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### Marijuana and Patents: The Complicated Relationship between Patent Rights and the Federal Criminalization of Marijuana

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MARIJUANA AND PATENTS:  
THE COMPLICATED RELATIONSHIP BETWEEN PATENT  
RIGHTS AND THE FEDERAL CRIMINALIZATION OF  
MARIJUANA

*Reza Roghani Esfahani and Howard Bromberg\**

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## I. INTRODUCTION

Difficult questions arise in the context of marijuana-related<sup>1</sup> inventions, patent procurement, and patent enforcement. These questions are a subset of the contradictions in the law of marijuana, where the federal government prohibits marijuana use and yet many of the states legalize, regulate, and tax it. This federal prohibition could discourage research into the health effects of marijuana and makes it difficult for marijuana-related innovations to satisfy statutory patentability requirements. It also renders enforcement of marijuana patents questionable, making marijuana businesses and patent owners vulnerable to non-practicing patent entities, sometimes called “patent trolls.”

Under the U.S. Controlled Substances Act (“CSA”) of 1970, marijuana is classified as a Schedule I drug, the most restrictive schedule.<sup>2</sup> Accordingly, possession and consumption of marijuana is essentially prohibited under federal law and is subject to harsh penalties.<sup>3</sup> Along with other narcotics—such as heroin, LSD, and ecstasy—the Drug Enforcement Administration (“DEA”) classifies marijuana as a Schedule I drug because it has determined that marijuana: (1) has a high potential for abuse; (2) has no accepted medical use; and (3) lacks an accepted safe use for medical treatment.<sup>4</sup> While possession and consumption of marijuana is by and large illegal under federal law, the majority of states have legalized marijuana use in some form or another.<sup>5</sup> For example, thirty-seven states

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<sup>1</sup> The term “marijuana” as it relates to the cannabis plant has been criticized for embodying anti-Latino sentiments associating a cultural vice with Mexican immigrants in the early twentieth century. While this criticism is certainly valid, this Article continues to use the term “marijuana,” as it is this term (along with “marihuana”) that is mostly used in the U.S. Controlled Substances Act and related federal legislation. See Robert A. Mikos & Cindy D. Kam, *Has the “M” Word Been Framed? Marijuana, Cannabis, and Public Opinion*, PLOS ONE (Oct. 31, 2019), <https://journals.plos.org/plosone/article?id=10.1371/journal.pone.0224289> [<https://perma.cc/3T36-CF63>].

<sup>2</sup> See Controlled Substances Act, Pub. L. No. 91-513, 84 Stat. 1242 (1970) (codified as amended at 21 U.S.C. §§ 801–971).

<sup>3</sup> See 21 U.S.C. §§ 841, 844, 863. For example, up to one year imprisonment for first-time possession offense, up to five years imprisonment for first time selling of even the smallest amount of marijuana and up to a life sentence for the maximum amount, and up to three years imprisonment for possession of marijuana paraphernalia. See 21 U.S.C. §§ 841, 844, 863.

<sup>4</sup> See 21 U.S.C. § 812(b)(1).

<sup>5</sup> See *State Medical Cannabis Laws*, NAT’L CONF. OF STATE LEGISLATURES (May 27, 2022), <https://www.ncsl.org/research/health/state-medical-marijuana->

have legalized marijuana for therapeutic and medical purposes.<sup>6</sup> Nineteen of those states have legalized recreational marijuana as well, making it available for adult use with restrictions relating mostly to quantity possessed.<sup>7</sup> Eleven additional states have legalized low-tetrahydrocannabinol (“THC”) cannabidiol (“CBD”), a chemical constituent of marijuana that is non-intoxicating.<sup>8</sup> Indications are that in 2022, some remaining states will further loosen restrictions on medical marijuana, at least as to CBD; and perhaps will legalize adult recreational use of marijuana.<sup>9</sup> While many states have gone beyond merely removing criminal penalties for marijuana possession and consumption and have erected elaborate regimes regulating and licensing marijuana producers and sellers by imposing various taxes and fees,<sup>10</sup> the strict federal prohibition against marijuana use has nevertheless remained relatively unchanged since 1970.<sup>11</sup>

Despite the federal prohibition, marijuana sales in legalizing states are booming. As of 2019, there were approximately 5,000 legal companies and 9,000

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laws.aspx#:~:text=A%20total%20of%2037%20states,medical%20use%20by%20qualified%20individuals [https://perma.cc/9SNZ-GYH8]. In 2019, over 30 percent of Americans lived in states that had legalized recreational use of marijuana. See Casey Leins et al., *States Where Recreational Marijuana Is Legal*, U.S. NEWS & WORLD REP. (May 27, 2022), <https://www.usnews.com/news/best-states/slideshows/where-is-pot-legal>.

<sup>6</sup> See *State Medical Cannabis Laws*, *supra* note 5.

<sup>7</sup> See *id.*; Leins et al., *supra* note 5.

<sup>8</sup> See *State Medical Cannabis Laws*, *supra* note 5; Aleksandra Kicman & Marek Toczek, *The Effects of Cannabidiol, a Non-Intoxicating Compound of Cannabis, on the Cardiovascular System in Health and Disease*, 21 INT’L J. MOLECULAR SCIS., Sept. 2020, at 1, 1.

<sup>9</sup> See Sean Williams, *3 States Likely to Legalize Marijuana Next*, MOTLEY FOOL (May 9, 2021, 6:36 AM), <https://www.fool.com/investing/2021/05/09/3-states-likely-to-legalize-marijuana-next/> [https://perma.cc/P3UH-49UK].

<sup>10</sup> See MARK K. OSBECK & HOWARD BROMBERG, *MARIJUANA LAW IN A NUTSHELL* 416–18 (2d ed. 2022).

<sup>11</sup> See *id.* at 69, 231–32, 550. The most significant change in the CSA was the 2019 removal of hemp from the CSA definition of marijuana, thereby legalizing derivatives of the marijuana plant with 0.3% or less tetrahydrocannabinol (THC). Although hemp is a variety of the *Cannabis sativa* plant species, it is an industrial crop and is non-intoxicating. See also Agriculture Improvement Act of 2018, Pub. L. No. 115-334, § 12619, 32 Stat. 5018.

growers in the marijuana business.<sup>12</sup> As of 2017, the marijuana business generated an estimated \$13 billion in annual revenue and paid an estimated \$4.7 billion in federal taxes.<sup>13</sup> Current projections are that national revenue from marijuana businesses will quadruple to some \$47.3 billion by 2027.<sup>14</sup> In 2021, states collected more than \$3.7 billion in state tax revenue from adult-use cannabis alone.<sup>15</sup> Since 2014, when Colorado became the first state to legalize adult-use marijuana, states have collected a combined total of \$11.2 billion in tax revenue from legal, adult-use marijuana sales.<sup>16</sup>

Notwithstanding this explosive growth in marijuana sales, including adult-use marijuana sales, the federal prohibition creates tremendous complications—even contradictions—for state-licensed and registered marijuana businesses. For example, under Section 280E of the federal income tax code, marijuana businesses are denied a deduction for the ordinary expenses of conducting their businesses, making those expenses taxable on their gross

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- <sup>12</sup> See Stephen McBride, *The Reason Pot Stocks Will Never Recover*, FORBES (Aug. 30, 2019, 8:55 AM), <https://www.forbes.com/sites/stephenmcbride/2019/08/30/the-reason-pot-stocks-will-never-recover/#629238687030> [<https://perma.cc/4P8J-FJGF>].
- <sup>13</sup> See Julie Weed, *Bags of Cash and Stealthy Deliveries: How Pot Start-Ups Pay Taxes*, N.Y. TIMES (May 18, 2018), <https://www.nytimes.com/2018/05/18/business/smallbusiness/marijuana-companies-federal-taxes.html> [<https://perma.cc/LVA4-J9EE>].
- <sup>14</sup> Thomas Pellechia, *Legal Cannabis Industry Poised for Big Growth, in North America and Around the World*, FORBES (Mar. 1, 2018, 8:35 AM), <https://www.forbes.com/sites/thomaspellechia/2018/03/01/double-digit-billions-puts-north-america-in-the-worldwide-cannabis-market-lead/#48e4cba65109> [<https://perma.cc/4APF-PR6G>] (finding that spending on legal cannabis worldwide expected to grow to \$57 billion by 2027).
- <sup>15</sup> See Kyle Jaeger, *States Collected More Than \$3.7 Billion in Recreational Marijuana Tax Revenue in 2021, Report Finds*, MARIJUANA MOMENT (Apr. 6, 2022), <https://www.marijuanamoment.net/states-collected-more-than-3-7-billion-in-recreational-marijuana-tax-revenue-in-2021-report-finds/> [<https://perma.cc/74RL-8T5Q>].
- <sup>16</sup> *Cannabis Tax Revenue in States that Regulate Cannabis for Adult Use*, MARIJUANA POL'Y PROJECT (Apr. 5, 2022), <https://www.mpp.org/issues/legalization/cannabis-tax-revenue-states-regulate-cannabis-adult-use/> [<https://perma.cc/DC5D-RLGA>].

income.<sup>17</sup> Notably, these deductions are ordinarily available even to illegal businesses such as illegal arms sales.<sup>18</sup>

Marijuana businesses also face obstacles in obtaining banking services, as the vast number of banks are federally chartered, insured, and regulated.<sup>19</sup> Given that marijuana businesses are technically engaged in federal crimes, banks that service them risk criminal and civil liability under federal laws targeted at money laundering, bank secrecy, and other strict banking regulations.<sup>20</sup> Likewise, marijuana businesses are frequently denied relief from creditor claims under

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<sup>17</sup> See I.R.C. § 280E (“No deduction or credit shall be allowed for any amount paid or incurred during the taxable year in carrying on any trade or business if such trade or business (or the activities which comprise such trade or business) consists of trafficking in controlled substances (within the meaning of schedule I and II of the Controlled Substances Act) which is prohibited by Federal law or the law of any State in which such trade or business is conducted.”); Bill Greenberg & Rebecca Greenberg, *26 USC Section 280E: Will the Dragon Now Be Slayed?*, 25 J.L. & POL’Y 549, 568 (2017); Memorandum from W. Thomas McElroy, Jr., Senior Technician Reviewer, to Matthew A. Houtsma, Assoc. Area Couns. 7 (Dec. 10, 2014), <https://www.irs.gov/pub/irs-wd/201504011.pdf> [<https://perma.cc/8GR7-P4T>].

<sup>18</sup> See Edward Roche Jr., *Federal Income Taxation of Medical Marijuana Businesses*, 66 TAX LAW. 429, 433–34 (2013) (stating that the IRS has allowed illegal arms businesses to deduct typical business expenses, and that courts have sustained such deductions for businesses involving “illegal gambling, [illegal lottery operations], prostitution, racketeering, and general organized crime”). Deductions for the ordinary expenses of conducting a business include employee salaries and wages, rent and utilities, employee health insurance and other employee benefits, taxes, various fees, and licenses, office supplies, equipment depreciation, professional legal and accounting services, transportation, meals and entertainment, and marketing and advertising expenses. See I.R.C. § 162.

<sup>19</sup> See Julie Andersen Hill, *Banks, Marijuana, and Federalism*, 65 CASE W. RESRV. L. REV. 597, 597, 600, 617 (2015).

<sup>20</sup> See *Biggest Risks Facing Cannabis Businesses*, OG CANNABIS INS.: INS. BLOG (Nov. 25, 2021), <https://www.ogcannabisinsurance.com/biggest-risks-facing-cannabis-businesses/> [<https://perma.cc/Q2ZU-8EFH>]; James J. Black & Marc-Alain Galeazzi, *Cannabis Banking: Proceed with Caution*, AM. BAR ASS’N (Feb. 6, 2020), [https://www.americanbar.org/groups/business\\_law/publications/blt/2020/02/cannabis-banking/](https://www.americanbar.org/groups/business_law/publications/blt/2020/02/cannabis-banking/) [<https://perma.cc/VU4M-GH7E>].

federal bankruptcy law.<sup>21</sup> Even companies that transact with marijuana businesses have been denied bankruptcy protection under the doctrine of unclean hands.<sup>22</sup> Marijuana businesses have had difficulty obtaining insurance; and when obtained, they have had difficulties receiving payment on claims, under the doctrine that making such payments would violate public policy.<sup>23</sup> For similar reasons, federal courts, and some state courts, have refused to enforce contracts involving marijuana suppliers.<sup>24</sup>

Additionally, marijuana businesses have faced issues in obtaining legal and accounting services. American Bar Association (“ABA”) Model Rule 1.2(d) mandates that it is unethical for a lawyer to assist a client, in conduct that the lawyer knows is criminal fraudulent or a violation of any law.<sup>25</sup> Although every state bar association has a similar rule, many states have made exceptions for lawyers counseling or assisting marijuana businesses, inasmuch as they are in compliance with state law.<sup>26</sup> Tax professionals providing services to marijuana businesses also face state disciplinary rules that could imperil their professional careers, such as those that require “good moral character” of accountants practicing in their state.<sup>27</sup> It has not been decisively resolved whether providing tax and accounting services to a marijuana business demonstrates bad moral character as a violation of federal law.

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- <sup>21</sup> Blake Marvis, Note, *Reefer Madness in Federal Court: An Overview of How Federal Courts Are Dealing with Cannabis Litigation and Why It Is Necessary to “Dig into the Weeds,”* 23 LEWIS & CLARK L. REV. 967, 979 (2019).
- <sup>22</sup> Steven Mare, Note, *He Who Comes into Court Must Not Come with Green Hands: The Marijuana Industry’s Ongoing Struggle with the Illegality and Unclean Hands Doctrines,* 44 HOFSTRA L. REV. 1351, 1365–66 (2016).
- <sup>23</sup> See Francis J. Mootz III & Jason Horst, Note, *Cannabis and Insurance,* 23 LEWIS & CLARK L. REV. 893, 896 (2019).
- <sup>24</sup> See Todd A. Wells et al., *The Enforcement of Cannabis-Related Contracts & Arbitration Awards,* 1 ITA REV. 3, 8 (2019).
- <sup>25</sup> MODEL RULES OF PRO. CONDUCT r. 1.2(d) (AM. BAR ASS’N 1983).
- <sup>26</sup> See Dennis A. Rendleman, *Ethical Issues in Representing Clients in the Cannabis Business: “One Toke Over the Line?,”* 26 PRO. LAW. 20, 24 (2019).
- <sup>27</sup> See Jim Arkell & H. Charles Sparks, *It’s Illegal! – Marijuana Related Businesses and the Accounting Profession,* 18 J. ACCT. & FIN. 23, 27 (2018) (stating that accountants will not face ethics actions against them as long as the businesses they work with comply with state laws); Alice Guy Azzaro, *Designing a Framework for Maintaining Good Moral Character When Providing Accounting Services to the Legal Cannabis Industry* 53 (Dec. 2018) (DBA dissertation, Liberty University).

The strict federal prohibition also hampers scientific and medical research into the health effects of marijuana,<sup>28</sup> which has in turn potentially affected the availability of patents. As marijuana is a Schedule I drug, researchers may need DEA approval to conduct tests and trials on marijuana.<sup>29</sup> To obtain this registration, a research plan must pass review by a host of federal agencies including the Food and Drug Administration (“FDA”) and the National Institute on Drug Abuse (“NIDA”).<sup>30</sup> In addition, marijuana researchers faced other restrictions, some of which have been lifted. For example researchers were required to submit their proposed study for additional approval by the U.S. Public Health Service—a requirement imposed on no other drug.<sup>31</sup> Even if researchers eventually gain DEA registration, they could obtain marijuana for their research from only one supplier—the NIDA Drug Supply Program, which licensed the University of Mississippi as the only grower.<sup>32</sup> This sole source was limited in both quantity and in variety of marijuana strains that scientists proposed researching,

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<sup>28</sup> NAT’L ACADEMIES OF SCI., ENG’G, AND MEDICINE, *THE HEALTH EFFECTS OF CANNABIS AND CANNABINOIDS: THE CURRENT STATE OF EVIDENCE AND RECOMMENDATIONS FOR RESEARCH* 378 (2017).

<sup>29</sup> See 21 C.F.R. § 1301.18 (2021) (stating that notice must be provided to the DEA before conducting research on a Schedule I drug).

<sup>30</sup> See *FDA and Cannabis: Research and Drug Approval Process*, U.S. FOOD & DRUG ADMIN. (last updated Oct. 1, 2020), <https://www.fda.gov/news-events/public-health-focus/fda-and-cannabis-research-and-drug-approval-process> [<https://perma.cc/SHN3-CB4W>]; OSBECK & BROMBERG, *supra* note 10, at 108–10 (stating that the DEA places stringent requirements on marijuana research and the NIDA funds scientific marijuana research).

<sup>31</sup> See OSBECK & BROMBERG, *supra* note 10, at 92. This restriction was imposed in 1999. See Nat’l Inst. Of Health, *Announcement of the Department of Health and Human Services’ Guidance on Procedures for the Provision of Marijuana for Medical Research* (May 21, 1999), <https://grants.nih.gov/grants/guide/notice-files/not99-091.html> [<https://perma.cc/R3RD-XEZH>] (requiring HHS approval for marijuana research). This restriction was then removed in 2015. See *Announcement of Revision to the Department of Health and Human Services Guidance on Procedures for the Provision of Marijuana for Medical Research as Published on May 21, 1999*, 80 Fed. Reg. 35,960, 35,960 (June 23, 2015).

<sup>32</sup> See OSBECK & BROMBERG, *supra* note 10, at 109 (stating that the DEA determined that the National Center for Natural Products Research at the University of Mississippi was the exclusive source of marijuana research until 2020).



but not necessarily high-grade.<sup>33</sup> And of course, without rigorous scientific studies, marijuana plants and constituents could hardly obtain approval under the federal Food, Drug, and Cosmetic Act (“FDCA”).<sup>34</sup>

Of the impediments that trouble businesses and entrepreneurs resulting from the dichotomy between federal and state marijuana laws, those involving intellectual property have received relatively little judicial or scholarly attention in spite of being one of the only rights explicitly protected in the U.S. Constitution. Congress is granted the enumerated 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.”<sup>35</sup>

Intellectual property rights have been governed by federal statutes since the first Copyright Act and Patent Act<sup>36</sup> were both enacted in 1790. Because marijuana is illegal under the CSA, federal trademark and patent protections for marijuana businesses have been labeled as “useless.”<sup>37</sup> This Article addresses some

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<sup>33</sup> NAT’L ACADEMIES OF SCI., ENG’G, AND MEDICINE, *supra* note 28, at 382–83 (stating that there was little variety in the marijuana provided through the NIDA and the marijuana provided was far weaker than what is sold to consumers).

<sup>34</sup> Codified as amended at 21 U.S.C. §§ 301–399i. Although perhaps not directly related to the CSA, the procedures of the FDA are also constrictive of the opportunity to patent marijuana plants and strains. Given the complexity of whole-plant drugs, botanical marijuana is unlikely to pass the rigorous trials required by the FDA for drug approval. *See* Rebecca S. Eisenberg & Deborah Leiderman, *Cannabis for Medical Use: FDA and DEA Regulation in the Hall of Mirrors*, 74 FOOD & DRUG L.J. 246, 263 (2019) (explaining that the complexity of marijuana plants leads to more difficulty in obtaining FDA approval). Absent FDA approval, the FDCA also makes the use in food and dietary supplements of a drug or substance undergoing clinical investigation illegal with the exception of several products that are “Generally Recognized as Safe” (GRAS) which generally do not contain active ingredients such as CBD and THC. 21 U.S.C. § 321.

<sup>35</sup> U.S. CONST. art. I, § 8, cl. 8.

<sup>36</sup> *See* Copyright Act of 1790, ch. 15, 1 Stat. 124, 124; Act of Apr. 10, 1790, ch. 7, 1 Stat. 109, § 2 (1790).

