹⁵¹ *Id.*

¹⁵² *Id.* at 7–8.

¹⁵³ *Id.* at 2, 27.

¹⁵⁴ *Id.* at 17.

¹⁵⁵ Rosalie Winn, *Hazy Future: The Impact of Federal and State Legal Dissonance on Marijuana Businesses*, 53 AM. CRIM. L. REV. 215, 219 (2016).

¹⁵⁶ *Id.* at 220.

¹⁵⁷ *Id.*

¹⁵⁸ *Id.*

¹⁵⁹ *Printz v. United States*, 521 U.S. 898, 933 (1997).

existing exemptions for recreational or medical marijuana. Even though the federal government is prohibited from requiring states to adopt laws supportive of federal policy, preemption generally prevents states from creating laws that contradict federal law.¹⁶⁰ The Supremacy Clause of the Constitution decrees that where state and federal laws are incompatible, federal law will preempt state law.¹⁶¹ There are three traditional categories of preemption (express preemption, conflict preemption, and field preemption),¹⁶² but there is a presupposition against preemption when it comes to the exercise of “historic police powers of the States.”¹⁶³ While it would appear that a state law that permits an activity that is expressly prohibited by federal law would necessarily create an incompatibility between state and federal laws, the preemptive power of the CSA is limited by statute to situations where “there is a positive conflict between [the CSA] and that State law so that the two cannot consistently stand together.”¹⁶⁴ As stated by Todd Garvey in a report prepared for members of Congress:

Instead, the relationship between the federal ban on marijuana and state medical marijuana exemptions must be considered in the context of two distinct sovereigns, each enacting separate and independent criminal regimes with separate and independent enforcement mechanisms, in which certain conduct may be prohibited under one sovereign and not the other. Although state and federal marijuana laws may be “logically inconsistent,” a decision not to criminalize—or even to expressly decriminalize—conduct for purposes of the law within one sphere does nothing to alter the legality of that same conduct in the other sphere.¹⁶⁵

This preemption issue has yet to be addressed in federal court, but state courts have reached differing results on whether state programs issuing ID cards for medical marijuana users are preempted by federal law. In *County of San*

¹⁶⁰ See Winn, *supra* note 155, at 220.

¹⁶¹ U.S. CONST. art. VI, cl. 2.

¹⁶² Winn, *supra* note 155, at 221.

¹⁶³ See *Rice v. Santa Fe Elevator Corp.*, 331 U.S. 218, 230 (1947) (“[W]e start with the assumption that the historic police powers of the States were not to be superseded . . . unless that was the clear and manifest purpose of Congress.”).

¹⁶⁴ Controlled Substances Act, 21 U.S.C. § 903 (2015).

¹⁶⁵ See Todd Garvey, *Medical Marijuana: The Supremacy Clause, Federalism, and the Interplay Between State and Federal Laws*, CONG. RESEARCH SERV. (CRS Report for Congress), Nov. 12, 2012, at 8.

Diego v. San Diego NORML, a California appellate court found that the ID provisions of California's medical marijuana law did not conflict with the CSA because the ID cards did not "insulate the bearer from federal laws."¹⁶⁶ Conversely, in *Emerald Steel Fabricators v. Bureau of Labor and Industries*, the Oregon Supreme Court held that a state law issuing medical marijuana ID cards was preempted by the CSA.¹⁶⁷ The Court reasoned that the law amounted to the state "[a]ffirmatively authorizing a use [for marijuana] that federal law prohibits," and therefore the state law created an "obstacle" to the purposes of the CSA.¹⁶⁸