<sup>37</sup> *See* Sam Kamin & Viva R. Moffat, *Trademark Laundering, Useless Patents, and Other IP Challenges for the Marijuana Industry*, 73 WASH. & LEE L. REV. 218, 259 (2016). Trade secrets are not addressed here for two reasons: (1) they are generally governed by state laws; and (2) they do not require registration with the federal government. *See, e.g.*, MICH. COMP. LAWS §§ 445.1901–445.1910 (1998). For a scathing critique of PTO’s requirement of trademark

of the difficult questions relating to marijuana patents, which may be among the most legally complicated and intractable, as they present novel questions that affect businesses, entrepreneurs, scientists, and medical researchers.

The first part of this Article evaluates the difficulties in obtaining or evaluating marijuana patents; particularly, the patentability requirements in view of the CSA and its ramifications. This part finds that because of the illegality of marijuana, satisfying patentability requirements may be more subjective than other fields and that the resulting patents may be inferior in quality. The second part addresses why illegality is likely not an impediment to patentability. The third part of this Article sets forth the challenges associated with enforcement of marijuana-related patents. This section starts by setting forth problems associated with securing counsel. Subsequently, this section examines issues that arise in the pleading stage and considers the shortcomings of discovery in this context. Next, this section assesses the judicial limitations in granting remedies. The last part of this Article suggests that the current approach to patenting illegal substances is bound to raise new patent troll problems.

## II. MARIJUANA ILLEGALITY AND THE PATENTABILITY REQUIREMENTS

There is tension at the heart of any discussion of marijuana in the patent context. Marijuana use is illegal under federal law, yet the federal government has issued many patents directed at marijuana use or cultivation in one form or another.<sup>38</sup> Exploration of this tension illustrates important points about both the nature of the federal prohibition for marijuana and patentability requirements. Additionally, with the rapid legalization of marijuana at the state level,<sup>39</sup> the rapid

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owners to comply with sundry non-trademark law see Robert A. Mikos, *Unauthorized and Unwise: The Lawful Use Requirement in Trademark Law*, 75 VAND. L. REV. 161, 237 (2022) [hereinafter Mikos, *Unauthorized and Unwise*] (stating that the PTO's requirement to comply with non-trademark laws indicates that the PTO has "lost sight of the statute it is supposed to administer").

<sup>38</sup> See Matthew Bultman, *Cannabis Patent Activity Surges Amid Industry Gold Rush*, LAW360 (Oct. 16, 2019, 5:25 PM), [https://www.law360.com/ip/articles/1203746/cannabis-patent-activity-surges-amid-industry-gold-rush?nl\\_pk=c5beb89a-d431-46af-87e7-106bf8075925&utm\\_source=newsletter&utm\\_medium=email&utm\\_campaign=ip](https://www.law360.com/ip/articles/1203746/cannabis-patent-activity-surges-amid-industry-gold-rush?nl_pk=c5beb89a-d431-46af-87e7-106bf8075925&utm_source=newsletter&utm_medium=email&utm_campaign=ip) [https://perma.cc/7HQD-9VU4] (showing that the USPTO issued more marijuana patents in 2017 and 2018 than it had in the seven years prior).

<sup>39</sup> OSBECK & BROMBERG, *supra* note 10, at 266.

rise of the cannabis industry,<sup>40</sup> and new questions of federalism and industry practice<sup>41</sup>, the question of patentability takes on new importance. In fact, “[t]he arms race for cannabis patents has already begun and is likely to intensify as markets and the regulatory landscape mature.”<sup>42</sup> Analysts have projected that the cannabis industry will likely grow from an approximate annual revenue of \$9.2 billion in 2017 to approximately \$47.3 billion in 2027 in North America alone.<sup>43</sup>

The United States Patent and Trademark Office (“USPTO”) has issued marijuana-related patents since 1942.<sup>44</sup> Given that federal law classifies marijuana as a Schedule I controlled substance,<sup>45</sup> does the Patent Act conflict with the Controlled Substances Act of 1970?<sup>46</sup> When federal law conflicts with a state law, preemption doctrine dictates the outcome: the federal law is supreme.<sup>47</sup> A more

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<sup>40</sup> See *id.* at 416 (showing that the marijuana market is expected to triple from 2019 to 2023).

<sup>41</sup> See *id.* at 165.

<sup>42</sup> Pauline Pelletier & Deborah Sterling, *What Cannabis Patent Applicants Can Learn From Biopharma*, LAW360 (Jan. 17, 2019), <https://www.law360.com/articles/1119184/what-cannabis-patent-applicants-can-learn-from-biopharma> [<https://perma.cc/72LY-467J>].

<sup>43</sup> See Pellechia, *supra* note 14.

<sup>44</sup> Isolation of Cannabidiol, U.S. Patent No. 2,304,669 (issued Dec. 8, 1942).

<sup>45</sup> 21 U.S.C. § 812(c)(c)(10).

<sup>46</sup> Compare 35 U.S.C. §§ 1–390, with 21 U.S.C. §§ 801–971.

<sup>47</sup> Article VI, Paragraph 2 of the U.S. Constitution is commonly referred to as the Supremacy Clause. *Supremacy Clause*, LEGAL INFO. INST., [https://www.law.cornell.edu/wex/supremacy\\_clause#:~:text=Article%20VI%2C%20Paragraph%20of,laws%2C%20and%20even%20state%20constitutions](https://www.law.cornell.edu/wex/supremacy_clause#:~:text=Article%20VI%2C%20Paragraph%20of,laws%2C%20and%20even%20state%20constitutions) [<https://perma.cc/LR7U-9UZY>]. The jurisprudence of preemption in the context of marijuana law is extensive and controversial. In brief, the Controlled Substances Act—the federal law that prohibits marijuana use by placing it on restricted schedule I—states that:

No provision of [the subchapter on control and enforcement of United States drug laws] shall be construed as indicating an intent on the part of the Congress to occupy the field . . . to the exclusion of any State law on the same subject matter which would otherwise be within the authority of the State, unless there is a positive conflict between that provision . . . and that State law so that the two cannot consistently stand together.

21 U.S.C. § 903. Since 1996, 37 states have legalized medical marijuana; 18 of those states have legalized adult recreational marijuana as well. An additional 11 states have legalized Cannabidiol (CBD), a compound of the marijuana plant, making a total of 48 states that have legalized cannabis in some form, in addition to the District of Columbia and such territorial possessions of the United States as Puerto Rico, Northern Mariana Islands, and Guam. *CBD Legal States 2022*, WORLD POPULATION REV., <https://worldpopulationreview.com/state-rankings/cbd-legal-states> [<https://perma.cc/3ETB-BTGC>]. Most courts that have ruled on this issue, have found that these state provisions legalizing marijuana do not represent a “positive conflict” with, and are thus not preempted (invalidated) by, the CSA. *See Nebraska v. Colorado*, 557 U.S. 1211, 1036 (2016); *White Mountain Health Ctr., Inc. v. Maricopa Cnty.*, 386 P.3d 416, 433 (Ariz. Ct. App. 2016); *Kirby v. County of Fresno*, 195 Cal. Rptr. 3d 815, 940, 963 (Ct. App. 2015); *Reed-Kaliher v. Hoggatt*, 332 P.3d 587, 591 (Ariz. Ct. App. 2014); *State v. Ehrensing*, 296 P.3d 1279, 1286 (Or. Ct. App. 2013); *Tracy v. USAA Casualty Ins., Co.*, No. 11-00487, 2012 WL 928186, at \*11–13 (D. Haw. Mar. 16, 2012); *Ter Beek v. City of Wyoming*, 823 N.W.2d 864, 871 (Mich. Ct. App. 2012); *Willis v. Winters*, 253 P.3d 1058, 1065 (Or. 2011); *Qualified Patients Ass'n v. City of Anaheim*, 115 Cal. Rptr. 3d 89, 108 (Ct. App. 2010); *Cnty. of San Diego v. San Diego NORML*, 81 Cal. Rptr. 3d 461, 481 (Ct. App. 2008); *City of Garden Grove v. Superior Court of Orange Cnty.*, 68 Cal. Rptr. 3d 656, 675–78 (Ct. App. 2007); *State v. Kama*, 39 P.3d 866, 868 (Or. Ct. App. 2002); *Erwin Chemerinsky et al., Cooperative Federalism and Marijuana Regulation*, 62 *UCLA L. REV.* 74, 113 (2015) (noting the tension between federal and state laws governing marijuana enforcement).

A minority of courts have found state legalization laws preempted, *People v. Crouse*, 388 P.3d 39, 40–42 (Colo. 2017); *Pack v. Superior Court*, 132 Cal. Rptr. 3d 633, 649 (Ct. App. 2011); *Emerald Steel Fabricators, Inc. v. Bureau of Lab. & Indus.*, 230 P.3d 518, 528–29 (Or. 2010).

Perhaps the strongest indication that state legalization regimes are not preempted by the CSA is *Nebraska v. Colorado*, 557 U.S. 1211 (2016). In that case, the U.S. Supreme Court declined to hear a challenge by two neighboring states to Colorado’s legalization regime as conflicting with the CSA even though the Court had original and exclusive jurisdiction over the case. 28 U.S.C. § 1251(a). By not taking up the case, the Court essentially found Colorado’s legalization regime non-preempted. Nevertheless, with the state of the law standing as it is, the question of whether the CSA preempts state legalization regimes adds another layer of uncertainty to marijuana law in the United States.

complicated question, however, arises when there is conflict between two federal statutes. Unlike for federal-state conflicts of laws, the preemption doctrine does not help navigate their nonconformity.<sup>48</sup>

To reconcile legislative enactments, courts often use the implied repeal doctrine—one of the oldest doctrines of statutory interpretation.<sup>49</sup> This doctrine, manifested in the Latin maxim *leges posteriores priores contrarias abrogant*, means “[s]ubsequent laws repeal prior conflicting ones.”<sup>50</sup> It has been applied by courts as early as 1614 in Sir Edward Coke’s report on *Dr. Foster’s Case*.<sup>51</sup> Courts, however, disfavor repeals by implication unless the two laws are in irreconcilable conflict and the intention of the legislature to repeal is clear and manifest.<sup>52</sup>

This question, however significant on first blush, may be easily resolved in this context. The Patent Act and the CSA deal with different areas of the law and are likely not irreconcilable. They have no conflicting legal provisions. It is simply that the CSA, having created an almost unparalleled regime in the United States where federal laws and state laws are in conflict over marijuana legality—presents new questions of patentability.<sup>53</sup> Theoretically, the legality of marijuana

<sup>48</sup> This is because the preemption doctrine is derived from the Supremacy Clause of Article VI of the Constitution, which applies uniformly among the federal laws. *See* U.S. CONST. art. VI, cl. 2.

<sup>49</sup> *See* ANTONIN SCALIA & BRYAN A. GARNER, *READING LAW: THE INTERPRETATION OF LEGAL TEXTS* 327–28 (2012).

<sup>50</sup> *Leges posteriores priores contrarias abrogant*, BLACK’S LAW DICTIONARY (11th ed. 2019).

<sup>51</sup> *Dr. Foster’s Case* (1614) 77 Eng. Rep. 1222, 1231.

<sup>52</sup> *Town of Red Rock v. Henry*, 106 U.S. 596, 601–02 (1883); *see also* SCALIA & GARNER, *supra* note 49, at 330. The first Congress enacted the Patent Act of 1790 titled “An Act to promote the Progress of Useful Arts” on April 10, 1790. *See* Act of Apr. 10, 1790, ch. 7, 1 Stat. 109 (1790). A series of repeals and amendments, over time, brought about the modern version of the Patent Act— Patent Act of 1952, Pub. L. No. 593, 66 Stat. 792. *See also* Leahy-Smith America Invents Act, Pub. L. No. 112-29, 125 Stat. 284 (codified as amended in scattered sections of 35 U.S.C. (2011)). The Controlled Substance Act was enacted as Title II of the Comprehensive Drug Abuse Prevention and Control Act of 1970, Pub. L. No. 91-513, 84 Stat. 1242. Thus, the Patent Act is nearly two centuries older than the CSA.

<sup>53</sup> A parallel, although concerning an issue of much greater significance, is that of enforcement of the Fugitive Slave Act of 1793 and, in particular, the Fugitive Slave Act of 1850. As with marijuana laws that differ by jurisdiction, the federal government was seeking to enforce a federal slave return law as to an institution that was legal in some states, illegal in others,

under state law should not matter as patents are a federally granted right, yet a recent study found marijuana related patent filings to be growing commensurate to the economic and legislative activity.<sup>54</sup> While there is no irreconcilable conflict between the Patent Act and the CSA, there are major marijuana patentability questions given the seeming conflict (as the law stands now) between federal and state marijuana law.

In the United States, an invention is patentable if it is novel, non-obvious, useful, and directed to eligible subject matter.<sup>55</sup> These, however, are merely some of the patentability requirements. For an invention to be patentable it must meet several other statutory requirements, which include enablement, written description, definiteness, and best mode.<sup>56</sup>

#### A. NOVELTY

An invention must be novel. To be patentable, what is claimed as an invention must be different from what is disclosed in any other single disclosure.<sup>57</sup>

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and unsettled in federal territories. *See, e.g., Prigg v. Pennsylvania*, 41 U.S. 539, 608–10 (1842). Although the horrific slavery regime was only eliminated by a civil war and constitutional amendment, ante-bellum slavery laws, such as those expounded in *Prigg*, introduced doctrines of federalism and property law that remain relevant to this day.

<sup>54</sup> Joseph Wyse & Gilad Luria, *Trends in Intellectual Property Rights Protection for Medical Cannabis and Related Products*, 3 J. CANNABIS RSCH. 1, 8–9 (2021) (“Approximately 570 patent families (2200 patent documents) have been filed in . . . downstream technologies, with the filing rate rising steadily since 2011–2013 . . . . The steep increase in patent filing and grants . . . since 2011–2013 is consistent with the recognition by industry that the number of US states allowing legal medical cannabis was reaching a critical number.”).

<sup>55</sup> 35 U.S.C. §§ 101–103.

<sup>56</sup> 35 U.S.C. § 112. While these statutory requirements also present interesting questions in the context of marijuana-related patents, this Article focuses on the four requirements of novelty, non-obviousness, usefulness, and subject matter eligibility.

<sup>57</sup> 35 U.S.C. § 102 (“A person shall be entitled to a patent unless (1) the claimed invention was patented, described in a printed publication, or in public use, on sale, or otherwise available to the public before the effective filing date of the claimed invention; or (2) the claimed invention was described in a patent issued . . . or in an application for patent published or deemed published . . . [that] names another inventor and was effectively filed before the effective filing date of the claimed invention.”).

Simply put, what is claimed as an invention cannot be shown, discussed, taught, or otherwise disclosed in any single previous patent, publication, or anything that is in public use or on sale.<sup>58</sup> If what is claimed by the patent applicant already publicly exists, such an applicant is not entitled to a monopoly.<sup>59</sup> There is one caveat, though. To reject a patent claim for lack of novelty, what is claimed as an invention must be entirely present within the four corners of a single patent, publication, or anything that is in public use or on sale.<sup>60</sup>

In the case of marijuana-related inventions, like any other field, it is easy to imagine that some permutation of compositions using active ingredients derived from cannabis, or method of extracting such compounds, or even method of preparing, processing, and cultivating cannabis could be novel and meet the definition set forth in § 102.<sup>61</sup> Due to the illegality of marijuana, however, the USPTO, the agency responsible for evaluating patent eligibility, may face several challenges in finding and evaluating prior art.<sup>62</sup> Prior art is a term commonly used in patent law which encompasses all information published or unpublished available to the public before an applicant's priority date.<sup>63</sup> These challenges are

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<sup>58</sup> *Id.*

<sup>59</sup> *Bonito Boats v. Thunder Craft Coats*, 489 U.S. 141, 148 (1989) (stating that § 102 bars a person from patenting what is already in the public domain as this section “express[s] a congressional determination that the creation of a monopoly in such information would not only serve no socially useful purpose, but would in fact injure the public by removing existing knowledge from public use”). In consideration for the full disclosure and public dedications of a new and useful invention, a patentee is granted limited monopoly. *See United States v. Dubilier Condenser Corp.*, 289 U.S. 178, 186 (1933).

<sup>60</sup> *Verdegaal Bros. v. Union Oil Co. of California*, 814 F.2d 628, 631 (Fed. Cir. 1987) (“A claim is anticipated only if each and every element as set forth in claim is found, either expressly or inherently described, in a single prior art reference.”).

<sup>61</sup> *See, e.g., Methods of Growing Cannabaceae Plants Using Artificial Lighting*, U.S. Patent No. 9,844,518 (filed Sept. 30, 2015) (issued Dec. 19, 2017); 35 U.S.C. § 102.

<sup>62</sup> *About Us*, USPTO, <https://www.uspto.gov/about-us> [<https://perma.cc/6VJG-V6YH>].

<sup>63</sup> *See John DiGiacomo, The Difference Between a Patent Filing Date and a Priority Date*, REVISION LEGAL (July 26, 2021), <https://revisionlegal.com/patent/the-difference-between-a-patent-filing-date-and-priority-date/> [<https://perma.cc/R2TU-L7CC>]. Priority date is a date that reflects the cut-off date for defining the universe of prior art. DONALD CHISUM, CHISUM ON

further discussed below. Moreover, it is at least questionable whether an interested person or entity, who already practices the “newly-claimed” invention, would contest the patentability of an application—possibly risking self-incrimination—based on the grounds that such invention is in public use or on sale.<sup>64</sup> Despite these challenges, it does not seem that the novelty requirement is a particularly unique barrier to patenting marijuana-related inventions. In other words, while it may affect the quality of the patents granted, as far as acquiring patent rights is concerned, it is of no special consequence.

## B. NON-OBVIOUSNESS

The non-obviousness requirement does not present unique hurdles for patent applicants either. Simply put, the non-obviousness requirement is whether a person of ordinary skill in the art would find the claimed invention obvious either on its face or by combination of two or more previous patents, publications, or anything that is in public use or on sale.<sup>65</sup> Section 103 of the Patent Act disallows patents if “the differences between the claimed invention and the prior art are such that the claimed invention”—*i.e.*, the invention sought to be patented, “would have been obvious” before the priority date of the application “to a person having ordinary skill in the art to which the claimed invention pertains.”<sup>66</sup> For marijuana innovations, like any other field, various claims as to compositions using cannabis-derived active ingredients, methods of preparation of such compositions, or processes of extracting, preparing, and cultivating cannabis could fit within the statutory requirements of this section.

However, the lack of substantial, relevant, and accessible prior art, noted above and discussed below, may be more troublesome in evaluating non-obviousness of a claimed invention.<sup>67</sup> This is because, unlike the novelty

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PATENTS, § 10.03 Priority Rules (1978). Art that pre-dates the priority date may be used to show that an application is not eligible for patenting because it lacks novelty or is obvious. *Id.*

<sup>64</sup> See 35 U.S.C. § 102.

<sup>65</sup> See 35 U.S.C. § 103. A person of ordinary skill in the art (POSA) (also known as a person having ordinary skill in the art (PHOSITA) or a skilled artisan) refers to a fictitious person with normal skills and knowledge in the field of technology in question. See Jonathan J. Darrow, *The Neglected Dimension of Patent Law’s PHOSITA Standard*, 23 HARV. J.L. & TECH. 227, 233–35 (2009).

<sup>66</sup> Leahy-Smith America Invents Act, Pub. L. No. 112-29, 125 Stat. 284 (codified as amended in scattered sections of 35 U.S.C. (2011)).