There are significant preemption questions between the CSA and state marijuana laws that need to be answered. Under the Obama Administration, these preemption questions were not answered. While Obama was in office, the Department of Justice took a relaxed approach to enforcing federal marijuana laws as long as certain criteria were met.¹⁶⁹ Through a 2013 memo written by former Deputy Attorney General James Cole, federal prosecutors were instructed to limit their investigations and resources to only watch for certain violations, such as distribution to minors or distribution across state lines.¹⁷⁰ However, in January of 2018, former Attorney General Jeff Sessions issued a new memo that rescinded the Cole memo and instructed "all U.S. Attorneys to enforce the laws enacted by Congress and to follow well-established principles when pursuing prosecutions related to marijuana activities."¹⁷¹ While this move allows federal prosecutors to go after state-legal marijuana at their own discretion, it still remains to be seen whether or not Session's memo will lead to more marijuana prosecutions. While the use of Department of Justice memos as a defense to estop marijuana-related prosecution has not prevented prosecution,¹⁷² federal judges have used the

¹⁶⁶ *County of San Diego v. San Diego NORML*, 81 Cal. Rptr. 3d 461, 481 (Cal. Ct. App. 2008).

¹⁶⁷ *Emerald Steel Fabricators, Inc. v. Bureau of Labor and Indus.*, 230 P.3d 518, 529 (Or. 2010).

¹⁶⁸ *Id.*

¹⁶⁹ Memorandum from Deputy Attorney Gen. James M. Cole to all United States Attorneys (Aug. 29, 2013) [hereinafter Cole Memo] (on file with Concordia Law Review).

¹⁷⁰ *Id.*

¹⁷¹ See Sessions Memo, *supra* note 11.

¹⁷² See *United States v. Washington*, 887 F. Supp. 2d 1077, 1094–95 (D. Mont. 2012); *United States v. Canori*, 737 F.3d 181, 183–85 (2d Cir. 2013) (holding that the Ogden Memo did not constitute a "de facto" rescheduling of marijuana under the CSA).

2013 Cole Memo as justification for lenient sentencing guidelines.¹⁷³ As evidenced by current DOJ memos, the current Trump Administration has not adopted the same stance towards marijuana as the Obama Administration, but at this time, state marijuana laws remain in place and have not been preempted under the Supremacy Clause.

C. *Cooperative Federalism*

Change is likely coming to the marijuana laws in the United States, but what will these changes be? As stated earlier, more than half of the states have enacted state-level legislation aimed at legalizing some use for marijuana—either medical or recreational.¹⁷⁴ While state legislators have kept up with the public support for marijuana, the federal government has been slow to react.¹⁷⁵ Numerous federal marijuana-related bills have been introduced in Congress recently but none have gained much traction. Separately, these bills proposed to: (1) reschedule marijuana as a Schedule II drug and allow states to operate medical marijuana programs without federal interference;¹⁷⁶ (2) end federal criminal penalties and civil asset forfeiture for individuals and businesses complying with state marijuana laws;¹⁷⁷ (3) eliminate all federal marijuana crimes, except for shipping or transporting marijuana into a state where it is illegal;¹⁷⁸ (4) legalize marijuana at the federal level and give oversight authority to the Bureau of Alcohol, Tobacco, Firearms and Explosives;¹⁷⁹ and (5) federally legalize marijuana and impose a 25% excise tax on recreational marijuana sales.¹⁸⁰ While there have been several opportunities for Congress to enact these laws or some version of them, Congress does not appear inclined to end or curtail the federal

¹⁷³ See *United States v. Dayi*, 980 F. Supp. 2d 682, 689 (D. Md. 2013) (“The Court therefore believes that a two-level variance from the Guidelines, which would reduce each defendant’s sentence by roughly 20 to 25%, is appropriate. Such a variance reflects national trends in the enforcement of marijuana—related offenses, while recognizing the undeniable illegality of defendants’ conduct.”).

¹⁷⁴ See Berke, *supra* note 146.

¹⁷⁵ See *America’s New Drug Policy Landscape*, PEW RESEARCH CENTER (April 2, 2014), <http://www.people-press.org/2014/04/02/americas-new-drug-policy-landscape> (“Majorities across nearly all demographic and partisan groups say the use of marijuana should be legal, at least for medicinal use.”).

¹⁷⁶ CARERS Act of 2017, S. 1347, 115th Cong. (2017).

¹⁷⁷ Responsibly Addressing the Marijuana Policy Gap Act, H.R. 1824, 115th Cong. (2017).