<sup>67</sup> See discussion, *supra* notes 62–63.



requirement, under which all elements of a claimed invention must be found within the four corners of a single prior art reference, the obviousness requirement is typically, but not always, evaluated based on a combination of prior art references.<sup>68</sup> For example, one feature of the claimed invention might be present in one prior patent, and another feature might be present in another, leaving a patent examiner to determine whether it would have been obvious to reach the claimed invention from the two separate references.<sup>69</sup>

In *KSR International Co. v. Teleflex Inc.*, the Supreme Court found that obviousness is a question of law based on underlying factual inquiries.<sup>70</sup> These factual inquiries concern (1) the scope and content of the prior art; (2) the differences between the claimed invention and the prior art; and (3) the level of ordinary skill in the pertinent art.<sup>71</sup> Stated another way, the Supreme Court in this case stated that non-obviousness of a claimed invention depends on what material relating to the invention is publicly available, what such material teach, how such material is different from the claimed invention, and how creative a fictitious person with ordinary skills in the relevant technology needs to be to derive what is claimed from the publicly available material.<sup>72</sup>

A quick study of these factual inquiries reveals the extent of the problem in the context of marijuana-related patent applications. Absent an accessible substantial library of patents, patent applications, and well-established channels

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<sup>68</sup> *In re Spooner*, 918 F.2d 186 (Fed. Cir. 1990) (“While no single reference discloses all three elements, it must be remembered that the rejection is based on § 103 for obviousness and not on § 102 for anticipation . . . Accordingly, all elements of the applicant’s invention need not be disclosed in a single prior art reference to warrant a rejection of the claims.”); *Advanced Display Sys. v. Kent State Univ.*, 212 F.3d 1272, 1282 (Fed. Cir. 2000) (“[I]nvalidity by anticipation requires that the four corners of a single, prior art document describe every element of the claimed invention, either expressly or inherently, such that a person of ordinary skill in the art could practice the invention without undue experimentation.”).

<sup>69</sup> *Arendi S.A.R.L. v. Apple Inc.*, 832 F.3d 1355, 1361 (Fed. Cir. 2016) (“Though less common, in appropriate circumstances, a patent can be obvious in light of a single prior art reference if it would have been obvious to modify that reference to arrive at the patented invention.”).

<sup>70</sup> *KSR Int’l Co. v. Teleflex Inc.*, 550 U.S. 415 (2007) (reaffirming the objective analysis of obviousness framework set forth in *Graham v. John Deere Co. of Kansas City*, 383 U.S. 1 (1966)).

<sup>71</sup> *Id.* at 399.

<sup>72</sup> *Id.*

of commerce, it is likely difficult for the USPTO to learn about the relevant prior art and evaluate their scope and attempt to ascertain the differences between the prior art and the claimed invention.<sup>73</sup> This could result in granting bad patents. A limited and hard to find universe of prior art makes it difficult for the examiners to adequately evaluate the novelty and non-obviousness of a claimed invention.<sup>74</sup> Without adequate evaluation, a patent applicant may claim, recapture, and monopolize something that is already public information. This defeats the purpose of patents. Patents simply grant a limited monopoly to patent owners in exchange for disclosing their invention to the public.<sup>75</sup> Patents do not permit recapture and re-monopolization of what was already devoted to the public.<sup>76</sup> Conversely, a limited and hard to find universe of prior art may lend itself to wastefulness. For example, an inventor could spend precious resources reinventing what is already in public—albeit hard to find—seek and receive a patent from the Patent Office which may face the same issue, only to have the patent invalidated down the road when the publicly available information comes to light.

Lack of substantial accessible prior art and well-established practices may also affect the ability of the person of ordinary skill in the art to determine if the claimed invention is obvious in view of common—yet secret—practices.<sup>77</sup> This

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<sup>73</sup> In patent law while the specification (*i.e.*, the patent application) could provide a background for the invention and elaborates on its subject matter, it is the scope of the claims that illustrate the boundaries (otherwise referred to as metes and bounds) of an invention. In other words, patent claims set the legal boundaries of what the patentee can exclude others from making, using, selling, offering to sell, importing to the U.S. See MANUAL OF PATENT EXAMINING PROCEDURE § 2173 (9th ed. Rev. 10.2019, June 2020) [hereinafter MPEP].

<sup>74</sup> See David S. Abrams & Bhaven N. Sampat, *What's the Value of Patent Citations? Evidence from Pharmaceuticals* 5 (June 9, 2017) (unpublished manuscript), <https://wwws.law.northwestern.edu/research-faculty/clbe/events/innovation/documents/abramssampatdrugcites060917.pdf> [<https://perma.cc/9ZSD-VHNX>].

<sup>75</sup> See *United States v. Dubilier Condenser Corp.*, 289 U.S. 178, 186 (1933).

<sup>76</sup> See *Eldred v. Ashcroft*, 537 U.S. 186, 240 (2003); *Thomas & Betts Corp. v. Panduit Corp.*, 65 F.3d 654, 658 (7th Cir. 1995).

<sup>77</sup> See *KSR Int'l Co. v. Teleflex Inc.*, 550 U.S. 415, 421 (2007) (“A person of ordinary skill is also a person of ordinary creativity, not an automaton.”); *In re Heck*, 699 F.2d 1331, 1333 (Fed. Cir. 1983) (stating that persons of ordinary skill in the art are presumed to be familiar with the art); *Malsbary Mfg. Co. v. ALD, Inc.*, 447 F.2d 809, 811 (7th Cir. 1971) (explaining that those with ordinary skill are those thoroughly familiar with the particular art).

could severely impact the ability of a person of ordinary skill in the art to use common sense, logic, and judgment to determine whether the claimed invention is obvious in view of limited universe of prior art.<sup>78</sup> Indeed, how can ordinary skills and experience in a field be defined when at least some of the science, technique, or knowhow is kept secret or hard to find?

Apart from the three *KSR* factors mentioned above,<sup>79</sup> courts often use secondary factors such as unexpected results, commercial success, long-felt but unsolved need, copying, failure of others, and teaching away to “give light to the circumstances surrounding the origin of the subject matter sought to be patented.”<sup>80</sup> Since these secondary factors are also factual in nature,<sup>81</sup> they, too, could be affected by lack of substantial accessible prior art and well-established practices. For example, without substantial and accessible prior art, how can the U.S. Patent and Trademark Office determine whether the claimed subject matter is thought away by prior art? The Open Cannabis Project (“OCP”), an Oregon non-profit corporation, was an effort, in part, to establish a library of prior art for marijuana to forestall patent trolls,<sup>82</sup> and more broadly, to inhibit the granting of marijuana patents so as to encourage the economic diversity of the cannabis industry as well as to protect the genetic diversity of the cannabis plant. The OCP collected genetic and chemotypic<sup>83</sup> data as to cannabis strains, which it stored in

<sup>78</sup> *Perfect Web Techs. Inc. v. InfoUSA, Inc.*, 587 F.3d 1324, 1329 (Fed. Cir. 2009) (stating that the analysis of obviousness “may include recourse to logic, judgment, and common sense available to the person of ordinary skill”).

<sup>79</sup> *See supra* text accompanying note 71.

<sup>80</sup> *Graham v. John Deere Co. of Kansas City*, 383 U.S. 1, 17–18 (1966).

<sup>81</sup> *See Specialty Composites v. Cabot Corp.*, 845 F.2d 981, 991 (Fed. Cir. 1988).

<sup>82</sup> *Open Cannabis Project: The Fight to Get Marijuana Patent Rights*, CANNA L. BLOG (Feb. 23, 2018), <https://harrisbricken.com/cannalawblog/open-cannabis-project-and-the/> [<https://perma.cc/GLV5-JV8R>]; *infra* Section IV.D.

<sup>83</sup> Kimberly Ross, *Leveraging Chemotyping Techniques for Data-Driven Classification of Cannabis*, ANALYTICAL CANNABIS (May 31, 2019), <https://www.analyticalcannabis.com/articles/leveraging-chemotyping-techniques-for-data-driven-classification-of-cannabis-311719#:~:text=The%20term%20chemotype%20refers%20to,in%20cannabis%20and%20other%20plants.&text=Chemotypic%20profiling%20of%20medicinal%20and,%2C%20sage%2C%20and%20many%20others> [<https://perma.cc/M3VA-57N9>] (“Chemotype is formally defined as ‘subspecies of a plant that have the same morphological characteristics (relating to form and structure) but produce different quantities of chemical components in their essential oils.’”).

an open-source repository at the National Center for Biotechnology Information.<sup>84</sup> Motivated in part by a progressive perspective on economic issues, the hope was that by making this prior art available to the Patent Office, large and well-resourced corporations (“Big Weed”) would be unable to monopolize the industry by securing overbroad patents of cannabis strains, and that small, independent, and individual farmers and producers would be able to search the repository for information on strains that were economical for them to produce.<sup>85</sup> Because the OCP would show cannabis strains that were naturally occurring or that were previously in use, these strains could not be patented.<sup>86</sup> Unfortunately, despite enthusiasm in the cannabis community, and several laboratories depositing their data in the OCP, it was dissolved on May 6, 2019, out of fear that its data would be used by large companies to create new cannabis strains.<sup>87</sup>

Despite the problems that arise because of lack of accessible, relevant, and cataloged prior art, obviousness does not present a particularly unique problem for marijuana patenting.

### C. UTILITY

Satisfying the utility requirement in this context could be more difficult than establishing novelty or obviousness. The statutory requirement of utility is found in § 101 and hinted at in § 112 of the Patent Act.<sup>88</sup> Section 101 states that “whoever invents or discovers any new and *useful* process, machine, manufacture, or composition of matter, or any new and *useful* improvement thereof,” is entitled to a patent.<sup>89</sup> Section 112 states that “the specification shall contain a written description of the invention, and of the manner and process of making and *using*

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<sup>84</sup> *Open Cannabis Project*, *supra* note 82.

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

<sup>86</sup> See 35 U.S.C. § 102; *Ass’n for Molecular Pathology v. Myriad Genetics, Inc.*, 569 U.S. 576, 589 (2013).

<sup>87</sup> Katie Shepherd, *Open Cannabis Project Dissolves in Response to Controversy Over Ag-Science Company Phyllos Bioscience’s Breeding Program*, WILLAMETTE WEEK (May 6, 2019, 12:48 PM), <https://www.wweek.com/news/business/2019/05/06/open-cannabis-project-dissolves-in-response-to-controversy-over-ag-science-company-phylos-biosciences-breeding-program/> [<https://perma.cc/N7CA-MP83>].

<sup>88</sup> 35 U.S.C. §§ 101, 112.

<sup>89</sup> 35 U.S.C. § 101 (emphasis added).

it.”<sup>90</sup> Accordingly, there is an overlap between the utility requirement of § 101 and the “how to use” requirement of § 112.<sup>91</sup> This statutory requirement comes from the language in the Constitution allowing Congress to provide patent protection for “useful arts.”<sup>92</sup>

To meet the utility requirement, an invention needs to be operable, beneficial, and substantial.<sup>93</sup> As to operability, an applicant must show the utility of the claimed invention with credible evidence of operability. An unbelievable, or “incredible” claim,<sup>94</sup> fails on both § 101 and § 112 grounds.<sup>95</sup> Section 101 failure indicates that the invention is not useful, while § 112 failure implies that the manner and process of using the invention is not sufficiently conveyed.<sup>96</sup> Because

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<sup>90</sup> 35 U.S.C. § 112 (emphasis added).

<sup>91</sup> Chisum, *supra* note 63, at § 4.04.

<sup>92</sup> U.S. CONST. art. I, § 8, cl. 8 (“The Congress shall have Power To lay and collect Taxes, Duties, Imposts and Excises, to pay the Debts and provide for the common Defence and general Welfare of the United States . . . To 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.”).

<sup>93</sup> See *Newman v. Quigg*, 877 F.2d 1575, 1581 (Fed. Cir. 1989) (stating “it is apparent that lack of utility because of inoperativeness, and absence of enablement, are closely related grounds of unpatentability”); *Lowell v. Lewis*, 15 F. Cas. 1018, 1019 (C.C.D. Mass. 1817) (stating “[t]he 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”); *In re Fisher*, 421 F.3d 1365, 1371 (Fed. Cir. 2005) (“[T]o satisfy the ‘substantial’ utility requirement, an asserted use must show that that claimed invention has a significant and presently available benefit to the public.”).

<sup>94</sup> *In re Citron*, 325 F.2d 248 (C.C.P.A. 1963) (stating that an incredible claim is claim that is unbelievable “in the light of the knowledge of the art, or [is] factually misleading”).

<sup>95</sup> See *id.*; *In re Ziegler*, 992 F.2d 1197, 1200–01 (Fed. Cir. 1993) (“The how to use prong of section 112 incorporates as matter of law the requirement of 35 U.S.C. § 101 that the specification disclose as a matter of fact a practical utility for the invention.”); see also *In re Fouche*, 439 F.2d 1237, 1243 (CCPA 1971) (stating that if “compositions are in fact useless, [a] specification cannot have taught how to use them”).

<sup>96</sup> See 35 U.S.C. §§ 101, 112.

situations in which claims are found “inoperable” are rare,<sup>97</sup> similar to § 102 and § 103 above, an applicant seeking a marijuana-related patent can presumably satisfy the operability aspect of the utility requirement with credible evidence by demonstrating that the invention actually works and is not a mere wonderful allegation.<sup>98</sup> For example, an applicant could claim a process of growing cannabis that yields a substantially higher CBD content.<sup>99</sup>

Establishing that an invention is beneficial may be more arduous. In the early nineteenth century, the court in *Lowell v. Lewis* held in an opinion by Justice Story that the utility requirement is satisfied as long as the invention has some beneficial use and is not “frivolous or injurious to the well-being, good policy, or sound morals of society.”<sup>100</sup> Marijuana-related inventions may not satisfy that requirement. As determined by the DEA, Schedule I drugs are “drugs with no currently accepted medical use and a high potential for abuse.”<sup>101</sup> Because

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<sup>97</sup> MPEP, *supra* note 73, § 2107 II.

<sup>98</sup> The Patent Office, for example, routinely rejects patent applications directed to perpetual motion machines because they claim to produce more energy than they consume which runs afoul of the law of conservation of energy and by extension the first law of thermodynamics. *See, e.g., Newman*, 877 F.2d at 1577.

<sup>99</sup> The Cannabis plant contains over 400 chemicals, including more than 60 cannabinoids. Zerrin Atakan, *Cannabis, a Complex Plant: Different Compounds and Different Effects on Individuals*, 2 THERAPEUTIC ADVANCES PSYCHOPHARMACOLOGY 241, 241. Cannabinoids refer to a class of compounds that act on cannabinoid receptors. *Id.* at 242. Generally, cannabinoids that originate in plants such as cannabis are called phytocannabinoids and include sativa hemp cannabidiol (CBD) and tetrahydrocannabinol (THC). *Id.* at 245. CBD and THC are the most common cannabinoids. *Id.* Cannabidiol or CBD is the second most prevalent active component of sativa plant (marijuana) that does not cause intoxication or euphoria. Peter Grinspoon, *Cannabidiol (CBD) — What We Know and What We Don't*, HARVARD HEALTH PUBL'G (Sept. 24, 2021), <https://www.health.harvard.edu/blog/cannabidiol-cbd-what-we-know-and-what-we-dont-2018082414476> [<https://perma.cc/X39Z-3P26>].

<sup>100</sup> *Lowell v. Lewis*, 15 F. Cas. 1018, 1019 (C.C.D. Mass. 1817).

<sup>101</sup> *Drug Scheduling*, U.S. DRUG ENF'T ADMIN. (July 10, 2018), <https://www.dea.gov/drug-information/drug-scheduling> [<https://perma.cc/373H-Y66S>] (stating “[t]he abuse rate is a determinate factor in the scheduling of the drug; for example, Schedule I drugs have a high potential for abuse and the potential to create severe psychological and/or physical dependence”).

marijuana is a Schedule I drug, at least some sectors of the U.S. government, therefore likely consider marijuana to be injurious to the well-being, good policy, or sound morals of society.<sup>102</sup>

Fortunately for marijuana-related patent applicants, the Supreme Court's mid-twentieth century decision in *Brenner v. Manson*<sup>103</sup> appeared to reject Justice Story's view of utility, stating that this definition "sheds little light on our subject."<sup>104</sup> Instead, the Supreme Court stated that

[t]he basic quid pro quo contemplated by the Constitution and the Congress for granting a patent monopoly is the benefit derived by the public from an invention with *substantial* utility. Unless and until a process is refined and developed to this point—where *specific* benefit exists in currently available form—there is insufficient justification for permitting an applicant to engross what may prove to be a broad field.<sup>105</sup>

This holding gave birth to the new utility requirements of specificity and substantiality. The Supreme Court, however, defined neither "specific" nor

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<sup>102</sup> Jason Blevins, *Pot Growers Cultivating in the Shadows Seek U.S. Patent Protection*, DENVER POST (Dec. 19, 2014, 12:57 PM), <https://www.denverpost.com/2014/12/19/pot-growers-cultivating-in-the-shadows-seek-u-s-patent-protection/> [<https://perma.cc/8DVN-E785>] ("The U.S. Patent and Trademark Office has rejected cannabis-related patents consistently, arguing that the invention is "immoral and scandalous" because marijuana is illegal or that the invention has no useful purpose because its use violates federal drug law."). In contrast, neither an FDA, nor a DEA approval, however, is necessary for finding a compound useful within the meaning of the patent laws. See *Scott v. Finney*, 34 F.3d 1058, 1063 (Fed. Cir. 1994) (holding that testing necessary to show adequate utility for invention to be patentable is much less stringent than testing necessary to demonstrate full safety and effectiveness of the invention to FDA). This is evident from the fact that marijuana-related patents were issued long before the FDA's endorsement of the benefits of marijuana in treating Lennox-Gastaut syndrome and Dravet syndrome, or de-scheduling of the CBD from the CSA, or the legalization of industrial hemp. See '669 Patent.

<sup>103</sup> *Brenner v. Manson*, 383 U.S. 519, 532–33 (1966).

<sup>104</sup> *Id.*; see also MPEP, *supra* note 73, § 2107 II (providing guidelines for examination of applications for compliance with the utility requirement no longer references *Lowell*).

<sup>105</sup> *Brenner*, 383 U.S. at 534–35 (emphasis added).

“substantial.”<sup>106</sup> Indeed, the Patent Office’s Manual of Patent Examining Procedure (“MPEP”) providing guidelines for examination of applications for compliance with the utility requirement does not reference *Lowell* at all.<sup>107</sup> Instead, it instruct the examiners that

[d]eficiencies under the ‘useful invention’ requirement of 35 U.S.C. § 101 will arise in one of two forms. The first is where it is not apparent why the invention is ‘useful.’ This can occur when an applicant fails to identify any specific and substantial utility for the invention or fails to disclose enough information about the invention to make its usefulness immediately apparent to those familiar with the technological field of the invention. . . . The second type of deficiency arises in the rare instance where an assertion of specific and substantial utility for the invention made by an applicant is not credible.<sup>108</sup>

Nearly four decades later, the Federal Circuit elaborated on the specificity requirement, stating that to satisfy specificity, “an application must disclose a use which is not so vague as to be meaningless.”<sup>109</sup> Furthermore, the Court reaffirmed the holding below of the Court of Customs and Patent Appeals that “to satisfy the ‘substantial’ utility requirement, an asserted use must show that that claimed invention has a significant and presently available benefit to the public.”<sup>110</sup> Accordingly, not only must an applicant show that their marijuana-related application is directed toward a meaningful end use, but they must also demonstrate that their claimed invention has a presently available benefit to the public.<sup>111</sup>

Unfortunately for such applicants, and despite the efforts of the pro-marijuana community in establishing the benefits of marijuana use for pain

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<sup>106</sup> *See id.*

<sup>107</sup> MPEP, *supra* note 73, § 2107.