¹⁷⁸ Ending Federal Marijuana Prohibition Act, H.R. 1227, 115th Cong. (2017).

¹⁷⁹ Regulate Marijuana Like Alcohol Act, H.R. 1841, 115th Cong. (2017).

¹⁸⁰ Marijuana Revenue and Regulation Act, S. 776, 115th Cong. (2017).

prohibition of marijuana. Since a complete end of marijuana prohibition or a rescheduling under the CSA seem unlikely (especially under the current administration), a federal approach that cooperates with state law could be a realistic alternative.

Cooperative federalism has been described as “a partnership between the States and the Federal Government, animated by a shared objective.”¹⁸¹ In other words, cooperative federalism permits state and federal laws to work together towards a group solution, instead of conflicting with each other.¹⁸² Using this approach, Congress could amend the CSA to allow states to opt out of its regulations, provided that they enact state law that meets certain criteria or requirements. If states choose not to enact their own marijuana-related laws, the state would still be governed by CSA regulations. This approach can already been found in several federal statutes, including the Clean Water Act¹⁸³ and the Clean Air Act.¹⁸⁴ Under the Clean Water Act, states are granted primary responsibility for water quality standards, but the federal government is permitted to take a more active role if the state fails to adhere to Environmental Protection Agency (EPA) mandates.¹⁸⁵ Similarly, under the Clean Air Act, each state has the primary responsibility for the air quality and pollution within its geographic area.¹⁸⁶ States are permitted to enact and carry out their own air pollution prevention plans, as long as those plans meet the requirements of the Clean Air Act.¹⁸⁷ If the state plans do not meet the requirements of the Clean Air Act, then the federal plan will be put into place instead.¹⁸⁸ Both the Clean Air Act and the Clean Water Act express congressional intent to have state and federal governments work together to prevent pollution, but neither Act requires state action.¹⁸⁹ States may choose to do nothing and be subject to federal regulation, or they may choose to enact their own regulations.

Amending the CSA to allow state and federal governments to enforce and regulate marijuana together, rather than contradicting one another, would

¹⁸¹ See *Arkansas v. Oklahoma*, 503 U.S. 91, 101 (1992).

¹⁸² See generally Erwin Chemerinsky, Jolene Forman, Allen Hopper & Sam Kamin, *Cooperative Federalism and Marijuana Regulation*, 62 UCLA L. REV. 74 (2015).

¹⁸³ 33 U.S.C. §§ 1251-1388 (2012).

¹⁸⁴ 42 U.S.C. §§ 7401-7671 (2006).

¹⁸⁵ Chemerinsky, Forman, Hopper & Kamin, *supra* note 182, at 117–18.

¹⁸⁶ *Id.*

¹⁸⁷ *Id.*

¹⁸⁸ *Id.*

¹⁸⁹ *Id.*

allow the federal government to influence marijuana regulations while allowing states to independently enact their own state laws.¹⁹⁰ “Federal law would supplement state law only when states defer to federal law or fail to satisfy federal requirements. Just as the EPA works with states to enforce air and water pollution laws, federal agencies could continue to cooperate with opt-out states and local governments to enforce marijuana laws.”¹⁹¹ This approach would give the federal government influence over regulatory priorities of the states that decide to craft their own legislation.¹⁹² Notably, this approach (or similar approaches) have been proposed by several prominent scholars as a “politically viable middle ground.”¹⁹³ However, most of those scholars propose state-opt-out-plans that would allow states to completely legalize marijuana use (as long as certain federal priorities are met).¹⁹⁴ This Comment proposes that a cooperative federalism approach should be used to promulgate the usage of marijuana in the medical and research fields. Under this approach, states would be able to opt out of the CSA if they enacted laws that regulated marijuana in the medical field or for research purposes. Similarly, this modification to the CSA would effectively legalize medical marijuana and legalize the use of marijuana for research purposes in all states that do not (or choose not to) enact their own state laws regarding marijuana. Utilizing this approach would be a safe middle ground between full decriminalization and full federal regulation, and would allow research and medical testing to continue (or begin) without worries of federal or state prosecution. Allowing unfettered access for researching and medical testing would take away much of the uncertainty and unknowns in the marijuana field.