<sup>108</sup> *Id.* § 2107.01 (citations omitted).

<sup>109</sup> *In re Fisher*, 421 F.3d 1365, 1371 (Fed. Cir. 2005).

<sup>110</sup> *Id.* at 1371 (citing *Nelson v. Bowler*, 626 F.2d 853, 856 (C.C.P.A. 1980)).

<sup>111</sup> Dawson Hahn, *That is Northern Lights Cannabis Indica . . . No, It’s Marijuana: Navigating Through the Haze of Cannabis and Patents*, 4 CONCORDIA L. REV. 254, 259 (2019) (“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.”).



management, for treatment of epilepsy and multiple sclerosis, and for relief from anxiety, stress, and depression, the federal government for the most part remains unpersuaded, at least as far as the DEA is concerned.<sup>112</sup> Yet, on June 25, 2018, the FDA approved Epidiolex, the first approved drug comprising an active ingredient derived from marijuana to treat rare and severe forms of epilepsy—Lennox-Gastaut syndrome and Dravet syndrome—and for tuberous sclerosis complex.<sup>113</sup> On September 28, 2018, the DEA classified Epidiolex in Schedule V, the first extract of the cannabis plant to be placed in a less stringent schedule than Schedule I.<sup>114</sup> Nearly two years later, on April 6, 2020, GW Pharmaceuticals revealed that the company had received notice from the DEA stating that the Epidiolex was no longer subject to the requirement of the CSA.<sup>115</sup>

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<sup>112</sup> Denial of Petition to Initiate Proceedings to Reschedule Marijuana, 81 Fed. Reg. 53688, 53689 (Aug. 12, 2016) (stating that the DEA and HHS concluded that “[m]arijuana meets the three criteria for placing a substance in Schedule I of the CSA under 21 U.S.C. 812(b)(1)” as it “has a high potential for abuse, no currently accepted medical use in treatment in the United States, and a lack of accepted safety for use under medical supervision”); Salomeh Keyhani et al., *Risks and Benefits of Marijuana Use: A National Survey of U.S. Adults*, 169 ANNALS INTERNAL MED. 282, 284–88 (2018) (illustrating the benefits of marijuana use for management of pain and treatment of disorders or conditions).

<sup>113</sup> *FDA Approves First Drug Comprised of an Active Ingredient Derived from Marijuana to Treat Rare, Severe Forms of Epilepsy*, U.S. FOOD & DRUG ADMIN. (June 25, 2018), <https://www.fda.gov/news-events/press-announcements/fda-approves-first-drug-comprised-active-ingredient-derived-marijuana-treat-rare-severe-forms#:~:text=The%20U.S.%20Food%20and%20Drug,years%20of%20age%20and%20older> [https://perma.cc/3H4K-SHLF]. Synthetic forms of marijuana have been approved by the FDA over the last 35 years. See *FDA and Cannabis: Research and Drug Approval Process*, *supra* note 30. Dronabinol, marketed under the brands Marinol and Syndros, was approved in 1985 and is currently classified in Schedule III. *Id.* The oral synthetic cannabinoid Nabilone was approved as a Schedule II drug in 1987 and is marketed under the name Casamet. *Id.*; see also ‘669 Patent.

<sup>114</sup> Schedules of Controlled Substances: Placement in Schedule V of Certain FDA-Approved Drugs Containing Cannabidiol, 83 Fed. Reg. 48950 (Sept. 28, 2018) (to be codified at 21 C.F.R. pt. 1308, 1312).

<sup>115</sup> Alexis Barnes, *DEA Removes CBD from Controlled Substances Act*, JD SUPRA (Apr. 16, 2020), <https://www.jdsupra.com/legalnews/dea-removes-cbd-from-controlled-71065/> [https://perma.cc/VG8D-C9RY].

On December 20, 2018, President Trump signed into law the 2018 Farm Bill, which legalized industrial hemp.<sup>116</sup> This act essentially modifies the definition of marijuana presented in Section 802 of the CSA to allow for production of non-intoxicating strains of marijuana.<sup>117</sup> As a result, the FDA released a Draft Guidance for Industry outlining FDA's current thinking on cannabis and cannabis-related compounds.<sup>118</sup> This guidance generally clarifies that cannabis below 0.3 percent THC does not need to be sourced from the federal government and provides a list of sources that should be consulted.<sup>119</sup> These advances appear to be contrary to the DEA's view that marijuana has no currently accepted medical use. Thus, at least from the perspective of these sectors of the U.S. government, marijuana inventions could meet the substantiality requirement and satisfy the utility requirement. Accordingly, a dichotomy appears to exist between different sectors of the U.S.

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<sup>116</sup> See Agriculture Improvement Act of 2018, Pub. L. No. 115-334, § 10113, 132 Stat. 4490. See also Agriculture Improvement Act § 297A(1) (defining hemp as, "the plant *Cannabis sativa* L. and any part of that plant, including the seeds thereof and all derivatives, extracts, cannabinoids, isomers, acids, salts, and salts of isomers, whether growing or not, with a delta-9 tetrahydrocannabinol concentration of not more than 0.3 percent on a dry weight basis").

<sup>117</sup> 21 U.S.C. § 802 states:

the term 'marihuana' means all parts of the plant *Cannabis sativa* L., whether growing or not; the seeds thereof; the resin extracted from any part of such plant; and every compound, manufacture, salt, derivative, mixture, or preparation of such plant, its seeds or resin . . . . The term 'marihuana' does not include . . . the mature stalks of such plant, fiber produced from such stalks, oil or cake made from the seeds of such plant, any other compound, manufacture, salt, derivative, mixture, or preparation of such mature stalks (except the resin extracted therefrom), fiber, oil, or cake, or the sterilized seed of such plant which is incapable of germination.

<sup>118</sup> See *Cannabis and Cannabis-Derived Compounds: Quality Considerations for Clinical Research*, U.S. FOOD & DRUG ADMIN. (July 21, 2020), <https://www.fda.gov/regulatory-information/search-fda-guidance-documents/cannabis-and-cannabis-derived-compounds-quality-considerations-clinical-research-guidance-industry> [<https://perma.cc/GPH8-BBU6>] ("outlin[ing the] FDA's current thinking on several topics relevant to the development of cannabis and cannabis-derived products").

<sup>119</sup> *Id.* at 3–4.

government. From the perspective of some, marijuana-inventions could meet the utility requirement while from the perspective of others they could not.

Looking inside the Patent Office fares no better. In the Patent Office, examiners are directed to “not impose a rejection based on lack of utility” if “the claimed invention has a well-established utility.”<sup>120</sup> Furthermore, the patent application examination guidelines, which are used by the patent examiners to evaluate patentability of an invention, state that

[a]n invention has a well-established utility if (i) a person of ordinary skill in the art would immediately appreciate why the invention is useful based on the characteristics of the invention (e.g., properties or applications of a product or process), and (ii) the utility is specific, substantial, and credible.<sup>121</sup>

These instructions are largely circular in shedding a light on how applicants establish substantiality as substantiality, itself, is a part of the definition used in showing that the invention has a well-established utility.<sup>122</sup> Thus, it is unclear whose perspective matters. Does marijuana have a presently available benefit to the public?

Applicants have, at least presumably, demonstrated the substantiality of their invention since the Patent Office has granted marijuana-related patents.<sup>123</sup> So how do the applicants establish the utility of their marijuana-related invention? There are two possible explanations. First, since the USPTO has the initial burden of challenging utility a patent applicant can avoid having to establish utility unless a patent examiner rejects the claims for lack of utility as the USPTO has the initial

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<sup>120</sup> MPEP, *supra* note 73, § 2107.

<sup>121</sup> *Id.*

<sup>122</sup> *See id.* (discussing recursively that “specific and substantial utility” is not “insubstantial,” or “nonspecific”).

<sup>123</sup> Smoking Device for Smoking Through a Liquid, U.S. Patent No. 8,905,038 (issued Dec. 9, 2014) (“The invention provides a portable hookah for smoking a smokable substance such as tobacco or medical marijuana.”); Methods for Preparing Cannabis and Related Products, U.S. Patent No. 8,753,696 (issued June 17, 2014) (“A method for preparing a medical marijuana mixture includes combining prepared medical marijuana and an alkaline substance in a pulverizing device.”). Notably, neither of these patents were objected to on the ground of lack of utility.

burden of challenging utility.<sup>124</sup> Second, marijuana's placebo effect associated with consumption may be sufficient to satisfy utility.<sup>125</sup>

First, in a relatively recent case, *In re Brana*, the Federal Circuit held that the Patent Office has the initial burden of challenging a presumptively correct assertion of utility by alleging that a person of ordinary skill in the art would reasonably doubt the asserted utility.<sup>126</sup> If the Patent Office meets this requirement, then the burden shifts back to the applicant to prove utility.<sup>127</sup>

Placing the initial burden on the Patent Office, instead of the applicant is perhaps the reason why applicants are able to prove—or rather avoid proving utility. After all, a significant body of literature, and a fair amount of media coverage, exists that conclude through medical evidence that marijuana is effective for treatment of chronic pain or treatment of nausea associated with chemotherapy.<sup>128</sup> But, notably, in comparison with the pharmaceutical industry, clinical data derived from studies of cannabinoid therapies are scarce. This scarcity is potentially the result of difficulties associated with obtaining the necessary

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<sup>124</sup> *In re Brana*, 51 F.3d 1560, 1566 (Fed. Cir. 1995).

<sup>125</sup> See *Juicy Whip, Inc. v. Orange Bang, Inc.*, 185 F.3d 1364, 1368 (Fed. Cir. 1999) (“Until such time as Congress [declares deceptive inventions unpatentable], we find no basis in section 101 to hold that inventions can be ruled unpatentable for lack of utility simply because they have the capacity to fool some members of the public.”). See generally Rebecca S. Eisenberg & Robert P. Merges, *Opinion Letter as to the Patentability of Certain Inventions Associated with the Identification of Partial cDNA Sequences*, 23 AIPLA Q.J. 1 (1995) (providing a comprehensive analysis of the PTO and Courts’ interpretation of pharmaceutical patents’ utility).

<sup>126</sup> *In re Brana*, 51 F.3d at 1566.

<sup>127</sup> *Id.* (“[O]nly after the PTO provides evidence showing that one of ordinary skill in the art would reasonably doubt the asserted utility does the burden shift to the applicant to provide rebuttal evidence sufficient to convince such a person of the invention's asserted utility.”).

<sup>128</sup> Donald I. Abrams, *The Therapeutic Effects of Cannabis and Cannabinoids: An Update from the National Academies of Sciences, Engineering and Medicine Report*, 49 EUR. J. INTERNAL MED. 7, 7–9 (2018) (referring to the National Academies of Sciences, Engineering and Medicine comprehensive review of medical literature on the health effects of cannabis and cannabinoids and concluding that “there was conclusive and substantial evidence that *Cannabis* or cannabinoids are effective for the treatment of pain in adults; chemotherapy-induced nausea and vomiting and spasticity associated with multiple sclerosis”).

permission.<sup>129</sup> Nevertheless, an examiner, reviewing the patent application through the lens of a person of ordinary skill in the art and adopting the examination guidelines discussed above, could be sufficiently convinced that the invention under review is useful and never shift the burden back to the applicant.<sup>130</sup> This process may make the patent examination process pertaining to marijuana-related inventions more subjective than other inventions. In other words, it would be up to each examiner to accept or reject an applicant's assertion that a claimed invention has utility.<sup>131</sup>

Alternatively, another explanation for historical grant of marijuana-related patents may be from the notion that even placebo effects associated with marijuana consumption may satisfy both the specificity and the substantiality requirements regardless of actual effects.<sup>132</sup> This theory is based on the Federal Circuit's decision in *Juicy Whip v. Orange Bang, Inc.*, holding that "[t]he fact that one product can be altered to make it look like another is in itself a specific benefit sufficient to satisfy the statutory requirement of utility," for the purpose of patentability.<sup>133</sup> Hence, it follows that, even absent actual medical benefits, the placebo effect of marijuana consumption could satisfy the utility requirement if the consuming public believe its implicit or explicit intended purpose.

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<sup>129</sup> See 21 C.F.R. § 1301.18 (2021) (detailing the requirements for research protocols for Schedule I drugs).

<sup>130</sup> See NAT'L ACADEMIES OF SCI., ENG'G, AND MEDICINE, *supra* note 28, at 1–9, 25–28 (summarizing and describing the background of the National Academy's research data, recommendations, and methodology, and noting the potential breadth of health benefits and hazards of medicinal cannabis use).

<sup>131</sup> In fact, the patent examination guidelines state:

practical considerations require the Office to rely on the inventor's understanding of the invention in determining whether and in what regard an invention is believed to be 'useful.' Because of this, Office personnel should focus on and be receptive to assertions made by the applicant that an invention is 'useful' for a particular reason.

MPEP, *supra* note 73, § 2107.

<sup>132</sup> See *Juicy Whip, Inc. v. Orange Bang, Inc.*, 185 F.3d 1364, 1368 (Fed. Cir. 1999) ("Until such time as Congress [declares deceptive inventions unpatentable], we find no basis in section 101 to hold that inventions can be ruled unpatentable for lack of utility simply because they have the capacity to fool some members of the public.").

<sup>133</sup> *Id.* at 1367.

Another avenue for acquiring patent protection is a plant patent granted under the Plant Patent Act of 1930.<sup>134</sup> The Plant Patent Act allows asexually propagated species of plants that are clearly distinguishable from other varieties to receive patent protection.<sup>135</sup> This federal legislation could inform applicants' approach to securing marijuana-related patents by characterizing and claiming asexually reproduced plants.<sup>136</sup> In fact, it appears that until recently, growers seemingly used plant patents more frequently than utility patents.<sup>137</sup> Even though plant patents offer similar protection to patentees as utility patents, i.e., preventing others from making (reproducing), using, offering to sell, or selling asexually reproduced plants for a period of twenty years, plant patents are limited to a single claim.<sup>138</sup> Since claims are the part of patents that define the boundaries of an invention, having a single claim is potentially narrower than having multiple claims. Additionally, and more importantly, to prove infringement, a patentee must prove that the alleged infringer asexually reproduced the plant, which may be very difficult.<sup>139</sup> Since plant patents provide the applicants with a very narrow protection, this Article focuses on utility patents, which allow applicants to gain broader protection.<sup>140</sup>

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<sup>134</sup> 35 U.S.C. §§ 161–164.

<sup>135</sup> *Id.* (“Asexually propagated plants are those that are reproduced by means other than from seeds, such as by the rooting of cuttings, by layering, budding, grafting, inarching, etc.”); MPEP, *supra* note 73, § 1601.

<sup>136</sup> *See* Imazio Nursery, Inc. v. Dania Greenhouse, 69 F.3d 1560, 1563–64 (Fed. Cir. 1995) (describing the requirements of an asexually propagated plant patent claim).

<sup>137</sup> *See* Brett Schuman et al., *Emerging Patent Issues in The Cannabis Industry*, LAW360 (Feb. 20, 2018), <https://www.law360.com/articles/1013575/emerging-patent-issues-in-the-cannabis-industry> [<https://perma.cc/L77W-DKKR>] (noting that the first cannabis utility patent was only issued in 2015); Natali De Corso, *Obtaining Marijuana Patents*, B.C. INTELL. PROP. & TECH. F. 6 (Jan. 16, 2018).

<sup>138</sup> Schuman et al., *supra* note 137. *See, e.g.*, Cannabis Plant Named ‘Ecuadorian Sativa’, U.S. Patent No. PP27475 (filed Mar.13, 2010) (issued Dec. 20, 2016) (claiming “[a] new and distinct cultivar of ‘Cannabis’ Plant as shown and described”); Blevins, *supra* note 102.

<sup>139</sup> *See* J.E.M. Ag Supply, Inc. v. Pioneer Hi-Bred Int’l, Inc., 534 U.S. 124, 133 (2001) (“Plant patents under the PPA . . . have very limited coverage and less stringent requirements than § 101 utility patents.”).

<sup>140</sup> *See id.*; Ann K. Wooster, Annotation, *Construction and Application of Plant Patent Act*, 35 U.S.C.A. §§ 161 *et seq.*, 135 A.L.R. Fed. 273 (1996). Similarly,

The reason for this delayed paradigm shift in applicants' approach, i.e., using utility patents instead of plant patents, could be directly attributed to patentable subject matter analysis below, and is perhaps the result of the Supreme Court's decision in *Diamond v. Chakrabarty* holding that genetically modified live organisms are patent-eligible as "manufactures" thereby expressly opening the gates for applicants to seek utility patents instead of plant patents.<sup>141</sup>

In summary, lack of uniformity between government sectors makes it unclear whose perspective matters when it comes to the usefulness of marijuana. While operability and substantial utility do not appear to pose any particular problems for marijuana-related inventions, there are interesting and unanswered questions regarding the beneficial aspect of the utility requirement for applicants seeking to protect marijuana-related inventions.<sup>142</sup>

#### D. PATENTABLE SUBJECT MATTER

Contrary to the often-recited phrase that patentable subject matter may include "anything under the sun that is made by man,"<sup>143</sup> to be patent-eligible an invention must be directed to one of the four statutory categories: "process, machine, manufacture, or composition of matter."<sup>144</sup> While seemingly straightforward on its face, patent eligibility is often a topic of ongoing controversy because of judicial exceptions to patentability.<sup>145</sup> Simply put, these judicial

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because protection for plants patented under the Plant Variety Protection Act comes from the Department of Agriculture instead of the USPTO this article does not address such patents. *See also* Joseph Dylan Summer, *Patenting Marijuana Strains: Baking up Patent Protection for Growers in the Legal Fog of This Budding Industry*, 23 J. INTELL. PROP. L. 169, 187, 189–90, 192–94, 203, 208 (2015) (elaborating on three different paths to gaining patent or patent-like protections using utility patents, PPA patents, or PVPA protections).

<sup>141</sup> *Diamond v. Chakrabarty*, 447 U.S. 303, 309–10 (1980).

<sup>142</sup> Manuela Cabal Carmona, *Dude, Where's My Patent: Illegality, Morality, and the Patentability of Marijuana*, 51 VAL. U.L. REV. 651, 673–84 (2017) (discussing the relationship between marijuana's illegality and its patentability).

<sup>143</sup> *Patent Law Codification and Revision: Hearing on H.R. 3760 Before the Subcomm. No. 3 of the H. Comm. on the Judiciary*, 82d Cong. 37 (1951).

<sup>144</sup> 35 U.S.C. § 101. For a general discussion of this topic, see Alan J. Gocha, *Avoiding the Rabbit Hole: An Ontological Model For Determining Section 101 Patent-Eligibility Under Alice*, 17 J. MARSHALL REV. INTELL. PROP. L. 192 (2017).

<sup>145</sup> *See* Dani Kass, *Fed. Circ. Judge Rebukes Panel for Alice Ax of Camera Patent*, LAW360 (June 11, 2021, 4:37 PM), <https://www.law360.com/articles/>

exceptions posit that an invention cannot be directed to laws of nature, natural phenomena, and abstract idea unless it includes some other inventive concept that amounts to significantly more than the judicial exception.<sup>146</sup> Stated in another way, an applicant is not entitled to a monopoly if the claimed invention is no more than recitation of a law of nature, natural phenomena, or an abstract idea—some other inventive concept is needed to bring the invention as a whole under the umbrella of patentable subject matter.