Additionally, there would certainly be value in a standard regulatory framework that communicates the strain, THC, or CBD levels, as well as other important characteristics, given the number of different marijuana strains in existence.¹⁹⁵

¹⁹⁰ *See id.* at 119.

¹⁹¹ *See id.*

¹⁹² *See id.*

¹⁹³ *See* Alex Kreit, *What Will Federal Marijuana Reform Look Like?*, 65 CASE W. RES. L. REV. 689, 706–07 (2015) (noting that Mark Kleiman, Erwin Chemerinsky, Jolene Forman, Allen Hopper, and Sam Kamin have all argued the possibilities of state waiver programs).

¹⁹⁴ *See* Chemerinsky, Forman, Hopper & Kamin, *supra* note 182, at 120.

¹⁹⁵ Ryan B. Stoa, *Marijuana Appellations: The Case for Cannabicultural Designations of Origin*, 11 HARV. L. & POL’Y REV. 513, 527–28 (2017).

The primary obstacle in administering marijuana in medicine, however, is the uncertainty that currently undergirds medical marijuana strains at legal dispensaries. Certain strains are higher in the chemicals that are beneficial for chronic pain or other therapeutic qualities which don't get users high. Many patients who seek treatment with marijuana when traditional pharmaceuticals don't adequately address their medical needs don't want to be stoned, and they face difficulties in obtaining consistent inventory.¹⁹⁶

Freeing medical professionals and researchers from the threat of federal prosecution will allow for less uncertainty in the marijuana market and lead to more advances in medicine and genetic studies.¹⁹⁷ As we stand right now, with the illegality of marijuana creating a void of scientific research, researchers and organizations have come to wide-ranging conclusions regarding the effects of marijuana. Some researchers claim that marijuana has been shown to have a wide range of useful medical properties, so it should not be classified as a Schedule I substance.¹⁹⁸ On the other side of the map, some researchers have claimed that marijuana is dangerously addictive.¹⁹⁹ Furthermore, based on a study funded by the National Institute of Drug Abuse (NIDA), one group has claimed that “chronic marijuana use causes the frontal cortex of the brain to shrink.”²⁰⁰ Regardless of the differing opinions on marijuana use, gaps in cannabis research will continue to exist until standards and clinical trials are accepted and used.

¹⁹⁶ David F. DuTremble, *Next Dance With Mary Jane? An Argument for the Patentability of Specific Genetic Strains of Marijuana Under Federal Patent Law*, 10 CHARLESTON L. REV. 446, 466–67 (2016).

¹⁹⁷ *Id.*

¹⁹⁸ Frank Robinson & Elvira Strehle-Henson, *Cannabis Laws and Research at Colorado Institutions of Higher Education*, 44 COLO. LAW. 73, 77 (2012). The University of California San Diego's Center for Medicinal Cannabis Research concluded:

Evidence is accumulating that cannabinoids may be useful medicine for certain indications The classification of marijuana as a Schedule I drug as well as the continuing controversy as to whether or not cannabis is of medical value are obstacles to medical progress in this area. Based on evidence currently available the Schedule I classification is not tenable; it is not accurate that cannabis has no medical value, or that information on safety is lacking.

Id. at n.73.

¹⁹⁹ *Id.*

²⁰⁰ *Id.* “Our findings provide evidence that heavy, chronic marijuana users have lower OFC gray matter volumes compared with nonusing controls.” *Id.* at n.75.