Some subject matter, for example inventions related to atomic energy or nuclear material, is precluded from patentability by statute.<sup>147</sup> But nowhere does the patentable subject matter provision of the Patent Act adopt a categorical ban

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1393248/fed-circ-judge-rebukes-panel-for-alice-ax-of-camera-patent [https://perma.cc/3PQS-DBR6] (discussing a recent Federal Circuit decision where the panel was split on the interpretation of § 101, with the majority finding the claim at issue was abstract and the dissent claiming the majority was “conflating patent eligibility and novelty”). Press Release, Thom Tillis, U.S. Sen. for North Carolina, Tillis Introduces Landmark Legislation to Restore American Innovation (Aug. 3, 2022), <https://www.tillis.senate.gov/2022/8/tillis-introduces-landmark-legislation-to-restore-american-innovation> [https://perma.cc/P783-BELE] (explaining that an Act has recently been proposed to address at least some of the ongoing controversy around patent eligibility).

<sup>146</sup> See, e.g., *Alice Corp. Pty. Ltd. v. CLS Bank Int'l*, 573 U.S. 208, 216, 218–21 (2014) (applying the *Mayo* two-step framework to abstract ideas, finding the concept of intermediated settlement was an abstract idea); *Ass'n for Molecular Pathology v. Myriad Genetics, Inc.*, 569 U.S. 576, 589, 591, 594–95 (2013) (finding the discovery and isolation of naturally occurring DNA was not patent eligible because even “[g]roundbreaking, innovative, or brilliant discovery does not by itself satisfy the § 101 inquiry,” while cDNA was patent eligible because it is not naturally occurring); *Mayo Collaborative Servs. v. Prometheus Lab’y, Inc.*, 566 U.S. 66, 70–73, 78–79 (2012) (holding a patent embodying a law of nature is unpatentable unless there is an additional feature, an inventive step, that is not well-understood, routine, and conventional to ensure the patent does not merely recite laws of nature); *Bilski v. Kappos*, 561 U.S. 593, 601–611 (2010) (explaining method claims for the concept of hedging risk in the energy markets was an abstract idea because it was a basic economic principle simply reduced to a mathematical formula).

<sup>147</sup> See 42 U.S.C. § 2181 (under the Atomic Energy Act of 1954, no patent shall be “granted for any invention or discovery which is useful solely in the utilization of special nuclear material or atomic energy in an atomic weapon”).



on illegal substances. Any such concern has historically been addressed through the utility requirement of the Patent Act as discussed above.<sup>148</sup> For example, in 1889, an Illinois court in *National Automatic Device Co. v. Lloyd*, held that a patent on a Toy Automatic Race-Course commonly used in bars for gambling was unpatentable because “it [was] not a useful device, within the meaning of the patent law, as its use so far has been only pernicious and hurtful.”<sup>149</sup> Similarly, in 1897, a California court in *Schultze v. Holtz*, held that a patent for a coin-operated device applied for gambling purposes was invalid where the inventor’s claimed utility was “the telling of a fortune, which may be effected by means of a prepared list of statements corresponding to the various positions of the indicating disk.”<sup>150</sup>

Nor does the MPEP, which provides patent examiners and patent attorneys with guidance regarding the Patent Office’s practice and procedure, take a position on whether illegal innovations are patentable.<sup>151</sup> This stance is contrary to the European Union Guidelines for Patent Examination, which provide that “[a]ny invention the commercial exploitation of which would be contrary to ‘*ordre public*’ or morality is specifically excluded from patentability.”<sup>152</sup> Yet Subsection (1) of the European Union guidelines provides that “[e]xploitation is not to be deemed to be contrary to ‘*ordre public*’ or morality merely because it is prohibited by law or regulation in some or all of the contracting states.”<sup>153</sup> This provision continues to state that “[o]ne reason for this is that a product could still be manufactured under a European patent for export to states in which its use is not prohibited.”<sup>154</sup> Accordingly, the United States’ justification for not prohibiting the patenting of illegal substances altogether could be similar to its European counterpart allowing patentability of illegal substances for use in countries in which the

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- <sup>148</sup> See *supra* Section II.C (explaining the utility requirement and potential hurdles applicants face when demonstrating the usefulness of marijuana-related inventions).
- <sup>149</sup> *Nat’l Automatic Device Co. v. Lloyd*, 40 F. 89, 90 (C.C.N.D. Ill. 1889).
- <sup>150</sup> *Schultze v. Holtz*, 82 F. 448, 449 (C.C.N.D. Cal. 1897).
- <sup>151</sup> See MPEP, *supra* note 73, §§ 2106–2107 (providing guidance on patent eligibility and utility without reference to the patent eligibility or utility of either marijuana or illegal substances).
- <sup>152</sup> EUR. PAT. OFF., GUIDELINES FOR EXAMINATION IN THE EUROPEAN PATENT OFFICE, pt. G, ch. II, art. 4.1 (2022).
- <sup>153</sup> *Id.* art. 4.1.1.
- <sup>154</sup> *Id.*

use is not prohibited. Yet, unlike the European Union, U.S. patent law is federal law and covers all places in which the patent is valid.<sup>155</sup>

Regardless, the patentable subject matter requirement does not appear to pose any unique problems for patenting marijuana-related inventions.

### III. ILLEGALITY AS AN IMPEDIMENT TO PATENTABILITY

There are several reasons why illegality may not be an impediment to patentability. These reasons apply especially in the case of marijuana.

First, as explained earlier, marijuana has been legalized for at least medical purposes in the majority of states in the nation.<sup>156</sup> Thus, it is difficult to maintain that marijuana is uniformly illegal in the United States. Theoretically, the federal prohibition is not in practical effect, except in certain areas, such as large scale, surreptitious growing and trafficking of marijuana.<sup>157</sup> Law enforcement in the United States is primarily an affair of the states.<sup>158</sup> It is estimated that of every 100 arrests that are made for marijuana crimes, ninety-nine are made by state officials and one by federal officials.<sup>159</sup>

Second, even the federal prohibition has itself become unstable to a large extent. Although marijuana's status on Schedule I is largely unchanged, federal action has substantially weakened the prohibition. In a series of memoranda promulgated from 2009 to 2014, the Department of Justice ("DOJ") announced that DOJ has certain enforcement priorities, and that outside of those priorities the federal government usually relies on local law enforcement to enforce their own local marijuana laws. It would not enforce the CSA's prohibition against marijuana if certain conditions are met.<sup>160</sup> Although Attorney General Jeff Sessions rescinded

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<sup>155</sup> See *id.* General Part 4 ("These Guidelines provide guidance in respect of the practice in proceedings before the [European Patent Office] in accordance with the European Patent Convention and its Implementing Regulations.").

<sup>156</sup> See Leins et al., *supra* note 5.

<sup>157</sup> See LISA N. SACCO, CONG. RSCH. SERV., R43749, DRUG ENFORCEMENT IN THE UNITED STATES: HISTORY, POLICY, AND TRENDS 14–15 (2014).

<sup>158</sup> *Id.* at 21 ("Most drug arrests are made by state and local law enforcement . . .").

<sup>159</sup> See MICH. COMP. LAWS § 333.26424 (2008) (referring to data from the Federal Bureau of Investigation Uniform Crime Reports and the Compendium of Federal Justice Statistics).

<sup>160</sup> See OSBECK & BROMBERG, *supra* note 10, at 152–58. In a 2013 memorandum, the Justice Department announced that it would not enforce the prohibition against marijuana in states that decriminalized its use so as long as the states

these memoranda on January 4, 2018, this rescission seems to have made no practical difference.<sup>161</sup> In fact, William Barr, who succeeded Sessions as U.S. Attorney General from 2019 to 2020, pledged in writing to the Senate that he “[did] not intend to go after parties who have complied with state law in reliance on the [prior DOJ] Memorandum.”<sup>162</sup> In the years since, the DOJ seems to be operating under the guidelines set out in the Obama Administration memoranda, which basically recognizes the legality of marijuana according to state law.<sup>163</sup> Under the Amendment, the DOJ is prohibited from using any of its funding to interfere with state laws authorizing the use, distribution, possession, or cultivation of medical marijuana.<sup>164</sup>

Third, it does not seem correct to describe marijuana use as illegal *per se*, in the same sense as acts such as arson or larceny. The CSA is essentially a public health measure, creating a comprehensive, closed system for regulating, distributing, and monitoring drugs.<sup>165</sup> The strictness of the controls is determined

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do not allow marijuana use that violates federal priorities. The memorandum lists eight federal enforcement priorities to guide the states: (1) preventing distribution of marijuana to minors, (2) preventing revenue from sale of marijuana going to criminal enterprises, (3) preventing diversion of marijuana from states where it is legal to other states, (4) preventing marijuana activity from being used as a cover for trafficking of illegal drugs, (5) preventing violence and the use of firearms in marijuana activity, (6) preventing marijuana driving and other adverse public health consequences, (7) preventing growing of marijuana on public lands, and (8) preventing marijuana possession and use on federal property. So long as states have adequate measures to prevent those eight outcomes, the Justice Department indicates that it will not interfere with state legalization of marijuana. Memorandum from James M. Cole, Deputy Att’y Gen., U.S. Dept. of Just., for All U.S. Att’ys (Aug. 29, 2013), <http://www.justice.gov/iso/opa/resources/3052013829132756857467.pdf> [<https://perma.cc/RLG5-GXPG>].

<sup>161</sup> See Memorandum from Jefferson B. Sessions, III, Att’y Gen., U.S. Dept. of Just., for All U.S. Att’ys (Jan. 4, 2018), <https://www.justice.gov/opa/pr/justice-department-issues-memo-marijuana-enforcement> [<https://perma.cc/2W35-CQ4A>]; OSBECK & BROMBERG, *supra* note 10, at 170.

<sup>162</sup> See Responses to Questions for the Record from William P. Barr, Nominee to Be U.S. Att’y Gen., to Sen. Cory Booker 217 (Jan. 27, 2019), <https://www.judiciary.senate.gov/download/01/28/2019/barr-responses-to-booker-questions-for-the-record> [<https://perma.cc/3DHS-2EFZ>].

<sup>163</sup> See Memorandum from James M. Cole, *supra* note 160, at 1–2.

<sup>164</sup> See 161 CONG. REC. H3745 (daily ed. June 2, 2015).

<sup>165</sup> See OSBECK & BROMBERG, *supra* note 10, at 74.

by a drug's classification on the CSA's five schedules.<sup>166</sup> Likewise, the DEA combines administrative and enforcement functions, in that its duties are related both to public health, in determining the scheduling of drugs, and in law enforcement, in monitoring drug distribution and violations thereof.<sup>167</sup> Public health concerns have always created exceptions to the marijuana classification on Schedule I.<sup>168</sup> Certainly, researchers have been able to make use of marijuana in controlled clinical trials, however difficult DEA registration has been to obtain.<sup>169</sup> In addition, since 1978, under the NIDA's single patient compassionate use Investigational New Drug Applications ("IND") program, the federal government has supplied marijuana to a limited number of patients to treat medical conditions.<sup>170</sup> This is not to deny that use of marijuana is generally a crime under federal law, punishable by severe penalties, but it does suggest that under the modern marijuana regime in the various jurisdictions of the United States, a strict application of the illegality doctrine, even if applicable in general patent law, would be unsuited for marijuana patents.

Even if marijuana were to be considered as strictly illegal, it should be noted that the absence of limitations on the patentability of immoral or illegal subjects in the United States is not unusual. In fact, the United States has adopted a similar approach in both copyright law and trademark law. For example, buying and selling sex is illegal in most states, yet when sex-for-hire is fixed in a tangible medium of expression, it is protected by copyright law.<sup>171</sup>

Trademarks are also similar. Section 2(a) of the Lanham Act states in part that no trademark shall be refused registration on the principle register unless it "consists of or comprises immoral, deceptive, or scandalous matter; or matter which may disparage or falsely suggest a connection with persons, living or dead, institutions, beliefs, or national symbols, or bring them into contempt, or disrepute."<sup>172</sup> Yet, the Supreme Court in *Matal v. Tam* held that the prohibition on

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<sup>166</sup> See *id.* at 79.

<sup>167</sup> See *id.* at 74, 88, 90.

<sup>168</sup> See *id.* at 89, 140–50.

<sup>169</sup> See *id.* at 88, 109, 111.

<sup>170</sup> See *FDA and Cannabis: Research and Drug Approval Process*, *supra* note 30. BLANCHARD RANDALL IV, CONG. RSCH. SERV., RL30274, MEDICAL USE OF MARIJUANA: POLICY AND REGULATORY ISSUES 22–23 (2002).

<sup>171</sup> See Ann Bartow, *Copyright Law and Pornography*, 91 OR. L. REV. 1, 3 (2012).

<sup>172</sup> See 15 U.S.C. § 1052.

registering trademarks that may “disparage” violates the First Amendment.<sup>173</sup> Following in the footsteps of *Matal*,<sup>174</sup> the Supreme Court in *Iancu v. Brunetti* held that the neighboring “immoral or scandalous” provision of Section 2(a) similarly violates the First Amendment.<sup>175</sup> Specifically, the Court stated that the discrimination of this provision—disfavoring certain ideas—violates the First Amendment.<sup>176</sup> Notably, trademark owners for cannabis and cannabis-related products faced a different problem than immorality for registering their marks. Specifically, they failed to establish use of the mark in commerce because any use of the mark in commerce must be lawful under the federal law to be the basis for federal registration.<sup>177</sup> Inability to legally use a mark in commerce disqualifies an applicant from securing the protection of the Lanham Act.<sup>178</sup>

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<sup>173</sup> See *Matal v. Tam*, 137 S. Ct. 1744, 1748 (2017).

<sup>174</sup> *Brunetti* was pending in front of the Federal Circuit when the decision for *Matal* was entered. *Id.* The case concerned USPTO’s refusal to register “FUCT” because it deemed it immoral or consisting of scandalous matter. See *In re Brunetti*, Serial No. 85310960 at \*5 (T.T.A.B. 2014) (holding that “from the dictionary definitions of record,” the various meanings of the proposed mark were “vulgar terms” whether “in the context of extreme misogyny, nihilism or violence,” and thus “extremely offensive terms” not capable of registration).

<sup>175</sup> *Iancu v. Brunetti*, 139 S. Ct. 2294, 2302 (2019).

<sup>176</sup> See *id.* at 2302.

<sup>177</sup> Viva R. Moffat et al., *Cannabis, Consumers, and the Trademark Laundering Trap*, 63 WM. & MARY L. REV. 1939, 1966 (2022). In 2010, USPTO created a new trademark category for “processed plant material for medicinal purposes, namely medical marijuana.” Within three months however USPTO abrogated this category, instead instructing its attorneys reviewing patent applications to ask applicants whether the goods or services at issue in the application violated the Controlled Substances Act (“CSA”). See De Corso, *supra* note 137, at 4; see *In re Stanley Bros. Soc. Enter., LLC*, Serial No. 86568478 at \*9 (T.T.A.B. 2020) (refusing to register a mark for a cannabis-derived dietary supplement).

<sup>178</sup> See TRADEMARK MANUAL OF EXAMINING PROCEDURE § 907 (July 2021). The 2018 Farm Bill and legalization of hemp eliminated this problem for application filed on or after December 20, 2018, that identify goods encompassing cannabis or CBD, “but *only* if the goods are derived from ‘hemp’.” See USPTO, EXAMINATION GUIDE 1-19 EXAMINATION OF MARKS FOR CANNABIS AND CANNABIS-RELATED GOODS AND SERVICES AFTER ENACTMENT OF THE 2018 FARM BILL 1 (May 2, 2019),

Additionally, the United States is a signatory to the Agreement on Trade Related Aspects of Intellectual Property (“TRIPS”), which requires patent protection to be equally available for all inventions without regard to subject matter.<sup>179</sup> Yet, Article 27 of TRIPS, like the European Patent Examination Guidelines, provides for an exception of patentability if commercial exploitation of such patents would violate “*ordre public*” or morality.<sup>180</sup> Thus, the United States’ refusal to adopt a law expressly limiting patentability based on legality, despite the existence of the framework in the TRIPS Agreement, bolsters the conclusion that the illegality of marijuana does not generally limit applicants’ ability to pursue marijuana-related patents.

This argument could be further evidenced by the legislative intent in the enactment of patent law. Simply put, if Congress desired to prevent patenting of what is illegal, it would have done so expressly. The Lanham Act, which is nearly a decade older than the modern Patent Act,<sup>181</sup> expressly states Congress’s intent to regulate what constitutes immoral (i.e., disparaging, immoral, and scandalous).<sup>182</sup> Thus, had Congress had the intention to regulate morality via the patent system,

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<https://www.uspto.gov/sites/default/files/documents/Exam%20Guide%201-19.pdf> [<https://perma.cc/YC4X-PZGQ>].

- <sup>179</sup> See Final Act Embodying the Results of the Uruguay Round of Multilateral Trade Negotiations, Apr. 15, 1994, 1867 U.N.T.S. 14, 33 I.L.M. 1143 (1994) [hereinafter Final Act]; Agreement on Trade-Related Aspects of Intellectual Property Rights, Apr. 15, 1994, Marrakesh Agreement Establishing the World Trade Organization, Annex 1C, 1869 U.N.T.S. 299, 331 I.L.M. 1197 (1994) [hereinafter TRIPS Agreement].
- <sup>180</sup> See TRIPS Agreement, *supra* note 179 (allowing an exception to patentability when commercial exploitation of patents violate the member country’s *ordre public* or morality); see also Schuman et al., *supra* note 137 (explaining that unlike the E.U. patent law, there is no morality or legality requirement for patent eligibility in U.S. patent law).
- <sup>181</sup> U.S. Patent Act of 1952, Pub. L. 93-596, 66 Stat. 792 (1952) (codified at 35 U.S.C. §§ 1–42) (Lanham Act was enacted in 1946 while the Patent Act was in 1952).
- <sup>182</sup> See Lanham Act, Pub. L. No. 87-772, 60 Stat. 427 (1946) (codified at 15 U.S.C. §§ 1051–1141); 15 U.S.C. § 1052(a) (stating that immoral, deceptive, or scandalous marks are not eligible for federal registration); see *supra* notes 151–152 (listing statutory and judicial exceptions to patentable subject matter).

it would have expressly said so.<sup>183</sup> This argument, however, is not dispositive of congressional intent.<sup>184</sup> In fact, at the time of the Patent Act's passage, Justice Story's construction of the utility requirement—uninjurious to the well-being, good policy, or sound morals of society—was controlling law, and had not yet sunk into contempt and disregard by Justice Fortas' opinion in *Brenner*.<sup>185</sup> Therefore, Congress did not necessarily need to expressly state its intentions.

Congress's intent concerning the patentability of illegal substances is perhaps better examined from a parallel situation—the Prohibition era.<sup>186</sup> Pursuant to the Eighteenth Amendment, the National Prohibition Act banned the manufacture, sale, and transport of alcoholic beverages in the United States from 1920 to 1933.<sup>187</sup> There is evidence to show, however, that patents pertaining to alcoholic beverages were granted during this period. For example, Patent No. 1,551,979 was granted on September 1, 1925, to Henry E. Decebach, for a "Process and Apparatus for Making Beer of Low Alcoholic Content."<sup>188</sup> Even though this application was "filed in 1919 between the ratifying of the National Prohibition Act in 1919 and Prohibition going into effect in 1920[,"]<sup>189</sup> it was still

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<sup>183</sup> See Carmona, *supra* note 142, at 693 ("If Congress intended to limit the patentability of illegal or immoral subject matter, . . . it would have included a morality or legality clause in the Patent Act.").

<sup>184</sup> *Cf. id.* (indicating that the "Patent Act is silent on morality").

<sup>185</sup> See *Brenner v. Manson*, 383 U.S. 519, 533–34 (1966); *Lowell v. Lewis*, 15 F. Cas. 1018, 1019 (C.C.D. Mass. 1817).

<sup>186</sup> See generally *Prohibition*, BRITANNICA, <https://www.britannica.com/event/Prohibition-United-States-history-1920-1933> [<https://perma.cc/ZGY4-9G5G>] (explaining that the manufacture, sale, and transportation of alcoholic beverages were legally prevented by the National Prohibition Act pursuant to the Eighteenth Amendment during the prohibition).