While there may be fears of the potential aftermath of any federal marijuana legalization, we can look at our neighbors to the North as a possible signpost of what to expect.²⁰¹ While recreational use of marijuana in Canada is now permitted, marijuana used to be federally prohibited through the Controlled Drugs and Substances Act.²⁰² However, in 2001, Canada enacted the Marihuana Medical Access Regulations (MMAR) which authorized possession of dried marijuana “for the medical purpose of the holder.”²⁰³ MMAR allowed Canadian residents over the age of 18 to possess medical marijuana if they had authorization from the Minister, and it allowed residents to manufacture marijuana if they had the proper license to produce.²⁰⁴ Following the MMAR, the Canadian Parliament passed a new set of medical marijuana regulations in 2013: the Marihuana for Medical Purposes Regulations (MMPR).²⁰⁵ These new regulations resulted in the termination of the prior MMAR and shifted medical marijuana production away from personal growers towards corporate production of medical marijuana.²⁰⁶ Because of these new regulations, the Canadian medical marijuana industry experienced a shift towards a commercial model, which is similar to the heavily regulated prescription drug retailers.²⁰⁷ While Canada has now legalized recreational marijuana,²⁰⁸ America can look to the previous enactments of MMAR and MMPR as policies to learn from.

D. *Patent Innovation*

While legalizing marijuana at the state level is a step in the right direction, innovation that is available through patent protections does not amount to much when federal enforcement actions are still possible. Despite the fact that the USPTO has issued patents for marijuana-related inventions

²⁰¹ See generally David Rudoj & Savannah Priebe, *The Development of Medical Marihuana Law in Canada and its Effect on the Michigan Marihuana Statutes*, 25 MICH. ST. INT’L. L. REV. 335 (2017) (discussing the legalization of marijuana in Canada and its influence on new marijuana laws in Michigan).

²⁰² See generally Controlled Drugs and Substances Act, S.C. 1996, c 19 (Can.).

²⁰³ See Rudoj & Priebe, *supra* note 201, at 339.

²⁰⁴ *Id.*

²⁰⁵ *Id.* at 342–43.

²⁰⁶ See *id.* at 343.

²⁰⁷ See *id.* at 351.

²⁰⁸ See Dan Bilefsky, *Legalizing Recreational Marijuana, Canada Begins a National Experiment*, THE NEW YORK TIMES (Oct. 17, 2018), <https://www.nytimes.com/2018/10/17/world/canada/marijuana-pot-cannabis-legalization.html>.

and processes—as evidenced by the ‘911 Patent—there are still concerns among inventors and patent attorneys due to the federal illegality of marijuana.²⁰⁹

First, some of the inventions can be used only for illegal purposes under federal law. Specifically, inventions particularly designed to be used in association with marijuana, and that can only be used for such purpose, would only be useful for illegal purposes. Nonetheless, some of the inventions can be used outside the marijuana industry. Second, the subject matter of some marijuana-related inventions is illegal; meaning the invention itself is illegal. Finally, in some cases, the application claims illegal subject matter and practicing the invention is illegal.²¹⁰

Specifically in regards to the application itself, there are risks involved in merely filing the application. As part of an application an inventor must describe the invention or process in detail and provide enough information to enable the invention, which could provide a federal prosecutor with a significant amount of evidence of a CSA violation.²¹¹ This risk also extends to patent attorneys. Aiding a marijuana business in its business affairs, such as applying for a patent, could be deemed a violation of the CSA and a case of professional misconduct.²¹² Thus, it seems expected that there would be a natural hesitation in pursuing and defending marijuana-related patents. Additionally, even if business does secure a marijuana patent, that patent may end up giving an imagined benefit to the patent holder. While the outcome of *UCANN v. PureHemp* may help to exemplify what benefits are afforded to marijuana patent holders, the fact remains that the risk will continue to exist as long as marijuana is illegal under federal law. “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.”²¹³

²⁰⁹ Manuela Cabal Carmona, *Dude, Where’s my Patent?: Illegality, Morality, and the Patentability of Marijuana*, 51 VAL. U. L. REV. 651, 673–74 (2017).

²¹⁰ *Id.*

²¹¹ Sam Kamin & Viva R. Moffat, *Trademark Laundering, Useless Patents, and Other IP Challenges for the Marijuana Industry*, 73 WASH. & LEE L. REV. 217, 264 (2016).

²¹² *Id.* at 265.

²¹³ *Id.* at 266–67.