<sup>187</sup> See U.S. CONST. amend. XVIII, *repealed by* U.S. CONST. amend. XXI (prohibiting the manufacture, sale, transportation, importation, or exportation of alcoholic beverages).

<sup>188</sup> See *Process and Apparatus for Making Beer of Low Alcoholic Content*, U.S. Patent No. 1,551,979 (filed Sep. 20, 1919) (issued Sep. 1, 1925) (showing that the patent was issued for a process and apparatus for making alcoholic beverages in 1925).

<sup>189</sup> John Horneber, *A Brief History of Beer and Patents*, SUITER SWANTS (Aug. 27, 2018), <https://www.suiter.com/a-brief-history-of-beer-and-patents/> [<https://perma.cc/9DBV-TMER>]

granted during the prohibition era.<sup>190</sup> Given that Congress's power "to legislate upon the subject of patents is plenary by the terms of the Constitution," if it had the desire to limit patentability based on legality, following the Prohibition era, it could have done so.<sup>191</sup>

Even the U.S. District Court for the Northern District of Texas, in *Whistler v. Autotronics, Inc.*, adjudicating a patent infringement case in 1988 about a radar detector noted the "incongruity of asking a court of law to protect a device used to circumvent the law," and upheld the patent as valid.<sup>192</sup> In doing so, this court observed "the matter is one for the legislatures of the states, or for the Congress, to decide."<sup>193</sup> Yet, at the time of *Whistler*, only two states had prohibited the use of such a device, leading the court to assert that "[u]nless and until detectors are banned outright, or Congress acts to withdraw patent protection for them, radar detector patentees are entitled to the protection of the patent laws."<sup>194</sup> With marijuana, however, Congress's ban is outright.<sup>195</sup> It is plausible that the court would not have deemed the patent valid had the radar detection device been illegal in every state or banned by Congress.

Although schools of statutory interpretation differ, three principal philosophies are commonly used by courts. These are textualism, intentionalism, and purposivism.<sup>196</sup> Although this Article cannot address the intricacies of these principal philosophies, it suffices to say that under any of these, as mentioned

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<sup>190</sup> See also *Process of Producing Nearly Nonalcoholic Liquors*, U.S. Patent No. 1,537,252 (filed May 10, 1924) (issued May 12, 1925) (showing that another patent pertaining to production of alcoholic beverages was granted in 1925).

<sup>191</sup> See *McClurg v. Kingsland*, 42 U.S. 202, 206 (1843) (stating that Congress has full authority to legislate upon the subject matter of patentability and "there are no restraints on its exercise"); see also *Boyden v. Comm'r of Pat.*, 441 F.2d 1041, 1043 (D.C. Cir. 1971) ("Certainly the powers of Congress in the patent law field are plenary for they stem directly from the Constitution.").

<sup>192</sup> See *Whistler Corp. v. Autotronics, Inc.*, No. CA3-85-2573-D, 1988 WL 212501 at \*1 (N.D. Tex. July 28, 1988) (deciding that radar detectors are protected by the patent law even if their purpose is to circumvent the law).

<sup>193</sup> See *id.*

<sup>194</sup> See *id.*

<sup>195</sup> Robert A. Mikos, *On the Limits of Supremacy: Medical Marijuana and the States' Overlooked Power to Legalize Federal Crime*, 62 VAND. L. REV. 1421, 1422 (2009).

<sup>196</sup> See Jonathan R. Siegel, *The Inexorable Radicalization of Textualism*, 158 U. PA. L. REV. 117, 118–119, 123–124 (2009) (introducing textualism, intentionalism and purposivism as main three approaches to statutory interpretation).



above, the Patent Act, on its face or through its underlying purpose, does not appear to conflict with the CSA despite the striking obstacles that marijuana-related patent applicants face in view of the illegality of marijuana.

Ironically, the U.S. Department of Health and Human Services (“HHS”) has a patent on non-psychoactive cannabinoids titled “Cannabinoids as Antioxidants and Neuroprotectants[.]”<sup>197</sup> This patent, issued in 2003, expressly states that the antioxidant properties of cannabinoids make them “useful in the treatment and prophylaxis of wide variety of oxidation associated diseases, such as ischemic, age-related, inflammatory and autoimmune diseases.”<sup>198</sup> This adds to the ambiguity surrounding whether or not the United States recognizes medical benefits of cannabis.

#### IV. ENFORCING MARIJUANA-RELATED PATENTS IN FEDERAL COURT

Despite the issues outlined above, it appears that the USPTO is truly non-judgmental and evaluates all patent applications the same way, whether mundane or controversial as evident through the grant of marijuana-related patents.<sup>199</sup> Yet, the interactions between the Patent Act and the CSA raise even more interesting questions when it comes to the enforcement of such patents. Since the Constitution gives Congress the power to regulate the patent system, only federal courts have subject matter jurisdiction to adjudicate patent infringement cases.<sup>200</sup> Thus, a patent infringement case can only be brought in one of the ninety-four federal

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<sup>197</sup> See *Cannabinoids as Antioxidants and Neuroprotectants*, U.S. Patent No. 6,630,507 (filed Apr. 21, 1999) (issued Oct. 7, 2003) (showing the HHS as an owner of the patent).

<sup>198</sup> See *id.*

<sup>199</sup> See Craig Nard, *Companies Are Quietly Patenting Marijuana, and It Could Lead to a Messy Legal Future*, BUSINESS INSIDER (July 8, 2017), <https://www.businessinsider.com/companies-are-patenting-pot-and-it-could-lead-to-a-messy-legal-future-2017-7> [<https://perma.cc/TT8L-PV2M>] (explaining that the USPTO has been evaluating and issuing cannabis-related patents based on the requirement of “amoral and nonjudgmental” from the U.S. patent law).

<sup>200</sup> See U.S. CONST. art. I, § 8, cl. 8; see also 28 U.S.C. § 1338(a) (2018) (“No State court shall have jurisdiction over any claim . . . arising under any Act of Congress relating to patents.”).

district courts that are bound to interpret and administer all federal laws—including the CSA.<sup>201</sup>

Federal courts have a duty to enforce all federal laws.<sup>202</sup> When it comes to enforcing marijuana patents, on the one hand, patent law demands that the court make the patentee whole at the expense of the wrongdoer, but on the other hand, the CSA criminalizes the very act for which the court is granting a remedy.<sup>203</sup> Thus, before addressing the challenges associated with litigating marijuana-related patents, the courts' willingness to address such issues should be considered. After all, there are a series of realistic policy-oriented objections associated with enforcement of marijuana-related patents.

One example of these objections is the doctrine of *ex turpi causa non oritur actio* ("No action arises from a wrongful contract"), meaning that a claimant cannot pursue a legal remedy if the claimant's cause of action arises from an illegal act.<sup>204</sup> This doctrine is deeply rooted in the fabric of common law, with its application recorded as early as 1725, and is alive and well to this day.<sup>205</sup> Application of this doctrine to marijuana would square with what federal courts have held time after time: "courts will not lend their aid to a criminal enterprise by adjudicating disputes over entitlement to the fruits of a criminal enterprise."<sup>206</sup> Therefore, in

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<sup>201</sup> See Admin. Off. of the U.S. Courts, *Court Role and Structure*, UNITED STATES COURTS, <https://www.uscourts.gov/about-federal-courts/court-role-and-structure> [<https://perma.cc/U3QE-5X97>].

<sup>202</sup> See *id.*

<sup>203</sup> See 35 U.S.C. § 284 ("Upon finding for the claimant the court shall award the claimant damages adequate to compensate for the infringement, but in no event less than a reasonable royalty for the use made of the invention by the infringer, together with interest and costs as fixed by the court."); see also 35 U.S.C. § 27 ("Except as otherwise provided in this title, 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."); 21 U.S.C. §§ 811–812.

<sup>204</sup> See *Ex Turpi Causa*, BLACK'S LAW DICTIONARY (11th ed. 2019); see also William J. McNichol, Jr., *The New Highwayman: Enforcement of U.S. Patents on Cannabis Products*, 101 J. PAT. & TRADEMARK OFF. SOC'Y 24, 40 (2019) (providing an example of a potential objection to a marijuana patent infringement case).

<sup>205</sup> See McNichol, *supra* note 204, at 40 (citing to the English case of *Everett v. Williams* known as the *Highwayman's Case* dated 1725 and the Federal Circuit case of *Formby-Denson v. Dep. of the Army* dated 2001).

<sup>206</sup> See *id.* at 49 (explaining that enforcement of a marijuana-related patent in a federal court cannot realistically be distinguished from *stare decisis* even

addition to the issues concerning securing a marijuana-related patent and the difficulties associated with enforcing the same, a court's willingness to make a patentee whole at the expense of the wrong doer poses yet another concern when the underlying action pertains to a "criminal enterprise."

Some of the challenges associated with enforcement of marijuana-related patents are outlined below.<sup>207</sup> In particular, this section begins by discussing that even securing legal counsel could pose a problem.<sup>208</sup> Subsequently, this section examines issues that arise in the pleading stage and considers the shortcomings of the discovery stage in this context.<sup>209</sup> Next, this section assesses the judicial limitations on granting remedies.<sup>210</sup> The last part of this Article suggests that our current approach to patenting illegal substances is bound to raise new patent troll problems.<sup>211</sup>

#### A. SECURING LEGAL REPRESENTATION

Rule 1.2(d) of the Model Rules of Professional Conduct states in part that "[a] lawyer shall not counsel a client to engage, or assist a client, in conduct that the lawyer knows is criminal or fraudulent."<sup>212</sup> Therefore, because of the illegality of marijuana, securing an attorney for the purposes of patent litigation can be challenging, especially as federal courts have exclusive jurisdiction over cases arising under any act of Congress related to patents.<sup>213</sup> This is true despite the fact that many states have modified their version of Rule 1.2(d) to the effect that

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though the majority of cases dealing with the doctrine of *ex turpi causa* concern contracts).

<sup>207</sup> See *infra* Sections IV.A-D.

<sup>208</sup> See *infra* Section IV.A.

<sup>209</sup> See *infra* Section IV.B.

<sup>210</sup> See *infra* Section IV.C.

<sup>211</sup> See *infra* Section IV.D.

<sup>212</sup> See MODEL RULES OF PRO. CONDUCT r. 1.2(d) (AM. BAR ASS'N 2002).

<sup>213</sup> See 28 U.S.C. § 1338(a) (2018) ("No State court shall have jurisdiction over any claim for relief arising under any Act of Congress relating to patents, plant variety protection, or copyrights . . . [t]he district courts shall have original jurisdiction of any civil action arising under any Act of Congress relating to patents, plant variety protection, copyrights and trademarks.").

lawyers do not commit an ethical violation if they represent marijuana clients, according to state parameters.<sup>214</sup>

The representation issue, however, does not end with the federal court. Securing an attorney to practice before the USPTO to secure patent rights or engage in post-grant proceedings may also be problematic. In fact, the USPTO replaced the USPTO Code of Professional Responsibility with the USPTO Rules of Professional Conduct to conform to the Model Rules of Professional Conduct promulgated by the American Bar Association.<sup>215</sup> The language of Rule 1.2(d) mentioned above is adopted almost verbatim by the USPTO.<sup>216</sup> Therefore,

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<sup>214</sup> See *Advising Clients on Marijuana Use, Sale*, AM. BAR ASS'N (Nov. 2017), <https://www.americanbar.org/news/abanews/publications/youraba/2017/november-2017/the-ethical-landmines-surrounding-advising-clients-about-marijuana/> [<https://perma.cc/9GEB-LNZN>] (stating that as of July of 2017 “16 states’ lawyer disciplinary offices . . . have modified the rule, adding official commentary and issuing binding ethics opinions, or announced a policy to permit counseling and assistance of a client with conduct permitted by state marijuana laws”). As of May, 2019, 25 states have so modified their rules. See *Has Your State Weighed in on Providing Advice to Cannabis Industry Clients?*, INT’L CANNABIS BAR ASS’N, <https://canbar.org/ethics-overview/> [<https://perma.cc/NDF6-W75B>]. On February 17, 2020, the ABA itself passed House of Delegates Resolution 103 urging “Congress to enact legislation to clarify and explicitly ensure that it does not constitute a violation of federal law for lawyers, acting in accord with state, territorial, and tribal ethical rules on lawyers’ professional conduct, to provide legal advice and services to clients regarding matters involving marijuana-related activities that are in compliance with state, territorial, and tribal law.” See Kyle Jaeger, *American Bar Association Wants Protections for Marijuana Banking and Lawyers Working with Cannabis Clients*, MARIJUANA MOMENT (Feb. 17, 2020), <https://www.marijuanamoment.net/american-bar-association-wants-protections-for-marijuana-banking-and-lawyers-working-with-cannabis-clients/> [<https://perma.cc/MUM3-LU3W>].

<sup>215</sup> See *Ethics Rules of Professional Conduct*, USPTO (2013), <https://www.uspto.gov/learning-and-resources/patent-and-trademark-practitioners/current-patent-practitioner/ethics-rules> [<https://perma.cc/W494-P76X>] (stating that the USPTO has replaced the USPTO Code of Professional Responsibility with the Model Rules of Professional Conduct of the ABA).

<sup>216</sup> See 37 C.F.R. § 11.102 (2018) (“A practitioner shall not counsel a client to engage, or assist a client, in conduct that the practitioner knows is criminal or fraudulent, but a practitioner may discuss the legal consequences of any proposed course of conduct with a client and may counsel or assist a client

representing a marijuana business “in conducting its business affairs, including applying for a patent, could under some circumstances be deemed both a violation of the CSA and an instance of professional misconduct.”<sup>217</sup>

Fortunately, marijuana-related patent applications, unlike an application for a trademark, do not require a declaration that the invention is being used or will be used in interstate commerce in connection with the sale of goods and services.<sup>218</sup> An application to register a trademark requires a declaration by the applicant that either the trademark is “in use in commerce” or only “not in use in commerce due to special circumstances.”<sup>219</sup> This is because “[t]rademark ownership in the U.S. is founded on the principal that the first to *use* a name (i.e. a trademark, or mark) ‘in commerce’ is the owner of that mark, with the right to exclude others from using a mark that is identical or confusingly similar to theirs.”<sup>220</sup> Therefore, an application for trademark could in and of itself demonstrate an intent to violate the CSA.<sup>221</sup>

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to make a good-faith effort to determine the validity, scope, meaning or application of the law.”).

<sup>217</sup> See Kamin & Moffat, *supra* note 37, at 265. Several bar associations in states that have legalized marijuana have revised their version of rule 1.2(d). By and large they have ruled that lawyers may counsel and assist clients in their marijuana businesses so long as they advise the clients as to the federal prohibition. See, e.g., COLO. RULES OF PRO. CONDUCT 1.2 (COLO. SUP. CT. 2020); N.Y. State Bar Ass’n Comm. on Pro. Ethics, Op. 1024 (2014); Md. State Bar Ass’n Comm. on Ethics, Ethics Docket No. 2016-10 (2016); Ill. State Bar Ass’n, Pro. Conduct Advisory Op. 14-07 (2014); Me. Bd. of Overseers of the Bar, Pro. Ethics Comm’n, Vacating Op. 215 (2017); R.I. Sup. Ct. Ethics Advisory Panel, Op. 2017-01 (2017); State Bar of Ariz. Ethics Comm., Op. 11-01 (2011).

<sup>218</sup> See Kamin & Moffat, *supra* note 37, at 264.

<sup>219</sup> See USPTO, DEFINITIONS FOR MAINTAINING A TRADEMARK REGISTRATION (Dec. 20, 2018), <https://www.uspto.gov/trademarks-maintaining-trademark-registration/forms-file/definitions-maintaining-trademark> [<https://perma.cc/4REH-ZM87>].

<sup>220</sup> See Bennett Collen, *Trademarks: Everything You Need to Know – Part I*, SCORE (Jul. 14, 2016), <https://www.score.org/blog/trademarks-everything-you-need-know-part-i> [<https://perma.cc/6FM2-YGNP>].

<sup>221</sup> Illegality of marijuana has forced the trademark owners in this industry to seek state-level IP and IP-like rights “to achieve what it cannot under federal law[.]” See Kamin & Moffat, *supra* note 37, at 244; see also Mikos, *Unauthorized and Unwise*, *supra* note 37, at 163 for a scathing critique of PTO’s requirement of trademark owners to comply with sundry nontrademark

In the patent context, however, neither filing an application for a patent nor an actual grant of a patent violates the CSA.<sup>222</sup> A patent is a negative right, meaning that a patent owner has the right to exclude others from making, using, offering to sell, selling, or importing into the United States its patented process, machine, manufacture, or composition of matter—but does not have to itself practice the invention.<sup>223</sup> In a sense, patents are like many other property rights. Owning a patent is like owning a car. The ownership does not give the owner the right to drive the car, but it does give the owner the right to exclude others from the driving the car.<sup>224</sup> In some ways, however, patents are different. For example, even after securing a patent, a patentee may not be able to practice his invention if practicing it would necessarily require infringing another patent.<sup>225</sup>

Accordingly, while application for or ownership of a marijuana-related patent does not necessarily violate any laws, an attempt to enforce such a patent against an alleged infringer may prove challenging for two reasons. First, admitting to practicing the patented invention would be in violation of federal law.<sup>226</sup> Second, any allegations made could incriminate the defendant.<sup>227</sup>

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law. Unfortunately, for patent owners, however, there are no state-level patent-like IP protection. See *Bonito Boats v. Thunder Craft Boats*, 489 U.S. 166, 164–65 (holding that that federal law preempts any and all patent-like state level protections, stating “[t]he states are simply not free in this regard to offer equivalent protections to ideas which Congress has determined should belong to all”).

- <sup>222</sup> There is, however, the problem that a patent holder answering questions in litigation to defend their patent, could expose themselves to the crime of violating the CSA. See Emily Pyclik, *Obstacles to Obtaining and Enforcing Intellectual Property Rights in the Marijuana Industry*, 9 AM. U. INTELL. PROP. BRIEF 26, 43 (2018); see also Mikos, *Unauthorized and Unwise*, *supra* note 37, at 206.
- <sup>223</sup> See 35 U.S.C. §§ 271(a), 101.
- <sup>224</sup> See Richard H. Shear & Thomas E. Kelley, *A Researcher’s Guide to Patents*, 132 PLANT PHYSIOLOGY 1127, 1127 (2003).
- <sup>225</sup> See *Acorda Therapeutics, Inc. v. Roxane Labs., Inc.*, 903 F.3d 1310, 1337 (Fed. Cir. 2018) (discussing how “[a] patent has been called a ‘blocking patent’ where practice of a later invention would infringe the earlier patent”).
- <sup>226</sup> See 21 U.S.C. §§ 841, 844 (2018) (discussing that it is illegal under federal law to possess and distribute marijuana).
- <sup>227</sup> See 35 U.S.C. § 271 (stating that “whoever without authority makes, uses, offers to sell, or sells any patented invention . . . during the term of the patent therefor, infringes the patent”).

Specifically, to bring a patent infringement suit, the plaintiff must allege that the defendant has made, used, offered to sell, sold, or imported into the United States its patented marijuana-related process, machine, manufacture, or composition.<sup>228</sup> When it comes to marijuana, the aforementioned conduct could constitute a federal crime.<sup>229</sup>

To make matters worse, as mentioned above, all patent infringement actions must be brought in one of the ninety-four federal district courts because federal courts have exclusive subject matter jurisdiction over patents.<sup>230</sup> At the federal level, the Freedom of Information Act, signed into law in 1966, provides the public—including the prosecutors' office—with access to federal agency records.<sup>231</sup> Therefore, a simple allegation of patent infringement could provide prosecutors with the necessary information to investigate or to bring a criminal action against the defendant. As far as the CSA is concerned, it is irrelevant whether or not the state in which the patent infringement action has legalized medical marijuana or recreational marijuana.<sup>232</sup>

## B. PLEADING MARIJUANA-RELATED PATENT INFRINGEMENT

Apart from problems associated with securing representation and the potential for self-incrimination, litigating a marijuana-related patent can raise many other challenges.<sup>233</sup> Even identifying the defendants can prove difficult

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<sup>228</sup> See 35 U.S.C. § 101 (stating that “[w]hoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent”); 35 U.S.C. § 271.

<sup>229</sup> See Controlled Substances Act § 401 (listing marijuana as a Schedule I controlled substance and making it unlawful for one to “to manufacture, distribute, or dispense, or possess with intent to manufacture, distribute, or dispense, a controlled substance”).

<sup>230</sup> See *Court Role and Structure*, *supra* note 201.

<sup>231</sup> See 5 U.S.C. § 552 (stating in part “each agency, upon any request for records which (i) reasonably describes such records and (ii) is made in accordance with published rules stating the time, place, fees (if any), and procedures to be followed, shall make the records promptly available to any person”).

<sup>232</sup> See *United States v. Oakland Cannabis Buyers' Coop.*, 532 U.S. 483, 489–90 (2001) (holding that there is no medical necessity exception to the federal Controlled Substance Act).

<sup>233</sup> See Pyclik, *supra* note 222, at 37.

because many marijuana growers cultivate marijuana in secret.<sup>234</sup> Operating under the radar can make it difficult to determine if such growers are infringing a patent.<sup>235</sup> Indirect infringement cases can make identifying the defendants even more challenging—if not impossible. In an inducement patent infringement action, for example, the patent owner must determine if the actions of one party could be construed as asking or inducing another to infringe on its patent.<sup>236</sup> Identifying the infringing parties could be difficult because the first party, the second party, or both, could be operating in secret.

Closely tied to this issue is the problem associated with identifying prior art. As discussed, because of the illegality of marijuana, patent examiners face a unique challenge in uncovering relevant art.<sup>237</sup> But the problems associated with prior art identification are not limited to patent procurement. It is a common practice for defendants to raise a patent invalidity defense asserting that a “patent holder did not satisfy the basic requirements to obtain a patent.”<sup>238</sup> The majority of such defenses challenge the novelty or the non-obviousness of the patented invention.<sup>239</sup> Even absent a patent infringement action, an entity fearing future

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<sup>234</sup> See William J. Meadows, *Cannabis Legalization: Dealing with the Black Market*, 13 OHIO STATE U. DRUG ENF'T & POL'Y CTR., Oct. 2019, at 19 (discussing that “illegal growers are producing five times more marijuana than licensed dealers in California”).

<sup>235</sup> Legalization of marijuana in many states as well as the grant of licenses of pot shops generally functioning under the umbrella of a corporate entity has to some extent alleviated this problem. Yet, the illegal market remains stubbornly robust. See Naomi Martin, *Why Most Mass. Marijuana Sales are on the Black Market, Two Years After Legalization*, BOSTON GLOBE (Feb. 2, 2019), <https://www.bostonglobe.com/news/marijuana/2019/02/02/illicit-pot-market-remains-stubbornly-robust/Fqq5baxLvqkrTB1ABJRbEL/story.html> [<https://perma.cc/9ETC-LPJK>] (discussing “[a]s more states legalize marijuana, they’re finding mixed success shrinking the criminal trade”).

<sup>236</sup> See 35 U.S.C. § 271(b) (2018) (stating that “[w]hoever actively induces infringement of a patent shall be liable as an infringer”).

<sup>237</sup> See Wyse & Luria, *supra* note 54, at 12–13 (defining “prior art” as “publicly available literature published before the date of the patent application”).

<sup>238</sup> See Roger Allan Ford, *Patent Invalidity Versus Noninfringement*, 99 CORNELL L. REV. 71, 73 (2013); see also 35 U.S.C. § 282(b) (stating in part that invalidity of the patent or any claim in suit on any ground as condition of patentability is a defense in a patent infringement action).

<sup>239</sup> See John R. Allison & Mark A. Lemley, *Empirical Evidence on the Validity of Litigated Patents*, 26 AIPLA Q. J. 185, 208 (1998) (citing data to corroborate



infringement actions can seek declaratory judgment of invalidity under the Declaratory Judgment Act of 1934.<sup>240</sup> Under such circumstances, assuming that the invalidity grounds are novelty or obviousness, it is the court's responsibility to examine the prior art asserted by the patent challenger to determine the validity of the patent-in-suit.<sup>241</sup> Without access to a substantial body of prior art, an accused infringer's chance of securing an invalidity judgment is severely abridged.

As a result, marijuana-related patent litigation cases disfavor defendants for two reasons. First, the consequences of such an action could go beyond civil liability and incriminate the defendant.<sup>242</sup> Second, the defendant may not have access to a substantial body of relevant art to mount an invalidity challenge sufficient to overcome a patent's assumption of validity.<sup>243</sup>

On the other hand, plaintiffs are generally dealt a better hand. First, the absence of substantial literature on marijuana-related compositions, processes, or products may make it easier to have a patent granted by the USPTO.<sup>244</sup> Second, a granted patent comes with a presumption of validity that is difficult to rebut by the defendant for the reasons stated above.<sup>245</sup> Third, a plaintiff may be able to strong-arm a defendant to settle because of the incrimination risk associated with discovery and litigation.<sup>246</sup>

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that a majority of patent invalidity determinations are based on the patent in question being identified as prior art or obvious).

<sup>240</sup> See 28 U.S.C. § 2202.

<sup>241</sup> See *Deep Welding, Inc. v. Sciaky Bros.*, 417 F.2d 1227, 1233 (7th Cir. 1969) (stating that the court "must examine the nature, content and scope of the prior art to see what it fairly taught one having ordinary skill in the art as the art existed on the date of invention. If the state of the art anticipated or made obvious the invention sought to be patented, 35 U.S.C. § 103 (as well as §§ 102(a), (b), (e) or (g)) requires a holding of invalidity").

<sup>242</sup> See 21 U.S.C. § 841.

<sup>243</sup> See 35 U.S.C. § 282(a) (stating that "[a] patent shall be presumed valid. Each claim of a patent . . . shall be presumed valid independently of the validity of other claims; dependent or multiple dependent claims shall be presumed valid even though dependent upon an invalid claim. The burden of establishing invalidity of a patent or any claim thereof shall rest on the party asserting such invalidity").

<sup>244</sup> See 35 U.S.C. §§ 102–103 (less literature available for patent examiners would make it easier for applicants to meet the novelty requirement under § 102).

<sup>245</sup> See 35 U.S.C. § 282(a).

<sup>246</sup> See 35 U.S.C. § 271.

Yet another advantage for the plaintiff in marijuana-related patent infringement actions is that a patent provides the owner with a negative right and not a positive privilege.<sup>247</sup> Because of this, a patent owner does not need to practice the patent; instead, the patent owner can simply exclude others from making, using, selling, or offering for sale its patented invention.<sup>248</sup> Therefore, a patent infringement action is not *per se* incriminating to the owner. The same, however, cannot be said about the defendants. Every action that can result in infringement of a marijuana-related patent constitutes a violation of the criminal law.<sup>249</sup> Accordingly, the negative right aspect of patents provides the plaintiffs with significant leverage over the defendants.

While a plaintiff may have leverage over a defendant because they can bring a patent infringement action without having to practice the patent, that does not necessarily mean they will not incriminate themselves. In fact, a patent holder may have an incentive to demonstrate that it is practicing the invention for two reasons. First, practicing entities have a much better chance of succeeding in trial, as opposed to non-practicing entities.<sup>250</sup> Second, establishing that the patent owner is a practicing entity qualifies the plaintiff to seek higher damages: lost profits, instead of reasonable royalties.<sup>251</sup>

Even if the plaintiffs do not disclose this themselves, the fact that the plaintiff is practicing the patent-in-suit or a variation thereof could become evident during the discovery stage. It is commonplace for the defendant in a patent infringement action to seek the plaintiff's financial documents including any license agreements on the patent(s)-in-suit.<sup>252</sup> Defendants generally use this

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<sup>247</sup> *See id.*

<sup>248</sup> *See id.*

<sup>249</sup> *See* Controlled Substances Act § 401(a).

<sup>250</sup> *See 2018 Patent Litigation Study*, PwC, May 2018, at 8 (finding that "[t]here is a pronounced difference in trial success rates for [non-practicing entities versus practicing entities] depending on the trier of fact").

<sup>251</sup> *See* 35 U.S.C. § 284 ("Upon finding for the claimant the court shall award the claimant damages adequate to compensate for the infringement, but in no event less than a reasonable royalty for the use made of the invention by the infringer, together with interest and costs as fixed by the court."); *see also* *Wechsler v. Macke Int'l Trade, Inc.*, 486 F.3d 1286, 1293 (Fed. Cir. 2007) (stating that to recover lost profits, the patent owner must "show 'causation in fact,' establishing that 'but for' the infringement, he would have made additional profits").

<sup>252</sup> *See* FED. TRADE COMM'N, PATENT ASSERTION ENTITY ACTIVITY 9 (Oct. 2016).

information to approximate damages and weigh their odds of winning against their potential liability.<sup>253</sup> Generally, a plaintiff's financial statements can reveal if it is engaged in production and sale of the patented invention or a variation thereof.<sup>254</sup>

Likewise, interrogatories and depositions could shed light on a plaintiff's own conduct.<sup>255</sup> Additionally, "[i]n almost every setting where important decisions turn on questions of fact, due process requires an opportunity to confront and cross-examine adverse witnesses."<sup>256</sup> Therefore, despite the fact that patents are negative rights, if the plaintiff is a practicing entity, it may still have to admit to the court that it has engaged in the practice of the claimed invention. This may prompt patentees to sell their patents to non-practicing entities as straw buyers or otherwise to avoid this issue.

Thus far, there have been very few marijuana patent infringement cases.<sup>257</sup> While none have reached to stages of litigation that could answer some of the questions raised here, one has a relatively developed docket. United Cannabis

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<sup>253</sup> See Kevin Neels et al., *A Quick Guide to Patent Damages Discovery*, LAW360 (Aug. 12, 2016), <https://www.law360.com/articles/826184/a-quick-guide-to-patent-damages-discovery> [<https://perma.cc/K7ZS-TABP>].

<sup>254</sup> See *id.*

<sup>255</sup> See FED. R. CIV. P. 33 ("A party may serve on any other party no more than 25 written interrogatories, including all discrete subparts . . . [and] [a]n interrogatory may relate to any matter that may be inquired into under Rule 26(b)."); see also FED. R. CIV. P. 30 ("A party may, by oral questions, depose any person, including a party, without leave of court except as provided in Rule 30(a)(2). The deponent's attendance may be compelled by subpoena under Rule 45.").

<sup>256</sup> See *Goldberg v. Kelly*, 397 U.S. 254, 269 (1970); see also *In re Alamance Cnty. Ct. Facilities*, 405 S.E.2d 125, 137 (N.C. 1991) (indicating that even in civil proceedings substantive right to confront and cross-examine applies) (citations omitted).

<sup>257</sup> *Canopy Growth Corp. v. GW Pharms. PLC*, No. 6-20-CV-01180, 2021 WL 801584 (W.D. Tex. Nov. 27, 2021), *appeal filed*, No. 22-1603 (Fed. Cir. Apr. 7, 2022); *Original Resinator, LLC v. TTT Innovations LLC*, No. 5:21-cv-02002 (C.D. Cal. filed Nov. 29, 2021). In 2019, the PTAB adjudicated its first ever marijuana-related patent in an *inter partes* review. The Board found claims 1 and 2 of the patent-in-suit invalid in view of prior art generally teaching administration of CBD to treat epilepsy. The Board, however, found claims 3–13 to be patentable. This example further illustrates the importance of the existence of prior art. See *Insys Dev. Co. v. GW Pharma Ltd.*, No. IPR2017-00503, 35 (P.T.A.B. Jan. 3, 2019).

Corporation (“UCANN”) sued Pure Hemp Collective Incorporation for infringement of UCANN’s patent entitled “Cannabis Extracts and Methods of Preparing and Using Same” (U.S. Patent No. 9,730,911, the “’911 patent”) in federal court.<sup>258</sup> This patent is generally directed to liquid cannabinol formulations comprising tetrahydrocannabinol (“THC”), cannabidiol (“CBD”), and numerous other terpenes.<sup>259</sup> An examination of this case can highlight some of the issues, discussed above, associated with enforcing a marijuana-related patent in federal court.

In its complaint, UCANN stated that it had “been involved with medical cannabis for almost two decades.”<sup>260</sup> Further, it expressly stated that following the issuance of the ’911 patent, it had developed its Prana Bio Nutrient Medicinals line, which consists of a variety of products divided into five categories with specific cannabinoid ratios and terpene profiles.<sup>261</sup> Additionally, UCANN alleged that, “Pure Hemp makes, uses, offers to sell, and sells a range of wellness products containing cannabis extracts, including tinctures, gel capsules, vape pens, salves, and topical ointments.”<sup>262</sup> Interestingly, UCANN acknowledged that it had purchased “Pure Hemp’s Vina Bell 5000mg product and ran chemical composition tests on it to determine whether the cannabinoid formulations within the product are covered by the ’911 Patent.”<sup>263</sup>

In its Answer, Pure Hemp raised a prior art argument similar to what was anticipated above. Specifically, after listing a few product brands that were around before the filing of the ’911 patent<sup>264</sup> that allegedly practiced the claimed invention,

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<sup>258</sup> See Cannabis Extracts and Methods of Preparing and Using Same, U.S. Patent No. 9,730,911 (filed Oct. 21, 2015) (issued Aug. 15, 2017).

<sup>259</sup> See *id.* Cannabis plant includes a number of terpenes such as myrcene, linalool, and limonene which provide cannabis with its characteristic scents. See Grinspoon, *supra* note 99.

<sup>260</sup> See Complaint for Patent Infringement & Demand for Jury Trial at 3, United Cannabis Corp. v. Pure Hemp Collective, Inc., No. 1:18-cv-01922 (D. Colo. July 30, 2018).

<sup>261</sup> See *id.* at 4 (stating that [t]he product line has enjoyed great medical success with observational data from more than 15,000 patients to date showing the products are safe and effective”).

<sup>262</sup> See *id.* at 5.

<sup>263</sup> See *id.* at 5–6.

<sup>264</sup> In essence, Pure Hemp argues that because products practicing the invention of the ’911 Patent were already on sale at the time of the application for this patent, the patent should not have been granted. See 35 U.S.C. § 102 (“A person shall be entitled to a patent unless the claimed

Pure Hemp argued that the inventions encompassed by the '911 patent are "ubiquitous" and "were not invented in this millennium . . ." <sup>265</sup> While Pure Hemp named several products that allegedly practice the '911 patent, supporting these allegations are a different story. <sup>266</sup> In patent litigation cases, defendants usually produce years, sometimes decades worth, of "scientific articles and other writings to demonstrate a given industry's preexisting research and knowledge." <sup>267</sup> But this wealth of evidence likely does not exist for Pure Hemp given the general illegality of marijuana to date. <sup>268</sup>

Pure Hemp raised another interesting challenge in its Answer: patentable subject matter. <sup>269</sup> In particular, it referred to the Supreme Court's framework concerning patentable subject matter and alleged that the claim asserted by UCANN is directed to a naturally occurring compound. <sup>270</sup> Because naturally

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invention was . . . on sale . . . before the effective filing date of the claimed invention.").

<sup>265</sup> See Defendant's Answer, Defenses, and Counterclaims at 7–8, *United Cannabis Corp. v. Pure Hemp Collective, Inc.*, No. 1:18-cv-01922 (D. Colo. Oct. 29, 2018).

<sup>266</sup> In its amended Response, Pure Hemp identifies U.S. Patent No. 2,304,669, titled *Isolation of Cannabidiol* as a potential prior art against the invention of the '911 Patent. See Defendant's First Amended Answer, Defenses, and Counterclaims at paras. 39–46, *United Cannabis Corp. v. Pure Hemp Collective, Inc.*, No. 1:18-cv-01922 (D. Colo. Nov. 5, 2018); see '669 Patent, *supra*; see also Defendant's First Amended Answer, Defenses, and Counterclaims at para. 71, *United Cannabis Corp. v. Pure Hemp Collective, Inc.*, No. 1:18-cv-01922 (D. Colo. Nov. 5, 2018) (alleging that publicity surrounding the lawsuit resulted in damage to the relationship between defendants and their suppliers, retailers, and affiliates).

<sup>267</sup> See Jihee Ahn, *Cannabis Patent Litigation Update: Is Extraction and Preparation Prior Art?*, HARRIS BRICKEN: CANNA L. BLOG (Mar. 4, 2019), <https://www.cannalawblog.com/cannabis-patent-litigation-update-is-extraction-and-preparation-prior-art/> [<https://perma.cc/E36N-TDDP>].

<sup>268</sup> See *id.* (stating that the illegality of marijuana to date makes it challenging for Pure Hemp to produce prior art supporting their argument).

<sup>269</sup> See Defendant's Answer, Defenses, and Counterclaims, *supra* note 265, at 9.

<sup>270</sup> See *id.*

occurring compounds are not patent eligible,<sup>271</sup> Pure Hemp argued that the asserted claims were invalid.<sup>272</sup>

Subsequently, Pure Hemp moved for partial summary judgment on the grounds that the claims in dispute are directed to patent-ineligible natural phenomena: cannabinoids and terpenes found naturally in the cannabis plant.<sup>273</sup> This motion invited the court to examine patent eligibility through the two-step framework most recently set forth by the Supreme Court in *Alice Corporation v. CLS Bank International* in 2014.<sup>274</sup> First, a court must determine whether the claims at issue are “directed to” one of the three patent-ineligible concepts: laws of nature, natural phenomena, and abstract ideas.<sup>275</sup> If the answer is “yes,” then the court must ask whether the claims at issue nonetheless offer an “inventive concept.”<sup>276</sup>

In opposition to this motion, UCANN argued that “the claims are not directed to laws of nature or natural phenomena because they claim human-modified liquid formulations that require converting solid cannabinoids into a different state with markedly different physiological characteristics.”<sup>277</sup> The court agreed.<sup>278</sup> In doing so, the court did not reach the second part of UCANN’s assertion concerning physiological characteristics of the liquid formulation.<sup>279</sup>

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<sup>271</sup> See *Mayo Collaborative Servs. v. Prometheus Lab’y, Inc.*, 566 U.S. 66, 70 (2012).

<sup>272</sup> See Defendant’s Answer, Defenses, and Counterclaims, *supra* note 265, at 9 (stating that “UCANN is intentionally asserting patent claims that are clearly invalid, which is an unreasonable and bad faith restraint on trade”).

<sup>273</sup> See Defendant’s Early Motion for Partial Summary Judgment at 1, *United Cannabis Corp. v. Pure Hemp Collective, Inc.*, No. 1:18-cv-01922 (D. Colo. Nov. 29, 2018).

<sup>274</sup> See *Alice Corp. Pty. Ltd. v. CLS Bank Int’l*, 573 U.S. 208, 217 (2014) (laying out the two-step framework for distinguishing patents that claim ineligible subject matter from those that claim patent-eligible applications of said ineligible subject matter).

<sup>275</sup> See *id.* at 218.

<sup>276</sup> See *id.* at 221.

<sup>277</sup> See *United Cannabis’ Opposition Brief to Pure Hemp Collective’s Early Motion for Partial Summary Judgment* at 7, *United Cannabis Corp. v. Pure Hemp Collective, Inc.*, No. 1:18-cv-01922 (D. Colo. Dec. 31, 2018).