While there is some debate between practitioners and academics on the effectiveness of certain patents in aiding innovation, patents are typically seen as beneficial in technological growth.²¹⁴ This has been reaffirmed by some through assertions that “[more] patents materially spur [more] innovation”²¹⁵ and that “technological innovation and economic growth” are undercut when patent filings diminish.²¹⁶ Broadly, this can be summed up by the policy stance that “more patents equals more innovation.”²¹⁷ Additionally, the chilling of these patent filings—especially in the growing marijuana industry—can undermine the invention of potentially groundbreaking innovations, which commonly arise from newer companies.²¹⁸

Although it is clear that the rate of individual patenting has been decreasing in the United States over time, it is widely believed that individuals and small entities have an important impact on the innovation ecosystem—perhaps an outsized impact. This is for several reasons. First, there is some evidence that the inventions from smaller entities are more likely to be disruptive in nature, moving the pace of technological change forward. Second, in some industries, such as high technology and pharmaceuticals, small companies and individuals serve as important innovation inputs into larger, established companies.²¹⁹

Due to the risk of federal prosecution, and the unknowingness as to the full benefits afforded to a marijuana-related patent, these small entities and

²¹⁴ See Reiko Watase, *The American Inventors Protection Act Of 1999: An Analysis Of The New Eighteen-Month Publication Provision*, 20 CARDOZO ARTS & ENT L.J. 649, 681 (2002) (“Perhaps one approach to resolve this conflict is to support the views of those who are awarded more patents, those endeavoring to serve the public interest by furthering technological and economic growth.”). See also Jonathan M. Barnett, *From Patent Thickets to Patent Networks: The Legal Infrastructure of the Digital Economy*, 55 JURIMETRICS J. 1, 2 (2014); cf. Simone A. Rose, *Further Reflections on Extinguishing the Fountainhead of Knowledge: A Call to Transition to the "Innovation Policy" Narrative in Patent Law*, 66 SMU L. REV. 609, 612 (2013) (questioning the conclusions of her earlier work).

²¹⁵ Maureen K. Ohlhausen, *Patent Rights in a Climate of Intellectual Property Rights Skepticism*, 30 HARV. J.L. & TECH. 103, 126 (2016).

²¹⁶ Simone A. Rose, *Patent "Monopolyphobia": A Means of Extinguishing the Fountainhead?*, 49 CASE W. RES. L. REV. 509, 527 (1999).

²¹⁷ See Peter Menell, *Forty Years of Wondering in the Wilderness and No Closer to the Promised Land: Bilski's Superficial Textualism and the Missed Opportunity to Return Patent Law to Its Technology Mooring*, 63 STAN. L. REV. 1289, 1306 (2011).

²¹⁸ See David S. Abrams & R. Polk Wagner, *Poisoning the Next Apple? The America Invents Act and Individual Inventors*, 65 STAN. L. REV. 517, 530 (2013).

²¹⁹ *Id.*

individuals are likely hesitant to publicly share their research and marijuana use through the patent system. Thus it appears that this chilling effect on marijuana-related patents is depriving the public important research. Important research that can create market competition and potentially ground-breaking innovations. The public will continue to be deprived of this research and innovation unless something changes in the current federal scheme.

CONCLUSION

By their very nature, patents are exclusionary. A patent grants the right to exclude others from making use of an invention or process. But patents are also tools to promote innovation. However, when an invalid patent is granted, the patent becomes an exclusionary tool that also chills innovation. UCANN's '911 Patent is an invalid patent that is chilling innovation in the cannabis market—specifically in the liquid CBD market. By invalidating the '911 Patent, the federal courts can help to promote innovation once again. But the '911 Patent is not the only thing hindering innovation in the cannabis market. While the Controlled Substances Act continues to prohibit cannabis at a federal level, researchers and medical professionals will be unsure of the legality of their actions. This naturally leads to another chilling effect in the use of cannabis in the medical field and within research firms. By amending the Controlled Substances Act to allow cannabis for medical and research purposes, and allowing states to opt out of the Act, the federal government can help to promote innovation in the cannabis market. This approach could eliminate the gaps in cannabis research and knowledge that continue to plague the U.S. to this day.