<sup>278</sup> See *Order Denying Defendant’s Early Motion for Partial Summary Judgment* at 13, *United Cannabis Corp. v. Pure Hemp Collective, Inc.*, No. 1:18-cv-01922 (D. Colo. Apr. 17, 2019).

<sup>279</sup> See *id.*

Specifically, the court stated that, “Pure Hemp has failed to establish beyond genuine dispute that a liquefied version of cannabinoids and related chemicals at the concentrations specified in the ’911 Patent is anything like a natural phenomenon.”<sup>280</sup>

Finding that the claims at issue were directed to “a non-naturally occurring delivery method of naturally occurring chemicals in . . . non-naturally occurring proportions and concentrations,” the court did not reach the second *Alice* inquiry.<sup>281</sup> Following the court’s denial of its motion for partial summary judgment, Pure Hemp sought to expand the scope of the claim construction briefing, challenging the validity of a certificate of correction.<sup>282</sup> UCANN acquired a certificate of correction for a claim in the ’911 patent with an alleged typo, which Pure Hemp argued improperly broadened the scope of the asserted claims.<sup>283</sup> On May 22, the Court denied Pure Hemp’s attempt to explain invalidity and found that “it is more appropriate for Defendant to raise, and the Parties to brief, the issue of the validity of the certificate of correction in the context of a motion for

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<sup>280</sup> *See id.*

<sup>281</sup> *See id.*

<sup>282</sup> *See* Motion for Leave to Brief the Invalidity of Certificate of Correction for U.S. Patent No. 9730911 in Conjunction with Claim Construction filed by Pure Hemp Collective Inc., United Cannabis Corp. v. Pure Hemp Collective Inc., No. 1:18-cv-01922, at 1 (Apr. 29, 2019). A claim construction brief, otherwise known as a *Markman* brief, is generally used to clarify the scope of a patent claim, i.e., the scope of the invention, through defining some of its terms. For guidance on submitting a certificate of correction, see 35 U.S.C. § 255, which states:

Whenever a mistake of a clerical or typographical nature, or of minor character, which was not the fault of the Patent and Trademark Office, appears in a patent and a showing has been made that such mistake occurred in good faith, the Director may, upon payment of the required fee, issue a certificate of correction, if the correction does not involve such changes in the patent as would constitute new matter or would require re-examination. Such patent, together with the certificate, shall have the same effect and operation in law on the trial of actions for causes thereafter arising as if the same had been originally issued in such corrected form.

<sup>283</sup> *See* Motion for Leave to Brief, *supra* note 282, at 1.

summary judgment pursuant to Rule 56 of the Federal Rules of Civil Procedure.”<sup>284</sup> Accordingly, this case was set to proceed to trial.<sup>285</sup> This was so until April 20, 2020, when UCANN filed a Chapter 11 bankruptcy petition in Colorado.<sup>286</sup> Judge William J. Martinez administratively closed the infringement case against Pure Hemp, while Pure Hemp’s counterclaims were automatically stayed.<sup>287</sup> Since this case was the first marijuana-related patent infringement case, it had major ramifications for the industry and had the potential to shape how federal courts treat such patents for years to come.<sup>288</sup>

Unfortunately, unable to reorganize its finances under the federal bankruptcy law, UCANN had to drop its case against Pure Hemp, leaving a host of questions unanswered.<sup>289</sup>

For example, had this action been reopened, Pure Hemp could still challenge the validity of the ‘911 patent on several grounds. While invalidity challenges based on novelty and obviousness were likely to face the same prior art issues stated above, the ‘911 patent was still vulnerable to enablement and definiteness challenges.<sup>290</sup> The broadness of the ‘911 patent claims made them particularly prone to definiteness challenges.<sup>291</sup> In fact, many intellectual property

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<sup>284</sup> Order Denying Defendant’s Opposed Motion for Leave, United Cannabis Corp. v. Pure Hemp Collective, Inc., No. 1:18-cv-01922, at 6 (May 22, 2019).

<sup>285</sup> See Ahn, *supra* note 267.

<sup>286</sup> See Chapter 11 Voluntary Petition for Non-Individual at 1, *In re* United Cannabis Corp., No. 1:20-bk-12692 (Bankr. D. Colo. Apr. 20, 2020).

<sup>287</sup> See Order Administratively Closing the Infringement Action, United Cannabis Corp. v. Pure Hemp Collective, Inc., No. 1:18-cv-01922 (Apr. 21, 2020).

<sup>288</sup> See Cheryl Miller, *Why Patent Lawyers Are Watching This Colorado Cannabis Case*, THE RECORDER (Aug 8, 2018), <https://www.law.com/therecorder/2018/08/08/why-patent-lawyers-are-watching-this-colorado-cannabis-case/?sreturn=20190414181648> [<https://perma.cc/57XR-8K2U>].

<sup>289</sup> See Stipulation of Dismissal by Plaintiff at 1, United Cannabis Corp. v. Pure Hemp Collective, Inc., No. 1:18-cv-01922 (D. Colo. March 31, 2021).

<sup>290</sup> See 35 U.S.C. § 112.

<sup>291</sup> See ‘911 Patent (Independent claim 1 is an example of the broadness of the ‘911 Patent claims which reads in its entirety: “A liquid cannabinoid formulation, wherein at least 95% of the total cannabinoids is tetrahydrocannabinolic acid (THCa)”).



scholars had strong opinions on the validity of the '911 patent claims arguing that the patent may not withstand definiteness challenges.<sup>292</sup>

UCANN's Chapter 11 bankruptcy petition itself brought about another test case for the industry.<sup>293</sup> In particular, because UCANN's patent involved THC, suggesting that its business debts were "incurred to further criminal conduct," United States Bankruptcy Trustee for Region 19 argued that UCANN's bankruptcy filing should be dismissed.<sup>294</sup> An argument that likely was found persuasive because on January 12, 2021 Judge Joseph Rosania dismissed the case.<sup>295</sup> This Order did not set forth Judge Rosania's reasons for dismissing the case but based on his Order to Show Cause he dismissed the case at least in part because "[d]espite being legal under state law, activities associated with the marijuana industry are illegal under federal law and cannot be condoned by the bankruptcy courts."<sup>296</sup>

This dismissal highlights the far-reaching consequence of disharmony between federal and state law in this context.

### C. REMEDIES FOR INFRINGEMENT OF A MARIJUANA-RELATED PATENT

*UCANN v. Pure Hemp* provided many issues of first impression and was closely watched by major players, such as Coca-Cola and Molson Coors, who may

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<sup>292</sup> Amanda C. Maxfield, *Intellectual Property Survey: Cannabis Plant Types, Methods of Extraction, IP Protection, and One Patent That Could Ruin It All*, 3 OHIO STATE U. DRUG ENF'T & POL'Y CTR., May 2019, at 8.

<sup>293</sup> See *Biggest Risks Facing Cannabis Businesses*, *supra* note 20; see also Diana Novak Jones, *United Cannabis Corp. Files for Ch. 11 In Colo.*, LAW360 (Apr. 21, 2020), <https://www.law360.com/articles/1265959/united-cannabis-corp-files-for-ch-11-in-colo-> [<https://perma.cc/ML23-GNW2>].

<sup>294</sup> See Jesse Mondry, *Cannabis Litigation: U.S. Trustee in UCANN Bankruptcy Requests Marijuana Patent Infringement Case Dismissal*, HARRIS BRICKEN: CANNA L. BLOG (June 23, 2020), <https://harrisbricken.com/cannalawblog/cannabis-litigation-u-s-trustee-in-ucann-bankruptcy-requests-marijuana-patent-infringement-case-dismissal/> [<https://perma.cc/D53M-MXWY>].

<sup>295</sup> See Order Granting the United States Trustee's Motion to Dismiss Chapter 11 Cases, *In re United Cannabis Corp.*, No. 1:20-bk-12692 (Bankr. D. Colo. Jan. 12, 2021).

<sup>296</sup> See Order to Show Cause, *In re United Cannabis Corp.*, No. 1:20-bk-12692 (Bankr. D. Colo. Apr. 22, 2020).

want to enter the market for formulations containing CBD or THC.<sup>297</sup> Perhaps the most interesting question of all, in view of the following bankruptcy courts' dismissal, was how a federal judge would determine a remedy for a practice that could constitute a violation of federal law. Under Sections 283 and 284 of the Patent Act, upon a finding of infringement, a court may grant an injunction or grant the patent owner compensatory damages in the form of either lost profits or reasonable royalty.<sup>298</sup>

To recover lost profits, the patent owner must show that, but for the alleged infringement, it would have earned the additional profits associated with practicing the patent.<sup>299</sup> This inquiry alone is problematic because it implies not only that the patent owner has broken the law by practicing the patent-in-suit, but also that it would have done so even more. In a sense, a grant of lost profit damages by the federal court amounts to endorsing such conduct. This is contradictory to the federal courts' responsibility of assuring compliance with the United States' laws and punishing those in violation even if courts do not have a duty to go out of their way to punish outside the criminal context.<sup>300</sup>

A remedy based on a reasonable royalty raises similar concerns. Although a grant of a reasonable royalty does not presume that the patent owner would have captured the market share associated with the practice of the patent, it implies that the patent owner is entitled to a market-dictated rate.<sup>301</sup> To determine the value of

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<sup>297</sup> See Jen Skerritt & Craig Giammona, *Coca-Cola is Eyeing the Cannabis Market*, BLOOMBERG (Sep. 17, 2018), <https://www.bloomberg.com/news/articles/2018-09-17/coca-cola-eyes-cannabis-market-in-push-beyond-sluggish-sodas#:~:text=Open,Aurora%20Cannabis%20Inc.,products%20as%20traditional%20sales%20slow> [<https://perma.cc/W4YG-ACDL>] (stating that Coca-Cola is monitoring the case and has an interest in drinks infused with CBD).

<sup>298</sup> See 35 U.S.C. §§ 283–284 (2018); *Lucent Tech., Inc. v. Gateway, Inc.*, 580 F.3d 1301, 1304 (Fed. Cir. 2009).

<sup>299</sup> See Zelin Yang, *Damaging Royalties: An Overview of Reasonable Royalty Damages*, 29 BERKELEY TECH. L.J. 647, 647 (Aug. 1, 2014).

<sup>300</sup> See U.S. CONST. art. III, § 2 (“The judicial Power shall extend to all Cases, in Law and Equity, arising under this Constitution, the Laws of the United States, and Treaties made, or which shall be made, under their Authority.”).

<sup>301</sup> See Mark A. Lemley, *Distinguishing Lost Profits from Reasonable Royalties*, 51 WM. & MARY L. REV. 655, 661 (2009) (explaining that reasonable royalty case law inquires into what the market would actually pay to license rights and that these remedies are very different from a patentee seeking lost profits from maintaining a monopoly).

reasonable royalty damages, courts generally use the fifteen factors set forth in *Georgia-Pacific v. United States Plywood Corp.* by the District Court for the Southern District of New York.<sup>302</sup>

A majority of these factors are factual and concern a patent owner's conduct. For example, these factors ask about patent owners' licensing practice not only for the patent at issue but for comparable patents also. Similarly, the utility of the patent and profitability of commercial products embodying the patents are considered.<sup>303</sup> Inquiring into each factor and awarding a reasonable royalty based on such inquiry, presents interesting questions concerning federal courts' willingness to turn a blind eye to the illegality of marijuana.

#### D. MARIJUANA-RELATED PATENTS AND PATENT ASSERTION ENTITIES

Apart from the absence of prior art during both prosecution and litigation of marijuana-related patents, pleading shortcomings, and the issues associated with the grant of relief, marijuana-related patents pose additional policy concerns. In particular, marijuana-related patents may have the potential to lend themselves to frivolous lawsuits. Some scholars believe that Patent Assertion Entities ("PAE") have been posing a problem for United States' businesses for decades.<sup>304</sup> A PAE, alternatively, a "non-practicing entity" or a "patent troll," is generally a non-inventor entity that secures patent portfolios for the sole purpose of extorting revenue through litigation rather than for creating products or protecting its intellectual property.<sup>305</sup> PAEs use their unduly broad patents to bring patent

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<sup>302</sup> See *Georgia-Pacific Corp. v. U.S. Plywood Corp.*, 318 F. Supp. 1116, 1120 (S.D.N.Y. 1970) (stating that the court set out 15 factors to determine the value of reasonable damages).

<sup>303</sup> See *id.* at 1120 (considering the utility and profitability of the patent in factor 8 and 9).

<sup>304</sup> See Prachi Agarwal, *Patent Troll: The Brewing Storm of Patent Reform in the United States of America*, 15 J. MARSHALL REV. INTELL. PROP. L. 63, 66 (2015) (stating that PAEs take advantage of the fact that legal defense costs are much higher than settlement demands and that PAEs use this to their advantage to extort large sums of money from honest businesses).

<sup>305</sup> See FED. TRADE COMM'N, *supra* note 252, at 15 (Oct. 2016) (stating that PAEs are entities who acquire patents solely to institute lawsuits against infringers).

infringement actions against businesses with products or innovations that are similar to the patents owned by the PAE.<sup>306</sup>

PAEs generally seek a “licensing fee” from small- and mid-size businesses that do not have the resources to face them in court.<sup>307</sup> This problem is particularly prevalent in the software and technology space because of the potential breadth of these patents in comparison with mechanical patents.<sup>308</sup> A recent study found that patent infringement lawsuits have increased by a factor of ten and that PAEs are responsible for nearly two-thirds of that increase.<sup>309</sup> The same study demonstrates that PAEs can influence unemployment and play a significant role in securing venture capital funding.<sup>310</sup>

Yet there is disagreement among scholars about the impact of PAEs on innovation:

Some claim that PAEs are antithetical to the Constitution’s mandate that the patent laws encourage innovation. They argue that PAEs hinder rather than encourage innovation, especially in the software field. Others claim that PAEs provide small inventors and companies an opportunity otherwise missing to receive rewards for their inventions.<sup>311</sup>

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<sup>306</sup> See *id.* at 14, 57–58 (suggesting that PAEs tend to pick lawsuit target companies whose products are similar to the patents they own, and some patents are overly broad).

<sup>307</sup> See Jay Walker, *Our System is so Broken, Almost No Patented Discoveries Ever Get Used*, WIRED (Jan. 5, 2015), <https://www.wired.com/2015/01/fixing-broken-patent-system/> [<https://perma.cc/MW68-REZD>] (stating that PAEs pick on small businesses who can’t afford litigation).

<sup>308</sup> See James Bessen, *The Patent Troll Crisis is Really a Software Patent Crisis*, WASH. POST (Sept. 3, 2013), <https://www.washingtonpost.com/news/the-switch/wp/2013/09/03/the-patent-troll-crisis-is-really-a-software-patent-crisis/> [<https://perma.cc/BA8D-BMBU>] (explaining that the patent troll problem is prevalent in the software industry because software patents are overly broad).

<sup>309</sup> See Ian Appel et al., *Patent Trolls and Startup Employment*, 133 J. FIN. ECON. 708, 708–11 (2019) (stating that patent litigation has increased tenfold since 2005 and that NPEs constitute 69% of it).

<sup>310</sup> See *id.* at 724 (“[F]ollowing the adoption of anti-troll legislation, employment at high-tech startups in a state increases by 4.4%—an increase that is driven by firms in the IT sector, where NPEs are most active.”).

<sup>311</sup> See David L. Schwartz & Jay P. Kesan, *Analyzing the Role of Non-Practicing Entities in the Patent System*, 99 CORNELL L. REV. 425, 427 (2014).

Surely, in some circumstances, patent infringement suits by PAEs provide patent owners with the opportunity to reap the fruits of their labor by suing infringers for the fair value of their innovation. For example, a patent infringement action provides a university's tech transfer office with the means to secure the fair value of its patented innovation even though it is technically a PAE.<sup>312</sup> In other cases, however, infringement action by PAEs can negatively impact small- and mid-size businesses.<sup>313</sup> Such lawsuits, for example, can take away "valuable time and money from the business to evaluate the claims and engage legal counsel to address the assertions."<sup>314</sup>

PAEs can pose a real problem in the context of marijuana-related patents for two reasons. First, in addition to the risk of losing when fighting a frivolous patent infringement action, PAEs could force businesses into settlement because of the risk of incrimination. PAEs, by definition, do not practice their patented innovation and thereby are not in violation of the federal drug laws.<sup>315</sup> This provides them with an advantage against the opposing party who is likely engaged in the sale, cultivation, or processing of marijuana in violation of federal laws. PAEs could use this moral high ground to their advantage and strong-arm businesses for "licensing fees" even though they would not be entitled to relief had the case gone to trial.

Second, PAEs can take advantage of the difficulties associated with invalidating a marijuana-related patent. As stated above, a common strategy for defendants in patent infringement actions is to attempt to invalidate the patent.<sup>316</sup> Particularly, defendants often attempt to invalidate patents based on lack of

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<sup>312</sup> See Mark A. Lemley, *Are Universities Patent Trolls?*, 18 FORDHAM INTELL. PROP. MEDIA & ENT. L.J. 611, 612 (2008) (arguing that universities should not be deemed trolls).

<sup>313</sup> See Minda Zetlin, *Patent Trolls Target Small Businesses with Lawsuit Threats. Here's How One Startup Fought Back*, INC. (Feb. 22, 2018), <https://www.inc.com/minda-zetlin/patent-trolls-target-small-businesses-with-lawsuit-threats-heres-how-one-startup-fought-back.html> [<https://perma.cc/NQ5T-ZJQG>] (suggesting that patent infringement suits may be a huge cost for small businesses).

<sup>314</sup> See *id.*

<sup>315</sup> Since patent trolls do not practice their patented innovation, they are not entitled to lost profit damages. As such, if their patent is found valid and infringed, the granted relief is usually reasonable royalty. See 35 U.S.C. § 284 (stating that the damage award for infringement is reasonable royalty).

<sup>316</sup> See Ford, *supra* note 238, at 73.

novelty or obviousness.<sup>317</sup> Because of the lack of substantial prior art, however, defendants in this area may find it difficult to invalidate patents.<sup>318</sup> If defendants fail to invalidate patents, their chance of losing the case is substantially higher. Therefore, they may resort to settling more frequently than they otherwise would have.

## V. CONCLUSION

The interface between the Patent Act and the CSA raises many interesting questions. Given some of the discrepancies between federal agencies' treatment of marijuana and its medical benefits, it is challenging to accept that the Patent Act and the current American marijuana regime, as represented by the CSA and discordant state marijuana laws, harmonize. Yet the status quo suggests that, as far as the USPTO is concerned, marijuana products and processes are patentable if they satisfy the statutory patentability requirements. Enforcement of such patents is a different question and raises even more interesting issues of first impression. Assuming that marijuana-related patents are duly granted and that the plaintiffs and the defendants have both secured competent legal counsel, a federal court's grant of a relief in a marijuana-related patent infringement action, could signal, by proxy, its endorsement of such conduct. Conversely, given that patents only vest in the owners a right to exclude, a federal court's grant of relief in a marijuana-related patent infringement action could be considered just that—relief anchored in property rights.

The debate regarding whether PAEs hinder innovation or provide inventors and small companies with a fighting chance against large corporations is not directly mirrored in the marijuana patent context. While a marijuana-related patent infringement action by a PAE, does provide the patentee with an opportunity to reap the benefit of its labor, it may also incentivize frivolous lawsuits directed at extracting settlements because of the incrimination risk. Absent statutory, judicial, or regulatory guidelines the problem associated with the PAEs may intensify as more states legalize marijuana and big corporations enter the market.

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<sup>317</sup> See generally 35 U.S.C. §§ 102–103 (stating that a patent cannot be obtained if it is obvious or lacks novelty, but without substantial prior art it may be difficult to prove in an infringement suit that an issued patent is nonobvious or is not novel).

<sup>318</sup> See *Abrams & Sampat*, *supra* note 74, at 5.

